# SECURITIES AND EXCHANGE COMMISSION Washington D.C. 20549

### **FORM 20-F**

|  | REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934 OR   |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|
| X  |   |  |  |  |  |  |  |  |
|  | TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the transition period from to   |  |  |  |  |  |  |  |
|  | SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  Date of event requiring this shell company report  Commission file number: 0-22320   |  |  |  |  |  |  |  |
|  | Trinity Biotech plc   |  |  |  |  |  |  |  |
|  | (Exact name of Registrant as specified in its charter and translation of Registrant's name into English)  |  |  |  |  |  |  |  |
|  | Ireland   |  |  |  |  |  |  |  |
|  | (Jurisdiction of incorporation or organization) IDA Business Park, Bray, Co. Wicklow, Ireland   |  |  |  |  |  |  |  |
|  | (Address of principal executive offices)  |  |  |  |  |  |  |  |
|  | Kevin Tansley<br>Chief Financial Officer<br>Tel: +353 1276 9800   |  |  |  |  |  |  |  |
|  | Fax: +353 1276 9888<br>IDA Business Park, Bray, Co. Wicklow, Ireland  |  |  |  |  |  |  |  |
|  | (Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)   |  |  |  |  |  |  |  |
|  | Securities registered or to be registered pursuant to Section 12(b) of the Act:   |  |  |  |  |  |  |  |
| Title of each class  American Depositary Shares (each representing 4 'A' Ordinary  Shares, par value U\$\$0.0109)  Name of each exchange on which registered  NASDAQ Global Market |   |  |  |  |  |  |  |  |
|  |   |  |  |  |  |  |  |  |
|  | American Depositary Shares (each representing 4 'A' Ordinary  NASDAQ Global Market  |  |  |  |  |  |  |  |
|  | American Depositary Shares (each representing 4 'A' Ordinary Shares, par value US\$0.0109)  Securities registered or to be registered pursuant to Section 12(g) of the Act: None  |  |  |  |  |  |  |  |
|  | American Depositary Shares (each representing 4 'A' Ordinary Shares, par value US\$0.0109)  Securities registered or to be registered pursuant to Section 12(g) of the Act: None Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None  Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:  94,308,358 Class 'A' Ordinary Shares (as of December 31, 2014)  Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No  NASDAQ Global Market   |  |  |  |  |  |  |  |
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### General

As used herein, references to "we", "us", "Trinity Biotech" or the "Group" in this Form 20-F shall mean Trinity Biotech plc and its world-wide subsidiaries, collectively. References to the "Company" in this annual report shall mean Trinity Biotech plc.

Our financial statements are presented in US Dollars and are prepared in accordance with International Financial Reporting Standards ("IFRS") both as issued by the International Accounting Standards Board ("IASB") and as adopted by the European Union ("EU"). The IFRS applied are those effective for accounting periods beginning 1 January 2014. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. All references in this annual report to "Dollars" and "\$" are to US Dollars, and all references to "Euro" or "€" are to European Union Euro. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

### Forward-Looking Statements

This Annual Report on Form 20-F contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbour from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors – please refer to the risk factors in Item 3 for a more comprehensive outline of these risks and the threats which they pose to the Company and its results.

### Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

### Item 2 Offer Statistics and Expected Timetable

Not applicable.

### Item 3 Key Information

The following selected consolidated financial data of Trinity Biotech as at December 31, 2014 and 2013 and for each of the years ended December 31, 2014, 2013 and 2012 have been derived from, and should be read in conjunction with, the audited consolidated financial statements and notes thereto set forth in Item 18 of this Annual Report. The selected consolidated financial data as at December 31, 2012, 2011 and 2010 and for the years ended December 31, 2011 and December 31, 2010 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

### CONSOLIDATED STATEMENT OF OPERATIONS DATA

|   | Year ended December, 31 |                   |   |                   |                   |
|---|-------------------------|-------------------|---|-------------------|-------------------|
|   | 2014                    | 2013              | 2012                                    | 2011              | 2010              |
|   | Total<br>US\$'000       | Total<br>US\$'000 | Total<br>US\$'000                       | Total<br>US\$'000 | Total<br>US\$'000 |
| Revenues  | 104,872                 | 91,216            | 82,510                                  | 77,948            | 89,635            |
| Cost of sales*  | (54,525)                | (45,996)          | (40,257)                                | (37,820)          | (45,690)          |
| Gross profit  | 50,347                  | 45,220            | 42,253                                  | 40,128            | 43,945            |
| Other operating income                                    | 424                     | 532               | 468                                     | 910               | 1,616             |
| Research and development expenses                         | (4,291)                 | (3,691)           | (3,130)                                 | (3,206)           | (4,603)           |
| Selling, general and administrative expenses              | (28,441)                | (33,066)          | (22,425)                                | (22,048)          | (26,929)          |
| Net gain on divestment of business and restructuring      |                         |                   |   |                   |                   |
| expenses  | _                       | _                 | _                                       | _                 | 46,474            |
| Operating profit  | 18,039                  | 8,995             | 17,166                                  | 15,784            | 60,503            |
| Financial income  | 97                      | 1,276             | 2,280                                   | 2,428             | 1,352             |
| Financial expenses  | (69)                    | (51)              | (88)                                    | (12)              | (495)             |
| Net financing income                                      | 28                      | 1,225             | 2,192                                   | 2,416             | 857               |
| Profit before tax   | 18,067                  | 10,220            | 19,358                                  | 18,200            | 61,360            |
| Income tax expense  | (853)                   | (574)             | (2,017)                                 | (2,607)           | (942)             |
| Profit for the year (all attributable to owners of the    |                         |                   |   |                   |                   |
| parent)   | 17,214                  | 9,646             | 17,341                                  | 15,593            | 60,418            |
| Basic earnings per ADS (US Dollars)                       | 0.76                    | 0.44              | 0.81                                    | 0.73              | 2.85              |
| Diluted earnings per ADS (US Dollars)                     | 0.73                    | 0.41              | 0.77                                    | 0.70              | 2.79              |
| Basic earnings per 'A' ordinary share (US Dollars)        | 0.19                    | 0.11              | 0.20                                    | 0.18              | 0.71              |
| Diluted earnings per 'A' ordinary share (US Dollars)      | 0.18                    | 0.10              | 0.19                                    | 0.18              | 0.70              |
| Weighted average number of shares used in computing basic |                         |                   |   |                   |                   |
| EPS per 'A' ordinary share                                | 90,998,904              | 87,746,588        | 85,675,284                              | 85,171,494        | 84,734,378        |
| Weighted average number of shares used in computing       |                         |                   |   |                   |                   |
| diluted EPS per 'A' ordinary share                        | 94,870,988              | 93,712,698        | 89,773,616                              | 88,912,596        | 86,661,535        |
| Weighted average number of shares used in computing basic |                         |                   | • |                   | • • • • • • • • • |
| EPS per ADS   | 22,749,726              | 21,936,647        | 21,418,821                              | 21,292,874        | 21,183,595        |
| Weighted average number of shares used in computing       | 22 717 747              | 22 420 155        | 22 442 464                              | 22 220 1 40       | 21 ((5 (6)        |
| diluted EPS per ADS                                       | 23,717,747              | 23,428,175        | 22,443,404                              | 22,228,149        | 21,665,684        |

<sup>\*</sup> Medical Device Excise Tax (MDET) was introduced in the USA on January 1, 2013. Cost of sales for 2014 includes MDET of US\$547,000 (2013: US\$691,000).

#### Consolidated Balance Sheet Data

|  | December 31,<br>2014<br>US\$'000 | December 31,<br>2013<br>US\$'000 | December 31,<br>2012<br>US\$'000 | December 31,<br>2011<br>US\$'000 | December 31,<br>2010<br>US\$'000 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Net current assets (current assets less current liabilities) | 46,888                           | 55,766                           | 97,531                           | 101,684                          | 89,068                           |
| Non-current liabilities                                      | (23,809)                         | (22,499)                         | (15,061)                         | (6,838)                          | (7,331)                          |
| Total assets   | 242,838                          | 226,486                          | 197,407                          | 171,499                          | 160,874                          |
| Capital stock  | 1,192                            | 1,170                            | 1,134                            | 1,106                            | 1,092                            |
| Shareholders' equity   | 196,972                          | 183,011                          | 169,380                          | 151,332                          | 141,287                          |

A final dividend of 22 cents per ADS was paid in 2014 in respect of the fiscal year 2013 (20 cents per ADS paid in 2013 in respect of the fiscal year 2012, 15 cents per ADS paid in 2012 in respect of the fiscal year 2011 and 10 cents per ADS paid in 2011 in respect of the fiscal year 2010).

#### Risk Factors

You should carefully consider all of the information set forth in this Form 20-F, including the following risk factors, when investing in our securities. The risks described below are not the only ones that we face. Additional risks not currently known to us or that we presently deem immaterial may also impair our business operations. We could be materially adversely affected by any of these risks.

### **Risks Related to our Business**

Our long-term success depends upon the successful development and commercialization of new products.

- Our long-term viability and growth will depend upon the successful discovery, development and commercialization of other products from our research and development ("R&D") activities. In order to remain competitive, we are committed to significant expenditures on R&D and the commercialization of new or enhanced products. The R&D process generally takes a significant amount of time from product inception to commercial launch. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. We may have to abandon a new or enhanced product in which we have invested substantial time and money. During the fiscal years ended December 31 2014, 2013 and 2012, we incurred US\$20.3 million, US\$18.4 million and US\$13.0 million, respectively, in capitalized R&D expenses. We expect to continue to incur significant costs related to our research and development activities.
- Successful products require significant development and investment, including testing to demonstrate their performance capabilities, cost-effectiveness or other benefits prior to commercialization. In addition, unless exempt, regulatory clearance or approval must be obtained before our medical device products may be sold. Additional development efforts on these products may be required before we are ready to submit applications for marketing authorisation to any regulatory authority. Regulatory authorities may not clear or approve these products for commercial sale or may substantially delay or condition clearance or approval. In addition, even if a product is successfully developed and all applicable regulatory clearances or approvals are obtained, there may be little or no market for the product. Accordingly, if we fail to develop and gain commercial acceptance for our products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flow and business.
- Our future growth in the United States is dependent in part on Food and Drug Administration ("FDA") clearance of products utilizing our Meritas platform, such as Troponin I and BNP. We expect to submit these products for FDA clearance later in 2015. If FDA clearance is delayed or not achieved for these products, it could have a material impact on the future growth of our business.

#### Our ability to sell products could be adversely affected by competition from new and existing diagnostic products.

- We have invested in research and development but there can be no guarantees that our R&D programmes will not be rendered technologically obsolete or financially non-viable by the technological advances of our competitors, which would also adversely affect our existing product lines and inventory. The main competitors of Trinity Biotech (and their principal products with which Trinity Biotech competes) include: Abbott Diagnostics (AxSYM<sup>TM</sup>, IMx<sup>TM</sup>, i-STAT®), Alere Inc. (Determine<sup>TM</sup>, Wampole<sup>TM</sup>, Athena<sup>TM</sup>, Biosite Triag®), Arkray (HA-8180), Bio-Rad (ELISA, WB, Bioplex<sup>TM</sup>, Variant II, Turbo and D10<sup>TM</sup>), Diasorin Inc. (Liasion<sup>TM</sup>, ETIMAX<sup>TM</sup>), Johnson & Johnson Ortho Clinical Diagnostics (Vitros<sup>TM</sup>), OraSure Technologies, Inc. (OraQuick®), Roche Diagnostics (COBAS AMPLICOR<sup>TM</sup>, Ampliscreen<sup>TM</sup>, Accutrend<sup>TM</sup>, Tina Quant<sup>TM</sup>), Siemens Beckman Coulter (Uni-Cel), Siemens Dade-Behring (BEP 2000, Enzygnost®), Siemens Bayer (Centaur<sup>TM</sup>), Siemens DPC (Immulite<sup>TM</sup>), Thermo Fisher (Konelab<sup>TM</sup>) and Tosoh (G8<sup>TM</sup>).
- The diagnostics industry is focused on the testing of biological specimens in a laboratory or at the point of care and is highly competitive and rapidly changing. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.
- We may in certain instances also face competition from products that are sold at a lower price. Where this occurs, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products. We may also be required to increase our marketing efforts in order to compete effectively, which would increase our costs.
- Our Troponin I and BNP tests compete with products made by our competitors. Multiple competitors are making investments in competing technologies and products, and a number of our competitors may have a competitive advantage because of their greater financial, technical, research and other resources. Some competitors offer broader product lines and may have greater market presence or name recognition than we have. If we receive FDA clearance, and in order to achieve market acceptance, we and/or our distributors will likely be required to undertake substantial marketing efforts and spend significant funds to inform potential customers and the public of the existence and perceived benefits of our products. Our marketing efforts for these products may not be successful. As such, there can be no assurance that these products will obtain significant market acceptance and fill the market needs that are perceived to exist on a timely basis, or at all.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

- Our medical device products and operations are subject to rigorous government regulation in the United States by the FDA, and numerous other federal, state and foreign governmental authorities, as well as and by comparable regulatory authorities in other jurisdictions. In particular, we are subject to strict governmental controls on the development, manufacture, labelling, storage, testing, advertising, promotion, marketing, distribution and import and export of our products. In addition, we or our distributors are often required to register with and/or obtain clearances or approvals from foreign governments or regulatory bodies before we can import and sell our products in foreign countries. The clearance and approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive.
- The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA.

The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. The 510(k) clearance process usually takes from three to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA, until an approval is obtained. There is no assurance that we will be able to obtain FDA clearance or approval for any of our new products on a timely basis, or at all.

- In the United States, the majority of our currently commercialized products have received pre-market clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we currently market only one device pursuant to an approved PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products.
- The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:
  - our ability to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended users;
  - insufficient data from our pre-clinical studies and clinical trials to support clearance or approval, where required; and
  - the failure of the manufacturing process or facilities we use to meet applicable requirements.
- In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. FDA's review of its 510(k) clearance process could result in additional changes to regulatory requirements or guidance documents which could increase the costs of compliance, or restrict our ability to maintain current clearances. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorised the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval.
- Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting clearance or approval from the applicable regulatory authorities. There is no certainty that such clearance or approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process. Further, regulatory authorities, including the FDA, may not approve or clear our future products for the indications that are necessary or desirable for successful commercialization. A regulatory authority may impose requirements as a condition to granting a marketing authorisation, may include significant restrictions or limitations as part of a marketing authorisation it grants and may delay or refuse to authorise a product for marketing, even though a product has been authorised for marketing without restrictions or limitations in another country or by another agency. Failure to receive clearance or approval for our new products, or commercially undesirable limitations on our clearances or approvals, would have an adverse effect on our ability to expand our business.

Clinical trials necessary to support future premarket submissions will be expensive and will require enrollment of suitable patients who may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

• Initiating and completing clinical trials necessary to support approval of our Troponin test and BNP test, as well as other possible future products under development, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

- Conducting successful clinical studies will require the enrollment of patients who may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, and the availability of appropriate clinical trial investigators. Patients may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.
- Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Any challenges to patient enrollment may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.
- Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50, 56 and 812, and Good Clinical Practices. Although the majority of our IVD clinical studies meet the definition of exempted investigations under 21 Part 812 and are exempt from the Investigational Device Exemption (IDE) regulations in 21 CFR Part 812, we are still required to meet the requirements of 21 CFR Parts 50 and 56 for informed consent and Institutional Review Board (IRB) approval. FDA may conduct Bioresearch Monitoring (BiMo) inspections of us and/or our clinical sites to assess compliance with FDA regulations, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action as well as refusal to accept all or part of our data in support of a 510(k) or PMA and/or we may need to conduct additional studies.

If the third parties on which we rely to conduct our pre-clinical studies and clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

• We may not have the ability to independently conduct our pre-clinical studies and clinical trials for our products and we may rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our pre-clinical or clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

### The results of our clinical trials may not support our product candidate claims.

• Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues.

Failure to comply with FDA or other regulatory requirements may require us to suspend production of our products or institute a recall which could result in higher costs and a loss of revenues.

- Even after we obtain clearance or approval for our medical devices, we are still subject to ongoing and extensive post market regulatory requirements. Regulation by the FDA and other federal, state and foreign regulatory agencies impacts many aspects of our operations, and the operations of our suppliers and distributors, including manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, marketing, record keeping, import and export. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections by the FDA to assess compliance with the QSR and other regulations, and by other comparable foreign regulatory authorities with respect to similar requirements in other jurisdictions. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved products or place conditions on any product clearances or approvals that could restrict the commercial applications of those products. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:
  - untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
  - unanticipated expenditures to address or defend such actions
  - customer notifications for repair, replacement, refunds;
  - recall, detention or seizure of our products;
  - operating restrictions or partial suspension or total shutdown of production;
  - refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
  - · operating restrictions;
  - withdrawing 510(k) clearances on PMA approvals that have already been granted;
  - refusal to grant export approval for our products; or
  - criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

- Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.
- In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

- In the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.
- In addition to the FDA and other regulations described above, laws and regulations in some states may restrict our ability to sell products in those states. While we intend to comply with any applicable restrictions, there is no guarantee we will be successful in these efforts.
- We must also comply with numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances and labour or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

### Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

- Manufacturers may, on their own initiative, initiate actions, including a non-reportable market withdrawal or a reportable product recall, for the purpose of correcting a material deficiency, improving device performance, or for other reasons. Additionally, the FDA and similar foreign health or governmental authorities have the authority to require an involuntary recall of commercialized products in the event of material deficiencies or defects in design, manufacturing or labeling or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated.
- Companies are required to maintain certain records of post-market actions, even if they determine such actions are not reportable to the FDA. If we determine that certain actions do not require notification of the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted or failing to timely report or initiate a reportable product action. Further, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner.

# If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

• We are also required to comply with the FDA's Medical Device Reporting, or MDR, requirements in the United States and comparable regulations worldwide. For example, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the Competent Authority in whose jurisdiction the incident occurred.

- Were this to happen to us, the relevant Competent Authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues. This would be carried out either by the Competent Authority or it could require that Orion, as the Notified Body, carry out the inspection or assessment.
- We have reported MDRs in the past, and we anticipate that in the future it is likely that we may experience events that would require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, or agency actions, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

# Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

- Any modification to a 510(k)-cleared device in the United States that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.
- For example, we obtained 510(k) clearance for our Primus Variant System for the separation and quantification of normal and abnormal haemoglobin species as an aid in the diagnosis of haemoglobinopathies. The sample type used by this system was blood tubes. We subsequently introduced two systems based on the original Primus Variant System and they were named as ultra<sup>2</sup> GeneSys Variant System and ultra<sup>2</sup> Resolution Variant System. The primary focus of the GeneSys was on newborn screening using Dried Blood Spots as the sample type, while the Resolution was intended for confirmatory testing on the adult population using blood tubes as the sample type. We determined that these modifications to the indications for use were within our existing clearance and did not require the submission of a new 510(k) notification. The FDA stated that the use of Dried Blood Spots was not part of the original submission and represented a new modified Intended Use. The FDA informed us that it disagreed with our decision not to seek new 510(k) clearances for these modifications, and we have agreed to file new 510(k) notifications to obtain clearance for these indications. We are currently in ongoing discussions with the FDA regarding the data that FDA will require to support new 510(k) clearances to support the modified indications for these products. Although the FDA has informed us that we may continue marketing these products pending submission and clearance of new 510(k) notifications, there is no guarantee that we will be able to obtain new 510(k) clearances on a timely basis, or at all or that the FDA will not withdraw its authorisation to continue marketing the products pending new 510(k) clearance. If we are not able to obtain new 510(k) clearances, or if the FDA withdraws its authorisation, we may be required to cease marketing for the currently-marketed indications and remove these products from U.S. commercial distribution.
- Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) notification for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) clearance will be required for modifications or changes to a previously cleared device. The FDA issued this report and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) clearance is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

• Our promotional materials must comply with FDA and other applicable laws and regulations. We believe that the specific uses for which our products are marketed fall within the scope of the indications for use that have been cleared or approved by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific uses until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials constitutes promotion of an unapproved use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

# If the FDA were to modify its policy of enforcement discretion with respect to our laboratory developed tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or other approvals.

- Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests, or LDTs, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to FDA regulation. The FDA defines the term "laboratory developed test" as an in vitro diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act, or FDA Act, with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims and erroneous results, the FDA issued guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing Congress and manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.
- We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for any of our LDTs, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our current LDTs or to develop and introduce new LDTs. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.
- If FDA premarket review, including clearance or approval, is required for our current or future LDTs (either alone or together with sample collection devices), products or services we may develop, or we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our LDTs while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our LDTs, there can be no assurance that any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of for our LDTs. If our LDTs are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational and we cannot offer the LDTs for diagnostic purposes, or if labeling claims the FDA allows us to make are limited, orders may decline.

• Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

#### We are also subject to various federal and state laws targeting fraud and abuse in the healthcare industry

- If we fail to comply with federal and state health care laws, including fraud and abuse, false claims, physician payment transparency and privacy and security laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected. We are subject to anti-kickback laws, self-referral laws, false claims laws, and laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of our products. The laws that may affect our ability to operate include, but are not limited to:
  - the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and wilfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
  - the Physician Self-Referral Law, also known as the "Stark Law", which provides for strict liability for referrals by physicians to entities with which they or their immediate family members have a financial arrangement for certain designated health services, including clinical laboratory services provided by our CLIA-certified laboratory owned and operated by Immco Diagnostics Inc., that are reimbursable by federal healthcare programs, unless an exception applies. Penalties for violating the Stark Law include denial of payment, civil monetary penalties of up to fifteen thousand dollars per claim submitted, and exclusion from federal health care programs, as well as a penalty of up to one-hundred thousand dollars for attempts to circumvent the law;
  - federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim:
  - the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
  - federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
  - the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. We cannot assure you that we have and will successfully report all transfers of value by us, and any failure to comply could result in significant fines and penalties. Failure to submit the required information may result in civil monetary penalties up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;
- federal and state laws governing the certification and licensing of clinical laboratories, including operational, personnel and quality requirements designed to ensure that testing services are accurate and timely, and federal and state laws governing the health and safety of clinical laboratory employees;
- the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorising the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which, pursuant to draft legislation being prepared by the German government, may make the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.
- Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbours available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or order our tests, our sales and marketing efforts and certain arrangements with customers, including those where we provide our instrumentation for free in exchange for minimum purchase requirements of our reagents, and our billing and claims processing practices, could be subject to challenge under one or more of such laws. By way of example, some of our consulting arrangements with physicians do not meet all of the criteria of the personal services safe harbour under the federal Anti-Kickback Statute. Accordingly, they do not qualify for safe harbour protection from government prosecution. A business arrangement that does not substantially comply with a safe harbour, however, is not necessarily illegal under the Anti-Kickback Statute, but may be subject to additional scrutiny by the government. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and distributors may engage in fraudulent or other illegal activity. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

- To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), has recently increased its scrutiny of interactions between health care companies and health care providers, which has led to a number of investigations, prosecutions, convictions and settlements in the health care industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with the DOJ or other law enforcement agencies have forced healthcare providers to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.
- Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.
- We have not yet developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are or may become subject. Although the development and implementation of such compliance programs can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, or any other laws that may apply to us, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other laws and regulations that apply to us, we could receive adverse publicity, face enforcement action and be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

### Our business could be adversely affected by changing conditions in the diagnostic market.

• The diagnostics industry is in transition with a number of changes that affect the market for diagnostic test products. The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. For example, major consolidation among reference laboratories and the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. There can be no assurance that we will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers. Further, this consolidation trend may result in the remaining companies having greater financial resources and technological capabilities, thereby intensifying competition in the industry, which could have a material adverse effect on our business.

# Future acquisitions may be less successful than expected, not generate the expected benefits, disrupt our ongoing business, distract our management, increase our expenses and adversely affect our business, and therefore, growth may be limited.

- Trinity Biotech has historically grown organically and through the acquisition of, and investment in, other companies, product lines and technologies. We may enter into strategic acquisitions or investments as a way to expand our business. These activities, and their impact on our business, are subject to many risks, including the following:
  - Suitable acquisitions or investments may not be found or consummated on terms or schedules that are satisfactory to us or consistent with our objectives;
  - The benefits expected to be derived from an acquisition may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, general economic conditions and increased competition;
  - We may be unable to successfully integrate an acquired company's personnel, assets, management systems, products and/or technology into our business;
  - Worse than expected performance of an acquired business may result in the impairment of intangible assets;
  - Acquisitions may require substantial expense and management time and could disrupt our business;

- We may not be able to accurately forecast the performance or ultimate impact of an acquired business;
- An acquisition and subsequent integration activities may require greater capital and other resources than originally anticipated at the time of acquisition;
- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;
- An acquisition may result in the loss of our or the acquired company's key personnel, customers, distributors or suppliers;
- An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations, and our inability to successfully assimilate differences in foreign business practices or overcome language or cultural barriers; and
- Our ability to integrate future acquisitions may be adversely affected by inexperience in dealing with new technologies.

The occurrence of one or more of the above or other factors may prevent us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business or otherwise achieve our financial and strategic objectives.

### Our revenues are highly dependent on a network of distributors worldwide.

- Trinity Biotech currently distributes its product portfolio through distributors in approximately 100 countries worldwide. Our
  continuing economic success and financial security is dependent on our ability to secure effective channels of distribution on
  favourable trading terms with suitable distributors.
- The loss or termination of our relationship with these key distributors could significantly disrupt our business unless suitable alternatives were timely found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

### Reductions in government funding to agencies and organizations we work with could adversely affect our business and financial results.

• We sell our products into the public health market, which consists of state, county and other governmental public health agencies, community based organizations, service organizations and similar entities. Many of these customers depend to a significant degree on grants or funding provided by governments or governmental agencies to run their operations, including programs that use our products, such as our HIV testing products. In international markets, we often sell our products to parties funded by such agencies. The level of available government grants or funding is unpredictable, and certain organizations may not have their contracts renewed for funding. Available funding may be affected by various factors including future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding or change in organizational contracts could cause our customers to delay, reduce or forego purchases of our products or cause short term or long term fluctuations in our product revenues through these channels.

### Trinity Biotech may be subject to liability resulting from its products or services.

- Trinity Biotech may be subject to claims for personal injuries or other damages if any of our products, or any product which is
  made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during
  product testing, manufacturing, marketing, sale or usage. There is no assurance that we would be successful in defending any
  product liability lawsuits brought against us. Regardless of merit or eventual outcome, product liability claims could result in:
  - Decreased demand for our products;
  - Lost revenues:
  - Damage to our image or reputation;
  - Costs related to litigation;
  - Diversion of management time and attention; and
  - Incurrence of damages payable to plaintiffs.
- Trinity Biotech has global product liability insurance in place for its manufacturing subsidiaries up to a maximum of €6,500,000 (US\$7,899,000) for any one accident, limited to a maximum of €6,500,000 (US\$7,899,000) in any one year period of insurance. A deductible of US\$25,000 is applicable to each insurance event that may arise. There can be no assurance that our product liability insurance is sufficient to protect us against liability that could have a material adverse effect on our business. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

# Significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results.

- Products manufactured at our facilities in Bray, Ireland, Jamestown and Buffalo, New York, Kansas City, Missouri and Carlsbad, California comprised approximately 86% of revenues during the fiscal year ended December 31, 2014. Our global supply of these products and services is dependent on the uninterrupted and efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products and product components.
- If we do not negotiate long-term contracts, our suppliers will likely not be required to provide us with any guaranteed minimum production levels. As a result, we cannot assure you that we will be able to obtain sufficient quantities of product in the future. In addition, our reliance on third-party suppliers involves a number of risks, including, among other things:
  - contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
  - we or our contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
  - we or our contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
  - we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
  - we may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from us or their other customers;
  - fluctuations in demand for products that our contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
  - our suppliers or those of our contract manufacturer may wish to discontinue supplying components or services to us for risk management reasons;

- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.
- The operations of our facilities or these third-party manufacturing facilities could be adversely affected by fire, power failures, natural or other disasters, such as earthquakes, floods, or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead-time. There can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.
- If any of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products. If we are unable to satisfy commercial demand for our products in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our products that are subject to FDA and other regulatory clearances or approvals. We may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Any significant interruption in the Group's or third-party manufacturing capabilities could materially and adversely affect our operating results.

# We are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees or the inability to attract and retain qualified personnel as necessary could adversely affect our operations.

- Trinity Biotech's success is dependent to a large extent upon the contributions of certain key management personnel. Our key employees at December 31, 2014 were Ronan O'Caoimh, our CEO and Chairman, Jim Walsh, our Chief Scientific Officer and Kevin Tansley, our CFO/Company Secretary. We may not be able to attract or retain a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products and other life science businesses.
- If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support research, development and clinical programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

### We are dependent on third-party suppliers for certain critical components and the primary raw materials required for our test kits.

• The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. If our third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work.

- Some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third-party vendors could adversely and materially affect our reputation, our attempts to complete our clinical trials or commercialization of our products and adversely and materially affect our business, operating results and prospects. We may also need to obtain FDA or other regulatory authorisations for the use of an alternative component or for certain changes to our products or manufacturing process. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including, warning letters, product recalls, termination of distribution, product seizures, or civil penalties. Completing that development and obtaining such authorisations could require significant time and expense and we may not obtain such authorisations on a timely basis, or at all. The availability of critical components and products from other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and United States import and customs regulations, which complicate and could delay shipments of components to us.
- Although Trinity Biotech does not expect to be dependent upon any one source for these critical components or raw materials, alternative sources of antibodies with the characteristics and quality desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

#### Global economic conditions may have a material adverse impact on our results.

- We currently generate significant operating cash flows, which combined with access to the credit markets provides us with discretionary funding capacity for research and development and other strategic activities. Uncertainty in global economic conditions may continue for the foreseeable future and intensify. This uncertainty poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. Volatile economic conditions have adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions.
- If global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. Even with the improvement of economic conditions, it may take time for our customers and suppliers to establish new budgets and return to normal purchasing and shipping patterns. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery.

# We face risks relating to our international sales and business operations, including regulatory risks, which could impact our current business operations and growth strategy.

Our international sales and operations are subject to various United States and foreign laws and regulations relating to export
controls (including, without limitation, the U.S. Commerce Department's Export Administration Regulations), economic
sanctions (including, without limitation, various sanctions regulations administered by the U.S. Treasury Department's Office of
Foreign Assets Control), and anti-corruption (including, without limitation, the United States Foreign Corrupt Practice
Act). Failure to comply with such applicable laws and regulations could subject us to civil or criminal penalties, government
investigations, debarment from export privileges, and reputational harm, which could have a material adverse effect on our
business.

### Our sales and operations are subject to the risks of fluctuations in currency exchange rates.

- A substantial portion of our operations is based in Ireland and Europe is one of our main sales territories. As a result, changes in the exchange rate between the U.S. Dollar and the Euro can have significant effects on our results of operations. Since the acquisition of Fiomi Diagnostics AB in 2012 and the blood bank screening business of Lab21 Ltd in 2013, the Group also has a currency exposure to the Swedish Kroner and Sterling. The Group also has an exposure to the Brazilian Real through its Brazilian entity.
- In the future, we may enter into hedging instruments to manage our currency exchange rate risk. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavourable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

#### The conversion of our outstanding employee share options would dilute the ownership interest of existing shareholders.

• The total share options exercisable at December 31, 2014, as described in Item 18, Note 18 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 "A" Ordinary Shares. The exercise of the share options exercisable will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders. For instance, should the options of the 4,056,991 "A" Ordinary Shares (1,014,248 ADSs) exercisable at December 31, 2014 be exercised, Trinity Biotech would have to issue 4,056,991 additional "A" Ordinary Shares (1,014,248 ADSs). On the basis of 94,308,358 "A" Ordinary Shares outstanding at December 31, 2014, this would effectively dilute the ownership interest of the existing shareholders by approximately 4%.

# It could be difficult for US holders of ADSs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.

• At present, no treaty exists between the United States and Ireland for the reciprocal enforcement of foreign judgments. The laws of Ireland do however, as a general rule, provide that the judgments of the courts of the United States have in Ireland the same validity as if rendered by Irish Courts. Certain important requirements must be satisfied before the Irish Courts will recognize the United States judgment. The originating court must have been a court of competent jurisdiction, the judgment may not be recognized if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgment obtained in contravention of the rules of natural justice will not be enforced in Ireland.

# Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.

- The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements.
- As a result, our products and the materials used in their manufacture or assembly undergo regular inspections and quality testing.
  Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in
  materials or production methods by our vendors, and other events or conditions could cause our products or the materials used to
  produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label
  claims or the expectations of our customers.
- Any failure or delay in our ability to meet the applicable specifications, performance standards, quality requirements or customer
  expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements.
  These events could, in turn, adversely affect our revenues and results of operations.

### Compliance with regulations governing public company corporate governance and reporting is complex and expensive.

• Many laws and regulations impose obligations on public companies, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Our implementation of certain aspects of these laws and regulations has required and will continue to require substantial management time and oversight and may require us to incur significant additional accounting and legal costs. We continually evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the ultimate amount of additional costs we may incur or the timing of such costs. These laws and regulations are also subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Although we are committed to maintaining high standards of corporate governance and public disclosure, if we fail to comply with any of these requirements, legal proceedings may be initiated against us, which may adversely affect our business.

### Failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.

- As a result of any number of risk factors identified herein, no assurance can be given that we will be successful in implementing our financial and strategic objectives. In addition, the funds for research, clinical development and other projects have in the past come primarily from our business operations. If our business slows and we have less money available to fund research and development and clinical programs, we will have to decide at that time which programs to cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our business. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product, clinical and market development efforts are unsuccessful or delayed.
- Furthermore, our failure to successfully introduce new or enhanced products and develop new markets could have a material adverse effect on our business and prospects.

### We may require future additional capital.

- Our future liquidity and ability to meet our future capital requirements will depend on numerous factors, including, but not limited to, the following:
  - The costs and timing of expansion of sales and marketing activities;
  - The timing and success of the commercial launch of new products;
  - The extent to which we gain or expand market acceptance for existing, new or enhanced products;
  - The costs and timing of the expansion of our manufacturing capacity;
  - The success of our research and product development efforts;
  - The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
  - The magnitude of capital expenditures;
  - Changes in existing and potential relationships with distributors and other business partners;
  - The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
  - The costs and liability associated with patent infringement or other types of litigation;
  - Competing technological and market developments; and
  - The scope and timing of strategic acquisitions.
- If additional financing is needed, we may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to us on satisfactory terms, or at all.

# Investor confidence and share value may be adversely impacted if we and/or our independent registered public accounting firm conclude that our internal control over financial reporting is not effective.

• As directed by the Sarbanes-Oxley Act of 2002, we are required to include a report in our Annual Reports on Form 20-F that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

- We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal control over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the overall quality of our internal controls may be affected by the internal control over financial reporting implemented by any business we acquire and our ability to assess and successfully integrate the internal controls of any such business.
- If, during any year, our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, operated, tested or assessed, then it may issue a report that is qualified. We also could conclude that our internal control over financial reporting is not effective. These events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our common stock.

### Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.

• To the extent that we or our strategic partners fail to maintain a high quality level of service and support for diagnostic products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could result in slower adoption rates and lower than anticipated utilisation of our products which could have a material adverse effect on our business, financial condition and results of operations.

# Consolidation of our customers or the formation of group purchasing organisations could result in increased pricing pressure that could adversely affect our operating results.

• The health care industry has undergone significant consolidation resulting in increased purchasing leverage for customers and consequently increased pricing pressures on our business. Additionally, some of our customers have become affiliated with group purchasing organisations. Group purchasing organisations typically offer members price discounts on laboratory supplies and equipment if they purchase a bundled group of one supplier's products, which results in a reduction in the number of manufacturers selected to supply products to the group purchasing organization and increases the group purchasing organization's ability to influence its members' buying decisions. Further consolidation among customers or their continued affiliation with group purchasing organizations may result in significant pricing pressures and correspondingly reduce the gross margins of our business or may cause our customers to reduce their purchases of our products, thereby adversely affecting our business, prospects, operating results or financial condition.

### We may be unable to protect or obtain proprietary rights that we utilise or intend to utilise.

- In developing and manufacturing our products, we employ a variety of proprietary and patented technologies. In addition, we have licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide any assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide any assurances that we will be successful in obtaining licenses or proprietary or patented technologies in the future, or that licenses granted to us by third parties will not be granted to other third parties who could potentially compete with us.
- Filing, prosecuting and defending patents covering our current and future products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

The scope of the patent protection we obtain may not be sufficiently broad to compete effectively in our markets; our patent applications could be rejected or the existing patents could be challenged; and trade secrets and confidential know-how could be obtained by competitors.

- Trinity Biotech currently owns 8 U.S. patents with remaining patent lives varying from six months to 16 years.
- We may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current products or any future products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.
- We can provide no assurance that third parties will not challenge the validity, enforceability or scope of the patents Trinity Biotech may apply for, or obtain, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products covered by those patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We can provide no assurance that our patents will continue to be commercially valuable.
- Trade secrets and confidential know-how are important to our scientific and commercial success. Although we seek to protect our proprietary information through confidentiality agreements and other contracts, we can provide no assurance that others will not independently develop the same or similar information or gain access to our proprietary information.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

• Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Organization ("USPTO") and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalise and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our current or future products, our competitors might be able to enter the market, which would have an adverse effect on our business.

### Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

- Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.
- For example, the United States has recently enacted and implemented wide-ranging patent reform legislation, which could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013.

Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have an adverse effect on our business and financial condition.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent
protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to
increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created
uncertainty with respect to the value of patents, once obtained.

### Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

- Litigation over intellectual property rights is prevalent in the diagnostic industry, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third-party may claim infringement against us. For example, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may infringe. Defence of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of managerial and financial resources from our business. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialise one or more of our products. The pendency of any litigation may cause our distributors and customers to reduce or terminate purchases of our products. If found to infringe, we may have to pay substantial damages, including treble damages and attorneys' fees for wilful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. Any substantial loss resulting from such a claim could cause our revenues to decrease and have a material adverse affect on our profitability, and the damage to our reputation in the industry could have a material adverse affect on our business.
- If we need to obtain a license as a result of litigation, we cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialisation of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialise one or more of our products, which could harm our business significantly.

# We may be involved in lawsuits to enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

• Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorised use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defence proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defence of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future products. Such a loss of patent protection could harm our business.

- We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.
- Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ordinary shares.

## Our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.

- We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, can cause all or portions of our websites to be unavailable, create system disruptions, shutdowns, erasure of critical data and software or unauthorised disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks and we have implemented solutions, processes, and procedures to help mitigate these risks, such as encryption, virus protection, security firewalls and comprehensive information security and privacy policies. However, despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. The age of our information technology systems, as well as the level of our protection and business continuity or disaster recovery capability, varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent further security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data, which could have a material adverse impact on our business, financial condition and results of operations. While we currently expend resources to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.
- In addition, the interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. If so, this could result in government-imposed fines or orders requiring that we change our data practices, which could have an adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

### Reductions in government funding and research budgets could adversely affect our business and financial results

We sell our products into the public health market, which consists of state, county and other governmental public health agencies, community based organisations, service organisations and similar entities. Many of these customers depend to a significant degree on grants or funding provided by governmental agencies to run their operations including programs that use our products. In international markets, we often sell our products to parties funded by such agencies. The level of available government grants or funding is unpredictable and may be affected by various factors including future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding could cause our customers to delay, reduce or forego purchases of our products.

#### **Risks Related to Government Regulation**

We could be adversely affected by healthcare reform legislation and other changes in coverage and reimbursement for our tests by third-party payors.

- Third-party payors for medical products and services, including state and federal governments, are increasingly concerned about escalating health care costs and can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. During 2010, following years of increasing pressure, the U.S. government enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act. The Affordable Care Act, among other things, established a 2.3% excise tax on the sales of medical devices beginning in calendar year 2013. In addition, it provided that payments under the Medicare Clinical Laboratory Fee Schedule, or CLFS, are to receive a negative 1.75% annual adjustment through 2015 and a productivity adjustment pursuant to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. In February 2012, the Middle Class Tax Relief and Job Creation Act of 2012 was signed into law, which, in part, reduced the potential future cost-based increases to the CLFS by 2%. Because some of our revenue is currently derived from the Medicare program, any changes in Medicare reimbursement may adversely impact our business. We cannot predict whether Medicare and other third-party payor reimbursement rates that mirror Medicare's will be sufficient to make our tests commercially attractive.
- Further, with respect to the CLFS, the Protecting Access to Medicare Act of 2014, or PAMA will make significant changes to the way that Medicare will pay for clinical laboratory services. Under the new law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is too early to predict the impact on reimbursement for our products.
- Also under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS must publicly report payment for the tests no later than January 1, 2016. We cannot determine at this time the full impact of the new law on our business, financial condition and results of operations.
- Other Medicare policy changes may include competitive bidding by clinical laboratories for the provision of services, which was
  the subject of a CMS demonstration project pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of
  2003, or MMA. In July 2008, the Patients and Providers Act of 2008 was enacted, which, among other things, repealed the
  competitive bidding demonstration project for clinical laboratory services. If competitive bidding is implemented in the future,
  competitive bidding could decrease our reimbursement rates for clinical laboratory tests.

- Healthcare legislative reforms affecting providers generally also include the Budget Control Act of 2011, which, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least US\$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. On April 1, 2013, the cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including our diagnostic tests, which, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to providers such as hospitals, imaging centres and cancer treatment centres, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of future diagnostic tests, increase costs, divert management's attention and adversely affect our ability to generate revenue and achieve profitability. Additionally, on several occasions, Congress has considered imposing a 20% co-insurance amount for clinical laboratory services, which would require beneficiaries to pay a portion of the cost of their clinical laboratory testing. Although that requirement has not been enacted at this time, Congress could decide to impose such an obligation at some point in the future, which would make it more difficult for us and our customers to collect adequate reimbursement for, and increase use of, our tests. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.
- Finally, some private insurers and other third-party payors link their rates to Medicare's reimbursement rates, and a reduction in Medicare reimbursement rates for clinical laboratory services could result in a corresponding reduction in the reimbursements we or our customers receive from such third-party payors. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any such initiatives or reductions in reimbursement levels for our tests may reduce the amount that will be reimbursed to us and our customers for such services and consequently could place constraints on the levels of overall pricing, which could have a material effect on our sales and/or results of operations.

Our laboratory business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, the law or regulations of the Clinical Laboratory Improvement Amendments of 1988, or CLIA, or those of other state or local agencies.

- Our laboratory operated by Immco Diagnostics Inc. is subject to CLIA, which is administered by CMS and extends federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA is designed to ensure the quality and reliability of clinical laboratories by, among other things, mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as the College of American Pathologists, among others. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties.
- We are also subject to regulation of laboratory operations under state clinical laboratory laws of New York and of certain other states from where we accept specimens. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. For example, California requires that we maintain a license to conduct testing in California, and California law establishes standards for our day-to-day laboratory operations, including the training and skill required of laboratory personnel and quality control. In some respects, notably with respect to qualifications of testing personnel, California's clinical laboratory laws impose more rigorous standards than does CLIA. Certain other states, including Florida, Maryland, New York and Pennsylvania, require that we hold licenses to test specimens from patients residing in those states, and additional states may require similar licenses in the future. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorisations, which could adversely affect our business and results of operations.

### Item 4 Information on the Company

Trinity Biotech develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. Trinity Biotech also is a significant provider of raw materials to the life sciences and research industries globally.

Trinity Biotech markets its portfolio of almost 850 products to customers in approximately 100 countries around the world through its own sales force and a network of international distributors and strategic partners.

Trinity Biotech was incorporated as a public limited company ("plc") registered in Ireland in 1992. The Company commenced operations in 1992 and, in October 1992, completed an initial public offering of its securities in the US. The principal offices of the Group are located at IDA Business Park, Bray, Co Wicklow, Ireland. The Group has expanded its product base through internal development and acquisitions.

In 2010, the Group sold its worldwide Coagulation product line to Diagnostica Stago for US\$90 million. Diagnostica Stago purchased the share capital of Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH and Trinity Biotech S.à r.l., along with Coagulation assets of Biopool US Inc. and Trinity Biotech Manufacturing Limited. Included in the sale were Trinity's lists of Coagulation customers and suppliers, all Coagulation inventory, intellectual property and developed technology. In total, 321 Trinity employees transferred their employment to Diagnostica Stago following the sale.

The following represents the acquisitions made by Trinity Biotech in recent years:

Acquisition of Phoenix Bio-tech Corp.

In 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation for US\$2.5 million of cash consideration and expected contingent consideration of US\$172,000. Phoenix Bio-tech manufactures and sells products for the detection of syphilis.

Phoenix Bio-tech was founded in 1992 and it sells its products under the TrepSure and TrepChek labels. Prior to the acquisition, Trinity Biotech distributed Phoenix Bio-tech's syphilis products on a non-exclusive basis in the U.S.

Acquisition of Fiomi Diagnostics AB

In 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB ("Fiomi") for US\$12.9m.

Fiomi, which is based in Uppsala, Sweden, is developing a range of point-of-care cardiac assays based on micro-pillar technology which will be marketed under the name Meritas. This technology is capable of providing extremely sensitive, highly reproducible, quantitative, multiplexed results making it significantly more accurate than the current established point-of-care tests in the market. In January 2014, Trinity received CE marking/EU regulatory approval of a Troponin I point-of-care test, the first test on this platform. In September 2014, CE marking/EU regulatory approval was received for a BNP point-of-care test. The Troponin I test is currently undergoing clinical trials, while trials for the BNP test will commence in 2015 with FDA submission for both tests expected during 2015. For more information please refer to Item 18, Note 22.

Acquisition of Immco Diagnostics Inc

In 2013, the Group acquired 100% of the common stock of Immco Diagnostics Inc ("Immco") for US\$32.88m.

Immco, which is headquartered in Buffalo, New York, specialises in the development, manufacture and sale of autoimmune test kits on a worldwide basis. This product line is complemented by specialised reference laboratory services in diagnostic immunology, pathology and immunogenetics, marketed to U.S.-based hospitals and reference laboratories. For more information please refer to Item 18, Note 22.

Acquisition of Blood Bank Screening Business

In 2013, the Group acquired the blood bank screening business of Lab21 Ltd for US\$7.45m.

The blood bank screening business acquired consists of a range of products for the screening of syphilis, malaria and cytomegalovirus (CMV), and was, at the time of acquisition based in Cambridge and Newmarket, UK. The business includes very high quality TPHA and ELISA products for screening. For more information please refer to Item 18, Note 22.

### **Principal Markets**

The primary market for Trinity Biotech's diagnostic products is the Americas (which consists principally of North America and South America). During fiscal year 2014, 58% (US\$61.1 million) (2013: 60% or US\$54.8 million) (2012: 60% or US\$49.6 million) of the Group's total revenues were derived from products sold in the Americas. Sales in the non-Americas (principally European, Asian and African countries) represented 42% (US\$43.7 million) of total sales for fiscal year 2014 (2013: 40% or US\$36.4 million) (2012: 40% or US\$32.9 million).

For a more comprehensive segment analysis please refer to Item 5, "Results of Operations" and Item 18, Note 2 to the consolidated financial statements.

### **Principal Products**

The brand names of the principal products of Trinity Biotech are listed below, organised first by point of use and second by application. The trademarks and registered marks noted below are owned by Trinity Biotech.

| Point                 | t-Of-Care                 | Clinical Laboratory |                       |                        |                    |                         |
|-----------------------|---------------------------|---------------------|-----------------------|------------------------|--------------------|-------------------------|
| Infectious Diseases   | <b>Emergency Medicine</b> | Infectious Diseases | Haemoglobin           | Autoimmune             | Clinical Chemistry | Blood Bank Screening    |
| UniGold <sup>TM</sup> | Meritas®                  | Bartels®            | Premier <sup>TM</sup> | ImmuBlot <sup>TM</sup> | EZTM               | Captia <sup>TM</sup>    |
| Recombigen®           |                           | MarDx <sup>®</sup>  | Ultra <sup>2TM</sup>  | $ImmuGlo^{TM}$         |                    | MicroTrak <sup>TM</sup> |
|                       |                           | MarBlot®            |                       | ImmuLisa <sup>TM</sup> |                    |                         |
|                       |                           |                     |                       | $OTOblot^{TM}$         |                    |                         |

Trinity Biotech also sells raw materials to the life sciences industry and research institutes globally through its wholly owned subsidiary, Benen Trading Ltd., trading as Fitzgerald Industries.

Trinity Biotech sells its products through its direct sales organisations in the United States, Brazil and to an extent the United Kingdom, and through its network of principal distributors and non-governmental bodies into approximately 100 countries globally.

### Point-of-Care (POC)

Point-of-care refers to diagnostic tests which are carried out in the presence of the patient.

### $Uni ext{-}Gold^{\operatorname{TM}}HIV$

We believe that Trinity Biotech makes a very significant contribution to the global effort to meet the challenge of human immuno-deficiency virus, or HIV, with its principal product, Uni-Gold<sup>TM</sup> HIV. In Africa, Uni-Gold<sup>TM</sup> HIV has been used for several years in voluntary counselling and testing centres in the sub-Saharan region where it provides a cornerstone to early detection and treatment intervention.

In the U.S., the Centers for Disease Control (CDC) recommend the use of rapid tests to control the spread of HIV/AIDS. As part of this, Uni-Gold<sup>TM</sup> HIV is used in public health facilities, hospitals and other outreach facilities.

During 2013, Trinity Biotech received approval from the FDA for a HIV-2 claim for the Uni-Gold<sup>TM</sup> Recombigen® product. The approval will expand the sales potential of the Uni-Gold<sup>TM</sup> Recombigen® product in the United States as this product can now participate in certain health programs previously not open to it and compete more effectively in the hospital market.

The Future of Point-Of-Care at Trinity Biotech

Point-of-care is strategically key to the growth of Trinity. During 2013, Trinity Biotech introduced Uni-Gold<sup>TM</sup> S. pneumoniae, Uni-Gold<sup>TM</sup> Legionella, Uni-Gold<sup>TM</sup> C. difficile and Uni-Gold<sup>TM</sup> Syphilis. All of these products are Conformité Européenne ("CE") marked and submissions for FDA clearance for the relevant products are in preparation. Future additions to this portfolio will include; *Helicobacter pylori* antigen, malaria and HIV.

These new point-of-care products will be sold through Trinity Biotech's sales and marketing organisation to clinical and reference laboratories directly in the United Kingdom and through independent distributors and strategic partners in other countries.

### **Emergency Medicine**

Emergency medicine diagnostics refers to acute care testing which is critical time-sensitive diagnostic tests performed in emergency rooms, STAT labs, pre/post-operative units, physician office labs and the central laboratory.

Emergency medicine is a strategic cornerstone of the future growth of Trinity Biotech. Following the acquisition of Fiomi Diagnostics AB in 2012, Trinity Biotech has developed a high sensitivity test for Troponin I under the Meritas brand capable of delivering laboratory based quality in the emergency room environment for the detection of heart attacks. Troponin I is a recognised marker for detecting acute myocardial infarctions. The objective in developing this product was to produce a test capable of meeting the Third Universal Definition of Myocardial Infarction (2007 guideline) with a testing time of no more than 15 minutes. CE marking/EU regulatory approval for this product was received in January 2014. The product is currently undergoing clinical trials with a view to submitting to the FDA later in 2015.

Trinity has also developed a Brain Natriuretic Peptide ("BNP") test on the same platform. BNP is a biomarker utilised in aiding the diagnosis of and determining the clinical severity of acute and chronic heart failure. In addition, BNP can be useful in a wide range of clinical applications including risk stratification and monitoring of patients with heart failure and heart attacks. CE marking and EU regulatory approval was received for this product in September 2014. Clinical trials for the product are anticipated to commence in 2015. Once approved, the BNP assay will run side by side, on the same platform as Trinity's Troponin product. An FDA submission is also expected to be made later in 2015.

Once the combined product offering is approved for commercialisation, Trinity will be positioned to successfully target and compete in the combined BNP and Troponin point-of-care market. The cardiac point-of-care market is estimated to be US\$1 billion per year.

A top priority for Trinity Biotech is to expand its offering on the Meritas POC Analyser. The focus of our development efforts is to continue to expand the test menu to include assays for deep vein thrombosis and pulmonary embolism (D-dimer), and other highly valuable areas of need in emergency medicine.

Currently, Trinity Biotech offers the Meritas Troponin and BNP products for sale in Europe and other selected markets through its specialist Cardiology Distributor network. Trinity Biotech will launch the products in the U.S. following FDA clearance.

### Clinical Laboratory

Trinity Biotech supplies the clinical laboratory segment of the *in-vitro* diagnostic market with a range of diagnostic tests and instrumentation which detect:

- Infectious diseases,
- Haemoglobin, and
- Autoimmune diseases

Trinity Biotech also supplies this market with reagent products and other products through its clinical chemistry business.

### Infectious Diseases

Trinity Biotech manufactures products for niche and specialised applications in infectious diseases. The products are used with patient samples and the results generated help physicians to guide diagnosis for a broad range of infectious diseases. The key disease areas that Trinity Biotech serves include:

- Lyme disease,
- sexually transmitted diseases, including syphilis, chlamydia and herpes simplex virus,
- respiratory infections, including legionella and influenza,
- · Epstein Barr virus, and
- other viral pathogens, including measles, mumps, rubella and varicella.

Trinity Biotech develops, manufactures and distributes products in immunofluorescence (IFA), enzyme-linked immunosorbent (ELISA), western blot (WB) and cytotoxicity assay formats for diagnosis of infectious diseases. As a complement to the product range, the automation offering includes ELISA and western blot processors.

The vast majority of the infectious diseases product line of Trinity Biotech is FDA cleared for sale in the United States and CE marked in Europe. Products are sold in approximately 100 countries, with the focus on the Americas, Europe and Asia. The infectious disease products are sold through the sales and marketing organisation of Trinity Biotech to clinical and reference laboratories directly in the U.S. and U.K. and through independent distributors and strategic partners in other countries.

#### Diabetes and haemoglobinapothies

Primus Corporation, a Trinity Biotech company, focuses on products for in-vitro diagnostic testing for haemoglobin A1c used in the monitoring and diagnosis of diabetes and Hb Variants for the detection of haemoglobinapothies. Haemoglobinapothies are genetic defects that results in abnormal structure of the haemoglobin molecule, the iron-containing oxygen-transport metalloprotein in the red blood cells. Haemoglobinapathies include sickle-cell diseases and are among the most common genetic disorders in the world.

Primus manufactures a range of instruments that use patented boronate affinity technology for point-of-care platforms and for high-performance liquid chromotography, or HPLC, platforms, as follows:

- Haemoglobin A1c, or HbA1c, is a measure of a patient's average blood sugar control over the last two to three months.
   HbA1c is a highly accurate biomarker available for the diagnosis of diabetes and is a strong indicator of a diabetics glycemic control. HbA1c is also used to identify those at risk of becoming diabetic; often referred to as impaired glucose tolerance;
- Haemoglobin Variants: The Primus Ultra<sup>2</sup> instrument is an accurate, precise method for detection of haemoglobin variants which is important for screening populations for genetic abnormalities that can lead to conditions such as sickle cell anaemia and thalassemia. With over 200 variants in its library The Primus Ultra<sup>2</sup> is in a leading position to address this complex yet common disorder;
- Neonatal Haemoglobin: The GeneSys system is designed for the detection of Haemoglobin variants in neonatal patients. This is a growing segment as more countries around the world expand their newborn screening programs.

The Premier Hb9210 was launched in Europe in the second half of 2011. Trinity Biotech distributes Premier Hb9210 through its European partner Menarini Diagnostics. FDA approval was obtained in the fourth quarter of 2011. In the U.S., Trinity Biotech sells the Premier Hb9210 through its direct sales organisation. The Premier's unique features, cost structure and core technology enables it to compete in most economies and settings.

Trinity is currently developing an ion exchange version of the Premier Hb9210 which will be capable of detecting both HbA1c and haemoglobin variants. This product, Premier Resolution, is expected to launch in 2015.

The current Primus products are sold through the Trinity Biotech sales and marketing organisation to clinical and reference laboratories directly in the U.S. and Brazil. Elsewhere the products are sold through Trinity Biotech's network of distribution partners.

#### Autoimmune Diseases

Autoimmune diseases are diseases that involve immune responses of a body against its own cells and tissues.

In 2013, Trinity Biotech acquired Immco Diagnostics, an autoimmunity company known for novel assay development and impactful contributions to autoimmune disease diagnostic research. Immco develops, manufactures and distributes products in the following formats for diagnosis of autoimmune diseases:

- IFA.
- ELISA,
- WB and
- line immunoassay, or LIA.

As a complement to the product range, the automation offering includes ELISA and IFA processors and the Immco IFA reading system, iSight.

The Immco products are a seamless fit for the instrumentation platforms that Trinity Biotech continues to market for ELISA and WB assays. The majority of Immco's product line is FDA cleared for sale in the United States and CE marked in Europe.

The diagnostic product line is complemented by specialised reference laboratory offering services in diagnostic immunology, pathology and immunogenetics, and is marketed to U.S.-based reference laboratories and hospitals.

The Immco product line addresses the high growth, lower throughput, speciality autoimmune segment, where competition is limited. The principal autoimmune conditions in this segment are rheumatoid arthritis, vasculitis, lupus, celiac and Crohn's disease, ulcerative colitis, neuropathy, Hashimoto's disease and Grave's disease.

The Immco products are sold through Trinity Biotech's sales and marketing organisation to clinical and reference laboratories directly in the U.S. and via distributors in other countries. Menarini Diagnostics, a European market leader in autoimmune testing, distributes Immco products in the key European markets.

### Clinical Chemistry

The speciality clinical chemistry business of Trinity Biotech includes reagent products such as ACE, bile acids, lactate, oxalate and glucose-6-phosphate dehydrogenase (or G6PDH) that are clearly differentiated in the marketplace. These products are suitable for both manual and automated testing and have proven performance in the diagnosis of many disease states from liver and kidney disease to G6PDH deficiency which is an indicator of haemolytic anaemia.

#### **Blood Bank Screening**

Trinity Biotech's blood bank screening business was acquired from Lab21 Ltd in July 2013. The business unit manufactures a number of products to screen donated blood for transfusion-transmissible infections.

The World Health Organisation estimates that there were 107 million blood donations in 2011 and half of these were within high income countries. In these countries it is mandatory to screen for HIV, HBV, HCV and syphilis by nucleic acid or immunoassay testing and recommends testing for other pathogens (e.g. CMV, malaria, chagas and HTLV) based on territory.

Trinity Biotech manufactures immunoassays for the detection of syphilis, CMV and malaria. These products are sold through direct and distributor sales channels and are manufactured under original equipment manufacturer agreements for other major third party diagnostic companies. The business has strong market share in Europe and while not currently operating in the United States, Trinity Biotech is planning for operations in the United States through internal synergies and external relationships.

### Sales and Marketing

Trinity Biotech sells its product through its own direct sales force in the United States. Our sales team in the United States is responsible for marketing and selling the Trinity Biotech range of point-of-care, infectious disease, Haemoglobins, autoimmune and clinical chemistry products.

Through its sales and marketing organisation in Ireland, Trinity Biotech sells:

- Its Clinical Chemistry product range directly to hospitals and laboratories in Germany and France;
- Infectious Diseases and Clinical Chemistry product ranges directly to hospitals and laboratories in the UK; and
- All product lines through independent distributors and strategic partners in a further 100 countries approximately.

### Competition

The diagnostic industry is very competitive. There are many companies, both public and private, engaged in the sale of medical diagnostic products and diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. Innovation in the market is rare but significant advantage can be made with the introduction of new disease markers or innovative techniques with patent protection.

The Group's competition includes several large companies such as, but not limited to: Abbott Diagnostics, Alere Inc., Arkray, Bio-Rad, Diasorin Inc., Euroimmun, Johnson & Johnson, OraSure Technologies Inc., Phadia, Roche Diagnostics, Siemens (from the combined acquisitions of Bayer, Dade-Behring and DPC), Thermo Fisher, Tosoh and Werfen.

#### Patents and Licences

#### **Patents**

Many of Trinity Biotech's tests are not protected by specific patents, due to the significant cost of putting patents in place for Trinity Biotech's wide range of products. However, Trinity Biotech believes that substantially all of its tests are protected by proprietary know-how, manufacturing techniques and trade secrets.

From time-to-time, certain companies have asserted exclusive patent, copyright and other intellectual property rights to technologies that are important to the industry in which Trinity Biotech operates. In the event that any of such claims relate to its planned products, Trinity Biotech intends to evaluate such claims and, if appropriate, seek a licence to use the protected technology. There can be no assurance that Trinity Biotech would, firstly, be able to obtain licences to use such technology or, secondly, obtain such licences on satisfactory commercial terms. If Trinity Biotech or its suppliers are unable to obtain or maintain a licence to any such protected technology that might be used in Trinity Biotech's products, Trinity Biotech could be prohibited from marketing such products. It could also incur substantial costs to redesign its products or to defend any legal action taken against it. If Trinity Biotech's products should be found to infringe protected technology, Trinity Biotech could also be required to pay damages to the infringed party.

#### Licences

Trinity Biotech has entered into a number of key licensing arrangements including the following:

In 2013, Trinity Biotech entered into a licence agreement with a leading market participant, giving the Group a non-exclusive, worldwide licence access to a significant HIV-2 patent portfolio for the purpose of making, using and selling a HIV test kit, subject to certain limitations. The Company recently received approval from the FDA for the HIV-2 claim on its Uni-gold™ HIV kit in the USA.

In 2012, Trinity Biotech entered into a licence agreement with the CDC in Atlanta, Georgia, United States for the rights to use Cardiolipin and other immunoassays and mechanisms in developing and producing a Syphilis rapid test.

In 2005, Trinity Biotech obtained a licence from the University of Texas for the use of certain Lyme disease antigens, thus enabling the inclusion of these antigens in the Group's Lyme diagnostic products. In 2005, Trinity also entered a Biological Materials License Agreement with the CDC for the rights to produce and sell the CDC developed HIV Incidence assay.

In 2006, Trinity Biotech entered into a new licence agreement with Inverness Medical Innovations ("IMI") to IMI's updated broad portfolio of lateral flow patents, which expanded the field of use to include over the counter ("OTC") for HIV products, thus ensuring Trinity Biotech's freedom to operate in the lateral flow market with its UniGold<sup>TM</sup> technology. As a platform technology, the lateral flow licences obtained from Inverness Medical Innovations also apply to the new Point-of-Care range which is in development at our Carlsbad facility.

On December 19, 1999 Trinity Biotech obtained a non-exclusive commercial licence from the National Institute of Health ("NIH") in the United States for NIH patents relating to the general method of producing HIV-1 in cell culture and methods of serological detection of antibodies to HIV-1.

Each of the key licensing arrangements disclosed under this subheading terminates on the date expiration or adjudication of invalidity or unenforceability of the last of the particular licensed patents covered by the respective agreement, except in the case of one of the agreements which expires in 2015. Each licensor has the right to terminate the arrangement in the event of non-performance by Trinity Biotech. The key licensing arrangements, with the exception of the agreement entered into in 2013 which provides for the payment of a lump sum licence fee, require the Group to pay a royalty to the licence holder which is based on sales of the products which utilise the relevant technology being licensed. The royalty rates vary from 1% to 10% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2014 was US\$1,049,000 (2013: US\$1,105,000).

### **Government Regulation**

The research, development, preclinical and clinical testing, as well as the manufacture, labelling, marketing, sales, record-keeping, advertising, distribution, and promotion of Trinity Biotech's products are subject to extensive and rigorous government regulation in the United States and in other countries in which Trinity Biotech's products are sought to be marketed.

The process of obtaining authorisation to market our products varies, depending on the product categorisation and the country, from merely notifying the authorities of intent to sell, to lengthy formal approval procedures which often require detailed laboratory and clinical testing and other costly and time-consuming processes. The main regulatory bodies which require extensive clinical testing are the FDA in the United States, the Health Product Regulatory Authority (as the authority over Trinity Biotech in Europe) and Health Canada.

The process in each country varies considerably depending on the nature of the test, the perceived risk to the user and patient, the facility at which the test is to be used and other factors. As 58% of Trinity Biotech's 2014 revenues were generated in the Americas (with a large concentration of this in the United States) and as the United States represents a substantial proportion of the worldwide diagnostics market, an overview of FDA regulation has been included below.

### Food and Drug Administration

All of our products sold in the United States are medical devices subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the U.S. Food and Drug Administration ("FDA"). Certain of our products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. Other of our products sold in the United States require premarket approval (PMA) to market.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- · criminal prosecution.

The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

### FDA premarket clearance and approval requirements

Access to US Market. Each medical device that Trinity Biotech may wish to commercially distribute in the U.S. will require either pre-market notification (more commonly known as 510(k)) clearance or approval of a pre-market approval ("PMA") application prior to commercial distribution, unless specifically exempt. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (the "General Controls"). Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other special controls as deemed necessary by FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees.

Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device are categorised as Class III, requiring approval of a PMA.

510(k) Clearance Pathway. When a 510(k) clearance is required, Trinity Biotech must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device, a device that was in commercial distribution before May 28, 1976 for which the U.S. Food and Drug Administration has not yet called for the submission of pre-market approval applications, or is a device that has been reclassified from Class III to either Class II or I. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. As a practical matter, the FDA's 510(k) clearance pathway usually takes from 3 to 12 months, but it can take longer, and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the U.S. Food and Drug Administration requires significant clinical data to support substantial equivalence.

In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could even require a PMA approval, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination.

If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. We have modified aspects of some of our devices since receiving regulatory clearance. Some of those modifications we believe could not significantly affect the safety or efficacy of the device, and therefore, we believe new 510(k) clearances or pre-market approvals are not required. We have also obtained new 510(k) clearances from the FDA for other modifications to our devices.

In the future, we may make additional modifications to our products after they have received FDA clearance or approval, and in appropriate circumstances, determine that new clearance or approval is unnecessary.

However, the FDA may disagree with our determination and if the FDA requires us to seek 510(k) clearance or pre-market approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain the required clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. In addition, the FDA continues to evaluate the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k)s and additional requirements that may significantly impact the process.

*PMA Approval Pathway*. A device that does not qualify for 510(k) clearance generally will be placed in class III and required to obtain PMA approval, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction for its intended use. A PMA application must provide extensive technical, preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labelling. In addition, an advisory panel made up of clinicians and/or other appropriate experts from outside the FDA is typically convened to evaluate the application and make recommendations to the FDA as to whether the device should be approved.

Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application", although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process.

After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labelling or its manufacturing process. The FDA imposes substantial user fees for the submission and review of PMA applications. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labelling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications to the manufacturing process, labelling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as the original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

#### Clinical Studies.

Devices that have not received FDA approval or clearance and are used in clinical trials are considered to be and must be labeled as investigational devices. FDA regulates these products under the IDE regulations. (See 21 C.F.R. § 812.)

Per the IDE regulations, clinical studies that involve investigational devices are divided into two categories, based on the type of device. Studies of devices considered by the agency to present a significant risk require prior approval by an Institutional Review Board ("IRB"), informed consent of patients, and FDA approval of an IDE application, which details in part the clinical study protocol, pursuant to 21 C.F.R. § 812. A significant risk device study is defined as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and falls into at least one of the following categories: (1) it is intended as an implant; (2) it is used in supporting or sustaining human life; (3) it is of substantial importance in diagnosing, curing, mitigating or treating a disease, or otherwise prevents impairment of human health; or (4) it otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. See 21 C.F.R. 812.3(m). Studies of non-significant risk investigational devices require IRB approval and informed consent; however, the sponsor of the study does not have to obtain FDA approval of an IDE application before beginning the study.

Most clinical studies of IVDs (all of which technically involve investigational use only, or IUO, devices) are exempted from the IDE regulation, so long as the IUO device and the study meet certain regulatory criteria. Specifically, devices are exempt from IDE requirements if they are intended for IUO and:

- Are noninvasive;
- Do not require an invasive sampling procedure that poses a significant risk;
- Do not introduce energy into a subject by design or intention;
- Are not to be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure; and
- Comply with the labeling requirements for IUO devices, as outlined in 21 C.F.R. § 812.2(c)(3).

If an IUO device does not meet all the requirements for exemption, studies involving that IUO device would be subject to the IDE regulations. The majority of our products are exempt from the IDE regulation. However, we are required to have IRB approval prior to and during our clinical trials and must obtain informed consent from study participants.

## Post-market Regulation

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication:
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their
  device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause
  or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- · regulations pertaining to voluntary recalls; and
- · notices of corrections or removals.

We have registered our facility with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers. If the FDA finds any failure to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunctions, and civil penalties; recall or seizure of products; the issuance of public notices or warnings; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

Unanticipated changes in existing regulatory requirements or adoption of new requirements could have a material adverse effect on the Group. Any failure to comply with applicable QSR or other regulatory requirements could have a material adverse effect on the Group's revenues, earnings and financial standing.

There can be no assurances that the Group will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not have a material adverse effect upon the Group's revenues, earnings and financial standing.

## Clinical Laboratory Improvement Amendments of 1988, or CLIA

Purchasers of Trinity Biotech's clinical diagnostic products and our reference laboratory in the United States may be regulated under The Clinical Laboratory Improvements Amendments of 1988 ("CLIA") and related federal and state regulations. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA established three levels of diagnostic tests ("waived", "moderately complex" and "highly complex") and the standards applicable to a clinical laboratory depend on the level of the tests it performs. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, we and our customers are required to meet certain laboratory licensing requirements for states with regulations beyond CLIA. For more information on state licensing requirements, see the sections entitled "Government Regulation – New York Laboratory Licensing" and "Government Regulation – Other States' Laboratory Licensing."

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of or assessment of health.

CLIA requires that a laboratory hold a certificate applicable to the type of laboratory examinations it performs and that it complies with, among other things, standards covering operations, personnel, facilities administration, quality systems and proficiency testing, which are intended to ensure that clinical laboratory testing services are accurate, reliable and timely. Laboratories must register and list their tests with the Centers for Medicare & Medicaid Services, or CMS, the agency that oversees CLIA.

CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by regulated facilities, including certification and survey costs.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. CLIA requires full validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any test used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time and any such changes could have a material effect on our business.

## Federal Oversight of Laboratory Developed Tests and Research Use Only Products

Trinity Biotech supplied clinical laboratories with raw materials, such as reagent products, that may be used by clinical laboratories in clinical laboratory tests, which are regulated under CLIA, as well as by applicable state laws. Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests, or LDTs. The FDA defines the term "laboratory developed test" as an in vitro diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic Act with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing, and concerns with several high-risk LDTs related to lack of evidentiary support for claims and erroneous results, the FDA issued guidance that, when finalized, would adopt a risk based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing Congress and manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

Some products are for research use only, or RUO, or for IUO. RUO and IUO products are not intended for human clinical use and must be properly labeled in accordance with FDA guidance. Claims for RUOs and IUOs related to safety, effectiveness, or diagnostic utility or that it are intended for human clinical diagnostic or prognostic use are prohibited. In November 2013, the FDA issued guidance titled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only - Guidance for Industry and Food and Drug Administration Staff." This guidance sets forth the requirements to utilize such designations, labeling requirements and acceptable distribution practices, among other requirements. Mere placement of an RUO or IUO label on an in vitro diagnostic product does not render the device exempt from otherwise applicable clearance, approval or other requirements. The FDA may determine that the device is intended for use in clinical diagnosis based on other evidence, including how the device is marketed.

We cannot predict the potential effect the FDA's current and forthcoming guidance on LDTs and IUOs/RUOs will have on our reagents or materials that we market to the life sciences industry, and that we may use in the development of assays in our reference laboratory. We cannot be certain that the FDA might not promulgate rules or issue guidance documents that could affect our ability to sell these materials to the market. Should any of the reagents marketed by us to the life sciences industry and used in conducting diagnostic services be affected by future regulatory actions, our business could be adversely affected by those actions.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for LDTs that rely on our reagents or through our reference laboratory, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress.

Legislative proposals addressing oversight of LDTs were introduced in recent years and we expect that new legislative proposals will be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements.

## Product Exports

Export of products subject to 510(k) notification requirements, but not yet cleared to market, are permitted without FDA export approval, if statutory requirements are met. Unapproved products subject to PMA requirements can be exported to any country without prior FDA approval provided, among other things, they are not contrary to the laws of the destination country, they are manufactured in substantial compliance with the QSR, and have been granted valid marketing authorisation in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or member countries of the European Union or of the European Economic Area ("EEA"). FDA approval must be obtained for exports of unapproved products subject to PMA requirements if these export conditions are not met.

There can be no assurance that Trinity Biotech will meet statutory requirements and/or receive required export approval on a timely basis, if at all, for the marketing of its products outside the United States.

## Healthcare Reform

The Protecting Access to Medicare Act of 2014, or PAMA, which was signed into law on April 1, 2014, significantly alters the current payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, beginning January 1, 2016, clinical laboratories must report laboratory test contracted payment data for each Medicare-covered clinical diagnostic laboratory test that it furnishes during a time period to be defined by future regulations, which we expect will cover the previous 12 months. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each contracted private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organisations). Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period.

Other recent laws make changes impacting clinical laboratories, many of which have already gone into effect. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, enacted in March 2010, among other things:

- includes a reduction in the annual update factor used to adjust payments under the CLFS for inflation. This update factor reflects the consumer price index for all urban consumers, or CPI-U, and the ACA reduces the CPI-U by 1.75% for the years 2011 through 2015. The Affordable Care Act also imposes a multifactor productivity adjustment in addition to the CPI-U, which may further reduce payment rates;
- requires certain medical device manufacturers to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA; and
- requires the coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and clinicians and initiatives to promote quality indicators in payment methodologies.

The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction (known as sequestration) to several government programs. This included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken.

Further, in February 2012, the Middle Class Tax Relief and Job Creation Act of 2012 was passed, which, among other things, reduced by 2% the 2013 Medicare CLFS and rebased payments at the reduced rate for subsequent years. Overall, when adding this 2% reduction to the ACA's 1.75% reduction to the update factor and the productivity adjustment, the payment rates under the CLFS declined by 2.95% and 0.75% for 2013 and 2014, respectively.

This reduction does not include the additional sequestration adjustment. Lastly, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

## State and Federal Privacy and Security Laws

Under the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of individually identifiable health information, also known as protected health information, or PHI, held, used or disclosed by health care providers, such as our reference laboratory, and other covered entities.

HIPAA also regulates standardisation of data content, codes and formats used in certain electronic health care transactions and standardisation of identifiers for health plans and providers. HIPAA also governs patient access to laboratory test reports. Effective October 6, 2014, individuals (or their personal representatives, as applicable) have the right to access test reports directly from laboratories and to direct that copies of those reports be transmitted to persons or entities designated by the individual. Penalties for violations of HIPAA regulations include civil and criminal penalties.

In addition to federal privacy regulations, there are a number of state laws governing the privacy, confidentiality and security of individually identifiable health information and other personal information that are applicable to our business. Where these state laws are stricter than the requirements imposed by HIPAA or impose different or additional requirements than HIPAA, we may be subject to additional restrictions and liability above and beyond HIPAA's requirements.

The laws governing privacy and security of health information and other personal information are rapidly changing and new laws governing privacy and security may be adopted in the future as well. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business or process personal information, or in which our patients reside, or that we will be able to keep up with the cost of complying with new or additional requirements. Failure to comply with privacy and security requirements could result in damage to our reputation, adversely affect customer or investor confidence in us and reduce the demand for our services from existing and potential customers. In addition, we could face litigation, penalties and regulatory actions including civil or criminal penalties and significant costs for compliance with new or changing requirements, all of which could generate negative publicity and which could have a materially adverse effect on our business

#### Federal and State Anti-Kickback Laws

The Federal Anti-Kickback Statute makes it a felony for a person or entity, including a laboratory, to knowingly and wilfully offer, pay, solicit or receive any remuneration, directly or indirectly, to induce or in return for either the referral of an individual or the purchase, lease or order, or arranging for the purchase, lease or order, of items, services or other business that is reimbursable under any federal health care program, including Medicare and Medicaid. Courts have stated that an arrangement may violate the Anti-Kickback Statute if any one purpose of the arrangement is to encourage patient referrals or other federal health care program business, regardless of whether there are other legitimate purposes for the arrangement. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry.

Recognising that the Anti-Kickback Statute may technically prohibit innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory safe harbours. Although full compliance with these safe harbours protects health care providers and other parties against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbour does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Penalties for the Federal Anti-Kickback Statute violations are severe and include imprisonment, criminal fines, civil money penalties and exclusion from participation in federal health care programs.

Federal and state law enforcement authorities scrutinise arrangements between health care entities or providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services.

The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between health care providers or entities and actual or potential referral sources.

Many states have also adopted statutes similar to the federal Anti-Kickback Statute, some of which apply to payments in connection with the referral of patients for healthcare items or services reimbursed by any source, not only governmental payor programs. There can be no assurance that our relationships with physicians, hospitals, clinical laboratories and other customers will not be subject to investigation or challenge under such laws.

## Physician Self-Referral Prohibitions

In addition to the Anti-Kickback Statute, a federal law directed at physician "self-referral," commonly known as the Stark Law, prohibits, among other things, physicians who personally or through an immediate family member, have a financial relationship, including an investment, ownership or compensation relationship with an entity, including clinical laboratories, from referring Medicare patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies.

In addition, the clinical laboratory is prohibited from billing for any tests performed pursuant to a prohibited referral. Recent court cases have extended the Stark law's prohibition to referral of Medicaid patients as well. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to US\$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to US\$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states also have anti- "self-referral" and other laws that are not limited to Medicare and Medicaid referrals.

Like the Anti-Kickback Statute, the Stark Law is broad in its application to health care transactions and arrangements. Accordingly, the Stark Law contains many exceptions, which protect certain arrangements and transactions from the Stark Law penalties. The Stark Law is a strict liability statute, however, so intent is irrelevant, *i.e.*, a physician's financial relationship with a laboratory must meet an exception under the Stark Law, or the referrals are prohibited. Thus, unlike the Anti-Kickback Statute's safe harbours, if a laboratory's financial relationship with a referring physician does not meet the requirements of a Stark Law exception, then the physician is prohibited from making Medicare and Medicaid referrals to the laboratory and any such referrals will result in overpayments to the laboratory and subject the laboratory to the Stark Law's penalties. Many states have also adopted statutes similar to the Stark Law, some of which apply to payments in connection with the referral of patients for healthcare items or services reimbursed by any source, not only governmental payor programs.

### Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law, among other things, prohibits the offering or giving of remuneration, including the provision of free items and services, to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program. Violations could lead to civil money penalties of up to \$10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

#### Other Federal and State Fraud and Abuse Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws apply to our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are ambiguous and subject to varying interpretations.

HIPAA also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

A violation of each of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental payor programs. Many states have similar statutes that may carry significant penalties.

The Federal False Claims Act prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment or retaining an overpayment by the federal government. Actions which violate the Anti-Kickback Statute or Stark Law also incur liability under the False Claims Act. In addition to actions initiated by the government itself, the statute's "qui tam" provisions authorise actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud.

Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from \$5,500 to \$11,000 for each separate false claim, exclusion from participation in federal health care programs and criminal penalties. Several states have also adopted comparable state false claims act, some of which apply to all payors.

The Affordable Care Act, among other things, also imposed new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

### New York Laboratory Licensing

Because our reference laboratory located in New York receives specimens from New York State, our clinical reference laboratory is required to be licensed under New York laws and regulations, which establish standards for, among other things:

- day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel;
- physical requirements of a facility;
- · equipment; and
- validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the state regulatory agency may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. The state regulatory agency also must approve any LDT before the test is offered in New York. Should we be found out of compliance with New York laboratory requirements, we could be subject to such sanctions, which could harm our business. We cannot provide assurance that the state will at all times find us to be in compliance with applicable laws.

## Other States' Laboratory Licensing

In addition to New York, other states including California, Florida, Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state and it is possible that other states do have such requirements or will have such requirements in the future.

#### Regulation outside the United States

Distribution of Trinity Biotech's products outside of the United States is also subject to foreign regulation. Each country's regulatory requirements for product approval and distribution are unique and may require the expenditure of substantial time, money, and effort. There can be no assurance that new laws or regulations will not have a material adverse effect on Trinity Biotech's business, financial condition, and results of operation. The time required to obtain needed product approval by particular foreign governments may be longer or shorter than that required for FDA clearance or approval. There can be no assurance that Trinity Biotech will receive on a timely basis, if at all, any foreign government approval necessary for marketing its products.

#### Organisational Structure

Trinity Biotech plc and its subsidiaries ("the Group") is a manufacturer of diagnostic test kits and instrumentation for sale and distribution worldwide. Trinity Biotech's executive offices are located at Bray, Ireland while its research and development, manufacturing and marketing activities are principally conducted at the following:

- Trinity Biotech Manufacturing Limited, based in Bray, Ireland;
- Trinity Biotech (USA), based in Jamestown, New York;
- MarDx Diagnostics Inc, based in Carlsbad, California;
- Primus Corporation, based in , Kansas City;
- Biopool US Inc, based in Jamestown, New York;
- Immco Diagnostics Inc, based in Amherst and Buffalo, New York;
- Nova Century Scientific Inc, based in Burlington, Canada; and
- Fiomi Diagnostics AB based in Uppsala.

The Group's distributor of raw materials for the life sciences industry, Benen Trading Ltd (trading as Fitzgerald Industries), is based in Bray, Ireland and Acton, Massachusetts, USA.

For a more comprehensive schedule of the subsidiary undertakings of the Group please refer to Item 18, Note 29 to the consolidated financial statements.

## Property, Plant and Equipment

Trinity Biotech has five manufacturing sites worldwide, four in the United States. (Buffalo and Jamestown, NY, Kansas City, MO and Carlsbad, CA), and one in Bray, Ireland, as well as a research and development facility in Uppsala, Sweden. An additional facility is owned in Burlington, Canada which serves as a distribution centre and also carries out some research and development activities.

The U.S. and Irish facilities are each FDA and ISO registered facilities. As part of its ongoing commitment to quality, Trinity Biotech was granted the latest ISO 9001: 2000 and ISO 13485: 2003 certification. This certificate was granted by the Underwriters Laboratory, an internationally recognised notified body. It serves as external verification that Trinity Biotech has established an effective quality system in accordance with an internationally recognised standard. By having an established quality system there is a presumption that Trinity Biotech will consistently manufacture products in a controlled manner. To achieve this certification Trinity Biotech performed an extensive review of the existing quality system and implemented any additional regulatory requirements.

Trinity Biotech has entered into a number of related party transactions with JRJ Investments ("JRJ"), a partnership currently owned by Mr O'Caoimh and Dr Walsh, directors of the Company, and directly with Mr O'Caoimh and Dr Walsh, to provide current and potential future needs for the Group's manufacturing and research and development facilities, located in Bray, Ireland. In November 2004, Trinity Biotech entered into an agreement for a 25 year lease with JRJ, for 16,700 square feet of offices at an annual rent of €381,000 (US\$463,000), payable from 2004. In December 2007, the Group entered into an agreement with Mr O'Caoimh and Dr Walsh pursuant to which the Group took a lease on an additional 43,860 square foot manufacturing facility in Bray, Ireland at a total annual rent of €787,000 (US\$956,000). See Item 7 – Major Shareholders and Related Party Transactions.

Trinity Biotech USA operates from a 25,610 square foot FDA and ISO 9001 approved facility in Jamestown, New York. The facility was purchased by Trinity Biotech USA in 1994. Additional warehousing space is also leased in Jamestown, New York at an annual rental charge of US\$155,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,436 square feet and is the subject of a three year lease, renewed in 2012, at an annual rental cost of US\$244,000. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, amended in 2012, at an annual rental cost of US\$176,000.

Fiomi Diagnostics AB operates from a 15,500 square foot facility based in Uppsala, in Sweden. This facility is the subject of a 3 year operating lease. The annual rent on this facility is 2,924,000 SEK (US\$429,000).

Immco Diagnostics Inc. operates from a 15,200 square foot facility and a 4,000 square foot facility in Buffalo, New York, subject to leases expiring in 2017 and 2015 respectively. The annual rent for these facilities is US\$531,000. An additional 4,200 square foot facility is owned in Burlington, Canada.

Trinity Biotech (UK) Ltd operated from a 20,000 square foot facility in Cambridge, UK and a 10,000 square foot facility in Newmarket, UK. The lease for the Cambridge facility expired in March, 2014, and the Newmarket facility was subject to a 3 month rolling lease and is now also expired. Trinity Biotech vacated both the Cambridge and Newmarket premises in 2014.

Additional office and factory space is leased by the Group in Ireland, Kansas City, Missouri, Acton, Massachusetts and Sao Paulo, Brazil at an annual cost of €115,000 (US\$140,000), US\$100,000, US\$91,000 and US\$29,000 respectively.

At present we have sufficient productive capacity to cover demand for our product range. We continue to review our level of capacity in the context of future revenue forecasts. In the event that these forecasts indicate capacity constraints, we will either obtain new facilities or expand our existing facilities.

We do not currently have any plans to expand our facilities. We intend to improve production efficiency in the next twelve months at our Bray, Ireland facility by introducing more automation into the production process.

In relation to products produced at our facilities – these are as follows:

Bray, Ireland - Point-of-Care/HIV, Immunofluorescence and Clinical Chemistry products are manufactured at this site.

**Jamestown, New York** – this site specializes in the production of Microtitre Plate EIA products for infectious diseases and auto-immunity.

Carlsbad, California – this facility specialises in the development and manufacture of products utilising Western Blot and lateral flow technology. Our suite of Lyme products is manufactured at this facility and our new Infectious Diseases Point-of-Care range are manufactured at this site.

Kansas City, Missouri – this site is responsible for the manufacture of the Group's haemoglobin range of products.

**Buffalo, New York** – these sites are responsible for the manufacture of autoimmune test kits and the majority of R&D activities for Immco Diagnostics, along with its reference laboratory business.

We are in material compliance with all environmental legislation, regulations and rules applicable in each jurisdiction in which we operate.

# Capital expenditures and divestitures

Please refer to Item 18, Note 22 with regard to the acquisition of Immco Diagnostics Inc and the blood bank screening business in 2013 and the acquisition of Fiomi Diagnostics AB in 2012.

## Item 4A Unresolved Staff Comments

Not applicable.

## Item 5 Operating and Financial Review and Prospects

## **Operating Results**

Trinity Biotech's consolidated financial statements include the attributable results of Trinity Biotech plc and all its subsidiary undertakings collectively. This discussion covers the years ended December 31, 2014, December 31, 2013 and December 31, 2012, and should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this Form 20-F. The financial statements have been prepared in accordance with IFRS both as issued by the International Accounting Standards Board ("IASB") and as subsequently adopted by the European Union ("EU") (together "IFRS"). Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU.

Trinity Biotech has availed of the exemption under SEC rules to prepare consolidated financial statements without a reconciliation to U.S. generally accepted accounting principles ("U.S. GAAP") as at and for the three year period ended December 31, 2014 as Trinity Biotech is a foreign private issuer and the financial statements have been prepared in accordance with IFRS as issued by the International Accounting Standards Board ("IASB").

## Overview

Trinity Biotech develops, manufactures and markets diagnostic test kits used for the clinical laboratory and Point-of-Care ("POC") segments of the diagnostic market. These test kits are used to detect infectious diseases, sexually transmitted diseases, blood disorders and autoimmune disorders, as well as monitoring and diagnosing diabetes and haemoglobin variants. The Group markets almost 850 different diagnostic products in approximately 100 countries. In addition, the Group manufactures its own and distributes third party infectious disease diagnostic instrumentation. Trinity Biotech, through its Fitzgerald subsidiary, is a provider of raw materials to the life sciences industry.

### Factors affecting our results

The global diagnostics market is growing due to, among other reasons, the ageing population and the increasing demand for rapid tests in a clinical environment.

Our revenues are directly related to our ability to identify high potential products while they are still in development and to bring them to market quickly and effectively. Efficient and productive research and development is crucial in this environment as we, like our competitors, search for effective and cost-efficient solutions to diagnostic problems. The growth in new technology will almost certainly have a fundamental effect on the diagnostics industry as a whole and upon our future development.

The comparability of our financial results for the years ended December 31, 2014, 2013, 2012, 2011 and 2010 have been impacted by acquisitions made by the Group in three of the five years and by the divestiture of the Coagulation product line in 2010. There were no acquisitions made in 2014 or 2010. In 2013, the Group acquired 100% of the common stock of Immco Diagnostics Inc. Immco specialises in the development, manufacture and sale of autoimmune test kits on a worldwide basis. In 2013, the Group also acquired the blood bank screening business of Lab21 Ltd, a UK based company. The acquired business generates revenues from syphilis and malaria products. In 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB. Fiomi is developing a range of point-of-care cardiac assays. In 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation. Phoenix Biotech manufactures and sells products for the detection of syphilis.

For further information about the Group's principal products, principal markets and competition please refer to Item 4, "Information on the Company".

#### Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with IFRS. The preparation of these financial statements requires us to make estimates and judgements that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities.

On an on-going basis, we evaluate our estimates, including those related to intangible assets, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the critical accounting policies described below reflect our more significant judgements and estimates used in the preparation of our consolidated financial statements.

#### Revenue Recognition

## Goods sold and services rendered

Revenue from the sale of goods is recognised in the statement of operations when the significant risks and rewards of ownership have been transferred to the buyer. Revenue from products is generally recorded as of the date of shipment, consistent with our typical exworks shipment terms. Where the shipment terms do not permit revenue to be recognised as of the date of shipment, revenue is recognised when the Group has satisfied all of its obligations to the customer in accordance with the shipping terms.

Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods supplied to external customers, net of discounts and excluding sales taxes.

Revenue from services rendered is recognised in the statement of operations in proportion to the stage of completion of the transaction at the balance sheet date.

Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group, that the risks and rewards of ownership have passed to the buyer and the revenue can be measured. No revenue is recognised if there is uncertainty regarding recovery of the consideration due at the outset of the transaction or the possible return of goods.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass to the customer, the fair value of the instrument is recognised as revenue at the commencement of the lease and is matched by the related cost of sale. In the case of operating leases revenue is recognised over the life of the lease.

## Research and development expenditure

We write-off research and development expenditure as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalised at cost within intangible assets and amortised over its expected useful life of 15 years, which commences when the product is launched.

In-process research and development ("IPR&D") is tested for impairment on an annual basis, in the fourth quarter, or more frequently if impairment indicators are present, using projected discounted cash flow models. If IPR&D becomes impaired or is abandoned, the carrying value of the IPR&D is written down to its revised fair value with the related impairment charge recognised in the period in which the impairment occurs. If the fair value of the asset becomes impaired as the result of unfavourable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercialising our programs, we could incur significant charges in the period in which the impairment occurs. The valuation techniques utilised in performing impairment tests incorporate significant assumptions and judgments to estimate the fair value, as described above. The use of different valuation techniques or different assumptions could result in materially different fair value estimates.

Factors which impact our judgement to capitalise certain research and development expenditure include the degree of regulatory approval for products and the results of any market research to determine the likely future commercial success of products being developed. We review these factors each year to determine whether our previous estimates as to feasibility, viability and recovery should be changed.

At December 31, 2014 the carrying value of capitalised development costs was US\$70,662,000 (2013: US\$51,648,000) (see Item 18, Note 11 to the consolidated financial statements). The increase in 2014 was mainly as a result of development costs of US\$20,323,000 being capitalised. These additions were partially offset by amortisation of US\$562,000.

## Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment annually, either individually or at the cash generating unit level. Factors considered important, as part of an impairment review, include the following:

- Significant underperformance relative to expected, historical or projected future operating results;
- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- Obsolescence of products;
- Significant decline in our stock price for a sustained period; and
- Our market capitalisation relative to net book value.

When we determine that the carrying value of intangibles, non-current assets and related goodwill may not be recoverable based upon the existence of one or more of the above indicators of impairment, any impairment is measured based on our estimates of projected net discounted cash flows expected to result from that asset, including eventual disposition. Our estimated impairment could prove insufficient if our analysis overestimated the cash flows or conditions change in the future.

Goodwill and other intangibles are subject to impairment testing on an annual basis. The recoverable amount of each of the cash-generating units ("CGU") is determined based on a value-in-use computation, which is the only methodology applied by the Group and which has been selected due to the impracticality of obtaining fair value less costs to sell measurements for each reporting period. For the purpose of the annual impairment tests, goodwill is allocated to the relevant CGU.

The value-in-use calculations use cash flow projections based on the 2015 budget and projections for a further four years using projected revenue and cost growth rates of between 3% and 15%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate, are used in the value-in-use calculations. The value-in-use represents the present value of the future cash flows, including the terminal value, discounted at a rate appropriate to each CGU.

The key assumptions employed in arriving at the estimates of future cash flows are subjective and include projected EBITDA, net cash flows, discount rates and the duration of the discounted cash flow model. The assumptions and estimates used were derived from a combination of internal and external factors based on historical experience. The pre-tax discount rates used range from 12% to 24% (2013: 13% to 25%).

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas;

- 1. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2014:
  - No reversal of impairment in the event of a 10% increase in the growth in revenues.
  - No impairment loss in the event of a 10% decrease in the growth in revenues.
- 2. Similarly if there was a 10% variation in the discount rate used to calculate the potential impairment of the carrying values, which would represent a reasonably likely range of outcomes, there would be the following impairment loss/write back would be recorded at December 31, 2014:
  - No reversal of impairment in the event of a 10% decrease in the discount rate.
  - No impairment loss in the event of a 10% increase in the discount rate.

#### Allowance for slow-moving and obsolete inventory

We evaluate the realisability of our inventory on a case-by-case basis and make adjustments to our inventory provision based on our estimates of expected losses. We write off inventory that has reached its "use-by" date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value. Given the allowance is calculated on the basis of the actual inventory on hand at the particular balance sheet date, there were no material changes in estimates made during 2014, 2013 or 2012 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2014 our allowance for slow moving and obsolete inventory was US\$4,636,000 which represents approximately 12.1% of gross inventory value. This compares with US\$4,462,000, or approximately 13.1% of gross inventory value, at December 31, 2013 (see Item 18, Note 14 to the consolidated financial statements) and US\$5,348,000, or approximately 20.5% of gross inventory value, at December 31, 2012. There has been a decrease in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2014 and 2013. In the case of raw materials and work in progress, the size of the provision has been based on expected future production of these products. Management is satisfied that the assumptions made with respect to future sales and production levels of these products are reasonable to ensure the adequacy of this provision. In the event that the estimate of the provision required for slow moving and obsolete inventory was to increase or decrease by 2% of gross inventory, which would represent a reasonably likely range of outcomes, then a change in allowance of US\$763,000 at December 31, 2014 (2013: US\$683,000) (2012: US\$522,000) would result.

# Allowance for impairment of receivables

We make judgements as to our ability to collect outstanding receivables and where necessary make allowances for impairment. Such impairments are made based upon a specific review of all significant outstanding receivables. In determining the allowance, we analyse our historical collection experience and current economic trends.

If the historical data we use to calculate the allowance for impairment of receivables does not reflect the future ability to collect outstanding receivables, additional allowances for impairment of receivables may be needed and the future results of operations could be materially affected. Given the specific manner in which the allowance is calculated, there were no material changes in estimates made during 2014, 2013 or 2012 which would have an impact on the carrying values of receivables in these periods. At December 31, 2014, the allowance was US\$2,205,000 which represents approximately 2.1% of Group revenues. This compares with US\$2,150,000 at December 31, 2013 which represented approximately 2.4% of Group revenues (see Item 18, Note 15 to the consolidated financial statements) and to US\$1,520,000 at December 31, 2012 which represented approximately 1.8% of Group revenues. In the event that this estimate was to increase or decrease by 0.5% of Group revenues, which would represent a reasonably likely range of outcomes, then a change in the allowance of US\$524,000 at December 31, 2014 (2013: US\$456,000) (2012: US\$413,000) would result.

## Accounting for income taxes

Significant judgement is required in determining our worldwide income tax expense provision. In the ordinary course of a global business, there are many transactions and calculations where the ultimate tax outcome is uncertain.

Some of these uncertainties arise as a consequence of revenue sharing and cost reimbursement arrangements among related entities, the process of identifying items of revenue and expense that qualify for preferential tax treatment and segregation of foreign and domestic income and expense to avoid double taxation. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. Although we believe that our estimates are reasonable, no assurance can be given that the final tax outcome of these matters will not be different than that which is reflected in our historical income tax provisions and accruals. Such differences could have a material effect on our income tax provision and profit in the period in which such determination is made. Deferred tax assets and liabilities are determined using enacted or substantively enacted tax rates for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities.

While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable.

The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. In management's opinion, adequate provisions for income taxes have been made.

Item 18, Note 12 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and includes details of the unrecognised deferred tax assets at year end. The Group does not recognise deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilised before they expire.

#### Share-based payments

For equity-settled share-based payments (share options), the Group measures the services received and the corresponding increase in equity at fair value at the measurement date (which is the grant date) using a trinomial model. Given that the share options granted do not vest until the completion of a specified period of service, the fair value, which is assessed at the grant date, is recognised on the basis that the services to be rendered by employees as consideration for the granting of share options will be received over the vesting period.

The share options issued by the Group are not subject to market-based vesting conditions as defined in IFRS 2, *Share-based Payment*. Non-market vesting conditions are not taken into account when estimating the fair value of share options as at the grant date; such conditions are taken into account through adjusting the number of equity instruments included in the measurement of the transaction amount so that, ultimately, the amount recognised equates to the number of equity instruments that actually vest. The expense in the statement of operations in relation to share options represents the product of the total number of options anticipated to vest and the fair value of those options; this amount is allocated to accounting periods on a straight-line basis over the vesting period.

Given that the performance conditions underlying the Group's share options are non-market in nature, the cumulative charge to the statement of operations is only reversed where the performance condition is not met or where an employee in receipt of share options relinquishes service prior to completion of the expected vesting period. Share based payments, to the extent they relate to direct labour involved in development activities, are capitalised.

The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised. The Group does not operate any cash-settled share-based payment schemes or share-based payment transactions with cash alternatives as defined in IFRS 2.

## **Impact of Recently Issued Accounting Pronouncements**

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") both as issued by the International Accounting Standards Board ("IASB") and as subsequently adopted by the European Union ("EU") (together "IFRS"). The IFRS applied are those effective for accounting periods beginning 1 January 2014. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB.

These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. During 2014, the IASB and the International Financial Reporting Interpretations Committee ("IFRIC") issued additional standards, interpretations and amendments to existing standards which are effective for periods starting after the date of these financial statements. A list of these additional standards, interpretations and amendments, and the potential impact on the financial statements of the Group, is outlined in Item 18, Note 1(xxviii).

## **Subsequent Events**

There are no other matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

- The entity's operations in future financial years;
- The results of those operations in future financial years; or
- The entity's state of affairs in future financial years.

## Results of Operations

## Year ended December 31, 2014 compared to the year ended December 31, 2013

The following compares our results in the year ended December 31, 2014 to those of the year ended December 31, 2013 under IFRS. Our analysis is divided as follows:

- 1. Overview
- 2. Revenues
- 3. Operating Profit
- 4. Profit for the year

#### 1. Overview

In 2014, revenues increased 15% from US\$91.2 million in 2013 to US\$104.9 million. Clinical Laboratory revenues grew by almost 19% due to higher diabetes sales driven by increased Premier placements and the full year impact of the Immco Diagnostics and blood bank screening acquisitions made during 2013. These were partly offset by lower Lyme sales due to the impact of adverse weather conditions, particularly in north-eastern USA. Meanwhile, point-of-care revenues increased by 1.4% from US\$19.8 million in 2013 to US\$20.0 million in 2014. This growth was due to higher sales of new point-of-care tests for streptococcus pneumonia and legionella, and increased demand for our point-of-care A1c analyser, Tri-stat.

Geographically, 58% of our sales were generated in the Americas, 24% in Africa/Asia and 18% in Europe.

The gross margin is 48.0% for 2014, which is 1.6% lower than the gross margin for 2013. The reduction in gross margin is due to several factors, the main ones being a higher level of sales of Premier instruments, lower sales of the high margin Lyme product, and the higher running costs associated with the two blood bank screening manufacturing facilities in the UK. These facilities were closed in Q3 2014, following the transfer of manufacturing to the Group's existing facilities in Ireland and New York.

The operating profit is US\$18.0 million for the year ended December 31, 2014 which compares to US\$9.0 million for the year ended December 31, 2013. The increase of US\$9.0m in operating profit in 2014 is mainly attributable to the increase in revenues, lower share-based payments, release of a contingent consideration accrual and several non-recurring charges in 2013. The non-recurring charges incurred in 2013 were as follows:

- a cost of US\$5.4 million was incurred in 2013 to acquire a licence to a significant HIV-2 patent portfolio,
- a restructuring charge of US\$0.7 million was recognised in 2013 for the blood bank screening business and,
- transaction costs of US\$0.3 million were incurred in 2013 in relation to two acquisitions.

The contingent consideration accrual relates to additional consideration payable to the previous owners of Fiomi Diagnostics on the expected timing of certain milestones in the development of a Troponin I assay. In 2014 there was a reduction in the estimated amount payable amounting to US\$2,057,000 when the deadline for a milestone was not met and the deadline for a future milestone is not expected to be met.

Net financial income decreased from US\$1.2 million to US\$28,000 mainly due to lower cash on deposit following two acquisitions in 2013.

The profit after tax for the year ended December 31, 2014 was US\$17.2 million which compares to a profit after tax for the year ended December 31, 2013 of US\$9.6 million.

## 2. Revenues

The Group's revenues consist of the sale of diagnostic kits and related instrumentation and the sale of raw materials to the life sciences industry. Revenues from the sale of the above products are generally recognised on the basis of shipment to customers. The Group ships its products on a variety of freight terms, including ex-works, CIF (carriage including freight) and FOB (free on board), depending on the specific terms agreed with customers. In cases where the Group ships on terms other than ex-works, the Group does not recognise the revenue until its obligations have been fulfilled in accordance with the shipping terms.

No right of return exists in relation to product sales except in instances where demonstrable product defects occur. The Group has defined procedures for dealing with customer complaints associated with such product defects as they arise.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass to the customer, the fair value of the instrument is recognised as revenue at the commencement of the lease and is matched by the related cost of sale. In the case of operating leases of instruments which typically involve commitments by the customer to pay a fee per test run on the instruments, revenue is recognised on the basis of customer usage of the instruments.

## Revenues by Product Line

Trinity Biotech's revenues for the year ended December 31, 2014 were US\$104,872,000 compared to revenues of US\$91,216,000 for the year ended December 31, 2013, which represents an increase of US\$13,656,000 or 15%. The following table sets forth selected sales data for each of the periods indicated.

|                     | Year ended December 31, |                  |                |  |
|---------------------|-------------------------|------------------|----------------|--|
|                     | 2014<br>US\$'000        | 2013<br>US\$'000 | % Change       |  |
| Revenues            |                         |                  |                |  |
| Clinical Laboratory | 77,240                  | 68,727           | 12.4%          |  |
| Point-of-Care       | 20,036                  | 19,754           | 1.4%           |  |
| Laboratory Services | 7,596                   | 2,735            | <u>177.7</u> % |  |
| Total               | 104,872                 | 91,216           | 15.0%          |  |

#### Clinical Laboratory

In 2014 Clinical Laboratory revenues increased by US\$8,513,000 which equates to growth of 12.4%.

The increase is mainly attributable to the full year impact of the two acquisitions in 2013 in our Clinical Laboratory division. Immco Diagnostics sells autoimmune tests, while the blood bank screening business has a particular emphasis on syphilis and malaria testing. Blood bank screening revenues increased to US\$3,583,000 in 2014 (2013: US\$2,445,000). The increase due to the two acquisitions was partly offset by a decrease in the volume of Lyme sales, which fell by US\$942,000 to US\$8,673,000 due to the impact of extreme cold weather conditions in north east USA resulting in the ticks that carry the bacteria which cause Lyme disease to be less active, thus reducing the risk of contraction by humans. Our sales prices tend to be relatively stable as we are unable to pass on sales price increases to our customers due to competitive factors.

## Point-of-Care

Point-of-Care revenues increased by US\$282,000, which represents an increase of 1.4%. Sales prices were relatively stable during 2014 and therefore the increase is more attributable to growth in sales volumes of (a) our Tri-stat A1c analyser which was launched in 2013 and (b) newly-developed point-of-care tests for diseases such as streptococcus pneumonia and Legionella. Revenues for our Unigold HIV test were US\$19.3 million in 2014, which is broadly consistent with 2013.

## Laboratory Services

In 2014 Laboratory Services revenues increased by US\$4,861,000 which equates to growth of 177.7%. The increase is entirely attributable to the laboratory of Immco Diagnostics, which was acquired in H2 2013 and achieved high organic growth in 2014 mainly due to strong demand for Sjögrens Syndrome testing. Revenues for Sjögrens Syndrome testing increased significantly as the year progressed and in Quarter 4, 2014 we recorded Sjögrens revenues of more than US\$500,000.

## Revenues by Geographical Region

The following table sets forth selected sales data, analysed by geographic region, based on location of customer:

|             | Year ended De    | Year ended December 31, |          |  |
|-------------|------------------|-------------------------|----------|--|
|             | 2014<br>US\$'000 | 2013<br>US\$'000        | % Change |  |
| Revenues    |                  |                         |          |  |
| Americas    | 61,142           | 54,761                  | 11.7%    |  |
| Asia/Africa | 25,161           | 24,061                  | 4.6%     |  |
| Europe      | 18,569           | 12,394                  | 49.8%    |  |
| Total       | 104,872          | 91,216                  | 15.0%    |  |

In the Americas, the 12% increase amounting to US\$6,381,000 is primarily attributable to the full year effect of the acquisition of Immco in H2 2013 and strong sales growth in our diabetes business in Brazil. This increase was partly offset by a reduction in sales of Lyme's disease products.

Asia/Africa revenues increased by 5%, or US\$1,100,000 compared to 2013. The main reasons for this are the higher sales of the Premier and Tri-stat analysers particularly in Asia.

Revenues in Europe increased by US\$6,175,000, or 50% compared to 2013. The increase was due to growth in sales of the Premier analyser and the full year impact of the two acquisitions in 2013.

For further information about the Group's principal products, principal markets and competition please refer to Item 4, "Information on the Company".

# 3. Operating Profit

The following table sets forth the Group's operating profit:

|                        | Year ended De | Year ended December 31, |               |  |
|------------------------|---------------|-------------------------|---------------|--|
|                        | 2014          | 2013                    |               |  |
|                        | US\$'000      | US\$'000                | % Change      |  |
| Revenues               | 104,872       | 91,216                  | 15.0%         |  |
| Cost of sales          | (54,525)      | (45,996)                | <u>18.5</u> % |  |
| Gross profit           | 50,347        | 45,220                  | 11.3%         |  |
| Other operating income | 424           | 532                     | (20.3%)       |  |
| Research & development | (4,291)       | (3,691)                 | 16.2%         |  |
| SG&A expenses          | (28,441)      | (33,066)                | (14.0%)       |  |
| Operating profit       | 18,039        | 8,995                   | 100.5%        |  |

## Cost of sales and gross margin

Total cost of sales increased by US\$8,529,000 from US\$45,996,000 for the year ended December 31, 2013 to US\$54,525,000, for the year ended December 31, 2014, an increase of 18.5%. The gross margin of 48.0% in 2014 compares to a gross margin of 49.6% in 2013.

The increase in cost of sales and the decrease in gross margin in 2014 is largely attributable to (a) a higher level of sales of Premier instruments (instruments have lower margins than the accompanying reagents and consumables), (b) lower sales of the high margin Lyme product and (c) the margin earned by the blood bank screening business, acquired in 2013, was lower than average due to high running costs associated with the two manufacturing facilities in the UK. These facilities were closed in quarter 3 2014, following the transfer of manufacturing to Trinity Biotech's facilities in Ireland and New York.

## Other operating income

Other operating income comprises rental income from sublet properties and income from the provision of services to Lab21 Ltd and Diagnostica Stago under Transition Services Agreements (TSAs). Other operating income decreased by US\$108,000 from US\$532,000 for the year ended December 31, 2013 to US\$424,000, for the year ended December 31, 2014. The decrease was largely attributable to a decrease in TSA income from Lab21 Ltd. The short term arrangements with Lab21 for the provision of facilities and information technology services commenced in 2013 and finished in quarter 2 of 2014.

## Research and development expenses

Research and development expenditure recorded in the Statement of Operations increased from US\$3,691,000 in 2013 to US\$4,291,000 in 2014. The increase of US\$600,000 was due to the full year impact of two acquisitions, Immco Diagnostics and the blood bank screening business of Lab21, during 2013. For details of the Company's various R&D projects see "Research and Products under Development" below.

Selling, General & Administrative expenses ("SG&A")

Total SG&A expenses decreased by US\$4,625,000 from US\$33,066,000 for the year ended December 31, 2013 to US\$28,441,000 for the year ended December 31, 2014.

The following table outlines the breakdown of SG&A expenses in 2014 compared to 2013.

|  | Year ended D<br>2014<br>US\$'000 | ecember 31,<br>2013<br>US\$'000 | Increase/(Decrease)<br>US\$'000 | % Change |
|--|----------------------------------|---------------------------------|---------------------------------|----------|
| CC 8x A (aval shows based payments and amortisation) |                                  |                                 |                                 |          |
| SG&A (excl. share-based payments and amortisation)   | 24,583                           | 29,186                          | (4,603)                         | (15.8%)  |
| Share-based payments                                 | 1,478                            | 1,978                           | (500)                           | (25.3%)  |
| Amortisation   | 2,380                            | 1,902                           | 478                             | 25.1%    |
| Total  | 28,441                           | 33,066                          | (4,625)                         | (14.0%)  |

Selling General & Administrative Expenditure (excluding share-based payments and amortisation)

SG&A expenses excluding share-based payments and amortisation decreased from US\$29,186,000 for the year ended December 31, 2013 to US\$24,583,000 for the year ended December 31, 2014, which represents a decrease of 16%. The decrease of US\$4,603,000 is mainly attributable to the following non-recurring costs incurred in 2013:

- a cost of US\$5,415,000 was incurred in 2013 to acquire a licence to a significant HIV-2 patent portfolio, including associated legal fees and net of implicit interest to reflect the contractual payment terms. There was no similar cost in 2014.
- in 2013, the Group decided to transfer the production activities of the newly acquired blood bank screening business from the UK to our existing manufacturing facilities in Ireland and USA. This resulted in redundancies in the UK and a restructuring charge of US\$690,000 was recognised in 2013.
- Transaction costs of US\$316,000 were incurred in 2013 in relation to the two acquisitions. There were no acquisitions in 2014.

SG&A expenses were reduced in 2014 by the release of a contingent consideration accrual of US\$1,956,000, with a further US\$101,000 being credited to financial expenses. The contingent consideration is payable to the previous owners of Fiomi Diagnostics on the expected timing of certain development milestones for a Troponin I assay. The estimated amount payable reduced when the deadline for a milestone was not met and the deadline for a future milestone is not expected to be met.

There was a partially offsetting increase of US\$3,774,000 in Selling General & Administrative Expenditure mainly relating to sales and marketing costs for the Meritas range of products for which there were no matching revenues, selling and marketing costs for our new Sjögrens test, and the full year effect of the acquisitions in 2013.

## Share-based payments

The expense represents the fair value of share options granted to directors and employees which is charged to the statement of operations over the vesting period of the underlying options. The Group has used a trinomial valuation model for the purposes of valuing these share options with the key inputs to the model being the expected volatility over the life of the options, the expected life of the option, the option price, the dividend yield and the risk free rate.

The Group recorded a total share-based payments charge of US\$1,496,000 (2013: US\$2,014,000). The decrease of US\$518,000 in the total share-based payments expense is due to the vesting of a significant number of options during 2014. The total charge is shown in the following expense headings in the statement of operations: US\$18,000 (2013: US\$36,000) was charged against cost of sales and US\$1,478,000 (2013: US\$1,978,000) was charged against selling, general & administrative expenses.

For further details refer to Item 18, Note 18 to the consolidated financial statements.

#### Amortisation

Amortisation increased from US\$1,902,000 for the year ended December 31, 2013 to US\$2,380,000 for the year ended December 31, 2014. The increase of US\$478,000 is due to a full year's amortisation charge on intangibles acquired in 2013 as part of the Immco Diagnostics and blood bank screening acquisitions. For further details of these business combinations refer to Item 18, Note 22 to the consolidated financial statements.

# 4. Profit for the year

The following table sets forth selected statement of operations data for each of the periods indicated.

|                      | Year ended December 31, |          |          |
|----------------------|-------------------------|----------|----------|
|                      | 2014                    | 2013     |          |
|                      | US\$'000                | US\$'000 | % Change |
| Operating profit     | 18,039                  | 8,995    | 101%     |
| Net financing income | 28                      | 1,225    | (98%)    |
| Profit before tax    | 18,067                  | 10,220   | 77%      |
| Income tax expense   | (853)                   | (574)    | 49%      |
| Profit of the year   | 17,214                  | 9,646    | 78%      |

## Net Financing income

Net financing income was U\$\$28,000 for year-end December 31, 2014 compared to U\$\$1,225,000 in 2013. Financial expenses remained broadly the same at U\$\$69,000. Financial income decreased from U\$\$1,276,000 for the year-end December 31, 2013 to U\$\$97,000 in 2014 due to the fall in deposit interest rates and a reduction in the amount of cash on deposit following two acquisitions in 2013.

#### **Taxation**

The Group recorded a tax charge of US\$853,000 for the year ended December 31, 2014 compared to US\$574,000 for the year ended December 31, 2013. The 2014 tax charge comprises US\$123,000 of current tax credit and US\$976,000 of deferred tax charge. The increase in the total tax charge in 2014 is primarily due to a 77% increase in profit before tax. The effective tax rate was broadly consistent in 2013 and 2014 at 4.7%. For further details on the Group's tax charge please refer to Item 18, Note 8 and Note 12 to the consolidated financial statements.

# Profit for the year

The profit for the year amounted to US\$17,214,000, which represents an increase of US\$7,568,000 when compared to US\$9,646,000 in 2013, representing an increase of 78%.

## Results of Operations

## Year ended December 31, 2013 compared to the year ended December 31, 2012

The following compares our results in the year ended December 31, 2013 to those of the year ended December 31, 2012 under IFRS. Our analysis is divided as follows:

- 5. Overview
- 6. Revenues
- 7. Operating Profit
- 8. Profit for the year

#### 5. Overview

In 2013, revenues were US\$91.2 million, which represented an increase of US\$8.7 million (11%) compared to 2012. Point-of-care revenues increased by over 3% from US\$19.2 million in 2012 to US\$19.8 million in 2013. This growth was due to the continuing strength of HIV sales in Africa. Meanwhile, Clinical Laboratory revenues grew by almost 13% due to higher diabetes sales driven by increased Premier placements, the impact of the Immco Diagnostics and blood bank screening acquisitions made during the year and higher sales of infectious diseases products in China. These was partly offset by lower Lyme sales due to the impact of adverse weather conditions in eastern USA, particularly in the first half of 2013.

Geographically, 60% of our sales were generated in the Americas, 26% in Africa/Asia and 14% in Europe.

The gross margin is 49.6% for 2013, which is 1.6% lower than the gross margin for 2012. The reduction in gross margin is due to several factors, the main ones being the new medical devices excise tax introduced by the US government in 2013 and a higher level of sales of A1c instruments. There was also higher running costs associated with the two blood bank screening manufacturing facilities in the UK. These facilities will be closed in 2014, following the transfer of manufacturing to the Group's existing facilities in Ireland and New York.

The operating profit is US\$9.0 million for the year ended December 31, 2013 which compares to US\$17.2 million for the year ended December 31, 2012. In addition to the factors discussed above, several other significant charges contributed to a reduction in operating profit in 2013, as follows:

- a licence to a significant HIV-2 patent portfolio cost US\$5.4 million including associated legal fees and net of implicit interest,
- a charge of US\$0.7 million was recognised for redundancy costs associated with the closure of the two UK operations
  acquired as part of the blood bank screening business, and
- acquisition costs of US\$0.3 million were incurred in relation to the two business combinations.

Net financial income decreased from US\$2.2 million to US\$1.2 million, mainly due to a combination of reduced deposit interest rates and lower cash on deposit following two acquisitions in 2013.

The profit after tax for the year ended December 31, 2013 was US\$9.6 million which compares to a profit after tax for the year ended December 31, 2012 of US\$17.3 million.

### 6. Revenues

The Group's revenues consist of the sale of diagnostic kits and related instrumentation and the sale of raw materials to the life sciences industry. Revenues from the sale of the above products are generally recognised on the basis of shipment to customers. The Group ships its products on a variety of freight terms, including ex-works, CIF (carriage including freight) and FOB (free on board), depending on the specific terms agreed with customers. In cases where the Group ships on terms other than ex-works, the Group does not recognise the revenue until its obligations have been fulfilled in accordance with the shipping terms.

No right of return exists in relation to product sales except in instances where demonstrable product defects occur. The Group has defined procedures for dealing with customer complaints associated with such product defects as they arise.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass to the customer, the fair value of the instrument is recognised as revenue at the commencement of the lease and is matched by the related cost of sale. In the case of operating leases of instruments which typically involve commitments by the customer to pay a fee per test run on the instruments, revenue is recognised on the basis of customer usage of the instruments.

## Revenues by Product Line

Trinity Biotech's revenues for the year ended December 31, 2013 were US\$91,216,000 compared to revenues of US\$82,510,000 for the year ended December 31, 2012, which represents an increase of US\$8,706,000 or 11%. The following table sets forth selected sales data for each of the periods indicated.

|                     | Year ended D     |                  |          |
|---------------------|------------------|------------------|----------|
|                     | 2013<br>US\$'000 | 2012<br>US\$'000 | % Change |
| Revenues            |                  |                  |          |
| Clinical Laboratory | 71,462           | 63,356           | 12.8%    |
| Point-of-Care       | 19,754           | 19,154           | 3.1%     |
| Total               | 91,216           | 82,510           | 10.6%    |

## Clinical Laboratory

In 2013 Clinical Laboratory revenues increased by US\$8,106,000 which equates to 12.8%.

The increase is mainly attributable to the two acquisitions in our Clinical Laboratory division, which generated incremental revenues of US\$8,444,000 in 2013. Immco Diagnostics sells autoimmune tests, while the blood bank screening business has a particular emphasis on syphilis and malaria testing. This increase was partly offset by a decrease of US\$253,000 in Lyme sales due to the impact of extreme cold weather conditions in north east USA resulting in the ticks that carry the bacteria which cause Lyme disease to remain underground, thus reducing the risk of contraction by humans.

## Point-of-Care

Our principal Point-of-Care product is Unigold<sup>TM</sup>, which tests for the presence of HIV antibodies. Our two main markets for Point-of-Care tests are USA and Africa. Point-of-Care revenues increased by US\$600,000, which represents an increase of 3.1%. This increase was due to a 4% increase in revenues in Africa, due to higher international and governmental funding in Nigeria, Tanzania and Zambia. This was partly offset by a 3% decrease in revenues in the USA due to lower federal funding for HIV testing programmes.

## Revenues by Geographical Region

The following table sets forth selected sales data, analysed by geographic region, based on location of customer:

|             | Year ended December 31, |           |          |  |
|-------------|-------------------------|-----------|----------|--|
|             | 2013                    | 2013 2012 |          |  |
|             | US\$'000                | US\$'000  | % Change |  |
| Revenues    |                         |           |          |  |
| Americas    | 54,761                  | 49,638    | 10.3%    |  |
| Europe      | 12,394                  | 10,214    | 21.3%    |  |
| Asia/Africa | 24,061                  | 22,658    | 6.2%     |  |
| Total       | 91,216                  | 82,510    | 10.6%    |  |

In the Americas, the 10% increase amounting to US\$5,123,000 is primarily attributable to the Immco acquisition. This increase was partly offset by a reduction in sales of Lyme's disease products.

Revenues in Europe increased by US\$2,180,000, or 21% compared to 2012. The increase was due to growth in sales of the Premier analyser and the impact of acquisitions in 2013.

Asia/Africa revenues increased by 6%, or US\$1,403,000 compared to 2012. The main reason for this is the strong growth in sales of Trinity's Unigold rapid HIV test in Africa. Higher sales of infectious diseases tests in China and the new Premier analyser also contributed to the growth.

For further information about the Group's principal products, principal markets and competition please refer to Item 4, "Information on the Company".

# 7. Operating Profit

The following table sets forth the Group's operating profit:

|                        | Year ended Do    |                  |          |
|------------------------|------------------|------------------|----------|
|                        | 2013<br>US\$'000 | 2012<br>US\$'000 | % Change |
| Revenues               | 91,216           | 82,510           | 10.6%    |
| Cost of sales          | (45,996)         | (40,257)         | 14.3%    |
| Gross profit           | 45,220           | 42,253           | 7.0%     |
| Other operating income | 532              | 468              | 13.7%    |
| Research & development | (3,691)          | (3,130)          | 17.9%    |
| SG&A expenses          | (33,066)         | (22,425)         | 47.5%    |
| Operating profit       | 8,995            | 17,166           | (47.6%)  |

## Cost of sales and gross margin

Total cost of sales increased by US\$5,739,000 from US\$40,257,000 for the year ended December 31, 2012 to US\$45,996,000, for the year ended December 31, 2013, an increase of 14%. The gross margin of 49.6% in 2013 compares to a gross margin of 51.2% in 2012.

The increase in cost of sales and the decrease in gross margin in 2013 is largely attributable to (a) the introduction of a medical devices excise tax by the US government on 1<sup>st</sup> January 2013, which resulted in additional costs of US\$691,000, (b) a higher level of sales of A1c instruments (instruments have lower margins than the accompanying reagents and consumables) and (c) the margin earned by the new blood bank screening business acquired in H2 2013 was lower than average due to high running costs associated with the two manufacturing facilities in the UK. These facilities will be closed in mid-2014, following the transfer of manufacturing to Trinity Biotech's facilities in Ireland and New York.

# Other operating income

Other operating income comprises rental income from sublet properties and income from the provision of services to Lab21 Ltd and Diagnostica Stago under Transition Services Agreements (TSAs). TSA income from Diagnostica Stago commenced in April 2010 and comprised a variety of services including accounting, information technology and logistics support and warehousing services. The majority of the TSA services derived from Diagnostica Stago were short term arrangements which ceased by the middle of 2012. TSA income from Lab21 Ltd commenced in 2013 and comprises facilities and information technology services.

#### Research and development expenses

Research and development ("R&D") expenditure recorded in the Statement of Operations increased from US\$3,130,000 in 2012 to US\$3,691,000 in 2013. The increase of US\$561,000 was mainly due to the impact of two acquisitions during 2013 and an increase in headcount in our US technical support team. For details of the Company's various R&D projects see "Research and Products under Development" below.

## Selling, General & Administrative expenses (SG&A)

Total SG&A expenses increased by US\$10,641,000 from US\$22,425,000 for the year ended December 31, 2012 to US\$33,066,000 for the year ended December 31, 2013.

The following table outlines the breakdown of SG&A expenses in 2013 compared to 2012.

|  | Year ended D     |                  |                                 |          |
|--|------------------|------------------|---------------------------------|----------|
|  | 2013<br>US\$'000 | 2012<br>US\$'000 | Increase/(Decrease)<br>US\$'000 | % Change |
| SG&A (excl. share-based payments and amortisation) | 29,186           | 19,268           | 9,918                           | 51%      |
| Share-based payments                               | 1,978            | 1,675            | 303                             | 18%      |
| Amortisation                                       | 1,902            | 1,482            | 420                             | 28%      |
| Total  | 33,066           | 22,425           | 10,641                          | 47%      |

Selling General & Administrative Expenditure (excluding share-based payments and amortisation)

SG&A expenses excluding share-based payments and amortisation increased from US\$19,268,000 for the year ended December 31, 2012 to US\$29,186,000 for the year ended December 31, 2013, which represents an increase of 51%. The increase of US\$9,918,000 is attributable to the following main reasons:

- the combined Selling General & Administrative Expenditure incurred by the two acquired businesses was US\$3,900,000, excluding share-based payments, amortisation costs and restructuring charges;
- in 2013, the Group acquired the blood bank screening business of Lab21 Ltd. In order to drive significant operational synergies and efficiencies, the production activities of the blood bank screening business will be transferred from its current UK premises to our existing manufacturing facilities in Bray, Ireland and Jamestown, New York during 2014. This will result in redundancies in the UK and we have recognised a restructuring charge in 2013 of US\$690,000;
- a cost of US\$5,415,000 to acquire a licence to a significant HIV-2 patent portfolio, including associated legal fees and net of implicit interest to reflect the contractual payment terms. The cost of the licence has been charged to the Statement Of Operations in 2013 as management have determined that the Company will not generate any incremental cash flows or otherwise generate any future economic benefit from the license. The Company recently received approval from the FDA for the HIV-2 claim on its Uni-gold<sup>TM</sup> HIV kit in the USA. Future growth in HIV revenues in the USA will result from the granting of the HIV-2 claim by the FDA, rather than from the HIV-2 licence itself.

## Share-based payments

The expense represents the fair value of share options granted to directors and employees which is charged to the statement of operations over the vesting period of the underlying options. The Group has used a trinomial valuation model for the purposes of valuing these share options with the key inputs to the model being the expected volatility over the life of the options, the expected life of the option, the option price and the risk free rate.

The Group recorded a total share-based payments charge of US\$2,014,000 (2012: US\$1,713,000). The increase of US\$301,000 in the total share-based payments expense is due to the full year effect of share options granted to employees and directors during 2012 and the impact of new share options granted during 2013. The total charge is shown in the following expense headings in the statement of operations: US\$36,000 (2012: US\$38,000) was charged against cost of sales and US\$1,978,000 (2012: US\$1,675,000) was charged against selling, general & administrative expenses.

For further details refer to Item 18, Note 18 to the consolidated financial statements.

## Amortisation

Amortisation increased from US\$1,482,000 for the year ended December 31, 2012 to US\$1,902,000 for the year ended December 31, 2013. The increase of US\$420,000 is mainly due to the amortisation charged on intangibles acquired in 2013 as part of the Immco Diagnostics and blood bank screening acquisitions and higher amortisation charges as new products were launched. For further details of these business combinations refer to Item 18, Note 22 to the consolidated financial statements.

## 8. Profit for the year

The following table sets forth selected statement of operations data for each of the periods indicated.

|                      | Year ended De    | Year ended December 31, |          |  |
|----------------------|------------------|-------------------------|----------|--|
|                      | 2013<br>US\$'000 | 2012<br>US\$'000        | % Change |  |
| Operating profit     | 8,995            | 17,166                  | (48%)    |  |
| Net financing income | 1,225            | 2,192                   | (44%)    |  |
| Profit before tax    | 10,220           | 19,358                  | (47%)    |  |
| Income tax expense   | (574)            | (2,017)                 | (72%)    |  |
| Profit of the year   | 9,646            | 17,341                  | (44%)    |  |

## Net Financing income

Net financing income is US\$1,225,000 for year-end December 31, 2013 compared to US\$2,192,000 in 2012. Financial expenses remained broadly the same at US\$51,000. Financial income decreased from US\$2,280,000 for the year-end December 31, 2012 to US\$1,276,000 in 2013 due to the fall in deposit interest rates and a reduction in the amount of cash on deposit following two acquisitions in 2013.

#### **Taxation**

The Group recorded a tax charge of US\$574,000 for the year ended December 31, 2013 compared to US\$2,017,000 for the year ended December 31, 2012. The 2013 tax charge comprises US\$175,000 of current tax credit and US\$749,000 of deferred tax charge. The decrease in the total tax charge in 2013 is primarily due to lower profits in our Irish operations and a higher R&D tax credit in 2013. For further details on the Group's tax charge please refer to Item 18, Note 8 and Note 12 to the consolidated financial statements.

#### Profit for the year

The profit for the year amounted to US\$9,646,000, which represents a decrease of US\$7,695,000 when compared to US\$17,341,000 in 2012, representing a decrease of 44%.

## Liquidity and Capital Resources

### **Financing**

The Group has no bank borrowings. During 2010 the Group repaid in full the outstanding portion of its US\$48,340,000 club banking facility with AIB plc and Bank of Scotland (Ireland) Limited ("the banks") using the proceeds from the divestiture of the Coagulation product line. This facility had been secured on the assets of the Group (see Item 18, Note 23(c)).

#### **Bank Facility**

In February 2015, the Group entered into an overall facility agreement with Allied Irish Bank which consists of separate revolver, overdraft and leasing facilities amounting to approximately US\$15 million.

## Working capital

In the Directors' opinion the Group will have access to sufficient funds to support its existing operations for at least the next 12 months by utilising existing cash resources and cash generated from operations.

The amount of cash generated from operations will depend on a number of factors which include the following:

- The ability of the Group to continue to generate revenue growth from its existing product lines;
- The ability of the Group to generate revenues from new products following the successful completion of its development projects;
- The extent to which capital expenditure is incurred on additional property plant and equipment;
- · The level of investment required to undertake both new and existing development projects; and
- Successful working capital management in the context of a growing business.

## Cash management

As at December 31, 2014, Trinity Biotech's consolidated cash and cash equivalents were US\$9,102,000. This compares to cash and cash equivalents of US\$22,317,000 at December 31, 2013.

Cash generated from operations for the year ended December 31, 2014 amounted to US\$15,690,000 (2013: US\$8,766,000), an increase of US\$6,924,000. The increase in cash generated from operations of US\$6,924,000 is attributable to an increase in operating cash flows before changes in working capital of US\$481,000 in addition to a decrease in working capital outflows of US\$6,443,000. The increase in operating cash flows before changes in working capital of US\$481,000 is primarily driven by the increase in profit during the current financial year. The working capital outflow decrease, when compared to the prior year, is partly due to the decrease in the cash outflows for trade and other receivables of US\$6,303,000 and decrease in cash outflows of US\$2,771,000 for inventories. This has been offset partially by the decrease in cash inflows from trade and other payables, when compared to the prior year, of US\$2,631,000. The cash generated from operations was attributable to an operating profit of US\$18,039,000 (2013: US\$8,995,000), as adjusted for non cash items of US\$2,243,000 (2013: US\$10,806,000) plus cash outflows due to changes in working capital of US\$4,592,000 (2013: cash outflows of US\$11,035,000).

The decrease in other non cash charges from US\$10,806,000 for the year ended December 31, 2013 to US\$2,243,000 for the year ended December 31, 2014 is mainly attributable to once-off charges incurred in 2013 relating to restructuring and new license agreements entered into, as well as a reduction of US\$2,057,000 in the estimated contingent consideration payable relating to the acquisition of Fiomi Diagnostics AB. Refer to Item 18, Note 22 for further detail.

The net cash outflows in 2014 due to changes in working capital of US\$4,592,000 are due to the following:

- An increase in trade and other receivables of US\$729,000 due to the increase in revenues and the increase, year on year, in
  the debtors days number;
- An increase in inventory of US\$4,487,000 due to the strategic build up of certain inventory items during the course of the year (most notably in relation to the Premier Hb9210 Instrument); and
- An increase in trade and other payables balance of US\$624,000 due to timing of payments.

Net interest received amounted to US\$96,000 (2013: US\$1,292,000). This consisted of interest received of US\$96,000 (2013: US\$1,292,000) on the Group's cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2014 amounted to US\$27,756,000 (2013: outflows of US\$61,193,000) which were principally made up as follows:

- Payments to acquire intangible assets of US\$19,486,000 (2013: US\$18,687,000), which principally related to development expenditure capitalised as part of the Group's on-going product development activities; and
- Acquisition of property, plant and equipment of US\$8,270,000 (2013: US\$4,489,000) incurred as part of the Group's investment programme for its manufacturing and distribution activities, and placement of instruments.
- There were no acquisitions of subsidiaries in the current year (2013: US\$39,424,000).

Net cash outflows from financing activities for the year ended December 31, 2014 amounted to US\$1,427,000 (2013: US\$798,000). The increase in outflows in 2014 is due to the fact that the Group paid higher dividends in 2014 compared to 2013. The main area of cash outflow from financing activities for the year was the annual dividend payment of US\$5,029,000 (2013: US\$4,373,000). Other cash outflows included expenses paid in connection with share issues and debt financing of US\$40,000 (2013: US\$87,000). These outflows were partially offset by the receipt of US\$3,642,000 from the issue of ordinary shares in 2014 (2013: US\$3,662,000). Ordinary shares issued in 2014 and 2013 are as a result of share options exercised during the course of the year.

The majority of the Group's transactions are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro denominated expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Trinity Biotech continuously monitors its exposure to foreign currency movements and expectations of future exchange rate exposure and, if deemed necessary, will cover a portion of this exposure through the use of forward contracts. When used, these forward contracts are cash flow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions.

As at December 31, 2014 and December 31, 2013 there was no interest-bearing debt outstanding. Cash and cash equivalents were US\$9,102,000 (2013: US\$22,317,000).

For a more comprehensive discussion of the Group's use of financial instruments, its currency and interest rate structure and its funding and treasury policies please refer to Item 11 "Quantitative and Qualitative Disclosures about Market Risk".

#### Contractual obligations

The following table summarises our minimum contractual obligations and commercial commitments, including interest, as of December 31, 2014:

|                             | Payments due by Period |          |           |           |           |
|-----------------------------|------------------------|----------|-----------|-----------|-----------|
|                             | less than 1            |          |           |           | more than |
|                             | Total                  | year     | 1-3 Years | 4-5 Years | 5 years   |
| Contractual Obligations     | US\$'000               | US\$'000 | US\$'000  | US\$'000  | US\$'000  |
| Operating lease obligations | 26,743                 | 3,109    | 4,586     | 2,986     | 16,062    |
| Total                       | 26,743                 | 3,109    | 4,586     | 2,986     | 16,062    |

In the past, Trinity Biotech incurred debt and raised equity to pursue its policy of growth through acquisition. However, since the divestiture of the Coagulation product line in 2010, the Group has eliminated bank debt and has adequate cash resources. The Group intends to grow organically for the foreseeable future and Trinity Biotech believes that it will have sufficient funds to meet its capital commitments and continue existing operations in to the future, in excess of 12 months. If the Group was to make a large and unanticipated cash outlay, the Group would have further funding requirements which could be met from drawing down on the Company's existing bank facilities or through access to equity and debt markets.

## Impact of Currency Fluctuation

Trinity Biotech's revenue and expenses are affected by fluctuations in currency exchange rates especially the exchange rate between the US Dollar and the Euro, Swedish Kroner and the Brazilian Real. Trinity Biotech's revenues are primarily denominated in US Dollars and its expenses are incurred principally in US Dollars, Euro, Swedish Kroner and Brazilian Real. The weakening of the US Dollar could have an adverse impact on future profitability. Management are actively seeking to reduce the mismatch in this regard to mitigate this risk. The revenues and costs incurred by US subsidiaries are denominated in US Dollars.

Trinity Biotech holds most of its cash assets in US Dollars. As Trinity Biotech reports in US Dollars, fluctuations in exchange rates do not result in exchange differences on these cash assets. Fluctuations in the exchange rate between the Euro, Swedish Kroner, or Brazilian Real and the US Dollar may impact on the Group's Euro, Kroner or Real monetary assets and liabilities and on Euro, Kroner or Real expenses and consequently the Group's earnings.

## Off-Balance Sheet Arrangements

After consideration of the following items the Group's management have determined that there are no off-balance sheet arrangements which need to be reflected in the financial statements.

# Leases with Related Parties

The Group has entered into lease arrangements for premises in Ireland with JRJ Investments ("JRJ"), a partnership currently owned by Mr O'Caoimh and Dr Walsh, directors of Trinity Biotech plc, and directly with Mr O'Caoimh and Dr Walsh. Independent valuers have advised Trinity Biotech that the rent fixed with respect to these leases represents a fair market rent. Details of these leases with related parties are set out in Item 4 "Information on the Company", Item 7 "Major Shareholders and Related Party Transactions" and Item 18, Note 24 to the consolidated financial statements.

# Research & Development ("R&D") carried out by third parties

Certain R&D activities of the Group have been outsourced to third parties. These activities are carried out in the normal course of business with these companies.

During 2014, a number of individuals acted as third party consultants and contractors; working principally on the Troponin I and Premier projects. The total amount paid to these R&D consultants and contractors in 2014 was US\$994,000 (2013: US\$2,894,000).

## Research and Products under Development

Trinity Biotech has research and development groups focusing separately on emergency medicine, haemoglobin products, infectious diseases and autoimmune products. These groups are located in Ireland, Sweden and the USA and largely mirror the production capability at each production site. In addition to in-house activities, Trinity Biotech sub-contracts some research and development from time to time to independent researchers based in the USA and Europe.

# **Principal Development Projects**

The following table sets forth for each of Trinity Biotech's main development projects, the costs incurred during each period presented and the cumulative costs incurred as at 31 December 2014:

|  |          |          | Total project costs to December 31, |
|--|----------|----------|-------------------------------------|
|  | 2014     | 2013     | 2014                                |
| Product Name                                   | US\$'000 | US\$'000 | US\$'000                            |
| Brain Natriuretic Peptide (BNP) assay          | 4,400    | 1,204    | 5,604                               |
| Premier Instrument for Haemoglobin A1c testing | 3,375    | 3,861    | 19,123                              |
| Troponin I assay and reader                    | 3,370    | 7,200    | 15,618                              |
| Genesys/Resolution column enhancement          | 725      | 685      | 1,410                               |
| Tristat Point-of-Care instrument               | 689      | 481      | 6,037                               |
| US Striped Lyme                                | 684      | 230      | 936                                 |
| Uni-Gold test enhancement                      | 675      | _        | 675                                 |
| HIV 1/2 rapid screening test                   | 587      | 121      | 708                                 |
| Malaria Point-of-Care screening test           | 485      | 23       | 508                                 |
| H Pylori Rapid Point-of-Care screening test    | 462      | 499      | 1,162                               |

The costs in the foregoing table mainly comprise the cost of internal resources, such as the payroll costs for the development teams and attributable overheads. The remainder mainly comprises materials, consumables, regulatory trial and third party consultants' costs.

The following table sets forth the estimated cost to complete each of the main development projects which were underway in 2014. The total estimated completion costs are anticipated to be incurred evenly up to the completion date of the relevant project.

|                                       | Total estimated cost to complete | Estimated date for completion |
|---------------------------------------|----------------------------------|-------------------------------|
| Product Name                          | US\$'000                         | 0015                          |
| Premier Resolution                    | 3,265                            | 2015                          |
| Troponin I assay and reader           | 3,000                            | 2017                          |
| Brain Natriuretic Peptide (BNP) assay | 2,000                            | 2016                          |
| TPHA enhancement                      | 1,500                            | 2017                          |
| P24 development                       | 1,200                            | 2016                          |
| D-Dimer development                   | 1,000                            | 2017                          |
| HIV 1/2 rapid screening test          | 1,000                            | 2016                          |
| US Striped Lyme                       | 985                              | 2016                          |
| Syphilis Rapid Point-of-Care test     | 800                              | 2016                          |
| Malaria Point-of-Care screening test  | 800                              | 2016                          |
| IgM Captia                            | 700                              | 2016                          |
| Unigold test enhancement              | 600                              | 2015                          |
| Tristat Point-of-Care instrument      | 501                              | 2015                          |
| Meritas analyser                      | 500                              | 2015                          |
| Genesys/Resolution column enhancement | 363                              | 2015                          |

There are inherent risks and uncertainties associated with completing development projects on schedule. In the experience of Trinity Biotech, the main risks to the achievement of a project's planned completion date occur primarily during the product's verification and validation phase. During this phase the product must attain successful results from in-house product testing and from third party clinical trials. Obtaining regulatory approval on a timely basis is another variable in achieving a project's planned completion date.

Some aspects of the development of a new product are outside of the control of Trinity Biotech. Notwithstanding the uncertainty surrounding these external factors, Trinity Biotech believes the planned completion dates of these projects are realistic and achievable. If major development projects were severely delayed, in the opinion of Trinity Biotech it would not impact significantly on Trinity Biotech's financial position or on the capitalisation criteria. As the manufacturing lead time for these new products is relatively short, it is anticipated that material cash inflows will commence shortly after each of the project's planned completion date.

The following is a description of the principal projects which are currently being undertaken by the research and development groups within Trinity Biotech:

## **Emergency Medicine Development Group**

During 2012, Trinity Biotech acquired Fiomi Diagnostics AB, a Swedish based company which was founded to develop diagnostic tests for the point of care cardiac market. Trinity Biotech has developed a point of care test for Troponin I, which is a recognised marker for detecting acute myocardial infarctions. The technology, which uses micro-pillar technology, is capable of providing extremely sensitive, highly reproducible, quantitative, multiplexed results which give more accurate results than the established point-of-care tests currently in the market.

CE marking for this product was received in January 2014, and is expected to be submitted for FDA approval during 2015. Using the same platform, the company has developed a test for BNP which is a marker for heart failure. CE marking for this product was received in 2014 with clinical trials expected to be completed in 2015. The point-of-care cardiac market is currently estimated to be US\$1 billion.

In the CE marking trials our Troponin I product exhibited sensitivity rates with a detection of 19ng/L of whole blood and a CV of 10% at 36ng/L, which corresponds to the 99th percentile of the reference population. Time zero sensitivity was shown to be 60%.

## Clinical Performance

In July 2014, results of an Independent clinical performance study were published at the American Association Clinical Chemistry Conference in Chicago. This study, carried out by Dr. Fred Apple at Hennepin County Medical Centre in Minneapolis demonstrated excellent clinical performance. Time zero whole blood sensitivity was 75% with corresponding specificity of 93.6%.

In addition to cardiac tests, we believe that diagnostic tests in a range of other fields are capable of being developed using the same platform. A D-dimer test is currently in development with other tests to follow.

## **Haemoglobin Development Group**

Premier Hb9210 Instrument for Haemoglobin A1c Testing

This project entails the development of a new HPLC instrument for testing HbA1c. The new instrument will allow access to markets not previously open to Trinity Biotech due to instrument price and test capability. Development was initiated in late 2007, and was launched outside of the United States in 2011 followed by within the United States in early 2012.

In response to increased lab automation as well as workstation consolidation, the Premier 9210 TLA project was initiated at the end of 2014. TLA (total lab automation) capability will enable the Premier 9210 to be interfaced with many of the TLA systems currently available.

HbA1c testing is rapidly growing due to the increased utility as a method for diagnosis and identification of pre-diabetics. Diabetes is the fourth leading cause of death by disease in the world. In 2013, 5.1 million people died due to diabetes. Every 6 seconds a person dies from the disease. The number of diabetic patients is expected to reach 592 million in 2035. In the U.S. alone some 24.4 million Americans (7 percent of the population) have the disease with a further 54 million Americans considered to be pre-diabetic. The total HbA1c market worldwide is estimated to be approximately US\$900 million.

Since 2012, the company focussed on the development of an ion exchange version of the Premier Hb9210 which will be capable of detecting both HbA1c and haemoglobin variants. This product is expected to be launched in 2015. The Premier Resolution combines the best of the Premier 9210 and Ultra 2 to offer customers of Trinity Biotech what we believe to be an even better solution for the expanding haemoglobinopathy market.

The Premier Genesys system is also currently under development. The Genesys system is designed to meet the growing demand for neonatal screening of sickle cell disease and Alpha and Beta Thallasemia in newborns.

## Point-of-Care ("POC") Development Group

During 2010, Trinity Biotech commissioned and staffed a new POC product development unit at its Carlsbad, California facility. This facility has been equipped with state-of-the-art POC assay development equipment and Trinity Biotech has commenced development of a portfolio of point-of-care / lateral flow infectious disease tests. Initial tests include an enteric panel of assays for the detection of giardia, cryptosporidium and C. difficile antigens in human stool samples. Trinity Biotech also is developing tests for the detection of treponemal and non-treponemal syphilis antibodies in human whole blood, H. pylori antigen and strep pneumoniae. Trinity Biotech is currently in the process of obtaining CE marking for these products after which FDA approval will be sought.

## Trend Information

For information on trends in future operating expenses and capital resources, see "Results of Operations" and "Liquidity and Capital Resources" under Item 5.

Chairman and Chief Executive Officer

## Item 6 Directors, Senior Management and Employees

Age

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#### **Directors**

Ronan O'Caoimh

| Jim Walsh, PhD           | 56 | Director, Chief Scientific Officer          |
|--------------------------|----|---|
| Denis R. Burger, PhD     | 71 | Non Executive Director                      |
| Peter Coyne              | 55 | Non Executive Director                      |
| Clint Severson           | 66 | Non Executive Director                      |
| James D. Merselis        | 61 | Non Executive Director                      |
| <b>Executive Officer</b> |    |   |
| Kevin Tansley            | 44 | Chief Financial Officer & Company Secretary |

## **Board of Directors & Executive Officers**

Ronan O'Caoimh, Chairman and Chief Executive Officer, co-founded Trinity Biotech in June 1992 and acted as Chief Financial Officer until March 1994 when he became Chief Executive Officer. He was also elected Chairman in May 1995. In November 2007, it was decided to separate the role of Chief Executive Officer and Chairman and Mr O'Caoimh assumed the role of Executive Chairman. In October 2008, following the resignation of the Chief Executive Officer, Mr O'Caoimh resumed the role of Chief Executive Officer and Chairman. Prior to joining Trinity Biotech, Mr O'Caoimh was Managing Director of Noctech Limited, an Irish diagnostics company. Mr O'Caoimh was Finance Director of Noctech Limited from 1988 until January 1991 when he became Managing Director. Mr O'Caoimh holds a Bachelor of Commerce degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland. On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by a management agreement with Darnick Company.

Jim Walsh, PhD, Executive Director, initially joined Trinity Biotech in October 1995 as Chief Operations Officer. Dr. Walsh resigned from the role of Chief Operations Officer in 2007 to become a Non Executive Director of the Company. In October, 2010 Dr. Walsh rejoined the company as Chief Scientific Officer. Prior to joining Trinity Biotech, Dr. Walsh was Managing Director of Cambridge Diagnostics Ireland Limited (CDIL). He was employed with CDIL since 1987. Before joining CDIL he worked with Fleming GmbH as Research & Development Manager. Dr. Walsh holds a PhD in Chemistry from University College Galway.

Denis R. Burger, PhD, Non executive director, co-founded Trinity Biotech in June 1992 and acted as Chairman from June 1992 to May 1995. He is currently Vice Chairman of CytoDyn Inc., an anti retroviral therapeutics, OTC:BB listed company and is also lead director of Aptose Biosciences, Inc, a cancer therapeutics, TSX and NASDAQ listed company. Until March 2007, Dr Burger was the Chairman and Chief Executive Officer of AVI Biopharma Inc, a NASDAQ listed biotechnology company. He was also a co-founder and, from 1981 to 1990, Chairman of Epitope Inc. In addition, Dr Burger has held a professorship in the Department of Microbiology and Immunology and Surgery (Surgical Oncology) at the Oregon Health and Sciences University in Portland. Dr Burger received his degree in Bacteriology and Immunology from the University of California in Berkeley in 1965 and his Master of Science and PhD in 1969 in Microbiology and Immunology from the University of Arizona.

Peter Coyne, Non-executive director, joined the board of Trinity Biotech in November 2001 as a non-executive director. Mr. Coyne trained as a chartered accountant in the Corporate Financial Services practice of Arthur Andersen & Co. Mr. Coyne was previously a director of AIB Corporate Finance and has extensive experience of advising boards on mergers and acquisitions and corporate strategy. Mr. Coyne is a partner of VISION Consulting, an international consulting firm delivering breakthrough solutions in customer service and leadership development. Mr. Coyne is a non-executive director of Ark Life Assurance Company Limited. Mr. Coyne holds a bachelor of engineering degree from University College Dublin, is a fellow of the Institute of Chartered Accountants in Ireland and is a CEDR Accredited Mediator.

Clint Severson, Non-executive director, joined the board of Trinity Biotech in November 2008 as a non-executive director. Mr. Severson is currently Chairman, President and CEO of Abaxis Inc., a NASDAQ traded diagnostics company based in Union City, California. From February 1989 to May 1996, Mr. Severson served as President and Chief Executive Officer of MAST Immunosystems, Inc., a privately-held medical diagnostic company and to date he has accumulated over 40 years experience in the medical diagnostics industry.

James D. Merselis, Non-executive director, joined the board of Trinity Biotech in February 2009 as a non-executive director. He is currently CEO and Director of Biosensia Ltd; a point-of-care diagnostics company located in Dublin, Ireland and is on the board of Abram Scientific Inc. located in Mountain View, California. Mr. Merselis has more than thirty-eight years experience in healthcare, with the first twenty-two years at Boehringer Mannheim Diagnostics (now Roche Diagnostics). Mr. Merselis has led a number of healthcare diagnostic start-ups. From 2002 to 2007, he served as President and CEO of HemoSense, Inc., a point-of-care diagnostics company providing patients and physicians with rapid test results to help manage the risk of stroke with the use of Warfarin or Coumadin. During this time he successfully took the company public (NASDAQ:HEM) followed two years later by its acquisition by Alere (NYSE:ALR). His leadership at other start-ups has included: Nexus Dx (now Samsung), Alverix, Inc. (now Becton Dickenson), and Micronics, Inc. (now SONY).

**Kevin Tansley, Chief Financial Officer**, joined Trinity Biotech in March 2003 and was appointed Chief Financial Officer and Secretary to the Board of Directors in November 2007. Mr. Tansley trained as a chartered accountant in the Corporate Financial Services practice of Arthur Andersen & Co. Prior to joining Trinity Biotech in 2003, Mr. Tansley held a number of financial positions in the Irish electricity utility ESB. Mr. Tansley holds a Masters of Accounting from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

#### Compensation of Directors and Officers

The basis for the executive directors' remuneration and level of annual bonuses is determined by the Remuneration Committee of the board. In all cases, bonuses and the granting of share options are subject to stringent performance criteria. The Remuneration Committee consists of Dr Denis Burger (committee chairman and senior non executive director), Mr Peter Coyne, Mr Clint Severson and Mr James Merselis. Directors' remuneration shown below comprises salaries, pension contributions and other benefits and emoluments in respect of executive directors. Non-executive directors are remunerated by fees and the granting of share options. The fees payable to non-executive directors are determined by the board. Each director is reimbursed for expenses incurred in attending meetings of the board of directors.

Total directors and non-executive directors' remuneration, excluding pension, for the year ended December 31, 2014 amounted to US\$2,353,000. The pension charge for the year amounted to US\$87,000. See Item 18, Note 5 to the consolidated financial statements. The split of directors' remuneration set out by director is detailed in the table below:

| Executive Director   | Salary/<br>Benefits<br>US\$'000 | Performance<br>related bonus<br>US\$'000 | Defined<br>contribution<br>pension<br>US\$'000 | Total<br>2014<br>US\$'000                                | Total<br>2013<br>US\$'000 |
|--|---------------------------------|--|--|--|---------------------------|
| Ronan O'Caoimh <sup>1</sup>  | 773                             | 176                                      | _  | 949  | 877                       |
| Rory Nealon <sup>2</sup>   | 378                             | 110                                      | 35   | 523  | 544                       |
| Jim Walsh  | 426                             | 110                                      | 52   | 588  | 478                       |
|  | 1,577                           | 396                                      | 87   | 2,060  | 1,899                     |
| Non-executive director  Denis R. Burger  Peter Coyne  James Merselis  Clint Severson |                                 | Fees<br>US\$*000<br>96<br>96<br>94<br>94 |  | Total<br>2013<br>US\$*000<br>84<br>84<br>74<br>74<br>316 |                           |
| Chief Financial Officer & Company Secretary  | Salary/<br>Benefits<br>US\$'000 | Performance<br>related bonus<br>US\$'000 | Defined contribution pension US\$'000          | Total<br>2014<br>US\$'000                                | Total<br>2013<br>US\$'000 |
| Kevin Tansley  | 410                             | 118                                      | 45   | 573  | 507                       |

As at December 31, 2014 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2013: NIL).

The total share-based compensation expense recognised in the consolidated statement of operations in 2014 in respect of options granted to both executive and non-executive directors and the Company Secretary amounted to US\$2,109,000. See Item 18, Note 5 to the consolidated financial statements.

Includes payments made to Darnick Company

Rory Nealon resigned from the board of directors on November 15, 2014

1,700,000 'A' share options (equivalent to 425,000 ADS options) were granted to the directors and the Company Secretary during 2014, the terms of which are set out below. 2,540,000 'A' share options (equivalent to 635,000 ADS options) were granted to the directors and the Company Secretary during 2013.

## **Share Options Granted in 2014:**

| Director/Executive Officer Ronan O'Caoimh | Number of Options Granted 800,000 'A' shares (200,000 ADS) | Exercise Price of Options Granted US\$4.23 per 'A' share (US\$16.90 per ADS) | Date of Option Grant*  5 December 2014 |
|---|--|--|--|
| Jim Walsh                                 | 160,000 'A' shares<br>(40,000 ADS)                         | US\$4.23 per 'A' share (US\$16.90 per ADS)                                   | 5 December 2014                        |
| Kevin Tansley                             | 500,000 'A' shares<br>(125,000ADS)                         | US\$4.23 per 'A' share (US\$16.90 per ADS)                                   | 5 December 2014                        |
| Denis Burger                              | 60,000 'A' shares<br>(15,000 ADS)                          | US\$4.23 per 'A' share (US\$16.90 per ADS)                                   | 5 December 2014                        |
| Peter Coyne                               | 60,000 'A' shares<br>(15,000 ADS)                          | US\$4.23 per 'A' share (US\$16.90 per ADS)                                   | 5 December 2014                        |
| Clint Severson                            | 60,000 'A' shares<br>(15,000 ADS)                          | US\$4.23 per 'A' share (US\$16.90 per ADS)                                   | 5 December 2014                        |
| James Merselis                            | 60,000 'A' shares<br>(15,000 ADS)                          | US\$4.23 per 'A' share<br>(US\$16.90 per ADS)                                | 5 December 2014                        |

<sup>\*</sup>Alloptions issued are subject to a 7 year life from date of grant.

In addition, see Item 7 – Major Shareholders and Related Party Transactions for further information on the compensation of Directors and Officers.

#### Directors' Service Contracts

The Company has entered into service contracts with its Executive Directors and Officers. These contracts contain certain termination provisions which are summarised below.

On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by an agreement with Darnick Company, a company wholly-owned by members of Mr. O'Caoimh's immediate family. Pursuant to the agreement, Darnick Company will provide the Company with the services of Mr O'Caoimh as Chief Executive Officer. The agreement contains certain non-competition and confidentiality provisions. The term of the agreement will continue until such time as it is terminated by either party, subject to the Company providing one year's notice. Where termination occurs within 12 months of a change of control of the Company, two year's notice will apply. Darnick Company may terminate the agreement on six months' notice. Mr. O'Caoimh remains as Chairman of the Board of Directors.

Under the terms of his service contract, Kevin Tansley, Chief Financial Officer, is entitled to 12 months salary and benefits in the event of termination by the Company. Where termination arises within 12 months of a change in control of the Company, Mr. Tansley is entitled to 18 months salary and benefits.

Under the terms of his service contract, Jim Walsh, Chief Scientific Officer, is entitled to 12 months salary and benefits in the event of termination by the Company. Where termination arises within 12 months of a change in control of the Company, Dr. Walsh is entitled to 18 months salary and benefits.

## **Board Practices**

The Articles of Association of Trinity Biotech provide that one third of the directors in office (other than the Managing Director or a director holding an executive office with Trinity Biotech) or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at every annual general meeting. If at any annual general meeting the number of directors who are subject to retirement by rotation is two, one of such directors shall retire and if the number of such directors is one that director shall retire. Retiring directors may offer themselves for re-election. The directors to retire at each annual general meeting shall be the directors who have been longest in office since their last appointment. As between directors of equal seniority the directors to retire shall, in the absence of agreement, be selected from among them by lot.

The Board of Directors has established Audit, Remuneration and Compensation Committees. The functions and membership of the Remuneration Committee are described above. The Audit Committee reviews the Group's annual and interim financial statements and reviews reports on the effectiveness of the Group's internal controls. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The Audit Committee comprises two of the four independent non-executive directors of the Group, Mr Peter Coyne (Committee Chairman) and Mr James Merselis. The Compensation Committee currently comprises Mr Ronan O'Caoimh (Committee Chairman) and Dr Jim Walsh. The Board of Directors administers the Employee Share Option Plan. The Board determines the exercise price and the term of the options. Individual option grants of less than 30,000 shares are approved by the Compensation Committee. Options granted to the members of the Compensation Committee are approved by the Remuneration Committee and share options granted to non-executive directors are decided by the other members of the board.

Because Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 5600 as they apply to U.S. domestic companies. The Group's corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process and (b) the Audit Committee of the Group currently consists of two members (both of whom are independent non-executive directors) – while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee and be comprised only of independent directors.

## **Employees**

As of December 31, 2014, Trinity Biotech had 545 employees (2013: 571) consisting of 69 research scientists and technicians, 337 manufacturing and quality assurance employees, and 139 finance, administration, sales and marketing staff (2013: 113 research scientists and technicians, 313 manufacturing and quality assurance employees, and 145 finance, administration, sales and marketing staff). Trinity Biotech's future hiring levels will depend on the growth of revenues.

The geographic spread of the Group's employees is as follows: 360 in our U.S. operations, 131 in Bray, Ireland, 35 in Uppsala, Sweden, 5 in the UK and 14 in Sao Paulo, Brazil.

## Stock Option Plans

The Board of Directors have adopted the Employee Share Option Plans (the "Plans"); with the most recently adopted Share Option Plan being the 2013 Plan. The purpose of these Plans is to provide Trinity Biotech's employees, consultants, officers and directors with additional incentives to improve Trinity Biotech's ability to attract, retain and motivate individuals upon whom Trinity Biotech's sustained growth and financial success depends. These Plans are administered by the Board of Directors. Options under the Plans may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

The exercise price of options is determined by the Board of Directors. The term of an option will be determined by the Board, provided that the term may not exceed ten years from the date of grant. Option grants up to 30,000 shares are administered by the Compensation Committee. The Committee will also determine the exercise price and term of these options. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity Biotech (or one year after such termination because of death or disability) except where a longer period is approved by the board of directors. Under certain circumstances involving a change in control of Trinity Biotech, the Committee may accelerate the exercisability and termination of options.

As of February 28, 2015, 6,185,000 (1,546,250 ADS equivalent) of the options outstanding were held by the directors and Company Secretary of Trinity Biotech as follows:

| Director/Company Secretary | Number of<br>Options 'A'<br>Shares | Number of<br>Options<br>ADS<br>Equivalent | Exercise<br>Price (Per<br>'A' Share) | Exercise Price<br>(Per ADS) | Expiration Date of Options |
|----------------------------|------------------------------------|---|--------------------------------------|-----------------------------|----------------------------|
| Ronan O'Caoimh             | 800,000                            | 200,000                                   | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 800,000                            | 200,000                                   | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 800,000                            | 200,000                                   | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| Denis Burger               | 20,000                             | 5,000                                     | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 60,000                             | 15,000                                    | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 60,000                             | 15,000                                    | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| Jim Walsh                  | 15,000                             | 3,750                                     | US\$1.52                             | US\$ 6.07                   | 21 May 2017                |
|                            | 100,000                            | 25,000                                    | US\$1.57                             | US\$ 6.26                   | 4 October 2017             |
|                            | 500,000                            | 125,000                                   | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 500,000                            | 125,000                                   | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 160,000                            | 40,000                                    | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| Peter Coyne                | 60,000                             | 15,000                                    | US\$0.66                             | US\$ 2.63                   | 8 May 2016                 |
|                            | 60,000                             | 15,000                                    | US\$1.52                             | US\$ 6.07                   | 21 May 2017                |
|                            | 60,000                             | 15,000                                    | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 60,000                             | 15,000                                    | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 60,000                             | 15,000                                    | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| Clint Severson             | 20,000                             | 5,000                                     | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 40,000                             | 10,000                                    | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 60,000                             | 15,000                                    | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| James Merselis             | 15,000                             | 3,750                                     | US\$1.52                             | US\$ 6.07                   | 21 May 2017                |
|                            | 40,000                             | 10,000                                    | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 60,000                             | 15,000                                    | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 60,000                             | 15,000                                    | US\$4.23                             | US\$16.90                   | 5 December 2021            |
| Kevin Tansley              | 150,000                            | 37,500                                    | US\$1.07                             | US\$ 4.28                   | 18 March 2015              |
|                            | 125,000                            | 31,250                                    | US\$1.52                             | US\$ 6.07                   | 21 May 2017                |
|                            | 500,000                            | 125,000                                   | US\$2.52                             | US\$10.09                   | 7 March 2019               |
|                            | 500,000                            | 125,000                                   | US\$4.21                             | US\$16.85                   | 24 May 2020                |
|                            | 500,000                            | 125,000                                   | US\$4.23                             | US\$16.90                   | 5 December 2021            |
|                            |                                    |   |                                      |                             |                            |

As of February 28, 2015 the following total options were outstanding:

|                           | Number of 'A'     | Range of           |                         |
|---------------------------|-------------------|--------------------|-------------------------|
|                           | Ordinary Shares   | Exercise Price     | Range of Exercise Price |
|                           | Subject to Option | per Ordinary Share | per ADS                 |
| Total options outstanding | 8,743,325         | US\$0.66-US\$4.79  | US\$2.63-US\$19.15      |

As of February 28, 2015 there were no warrants to purchase 'A' Ordinary Shares in the Company outstanding.

## Item 7 Major Shareholders and Related Party Transactions

As of February 28, 2015 Trinity Biotech has outstanding 94,856,690 'A' Ordinary shares. Such totals exclude 8,743,325 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2015, the Trinity Biotech 'A' Ordinary Shares beneficially held by (i) each person believed by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and the Company Secretary of Trinity Biotech, and (iii) all directors and the Company Secretary as a group.

Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Group is not controlled by another corporation or government.

|   | Number of 'A' Ordinary Shares Beneficially Owned | Number of<br>ADSs<br>Beneficially<br>Owned | Percentage<br>'A' Ordinary<br>Shares (8) | Percentage<br>Total<br>Voting<br>Power |
|---|--|--|--|--|
| Ronan O'Caoimh                          | 6,037,496(1)                                     | 1,509,374                                  | 5.8%                                     | 5.8%                                   |
| Jim Walsh                               | 2,668,612(2)                                     | 667,153                                    | 2.6%                                     | 2.6%                                   |
| Denis Burger                            | 267,000(3)                                       | 66,750                                     | 0.3%                                     | 0.3%                                   |
| Peter Coyne                             | 305,600(4)                                       | 76,400                                     | 0.3%                                     | 0.3%                                   |
| Clint Severson                          | 408,000(5)                                       | 102,000                                    | 0.4%                                     | 0.4%                                   |
| James Merselis                          | 363,600(6)                                       | 90,900                                     | 0.4%                                     | 0.4%                                   |
| Kevin Tansley                           | 1,775,000(7)                                     | 443,750                                    | 1.7%                                     | 1.7%                                   |
| Directors & Co. Secretary as a group (7 |  |  |  |  |
| persons)                                | 11,825,308 (1)(2)(3)(4)(5)(6)(7)                 | 2,956,327                                  | 11.4%                                    | 11.4%                                  |

- (1) Includes 2,400,000 'A' Ordinary shares issuable upon exercise of options.
- (2) Includes 1,275,000 'A' Ordinary shares issuable upon exercise of options. Note that 1,200,000 'A' Ordinary shares (300,000 ADSs) of Dr Walsh's shares are held in trust for the benefit of Dr Walsh's immediate family.
- (3) Includes 140,000 'A' Ordinary shares issuable upon exercise of options.
- (4) Includes 300,000 'A' Ordinary shares issuable upon exercise of options.
- (5) Includes 120,000 'A' Ordinary shares issuable upon exercise of options.
- (6) Includes 175,000 'A' Ordinary shares issuable upon exercise of options.
- (7) Includes 1,775,000 'A' Ordinary shares issuable upon exercise of options.
- (8) Percentage 'A' Ordinary shares is based upon total outstanding 'A' Ordinary shares and total number of shares issuable upon exercise of options.

#### Related Party Transactions

The Group has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of Trinity Biotech, and directly with Mr O'Caoimh and Dr Walsh, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland.

In November 2002, the Group entered into an agreement for a 25 year lease with JRJ for offices that have been constructed adjacent to its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. The annual rent of €381,000 (US\$463,000) is payable from January 1, 2004. There was a rent review performed on this premises in 2009 and further to this review, there was no change to the annual rental charge.

In December 2007, the Group entered into an agreement with Mr. O'Caoimh and Dr Walsh pursuant to which the Group took a lease on an additional 43.860 square foot manufacturing facility in Bray, Ireland at a total annual rent of €787,000 (US\$956,000).

Independent valuers have advised the Group that the rent in respect of each of the leases represents a fair market rent.

Trinity Biotech and its directors (excepting Mr O'Caoimh and Dr Walsh who express no opinion on this point) believe at the time that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises.

Darnick Company is wholly-owned by members of Mr. O'Caoimh's immediate family. On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by a management agreement with Darnick Company. Pursuant to the agreement, Darnick Company will provide Trinity Biotech with the services of Mr O'Caoimh as Chief Executive Officer. In 2014, the Group paid US\$696,000 to Darnick Company in respect of Director's compensation. There is no balance payable to or receivable from Darnick Company as at December 31, 2014.

Rayville Limited, an Irish registered company, which is wholly owned by the three executive directors and certain other executives of the Group, owns all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries. The 'B' shares do not entitle the holders thereof to receive any assets of the company on a winding up. All of the 'A' voting ordinary shares in Trinity Research Limited are held by the Group. Trinity Research Limited may, from time to time, declare dividends to Rayville Limited and Rayville Limited may declare dividends to its shareholders out of those amounts. Any such dividends paid by Trinity Research Limited are ordinarily treated as a compensation expense by the Group in the consolidated financial statements prepared in accordance with IFRS, notwithstanding their legal form of dividends to minority interests, as this best represents the substance of the transactions.

There were no director loans advanced during 2014 and there were no loan balances payable to or receivable from directors at January 1, 2014 and at December 31, 2014.

In June 2009, the Board approved the payment of a dividend of US\$2,830,000 by Trinity Research Limited to Rayville Limited on the 'B' shares held by it. This amount was then lent back by Rayville to Trinity Research Limited. As the dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2012 & 2013 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US\$Nil, US\$Nil and US\$231,000 for 2014, 2013 and 2012 respectively, of which US\$Nil, US\$Nil and US\$206,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2014, 2013 or 2012.

## Item 8 Financial Information

# Legal Proceedings

In 2008 Trinity Biotech filed a civil suit with a New York court against the former shareholders of Primus Corporation. Trinity Biotech claimed that the defendants unjustly received an overpayment of US\$512,000 based on the fraudulent and wrongful calculation of the earnout payable to the shareholders of Primus Corporation. Trinity Biotech also alleged that one of the former shareholders, Mr Thomas Reidy, failed to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of a US\$3 million promissory note given to the defendants by Trinity Biotech as part of compensation under the share purchase agreement for acquiring Primus. During 2009, all of the defendants with the exception of Mr. Reidy settled the legal action. The US District Court, Southern District of New York granted a judgment against Mr. Reidy ordering him to pay Trinity damages of US\$200,000 plus interest and to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of the US\$3 million promissory note. Mr Reidy has not yet paid any damages or interest due to Trinity Biotech.

In 2010, Laboratoires Nephrotek, formerly a distributor for Trinity Biotech, took a legal action in France against the Group, claiming damages of US\$0.8 million. They claimed that certain instruments supplied by Trinity Biotech did not operate properly in the field. In 2013, Trinity Biotech successfully defended this claim in the French courts. Nephrotek are in the process of appealing this decision.

The ultimate resolution of the aforementioned proceedings is not expected to have a material adverse effect on our financial position, results of operations or cash flows.

# Item 9 The Offer and Listing

Trinity Biotech's ADSs are listed on the NASDAQ Global Market under the symbol "TRIB". In 2005, Trinity Biotech adjusted the ratio of ADSs to Ordinary Shares and changed its NASDAQ Listing from the NASDAQ Small Capital listing to a NASDAQ National Market Listing. The ratio of ADSs to underlying Ordinary Shares has changed from 1 ADS: 1 Ordinary Share to 1 ADS: 4 Ordinary Shares and all historical data has been restated as a result.

The Group's 'A' Ordinary Shares were also listed and traded on the Irish Stock Exchange until November 2007, whereby the Company de-listed from the Irish Stock Exchange. The Group's depository bank for ADSs is The Bank of New York Mellon. On February 28, 2015, the reported closing sale price of the ADSs was US\$17.76 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech's ADSs for (a) the years ended December 31, 2010, 2011, 2012, 2013 and 2014; (b) the quarters ended March 31, June 30, September 30 and December 31, 2013; March 31, June 30, September 30 and December 31, 2014; and (c) the months of March, April, May, June, July, August, September, October, November and December 2014 and January and February 2015 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

# **ADSs**

| Year Ended December 31 | High      | Low       |
|------------------------|-----------|-----------|
| 2010                   | US\$ 8.93 | US\$ 3.76 |
| 2011                   | US\$11.00 | US\$ 8.00 |
| 2012                   | US\$15.75 | US\$ 8.81 |
| 2013                   | US\$25.63 | US\$14.30 |
| 2014                   | US\$28.06 | US\$14.00 |

# **ADSs**

| 2013                       | High      | Low       |
|----------------------------|-----------|-----------|
| Quarter ended March 31     | US\$19.00 | US\$14.30 |
| Quarter ended June 30      | US\$17.92 | US\$15.12 |
| Quarter ended September 30 | US\$22.00 | US\$16.40 |
| Quarter ended December 31  | US\$25.63 | US\$21.28 |

# **ADSs**

| <u>2014</u>                | High      | Low       |
|----------------------------|-----------|-----------|
| Quarter ended March 31     | US\$28.06 | US\$22.58 |
| Quarter ended June 30      | US\$26.00 | US\$22.53 |
| Quarter ended September 30 | US\$24.00 | US\$18.15 |
| Quarter ended December 31  | US\$18.49 | US\$14.00 |

# **ADSs**

| Month Ended        | High      | Low       |
|--------------------|-----------|-----------|
| March 31, 2014     | US\$28.06 | US\$22.58 |
| April 30, 2014     | US\$26.00 | US\$22.53 |
| May 31, 2014       | US\$24.95 | US\$23.00 |
| June 30, 2014      | US\$24.38 | US\$22.90 |
| July 31, 2014      | US\$24.00 | US\$22.80 |
| August 31, 2014    | US\$23.48 | US\$19.55 |
| September 30, 2014 | US\$22.11 | US\$18.15 |
| October 31, 2014   | US\$18.49 | US\$14.00 |
| November 30, 2014  | US\$18.43 | US\$16.54 |
| December 31, 2014  | US\$18.40 | US\$16.35 |
| January 31, 2015   | US\$20.24 | US\$17.50 |
| February 28, 2015  | US\$19.66 | US\$17.00 |

The number of record holders of Trinity Biotech's ADSs as at February 28, 2015 amounts to 526, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clients (with each such brokerage house and/or clearing house being considered as one holder).

# Item 10 Additional Information

The following is a summary of certain provisions of the Articles of Association of Trinity Biotech plc. This summary does not purport to be complete and is qualified in its entirety by reference to the complete text of the Articles, which are included as an exhibit to this annual report.

# **Objects**

The Company's objects, detailed in Clause 3 of its Memorandum of Association, are varied and wide ranging and include the carrying on of the business of researchers, manufacturers, buyers, sellers and distributors of all kinds of patents, pharmaceutical, medicinal and diagnostic preparations, equipment, drugs and accessories of every description. They also include the power to acquire shares or other interests or securities in other companies or businesses and to exercise all rights in relation thereto. The Company's registered number in Ireland is 183476.

# Powers and Duties of Directors

The directors may make such arrangements as may be thought fit for the management of the Company's affairs in the Republic of Ireland or abroad.

A director may enter into a contract and be interested in any contract or proposed contract with the Company either as vendor, purchaser or otherwise and shall not be liable to account for any profit made by him resulting therefrom provided that he has first disclosed the nature of his interest in such a contract at a meeting of the board as required by Section 194 of the Irish Companies Act 1963. Generally, a director must not vote in respect of any contract or arrangement or any proposal in which he has a material interest (otherwise than by virtue of his holding of shares or debentures or other securities in or through the Company). In addition, a director shall not be counted in the quorum at a meeting in relation to any resolution from which he is barred from voting.

A director is entitled to vote and be counted in the quorum in respect of certain arrangements in which he is interested (in the absence of some other material interest). These include the giving of a security or indemnity to him in respect of money lent or obligations incurred by him for the Group, the giving of any security or indemnity to a third party in respect of a debt or obligation of the Group for which he has assumed responsibility, any proposal concerning an offer of shares or other securities in which he may be interested as a participant in the underwriting or sub-underwriting and any proposal concerning any other company in which he is interested provided he is not the holder of or beneficially interested in 1% or more of the issued shares of any class of share capital of such company or of voting rights.

The Board may exercise all the powers of the Company to borrow money, to mortgage or charge its undertaking, property and uncalled capital and to issue debentures and other securities. The Board is obliged to restrict its borrowings to ensure that the aggregate amount outstanding of all monies borrowed by the Group does not, without the previous sanction of an ordinary resolution of the Company, exceed an amount equal to twice the Adjusted Capital and Reserves (as defined in the Articles of Association). However, no lender or other person dealing with the Company shall be obliged to see or to inquire whether the limit imposed is observed and no debt incurred in excess of such limit will be invalid or ineffectual unless the lender has express notice at the time when the debt is incurred that the limit was or was to be exceeded.

Directors are not required to retire upon reaching any specific age and are not required to hold any shares in the capital of the Group. The Articles provide for retirement of the directors by rotation.

One third of the directors other than a director holding executive office or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at each annual general meeting. If, however, the number of directors subject to retirement by rotation is two, one of such directors shall retire. If the number of such directors is one, that director shall retire. Subject to the terms of the Articles, the directors to retire at each annual general meeting shall be the directors who have been longest in office since their last appointment. Where directors are of equal seniority, the directors to retire shall, in the absence of agreement, be selected by lot. A retiring director shall be eligible for re-appointment and shall act as director throughout the meeting at which he retires. A separate motion must be put to a meeting in respect of each director to be appointed unless the meeting itself has first agreed that a single resolution is acceptable without any vote being given against it.

# Rights, Preferences and Restrictions Attaching to Shares

The Company may, subject to the provisions of the Companies Acts, 1963 to 2013 of Ireland, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution.

At a general meeting, on a show of hands, every member who is present in person or by proxy and entitled to vote shall have one vote (so, however, that no individual shall have more than one vote) and upon a poll, every member present in person or by proxy shall have one vote for every share carrying voting rights of which he is the holder. In the case of joint holders, the vote of the senior (being the first person named in the register of members in respect of the joint holding) who tendered a vote, whether in person or by proxy, shall be accepted to the exclusion of votes of the other joint holders.

Subject to any conditions of allotment, the directors may from time to time make calls on members in respect of monies unpaid on their shares. At least 14 days notice must be given of each call. A call shall be deemed to have been made at the time when the resolution of the directors authorising such call was passed.

Where a shareholder or person who appears to be interested in shares fails to comply with a request for information from the Company in relation to the capacity in which such shares or interest are held, who is interested in them or whether there are any voting arrangements, that shareholder or person may be served with a disenfranchisement notice and may thereby be restricted from transferring the shares and exercising the voting rights or receiving any sums in respect of the shares (except in the case of a liquidation).

In addition, if cheques in respect of the last three dividends paid to a shareholder remain uncashed, the Company is, subject to compliance with the procedure set out in the Articles of Association, entitled to sell the shares of that shareholder.

Before recommending a dividend, the directors may reserve out of the profits of the Company such sums as they think proper which shall be applicable for any purpose to which the profits of the Company may properly be applied and, pending such application, may be either employed in the business of the Company or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

The Company may by ordinary resolution convert any paid up shares into stock and reconvert any stock into paid up shares of any denomination. The holders of stock may transfer the same or any part thereof in the same manner and according to the same regulations to which the converted shares were subject.

# Action Necessary to Change the Rights of Shareholders

In order to change the rights attaching to any class of shares, a special resolution passed at a class meeting of the holders of such shares is required. The provisions in relation to general meetings apply to such class meetings except the quorum shall be two persons holding or representing by proxy at least one third in nominal amount of the issued shares of that class. In addition, in order to amend any provisions of the Articles of Association in relation to rights attaching to shares, a special resolution of the shareholders as a whole is required. The special rights attached to any class of shares in the capital of the Company shall not be deemed to be varied by the creation or issue of further shares ranking pari passu.

# Calling of AGMs and EGMs of Shareholders

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in the Republic of Ireland unless all of the members entitled to attend and vote at such meeting consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2013 of Ireland.

In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days' notice of the meeting is required and in any other case seven clear days' notice is required. Notice must be given in writing to all members and to the auditors in accordance with the Articles of Association and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided for in the Companies Acts, 1963 to 2013 of Ireland, extended notice of a general meeting is required. These include a meeting at which a resolution for the removal of a director before the expiration of his term of office is proposed.

No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum. The Company is not obliged to serve notices upon members who have not served notice on the Company of an address in the Republic of Ireland or the U.S. but otherwise there are no specific limitations in the Articles of Association restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights respect of shares in the Company.

However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in "Exchange Controls" below. In addition, Irish competition law may restrict the acquisition by a party of shares in the Company but this does not apply on the basis of nationality or residence.

# Other Provisions of the Memorandum and Articles of Association

The Memorandum and Articles of Association do not contain any specific provisions:

- which would have an effect of delaying, deferring or preventing a change in control of the Company and which would
  operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of its
  subsidiaries); or
- governing the ownership threshold above which a shareholder ownership must be disclosed; or
- imposing conditions governing changes in the capital which are more stringent than is required by Irish law.

The Company incorporates by reference all other information concerning its Memorandum and Articles of Association from the Registration Statement on Form F-1 on June 12, 1992.

# Irish Law

Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept at the registered office of the Company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper books of account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the Company (changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office (the "CRO") in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the Company carrying the right of voting at general meetings of the Company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the Company. Any shareholder who complains that the affairs of the Company are being conducted or that the powers of the directors of the Company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the Company.

Ordinarily, our directors owe their duties only to Trinity Biotech and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to Trinity Biotech. Those duties include duties to act in good faith towards Trinity Biotech in any transaction, not to make use of any money or other property of Trinity Biotech, not to gain directly or indirectly any improper advantage for himself at the expense of Trinity Biotech, to act bona fide in the interests of Trinity Biotech and exercise powers for the proper purpose. A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. When directors, as agents in transactions, make contracts on behalf of the Company, they generally incur no personal liability under these contracts.

It is Trinity Biotech, as principal, which will be liable under them, as long as the directors have acted within Trinity Biotech's objects and within their own authority. A director who commits a breach of his fiduciary duties shall be liable to Trinity Biotech for any profit made by him or for any damage suffered by Trinity Biotech as a result of the breach. In addition to the above, a breach by a director of his duties may lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to Trinity Biotech for profit made and restriction of the director from acting as a director in the future.

# **Material Contracts**

Other than contracts entered into in the ordinary course of business, the following represents the material contracts entered into by the Group:

# **Acquisition of Immco Diagnostics Inc**

In 2013, the Group purchased 100% of the common stock of Immco Diagnostics Inc for a total consideration of US\$32.88m. Immco, which is headquartered in Buffalo, New York, is a diagnostic company specialising in the development, manufacture and sale of autoimmune test kits on a worldwide basis.

The key terms of the acquisition are as follows:

- Cash consideration of US\$31,652,000;
- Issuance of share option as at the acquisition date with a fair value of US\$1,121,000; and
- The transfer of 5,566 Trinity Biotech ADSs as at the acquisition date (fair value of US\$110,000).

Please refer to Item 18, Note 22 for further information.

# Acquisition of Fiomi Diagnostics AB

In 2012, the Group purchased 100% of the common stock of Fiomi Diagnostics AB for a total consideration of US\$12.9 million (including US\$3.2m of contingent payments – net of interest of US\$0.2m). Fiomi, which is based in Uppsala, Sweden, is at an advanced stage in developing a range of Point-of-Care cardiac assays.

The key terms of the acquisition are as follows:

- An up-front cash payment of US\$5.6m;
- The transfer of 408,000 Trinity Biotech ADSs as at the acquisition date (fair value of US\$4.1m); and
- Contingent cash consideration (net present value) of US\$3.2m.

Please refer to Item 18, Note 22 for further information.

# Divestiture of Coagulation product line to Diagnostica Stago SAS

In April 2010, the Group sold its worldwide Coagulation product line to Diagnostica Stago for US\$89.9 million. The gain on the divestiture was US\$46.8m. Diagnostica Stago purchased the share capital of Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH and Trinity Biotech S.à r.l., along with Coagulation assets of Biopool US Inc. and Trinity Biotech Manufacturing Limited. As part of the sale, the Group also assigned leasing arrangements on a facility in Bray, Ireland to Diagnostica Stago. Included in the sale are Trinity's lists of Coagulation customers and suppliers, all Coagulation inventory, intellectual property and developed technology. In total, 321 Trinity employees transferred their employment to Diagnostica Stago as part of the divestiture of the Coagulation product line.

The Group received consideration of US\$68.4 million in 2010. A further US\$11.25 million was received from Diagnostica Stago in April 2011 and the remaining US\$11.25 million was received in April 2012. No conditions or earnout provisions were applied to this deferred element of the consideration, which has now been fully received.

# Exchange Controls and Other Limitations Affecting Security Holders

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of Ireland dealing in domestic securities, which includes shares or depositary receipts of Irish companies such as Trinity Biotech. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to make provision for the restriction of financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of ADSs or ADRs representing shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition.

At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People's Republic of Korea (North Korea), Iran, Iraq, Côte d'Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbour certain terrorist groups, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, an ADS involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. We do not anticipate that orders under the Financial Transfers Act, 1992 or United Nations sanctions implemented into Irish law will have a material effect on our business.

# **Taxation**

The following discussion is based on U.S. and Republic of Ireland tax law, statutes, treaties, regulations, rulings and decisions all as of the date of this annual report. Taxation laws are subject to change, from time to time, and no representation is or can be made as to whether such laws will change, or what impact, if any, such changes will have on the statements contained in this summary. No assurance can be given that proposed amendments will be enacted as proposed, or that legislative or judicial changes, or changes in administrative practice, will not modify or change the statements expressed herein.

This summary is of a general nature only. It does not constitute legal or tax advice nor does it discuss all aspects of Irish taxation that may be relevant to any particular Irish Holder or U.S. Holder of ordinary shares or ADSs.

This summary does not discuss all aspects of Irish and U.S. federal income taxation that may be relevant to a particular holder of Trinity Biotech ADSs in light of the holder's own circumstances or to certain types of investors subject to special treatment under applicable tax laws (for example, financial institutions, life insurance companies, tax-exempt organisations, and non-U.S. taxpayers) and it does not discuss any tax consequences arising under the laws of taxing jurisdictions other than the Republic of Ireland and the U.S. federal government. The tax treatment of holders of Trinity Biotech ADSs may vary depending upon each holder's own particular situation.

Prospective purchasers of Trinity Biotech ADSs are advised to consult their own tax advisors as to the US, Irish or other tax consequences of the purchase, ownership and disposition of such ADSs.

# U.S. Federal Income Tax Consequences to U.S. Holders

The following is a summary of certain material U.S. federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADSs, in the case of a holders of such ADSs who is a U.S. Holder (as defined below) and who holds the ADSs as capital assets. This summary is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. For the purposes of this summary, a U.S. Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organised in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to U.S. federal income tax regardless of its source; or a trust that (a) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons or (b) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary does not address all tax considerations that may be relevant with respect to an investment in ADSs. This summary does not discuss all the tax consequences that may be relevant to a U.S. Holder in light of such Holder's particular circumstances or to U.S. Holders subject to special rules, including persons that are not U.S. holders, broker dealers, financial institutions, certain insurance companies, investors liable for alternative minimum tax, tax exempt organisations, regulated investment companies, non-resident aliens of the U.S. or taxpayers whose functional currency is not the U.S. Dollar, persons who hold ADSs through partnerships or other pass-through entities, persons who acquired their ADSs through the exercise or cancellation of employee stock options or otherwise as compensation for services, investors that actually or constructively own 10% or more of Trinity Biotech's voting shares, and investors holding ADSs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction.

If an entity treated as a partnership for U.S. federal income tax purposes owns ADSs, the U.S. federal income tax treatment of a partner in such a partnership will generally depend upon the status of the partner and the activities of the partnership. The partners in a partnership which owns ADSs should consult their tax advisors about the U.S. federal income tax consequences of holding and disposing of ADSs.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of state, local or foreign taxation. You are urged to consult your tax advisors regarding the foreign and U.S. federal, state and local tax considerations of an investment in ADSs.

For U.S. federal income tax purposes, U.S. Holders of Trinity Biotech ADSs will be treated as owning the underlying Class 'A' Ordinary Shares represented by the ADSs held by them. This discussion assumes such treatment is respected.

# Dividends and Other Distributions on ADSs

The gross amount of any distribution made by Trinity Biotech to U.S. Holders with respect to the underlying shares represented by the ADSs held by them, including the amount of any Irish taxes withheld from such distribution, will be treated for U.S. federal income tax purposes as a dividend to the extent of Trinity Biotech's current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of any such distribution that exceeds Trinity Biotech's current and accumulated earnings and profits will be applied against and reduce a U.S. Holder's tax basis in the U.S. Holder's ADSs, and any amount of the distribution remaining after the U.S. Holder's tax basis has been reduced to zero will constitute capital gain. However, there can be no assurances we will calculate earnings and profits under U.S. federal income tax principles. Therefore, any distribution we make to you may be reported as a dividend. The capital gain will be treated as a long-term or short-term capital gain depending on whether or not the U.S. Holder's ADSs have been held for more than one year as of the date of the distribution.

Dividends paid by Trinity Biotech generally will not qualify for the dividends received deduction otherwise available to U.S. corporate shareholders.

Subject to complex limitations, any Irish withholding tax imposed on such dividends will be a foreign income tax eligible for credit against a U.S. Holder's U.S. federal income tax liability (or, alternatively, for deduction against income in determining such tax liability) where certain conditions are satisfied. The limitations set out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income, commonly referred to as "baskets," cannot exceed the U.S. federal income taxes otherwise payable with respect to each such class of income. Dividends generally will be treated as foreign-source passive category income or, in the case of certain U.S. Holders, general category income for U.S. foreign tax credit purposes. Further, there are special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to a reduced tax, see discussion below.

A U.S. Holder will be denied a foreign tax credit with respect to Irish income tax withheld from dividends received on the ADSs to the extent such U.S. Holder has not held the ADSs for at least 16 days of the 31-day period beginning on the date which is 15 days before the ex-dividend date, or to the extent such U.S. Holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a U.S. Holder has substantially diminished its risk of loss on the ADSs are not counted toward meeting the 16-day holding period required by the Code. If a refund of the tax withheld is available to you under the laws of Ireland or under the United States and Ireland treaty (the "Treaty"), the amount of tax withheld that is refundable will not be eligible for such credit against your U.S. federal income tax liability (and will not be eligible for the deduction against your U.S. federal taxable income). The rules relating to the determination of the foreign tax credit are complex, and you should consult with your personal tax advisors to determine whether and to what extent you would be entitled to this credit against your U.S. federal income tax liability.

Subject to certain limitations, including the PFIC rules discussed below, "qualified dividend income" received by a noncorporate U.S. Holder will be subject to tax at lower rates. Distributions taxable as dividends paid on the ADSs should qualify as qualified dividend income provided that either: (i) we are entitled to benefits under the Treaty or (ii) the ADSs are readily tradable on an established securities market in the U.S. and certain other requirements are met. We believe that we are entitled to benefits under the Treaty and that the ADSs currently are readily tradable on an established securities market in the U.S. However, no assurance can be given that the ordinary shares will remain readily tradable. The rate reduction does not apply unless certain holding period requirements are satisfied. With respect to the ADSs, the U.S. Holder must have held such ADSs for at least 61 days during the 121-day period beginning 60 days before the ex-dividend date. The rate reduction also does not apply to dividends received from passive foreign investment companies, see discussion below, or in respect of certain hedged positions or in certain other situations. The legislation enacting the reduced tax rate contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the reduced tax rate. U.S. Holders of ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

# Dispositions of the ADSs

Upon a sale or exchange of ADSs, a U.S. Holder will recognise a gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realised on the sale or exchange and the U.S. Holder's adjusted tax basis in the ADSs sold or exchanged. Such gain or loss generally will be capital gain or loss and will be long-term or short-term capital gain or loss depending on whether the U.S. Holder has held the ADSs sold or exchanged for more than one year at the time of the sale or exchange. If you are a non-corporate U.S. Holder, long-term capital gains may be eligible for reduced tax rates.

# Passive Foreign Investment Company

For U.S. federal income tax purposes, a foreign corporation is treated as a "passive foreign investment company" (or "PFIC") in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable "look through" rules, either (1) at least 75% of the corporation's gross income is passive income or (2) at least 50% of the average value of the corporation's assets is attributable to assets that produce passive income or are held for the production of passive income. Based on the nature of its present business operations, assets and income, Trinity Biotech believes that for the year 2014, it is not a PFIC. However, no assurance can be given that changes will not occur in Trinity Biotech's business operations, assets and income that might cause it to be treated as a PFIC at some future time.

If Trinity Biotech were to become a PFIC, a U.S. Holder of ADSs would be required to allocate to each day in the holding period for such U.S. Holder's ADSs a pro rata portion of any distribution received (or deemed to be received) by the U.S. Holder from Trinity Biotech, to the extent the distribution so received constitutes an "excess distribution," as defined under U.S. federal income tax law. Generally, a distribution received during a taxable year by a U.S. Holder with respect to the underlying shares represented by any of the U.S. Holder's ADSs would be treated as an "excess distribution" to the extent that the distribution so received, plus all other distributions received (or deemed to be received) by the U.S. Holder during the taxable year with respect to such underlying shares, is greater than 125% of the average annual distributions received by the U.S. Holder with respect to such underlying shares during the three preceding years (or during such shorter period as the U.S. Holder may have held the ADSs). Any portion of an excess distribution that is treated as allocable to one or more taxable years prior to the year of distribution during which Trinity Biotech was classified as a PFIC would be subject to U.S. federal income tax in the year in which the excess distribution is made, but it would be subject to tax at the highest tax rate applicable to the U.S. Holder in the prior tax year or years. The U.S. Holder also would be subject to an interest charge, in the year in which the excess distribution is made, on the amount of taxes deemed to have been deferred with respect to the excess distribution. In addition, any gain recognised on a sale or other disposition of a U.S. Holder's ADSs, including any gain recognised on a liquidation of Trinity Biotech, would be treated in the same manner as an excess distribution. Any such gain would be treated as ordinary income rather than as capital gain.

If Trinity Biotech became a PFIC, a U.S. Holder may make a "qualifying electing fund" (or "QEF") election in the year Trinity Biotech first becomes a PFIC or in the year the U.S. Holder acquires the ADSs, whichever is later. This election provides for a current inclusion of Trinity Biotech's ordinary income and capital gain income in the U.S. Holder's U.S. taxable income. In return, any gain on sale or other disposition of a U.S. Holder's ADSs in Trinity Biotech, if it were classified as a PFIC, will be treated as capital, and the interest penalty will not be imposed. This election is not made by Trinity Biotech, but by each U.S. Holder. Trinity Biotech must provide certain information to the U.S. Holder in order to qualify as a QEF. U.S. Holders should contact their tax advisor for further information on this area.

Alternatively, if the ADSs are considered "marketable stock" a U.S. Holder may elect to "mark-to-market" its ADSs, and such U.S. Holder would not be subject to the rules described above. Instead, such U.S. Holder would generally include in income any excess of the fair market value of the ADSs at the close of each tax year over its adjusted basis in the ADSs. If the fair market value of the ADSs had depreciated below the U.S. Holders adjusted basis at the close of the tax year, the U.S. Holder may generally deduct the excess of the adjusted basis of the ADSs over its fair market value at that time. However, such deductions generally would be limited to the net mark-to-market gains, if any, that the U.S. Holder included in income with respect to such ADSs in prior years. Income recognised and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of ADSs with respect to which the mark-to-market election is made, is treated as ordinary income or loss (except that loss is treated as capital loss to the extent the loss exceeds the net mark-to-market gains, if any, that a U.S. Holder included in income with respect to such ADSs in prior years). However, gain or loss from the disposition of ADSs (as to which a "mark-to-market" election was made) in a year in which Trinity Biotech is no longer a PFIC, will be capital gain or loss. The ADSs should be considered "marketable stock" if they traded at least 15 days during each calendar quarter of the relevant calendar year in more than de minimis quantities.

If a U.S. Holder owns ADSs during any year in which we are a PFIC, the U.S. Holder generally must file an IRS Form 8621 with respect to Trinity Biotech, generally with the U.S. Holder's federal income tax return for that year.

# Information Reporting and Backup Withholding

Distributions made with respect to underlying shares represented by ADSs and proceeds from the sale, exchange or other disposition of ADSs may be subject to information reporting to the IRS and to US backup withholding tax. Backup withholding will not apply, however, if the U.S. Holder (i) is a corporation or comes within certain exempt categories, and demonstrates its eligibility for exemption when so required, or (ii) furnishes a correct taxpayer identification number and makes any other required certification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder's U.S. tax liability, and a U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS.

## Information with Respect to Foreign Financial Assets

U.S. individuals (and, under proposed regulations, certain entities) that hold certain specified foreign financial assets, including stock in a foreign corporation, with values in excess of certain thresholds are required to file with their U.S. federal income tax return Form 8938, on which information about the assets, including their value, is provided. Taxpayers who fail to file the form when required are subject to penalties. An exemption from reporting applies to foreign assets held through certain financial institutions. Investors are encouraged to consult with their own tax advisors regarding the possible application of this disclosure requirement to their investment in our ordinary shares.

#### Medicare Contribution Tax

In addition to the income taxes described above, U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds will be subject to a 3.8% Medicare contribution tax on net investment income, which includes dividends and capital gains.

U.S. Holders may be subject to state or local income and other taxes with respect to their purchase, ownership and disposition of ADSs. U.S. Holders of ADSs should consult their own tax advisers as to the applicability and effect of any such taxes.

# Republic of Ireland Taxation

For the purposes of this summary, an "Irish Holder" means a holder of ordinary shares or ADSs evidenced by ADSs that (i) beneficially owns the ordinary shares or ADSs registered in its name; (ii) in the case of individual holders, are resident, ordinarily resident and domiciled in Ireland under Irish taxation laws; (iii) in the case of holders that are companies, are resident in Ireland under Irish taxation laws; and (iv) are not also resident in any other country under any double taxation agreement entered into by Ireland.

For Irish taxation purposes, Irish Holders of ADSs will be treated as the owners of the underlying ordinary shares represented by such ADSs.

Solely for the purposes of this summary of Irish Tax considerations, a "U.S. Holder" means a holder of ordinary shares or ADSs evidenced by ADSs that (i) beneficially owns the ordinary shares or ADSs registered in its name; (ii) is resident in the United States for the purposes of the Republic of Ireland/United States Double Taxation Convention (the Treaty); (iii) in the case of an individual holder, is not also resident or ordinarily resident in Ireland for Irish tax purposes; (iv) in the case of a corporate holder, is not a resident in Ireland for Irish tax purposes and is not ultimately controlled by persons resident in Ireland; and (v) is not engaged in any trade or business in Ireland and does not perform independent personal services through a permanent establishment or fixed base in Ireland.

In 2011, the Board decided that it was an appropriate time to commence a dividend policy for the first time in the Company's history. The payment of a dividend is generally subject to dividend withholding tax (DWT) at the standard rate of income tax in force at the time the dividend is paid, currently 20%. Under current legislation, where DWT applies, Trinity Biotech will be responsible for withholding it at source.

DWT will not be withheld where an exemption applies and where Trinity Biotech has received all necessary documentation from the recipient prior to payment of the dividend.

Corporate Irish Holders will generally be entitled to claim an exemption from DWT by delivering a declaration which confirms that the company is resident in Ireland for tax purposes to Trinity Biotech in the form prescribed by the Irish Revenue Commissioners. Such corporate Irish Holders will generally not otherwise be subject to Irish tax in respect of dividends received.

Individual Irish Holders will be subject to income tax on the gross amount of any dividend (that is the amount of the dividend received plus any DWT withheld), at their marginal rate of income tax, currently either 20% or 41% (this upper limit has been reduced to 40% with effect from 1 January 2015) depending on the individual's circumstances excluding PRSI and the universal social charge. Individual Irish Holders will be able to claim a credit against their resulting income tax liability in respect of DWT withheld. Individual Irish Holders may, depending on their circumstances, also be subject to the Irish Universal Social Charge of up to 7% (this upper limit rate has increased to 8% with effect from 1 January 2015, with a further 3% surcharge also arising on certain income in excess of €100,000) and Pay Related Social Insurance contribution of up to 4% in respect of their dividend income.

Under the Irish Taxes Consolidation Act 1997, dividends paid by Trinity Biotech to non-Irish shareholders will, unless exempted, be subject to DWT. Such non-Irish shareholders will not suffer DWT on dividends if the shareholder is:

- an individual resident in the U.S. (or certain other countries with which Ireland has a double taxation treaty) and who is neither resident nor ordinarily resident in Ireland; or
- a U.S. tax resident corporation not under the control of Irish residents; or
- a corporation that is not resident in Ireland and which is ultimately controlled by persons resident in the U.S. (or certain other countries with which Ireland has a double taxation treaty) and is not under the control of persons who are not so resident; or
- a corporation that is not resident in Ireland and the principal class of whose shares (or its 75% parent's principal class of shares) is substantially or regularly traded on a recognised stock exchange; or
- is otherwise entitled to an exemption from DWT.

In order to avail of the above exemption, certain declarations must be made in advance to the paying company.

A self-assessment system applies to a company tax resident in a treaty jurisdiction receiving dividends, under which a non-resident company will provide a declaration and certain information to the dividend paying company or intermediary to claim the exemption.

Special DWT arrangements are available in the case of shares in Irish companies held by U.S. resident holders through American depository banks using ADSs where such banks enter into intermediary agreements with the Irish Revenue Commissioners and are viewed as qualifying intermediaries under Irish Tax legislation. Under such agreements, American depository banks who receive dividends from Irish companies and pay the dividends on to the U.S. resident ADS holders are allowed to receive and pass on a dividend from the Irish company on a gross basis (without any withholding) if:

- the depository bank's ADS register shows that the direct beneficial owner of the dividends has a U.S. address on the register, and
- there is an intermediary between the depository bank and the beneficial shareholder and the depository bank receives
  confirmation from the intermediary that the beneficial shareholder's address in the intermediary's records is in the U.S.

Where the above procedures have not been complied with and DWT is withheld from dividend payments to U.S. Holders of ordinary shares or ADSs evidenced by ADSs, such U.S. Holders can apply to the Irish Revenue Commissioners claiming a full refund of DWT paid by filing a declaration / claim in the form prescribed by the Irish Revenue Commissioners. Certain accompanying information should also be included when making such claims.

The DWT rate applicable to U.S. Holders is reduced to 5% under the terms of the Treaty for corporate U.S. Holders holding 10% or more of voting shares and to 15% for other U.S. Holders. While this will, subject to the application of Article 23 of the Treaty, generally entitle U.S. Holders to claim a partial refund of DWT from the Irish Revenue Commissioners, U.S. Holders will, in most circumstances, likely prefer to seek a full refund of DWT under Irish domestic legislation (see above).

## Disposals of Ordinary Shares or ADSs

Irish Holders that acquire ordinary shares or ADSs will generally be considered, for Irish tax purposes, to have acquired their ordinary shares or ADSs at a base cost equal to the amount paid for the ordinary shares or ADSs. On subsequent dispositions, ordinary shares or ADSs acquired at an earlier time will generally be deemed, for Irish tax purposes, to be disposed of on a "first in first out" basis before ordinary shares or ADSs acquired at a later time. Irish Holders that dispose of their ordinary shares or ADSs will be subject to Irish capital gains tax (CGT) to the extent that the proceeds realised from such disposition exceed the indexed base cost of the ordinary shares or ADSs disposed of and any incidental expenses. The current rate of CGT is 33% and this applies to disposals made on or after 6 December 2012. Indexation of the base cost of the ordinary shares or ADSs is available up to 31 December 2002, and only in respect of ordinary shares or ADSs held for more than 12 months prior to their disposal.

Irish Holders that have unutilised capital losses from other sources in the current, or any previous tax year, can generally apply such losses to reduce gains realised on the disposal of the ordinary shares or ADSs.

An annual exemption allows individuals to realise chargeable gains of up to €1,270 in each tax year without giving rise to CGT. This exemption is specific to the individual and cannot be transferred between spouses. Irish Holders are required, under Ireland's self-assessment system, to file tax returns reporting any chargeable gains arising to them in a particular tax year.

Where disposal proceeds are received in a currency other than Euro they must be translated into euro amounts to calculate the amount of any chargeable gain or loss. Similarly, acquisition costs denominated in a currency other than Euro must be translated at the date of acquisition in Euro amounts.

Irish Holders that realise a loss on the disposal of ordinary shares or ADSs will generally be entitled to offset such allowable losses against capital gains realised from other sources in determining their CGT liability in that year. Allowable losses which remain unrelieved in a year may generally be carried forward indefinitely for CGT purposes and applied against capital gains in future years.

Transfers between spouses who live together will not give rise to any chargeable gain or loss for CGT purposes with the acquiring spouse acquiring the same pro rata base cost and acquisition date as that of the transferring spouse.

U.S. Holders will not be subject to Irish capital gains tax (CGT) on the disposal of ordinary shares or ADSs provided that such ordinary shares or ADSs are quoted on a stock exchange at the time of disposition. The stock exchange for this purpose is the Nasdaq National Market (NASDAQ). While it is our intention to continue the quotation of ADSs on NASDAQ, no assurances can be given in this regard.

If, for any reason, our ADSs cease to be quoted on NASDAQ, U.S. Holders will not be subject to CGT on the disposal of their ordinary shares or ADSs provided that the ordinary shares or ADSs do not, at the time of the disposal, derive the greater part of their value from land, buildings, minerals, or mineral rights or exploration rights in Ireland.

A gift or inheritance of ordinary shares will be, or in the case of ADSs may be, within the charge to capital acquisitions tax, regardless of where the disponer or the donee/successor in relation to the gift/inheritance is domiciled, resident or ordinarily resident. Capital acquisitions tax is levied at a rate of 33% on the taxable value of the gift or inheritance above certain tax-free thresholds and this rate applies in respect of gifts and inheritances taken on or after 6 December 2012 (the rate was 30% between 7 December 2011 and 5 December 2012). The tax-free threshold is determined by the amount of the current benefit and of previous benefits received within the group threshold since December 5, 1991, which are within the charge to capital acquisitions tax and the relationship between the former holder and the successor. Gifts and inheritances between spouses are not subject to the capital acquisitions tax. Gifts of up to €3,000 can be received each year from any given individual without triggering a charge to capital acquisitions tax. Where a charge to Irish CGT and capital acquisitions tax arises on the same event, capital acquisitions tax payable on the event can be reduced by the amount of the CGT payable. There should be no clawback of the same event credit of CGT offset against capital acquisitions tax provided the donee/successor does not dispose of the ordinary shares or ADSs within two years from the date of gift/inheritance.

The Estate Tax Convention between Ireland and the United States generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited, in whole or in part, against tax payable in the United States, in the case where an inheritance of ordinary shares or ADSs is subject to both Irish capital acquisitions tax and U.S. federal estate tax. The Estate Tax Convention does not apply to Irish capital acquisitions tax paid on gifts.

Irish stamp duty, which is a tax imposed on certain documents, is payable on all transfers of ordinary shares of an Irish registered company (other than transfers made between spouses, transfers made between 90% associated companies, or certain other exempt transfers) regardless of where the document of transfer is executed. Irish stamp duty is also payable on electronic transfers of ordinary shares. A transfer of ordinary shares made as part of a sale or gift will generally be stampable at the ad valorem rate of 1% of the value of the consideration received for the transfer, or, if higher, the market value of the shares transferred. Any instrument executed on or after 24 December 2008 which transfers stock or marketable securities on sale where the amount or value of the consideration is €1,000 or less may be exempt from stamp duty. Where the consideration for a sale is expressed in a currency other than Euro, the duty will be charged on the Euro equivalent calculated at the rate of exchange prevailing at the date of the transfer.

Transfers of ordinary shares where no beneficial interest passes (e.g. a transfer of shares from a beneficial owner to a nominee) will generally be exempt from stamp duty.

Transfers of ADSs are exempt from Irish stamp duty as long as the ADSs are quoted on any recognised stock exchange in the U.S. or Canada.

Transfers of ordinary shares from the Depositary or the Depositary's custodian upon surrender of ADSs for the purposes of withdrawing the underlying ordinary shares from the ADS system, and transfers of ordinary shares to the Depositary or the Depositary's custodian for the purposes of transferring ordinary shares onto the ADS system, will be stampable at the ad valorem rate of 1% of the value of the shares transferred if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of ordinary shares. Such transfers will be exempt from Irish stamp duty if the transfer does not relate to or involve any change in the beneficial ownership in the underlying ordinary shares and the transfer form contains the appropriate certification. The person accountable for the payment of stamp duty is the transferee or, in the case of a transfer by way of gift or for consideration less than the market value, both parties to the transfer. Stamp duty is normally payable within 30 days after the date of execution of the transfer. Late or inadequate payment of stamp duty will result in liability for interest, penalties, surcharge and fines.

# **Dividend Policy**

In 2011, the Board decided that it was an appropriate time to pay a dividend for the first time in the Company's history. The Board proposed a final dividend of 22 cents per ADS in respect of the 2013 financial year and this proposal was approved by the shareholders at the 2014 Annual General Meeting of the Company and subsequently paid during the course of 2014. A dividend of 20 cents per ADS was approved and paid in 2013, in respect of the 2012 financial year. A dividend of 15 cents per ADS was approved and paid in 2012, in respect of the 2011 financial year. A dividend of 10 cents per ADS was approved and paid in 2011, in respect of the 2010 financial year. Dividends or other distributions are declared and paid in US Dollars. Any future cash dividends will depend upon the Company's results of operations, financial condition, cash requirements, availability of surplus and such other factors as the Board of Directors may deem relevant, and will be subject to approval by the Company's shareholders. Accordingly, there can be no assurance that a dividend will be declared each year or that, if a dividend is declared, it will be comparable with the one declared the previous year.

# **Documents on Display**

This annual report and the exhibits thereto and any other document that we have to file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549; and on the Securities and Exchange Commission Internet site (http://www.sec.gov). You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the Securities and Exchange Commission at 1-800-SEC-0330 or by visiting the Securities and Exchange Commission's website at http://www.sec.gov, and may obtain copies of our filings from the public reference room by calling (202) 551-8090. The Exchange Act file number for our Securities and Exchange Commission filings is 000-22320. The information on our website is not incorporated by reference into this annual report.

## Item 11 Ouantitative and Qualitative Disclosures about Market Risk

## **Quantitative information about Market Risk**

#### Interest rate sensitivity

Trinity Biotech monitors its exposure to changes in interest and exchange rates by estimating the impact of possible changes on reported profit before tax and net worth. The Group accepts interest rate and currency risk as part of the overall risks of operating in different economies and seeks to manage these risks by following the policies set above.

Trinity Biotech estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Group is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be an increase in the profit before tax for 2014 by approximately 0.5%.

# Exchange rate sensitivity

At year-end 2014, approximately 11.5% of the Group's US\$196,972,000 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the Euro, Canadian Dollar, Swedish Kroner and Brazilian Real.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Group operates, would have the approximate effect of reducing or increasing the Group's 2014 year-end net worth by US\$2,272,000.

# Qualitative information about Market Risk

Trinity Biotech's treasury policy is to manage financial risks arising in relation to or as a result of underlying business needs. The activities of the treasury function, which does not operate as a profit centre, are carried out in accordance with board approved policies and are subject to regular internal review. These activities include the Group making use of spot and forward foreign exchange markets.

Trinity Biotech uses a range of financial instruments (including cash, forward contracts and finance leases) to fund its operations. These instruments are used to manage the liquidity of the Group in a cost effective, low-risk manner. Working capital management is a key additional element in the effective management of overall liquidity. Trinity Biotech does not trade in financial instruments or derivatives.

The main risks arising from the utilisation of these financial instruments are interest rate risk, liquidity risk and foreign exchange risk.

Trinity Biotech's reported net income and net assets are all affected by movements in foreign exchange rates.

At December 31, 2014, 2013 and 2012 the Group had no borrowings. At December 31, 2011 Group borrowings were at fixed rates of interest and consisted entirely of Euro denominated finance leases. At December 31, 2011 year-end borrowings totalled US\$108,000, at interest rates ranging from 5.02% to 5.29% - see Item 18, Note 25.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US\$91,000 (2013: US\$223,000) and would not affect the interest expense in 2014 or 2013; resulting in an increase in interest income of US\$91,000 (2013: US\$223,000).

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro, Swedish Kroner and Brazilian Real denominated expenses as a result of the movement in the exchange rate between the US Dollar and those currencies. Arising from this, where considered necessary, the Group periodically pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro, Kroner and Real expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro, Kroner or Real forecasted transactions. These forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at 31 December, 2014.

The Group had foreign currency denominated cash balances equivalent to US\$2,073,000 at December 31, 2014 (2013: US\$1,624,000).

## Item 12 Description of Securities Other than Equity Securities

# Fees and Charges Payable by ADS Holders

The table below summarizes the fees and charges that a holder of our ADSs may have to pay, directly or indirectly, to our depositary, The Bank of New York Mellon, pursuant to the deposit agreement (filed with the SEC on January 15, 2004 as an exhibit to our Form F-6, registration no. 333-111946) and the types of services and the amount of the fees or charges paid for such services. The actual fees payable by Trinity Biotech and the holders of ADSs are negotiated between Trinity Biotech and the depositary. In connection with these arrangements, Trinity Biotech has agreed to pay various fees and expenses of the depositary. Trinity Biotech will pay any fee chargeable upon the issuance of ADSs in connection with the exchange of the notes. Currently, ADS holders are responsible for paying a fee upon the delivery of ordinary shares against the surrender of ADSs.

The fees and charges that an ADS holder may be required to pay can be changed in the future upon mutual agreement between Trinity Biotech and by the depositary and may include:

| Service (1) Issuance of ADSs upon deposit of ordinary shares.   | Rate Up to \$10.00 per 100 ADSs (or portion                     | By whom paid Persons depositing ordinary shares or person receiving ADSs.                 |
|---|---|---|
| (2) Delivery of deposited securities against surrender of   | thereof) issued. Up to \$10.00 per 100                          | Persons surrendering ADSs for the purpose of  |
| ADSs.   | ADSs (or portion thereof) issued.                               | withdrawal of deposited securities or persons to whom deposited securities are delivered. |
| (3) Issuance of ADSs in connection with a distribution of shares.   | Up to \$10.00 per 100 ADSs (or portion thereof) issued.         | Person to whom distribution is made.  |
| (4) Distribution of cash dividends or other cash distributions, including distribution of cash proceeds following the sale of rights, shares or other property in accordance with the deposit agreement | Up to \$0.02 per 1<br>ADS                                       | Person to whom distribution is made.  |
| (5) Transfer of ADSs  | Up to \$1.50 per<br>certificate for ADRs<br>or ADRs transferred | Person to whom Receipt is transferred.  |

In addition, ADS holders are responsible for certain fees and expenses incurred by the depositary and certain taxes and governmental charges such as:

- transfer and registration fees of securities on Trinity Biotech's securities register to or from the name of the depositary or its agent when ADS holders deposit or withdrawal securities;
- expenses for cable, telex and fax transmissions and for delivery of securities;
- expenses incurred for converting foreign currency into U.S. dollars; and
- taxes and duties upon the transfer of securities (i.e., when ordinary shares are deposited or withdrawn from deposit, other than taxes for which Trinity Biotech is liable).

Depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary and by the brokers (on behalf of their clients) delivering the ADSs to the depositary for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary to the holders of record of ADSs as of the applicable ADS record date.

The Depositary fees payable for cash distributions are generally deducted from the cash being distributed. In the case of distributions other than cash (e.g., stock dividend, rights), the depositary charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor, the depositary sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary.

In the event of refusal to pay taxes or other governmental charges by the holder of an ADS, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of such tax or other governmental charge from any distribution to be made to the ADS holder, and the ADS holder would remain liable for any deficiency.

The disclosure under this heading "Fees and Charges Payable by ADS Holders" is subject to and qualified in its entirety by reference to the full text of the Deposit Agreement.

#### Part II

# Item 13 Defaults, Dividend Arrearages and Delinquencies

Not applicable.

# Item 14 Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

#### Item 15 Controls and Procedures

## **Evaluation of Disclosure Controls and Procedures**

The Group's disclosure and control procedures are designed so that information required to be disclosed in reports filed or submitted under the Securities Exchange Act 1934 is prepared and reported on a timely basis and communicated to management, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(d) of the Securities Exchange Act of 1934 as of the end of the period covered by this Form 20-F. The Chief Executive Officer and Chief Financial Officer have concluded that disclosure controls and procedures were effective as of December 31, 2014.

In designing and evaluating our disclosure controls and procedures, our management, with the participation of the Chief Executive Officer and Chief Financial Officer, recognised that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Group have been detected.

# Management's Annual Report on Internal Control over Financial Reporting

The management of Trinity Biotech are responsible for establishing and maintaining adequate internal control over financial reporting. Trinity Biotech's internal control over financial reporting is a process designed under the supervision and with the participation of the principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and preparation of Trinity Biotech's financial statements for external reporting purposes in accordance with IFRS both as issued by the IASB and as subsequently adopted by the EU.

Trinity Biotech's internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of the financial statements in accordance with IFRS and that receipts and expenditures are being made only in accordance with the authorisation of management and the directors of Trinity Biotech; and provide reasonable assurance regarding prevention or timely detection of unauthorised acquisition, use or disposition of Trinity Biotech's assets that could have a material effect on our financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements.

It is not always possible to conduct an assessment of an acquired business's internal control over financial reporting in the period between the purchase date and the date of management's assessment. In such cases, management will note that it has excluded the acquired business or businesses from its report on internal control over financial reporting. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, and that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of internal control over financial reporting based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that the Group's internal control over financial reporting was effective as of December 31, 2014.

Our auditor, Grant Thornton, an independent registered public accounting firm, has issued an attestation report on the Group's internal control over financial reporting as of December 31, 2014 (see Item 18).

# Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 16

# 16A Audit Committee Financial Expert

Mr Peter Coyne is an independent director and a member of the Audit Committee.

Our board of directors has determined that Mr Peter Coyne meets the definition of an audit committee financial expert, as defined in Item 401 of Regulation S-K.

This determination is made on the basis that Mr Coyne is a Fellow of the Institute of Chartered Accountants in Ireland and has extensive experience in advising public and private groups on all aspects of corporate strategy. Mr Coyne was formerly a director of AIB Corporate Finance, a subsidiary of AIB Group plc, and was also formerly a senior manager in Arthur Andersen's Corporate Financial Services practice.

# 16B Code of Ethics

Trinity Biotech has adopted a code of ethics that applies to the Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and all organisation employees. Written copies of the code of ethics are available free of charge upon written request to us at the address on the first page of this annual report. If we make any substantive amendments to the code of ethics or grant any waivers, including any implicit waiver, from a provision of these codes to our Chief Executive Officer, Chief Financial Officer or Chief Accounting Officer, we will disclose the nature of such amendment or waiver on our website.

# 16C Principal Accountant Fees and Services

Fees Billed by Independent Public Accountants

The following table sets forth, for each of the years indicated, the fees billed by our independent public accountants and the percentage of each of the fees out of the total amount billed by the accountants.

|               | Year ended Do<br>201 |     | Year ended Dec<br>2013 |     |
|---------------|----------------------|-----|------------------------|-----|
|               | US\$'000             | %   | US\$'000               | %   |
| Audit         | 457                  | 88% | 574                    | 85% |
| Audit-related | 5                    | 1%  | 16                     | 2%  |
| Tax           | 55                   | 11% | 89                     | 13% |
| Total         | 517                  |     | 679                    |     |

Audit services include audit of our consolidated financial statements, as well as work only the independent auditors can reasonably be expected to provide, including statutory audits. Audit related services are for assurance and related services performed by the independent auditor, including due diligence related to acquisitions and any special procedures required to meet certain regulatory requirements. Tax fees consist of fees for professional services for tax compliance and tax advice.

# **Pre-Approval Policies and Procedures**

Our Audit Committee has adopted policies and procedures for the pre-approval of audit and non-audit services rendered by our independent public accountants, Grant Thornton. The policy generally pre-approves certain specific services in the categories of audit services, audit-related services, and tax services up to specified amounts, and sets requirements for specific case-by-case pre-approval of discrete projects, those which may have a material effect on our operations or services over certain amounts.

Pre-approval may be given as part of the Audit Committee's approval of the scope of the engagement of our independent auditor or on an individual basis. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be presented to the full Audit Committee at its next scheduled meeting. The policy prohibits retention of the independent public accountants to perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the SEC, and also considers whether proposed services are compatible with the independence of the public accountants.

# 16D Exemptions from the Listing Standards for Audit Committees

Not applicable.

# 16 E Purchases of Equity Securities by the Issuer and Affiliated Purchasers

On March 3, 2011 the Company announced its intention to commence a Share Buyback Program for the first time in the Company's history. Under the authority given by the passing of Resolution 6 at the 2012 AGM, the maximum number of shares that may yet be purchased by Trinity Biotech or on the Group's behalf at December 31, 2014 was 7,244,556 (1,811,139 ADSs) (2013: 7,244,556 (1,811,139 ADSs)).

# 2014 Share Buyback

There were no shares purchased by Trinity Biotech or on the Group's behalf in the year ended December 31, 2014 (2013: Nil).

# 16 F Change in Registrant's Certifying Accountant

Not applicable.

# 16 G Corporate Governance

As Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 5600 as they apply to U.S. domestic companies. The Group's corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process. At present, the Board as a whole address the nominations process; and (b) the Audit Committee of the Group currently consists of two members (both of whom are independent non-executive directors) – while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee.

# 16 H Mine Safety Disclosure

Not applicable.

# Part III

# Item 17 Financial Statements

The registrant has responded to Item 18 in lieu of responding to this item.

# Item 18 Financial Statements

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited the internal control over financial reporting of Trinity Biotech plc and subsidiaries (the "Company") as of December 31, 2014, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting ("Management's Report"). Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorisations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorised acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2014, and our report dated March 25, 2015 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON

Dublin, Ireland March 25, 2015

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited the accompanying consolidated statements of financial position of Trinity Biotech plc and subsidiaries (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive income, changes in equity, and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Trinity Biotech plc and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and International Financial Reporting Standards as adopted by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 25, 2015, expressed an unqualified opinion.

/s/ GRANT THORNTON

Dublin, Ireland March 25, 2015

# CONSOLIDATED STATEMENT OF OPERATIONS

|  |       | Year ei  | nded December   | ·, 31    |
|--|-------|----------|-----------------|----------|
|  |       | 2014     | 2013            | 2012     |
|  | 17 .  | Total    | Total           | Total    |
| D.   | Notes | US\$'000 | US\$'000        | US\$'000 |
| Revenues   | 2     | 104,872  | 91,216          | 82,510   |
| Cost of sales  |       | (54,525) | <u>(45,996)</u> | (40,257) |
| Gross profit   |       | 50,347   | 45,220          | 42,253   |
| Other operating income   | 4     | 424      | 532             | 468      |
| Research and development expenses                              |       | (4,291)  | (3,691)         | (3,130)  |
| Selling, general and administrative expenses                   |       | (28,441) | (33,066)        | (22,425) |
| Operating profit   |       | 18,039   | 8,995           | 17,166   |
| Financial income   | 2, 3  | 97       | 1,276           | 2,280    |
| Financial expenses   | 2, 3  | (69)     | (51)            | (88)     |
| Net financing income   |       | 28       | 1,225           | 2,192    |
| Profit before tax  | 5     | 18,067   | 10,220          | 19,358   |
| Total income tax expense                                       | 2, 8  | (853)    | (574)           | (2,017)  |
| Profit for the year (all attributable to owners of the parent) | 2     | 17,214   | 9,646           | 17,341   |
| Basic earnings per ADS (US Dollars)                            | 9     | 0.76     | 0.44            | 0.81     |
| Diluted earnings per ADS (US Dollars)                          | 9     | 0.73     | 0.41            | 0.77     |
| Basic earnings per 'A' ordinary share (US Dollars)             | 9     | 0.19     | 0.11            | 0.20     |
| Diluted earnings per 'A' ordinary share (US Dollars)           | 9     | 0.18     | 0.10            | 0.19     |

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

|   |       | Year e   | nded Decembe | er 31,   |
|---|-------|----------|--------------|----------|
|   |       | 2014     | 2013         | 2012     |
|   | Notes | US\$'000 | US\$ '000    | US\$'000 |
| Profit for the year   | 2     | 17,214   | 9,646        | 17,341   |
| Other comprehensive income  |       |          |              |          |
| Items that will be reclassified subsequently to profit or loss        |       |          |              |          |
| Foreign exchange translation differences                              |       | (4,359)  | 194          | 127      |
| Cash flow hedges:   |       |          |              |          |
| Effective portion of changes in fair value                            |       |          | _            | 6        |
| Deferred tax on income and expenses recognised directly in equity     |       |          |              | 1        |
| Other comprehensive income  |       | (4,359)  | 194          | 134      |
| Total Comprehensive Income (all attributable to owners of the parent) |       | 12,855   | 9,840        | 17,475   |

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

|   |        | At Decem         | , .              |
|---|--------|------------------|------------------|
|   | Notes  | 2014<br>US\$'000 | 2013<br>US\$'000 |
| ASSETS  | 110163 | Ουφ σσσ          | Ουφ σσσ          |
| Non-current assets                                      |        |                  |                  |
| Property, plant and equipment                           | 10     | 17,877           | 12,991           |
| Goodwill and intangible assets                          | 11     | 145,024          | 128,547          |
| Deferred tax assets                                     | 12     | 9,798            | 7,044            |
| Other assets  | 13     | 1,194            | 1,162            |
| Total non-current assets                                |        | 173,893          | 149,744          |
| Current assets  |        |                  |                  |
| Inventories   | 14     | 33,516           | 29,670           |
| Trade and other receivables                             | 15     | 25,976           | 24,268           |
| Income tax receivable                                   |        | 351              | 487              |
| Cash and cash equivalents                               | 16     | 9,102            | 22,317           |
| Total current assets                                    |        | 68,945           | 76,742           |
|   |        |                  |                  |
| TOTAL ASSETS  | 2      | 242,838          | 226,486          |
| EQUITY AND LIABILITIES                                  |        |                  |                  |
| Equity attributable to the equity holders of the parent |        |                  |                  |
| Share capital   |        | 1,192            | 1,170            |
| Share premium   |        | 12,422           | 8,842            |
| Treasury Shares   | 17     | (7,367)          | (7,367)          |
| Accumulated surplus                                     |        | 190,755          | 176,037          |
| Translation reserve                                     |        | (4,582)          | (223)            |
| Other reserves  |        | 4,552            | 4,552            |
| Total equity  |        | 196,972          | 183,011          |
| Current liabilities                                     |        |                  |                  |
| Income tax payable                                      |        | 785              | 770              |
| Trade and other payables                                | 19     | 21,197           | 20,131           |
| Provisions  | 20     | 75               | 75               |
| Total current liabilities                               |        | 22,057           | 20,976           |
| Non-current liabilities                                 |        |                  |                  |
| Other payables  | 21     | 2,370            | 4,596            |
| Deferred tax liabilities                                | 12     | 21,439           | 17,903           |
| Total non-current liabilities                           |        | 23,809           | 22,499           |
| TOTAL LIABILITIES                                       | 2      | 45,866           | 43,475           |
|   |        |                  |                  |
| TOTAL EQUITY AND LIABILITIES                            |        | 242,838          | 226,486          |

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| Balance at December 31, 2014 | Dividends (Note 26) | Share issue expenses | Options or warrants exercised | Share-based payments (Note 18) | Total comprehensive income | Other comprehensive income | Profit for the period | Balance at January 1, 2014 | Balance at December 31, 2013 | Dividends (Note 26) | Shares or options issued as consideration | Share issue expenses | Options or warrants exercised | Share-based payments (Note 18) | Total comprehensive income | Other comprehensive income | Profit for the period | Balance at January 1, 2013 | Balance at December 31, 2012 | Treasury shares re-issued | Treasury shares acquired during the year | Dividends (Note 26) | 'B' share conversion | Share issue expenses | Options or warrants exercised | Share-based payments (Note 18) | Total comprehensive income | Other comprehensive income | Profit for the period | Balance at January 1, 2012 |  |
|------------------------------|---------------------|----------------------|-------------------------------|--------------------------------|----------------------------|----------------------------|-----------------------|----------------------------|------------------------------|---------------------|---|----------------------|-------------------------------|--------------------------------|----------------------------|----------------------------|-----------------------|----------------------------|------------------------------|---------------------------|--|---------------------|----------------------|----------------------|-------------------------------|--------------------------------|----------------------------|----------------------------|-----------------------|----------------------------|--|
| 1,192                        |                     | 1                    | 22                            | 1                              | 1                          |                            | l                     | 1,170                      | 1,170                        |                     | 1   | 1                    | 36                            | 1                              | 1                          |                            | 1                     | 1,134                      | 1,134                        |                           | 1  | 1                   | 13                   |                      | 27                            |                                | ļ                          |                            |                       | 1,094                      | Share capital 'A' ordinary shares US\$'000 |
| I                            |                     | 1                    | 1                             | 1                              |                            |                            |                       | 1                          | <br> 1                       |                     | 1   | 1                    |                               | 1                              |                            |                            | 1                     | 1                          |                              |                           | 1  |                     | (12)                 | 1                    |                               |                                |                            |                            |                       | 12                         | Share capital 'B' ordinary shares US\$'000 |
| 12,422                       |                     | (40)                 | 3,620                         | I                              | l                          |                            | I                     | 8,842                      | 8,842                        |                     | 110                                       | (32)                 | 3,626                         | l                              |                            |                            | l                     | 5,138                      | 5,138                        |                           | 1  |                     |                      | (76)                 | 2,478                         |                                |                            |                            |                       | 2,736                      | Share<br>premium<br>US\$'000               |
| (7,367)                      |                     | 1                    | I                             | 1                              | l                          |                            | I                     | (7,367)                    | (7,367)                      |                     | 1   | ĺ                    | I                             | ĺ                              |                            |                            | 1                     | (7,367)                    | (7,367)                      | 4,070                     | (5,343)                                  | 1                   |                      |                      |                               |                                |                            | 1                          | 1                     | (6,094)                    | Treasury<br>Shares<br>US\$'000             |
| (4,582)                      |                     |                      |                               | 1                              | (4,359)                    | (4,359)                    | 1                     | (223)                      | (223)                        |                     |   | 1                    |                               | 1                              | 194                        | 194                        |                       | (417)                      | (417)                        |                           | 1  |                     |                      |                      |                               |                                | 127                        | 127                        |                       | (544)                      | Translation<br>reserve<br>US\$'000         |
| 4,529                        |                     | 1                    | I                             | 1                              | I                          |                            | I                     | 4,529                      | 4,529                        |                     | I   | I                    | I                             | l                              |                            |                            | I                     | 4,529                      | 4,529                        |                           | I  |                     |                      |                      |                               |                                | I                          |                            | I                     | 4,529                      | Warrant<br>reserve<br>US\$'000             |
| 23                           |                     | 1                    | I                             | 1                              |                            |                            | I                     | 23                         | 23                           |                     | I   | l                    | I                             | l                              |                            |                            | I                     | 23                         | 23                           |                           | I  |                     |                      |                      |                               |                                | 7                          | 7                          | l                     | 16                         | Hedging<br>reserves<br>US\$'000            |
| 190,755                      | (5,029)             |                      | I                             | 2,533                          | 17,214                     |                            | 17,214                | 176,037                    | 176,037                      | (4,373)             | 1,121                                     |                      | l                             | 3,303                          | 9,646                      |                            | 9,646                 | 166,340                    | 166,340                      |                           | 1  | (3,224)             |                      |                      |                               | 2,640                          | 17,341                     |                            | 17,341                | 149,583                    | Accumulated surplus/ ( deficit) US\$'000   |
| 196,972                      | (5,029)             | (40)                 | 3,642                         | 2,533                          | 12,855                     | (4,359)                    | 17,214                | 183,011                    | 183,011                      | (4,373)             | 1,231                                     | (32)                 | 3,662                         | 3,303                          | 9,840                      | 194                        | 9,646                 | 169,380                    | 169,380                      | 4,070                     | (5,343)                                  | (3,224)             | 1                    | (76)                 | 2,505                         | 2,640                          | 17,475                     | 134                        | 17,341                | 151,332                    | Total<br>US\$'000                          |

# CONSOLIDATED STATEMENT OF CASH FLOWS

|   |        | Year e   | nded Decembe | r 31,          |
|---|--------|----------|--------------|----------------|
|   | M-4    | 2014     | 2013         | 2012           |
| Cash flows from operating activities  | Notes  | US\$'000 | US\$ '000    | US\$ '000      |
| Profit for the year   |        | 17,214   | 9,646        | 17,341         |
| Adjustments to reconcile net profit to cash provided by operating activities: |        | 17,211   | 7,010        | 17,511         |
| Depreciation  |        | 2,115    | 1,688        | 1,349          |
| Amortisation  | 11     | 2,380    | 1,902        | 1,482          |
| Income tax expense  | 8      | 853      | 574          | 2,017          |
| Financial income  | 3      | (97)     | (1,276)      | (2,280)        |
| Financial expense   | 3      | 69       | 51           | 88             |
| Share-based payments  | 18     | 1,496    | 2,014        | 1,713          |
| Foreign exchange gains/(losses) on operating cash flows                       |        | (308)    | 46           | (60)           |
| Loss on disposal or retirement of property, plant and equipment               |        | _        | 1            | 5              |
| Licence fees  | 19, 21 | _        | 4,135        |                |
| Other non-cash items  |        | (3,440)  | 1,020        | 578            |
| Operating cash flows before changes in working capital                        |        | 20,282   | 19,801       | 22,233         |
| Increase in trade and other receivables                                       |        | (729)    | (7,032)      | (2,059)        |
| Increase in inventories   |        | (4,487)  | (7,258)      | (1,374)        |
| Increase in trade and other payables  |        | 624      | 3,255        | 22             |
| Cash generated from operations  |        | 15,690   | 8,766        | 18,822         |
| Interest paid   |        | _        | _            | (3)            |
| Interest received   |        | 96       | 1,292        | 2,189          |
| Income taxes refunded/(paid)  |        | 273      | (701)        | (1,047)        |
| Net cash generated by operating activities                                    |        | 16,059   | 9,357        | 19,961         |
| Cash flows from investing activities  |        |          |              |                |
| Payments to acquire subsidiaries  |        | _        | (39,424)     | (5,958)        |
| Cash received with acquired subsidiary  |        | _        | 1,407        | 44             |
| Proceeds from divestiture of Coagulation product line                         |        | _        | _            | 11,250         |
| Payments to acquire intangible assets   |        | (19,486) | (18,687)     | (12,631)       |
| Acquisition of property, plant and equipment                                  |        | (8,270)  | (4,489)      | (2,665)        |
| Net cash used in investing activities   |        | (27,756) | (61,193)     | (9,960)        |
| Cash flows from financing activities  |        |          |              |                |
| Proceeds from issue of ordinary share capital                                 | 17     | 3,642    | 3,662        | 2,505          |
| Purchase of treasury shares   | 17     | _        | _            | (5,343)        |
| Expenses paid in connection with share issue and debt financing               |        | (40)     | (87)         | (22)           |
| Dividends paid to equity holders of the parent                                | 26     | (5,029)  | (4,373)      | (3,224)        |
| Payment of finance lease liabilities  |        |          |              | (109)          |
| Net cash used in financing activities   |        | (1,427)  | <u>(798)</u> | <u>(6,193)</u> |
| (Decrease)/increase in cash and cash equivalents                              |        | (13,124) | (52,634)     | 3,808          |
| Effects of exchange rate movements on cash held                               |        | (91)     | 4            | 54             |
| Cash and cash equivalents at beginning of year                                |        | 22,317   | 74,947       | 71,085         |
| Cash and cash equivalents at end of year                                      | 16     | 9,102    | 22,317       | 74,947         |

# 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies adopted by Trinity Biotech plc ("the Company") and its subsidiaries ("the Group") are as follows:

# *i)* Statement of compliance

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") both as issued by the International Accounting Standards Board ("IASB") and as subsequently adopted by the European Union ("EU") (together "IFRS"). The IFRS applied are those effective for accounting periods beginning 1 January 2014. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU.

# ii) Basis of preparation

The consolidated financial statements have been prepared in United States Dollars (US\$), rounded to the nearest thousand, under the historical cost basis of accounting, except for derivative financial instruments, certain balances arising on acquisition of subsidiary entities and share-based payments which are initially recorded at fair value. Derivatives are also subsequently carried at fair value.

The preparation of financial statements in conformity with IFRS requires management to make judgements, estimates and assumptions that affect the application of policies and amounts reported in the financial statements and accompanying notes. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

Judgements made by management that have a significant effect on the financial statements and estimates with a significant risk of material adjustment in the next year are discussed in Note 28.

Having considered the Group's current financial position and its cashflow projections, the directors believe that the Group will be able to continue in operational existence for at least the next 12 months from the date of approval of these consolidated financial statements and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements. The accounting policies have been applied consistently by all Group entities.

# iii) Basis of consolidation

# **Subsidiaries**

Subsidiaries are entities controlled by the Company. Control exists when the Company has the power, directly or indirectly, to govern the financial and reporting policies of an entity so as to obtain benefits from its activities. In assessing control, potential voting rights that presently are exercisable or convertible are taken into account. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases.

# Transactions eliminated on consolidation

Intra-group balances and any unrealised gains or losses or income and expenses arising from intra-group transactions are eliminated in preparing the consolidated financial statements.

- BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)
- iv) Property, plant and equipment

# Owned assets

Items of property, plant and equipment are stated at cost less any accumulated depreciation and any impairment losses (see Note 1(viii)). The cost of self-constructed assets includes the cost of materials, direct labour and attributable overheads. It is not Group policy to revalue any items of property, plant and equipment.

Depreciation is charged to the statement of operations on a straight-line basis to write-off the cost of the assets over their expected useful lives as follows:

| • | Leasehold improvements        | 5-15 years |
|---|-------------------------------|------------|
| • | Office equipment and fittings | 10 years   |
| • | Buildings                     | 50 years   |
| • | Computer equipment            | 3-5 years  |
| • | Plant and equipment           | 5-15 years |

Land is not depreciated. The residual values, if not insignificant, useful lives and depreciation methods of property, plant and equipment are reviewed and adjusted if appropriate on a prospective basis, at each balance sheet date. There were no changes to useful lives in the year.

# Leased assets - as lessee

Leases under terms of which the Group assumes substantially all the risks and rewards of ownership are classified as finance leases. Property, plant and equipment acquired by way of finance lease is stated at an amount equal to the lower of its fair value and present value of the minimum lease payments at inception of the lease, less accumulated depreciation and any impairment losses. Lease payments are apportioned between finance charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognised in financial expenses in the statement of operations.

Depreciation is calculated in order to write-off the amounts capitalised over the estimated useful lives of the assets, or the lease term if shorter, by equal annual instalments. The excess of the total rentals under a lease over the amount capitalised is treated as interest, which is charged to the statement of operations in proportion to the amount outstanding under the lease. Leased assets are reviewed for impairment (see Note 1(viii)).

Leases other than finance leases are classified as "operating leases", and the rentals thereunder are charged to the statement of operations on a straight-line basis over the period of the leases. Lease incentives are recognised in the statement of operations on a straight-line basis over the lease term.

# Leased assets - as lessor

Leases where the Group substantially transfers the risks and benefits of ownership of the asset to the customer are classified as finance leases within finance lease receivables. The Group recognises the amount receivable from assets leased under finance leases at an amount equal to the net investment in the lease. Finance lease income is recognised as revenue in the statement of operations reflecting a constant periodic rate of return on the Group's net investment in the lease.

Assets provided to customers under leases other than finance leases are classified as operating leases and carried in property, plant and equipment at cost and are depreciated on a straight-line basis over the useful life of the asset or the lease term, if shorter.

# Subsequent costs

The Group recognises in the carrying amount of an item of property, plant and equipment the cost of replacing part of such an item when that cost is incurred if it is probable that the future economic benefits embodied within the item will flow to the Group and the cost of the replaced item can be measured reliably. All other costs are recognised in the statement of operations as an expense as incurred.

## 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# v) Business combinations

All business combinations are accounted for by applying the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred (excluding amounts relating to the settlement of pre-existing relationships), the amount of any non-controlling interest in the acquiree and, in a business combination achieved in stages, the acquisition-date fair value of the acquirer's previously-held equity interest in the acquiree. Acquisition-related costs of the combination are recorded as an expense in the statement of operations and any contingent consideration is measured at fair value at the acquisition date. If the contingent consideration arrangement gives rise to a financial liability, any subsequent changes are generally recognised in profit or loss. Assets and liabilities assumed are measured at their acquisition date fair values.

# vi) Goodwill

In respect of business combinations that have occurred since January 1, 2004 (being the transition date to IFRS), goodwill represents the difference between the cost of the acquisition and the fair value of the net identifiable assets acquired.

In respect of acquisitions prior to this date, goodwill is included on the basis of its deemed cost, which represents the amount recorded under the old basis of accounting, Irish GAAP, ("Previous GAAP"). Save for retrospective restatement of deferred tax as an adjustment to retained earnings in accordance with IAS 12, *Income Taxes*, the classification and accounting treatment of business combinations undertaken prior to the transition date were not reconsidered in preparing the Group's opening IFRS balance sheet as at January 1, 2004.

To the extent that the Group's interest in the net fair value of the identifiable assets, liabilities and contingent liabilities acquired exceeds the cost of a business combination, the identification and measurement of the related assets, liabilities and contingent liabilities are revisited accompanied by a reassessment of the cost of the transaction, and any remaining balance is immediately recognised in the statement of operations.

At the acquisition date, any goodwill is allocated to each of the cash generating units expected to benefit from the combination's synergies. Following initial recognition, goodwill is stated at cost less any accumulated impairment losses (see Note 1(viii)).

# vii) Intangibles, including research and development (other than goodwill)

An intangible asset, which is an identifiable non-monetary asset without physical substance, is recognised to the extent that it is probable that the expected future economic benefits attributable to the asset will flow to the Group and that its cost can be measured reliably. The asset is deemed to be identifiable when it is separable (that is, capable of being divided from the entity and sold, transferred, licensed, rented or exchanged, either individually or together with a related contract, asset or liability) or when it arises from contractual or other legal rights, regardless of whether those rights are transferable or separable from the Group or from other rights and obligations.

Intangible assets acquired as part of a business combination are capitalised separately from goodwill if the intangible asset meets the definition of an asset and the fair value can be reliably measured on initial recognition. Subsequent to initial recognition, these intangible assets are carried at cost less any accumulated amortisation and any accumulated impairment losses (Note 1(viii)). Intangible assets with definite useful lives are reviewed for indicators of impairment annually while intangible assets with indefinite useful lives and those not yet brought into use are tested for impairment annually, either individually or at the cash generating unit level.

Expenditure on development activities, whereby research findings are applied to a plan or design for the production of new or substantially improved products and processes, is capitalised if the product or process is technically and commercially feasible and the Group has sufficient resources to complete the development. The expenditure capitalised includes the cost of materials, direct labour and attributable overheads and third party costs. Subsequent expenditure on capitalised intangible assets is capitalised only when it increases the future economic benefits embodied in the specific asset to which it relates.

The technical feasibility of a new product is determined by a specific feasibility study undertaken at the first stage of any development project. The majority of our new product developments involve the transfer of existing product know-how to a new application. Since the technology is already proven in an existing product which is being used by customers, this facilitates the proving of the technical feasibility of that same technology in a new product.

## 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

The results of the feasibility study are reviewed by a design review committee comprising senior managers. The feasibility study occurs in the initial research phase of a project and costs in this phase are not capitalized.

The commercial feasibility of a new product is determined by preparing a discounted cash flow projection. This projection compares the discounted sales revenues for future periods with the relevant costs. As part of preparing the cash flow projection, the size of the relevant market is determined, feedback is sought from customers and the strength of the proposed new product is assessed against competitors' offerings. Once the technical and commercial feasibility has been established and the project has been approved for commencement, the project moves into the development phase.

All other development expenditure is expensed as incurred. Subsequent to initial recognition, the capitalised development expenditure is carried at cost less any accumulated amortisation and any accumulated impairment losses (Note 1(viii)).

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in the statement of operations as an expense as incurred.

Expenditure on internally generated goodwill and brands is recognised in the statement of operations as an expense as incurred.

## Amortisation

Amortisation is charged to the statement of operations on a straight-line basis over the estimated useful lives of intangible assets, unless such lives are indefinite. Intangible assets are amortised from the date they are available for use. The estimated useful lives are as follows:

Patents and licences
 Capitalised development costs
 Other (including acquired customer and supplier lists)
 6-15 years
 6-15 years

The Group uses a useful economic life of 15 years for capitalized development costs. This is a conservative estimate of the likely life of the products. The Group is confident that products have a minimum of 15 years life given the inertia that characterizes the medical diagnostics industry and the barriers to enter into the industry. The following factors have been considered in estimating the useful life of developed products:

- (a) once a diagnostic test becomes established, customers are reluctant to change to new technology until it is fully proven, thus resulting in relatively long product life cycles. There is also reluctance in customers to change to a new product as it can be costly both in terms of the initial changeover cost and as new technology is typically more expensive.
- (b) demand for the diagnostic tests is enduring and robust within a wide geographic base. The diseases that the products diagnose are widely prevalent (HIV, Diabetes and Chlamydia being just three examples) in many countries. There is a general consensus that these diseases will continue to be widely prevalent in the future.
- (c) there are significant barriers to new entrants in this industry. Patents and/or licences are in place for many of our products, though this is not the only barrier to entry. There is a significant cost and time to develop new products, it is necessary to obtain regulatory approval and tests are protected by proprietary know-how, manufacturing techniques and trade secrets.

Certain trade names acquired are deemed to have an indefinite useful life as there is no foreseeable limit to the period over which these assets are expected to generate cash inflows for the Group.

Where amortisation is charged on assets with finite lives, this expense is taken to the statement of operations through the 'selling, general and administrative expenses' line.

Useful lives are examined on an annual basis and adjustments, where applicable, are made on a prospective basis.

# 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# viii) Impairment

The carrying amount of the Group's assets, other than inventories and deferred tax assets, are reviewed at each balance sheet date to determine whether there is any indication of impairment. If any such indication exists, the asset's recoverable amount (being the greater of fair value less costs to sell and value in use) is assessed at each balance sheet date.

Fair value less costs to sell is defined as the amount obtainable from the sale of an asset or cash-generating unit in an arm's length transaction between knowledgeable and willing parties, less the costs that would be incurred in disposal. Value in use is defined as the present value of the future cash flows expected to be derived through the continued use of an asset or cash-generating unit. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the future cash flow estimates have not yet been adjusted. The estimates of future cash flows exclude cash inflows or outflows attributable to financing activities and income tax. For an asset that does not generate largely independent cash flows, the recoverable amount is determined by reference to the cash generating unit to which the asset belongs.

For goodwill, assets that have an indefinite useful life and intangible assets that are not yet available for use, the recoverable amount is estimated at each balance sheet date at the cash generating unit level. The goodwill and indefinite-lived assets were reviewed for impairment at December 31, 2012, December 31, 2013 and December 2014. See Note 11.

IPR&D is tested for impairment on an annual basis, in the fourth quarter, or more frequently if impairment indicators are present, using projected discounted cash flow models. If IPR&D becomes impaired or is abandoned, the carrying value of the IPR&D is written down to its revised fair value with the related impairment charge recognised in the period in which the impairment occurs. If the fair value of the asset becomes impaired as the result of unfavorable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercializing our programs, we could incur significant charges in the period in which the impairment occurs. The valuation techniques utilized in performing impairment tests incorporate significant assumptions and judgments to estimate the fair value, as described above. The use of different valuation techniques or different assumptions could result in materially different fair value estimates.

An impairment loss is recognised whenever the carrying amount of an asset or its cash-generating unit exceeds its recoverable amount. Impairment losses are recognised in the statement of operations.

Impairment losses recognised in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to cash-generating units and then to reduce the carrying amount of other assets in the cash-generating units on a pro-rata basis.

An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

An impairment loss in respect of goodwill is not reversed.

Following recognition of any impairment loss (and on recognition of an impairment loss reversal), the depreciation or amortisation charge applicable to the asset or cash generating unit is adjusted prospectively with the objective of systematically allocating the revised carrying amount, net of any residual value, over the remaining useful life.

## *ix) Inventories*

Inventories are stated at the lower of cost and net realisable value. Cost is based on the first-in, first-out principle and includes all expenditure which has been incurred in bringing the products to their present location and condition, and includes an appropriate allocation of manufacturing overhead based on the normal level of operating capacity. Net realisable value is the estimated selling price of inventory on hand in the ordinary course of business less all further costs to completion and costs expected to be incurred in selling these products.

The Group provides for inventory, based on estimates of the expected realisability of the Group's inventory. The estimated realisability is evaluated on a case-by-case basis and any inventory that is approaching its "use-by" date and for which no further re-processing can be performed is written off. Any reversal of an inventory provision is recognised in the statement of operations in the year in which the reversal occurs.

# 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# *x)* Trade and other receivables

Trade and other receivables are stated at their amortised cost less impairment losses incurred. Cost approximates fair value given the short dated nature of these assets.

# xi) Trade and other payables

Trade and other payables are stated at cost. Cost approximates fair value given the short dated nature of these liabilities.

## *xii) Cash and cash equivalents*

Cash and cash equivalents comprise cash balances and short-term deposits. The Group has no short-term bank overdraft facilities. Where restrictions are imposed by third parties, such as lending institutions, on cash balances held by the Group these are treated as financial assets in the financial statements.

# xiii) Share-based payments

For equity-settled share-based payments (share options), the Group measures the services received and the corresponding increase in equity at fair value at the measurement date (which is the grant date) using a trinomial model. Given that the share options granted do not vest until the completion of a specified period of service, the fair value, which is assessed at the grant date, is recognised on the basis that the services to be rendered by employees as consideration for the granting of share options will be received over the vesting period.

The share options issued by the Group are not subject to market-based vesting conditions as defined in IFRS 2, *Share-based Payment*. Non-market vesting conditions are not taken into account when estimating the fair value of share options as at the grant date; such conditions are taken into account through adjusting the number of equity instruments included in the measurement of the transaction amount so that, ultimately, the amount recognised equates to the number of equity instruments that actually vest. The expense in the statement of operations in relation to share options represents the product of the total number of options anticipated to vest and the fair value of those options; this amount is allocated to accounting periods on a straight-line basis over the vesting period. Given that the performance conditions underlying the Group's share options are non-market in nature, the cumulative charge to the statement of operations is only reversed where the performance condition is not met or where an employee in receipt of share options relinquishes service prior to completion of the expected vesting period. Share based payments, to the extent they relate to direct labour involved in development activities, are capitalised, see Note 1(vii).

The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised. The Group does not operate any cash-settled share-based payment schemes or share-based payment transactions with cash alternatives as defined in IFRS 2.

# xiv) Government grants

Grants that compensate the Group for expenses incurred such as research and development, employment and training are recognised as revenue or income in the statement of operations on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate the Group for the cost of an asset are recognised in the statement of operations as other operating income on a systematic basis over the useful life of the asset.

# 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# xv) Revenue recognition

## Goods sold and services rendered

Revenue from the sale of goods is recognised in the statement of operations when the significant risks and rewards of ownership have been transferred to the buyer. Revenue from products is generally recorded as of the date of shipment, consistent with typical ex-works shipment terms. Where the shipment terms do not permit revenue to be recognised as of the date of shipment, revenue is recognised when the Group has satisfied all of its obligations to the customer in accordance with the shipping terms. Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods supplied to external customers, net of discounts and excluding sales taxes.

Revenue from services rendered is recognised in the statement of operations in proportion to the stage of completion of the transaction at the balance sheet date.

Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group, that the risks and rewards of ownership have passed to the buyer and the revenue can be measured. No revenue is recognised if there is uncertainty regarding recovery of the consideration due at the outset of the transaction or the possible return of goods.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass to the customer, the fair value of the instrument is recognised as revenue at the commencement of the lease and is matched by the related cost of sale. In the case of operating leases of instruments which typically involve commitments by the customer to pay a fee per test run on the instruments, revenue is recognised on the basis of customer usage of the instruments. See also Note 1(iv).

# Other operating income

Rental income from sub-leasing premises under operating leases, where the risks and rewards of the premises remain with the lessor, is recognised in the statement of operations as other operating income on a straight-line basis over the term of the lease.

Other income also comprises income recognised under Transitional Services Agreements (TSA) with Lab 21 Limited and Diagnostica Stago. As part of the acquisition of the blood bank screening business in July 2013 from Lab 21 Limited, the Group entered into a TSA. The services provided by the Group to Lab 21 under the TSA comprise of mainly facilities and information technology. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

# xvi) Employee benefits

# Defined contribution plans

The Group operates defined contribution schemes in various locations where its subsidiaries are based. Contributions to the defined contribution schemes are recognised in the statement of operations in the period in which the related service is received from the employee.

# Other long-term benefits

Where employees participate in the Group's other long-term benefit schemes (such as permanent health insurance schemes under which the scheme insures the employees), or where the Group contributes to insurance schemes for employees, the Group pays an annual fee to a service provider, and accordingly the Group expenses such payments as incurred.

# Termination benefits

Termination benefits are recognised as an expense when the Group is demonstrably committed, without realistic possibility of withdrawal, to a formal detailed plan to either terminate employment before normal retirement date, or to provide termination benefits as a result of an offer made to encourage voluntary redundancy.

# 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

## xvii) Foreign currency

A majority of the revenue of the Group is generated in US Dollars. The Group's management has determined that the US Dollar is the primary currency of the economic environment in which the Company and its subsidiaries (with the exception of the Group's subsidiaries in Sweden, Brazil and Canada) principally operate. Thus the functional currency of the Company and its subsidiaries (other than the Swedish, Brazilian and Canadian subsidiaries) is the US Dollar. The functional currency of the Swedish subsidiary is the Swedish Kroner, the currency of the Brazilian entity is the Brazilian Real, and the currency of the Canadian subsidiary is the Canadian Dollar. The presentation currency of the Company and Group is the US Dollar. Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the balance sheet date. The resulting gains and losses are included in the statement of operations. Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

Results and cash flows of subsidiary undertakings, which have a functional currency other than the US Dollar, are translated into US Dollars at average exchange rates for the year, and the related balance sheets have been translated at the rates of exchange ruling on the balance sheet date. Any exchange differences arising from the translations are recognised in the currency translation reserve via the statement of changes in equity.

Where Euro, Sterling, Brazilian Real or Swedish Kroner amounts have been referenced in this document, their corresponding US Dollar equivalent has also been included and these equivalents have been calculated with reference to the foreign exchange rates prevailing at December 31, 2014.

## xviii) Derivative financial instruments

The activities of the Group expose it primarily to changes in foreign exchange rates and interest rates. The Group uses derivative financial instruments, when necessary, such as forward foreign exchange contracts to hedge these exposures.

The Group enters into forward contracts to sell US Dollars forward for Euro. The principal exchange risk identified by the Group is with respect to fluctuations in the Euro as a substantial portion of its expenses are denominated in Euro but its revenues are primarily denominated in US Dollars. Trinity Biotech monitors its exposure to foreign currency movements and may use these forward contracts as cash flow hedging instruments whose objective is to cover a portion of this Euro expense.

At the inception of a hedging transaction entailing the use of derivatives, the Group documents the relationship between the hedged item and the hedging instrument together with its risk management objective and the strategy underlying the proposed transaction. The Group also documents its quarterly assessment of the effectiveness of the hedge in offsetting movements in the cash flows of the hedged items.

Derivative financial instruments are recognised at fair value. Where derivatives do not fulfil the criteria for hedge accounting, they are classified as held-for-trading and changes in fair values are reported in the statement of operations. The fair value of forward exchange contracts is calculated by reference to current forward exchange rates for contracts with similar maturity profiles and equates to the current market price at the balance sheet date.

The portion of the gain or loss on a hedging instrument that is deemed to be an effective cash flow hedge is recognised directly in the hedging reserve in equity and the ineffective portion is recognised in the statement of operations. As the forward contracts are exercised the net cumulative gain or loss recognised in the hedging reserve is transferred to the statement of operations and reflected in the same line as the hedged item.

## xix) Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Board of Directors.

# *xx*) *Tax* (*current and deferred*)

Income tax on the profit or loss for the year comprises current and deferred tax. Income tax is recognised in the statement of operations except to the extent that it relates to items recognised directly in equity, in which case it is recognised in equity.

#### 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Current tax represents the expected tax payable (or recoverable) on the taxable profit for the year using tax rates enacted or substantively enacted at the balance sheet date and taking into account any adjustments stemming from prior years.

Deferred tax is provided on the basis of the balance sheet liability method on all temporary differences at the balance sheet date which is defined as the difference between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred tax assets and liabilities are not subject to discounting and are measured at the tax rates that are anticipated to apply in the period in which the asset is realised or the liability is settled based on tax rates and tax laws that have been enacted or substantively enacted at the balance sheet date. Deferred tax assets are recognised when it is probable that future taxable profits will be available to utilize the associated losses or temporary differences. The amount of deferred tax provided is based on the expected manner of realisation or settlement of the carrying amount of assets and liabilities.

Deferred tax assets and liabilities are recognised for all temporary differences (that is, differences between the carrying amount of the asset or liability and its tax base) with the exception of the following:

- i. Where the deferred tax liability arises from goodwill not deductible for tax purposes or the initial recognition of an asset or a liability in a transaction that is not a business combination and affects neither the accounting profit nor the taxable profit or loss at the time of the transaction; and
- ii. Where, in respect of temporary differences associated with investments in subsidiary undertakings, the timing of the reversal of the temporary difference is subject to control and it is probable that the temporary difference will not reverse in the foreseeable future.

Where goodwill is tax deductible, a deferred tax liability is not recognised on initial recognition of goodwill. It is recognised subsequently for the taxable temporary difference which arises when the goodwill is amortised for tax with no corresponding adjustment to the carrying value of the goodwill.

The carrying amounts of deferred tax assets are subject to review at each balance sheet date and are derecognised to the extent that future taxable profits are considered to be inadequate to allow all or part of any deferred tax asset to be utilised.

#### xxi) Provisions

A provision is recognised in the balance sheet when the Group has a present legal or constructive obligation as a result of a past event, and it is probable that an outflow of economic benefits will be required to settle the obligation.

### xxii) Cost of sales

Cost of sales comprises product cost including manufacturing and payroll costs, quality control, shipping, handling, and packaging costs and the cost of services provided.

#### xxiii) Finance income and costs

Financing expenses comprise interest costs payable on leases. Interest payable on finance leases is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability. Financing expenses also includes the financing element of long term liabilities which have been discounted.

Finance income includes interest income on deposits and is recognised in the statement of operations as it accrues, using the effective interest method. Finance income also includes interest on the deferred consideration due to the Group as part of the divestiture of the Coagulation product line in 2010.

#### xxiv) Warrant reserve

The Group calculates the fair value of warrants at the date of issue taking the amount directly to equity. The fair value is calculated using a recognised valuation methodology for the valuation of financial instruments (that is, the trinomial model). The fair value which is assessed at the grant date is calculated on the basis of the contractual term of the warrants.

#### BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### xxv) Treasury shares

Own equity instruments that are reacquired (treasury shares) are recognised at cost and deducted from equity. No gain or loss is recognised in the statement of operations on the purchase, sale, issue or cancellation of the Group's own equity instruments. Any difference between the carrying amount and the consideration, if reissued, is recognised in share premium. Voting rights related to treasury shares are nullified for the Group and no dividends are allocated to them.

#### xxvi) Equity

Share capital represents the nominal (par) value of shares that have been issued. Share premium includes any premiums received on issue of share capital. Any transaction costs associated with the issuing of shares are deducted from share premium, net of any related income tax benefits.

### xxvii) Fair values

For financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2: valuation techniques for which the lowest level of inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly

Level 3: valuation techniques for which the lowest level of inputs that have a significant effect on the recorded fair value are not based on observable market data

#### xxviii) New IFRS Standards and Interpretations not applied

The IASB and IFRIC have issued additional standards and interpretations which are effective for periods starting after January 1, 2014, all of which have not yet been adopted by the EU. The following standards and interpretations have yet to be adopted by the Group:

| International I | Financial Reporting Standards (IFRS/IAS)               | Effective date                              |
|-----------------|--|---|
| IAS 1           | Presentation of Financial Statements (Amendment)       | January 1, 2016 (not yet adopted by the EU) |
| IAS 16          | Property, Plant and Equipment (Amendment)              | July 1, 2014 (not yet adopted by the EU)    |
| IAS 19          | Employee Benefits (Amendment)                          | January 1, 2016 (not yet adopted by the EU) |
| IAS 24          | Related Party Disclosures (Amendment)                  | July 1, 2014 (not yet adopted by the EU)    |
| IAS 27          | Separate Financial Statements (Amendment)              | January 1, 2016 (not yet adopted by the EU) |
| IAS 28          | Investments in Associates and Joint Ventures           | January 1, 2016 (not yet adopted by the EU) |
|                 | (Amendment)  |   |
| IAS 34          | Interim Financial Reporting                            | January 1, 2016 (not yet adopted by the EU) |
| IAS 38          | Intangible Assets (Amendment)                          | January 1, 2016 (not yet adopted by the EU) |
| IAS 40          | Investment Property (Amendment)                        | July 1, 2014 (not yet adopted by the EU)    |
| IAS 41          | Agriculture (Amendments)                               | January 1, 2016 (not yet adopted by the EU) |
| IFRS 2          | Share Based Payments (Amendment)                       | July 1, 2014 (not yet adopted by the EU)    |
| IFRS 3          | Business Combinations (Amendment)                      | July 1, 2014 (not yet adopted by the EU)    |
| IFRS 5          | Non-Current Assets Held for Sale and Discontinued      | January 1, 2016 (not yet adopted by the EU) |
|                 | Operations (Amendment)                                 |   |
| IFRS 7          | Financial Instruments Disclosures (Amendment)          | January 1, 2016 (not yet adopted by the EU) |
| IFRS 8          | Operating Segments (Amendment)                         | July 1, 2014 (not yet adopted by the EU)    |
| IFRS 9          | Financial Instruments – Classification and Measurement | January 1, 2018 (not yet adopted by the EU) |
| IFRS 10         | Consolidated Financial Statements (Amendment)          | January 1, 2016 (not yet adopted by the EU) |
| IFRS 11         | Joint Arrangements (Amendment)                         | January 1, 2016 (not yet adopted by the EU) |
| IFRS 12         | Disclosure of Interest in Other Entities (Amendment)   | January 1, 2016 (not yet adopted by the EU) |
| IFRS 13         | Fair Value Measurement (Amendment)                     | July 1, 2014 (not yet adopted by the EU)    |
| IFRS 14         | Regulatory Deferral Accounts                           | January 1, 2016 (not yet adopted by the EU) |
| IFRS 15         | Revenue from Contracts with Customers                  | January 1, 2017 (not yet adopted by the EU) |
|                 |  |   |

The Group does not anticipate that the adoption of these standards and interpretations will have a material effect on its financial statements on initial adoption.

#### 1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

The Group has adopted the following standards and amendments during the year:

- IAS 36 Impairment of Assets (Amendment)
- IFRS 10 Consolidated Financial Statements (Amendment)

The application of the above standards did not result in material changes in the Group's consolidated accounts.

#### 2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing the performance of the operating segments, has been identified as the Board of Directors. Management has determined the operating segments based on the reports reviewed by the Board of Directors, which are used to make strategic decisions. The Board considers the business from a geographic perspective based on the Group's management and internal reporting structure. Sales of product between companies in the Group are made on commercial terms which reflect the nature of the relationship between the relevant companies. Segment results, assets and liabilities include items directly attributable to a segment as well as those that can be allocated on a reasonable basis. Unallocated items comprise interest-bearing loans, borrowings and expenses and corporate expenses. Segment capital expenditure is the total cost during the year to acquire segment plant, property and equipment and intangible assets that are expected to be used for more than one period, whether acquired on acquisition of a business combination or through acquisitions as part of the current operations.

The Group comprises two main geographical segments (i) the Americas and (ii) Rest of World. The Group's geographical segments are determined by the location of the Group's assets and operations. The Group has also presented a geographical analysis of the segmental data for Ireland as is consistent with the information used by the Board of Directors.

The reportable operating segments derive their revenue primarily from one source (i.e. the market for diagnostic tests for a range of diseases and other medical conditions). In determining the nature of its segmentation, the Group has considered the nature of the products, their risks and rewards, the nature of the production base, the customer base and the nature of the regulatory environment. The Group acquires, manufactures and markets a range of diagnostic products. The Group's products are sold to a similar customer base and the main body whose regulation the Group's products must comply with is the Food and Drug Administration ("FDA") in the US.

The following presents revenue and profit information and certain asset and liability information regarding the Group's geographical segments.

i) The distribution of revenue by geographical area based on location of assets was as follows:

|                                 |                  | Rest of  | World    |              |             |
|---------------------------------|------------------|----------|----------|--------------|-------------|
| Revenue                         | Americas         | Ireland  | Other    | Eliminations | Total       |
| Year ended December 31, 2014    | US\$'000         | US\$'000 | US\$'000 | US\$'000     | US\$'000    |
| Revenue from external customers | 61,611           | 40,975   | 2,286    | _            | 104,872     |
| Inter-segment revenue           | 36,273           | 6,905    | 17,018   | (60,196)     |             |
| Total revenue                   | 97,884           | 47,880   | 19,304   | (60,196)     | 104,872     |
|                                 | <del></del>      |          |          |              | <del></del> |
|                                 |                  | Rest of  | f World  |              |             |
|                                 | Americas         | Ireland  | Other    | Eliminations | Total       |
| Year ended December 31, 2013    | US\$'000         | US\$'000 | US\$'000 | US\$'000     | US\$'000    |
|                                 |                  |          |          |              | 039 000     |
| Revenue from external customers | 48,679           | 40,616   | 1,921    | _            | 91,216      |
| Inter-segment revenue           | 48,679<br>35,474 |          |          | (53,995)     |             |
|                                 | /                | 40,616   | 1,921    | _            |             |

### 2. SEGMENT INFORMATION (CONTINUED)

|                                 | Rest of World |          |           |              |          |
|---------------------------------|---------------|----------|-----------|--------------|----------|
|                                 | Americas      | Ireland  | Other     | Eliminations | Total    |
| Year ended December 31, 2012    | US\$'000      | US\$'000 | US\$ '000 | US\$'000     | US\$'000 |
| Revenue from external customers | 42,029        | 40,481   | _         | _            | 82,510   |
| Inter-segment revenue           | 32,466        | 7,655    | 5,558     | (45,679)     |          |
| Total revenue                   | 74,495        | 48,136   | 5,558     | (45,679)     | 82,510   |

### ii) The distribution of revenue by customers' geographical area was as follows:

| Revenue                      | December 31, 2014<br>US\$ '000 | December 31, 2013<br>US\$ '000 | December 31, 2012<br>US\$'000 |
|------------------------------|--------------------------------|--------------------------------|-------------------------------|
| Americas                     | 61,142                         | 54,761                         | 49,638                        |
| Europe (including Ireland) * | 18,569                         | 12,394                         | 10,214                        |
| Asia / Africa                | 25,161                         | 24,061                         | 22,658                        |
|                              | 104,872                        | 91,216                         | 82,510                        |

<sup>\*</sup> Revenue from customers in Ireland is not disclosed separately due to the immateriality of these revenues.

### iii) The distribution of revenue by major product group was as follows:

| Revenue             | December 31, 2014<br>US\$ '000 | December 31, 2013<br>US\$ '000 | December 31, 2012<br>US\$'000 |
|---------------------|--------------------------------|--------------------------------|-------------------------------|
| Clinical laboratory | 77,240                         | 68,727                         | 63,356                        |
| Point-of-Care       | 20,036                         | 19,754                         | 19,154                        |
| Laboratory services | 7,596                          | 2,735                          |                               |
|                     | 104,872                        | 91,216                         | 82,510                        |

### iv) The distribution of segment results by geographical area was as follows:

|                               |          | Rest of World |           |          |  |
|-------------------------------|----------|---------------|-----------|----------|--|
|                               | Americas | Ireland       | Other     | Total    |  |
| Year ended December 31, 2014  | US\$'000 | US\$'000      | US\$ '000 | US\$'000 |  |
| Result                        | 5,350    | 9,383         | 4,188     | 18,921   |  |
| Unallocated expenses *        |          |               |           | (882)    |  |
| Operating profit              |          |               |           | 18,039   |  |
| Net financing income (Note 3) |          |               |           | 28       |  |
| Profit before tax             |          |               |           | 18,067   |  |
| Income tax expense (Note 8)   |          |               |           | (853)    |  |
| Profit for the year           |          |               |           | 17,214   |  |
|                               |          | Rest of       | `World    |          |  |

| Rest of World |           |                                       |                            |
|---------------|-----------|---------------------------------------|----------------------------|
| Americas      | Ireland   | Other                                 | Total                      |
| US\$'000      | US\$ '000 | US\$'000                              | US\$'000                   |
| 5,730         | 5,014     | (968)                                 | 9,776                      |
|               |           |                                       | (781)                      |
|               |           |                                       | 8,995                      |
|               |           |                                       | 1,225                      |
|               |           |                                       | 10,220                     |
|               |           |                                       | (574)                      |
|               |           |                                       | 9,646                      |
|               | US\$'000  | Americas Ireland<br>US\$*000 US\$*000 | US\$'000 US\$'000 US\$'000 |

### 2. SEGMENT INFORMATION (CONTINUED)

|                               |          | Rest of World |          |          |  |
|-------------------------------|----------|---------------|----------|----------|--|
|                               | Americas | Ireland       | Other    | Total    |  |
| Year ended December 31, 2012  | US\$'000 | US\$'000      | US\$'000 | US\$'000 |  |
| Result                        | 6,299    | 11,739        | (39)     | 17,999   |  |
| Unallocated expenses *        |          |               |          | (833)    |  |
| Operating profit              |          |               |          | 17,166   |  |
| Net financing income (Note 3) |          |               |          | 2,192    |  |
| Profit before tax             |          |               |          | 19,358   |  |
| Income tax expense (Note 8)   |          |               |          | (2,017)  |  |
| Profit for the year           |          |               |          | 17,341   |  |
|                               |          |               |          |          |  |

<sup>\*</sup> Unallocated expenses represent head office general and administration costs of the Group which cannot be allocated to the results of any specific geographical area.

### v) The distribution of segment assets and segment liabilities by geographical area was as follows:

|  |                      | Rest of V           | World             |                            |
|--|----------------------|---------------------|-------------------|----------------------------|
| As at December 31, 2014  | Americas<br>US\$'000 | Ireland<br>US\$'000 | Other<br>US\$'000 | Total<br>US\$'000          |
| Assets and liabilities   | 039 000              | 03\$ 000            | 03\$ 000          | 039 000                    |
| Segment assets   | 105,434              | 100,237             | 17,916            | 223,587                    |
| Unallocated assets:  |                      |                     |                   |                            |
| Income tax assets (current and deferred)   |                      |                     |                   | 10,149                     |
| Cash and cash equivalents  |                      |                     |                   | 9,102                      |
| Total assets as reported in the Group balance sheet  |                      |                     |                   | 242,838                    |
| Segment liabilities  | 9,035                | 12,573              | 2,034             | 23,642                     |
| Unallocated liabilities:   |                      |                     |                   |                            |
| Income tax liabilities (current and deferred)  |                      |                     |                   | 22,224                     |
| Total liabilities as reported in the Group balance sheet   |                      |                     |                   | 45,866                     |
|  |                      |                     |                   |                            |
|  |                      | Rest of             |                   |                            |
| As at December 31, 2013  | Americas<br>US\$'000 | Ireland<br>US\$'000 | Other<br>US\$'000 | Total                      |
|  |                      |                     |                   | 1/88/000                   |
| Assets and liabilities   |                      |                     | 039 000           | US\$'000                   |
|  | 92,470               | 83,044              |                   |                            |
| Assets and liabilities Segment assets Unallocated assets:  | 92,470               | 83,044              | 21,124            | 196,638                    |
| Segment assets   | 92,470               | 83,044              |                   |                            |
| Segment assets Unallocated assets:   | 92,470               | 83,044              |                   | 196,638                    |
| Segment assets  Unallocated assets: Income tax assets (current and deferred)   | 92,470               | 83,044              |                   | 196,638<br>7,531           |
| Segment assets  Unallocated assets: Income tax assets (current and deferred) Cash and cash equivalents   | 92,470               | 83,044              |                   | 196,638<br>7,531<br>22,317 |
| Segment assets  Unallocated assets:  Income tax assets (current and deferred)  Cash and cash equivalents  Total assets as reported in the Group balance sheet                  |                      |                     | 21,124            | 7,531<br>22,317<br>226,486 |
| Segment assets  Unallocated assets: Income tax assets (current and deferred) Cash and cash equivalents Total assets as reported in the Group balance sheet Segment liabilities |                      |                     | 21,124            | 7,531<br>22,317<br>226,486 |

### 2. SEGMENT INFORMATION (CONTINUED)

vi) The distribution of long-lived assets, which are property, plant and equipment, goodwill and intangible assets and other non-current assets (excluding deferred tax assets), by geographical area was as follows:

|                         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-------------------------|-------------------------------|-------------------------------|
| Rest of World – Ireland | 74,492                        | 59,160                        |
| Rest of World – Other   | 16,827                        | 18,458                        |
| Americas                | 72,776                        | 65,082                        |
|                         | 164,095                       | 142,700                       |

vii) The distribution of depreciation and amortisation by geographical area was as follows:

|                         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$`000 |
|-------------------------|-------------------------------|-------------------------------|-------------------------------|
| Depreciation:           |                               |                               |                               |
| Rest of World – Ireland | 478                           | 447                           | 408                           |
| Rest of World – Other   | 160                           | 95                            | 32                            |
| Americas                | 1,538                         | 1,316                         | 1,023                         |
|                         | 2,176                         | 1,858                         | 1,463                         |
| Amortisation:           |                               |                               |                               |
| Rest of World – Ireland | 1,355                         | 1,272                         | 1,174                         |
| Rest of World – Other   | _                             | _                             | _                             |
| Americas                | 1,025                         | 630                           | 308                           |
|                         | 2,380                         | 1,902                         | 1,482                         |

viii) The distribution of share-based payment expense by geographical area was as follows:

|                         | December 31, 2014<br>US\$`000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|-------------------------|-------------------------------|-------------------------------|-------------------------------|
| Rest of World – Ireland | 1,350                         | 1,791                         | 1,482                         |
| Rest of World – Other   | 22                            | 20                            | _                             |
| Americas                | 124                           | 203                           | 231                           |
|                         | 1,496                         | 2,014                         | 1,713                         |

See Note 18 for further information on share-based payments.

### 2. SEGMENT INFORMATION (CONTINUED)

ix) The distribution of interest income and interest expense by geographical area was as follows:

|   |                      | Rest of                                | World             |                          |                   |
|---|----------------------|--|-------------------|--------------------------|-------------------|
| Interest Income                                     | Americas             | Ireland                                | Other             | Eliminations             | Total             |
| Year ended December 31, 2014                        | US\$'000             | US\$ '000                              | US\$'000          | US\$'000                 | US\$'000          |
| Interest income earned                              | 2                    | _                                      | 95                | <u> </u>                 | 97                |
| Inter-segment interest income                       |                      |  | 4,853             | (4,853)                  |                   |
| Total   | 2                    |  | 4,949             | (4,853)                  | 97                |
|   |                      |  |                   |                          |                   |
|   |                      | Rest of                                |                   |                          |                   |
| Interest Expense                                    | Americas             | Ireland                                | Other             | Eliminations             | Total             |
| Year ended December 31, 2014                        | US\$'000             | US\$'000<br>132                        | US\$'000          | US\$'000                 | US\$'000          |
| Interest on deferred consideration                  | 4,853                | 132                                    | (63)              | (4.952)                  | 69                |
| Inter-segment interest expense                      |                      |  |                   | (4,853)                  |                   |
| Total   | 4,853                | 132                                    | (63)              | (4,853)                  | 69                |
|   |                      |  |                   |                          |                   |
|   |                      | Rest of                                |                   |                          |                   |
| Interest Income<br>Year ended December 31, 2013     | Americas<br>US\$'000 | Ireland<br>US\$'000                    | Other<br>US\$'000 | Eliminations<br>US\$'000 | Total<br>US\$'000 |
| Interest income earned                              | 2                    | —————————————————————————————————————— | 1,274             | U3\$ 000<br>—            | 1,276             |
| Inter-segment interest income                       |                      |  | 3,930             | (3,930)                  | 1,270             |
|   |                      |  |                   |                          | 1 276             |
| Total   | 2                    |  | 5,204             | (3,930)                  | 1,276             |
|   |                      |  |                   |                          |                   |
| Interest Francisco                                  | A                    | Rest of                                |                   | Elimin eti ene           | T-4-1             |
| Interest Expense Year ended December 31, 2013       | Americas<br>US\$'000 | Ireland<br>US\$'000                    | Other<br>US\$'000 | Eliminations<br>US\$'000 | Total<br>US\$'000 |
| Interest on deferred consideration                  | —                    | —                                      | 51                | —                        | 51                |
| Inter-segment interest expense                      | 3,930                | _                                      | _                 | (3,930)                  | _                 |
| Total   | 3,930                |  | 51                | (3,930)                  | 51                |
| Total   | 3,930                |  |                   | (3,930)                  | <u> </u>          |
|   |                      | D                                      | 117 11            |                          |                   |
| Interest Income                                     | Americas             | Rest of<br>Ireland                     | worıa<br>Other    | Eliminations             | Total             |
| Year ended December 31, 2012                        | US\$'000             | US\$ '000                              | US\$ '000         | US\$'000                 | US\$ '000         |
| Interest income earned                              | _                    | 2                                      | 2,166             | _                        | 2,168             |
| Interest on deferred consideration                  | 25                   | 87                                     | ·                 | _                        | 112               |
| Inter-segment interest income                       | _                    | _                                      | 3,270             | (3,270)                  | _                 |
| Total   | 25                   | 89                                     | 5,436             | (3,270)                  | 2,280             |
| 10001   |                      |  | 2,.30             | (3,270)                  |                   |
|   |                      | Rest of                                | World             |                          |                   |
| Interest Expense                                    | Americas             | Ireland                                | Other             | Eliminations             | Total             |
| Year ended December 31, 2012                        | US\$'000             | US\$ '000                              | US\$ '000         | US\$'000                 | US\$'000          |
| T .   |                      |  |                   |                          |                   |
| Interest expense                                    | 1                    | 2                                      | _                 | _                        | 3                 |
| Interest expense Interest on deferred consideration | _                    | 2                                      | —<br>85           | <u> </u>                 | 3<br>85           |
|   | 3,270                | 2<br>                                  | 85<br>—           | (3,270)                  |                   |
| Interest on deferred consideration                  | _                    | $-\frac{2}{-\frac{2}{2}}$              | 85<br>—<br>85     | (3,270)<br>(3,270)       |                   |

- 2. SEGMENT INFORMATION (CONTINUED)
- x) The distribution of taxation expense by geographical area was as follows:

|                         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|-------------------------|-------------------------------|-------------------------------|-------------------------------|
| Rest of World – Ireland | (395)                         | (22)                          | (880)                         |
| Rest of World – Other   | (410)                         | 18                            | (80)                          |
| Americas                | (48)                          | (570)                         | (1,057)                       |
|                         | (853)                         | (574)                         | (2,017)                       |

- xi) During 2014, 2013 and 2012 there were no customers generating 10% or more of total revenues.
- xii) The distribution of capital expenditure by geographical area was as follows:

|                         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-------------------------|-------------------------------|-------------------------------|
| Rest of World – Ireland | 8,872                         | 15,790                        |
| Rest of World – Other   | 4,346                         | 8,493                         |
| Americas                | 16,194                        | 38,978                        |
|                         | 29,412                        | 63,261                        |

#### 3. FINANCIAL INCOME AND EXPENSES

|                        | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|------------------------|-------------------------------|-------------------------------|-------------------------------|
| Financial income:      |                               |                               |                               |
| Interest income        | 97                            | 1,276                         | 2,168                         |
| Other interest income  | <del></del>                   | _                             | 112                           |
|                        | 97                            | 1,276                         | 2,280                         |
| Financial expense:     |                               |                               |                               |
| Finance lease interest |                               | _                             | (2)                           |
| Other interest expense | (69)                          | (51)                          | (86)                          |
|                        | (69)                          | (51)                          | (88)                          |
| Net Financing Income   | 28                            | 1,225                         | 2,192                         |

Other interest income recognised in 2012 is comprised of interest income relating to the deferred consideration due to the Company as a result of the sale of the Coagulation product line in 2010.

Other interest expense for 2014 includes US\$69,000 (2013: US\$51,000) (2012: US\$86,000) related to the deferred consideration arising as a result of the acquisition of Fiomi Diagnostics AB by the Group in 2012 (see Note 22).

#### 4. OTHER OPERATING INCOME

|                             | December 31, 2014<br>US\$ '000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|-----------------------------|--------------------------------|-------------------------------|-------------------------------|
| Rental income from premises | 252                            | 250                           | 243                           |
| Other income                | <u> </u>                       | 282                           | 225                           |
|                             | 424                            | 532                           | 468                           |

Other income mainly comprises income recognised under Transitional Services Agreements (TSA) with Lab 21 Limited and Diagnostica Stago. As part of the acquisition of the blood bank screening business in July 2013 from Lab 21 Limited, the Group entered into a TSA. The services provided by the Group to Lab 21 under the TSA comprise of mainly facilities and information technology. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

#### 5. PROFIT BEFORE TAX

The following amounts were charged / (credited) to the statement of operations:

|   | December 31, 2014<br>US\$`000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|---|-------------------------------|-------------------------------|-------------------------------|
| Directors' emoluments (including non-   |                               |                               |                               |
| executive directors):                   |                               |                               |                               |
| Remuneration                            | 2,353                         | 2,155                         | 1,812                         |
| Pension                                 | 87                            | 60                            | 270                           |
| Share based payments                    | 1,681                         | 2,008                         | 1,499                         |
| Auditors' remuneration                  |                               |                               |                               |
| Audit fees                              | 540                           | 586                           | 506                           |
| Non audit fees                          | 80                            | 123                           | 99                            |
| Depreciation*                           | 2,115                         | 1,688                         | 1,349                         |
| Amortisation                            | 2,380                         | 1,902                         | 1,482                         |
| Loss on the disposal of property, plant |                               |                               |                               |
| and equipment                           | _                             | <del></del>                   | 5                             |
| Net foreign exchange differences        | 207                           | 224                           | (41)                          |
| Restructuring costs                     | _                             | 690                           | _                             |
| Operating lease rentals:                |                               |                               |                               |
| Land and buildings                      | 3,795                         | 2,980                         | 2,447                         |
| Other equipment                         | 7                             | 6                             | 9                             |

<sup>\*</sup> Note that US\$61,000 (2013: US\$170,000) of depreciation was charged to research and development projects during 2014 in line with the Group's capitalisation policy for Intangible projects.

#### 6. PERSONNEL EXPENSES

|                      | December 31, 2014<br>US\$`000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|----------------------|-------------------------------|-------------------------------|-------------------------------|
| Wages and salaries   | 26,188                        | 22,504                        | 19,066                        |
| Social welfare costs | 2,663                         | 2,162                         | 1,842                         |
| Pension costs        | 833                           | 704                           | 669                           |
| Share-based payments | 2,769                         | 2,014                         | 1,713                         |
| Restructuring costs  | <del>_</del>                  | 690                           | _                             |
|                      | 32,453                        | 28,074                        | 23,290                        |

Personnel expenses are shown net of capitalisations. Total personnel expenses, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2014 amounted to US\$43,897,000 (2013: US\$37,455,000) (2012: US\$29,181,000). Total share based payments, inclusive of amounts capitalised in the balance sheet, amounted to US\$2,533,000 for the year ended December 31, 2014 (2013: US\$3,303,000) (2012: US\$2,640,000). See Note 18 for further details.

There were no restructuring costs incurred for the year ended December 31, 2014. Restructuring costs for the year ended December 31, 2013 were US\$690,000 and relate to UK operations.

The average number of persons employed by the Group in the financial year was 570 (2013: 496) (2012: 385) and is analysed into the following categories:

|                           | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2012 |
|---------------------------|----------------------|----------------------|----------------------|
| Research and development  | 83                   | 95                   | 57                   |
| Administration and sales  | 147                  | 127                  | 110                  |
| Manufacturing and quality | 340                  | 274                  | 218                  |
|                           | 570                  | 496                  | 385                  |

#### 7. PENSION SCHEMES

The Group operates defined contribution pension schemes for certain of its full time employees. The benefits under these schemes are financed by both Group and employee contributions. Total contributions made by the Group in the financial year and charged against income amounted to US\$833,000 (2013: US\$711,000) (2012: US\$837,000) (Note 6). The pension accrual for the Group at December 31, 2014 was US\$187,000 (2013: US\$333,000), (2012: US\$213,000).

#### 8. INCOME TAX EXPENSE

(a) The charge for tax based on the profit comprises:

|  | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$ '000 | December 31, 2012<br>US\$'000 |
|--|-------------------------------|--------------------------------|-------------------------------|
| Current tax expense                                |                               |                                |                               |
| Irish Corporation tax                              | (942)                         | (400)                          | 316                           |
| Foreign taxes (a)                                  | 808                           | 252                            | 176                           |
| Adjustment in respect of prior years               | 11                            | (27)                           | (154)                         |
| Total current tax expense                          | (123)                         | (175)                          | 338                           |
| Deferred tax expense (b)                           |                               |                                |                               |
| Origination and reversal of                        |                               |                                |                               |
| temporary differences (see Note                    |                               |                                |                               |
| 12)  | 1,354                         | 3,235                          | 2,599                         |
| Origination and reversal of net                    |                               |                                |                               |
| operating losses (see Note 12)                     | (378)                         | (2,486)                        | (920)                         |
| Total deferred tax expense                         | 976                           | 749                            | 1,679                         |
| Total income tax charge in statement of operations | 853                           | 574                            | 2,017                         |

(a) The foreign taxes relate primarily to USA, Canada and Sweden.

(b) In 2014, there was a deferred tax charge of US\$1,282,000 (2013: US\$393,000; 2012: US\$561,000) recognised in respect of Ireland and a deferred tax credit of US\$306,000 (2013: US\$356,000 charge; 2012: US\$1,118,000 charge) recognised in respect of overseas tax jurisdictions.

| Effective tax rate               | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|----------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Profit before taxation           | 18,067                        | 10,220                        | 19,358                        |
| As a percentage of profit before |                               |                               |                               |
| tax:                             |                               |                               |                               |
| Current tax                      | (0.68%)                       | (1.72%)                       | 1.75%                         |
| Total (current and deferred)     | 4.72%                         | 5.61%                         | 10.42%                        |

The following table reconciles the applicable Republic of Ireland statutory tax rate to the effective total tax rate for the Group:

|  | December 31, 2014 | December 31, 2013 | December 31, 2012 |
|--|-------------------|-------------------|-------------------|
| Irish corporation tax  | 12.5%             | 12.50%            | 12.50%            |
| Effect of current year net operating losses and temporary differences for which no |                   |                   |                   |
| deferred tax asset was recognised (a)  | 0.34%             | 5.13%             | 0.82%             |
| Effect of tax rates on overseas earnings   | (0.67%)           | (5.10%)           | (0.66%)           |
| Effect of Irish income taxable at higher tax                                       |                   |                   |                   |
| rate   | 0.08%             | 0.12%             | 0.13%             |
| Adjustments in respect of prior years  | 0.06%             | (0.27%)           | (0.80%)           |
| R&D tax credits  | (7.90%)           | (4.03%)           | (0.17%)           |
| Other items (b)  | 0.31%             | (2.74%)           | (1.40%)           |
| Effective tax rate   | 4.72%             | 5.61%             | 10.42%            |

(a) The effect of current year net operating losses and temporary differences for which no deferred tax asset was recognized is analyzed further in the table below (see also Note 12). No deferred tax asset was recognized because there was no reversing deferred tax liability in the same jurisdiction reversing in the same period and no future taxable income in the same jurisdiction.

#### 8. INCOME TAX EXPENSE (CONTINUED)

| Unrecognised deferred tax assets       | Effect in<br>2014<br>US\$'000 | Percentage<br>effect in<br>2014 | Effect in 2013<br>US\$'000 | Percentage<br>effect in<br>2013 |
|--|-------------------------------|---------------------------------|----------------------------|---------------------------------|
| Temporary differences arising in USA   | (23)                          | (0.13%)                         | 8                          | 0.08%                           |
| Net operating losses arising in Brazil | (313)                         | (1.73%)                         | 208                        | 2.04%                           |
| Net operating losses arising in UK     | 73                            | 0.40%                           | 73                         | 0.71%                           |
| Net operating losses arising in Sweden | 325                           | 1.80%                           | 235                        | 2.30%                           |
|  | 62                            | 0.34%                           | 524                        | 5.13%                           |

(b) Other items comprise items not chargeable to tax/expenses not deductible for tax.

### Deferred tax recognised directly in equity

|                                  | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|----------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Relating to forward contracts as |                               |                               |                               |
| hedged instruments               |                               |                               | <u> </u>                      |
|                                  |                               | _                             | 1                             |

a. The distribution of profit before taxes by geographical area was as follows:

|                         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|-------------------------|-------------------------------|-------------------------------|-------------------------------|
| Rest of World – Ireland | 8,368                         | 4,233                         | 10,992                        |
| Rest of World – Other   | 9,200                         | 4,185                         | 5,313                         |
| Americas                | 499                           | 1,802                         | 3,053                         |
|                         | 18,067                        | 10,220                        | 19,358                        |

b. At December 31, 2014, the Group had unutilised net operating losses as follows:

|         | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$`000 |
|---------|-------------------------------|-------------------------------|-------------------------------|
| USA     | 7,457                         | 9,795                         | 5,444                         |
| Ireland | 13,738                        | 8,073                         | _                             |
| Brazil  | 1,687                         | 768                           | 156                           |
| UK      | _                             | 317                           | _                             |
| Sweden  | _                             | 1,249                         | 347                           |
|         | 22,882                        | 20,202                        | 5,947                         |

In the USA, the utilisation of net operating loss carryforwards is limited to future profits in the USA. The net operating losses for USA have a maximum carryforward of 20 years. In respect of the USA, US\$672,000 will expire by December 31, 2031, US\$2,408,000 will expire by December 31, 2032 and US\$4,377,000 will expire by December 31, 2033.

#### 8. INCOME TAX EXPENSE (CONTINUED)

At December 31, 2014, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

|                                 | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 | December 31, 2012<br>US\$'000 |
|---------------------------------|-------------------------------|-------------------------------|-------------------------------|
| USA – unused tax credits        | 404                           | 381                           | 373                           |
| Brazil – unused tax losses      | 574                           | 261                           | 52                            |
| Sweden – unused tax losses      | _                             | 325                           | 90                            |
| UK – unused tax losses          |                               | 73                            |                               |
| Unrecognised Deferred Tax Asset | 978                           | 1,040                         | 515                           |

The accounting policy for deferred tax is to calculate the deferred tax asset that is deemed recoverable, considering all sources for future taxable profits. The deferred tax assets in the above table have not been recognised due to uncertainty regarding the full utilization of these losses in the related tax jurisdiction in future periods. Only when it is probable that future profits will be available to utilize the forward losses or temporary differences is a deferred tax asset recognised. When there is a reversing deferred tax liability in that jurisdiction that reverses in the same period, the deferred tax asset is restricted so that it equals the reversing deferred tax liability.

The Group has US state credit carryforwards of US\$404,000 at December 31, 2014 (2013: US\$ 381,000; 2012: US\$373,000). A deferred tax asset of US\$404,000 (2013: US\$ 381,000; 2012: US\$373,000) in respect of US state credit carryforwards was not recognized in 2014 due to uncertainties regarding future full utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

#### 9. EARNINGS PER SHARE

Basic earnings per ordinary share

Basic earnings per ordinary share for the Group is computed by dividing the profit after taxation of US\$17,214,000 (2013: US\$9,646,000) (2012: US\$17,341,000) for the financial year by the weighted average number of 'A' ordinary shares and 'B' ordinary shares in issue. As at December 31, 2014, this amounted to 90,998,904 shares (2013: 87,746,588 shares) (2012: 85,675,284 shares). As at December 31, 2011, 1,400,000 of the total weighted average shares used as the EPS denominator related to the 700,000 'B' ordinary shares which were in issue at that time. At an EGM held in September 2012, it was resolved that the 'B' ordinary shares would be converted to 'A' ordinary Shares (see below). Prior to this conversion, the 'B' ordinary shares were treated the same as 'A' ordinary shares except for the fact that they had two voting rights per share, rights to participate in any liquidation or sale of the Group and to receive dividends as if each Class 'B' ordinary share were two Class 'A' ordinary shares. Hence the earnings per share for a 'B' ordinary share was exactly twice the earnings per share of an 'A' ordinary share.

|  | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2012 |
|--|----------------------|----------------------|----------------------|
| 'A' ordinary shares  | 90,998,904           | 87,746,588           | 85,675,284           |
| 'B' ordinary shares (multiplied by 2)                              |                      |                      |                      |
| Basic earnings per share denominator                               | 90,998,904           | 87,746,588           | 85,675,284           |
| Reconciliation to weighted average earnings per share denominator: |                      |                      |                      |
| Number of A ordinary shares at January 1 (Note 17)                 | 92,296,506           | 88,994,069           | 85,321,081           |
| Weighted average number of shares issued during the year*          | 1,337,826            | 1,387,947            | 2,327,661            |
| Weighted average number of treasury shares                         | (2,635,428)          | (2,635,428)          | (1,973,458)          |
| Basic earnings per share denominator                               | 90,998,904           | 87,746,588           | 85,675,284           |

<sup>\*</sup> The weighted average number of shares issued during the year is calculated by taking the number of shares issued multiplied by the number of days in the year each share is in issue, divided by 365 days. In 2012, this includes the 700,000 'B' ordinary shares (equivalent to 1,400,000 'A' ordinary shares) up to the date of their conversion into 'A' ordinary shares on the 27 September 2012. Following on from the 'B' share conversion, 1,190,000 'A' ordinary shares were included in their place. In 2012, the weighted average number has been impacted by the Company's repurchase of its own shares (see Note 17). There were no repurchases of treasury shares in 2013 or 2014.

#### Diluted earnings per ordinary share

Diluted earnings per ordinary share is computed by dividing the profit after tax of US\$17,214,000 (2013: US\$9,646,000) (2012: US\$17,341,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 94,870,988 (2013: 93,712,698) (2012: 89,773,616).

The basic weighted average number of shares for the Group may be reconciled to the number used in the diluted earnings per ordinary share calculation as follows:

|  | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2012 |
|--|----------------------|----------------------|----------------------|
| Basic earnings per share denominator (see above) | 90,998,904           | 87,746,588           | 85,675,284           |
| Issuable on exercise of options and warrants     | 3,872,084            | 5,966,110            | 4,098,332            |
| Diluted earnings per share denominator           | 94,870,988           | 93,712,698           | 89,773,616           |

#### 9. EARNINGS PER SHARE (CONTINUED)

Earnings per ADS

In June 2005, Trinity Biotech adjusted its ADS ratio from 1 ADS: 1 ordinary share to 1 ADS: 4 ordinary shares. Earnings per ADS for all periods presented have been restated to reflect this exchange ratio.

Basic earnings per ADS for the Group is computed by dividing the profit after taxation of US\$17,214,000 (2013: US\$9,646,000) (2012: US\$17,341,000) for the financial year by the weighted average number of ADS in issue of 22,749,726 (2012: 21,936,647); (2012: 21,418,821).

|                                      | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2012 |
|--------------------------------------|----------------------|----------------------|----------------------|
| 'A' ordinary shares – ADS            | 22,749,726           | 21,936,647           | 21,418,821           |
| 'B' ordinary shares – ADS            |                      |                      |                      |
| Basic earnings per share denominator | 22,749,726           | 21,936,647           | 21,418,821           |

Diluted earnings per ADS for the Group is computed by dividing the profit after taxation of US\$17,214,000 (2013: US\$9,646,000) (2012: US\$17,341,000) for the financial year, by the diluted weighted average number of ADS in issue of 23,824,169 (2013: 23,428,175) (2012: 22,443,404).

The basic weighted average number of ADS shares for the Group may be reconciled to the number used in the diluted earnings per ADS share calculation as follows:

|  | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2012 |
|--|----------------------|----------------------|----------------------|
| Basic earnings per share denominator (see above) | 22,749,726           | 21,936,647           | 21,418,821           |
| Issuable on exercise of options and warrants     | 968,021              | 1,491,528            | 1,024,583            |
| Diluted earnings per share denominator           | 23,717,747           | 23,428,175           | 22,443,404           |

### 10. PROPERTY, PLANT AND EQUIPMENT

|  | Freehold land<br>and buildings<br>US\$'000 | Leasehold<br>improvements<br>US\$'000 | Computers,<br>fixtures and<br>fittings<br>US\$'000 | Plant and<br>equipment<br>US\$'000 | Total<br>US\$'000 |
|--|--|---------------------------------------|--|------------------------------------|-------------------|
| Cost   |  |                                       |  |                                    |                   |
| At January 1, 2013                             | 2,097                                      | 2,460                                 | 4,822  | 17,847                             | 27,226            |
| Acquisitions through business combinations     |  |                                       |  |                                    |                   |
| (Note 22)                                      | 560  | 42                                    | 358  | 421                                | 1,381             |
| Other additions                                |  | 241                                   | 322  | 4,051                              | 4,614             |
| Disposals or retirements                       |  |                                       | (193)  | (1,893)                            | (2,086)           |
| Exchange adjustments                           | (22)                                       | 3                                     | 2  | <u> 15</u>                         | (2)               |
| At December 31, 2013                           | 2,635                                      | 2,746                                 | 5,311  | 20,441                             | 31,133            |
| At January 1, 2014                             | 2,635                                      | 2,746                                 | 5,311  | 20,441                             | 31,133            |
| Other additions                                | 1  | 103                                   | 318  | 7,420                              | 7,842             |
| Disposals or retirements                       |  | (1)                                   | (8)  | (340)                              | (349)             |
| Exchange adjustments                           | (43)                                       | (36)                                  | (41)   | (532)                              | (652)             |
| At December 31, 2014                           | 2,593                                      | 2,812                                 | 5,580  | 26,989                             | 37,974            |
| Accumulated depreciation and impairment losses |  |                                       |  |                                    |                   |
| At January 1, 2013                             | (902)                                      | (2,135)                               | (4,001)  | (11,305)                           | (18,343)          |
| Charge for the year                            | (71)                                       | (133)                                 | (296)  | (1,358)                            | (1,858)           |
| Disposals or retirements                       | _  | _                                     | 192  | 1,868                              | 2,060             |
| Exchange adjustments                           |  |                                       |  | (1)                                | (1)               |
| At December 31, 2013                           | (973)                                      | (2,268)                               | (4,105)  | (10,796)                           | (18,142)          |
| At January 1, 2014                             | (973)                                      | (2,268)                               | (4,105)  | (10,796)                           | (18,142)          |
| Charge for the year                            | (78)                                       | (138)                                 | (425)  | (1,535)                            | (2,176)           |
| Disposals or retirements                       | _  | _                                     | 1  | 189                                | 190               |
| Exchange adjustments                           | 1  | 5                                     | 9  | 16                                 | 31                |
| At December 31, 2014                           | (1,050)                                    | (2,401)                               | (4,520)  | (12,126)                           | (20,097)          |
| Carrying amounts                               |  |                                       |  |                                    |                   |
| At December 31, 2014                           | 1,543                                      | 411                                   | 1,060  | 14,863                             | 17,877            |
| At December 31, 2013                           | 1,662                                      | 478                                   | 1,206  | 9,645                              | 12,991            |

The annual impairment review performed at December 31, 2014 and December 31, 2013, showed that the carrying value of the Group's assets did not exceed the amount that could be recovered through their use or sale and, on that basis, there was no impairment in 2014 or 2013.

#### 10. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

#### Assets held under operating leases (where the Company is the lessor)

Included in the carrying amount of property, plant and equipment are a number of assets included in plant and equipment which generate operating lease revenue for the Group. The net book value of these assets as at December 31, 2014 is US\$1,149,000 (2013: US\$749,000). Depreciation charged on these assets in 2014 amounted to US\$458,000 (2013: US\$347,000).

Included in disposals/retirements in 2014 is US\$84,000 (2013: US\$26,000) relating to the net book value of leased instruments reclassified as inventory on return from customers.

#### Property, plant and equipment under construction

Included in property, plant and equipment at December 31, 2014 is an amount of US\$4,769,000 (2013: US\$3,044,000) relating to assets in the course of construction.

### 11. GOODWILL AND INTANGIBLE ASSETS

|  | Goodwill<br>US\$'000 | Development<br>costs<br>US\$`000 | Patents and<br>licences<br>US\$'000 | Other<br>US\$'000 | Total<br>US\$'000 |
|--|----------------------|----------------------------------|-------------------------------------|-------------------|-------------------|
| Cost   |                      |                                  |                                     |                   |                   |
| At January 1, 2013                                   | 56,173               | 52,072                           | 10,884                              | 20,785            | 139,914           |
| Acquisitions through business combinations (Note 22) | 26,428               | _                                | _                                   | 12,339            | 38,767            |
| Other additions                                      | _                    | 18,390                           | _                                   | 109               | 18,499            |
| Exchange Adjustments                                 | 76                   |                                  | 61                                  |                   | 137               |
| At December 31, 2013                                 | 82,677               | 70,462                           | 10,945                              | 33,233            | 197,317           |
| At January 1, 2014                                   | 82,677               | 70,462                           | 10,945                              | 33,233            | 197,317           |
| Other additions                                      | 1,068                | 20,323                           | 20                                  | 159               | 21,570            |
| Disposals / retirements                              | _                    | _                                | _                                   | (43)              | (43)              |
| Exchange Adjustments                                 | (1,213)              | (747)                            | (723)                               | (1)               | (2,684)           |
| At December 31, 2014                                 | 82,532               | 90,038                           | 10,242                              | 33,348            | 216,160           |
| Accumulated amortisation and Impairment losses       |                      |                                  |                                     |                   |                   |
| At January 1, 2013                                   | (29,426)             | (18,368)                         | (5,976)                             | (13,098)          | (66,868)          |
| Charge for the year                                  |                      | (446)                            | (93)                                | (1,363)           | (1,902)           |
| At December 31, 2013                                 | (29,426)             | (18,814)                         | (6,069)                             | (14,461)          | (68,770)          |
| At January 1, 2014                                   | (29,426)             | (18,814)                         | (6,069)                             | (14,461)          | (68,770)          |
| Charge for the year                                  |                      | (562)                            | (84)                                | (1,734)           | (2,380)           |
| Disposals / retirements                              |                      |                                  |                                     | 14                | 14                |
| At December 31, 2014                                 | (29,426)             | (19,376)                         | (6,153)                             | (16,181)          | (71,136)          |
| Carrying amounts                                     |                      |                                  |                                     |                   |                   |
| At December 31, 2014                                 | 53,106               | 70,662                           | 4,089                               | 17,167            | 145,024           |
|  |                      |                                  |                                     |                   |                   |
| At December 31, 2013                                 | 53,251               | 51,648                           | 4,876                               | 18,772            | 128,547           |

Included within development costs are costs of US\$41,665,000 which were not amortised in 2014 (2013: US\$26,264,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at December 31, 2014 or at December 31, 2013. As at December 31, 2014 these projects are expected to be completed during the period from January 1, 2015 to December 31, 2017 at an expected further cost of approximately US\$16,843,000.

### 11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

The following represents the costs incurred during each period presented for each of the principal development projects:

| Product Name  | 2014<br>US\$'000 | 2013<br>US\$'000 |
|---|------------------|------------------|
| Brain Natriuretic Peptide (BNP) assay                       | 4,400            | 1,204            |
| Premier Instrument for Haemoglobin A1c testing <sup>1</sup> | 3,375            | 3,861            |
| Troponin I assay and reader <sup>2</sup>                    | 3,370            | 7,200            |
| Genesys/Resolution column enhancement                       | 725              | 685              |
| Tristat Point-of-Care instrument                            | 689              | 481              |
| US Striped Lyme   | 684              | 230              |
| Uni-gold test enhancement                                   | 675              |                  |
| HIV 1/2 rapid test  | 587              | 121              |
| D-Dimer development   | 580              |                  |
| Malaria Point-of-Care test                                  | 485              | 23               |
| H Pylori Rapid Point-of-Care test                           | 462              | 499              |
| Cardiac analyser  | 423              |                  |
| Unigold Recombigen HIV Rapid enhancement                    | 398              | 463              |
| Enhanced TPHA/CMV   | 347              |                  |
| IgM Captia  | 314              | 363              |
| Syphilis Rapid Point-of-Care test                           | 260              | 859              |
| LIA Panels  | 251              | 59               |
| Ion Exchange  | 247              | 22               |
| Uni-Gold antigen improvement                                | 247              | 166              |
| Sjögren's Early Marker Test                                 | 232              |                  |
| Ro60 Transfection   | 186              | 47               |
| CCP ELISA   | 170              | 60               |
| AMA M2 ELISA  | 161              | _                |
| Parvo   | 128              | 22               |
| Antigen Projects  | 130              | _                |
| Unigold 8mm Expansion Study                                 | 111              | 28               |
| Western Blot Yield Enhancement                              | 106              | _                |
| Other projects with spend less than US\$100,000 in 2014     | 580              | 1,997            |
| Total capitalized development costs                         | 20,323           | 18,390           |

<sup>1.</sup> The Premier project entails the development of a High Performance Liquid Chromotography (HPLC) instrument for testing haemoglobin A1c (HbA1c). Several versions of the instrument are being developed including an Ion Exchange version. At December 31, 2014 this project had a total carrying amount of \$17,854,000. Amortisation will occur over a 15 year period, commencing on commercialization of each version of the instrument.

#### 11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

2. The Troponin I assay and reader project commenced in 2012 following the acquisition of Fiomi Diagnostics AB in February 2012 (see Note 22). The amount of US\$3,370,000 incurred in 2014 represents the costs incurred on this project during the year and, as the project is not yet complete, no amortisation has been charged to date.

All of the development projects for which costs have been capitalized are judged to be technically feasible, commercially viable and likely to produce future economic benefits. In reaching this conclusion, many factors have been considered including the following:

- (a) The Group only develops products within its field of expertise. The R&D team is experienced in developing new products in this field and this experience means that only products which have a high probability of technical success are put forward for consideration as potential new products.
- (b) A technical feasibility study is undertaken in advance of every project. The feasibility study for each project is reviewed by the R&D team leader, and by other senior management depending on the size of the project. The feasibility study occurs in the initial research phase of the project and costs in this phase are not capitalized.
- (c) Nearly all of our new product developments involve the transfer of our existing product know-how to a new application. The Group does not engage in pure research. Every development project is undertaken with the intention of bringing a particular new product to market for which there is a known demand.
- (d) The commercial feasibility of each new product is established prior to commencement of a project by ensuring it is projected to achieve an acceptable income after applying appropriate discount rates.

#### Other intangible assets

Other intangible assets consist primarily of acquired customer and supplier lists, trade names, website and software costs.

#### Amortisation

Amortisation is charged to the statement of operations through the selling, general and administrative expenses line.

#### Impairment testing for intangibles including goodwill and indefinite lived assets

Goodwill and other intangibles are subject to impairment testing on an annual basis. The recoverable amount of each of the cash-generating units ("CGU") is determined based on a value-in-use computation, which is the only methodology applied by the Group and which has been selected due to the impracticality of obtaining fair value less costs to sell measurements for each reporting period. For the purpose of the annual impairment tests, goodwill is allocated to the relevant CGU. The annual impairment analysis is based on a valuation technique involving level 3 inputs, see Note 1 (xxvi).

The value-in-use calculations use cash flow projections based on the 2015 budget and projections for a further four years using projected revenue and cost growth rates of between 3% and 15%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate, are used in the value-in-use calculations. The value-in-use represents the present value of the future cash flows, including the terminal value, discounted at a rate appropriate to each CGU. The key assumptions employed in arriving at the estimates of future cash flows are subjective and include projected EBITDA, net cash flows, discount rates and the duration of the discounted cash flow model. The assumptions and estimates used were derived from a combination of internal and external factors based on historical experience. The pre-tax discount rates used range from 12% to 24% (2013: 13% to 25%).

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas;

- 1. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss or write back would be recorded at December 31, 2014:
- No reversal of impairment in the event of a 10% increase in the growth in revenues.
- No impairment loss in the event of a 10% decrease in the growth in revenues.

#### 11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

- 2. Similarly if there was a 10% variation in the discount rate used to calculate the potential impairment of the carrying values, which would represent a reasonably likely range of outcomes, there would be the following impairment loss or write back would be recorded at December 31, 2014:
- No reversal of impairment in the event of a 10% decrease in the discount rate.
- No impairment loss in the event of a 10% increase in the discount rate.

### Significant Goodwill and Intangible Assets with Indefinite Useful Lives

CGUs or combinations of CGUs for which the carrying amount of goodwill is significant for the purposes of impairment testing in comparison with the Group's total carrying amount of goodwill are those where the percentage is greater than 20% of the total.

The additional disclosures required for the CGU with significant goodwill are as follows:

|  | Immco Diagnostics    |                      | Fitzgerald I         | ndustries            |
|--|----------------------|----------------------|----------------------|----------------------|
|  | December 31,<br>2014 | December 31,<br>2013 | December 31,<br>2014 | December 31,<br>2013 |
| Carrying amount of goodwill (US\$'000)   | 20,365               | 20,365               | 12,592               | 12,592               |
| Discount rate applied (real pre-tax)     | 17.91%               | 19.40%               | 11.80%               | 12.85%               |
| Excess value-in-use over carrying amount |                      |                      |                      |                      |
| (US\$'000)                               | 25,567               | 12,748               | 27,107               | 25,363               |
| % EBITDA would need to decrease for an   |                      |                      |                      |                      |
| impairment to arise                      | 37.6%                | 24.30%               | 55.0%                | 53.90%               |

The key assumptions and methodology used in respect of this CGU are consistent with those described above. The assumptions and estimates used are specific to the individual CGU and were derived from a combination of internal and external factors based on historical experience.

| Intangible Assets with Indefinite Useful lives (included in other intangibles) | December 31, 2014<br>US\$`000 | December 31, 2013<br>US\$'000 |
|--|-------------------------------|-------------------------------|
| Fitzgerald Industries International CGU  |                               |                               |
| Fitzgerald trade name  | 970                           | 970                           |
| RDI trade name   | 560                           | 560                           |
| Primus Corporation CGU   |                               |                               |
| Primus trade name  | 670                           | 670                           |
| Immco Diagnostic CGU   |                               |                               |
| Immco Diagnostic trade name  | 3,393                         | 3,393                         |
| Total  | 5,593                         | 5,593                         |

The trade name assets purchased as part of the acquisition of Fitzgerald in 2004, Primus and RDI in 2005 and Immco Diagnostics in 2013 were valued using the relief from royalty method and based on factors such as (1) the market and competitive trends and (2) the expected usage of the name. It was considered that these trade names will generate net cash inflows for the Group for an indefinite period.

#### 12. DEFERRED TAX ASSETS AND LIABILITIES

#### Recognised deferred tax assets and liabilities

Deferred tax assets and liabilities of the Group are attributable to the following:

|  | Assets   |          | Liabilities |          | Net      |          |
|--|----------|----------|-------------|----------|----------|----------|
|  | 2014     | 2013     | 2014        | 2013     | 2014     | 2013     |
|  | US\$'000 | US\$'000 | US\$'000    | US\$'000 | US\$'000 | US\$'000 |
| Property, plant and equipment              | 22       | 129      | (1,024)     | (806)    | (1,002)  | (677)    |
| Intangible assets                          | _        | _        | (18,874)    | (16,048) | (18,874) | (16,048) |
| Inventories                                | 813      | 659      | _           | _        | 813      | 659      |
| Provisions                                 | 3,061    | 800      |             |          | 3,061    | 800      |
| Other items                                | 1,184    | 1,116    | (1,541)     | (1,049)  | (357)    | 67       |
| Tax value of loss carryforwards recognised | 4,718    | 4,340    |             |          | 4,718    | 4,340    |
| Deferred tax assets/(liabilities)          | 9,798    | 7,044    | (21,439)    | (17,903) | (11,641) | (10,859) |

The deferred tax asset in 2014 is mainly due to deductible temporary differences relating to net operating losses, provisions, share-based payments and the elimination of unrealised intercompany inventory profit. The deferred tax asset increased by US\$2,754,000 in 2014 principally due to increases in provisions and net operating losses carried forward.

The deferred tax liability is caused by the net book value of non-current assets being greater than the tax written down value of non-current assets, temporary differences due to the acceleration of the recognition of certain charges in calculating taxable income permitted in Ireland and the USA and deferred tax recognised on fair value asset uplifts in connection with business combinations. The deferred tax liability increased by US\$3,536,000 in 2014, principally because of increased temporary differences between the carrying value of assets and their asset base due to the capital expenditure incurred during 2014.

Deferred tax assets and liabilities are only offset when the entity has a legally enforceable right to set off current tax assets against current tax liabilities and where the intention is to settle current tax liabilities and assets on a net basis or to realise the assets and settle the liabilities simultaneously. At December 31, 2014 and at December 31, 2013 no deferred tax assets and liabilities are offset as it is not certain as to whether there is a legally enforceable right to set off current tax assets against current tax liabilities and it is also uncertain as to what current tax assets may be set off against current tax liabilities and in what periods.

#### Unrecognised deferred tax assets

Deferred tax assets have not been recognised by the Group in respect of the following items:

|                               | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-------------------------------|-------------------------------|-------------------------------|
| Capital losses                | 8,293                         | 8,513                         |
| Net operating losses          | 1,687                         | 2,334                         |
| US state credit carryforwards | 404                           | 381                           |
|                               | 10,384                        | 11,228                        |

#### 12. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

There was a decrease of US\$624,000 in the unrecognised deferred tax assets during the year ended December 31, 2014. For comments on the uncertainty prompting less than full recognition refer to Note 8. The movement in the unrecognised deferred tax assets during the year ended December 31, 2014 is analysed as follows:

|  | Increase /<br>(decrease) | Applicable tax rate | Tax<br>effect |
|--|--------------------------|---------------------|---------------|
| Movement in Unrecognised deferred tax assets | US\$'000                 | %                   | US\$'000      |
| Net operating losses Brazil                  | 920                      | 34%                 | 313           |
| Net operating losses UK                      | (318)                    | 23%                 | (73)          |
| Net operating losses Sweden                  | (1,249)                  | 26%                 | (325)         |
| US state credit carryforwards                | 23                       | <u>n/a</u>          | 23            |
|  | (624)                    |                     | (62)          |

A deferred tax asset of US\$404,000 (2013: US\$381,000) in respect of US state credit carryforwards was not recognised due to uncertainties regarding the timing of the utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

A deferred tax asset of US\$574,000 was not recognised in respect of net operating losses in Brazil. The entity in Brazil was incorporated in 2012 and has made losses to date. The deferred tax asset has not been recognised for Brazil due to uncertainty regarding the full utilization of these losses in the related tax jurisdiction in future periods. Only when it is probable that future profits will be available to utilize the forward losses or temporary differences is a deferred tax asset recognised.

No deferred tax asset is recognised in respect of a capital loss forward of US\$8,293,000 (2013: US\$8,513,000) in Ireland as it is not probable that there will be future capital gains against which to offset these capital losses.

#### Unrecognised deferred tax liabilities

At December 31, 2014 and 2013, there was no recognised or unrecognised deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Company is able to control the timing of the reversal of the temporary differences of its subsidiaries and it is probable that these temporary differences will not reverse in the foreseeable future.

#### Movement in temporary differences during the year

|  | Balance                               |               | Foreign  | Balance      |
|--|---------------------------------------|---------------|----------|--------------|
|  | January, 1                            | Recognised in | Exchange | December 31, |
|  | 2014                                  | income        | movement | 2014         |
|  | US\$'000                              | US\$'000      | US\$'000 | US\$'000     |
| Property, plant and equipment              | (677)                                 | (325)         | _        | (1,002)      |
| Intangible assets                          | (16,048)                              | (3,020)       | 194      | (18,874)     |
| Inventories                                | 659                                   | 154           | _        | 813          |
| Provisions                                 | 800                                   | 2,261         |          | 3,061        |
| Other items                                | 67                                    | (424)         | _        | (357)        |
| Tax value of loss carryforwards recognised | 4,340                                 | 378           |          | 4,718        |
|  | (10,859)                              | (976)         | 194      | (11,641)     |
|  | · · · · · · · · · · · · · · · · · · · |               |          |              |

#### 12. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

|  | Balance<br>January, 1<br>2013<br>US\$'000 | Recognised in<br>income<br>US\$'000 | Recognised<br>in goodwill<br>US\$'000 | Balance<br>December 31,<br>2013<br>US\$'000 |
|--|---|-------------------------------------|---------------------------------------|---|
| Property, plant and equipment              | (401)                                     | (276)                               | _                                     | (677)                                       |
| Intangible assets                          | (9,516)                                   | (3,092)                             | (3,440)                               | (16,048)                                    |
| Inventories                                | 647                                       | 12                                  | _                                     | 659   |
| Provisions                                 | 575                                       | 225                                 |                                       | 800   |
| Other items                                | 171                                       | (104)                               | _                                     | 67  |
| Tax value of loss carryforwards recognised | 1,854                                     | 2,486                               |                                       | 4,340                                       |
|  | (6,670)                                   | (749)                               | (3,440)                               | (10,859)                                    |

#### 13. OTHER ASSETS

|   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|---|-------------------------------|-------------------------------|
| Finance lease receivables (see Note 15) | 1,116                         | 1,084                         |
| Other assets                            | 78                            | 78                            |
|   | 1,194                         | 1,162                         |

The Group leases instruments as part of its business. For details of future minimum finance lease receivables with non-cancellable terms, please refer to Note 15.

#### 14. INVENTORIES

|                               | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-------------------------------|-------------------------------|-------------------------------|
| Raw materials and consumables | 10,887                        | 8,514                         |
| Work-in-progress              | 7,986                         | 6,136                         |
| Finished goods                | 14,643                        | 15,020                        |
|                               | 33,516                        | 29,670                        |

All inventories are stated at the lower of cost or net realisable value. Total inventories for the Group are shown net of provisions of US\$4,636,000 (2013: US\$4,462,000). Cost of sales in 2014 includes inventories expensed of US\$54,029,000 (2013: US\$46,037,000), (2012: US\$39,784,000).

The movement on the inventory provision for the three year period to December 31, 2014 is as follows:

|                                  | December 31,<br>2014<br>US\$'000 | December 31,<br>2013<br>US\$'000 | December 31,<br>2012<br>US\$'000 |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Opening provision at January 1   | 4,462                            | 5,348                            | 5,930                            |
| Charged during the year          | 603                              | 123                              | 824                              |
| Utilised during the year         | (322)                            | (845)                            | (1,055)                          |
| Released during the year         | (107)                            | (164)                            | (351)                            |
| Closing provision at December 31 | 4,636                            | 4,462                            | 5,348                            |

During 2014 US\$107,000 (2013: US\$164,000), (2012: US\$351,000) of inventory provision relating to net realisable value was released to the statement of operations following a current year review of inventory usage.

#### 15. TRADE AND OTHER RECEIVABLES

|   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|---|-------------------------------|-------------------------------|
| Trade receivables, net of impairment losses | 20,277                        | 19,762                        |
| Prepayments                                 | 4,852                         | 3,106                         |
| Value added tax                             | 273                           | 886                           |
| Finance lease receivables                   | 574                           | 514                           |
|   | 25,976                        | 24,268                        |

Trade receivables are shown net of an impairment losses provision of US\$2,205,000 (2013: US\$2,150,000) (see Note 25).

#### Leases as lessor

(i) Finance lease commitments – Group as lessor

The Group leases instruments as part of its business. Future minimum finance lease receivables with non-cancellable terms are as follows:

|                                      |                     | December 31, 2014<br>US\$'000 | Minimum                |
|--------------------------------------|---------------------|-------------------------------|------------------------|
|                                      | Gross investment    | Unearned income               | payments<br>receivable |
| Less than one year                   | 966                 | 392                           | 574                    |
| Between one and five years (Note 13) | 1,950               | 834                           | 1,116                  |
|                                      | 2,916               | 1,226                         | 1,690                  |
|                                      |                     | December 31, 2013<br>US\$'000 |                        |
|                                      |                     | T.T 1                         | Minimum                |
|                                      | Gross<br>investment | Unearned income               | payments<br>receivable |
| Less than one year                   | 839                 | 325                           | 514                    |
| Between one and five years (Note 13) | 1,869               | 785                           | 1,084                  |
|                                      | 2,708               | 1,110                         | 1,598                  |

The Group classified future minimum lease receivables between one and five years of US\$1,116,000 (2013: US\$1,084,000) as Other Assets, see Note 13. Under the terms of the lease arrangements, no contingent rents are receivable.

#### 15. TRADE AND OTHER RECEIVABLES (CONTINUED)

#### (ii) Operating lease commitments – Group as lessor

The Group has leased a facility consisting of 9,000 square feet in Dublin, Ireland. This property has been sub-let by the Group. The lease contains a clause to enable upward revision of the rent charge on a periodic basis. The Group also leases instruments under operating leases as part of its business.

Future minimum rentals receivable under non-cancellable operating leases are as follows:

|                            |                    | December 31, 2014<br>US\$'000 |       |
|----------------------------|--------------------|-------------------------------|-------|
|                            | Land and buildings | Instruments                   | Total |
| Less than one year         | 219                | 707                           | 926   |
| Between one and five years | 155                | 725                           | 880   |
|                            | 374                | 1,432                         | 1,806 |
|                            |                    |                               |       |
|                            |                    | December 31, 2013<br>US\$'000 |       |
|                            | Land and           |                               |       |
|                            | buildings          | Instruments                   | Total |
| Less than one year         | 232                | 1,137                         | 1,369 |
| Between one and five years | 403                | 780                           | 1,183 |
|                            |                    |                               |       |

### 16. CASH AND CASH EQUIVALENTS

|   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|---|-------------------------------|-------------------------------|
| Cash at bank and in hand                                  | 7,221                         | 9,034                         |
| Short-term deposits                                       | 1,881                         | 13,283                        |
| Cash and cash equivalents in the statements of cash flows | 9,102                         | 22,317                        |

#### 17. CAPITAL AND RESERVES

Share capital

|   | Class 'A'       | Class 'A'       |
|---|-----------------|-----------------|
|   | Ordinary shares | Ordinary shares |
| In thousands of shares                      | 2014            | 2013            |
| In issue at January 1                       | 92,296          | 88,994          |
| Issued for cash                             | 2,012           | 3,280           |
| Issued as part of acquisition consideration |                 | 22              |
| In issue at December 31                     | 94,308          | 92,296          |

#### 17. CAPITAL AND RESERVES (CONTINUED)

|   | Class 'A'<br>Treasury shares | Class 'A'<br>Treasury shares |
|---|------------------------------|------------------------------|
| In thousands of shares                              | 2014                         | 2013                         |
| Balance at January 1                                | 2,635                        | 2,635                        |
| Purchased during the year                           | _                            |                              |
| Issued as part of acquisitions made during the year | _                            | _                            |
| Balance at December 31                              | 2,635                        | 2,635                        |

The Group had authorised share capital of 200,700,000 'A' ordinary shares of US\$0.0109 each (2013: 200,700,000 'A' ordinary shares of US\$0.0109 each) and Nil 'B' ordinary shares (2013: Nil 'B' ordinary shares of US\$0.0109 each) as at December 31, 2014.

- (a) During 2014, the Group issued 2,012,000 'A' Ordinary shares from the exercise of employee options for a consideration of US\$3,642,000 settled in cash. The Group incurred costs of US\$40,000 in connection with the issue of shares. All shares in issue at December 31, 2014 are fully paid up.
- (b) The Group acquired Immco Diagnostics Inc (see Note 22) during 2013. As part of the purchase consideration, the Group issued 22,264 'A' Ordinary Shares (5,566 ADS's).
- (c) Following shareholder approval at the 2014 AGM, the Board approved the payment of a final dividend of 22 cents per ADS in respect of the 2013 financial year (20 cents per ADS in respect of the 2012 financial year), (15 cents per ADS in respect of the 2011 financial year). As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars (see Note 26 for further information).
- (d) During 2012, the Group purchased 1,829,000 'A' Ordinary shares (457,000 ADS's) 'Treasury shares'. The total cost of these shares was US\$5,343,000. There was no purchase of treasury shares in 2013 or 2014.
- (e) An Extraordinary General Meeting ('EGM') of the Company was held on 27 September 2012 and, at this meeting, it was approved by the shareholders that the 700,000 existing 'B' Ordinary Shares be redesignated as 'A' Ordinary Shares. It was further approved that a bonus issue of 490,000 'A' Ordinary Shares be allocated to the existing 'B' Ordinary Shareholders on the basis of 7,000 'A' Ordinary Shares per existing holding of 10,000 'B' Ordinary Shares and that, following this, the Class 'B' Shareholding be cancelled.

Prior to this EGM, the 'B' Ordinary Shares had two votes per share and had the right to participate in any liquidation or sale of the Group and to receive dividends as if each Class 'B' Ordinary Share were two Class 'A' Ordinary Shares.

#### Share Premium

Following the passing of a Special Resolution of the Company in September 2010 and the approval of a petition placed before the High Court of Ireland, the Company was permitted to reduce its share premium in the amount of US\$160,000,000 during 2011. This amount was, therefore, transferred to retained earnings in the 2011 financial statements.

#### Currency translation reserve

The currency translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of foreign currency denominated operations of the Group since January 1, 2004.

#### Warrant reserve

The Group calculates the fair value of warrants at the date of issue taking the amount directly to a separate reserve within equity. The fair value is calculated using the trinomial model. The fair value which is assessed at the grant date is calculated on the basis of the contractual term of the warrants.

In accordance with IFRS 2, 3,477,068 warrants with a fair value of US\$4,529,000 (2013: 3,477,068 warrants with a fair value of US\$4,529,000) have been classified as a separate reserve. There were no new warrants issued by the Group in 2014 or 2013.

#### 17. CAPITAL AND RESERVES (CONTINUED)

#### Hedging reserve

The hedging reserve comprises the effective portion of the cumulative net change in the fair value of cash flow hedging instruments related to hedged transactions entered into but not yet crystallised.

#### 18. SHARE OPTIONS AND SHARE WARRANTS

#### Warrants

There were no warrants granted in either 2014 or 2013.

|                                  | December 31, 2014<br>Class 'A' Ordinary<br>Shares | December 31, 2013<br>Class 'A' Ordinary<br>Shares |
|----------------------------------|---|---|
| Outstanding at beginning of year | _   | 933,120   |
| Exercised                        | <del>_</del>                                      | (924,120)   |
| Expired                          |   | (9,000)   |
| Outstanding at end of year       |   |   |

#### **Options**

Under the terms of the Company's Employee Share Option Plans, options to purchase 9,291,652 'A' Ordinary Shares were outstanding at December 31, 2014. Under the Plans, options are granted to officers, employees and consultants of the Group at the discretion of the Compensation Committee (designated by the board of directors), under the terms outlined below.

Certain options have been granted to consultants of the Group and, where this is the case, the Group has measured the fair value of the services provided by these consultants by reference to the fair value of the equity instruments granted. This approach has been adopted in these cases as it is impractical for the Group to reliably estimate the fair value of such services.

The terms and conditions of the grants are as follows, whereby all options are settled by physical delivery of shares:

#### Vesting conditions

The options vest following a period of service by the officer or employee. The required period of service is determined by the Compensation Committee at the date of grant of the options (usually the date of approval by the Compensation Committee) and it is generally over a three to four year period. There are no market conditions associated with the share option vesting periods.

### Contractual life

The term of an option is determined by the Board, Compensation Committee, and Remuneration Committee provided that the term may not exceed a period of between seven to ten years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with the Group (or one year after such termination because of death or disability) except where a longer period is approved by the Board of Directors. Under certain circumstances involving a change in control of the Group, the Compensation Committee may accelerate the exercisability and termination of options.

### 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The number and weighted average exercise price of share options and warrants per ordinary share is as follows (as required by IFRS 2, this information relates to all grants of share options and warrants by the Group):

|   | Options and<br>warrants<br>'A' Ordinary<br>Shares  | Weighted-<br>average exercise<br>price<br>US\$<br>Per 'A' Ordinary<br>Share  | Range<br>US\$<br>Per 'A' Ordinary<br>Share  |
|---|--|--|---|
| Outstanding January 1, 2012   | 9,022,354  | 1.40   | 0.66 - 2.80   |
| Granted   | 4,098,000  | 2.59   | 2.50 - 3.27   |
| Exercised   | (2,663,636)  | 1.17   | 0.66 - 2.23   |
| Forfeited   | (30,000)   | 1.57   | 1.52 - 1.65   |
| Outstanding at end of year  | 10,426,718   | 1.93   | 0.66 - 3.27   |
| Exercisable at end of year  | 4,389,052  | 1.43   | 0.66 - 2.80   |
| Outstanding January 1, 2013   | 10,426,718   | 1.93   | 0.66 - 3.27   |
| Granted   | 3,027,652  | 3.93   | 1.66 - 4.79   |
| Exercised   | (3,625,961)  | 1.44   | 0.66 - 2.80   |
| Forfeited   | (47,000)   | 1.52   | 1.39 - 1.78   |
| Outstanding at end of year  | 9,781,409  | 2.73   | 0.66 - 4.79   |
| Exercisable at end of year  | 3,018,915  | 1.89   | 0.66 - 3.27   |
| Outstanding January 1, 2014   | 9,781,409  | 2.73   | 0.66 - 4.79   |
| Granted   | 2,018,000  | 4.22   | 4.21 - 4.34   |
| Exercised   | (2,048,092)  | 1.91   | 1.07 - 4.21   |
| Forfeited   | (459,665)  | 3.53   | 1.50 - 4.21   |
| Outstanding at end of year  | 9,291,652  | 3.20   | 0.66 - 4.79   |
| Exercisable at end of year  | 4,056,991  | 2.56   | 0.66 - 4.21   |
|   |  |  |   |
|   | Options and warrants   | Weighted-<br>average exercise<br>price<br>US\$<br>Per 'ADS'  | Range<br>US\$<br>Per 'ADS'  |
| Outstanding January 1, 2012   | warrants 'ADS' Equivalent  | average exercise<br>price<br>US\$<br>Per 'ADS'   | US\$<br>Per 'ADS'   |
| Outstanding January 1, 2012 Granted   | warrants   | average exercise<br>price<br>US\$  | US\$  |
|   | warrants 'ADS' Equivalent 2,255,589  | average exercise price US\$ Per 'ADS' 5.60   | US\$<br>Per 'ADS'<br>2.63 – 11.20   |
| Granted   | warrants 'ADS' Equivalent 2,255,589 1,024,500  | average exercise price US\$ Per 'ADS' 5.60 10.36   | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08   |
| Granted Exercised   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909)  | average exercise price US\$ Per 'ADS' 5.60 10.36 4.68  | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  |
| Granted Exercised Forfeited   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500)  | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72  | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20   |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680  | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72   | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08   |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912  | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71   | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15   |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490)  | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74  | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20   |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750)   | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08                                   | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year  | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490)  | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74  | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 19.15  |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year   | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750)   | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08                                   | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2014                                       | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750) 2,445,352 754,729 2,445,352                             | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08 10.92 7.56 10.92                  | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 13.08  2.63 - 19.15  |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2014 Granted                               | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750) 2,445,352 754,729 2,445,352 504,500                     | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08 10.92 7.56 10.92 16.88            | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 13.08  2.63 - 19.15  16.84 - 17.36                             |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2014 Granted Exercised                     | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750) 2,445,352 754,729 2,445,352 504,500 (512,023)           | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08 10.92 7.56 10.92 16.88 7.64       | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 13.08  2.63 - 19.15  16.84 - 17.36  4.28 - 16.84               |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2014 Granted Exercised Forfeited Forfeited | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750) 2,445,352 754,729 2,445,352 504,500 (512,023) (114,916) | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08 10.92 7.56 10.92 16.88 7.64 14.12 | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 13.08  2.63 - 19.15  16.84 - 17.36  4.28 - 16.84  6.00 - 16.84 |
| Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2013 Granted Exercised Forfeited Outstanding at end of year Exercisable at end of year Outstanding January 1, 2014 Granted Exercised                     | warrants 'ADS' Equivalent 2,255,589 1,024,500 (665,909) (7,500) 2,606,680 1,097,263 2,606,680 756,912 (906,490) (11,750) 2,445,352 754,729 2,445,352 504,500 (512,023)           | average exercise price US\$ Per 'ADS'  5.60 10.36 4.68 6.28 7.72 5.72 7.72 15.71 5.74 6.08 10.92 7.56 10.92 16.88 7.64       | US\$ Per 'ADS'  2.63 - 11.20  10.00 - 13.08  2.63 - 8.92  6.08 - 6.60  2.63 - 13.08  2.63 - 11.20  2.63 - 13.08  6.64 - 19.15  2.63 - 11.20  5.54 - 7.12  2.63 - 13.08  2.63 - 19.15  16.84 - 17.36  4.28 - 16.84               |

#### 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The weighted average share price per 'A' Ordinary share at the date of exercise for options exercised in 2014 was: US\$5.19 (\$20.76 per ADS), 2013: US\$5.10 per 'A' Ordinary share (US\$20.40 per ADS) and 2012: US\$3.13 per 'A' Ordinary share (US\$12.52 per ADS).

The opening share price per 'A' Ordinary share at the start of the financial year was US\$6.25 or US\$25.00 per ADS (2013: US\$3.64 or US\$14.55 per ADS) (2012: US\$2.54 or US\$10.15 per ADS) and the closing share price at December 31, 2014 was US\$4.38 or US\$17.51 per ADS (2013: US\$6.28 or US\$25.14 per ADS) (2012: US\$3.61 or US\$14.42 per ADS). The average share price for the year ended December 31, 2014 was US\$5.54 per 'A' Ordinary share or US\$22.15 per ADS.

A summary of the range of prices for the Company's stock options for the year ended December 31, 2014 follows:

|                      | Outstanding      |                      |                      |                  | Exercisable          |                      |
|----------------------|------------------|----------------------|----------------------|------------------|----------------------|----------------------|
|                      |                  |                      | Weighted-<br>average |                  |                      | Weighted-<br>average |
|                      |                  | Weighted-<br>average | contractual<br>life  |                  | Weighted-<br>average | contractual<br>life  |
|                      | No. of           | exercise             | remaining            | No. of           | exercise             | remaining            |
| Exercise price range | options/warrants | price                | (years)              | options/warrants | price                | (years)              |
| US\$0.66-US\$0.99    | 74,000           | 0.69                 | 1.23                 | 74,000           | 0.69                 | 1.23                 |
| US\$1.00-US\$2.05    | 1,240,654        | 1.50                 | 2.66                 | 1,240,654        | 1.50                 | 2.30                 |
| US\$2.06- US\$2.99   | 3,372,667        | 2.54                 | 4.19                 | 1,758,669        | 2.53                 | 4.19                 |
| US\$3.00 -US\$4.79   | 4,604,334        | 4.18                 | 6.04                 | 983,668          | 4.08                 | 5.27                 |
|                      | 9,291,655        |                      |                      | 4,056,991        |                      |                      |

|                      | (                | Outstanding       |                                     |                  | Exercisable       |                                     |  |
|----------------------|------------------|-------------------|-------------------------------------|------------------|-------------------|-------------------------------------|--|
|                      |                  | Weighted-         | Weighted-<br>average<br>contractual |                  | Weighted-         | Weighted-<br>average<br>contractual |  |
|                      | No. of           | average           | life<br>remaining                   | No. of           | average           | life<br>remaining                   |  |
| Exercise price range | options/warrants | exercise<br>price | (years)                             | options/warrants | exercise<br>price | (years)                             |  |
| US\$2.63-US\$3.96    | 18,500           | 2.76              | 1.23                                | 18,500           | 2.76              | 1.23                                |  |
| US\$4.00-US\$8.20    | 310,163          | 6.00              | 2.66                                | 310,164          | 6.00              | 2.30                                |  |
| US\$8.24- US\$11.96  | 843,167          | 10.16             | 4.19                                | 439,667          | 10.12             | 4.19                                |  |
| US\$12.00 -US\$19.15 | 1,151,084        | 16.72             | 6.04                                | 245,917          | 16.32             | 5.27                                |  |
|                      | 2,322,914        |                   |                                     | 1,014,248        |                   |                                     |  |

### 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The weighted-average remaining contractual life of options outstanding at December 31, 2014 was 4.88 years (2013: 4.96 years).

A summary of the range of prices for the Company's stock options for the year ended December 31, 2013 follows:

|                      |           | Outstanding |             |           | Exercisable |             |  |
|----------------------|-----------|-------------|-------------|-----------|-------------|-------------|--|
|                      |           |             | Weighted-   |           |             | Weighted-   |  |
|                      |           |             | average     |           |             | average     |  |
|                      |           | Weighted-   | contractual |           | Weighted-   | contractual |  |
|                      | No. of    | average     | life        | No. of    | average     | life        |  |
|                      | options/  | exercise    | remaining   | options/  | exercise    | remaining   |  |
| Exercise price range | warrants  | price       | (years)     | warrants  | price       | (years)     |  |
| US\$0.66-US\$0.99    | 74,008    | 0.69        | 2.23        | 74,008    | 0.69        | 2.23        |  |
| US\$1.00-US\$2.05    | 2,511,073 | 1.50        | 3.31        | 1,757,242 | 1.49        | 3.26        |  |
| US\$2.06- US\$2.99   | 4,348,328 | 2.54        | 5.05        | 1,071,665 | 2.49        | 4.64        |  |
| US\$3.00 -US\$4.79   | 2,848,000 | 4.16        | 6.35        | 116,000   | 3.25        | 5.39        |  |
|                      | 9,781,409 |             |             | 3,018,915 |             |             |  |

|                      | Outstanding     |                                  |  | Exercisable     |                                  |  |
|----------------------|-----------------|----------------------------------|--|-----------------|----------------------------------|--|
|                      | No. of options/ | Weighted–<br>average<br>exercise | Weighted-<br>average<br>contractual<br>life<br>remaining | No. of options/ | Weighted–<br>average<br>exercise | Weighted-<br>average<br>contractual<br>life<br>remaining |
| Exercise price range | warrants        | price                            | (years)  | warrants        | price                            | (years)  |
| US\$2.63-US\$3.96    | 18,502          | 2.76                             | 2.23   | 18,502          | 2.76                             | 2.23   |
| US\$4.00-US\$8.20    | 627,768         | 6.00                             | 3.31   | 439,311         | 5.96                             | 3.26   |
| US\$8.24- US\$11.96  | 1,087,082       | 10.16                            | 5.05   | 267,916         | 9.96                             | 4.64   |
| US\$12.00 -US\$19.15 | 712,000         | 16.64                            | 6.35   | 29,000          | 13.00                            | 5.39   |
|                      | 2,445,352       |                                  |  | 754,729         |                                  |  |

The recognition and measurement principles of IFRS 2 have been applied to share options granted under the Company's Share Option Plans since November 7, 2002 which have not vested by January 1, 2005 in accordance with IFRS 2.

#### 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

#### Charge for the year under IFRS 2

The charge for the year is calculated based on the fair value of the options granted which have not yet vested.

The fair value of the options is expensed over the vesting period of the option. US\$1,496,000 was charged to the statement of operations in 2014, (2013: US\$2,014,000), (2012: US\$1,713,000) split as follows:

|  | December 31,<br>2014<br>US\$'000 | December 31,<br>2013<br>US\$'000 | December 31,<br>2012<br>US\$'000 |
|--|----------------------------------|----------------------------------|----------------------------------|
| Share-based payments – cost of sales                       | 18                               | 36                               | 38                               |
| Share-based payments – selling, general and administrative | 1,478                            | 1,978                            | 1,675                            |
| Total  | 1,496                            | 2,014                            | 1,713                            |

The total share based payments charge for the year was US\$2,533,000 (2013: US\$3,303,000) (2012: US\$2,640,000). However, a total of US\$1,037,000 (2013: US\$1,289,000) (2012: US\$927,000) of share based payments was capitalised in intangible development project assets during the year.

The fair value of services received in return for share options granted are measured by reference to the fair value of share options granted. The estimate of the fair value of services received is measured based on a trinomial model. The following are the input assumptions used in determining the fair value of share options granted in 2014, 2013 and 2012:

|   | Key<br>management<br>personnel<br>2014 | Other employees 2014      | Key management personnel 2013 | Other employees 2013      | Key<br>management<br>personnel<br>2012 | Other employees 2012      |
|---|--|---------------------------|-------------------------------|---------------------------|--|---------------------------|
| Weighted average fair value<br>at measurement date per<br>'A' share / (per ADS) | US\$1.13 /<br>(US\$4.52)               | US\$0.74/<br>(US\$2.96)   | US\$1.64 /<br>(US\$6.56)      | US\$2.69 /<br>(US\$10.76) | US\$1.21 /<br>(US\$4.84)               | US\$1.18 / (US\$4.72)     |
| Total 'A' share options<br>granted / (ADS's<br>equivalent)                      | 1,700,000 /<br>(425,000)               | 318,000/<br>(79,500)      | 2,540,000 /<br>(635,000)      | 487,652/<br>(121,913)     | 2,540,000 /<br>(635,000)               | 1,558,000/<br>(389,500)   |
| Weighted average share price per 'A' share / (per ADS)                          | US\$4.23 /<br>(US\$16.90)              | US\$4.22 /<br>(US\$16.88) | US\$4.21 /<br>(US\$16.85)     | US\$4.75 /<br>(US\$19.00) | US\$2.52 /<br>(US\$10.08)              | US\$2.67 /<br>(US\$10.68) |
| Weighted average exercise<br>price per 'A' share / (per<br>ADS)                 | US\$4.23 /<br>(US\$16.90)              | US\$4.22/<br>(US\$16.88)  | US\$4.21 /<br>(US\$16.85)     | US\$2.45 /<br>(US\$9.80)  | US\$2.52 /<br>(US\$10.08)              | US\$2.67 /<br>(US\$10.68) |
| Weighted average expected volatility  | 32.54%                                 | 24.54%                    | 49.69%                        | 12.06%                    | 62.54%                                 | 62.02%                    |
| Weighted average expected life  | 4.68                                   | 3.58                      | 4.80                          | 4.09                      | 4.88                                   | 4.18                      |
| Weighted average risk free interest rate  | 1.53%                                  | 1.22%                     | 0.90%                         | 0.27%                     | 0.87%                                  | 0.61%                     |
| Expected dividend yield   | 1.11%                                  | 1.11%                     | 1%                            | 1%                        | 1%                                     | 1%                        |

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility is based on the historic volatility (calculated based on the expected life of the options). The Group has considered how future experience may affect historical volatility. The profile and activities of the Group are not expected to change in the immediate future and therefore Trinity Biotech would expect estimated volatility to be consistent with historical volatility.

#### 19. TRADE AND OTHER PAYABLES

|                                   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-----------------------------------|-------------------------------|-------------------------------|
| Trade payables                    | 9,470                         | 8,154                         |
| Payroll taxes                     | 406                           | 310                           |
| Employee related social insurance | 297                           | 208                           |
| Accrued liabilities               | 10,699                        | 9,362                         |
| Deferred consideration            | 125                           | 1,953                         |
| Deferred income                   | 200                           | 144                           |
|                                   | 21,197                        | 20,131                        |

The deferred consideration payable in 2014 arises as a result of the acquisition of Phoenix Biotech in 2011. Accrued liabilities include US\$2,195,000 relating to contracted licence payments for HIV-2 licence.

#### 20. PROVISIONS

|   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|---|-------------------------------|-------------------------------|
| Provisions  | 75                            | 75                            |
| Movement on provisions during the year is as follows: |                               |                               |
|   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
| Balance at January 1                                  | 75                            | 50                            |
| Additional provisions related to acquisitions         |                               | 25                            |
| Balance at December 31                                | 75                            | 75                            |

During 2014 the Group experienced no significant product warranty claims. However, the Group believes that it is appropriate to retain a product warranty provision to cover any future claims. The provision at December 31, 2014 represents the estimated cost of product warranties, the exact amount which cannot be determined. US\$75,000 represents management's best estimate of these obligations at December 31, 2014.

### 21. OTHER PAYABLES DUE AFTER ONE YEAR

|                        | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|------------------------|-------------------------------|-------------------------------|
| Other payables         | 2,071                         | 3,055                         |
| Deferred Consideration | 299                           | 1,541                         |
|                        | 2,370                         | 4,596                         |

The deferred consideration payable arises as a result of the acquisition of Fiomi Diagnostics AB in 2012 and is shown net of deferred interest expense of US\$17,000. For further information on the acquisition of Fiomi Diagnostics, please refer to Note 22.

Other payables in 2014 and 2013 are entirely comprised of amounts relating to contracted licence payments for HIV-2 licence.

#### 22. BUSINESS COMBINATIONS

#### 2013 Acquisitions

In 2013, the Group acquired Immco Diagnostics ('Immco') and the Blood bank screening business of Lab21 Ltd.

#### **Immco Diagnostics**

The Group acquired 100% of the common stock of Immco Diagnostics Inc. for US\$32,883,000. Immco is headquartered in Buffalo, New York, and employs 90 people. It specializes in the development, manufacture and sale of autoimmune test kits on a worldwide basis. This product line is complemented by specialized reference laboratory services in diagnostic immunology, pathology and immunogenetics, marketed to US-based reference laboratories and hospitals. Immco has a wholly-owned Canadian subsidiary, Nova Century Scientific Inc.

Autoimmune diseases are now the second leading cause of chronic illness and the leading cause of death amongst women over 65. Immco is positioned in the lower throughput, speciality autoimmune segment of the market, where the competition is limited to a small number of key players, principally Bio-Rad, Werfen-Inova and Phadia. Immco offers a comprehensive range of more than 120 products across all the main autoimmune segments. The principal autoimmune conditions in this segment are Rheumatoid Arthritis, Vasculitis, Lupus, Celiac and Crohn's disease, Ulcerative Colitis, Neuropathy, Hashimoto's and Graves disease. Meanwhile, the two key technologies employed are Immunoflourescence (IFA) and Immunoassay (EIA). Prior to acquisition by Trinity Biotech, Immco sold its products through a network of distributors, mainly outside the US. Immco's very low level of sales in the US was due to a lack of FDA product approvals and a sales force. However, Immco had succeeded in harmonizing its complete IFA and EIA product ranges in 2012 and 2013, virtually all of which had then been FDA 510K cleared.

The consideration comprised the following:

- An up-front cash payment of US\$31,652,000,
- Share options in Trinity Biotech ADSs which vested immediately and were "in the money" upon vesting. The fair value was US\$1,121,000 as at the acquisition date and,
- 5,566 Trinity Biotech ADSs with a fair value of US\$110,000 as at the acquisition date.

Goodwill recognised during 2013 in respect of the Immco acquisition amounted to US\$20,365,000 and comprised:

|   | Book values US\$'000 | Fair value adjustments US\$'000 | Fair value | Purchase<br>Consideration*<br>US\$'000 | Goodwill<br>US\$'000 |
|---|----------------------|---------------------------------|------------|--|----------------------|
| Immco Diagnostic                                | US\$ 000             | 03\$ 000                        | US\$ 000   | 03\$ 000                               | 03\$ 000             |
| Property, plant & equipment                     | 1,632                | (355)                           | 1,277      |  |                      |
| Intangible assets                               | 356                  | 10,211                          | 10,567     |  |                      |
| Trade & other receivables                       | 3,437                | (549)                           | 2,888      |  |                      |
| Inventory                                       | 2,538                | (927)                           | 1,611      |  |                      |
| Cash  | 2,282                | _                               | 2,282      |  |                      |
| Deferred tax asset                              | 9                    | (9)                             |            |  |                      |
|   | 10,254               | 8,371                           | 18,625     |  |                      |
| Trade & other payables                          | (1,686)              | _                               | (1,686)    |  |                      |
| Taxes payable                                   | (403)                | _                               | (403)      |  |                      |
| Loan liabilities                                | (955)                | _                               | (955)      |  |                      |
| Deferred tax liability                          |                      | (3,063)                         | (3,063)    |  |                      |
|   | (3,044)              | (3,063)                         | (6,107)    |  |                      |
| Total identifiable net assets at fair value     |                      |                                 | 12,518     | 32,883                                 | 20,365               |
| *Purchase Consideration                         | US\$ '000            |                                 |            |  |                      |
| Cash Paid                                       | 31,652               |                                 |            |  |                      |
| Shares and share options transferred as part of |                      |                                 |            |  |                      |
| consideration                                   | 1,231                |                                 |            |  |                      |
| Total Purchase Consideration                    | 32,883               |                                 |            |  |                      |
|   |                      |                                 |            |  |                      |

#### 22. BUSINESS COMBINATIONS (CONTINUED)

The gross contractual value of trade and other receivables as at the date of acquisition amounted to US\$3,730,000. The fair value of these receivables was US\$2,888,000 and was inclusive of an aggregate allowance for impairment of US\$841,000.

The fair value of intangible assets was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the intangible assets reflects significant assumptions regarding the estimates a market participant would make, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The Group recognised US\$10,567,000 of intangible assets in 2013 as part of the Immco acquisition.

The principal factor contributing to the recognition of goodwill of US\$20,365,000 on acquisition was the realisation of synergies with existing entities in the Group which do not qualify for separate recognition as intangible assets. In particular, there was a major opportunity to grow Immco's revenues in the US by leveraging both the Group's existing installed base and its sales force. Secondly, the combination of the Group's existing infectious diseases products with Immco's autoimmune products created a portfolio effect which was to the benefit of both product lines. Lastly, the addition of the reference laboratory was beneficial for new product introduction and obtaining human samples. None of the goodwill recognised was deductible for income tax purposes.

Transaction costs of US\$153,000 were expensed during 2013 and were included within selling, general and administrative expenses. No contingent liabilities were recognised on the acquisition.

### Blood bank screening business of Lab21 Ltd

The blood bank screening business of Lab21 Ltd was acquired by a newly incorporated Group entity, Trinity Biotech (UK) Ltd., for cash consideration of US\$7,456,000. The business consists of a range of products for the screening of syphilis, malaria and cytomegalovirus (CMV) in blood donations. Located in Cambridge and Newmarket in the United Kingdom, the business employed 45 people between the two sites. The products, comprising very high quality TPHA, RPR and ELISA tests, have an excellent balance between sensitivity and specificity and compete in a market which has limited competition. The syphilis products had a market share of over 75% of the syphilis blood bank markets in the UK, France, Germany, Netherlands, Switzerland, Austria and Belgium. The malaria test is well positioned to avail of the increase in malaria blood bank testing in the developed world given the increased prevalence of malaria as a result of foreign travel. The CMV product was launched in late 2012 and has excellent revenue growth prospects.

Goodwill recognised during 2013 in respect of the blood bank screening business acquisition amounted to US\$6,063,000 and comprised:

|   | Book values<br>US\$'000 | Fair value<br>adjustments<br>US\$'000 | Fair value<br>US\$'000 | Purchase<br>Consideration<br>US\$'000 | Goodwill<br>US\$'000 |
|---|-------------------------|---------------------------------------|------------------------|---------------------------------------|----------------------|
| Blood bank screening business               |                         |                                       |                        |                                       |                      |
| Property, plant & equipment                 | 153                     | (49)                                  | 104                    |                                       |                      |
| Intangible assets                           | _                       | 1,772                                 | 1,772                  |                                       |                      |
| Inventory                                   | 76                      | 9                                     | 85                     |                                       |                      |
|   | 229                     | 1,732                                 | 1,961                  |                                       |                      |
| Trade & other payables                      |                         | (199)                                 | (199)                  |                                       |                      |
| Deferred tax liability                      |                         | (369)                                 | (369)                  |                                       |                      |
|   |                         | (568)                                 | (568)                  |                                       |                      |
| Total identifiable net assets at fair value |                         |                                       | 1,393                  | 7,456                                 | 6,063                |

#### 22. BUSINESS COMBINATIONS (CONTINUED)

The fair value of intangible assets was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the intangible assets reflects significant assumptions regarding the estimates a market participant would make, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The Group recognised US\$1,772,000 of intangible assets in 2013 as part of the blood banking business acquisition.

The principal factor contributing to the recognition of goodwill of US\$6,063,000 on acquisition is the realisation of cost savings and other synergies with existing entities in the Group which do not qualify for separate recognition as intangible assets. In 2014, the production activities of the business were transferred from its existing manufacturing facilities in the UK to the Group's current facilities in Bray, Ireland and Jamestown, New York.

Transaction costs of US\$163,000 were expensed during 2013 and were included within selling, general and administrative expenses. No contingent liabilities were recognised on the acquisition.

#### 2012 Acquisition

In February, 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB ('Fiomi').

Fiomi, which is based in Uppsala, Sweden, is at an advanced stage in developing a range of point-of-care cardiac assays based on micro-pillar technology. This technology is capable of providing extremely sensitive, highly reproducible, quantitative, multiplexed results making it significantly more accurate than the current established point-of-care tests in the market.

Goodwill recognised during 2012 in respect of the Fiomi Diagnostics AB acquisition amounted to US\$7,061,000 and comprised:

|   | Book values | Fair value adjustments | Fair value | Purchase<br>Consideration* | Goodwill |
|---|-------------|------------------------|------------|----------------------------|----------|
|   | US\$'000    | US\$'000               | US\$'000   | US\$'000                   | US\$'000 |
| Fiomi Diagnostics AB                            |             |                        |            |                            |          |
| Property, plant & equipment                     | 43          | _                      | 43         |                            |          |
| Intangible assets                               | 4,130       | 4,348                  | 8,478      |                            |          |
| Trade & other receivables                       | 78          | _                      | 78         |                            |          |
| Cash  | 44          | _                      | 44         |                            |          |
|   | 4,295       | 4,348                  | 8,643      |                            |          |
| Trade & other payables                          | (646)       | _                      | (646)      |                            |          |
| Other non-current liabilities                   | (1,000)     | _                      | (1,000)    |                            |          |
| Deferred tax liability                          | <u></u> _   | (1,131)                | (1,131)    |                            |          |
|   | (1,646)     | (1,131)                | (2,777)    |                            |          |
| Total identifiable net assets at fair value     |             |                        | 5,866      | 12,927                     | 7,061    |
|   |             |                        |            |                            |          |
| *Purchase Consideration                         | US\$ '000   |                        |            |                            |          |
| Cash Paid                                       | 5,624       |                        |            |                            |          |
| Shares Transferred as part of consideration     | 4,070       |                        |            |                            |          |
| Contingent consideration liability (net present |             |                        |            |                            |          |
| value)  | 3,233       |                        |            |                            |          |
| Total Purchase Consideration                    | 12,927      |                        |            |                            |          |
|   |             |                        |            |                            |          |

#### 22. BUSINESS COMBINATIONS (CONTINUED)

Under the terms of the purchase agreement, the previous owners of Fiomi are entitled to additional consideration which is based on the CE Marking, FDA submission and approval of a Troponin I assay. At the acquisition date, the net present value of this contingent consideration was estimated to be US\$3,233,000 (net of interest of US\$182,000). At December 31, 2014, the net present value of contingent consideration was US\$298,000 (2013: US\$3,369,000). The decrease in contingent consideration includes milestone payment for the achievement of CE marking milestone amounting to US\$1,050,000, as well as a reduction in the estimated amount payable when milestones were not met amounting to US\$2,057,000.

The fair value of the in-process research and development (IPR&D) intangible asset was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the IPR&D reflects significant assumptions regarding the estimates a market participant would make in order to evaluate a diagnostic assay development asset, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk and regulatory risk. The Group recognised US\$4,348,000 of IPR&D as part of the Fiomi acquisition.

Development of the Troponin I cardiac assay requires various levels of in-house and external testing, clinical trials and approvals from the FDA or comparable foreign regulatory authorities before it could be commercialized in the U.S. or other territories. Assuming successful results in clinical trials, the Group expects to submit the cardiac assay for regulatory approval in 2015. The estimated costs to complete the project represent management's best estimate of expected costs, but are subject to change based on additional information to be received as development activities advance.

IPR&D is tested annually for impairment (see Note 1(viii)). We did not recognise any impairment charges related to IPR&D during the years ended December 31, 2014, 2013 and 2012.

The fair value of the trade and other receivables amounted to US\$78,000 (i.e. the book value on the date of acquisition). None of the trade and other receivables was impaired as all of these receivables were collected by the Company.

Trade and other payables were valued at US\$646,000 and other non-current liabilities, comprising contracted licence fees for technology, were valued at US\$1,000,000.

The goodwill of US\$7,061,000 represented the future economic benefits arising from the acquisition that have not been individually identified and separately recognised. None of the goodwill recognised is expected to be deductible for income tax purposes.

Transaction costs of US\$90,000 were expensed in 2012 and are included within selling, general and administrative expenses.

During 2014, Fiomi was engaged principally in the development of its point-of-care cardiac marker assays and, as such, the majority of its costs were capitalised to these projects. Fiomi has yet to make its first commercial sale and did not contribute to the Group's revenue in 2012, 2013 or 2014.

The key terms of the acquisition are as follows:

- An up-front cash payment of US\$5.6m;
- The transfer of 408,000 Trinity Biotech ADS's as at the acquisition date (fair value of US\$4.1m); and
- Contingent cash consideration of US\$3.4m.

#### 23. COMMITMENTS AND CONTINGENCIES

#### (a) Capital Commitments

The Group has capital commitments authorised and contracted for of US\$1,610,000 as at December 31, 2014 (2013: US\$Nil).

#### (b) Leasing Commitments

The Group leases a number of premises under operating leases. The leases typically run for periods up to 25 years. Lease payments are reviewed periodically (typically on a 5 year basis) to reflect market rentals. Operating lease commitments payable during the next 12 months amount to US\$3,109,000 (2013: US\$3,510,000) payable on leases of buildings at Dublin and Bray, Ireland, Jamestown, Buffalo and Amherst, New York, Acton, Massachusetts, Carlsbad, California, Uppsala, Sweden, and Sao Paulo, Brazil. US\$371,000 (2013: US\$328,000) of these operating lease commitments relates to leases whose remaining term will expire within one year, US\$711,000 (2013: US\$881,000) relates to leases whose remaining term expires between one and two years, US\$608,000 (2013: US\$692,000) between two and five years and the balance of US\$1,419,000 (2013: US\$1,610,000) relates to leases which expire after more than five years. See Note 24 for related party leasing arrangements.

Future minimum operating lease commitments with non-cancellable terms in excess of one year are as follows:

|                         | Year ended<br>2014<br>Operating leases<br>US\$'000 |
|-------------------------|--|
| 2015                    | 3,109  |
| 2016                    | 2,637  |
| 2017                    | 1,949  |
| 2018                    | 1,522  |
| 2019                    | 1,464  |
| Later years             | 16,062   |
| Total lease obligations | 26,743   |
|                         |  |
|                         | Year ended   |
|                         | 2013<br>Operating leases                           |
|                         | US\$'000   |
| 2014                    | 3,510  |
| 2015                    | 2,961  |
| 2016                    | 2,537  |
| 2017                    | 2,010  |
| 2018                    | 1,610  |
| Later years             | 19,833   |
|                         | ,  |

### (c) Bank Security

The Group repaid in full its bank borrowings in April 2010, at which point all previous charges against Group assets were released. The Group had no bank borrowings as at December 31, 2014.

#### 23. COMMITMENTS AND CONTINGENCIES (CONTINUED)

#### (d) Section 17 Guarantees

Pursuant to the provisions of Section 17, Irish Companies (Amendment) Act, 1986, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, Trinity Research Limited, Benen Trading Limited and Trinity Biotech Financial Services Limited subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2014 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 17, Irish Companies (Amendment) Act, 1986. Where the Company enters into these guarantees of the indebtedness of other companies within its Group, the Company considers these to be insurance arrangements and accounts for them as such. The Company treats the guarantee contract as a contingent liability until such time as it becomes probable that the company will be required to make a payment under the guarantee. The Company does not enter into financial guarantees with third parties.

## (e) Government Grant Contingencies

The Group has received training and employment grant income from Irish development agencies. Subject to existence of certain conditions specified in the grant agreements, this income may become repayable. No such conditions existed as at December 31, 2014. However if the income were to become repayable, the maximum amounts repayable as at December 31, 2014 would amount to US\$3,070,000 (2013: US\$3,483,000).

### (f) Litigation

In 2010, Laboratoires Nephrotek, formerly a distributor for Trinity Biotech, took a legal action in France against the Group, claiming damages of US\$0.8 million. They claimed that certain instruments supplied by Trinity Biotech did not operate properly in the field. In 2013, Trinity Biotech successfully defended this claim in the French courts. Nephrotek are in the process of appealing this decision. There are also a small number of legal cases being brought against the Group by certain of its former employees in the previously owned French subsidiary, Trinity Biotech France S.à.r.l. The ultimate resolution of the aforementioned proceedings is not expected to have a material adverse effect on the Group's financial position, results of operations or cash flows.

### 24. RELATED PARTY TRANSACTIONS

The Group has related party relationships with its subsidiaries, and with its directors and executive officers.

### Leasing arrangements with related parties

The Group has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of the Company, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland.

In November 2004, the Group entered into an agreement for a 25 year lease with JRJ for offices that have been constructed adjacent to its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. The annual rent of €381,000 (US\$463,000) is payable from January 1, 2004. There was a rent review performed on this premises in 2009 and further to this review, there was no change to the annual rental charge.

In December 2007, the Group entered into an agreement with Mr. O'Caoimh and Dr Walsh pursuant to which the Group took a lease on an additional 43,860 square foot manufacturing facility in Bray, Ireland at a rate of €17.94 per square foot (including fit out) giving a total annual rent of €787,000 (US\$956,000).

Trinity Biotech and its directors (excepting Mr O'Caoimh and Dr Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises. At December 31, 2014 rental payments outstanding amounted to US\$257,000 (2013: US\$248,000).

#### 24. RELATED PARTY TRANSACTIONS (CONTINUED)

Compensation of key management personnel of the Group

At December 31, 2013 the key management personnel of the Group were made up of four key personnel: the three executive directors; Mr. Ronan O'Caoimh, Mr. Rory Nealon and Dr. Jim Walsh and Mr. Kevin Tansley, our Chief Financial Officer/Company Secretary. On November 15, 2014 Rory Nealon retired from the company, and as at December 31, 2014 the key management personnel of the Group were made up of Mr. Ronan O'Caoimh, Dr. Jim Walsh, and Mr. Kevin Tansley. Compensation payable to Mr. Rory Nealon relating to 2014 is included in the information below.

Compensation for the year ended December 31, 2014 of these personnel is detailed below:

|                                   | December 31, 2014<br>US\$'000 | December 31, 2013<br>US\$'000 |
|-----------------------------------|-------------------------------|-------------------------------|
| Short-term employee benefits      | 1,987                         | 1,938                         |
| Performance related bonus         | 514                           | 374                           |
| Post-employment benefits          | 132                           | 95                            |
| Share-based compensation benefits | 1,903                         | 2,263                         |
|                                   | 4,536                         | 4,670                         |

Note 5 includes non executive directors' fees of US\$380,000 (2013: US\$315,000) and share-based compensation benefits of US\$206,000 (2013: US\$235,000). Note 5 excludes the compensation costs of the Chief Financial Officer comprising total remuneration of US\$573,000 (2013: US\$507,000) and share-based compensation of US\$428,000 (2013: US\$490,000). Total directors' remuneration is also included in "personnel expenses" (Note 6). On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by an agreement with Darnick Company, a company wholly-owned by members of Mr. O'Caoimh's immediate family. Directors' compensation includes payments made to Darnick Company.

Directors' and Company Secretary's interests in the Company's shares and share option plan

|   | 'A' Ordinary Shares              | Share options            |
|---|----------------------------------|--------------------------|
| At January 1, 2014                      | 5,930,306                        | 7,188,759                |
| Exercised                               | 55,000                           | (1,203,752)              |
| Granted                                 | <del>_</del>                     | 1,700,000                |
| Expired Options                         | <del>_</del>                     | (166,666)                |
| Shares purchased/(sold) during the year | (600,000)                        | _                        |
| At December 31, 2014                    | 5,385,306                        | 7,518,341                |
|   |                                  |                          |
|   | 'A' Ordinary Shares              | Share options            |
| At January 1, 2013                      | 'A' Ordinary Shares<br>5,723,306 | Share options 6,703,759  |
| At January 1, 2013<br>Exercised         |                                  | •                        |
| <b>3</b> /                              | 5,723,306                        | 6,703,759                |
| Exercised                               | 5,723,306                        | 6,703,759<br>(2,055,000) |
| Exercised Granted                       | 5,723,306                        | 6,703,759<br>(2,055,000) |

Rayville Limited, an Irish registered company, which is wholly owned by the three executive directors and certain other executives of the Group, owns all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries. The 'B' shares do not entitle the holders thereof to receive any assets of the company on a winding up. All of the 'A' voting ordinary shares in Trinity Research Limited are held by the Group. Trinity Research Limited may, from time to time, declare dividends to Rayville Limited and Rayville Limited may declare dividends to its shareholders out of those amounts. Any such dividends paid by Trinity Research Limited are ordinarily treated as a compensation expense by the Group in the consolidated financial statements prepared in accordance with IFRS, notwithstanding their legal form of dividends to minority interests, as this best represents the substance of the transactions.

There were no director loans advanced during 2014 or 2013.

#### 24. RELATED PARTY TRANSACTIONS (CONTINUED)

In June 2009, the Board approved the payment of a dividend of \$2,830,000 by Trinity Research Limited to Rayville Limited on the 'B' shares held by it. This amount was then lent back by Rayville to Trinity Research Limited. As the dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2013 and 2014 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US\$Nil, US\$Nil and US\$231,000 for 2014, 2013 and 2012 respectively, of which US\$Nil, US\$Nil and US\$206,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2014, 2013 or 2012.

#### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS

The Group uses a range of financial instruments (including cash, finance leases, receivables, payables and derivatives) to fund its operations. These instruments are used to manage the liquidity of the Group in a cost effective, low-risk manner. Working capital management is a key additional element in the effective management of overall liquidity. The Group does not trade in financial instruments or derivatives. The main risks arising from the utilization of these financial instruments are interest rate risk, liquidity risk and credit risk.

#### Interest rate risk

### Effective and repricing analysis

The following table sets out all interest-earning financial assets and interest bearing financial liabilities held by the Group at December 31, indicating their effective interest rates and the period in which they re-price:

| As at December 31, 2014  | Note             | Effective<br>interest<br>rate    | Total<br>US\$'000           | 6 mths or less<br>US\$'000 | 6-12 mths<br>US\$'000 | 1-2 years<br>US\$'000 | 2-5 years<br>US\$'000 |
|--|------------------|----------------------------------|-----------------------------|----------------------------|-----------------------|-----------------------|-----------------------|
| Cash and cash equivalents  | 16               | 0.1%                             | 9,102                       | 9,102                      | _                     | _                     | _                     |
| Finance lease receivable   | 15               | 4.2%                             | 1,690                       | 298                        | 276                   | 478                   | 638                   |
| Deferred Consideration   | 19, 21           | 3.1%                             | (424)                       | _                          | (125)                 | (299)                 | _                     |
| Licence payments   | 19, 21           | 3.0%                             | (4,266)                     | (1,112)                    | (1,083)               | (1,051)               | (1,020)               |
| Total  |                  |                                  | 6,102                       | 8,288                      | (932)                 | (872)                 | (382)                 |
|  |                  |                                  |                             |                            |                       |                       |                       |
| As at December 21, 2012  | Note             | Effective interest               | Total                       | 6 mths or less             | 6-12 mths             | 1-2 years             | 2-5 years             |
| As at December 31, 2013 Cash and cash equivalents                          | Note<br>16       | interest<br>rate                 | US\$'000                    | US\$'000                   | 6-12 mths<br>US\$'000 | 1-2 years<br>US\$'000 | 2-5 years<br>US\$'000 |
| As at December 31, 2013 Cash and cash equivalents Finance lease receivable | Note<br>16<br>15 | interest                         |                             |                            |                       |                       |                       |
| Cash and cash equivalents  | 16               | interest<br>rate<br>0.1%         | <i>US\$'000</i> 22,317      | US\$'000<br>22,317         | US\$'000<br>—         | US\$'000<br>—         | US\$'000<br>—         |
| Cash and cash equivalents Finance lease receivable                         | 16<br>15         | interest<br>rate<br>0.1%<br>4.2% | US\$'000<br>22,317<br>1,598 | US\$'000<br>22,317<br>267  | US\$'000<br>—         | US\$'000<br>—<br>428  | US\$'000<br>—         |

Year-end cash and cash equivalents amounted to US\$9,102,000 (2013: US\$22,317,000) which attracted an average rate of interest of 0.1% (2013: 0.1%).

In broad terms, a one-percentage point increase in interest rates would increase interest income by US\$91,000 (2013: US\$223,000) and would not affect the interest expense (2013: nil impact also) resulting in an increase in net interest income of US\$91,000 (2013: increase in net interest income of US\$223,000).

#### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

### Interest rate profile of financial assets / liabilities

The interest rate profile of financial assets/liabilities of the Group was as follows:

|   | December 31, 2014<br>US\$ '000 | December 31, 2013<br>US\$ '000 |
|---|--------------------------------|--------------------------------|
| Fixed rate instruments                          |                                |                                |
| Fixed rate financial liabilities (deferred      |                                |                                |
| consideration)                                  | (424)                          | (3,369)                        |
| Fixed rate financial liabilities (licence fees) | (4,266)                        | (4,135)                        |
| Financial assets (cash and short-term deposits) | 2,699                          | 13,283                         |
| Financial assets (finance lease receivables)    | 1,690                          | 1,598                          |
| Variable rate instruments                       |                                |                                |
| Financial assets (cash and short-term deposits) | 6,403                          | 9,034                          |
|   | 6,102                          | 16,411                         |

In 2014 and 2013, the fixed rate financial liabilities relating to deferred consideration arises as a result of the Fiomi acquisition (see Note 22). The weighted average interest rate and weighted average period for which the rate is fixed is as follows:

|   | December 31, 2014 | December 31, 2013 |
|---|-------------------|-------------------|
| Fixed rate financial liabilities (deferred      |                   |                   |
| consideration)                                  |                   |                   |
| Weighted average interest rate                  | 3.1%              | 3.1%              |
| Weighted average period for which rate is fixed | 1.67 years        | 0.55 years        |

Financial assets comprise cash and cash equivalents as at December 31, 2014 and December 31, 2013 (see Note 16).

#### Fair value sensitivity analysis for fixed rate instruments

The Group does not account for any fixed rate financial liabilities at fair value through profit and loss. Therefore a change in interest rates at December 31, 2014 would not affect profit or loss.

## Cash flow sensitivity analysis for variable rate instruments

A change of 100 basis points in interest rates at the reporting date would have no effect on profit or loss for the period. This assumes that all other variables, in particular foreign currency rates, remain constant.

#### Interest rates used for determining fair value

The interest rates used to discount estimated cash flows, where applicable, based on observable market rates plus a premium which reflects the risk profile of the Group at the reporting date, were as follows:

|                        | December 31, 2014 | December 31, 2013 |
|------------------------|-------------------|-------------------|
| Deferred Consideration | 3.1%              | 3.1%              |

There was no significant difference between the fair value and carrying value of the Group's trade receivables and trade and other payables at December 31, 2014 and December, 31 2013 as all fell due within 6 months.

#### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

### Liquidity risk

The Group's operations are cash generating. Short-term flexibility is achieved through the management of the Group's short-term deposits.

The following are the contractual maturities of financial liabilities, including estimated interest payments:

| As at December 31, 2014<br>US\$`000 | Carrying<br>amount<br>US\$'000 | Contractual<br>cash flows<br>US\$'000 | 6 mths or<br>less<br>US\$'000 | 6 mths –<br>12 mths<br>US\$'000 | 1-2 years<br>US\$'000 | 2-5 years<br>US\$'000 |
|-------------------------------------|--------------------------------|---------------------------------------|-------------------------------|---------------------------------|-----------------------|-----------------------|
| Financial liabilities               |                                |                                       |                               |                                 |                       |                       |
| Trade & other payables              | 23,567                         | 23,567                                | 20,117                        | 1,080                           | 1,350                 | 1,020                 |
|                                     | 23,567                         | 23,567                                | 20,117                        | 1,080                           | 1,350                 | 1,020                 |
| As at December 31, 2013<br>US\$`000 | Carrying<br>amount<br>US\$'000 | Contractual<br>cash flows<br>US\$'000 | 6 mths or<br>less<br>US\$'000 | 6 mths –<br>12 mths<br>US\$'000 | 1-2 years<br>US\$'000 | 2-5 years<br>US\$'000 |
| Financial liabilities               |                                |                                       |                               |                                 |                       |                       |
| Trade & other payables              | 24,727                         | 24,727                                | 20,131                        |                                 | 4,596                 |                       |
|                                     | 24,727                         | 24,727                                | 20,131                        |                                 | 4,596                 |                       |

#### Foreign exchange risk

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro denominated expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, where considered necessary, the Group pursues a treasury policy which periodically aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions. Forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at December 31, 2014.

Foreign currency short term financial assets and liabilities which expose the Group to currency risk are disclosed below. The amounts shown are those reported to key management translated into US Dollars at the closing rate:

|                                 | EUR           | GBP             | SEK                | CAD             | BRL        | Other   |
|---------------------------------|---------------|-----------------|--------------------|-----------------|------------|---|
| As at 31 December 2014          | US\$ '000     | US\$'000        | US\$'000           | US\$'000        | US\$ '000  | US\$'000  |
| Cash                            | 819           | 295             | 579                | 178             | 190        | 12  |
| Trade and other receivable      | 1,547         | 287             | 233                | 358             | 1,296      | 7   |
| Trade and other payables        | (2,515)       | (270)           | (1,517)            | (100)           | (876)      |   |
| Total exposure                  | <u>(149</u> ) | 312             | <u>(705</u> )      | 436             | 610        | 19  |
|                                 | EUR           | GBP             | SEK                | CAD             | BRL.       | Other   |
| As at 31 December 2013          |               |                 |                    |                 |            |   |
| As at 51 December 2015          | US\$ '000     | US\$'000        | US\$'000           | US\$'000        | US\$ '000  | US\$'000  |
| Cash                            | 271           | US\$'000<br>416 | <i>US\$</i> '000 6 | US\$'000<br>817 | 114        | US\$ '000                                       |
|                                 | /             |                 |                    |                 |            | US\$ '000<br>——                                 |
| Cash                            | 271           | 416             | 6                  | 817             | 114        | US\$ '000<br>—————————————————————————————————— |
| Cash Trade and other receivable | 271<br>2,528  | 416<br>1,193    | 6<br>626           | 817<br>522      | 114<br>172 | US\$*000<br>——————————————————————————————————  |

#### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

The Group states its forward exchange contracts at fair value in the balance sheet. The Group classifies its forward exchange contracts as hedging forecasted transactions and thus accounts for them as cash flow hedges. During 2014 and 2013, changes in the fair value of these contracts were recognised in equity and then in the case of contracts which were exercised during 2014 and 2013, the cumulative gain or losses were transferred to the statement of operations.

There were no forward exchange contracts in place at December 31, 2014 or December 31, 2013.

#### Sensitivity analysis

A 10% strengthening of the US Dollar against the following currencies at December 31, 2014 would have increased profit and other equity by the amounts shown below. This analysis assumes that all other variables, in particular interest rates, remain constant.

|                   | Profit or loss<br>US\$'000 | Other equity<br>movements<br>US\$'000 |
|-------------------|----------------------------|---------------------------------------|
| December 31, 2014 |                            |                                       |
| Euro              | 2,057                      | _                                     |
| December 31, 2013 |                            |                                       |
| Euro              | 2,429                      | _                                     |

A 10% weakenening of the US Dollar against the following currencies at December 31, 2014 would have decreased profit and other equity by the amounts shown below. This analysis assumes that all other variables, in particular interest rates, remain constant.

|                   | Profit or loss<br>US\$'000 | Other equity<br>movements<br>US\$'000 |
|-------------------|----------------------------|---------------------------------------|
| December 31, 2014 |                            |                                       |
| Euro              | (2,515)                    | _                                     |
| December 31, 2013 |                            |                                       |
| Euro              | (2,969)                    |                                       |
| Euro              | (2,909)                    |                                       |

#### Credit Risk

The Group has no significant concentrations of credit risk. Exposure to credit risk is monitored on an ongoing basis. The Group maintains specific provisions for potential credit losses. To date such losses have been within management's expectations. Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

With respect to credit risk arising from the other financial assets of the Group, which comprise cash and cash equivalents and deferred consideration, the Group's exposure to credit risk arises from default of the counter-party, with a maximum exposure equal to the carrying amount of these instruments.

The Group maintains cash and cash equivalents and enters into forward contracts, when necessary, with various financial institutions. The Group performs regular and detailed evaluations of these financial institutions to assess their relative credit standing. The carrying amount reported in the balance sheet for cash and cash equivalents and forward contracts approximate their fair value.

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

### Exposure to credit risk

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk is as follows:

|                                 | Carrying Value    | Carrying Value    |
|---------------------------------|-------------------|-------------------|
|                                 | December 31, 2014 | December 31, 2013 |
|                                 | US\$'000          | US\$'000          |
| Third party trade receivables   | 20,277            | 19,762            |
| Finance lease income receivable | 1,690             | 1,598             |
| Cash & cash equivalents         | 9,102             | 22,317            |
|                                 | 31,069            | 43,677            |

The maximum exposure to credit risk for trade receivables and finance lease income receivable by geographic location is as follows:

|                          | Carrying Value<br>December 31, 2014<br>US\$'000 | Carrying Value<br>December 31, 2013<br>US\$'000 |
|--------------------------|---|---|
| United States            | 11,332  | 12,743  |
| Euro-zone countries      | 1,813   | 1,452   |
| UK                       | 388   | 582   |
| Other European countries | 22  | 173   |
| Other regions            | 8,412   | 6,410   |
|                          | 21,967  | 21,360  |

The maximum exposure to credit risk for trade receivables and finance lease income receivable by type of customer is as follows:

|                                | Carrying Value    | Carrying Value    |
|--------------------------------|-------------------|-------------------|
|                                | December 31, 2014 | December 31, 2013 |
|                                | US\$'000          | US\$'000          |
| End-user customers             | 10,675            | 9,738             |
| Distributors                   | 10,631            | 10,847            |
| Non-governmental organisations | 661               | 775               |
|                                | 21,967            | 21,360            |

Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

## **Impairment Losses**

The ageing of trade receivables at December 31, 2014 is as follows:

| In thousands of US\$  | Gross<br>2014 | Impairment<br>2014 | Gross<br>2013 | Impairment<br>2013 |
|-----------------------|---------------|--------------------|---------------|--------------------|
| Not past due          | 13,241        | _                  | 13,913        | 2                  |
| Past due 0-30 days    | 3,359         | _                  | 3,242         | 1                  |
| Past due 31-120 days  | 2,637         | 22                 | 1,893         | 43                 |
| Greater than 120 days | 3,245         | 2,183              | 2,864         | 2,104              |
|                       | 22,482        | 2,205              | 21,912        | 2,150              |

#### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

The movement in the allowance for impairment in respect of trade receivables during the year was as follows:

| In thousands of US\$                | 2014  | 2013  | 2012  |
|-------------------------------------|-------|-------|-------|
| Balance at January 1                | 2,150 | 1,520 | 1,507 |
| Charged to costs and expenses       | 237   | 62    | 72    |
| Related to acquisitions             | _     | 700   | _     |
| Charged to other accounts           | (19)  | _     | _     |
| Amounts recovered during the year   | _     | _     | _     |
| Amounts written off during the year | (163) | (132) | (59)  |
| Balance at December 31              | 2,205 | 2,150 | 1,520 |

The allowance for impairment in respect of trade receivables is used to record impairment losses unless the Group is satisfied that no recovery of the account owing is possible. At this point the amount is considered irrecoverable and is written off against the financial asset directly.

### **Capital Management**

The Group's policy is to maintain a strong capital base so as to maintain investor, creditor and market confidence and to sustain future development of the business. The Board of Directors monitors earnings per share as a measure of performance, which the Group defines as profit after tax divided by the weighted average number of shares in issue.

Following the divestiture of the Coagulation product line in 2010, the Group eliminated all bank debt. In the past, the Group has funded acquisitions using both equity and long term debt depending on the size of the acquisition and the capital structure in place at the time of the acquisition.

Although at December 31, 2014 the Group has no debt, it maintains a relationship with a number of lending banks and Trinity Biotech is listed on the NASDAQ which allows the Group to raise funds through equity financing where necessary. In February 2015, the Group entered into an overall facility agreement with Allied Irish Bank which consists of separate revolver, overdraft and leasing facilities amounting to approximately US\$15 million.

The Board of Directors is authorised to purchase its own shares on the market on the following conditions;

- the aggregate nominal value of the shares authorised to be acquired shall not exceed 10% of the aggregate nominal value of the issued share capital of the Company at the close of business on the date of the passing of the resolution:
- the minimum price (exclusive of taxes and expenses) which may be paid for a share shall be the nominal value of that share:
- the maximum price (exclusive of taxes and expenses) which may be paid for a share shall not be more than the average of the closing bid price on NASDAQ in respect of the ten business days immediately preceding the day on which the share is purchased.

### 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

#### Fair Values

The table below sets out the Group's classification of each class of financial assets/liabilities and their fair values:

|  | Note   | Loans and receivables | Liabilities at<br>amortised cost | Total<br>carrying<br>amount | Fair<br>Value |
|--|--------|-----------------------|----------------------------------|-----------------------------|---------------|
| December 31, 2014                                    |        |                       |                                  |                             |               |
| Trade receivables                                    | 15     | 20,277                | _                                | 20,277                      | 20,277        |
| Cash and cash equivalents                            | 16     | 9,102                 | _                                | 9,102                       | 9,102         |
| Finance lease receivable                             | 13, 15 | 1,690                 |                                  | 1,690                       | 1,690         |
| Net Deferred Consideration Payable ('Fiomi')         | 21     | _                     | (299)                            | (299)                       | (299)         |
| Other Payables                                       | 21     |                       | (2,071)                          | (2,071)                     | (2,071)       |
| Deferred Consideration (Phoenix Bio-tech)            | 19     | _                     | (125)                            | (125)                       | (125)         |
| Trade and other payables (excluding deferred income) | 19     |                       | (20,872)                         | (20,872)                    | (20,872)      |
| Provisions   | 20     |                       | (75)                             | (75)                        | (75)          |
|  |        | 31,069                | (23,442)                         | 7,627                       | 7,627         |

At December 31, 2014 consideration payable of US\$299,000 and other payables relating to licence fees of US\$2,071,000 are valued using Level 2 inputs. All other items are valued using Level 1 inputs. Valuation methods for Levels 1, 2 and 3 are described in the "fair value hierarchy" section of the accounting policies, see Note 1(xxvi).

|  | Note   | Loans and receivables | Liabilities at | Total<br>carrying<br>amount | Fair<br>Value |
|--|--------|-----------------------|----------------|-----------------------------|---------------|
| December 31, 2013                                    | 71070  | 700077410705          | umornisca cost | Carro tara                  | 7 67776       |
| Trade receivables                                    | 15     | 19,762                | _              | 19,762                      | 19,762        |
| Cash and cash equivalents                            | 16     | 22,317                | _              | 22,317                      | 22,317        |
| Finance lease receivable                             | 13, 15 | 1,598                 | _              | 1,598                       | 1,598         |
| Net Deferred Consideration Payable ('Fiomi')         | 19, 21 | _                     | (3,369)        | (3,369)                     | (3,369)       |
| Other Payables                                       | 21     | _                     | (3,055)        | (3,055)                     | (3,055)       |
| Deferred Consideration (Phoenix Bio-tech)            |        | _                     | (125)          | (125)                       | (125)         |
| Trade and other payables (excluding deferred income) | 19     |                       | (18,034)       | (18,034)                    | (18,034)      |
| Provisions   | 20     |                       | (75)           | (75)                        | (75)          |
|  |        | 43,677                | (24,658)       | 19,019                      | 19,019        |

At December 31, 2013 consideration payable of US\$3,369,000 and other payables relating to licence fees of US\$3,055,000 are valued using Level 2 inputs. All other items are valued using Level 1 inputs. Valuation methods for Levels 1, 2 and 3 are described in the "fair value hierarchy" section of the accounting policies, see Note 1(xxvi).

#### 26. DIVIDENDS PAID

A dividend of 22 cents per ADS was approved and paid during 2014 in respect of the 2013 financial year (20 cents per ADS approved and paid in 2013 in respect of the 2012 financial year).

|  | 2014<br>US\$'000 | 2013<br>US\$'000 |
|--|------------------|------------------|
| Declared and paid during the year:   |                  |                  |
| Dividends on ordinary shares:  |                  |                  |
| Final dividend in respect of FY 2013: US\$0.055 per 'A' share (US\$0.22 per ADS) (FY 2013: |                  |                  |
| US\$0.20).   | 5,029            | 4,373            |

### 27. POST BALANCE SHEET EVENTS

There are no other matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

- The entity's operations in future financial years;
- The results of those operations in future financial years; or
- The entity's state of affairs in future financial years.

#### 28. ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of these financial statements requires the Group to make estimates and judgements that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities.

On an on-going basis, the Group evaluates these estimates, including those related to intangible assets, contingencies and litigation. The estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

#### **Key sources of estimation uncertainty**

Note 11 contains information about the assumptions and the risk factors relating to goodwill impairment. Note 18 outlines information regarding the valuation of share options and warrants. Note 22 outlines the valuation techniques used by the Company in determining the fair value of business combinations. In Note 25, detailed analysis is given about the interest rate risk, credit risk, liquidity risk and foreign exchange risk of the Group.

### Critical accounting judgements in applying the Group's accounting policies

Certain critical accounting judgements in applying the group's accounting policies are described below:

#### Research and development expenditure

Under IFRS as adopted by the EU, we write-off research and development expenditure as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalised at cost within intangible assets and amortised over its expected useful life of 15 years, which commences when commercial production starts.

Acquired in-process research and development (IPR&D) is valued at its fair value at acquisition date in accordance with IFRS 3. The Company determines this fair value by adopting the income approach valuation technique. Once the fair value has been determined, the Company will recognise the IPR&D as an intangible asset when it: (a) meets the definition of an asset and (b) is identifiable (i.e. is separable or arises from contractual or other legal rights).

#### 28. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

Factors which impact our judgement to capitalise certain research and development expenditure include the degree of regulatory approval for products and the results of any market research to determine the likely future commercial success of products being developed. We review these factors each year to determine whether our previous estimates as to feasibility, viability and recovery should be changed.

#### Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment annually, individually or at the cash generating unit level.

Factors considered important, as part of an impairment review, include the following:

- Significant underperformance relative to expected historical or projected future operating results;
- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- Obsolescence of products;
- Significant decline in our stock price for a sustained period; and
- Our market capitalisation relative to net book value.

When we determine that the carrying value of intangibles, non-current assets and related goodwill may not be recoverable based upon the existence of one or more of the above indicators of impairment, any impairment is measured based on our estimates of projected net discounted cash flows expected to result from that asset, including eventual disposition. Our estimated impairment could prove insufficient if our analysis overestimated the cash flows or conditions change in the future.

### Allowance for slow-moving and obsolete inventory

We evaluate the realisability of our inventory on a case-by-case basis and make adjustments to our inventory provision based on our estimates of expected losses. We write-off any inventory that is approaching its "use-by" date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value.

### Allowance for impairment of receivables

We make judgements as to our ability to collect outstanding receivables and where necessary make allowances for impairment. Such impairments are made based upon a specific review of all significant outstanding receivables. In determining the allowance, we analyse our historical collection experience and current economic trends. If the historical data we use to calculate the allowance for impairment of receivables does not reflect the future ability to collect outstanding receivables, additional allowances for impairment of receivables may be needed and the future results of operations could be materially affected.

## Accounting for income taxes

Significant judgement is required in determining our worldwide income tax expense provision. In the ordinary course of a global business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Some of these uncertainties arise as a consequence of revenue sharing and cost reimbursement arrangements among related entities, the process of identifying items of revenue and expense that qualify for preferential tax treatment and segregation of foreign and domestic income and expense to avoid double taxation. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. Although we believe that our estimates are reasonable, no assurance can be given that the final tax outcome of these matters will not be different than that which is reflected in our historical income tax provisions and accruals. Such differences could have a material effect on our income tax provision and profit in the period in which such determination is made. In management's opinion, adequate provisions for income taxes have been made.

#### 28. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

Deferred tax assets and liabilities are determined for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities, using tax rates projected to be in effect for the year in which the differences are expected to reverse. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable. The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made.

Note 12 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and includes details of the unrecognised deferred tax assets at year end. The Group derecognised deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilized before they expire. The derecognition of these deferred tax assets was considered appropriate in light of the increased tax losses caused by the restructuring and uncertainty over the timing of the utilization of the tax losses. Except for the derecognition of deferred tax assets there were no material changes in estimates used to calculate the income tax expense provision during 2014, 2013 or 2012.

## 29. GROUP UNDERTAKINGS

The consolidated financial statements include the financial statements of Trinity Biotech plc and the following principal subsidiary undertakings:

| Name and registered office Trinity Biotech plc IDA Business Park, Bray Co. Wicklow, Ireland                                    | Principal activity Investment and holding company                | Principal Country of<br>incorporation and<br>operation<br>Ireland | Group % holding<br>Holding<br>company |
|--|--|---|---------------------------------------|
| Trinity Biotech Manufacturing Limited IDA Business Park, Bray Co. Wicklow, Ireland   | Manufacture and sale of diagnostic test kits                     | Ireland   | 100%                                  |
| Trinity Research Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland  | Research and development   | Ireland   | 100%                                  |
| Benen Trading Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland   | Trading  | Ireland   | 100%                                  |
| Trinity Biotech Manufacturing Services Limited IDA Business Park, Bray Co. Wicklow, Ireland                                    | Engineering services   | Ireland   | 100%                                  |
| Trinity Biotech Luxembourg Sarl<br>1, rue Nicolas Simmer,<br>L-2538 Luxembourg   | Investment and provision of financial services                   | Luxembourg  | 100%                                  |
| Trinity Biotech Inc<br>Girts Road,<br>Jamestown,<br>NY 14702, USA  | Holding Company  | U.S.A.  | 100%                                  |
| Clark Laboratories Inc<br>Trading as Trinity Biotech (USA)<br>Girts Road, Jamestown<br>NY14702, USA                            | Manufacture and sale of diagnostic test kits                     | U.S.A.  | 100%                                  |
| Mardx Diagnostics Inc<br>5919 Farnsworth Court<br>Carlsbad<br>CA 92008, USA  | Manufacture and sale of diagnostic test kits                     | U.S.A.  | 100%                                  |
| Fitzgerald Industries International, Inc<br>2711 Centerville Road, Suite 400<br>Wilmington, New Castle<br>Delaware, 19808, USA | Management services company                                      | U.S.A.  | 100%                                  |
| Biopool US Inc (trading as Trinity Biotech<br>Distribution)<br>Girts Road, Jamestown<br>NY14702, USA                           | Sale of diagnostic test kits                                     | U.S.A.  | 100%                                  |
| Primus Corporation<br>4231 E 75 <sup>th</sup> Terrace<br>Kansas City,<br>MO 64132, USA   | Manufacture and sale of diagnostic test kits and instrumentation | U.S.A.  | 100%                                  |

## 29. GROUP UNDERTAKINGS (CONTINUED)

| Name and registered office Phoenix Bio-tech Corp. 1166 South Service Road West Oakville, ON L6L 5T7 Canada. | Principal activity  Manufacture and sale of diagnostic test kits | Principal Country of incorporation and operation Canada | Group % holding<br>100% |
|---|--|---|-------------------------|
| Fiomi Diagnostics Holding AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden                       | Holding Company  | Sweden  | 100%                    |
| Fiomi Diagnostics AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden                               | Research and development   | Sweden  | 100%                    |
| Trinity Biotech Do Brasil<br>Rua Claudio Soares<br>Sao Paulo<br>Brazil                                      | Sale of diagnostic test kits                                     | Brazil  | 100%                    |
| Trinity Biotech (UK) Ltd<br>184 Cambridge Science Park<br>Cambridge CB4 0GA<br>United Kingdom               | Manufacture of blood bank screening products                     | UK  | 100%                    |
| Immco Diagnostics Inc<br>60 Pineview Drive<br>Buffalo<br>NY 14228, USA                                      | Manufacture and sale of autoimmune products                      | U.S.A.  | 100%                    |
| Nova Century Scientific Inc<br>5022 South Service Road<br>Burlington<br>Ontario<br>Canada                   | Manufacture and sale of autoimmune products                      | Canada  | 100%                    |

## 30. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on March 25, 2015.

## Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorised the undersigned to sign this Annual Report on its behalf.

### TRINITY BIOTECH PLC

By: /s/ RONAN O'CAOIMH

Mr Ronan O'Caoimh Director/

Chief Executive Officer

Date: March 25, 2015

By: /s/ KEVIN TANSLEY

Mr Kevin Tansley Company secretary/ Chief Financial Officer

Date: March 25, 2015

## Item 19 Exhibits

| Exhibit No.<br>1.1 | Description of Exhibit Memorandum and Articles of Association of Trinity Biotech plc (included as Exhibit 1 to our Annual Report on Form 20-F (File No. 000-22320), filed with the SEC on March 31, 2006).  |
|--------------------|---|
| 2.0                | Form of Deposit Agreement dated as of October 21, 1992, as amended and restated, among Trinity Biotech plc, The Bank of New York as Depositary, and all Owners and holders from time to time of American Depositary Receipts issued thereunder (included as Exhibit 1 to our Form F-6 (File No. 333-111946), filed with the SEC on January 15, 2004.) |
| 4.1                | Trinity Biotech plc Employee Share Option Plan 2013 (included as Exhibit 4.1 to our Registration Statement on Form S-8 (File No. 333-195232), filed with the SEC on April 11, 2014).  |
| 4.2                | Trinity Biotech plc Employee Share Option Plan 2011 (included as Exhibit 4 to our Registration Statement on Form S-8 (File No. 333-182279), filed with the SEC on June 22, 2012).   |
| 4.3                | Share Option Agreement dated as of July 26, 2013 between Trinity Biotech Public Limited Company and William J. Maggio (102,400 shares) (included as Exhibit 4.2 to our Registration Statement on Form S-8 (File No. 333-195232), filed with the SEC on April 11, 2014).   |
| 4.4                | Share Option Agreement dated as of July 26, 2013 between Trinity Biotech Public Limited Company and William J. Maggio (36,452 shares) (included as Exhibit 4.3 to our Registration Statement on Form S-8 (File No. 333-195232), filed with the SEC on April 11, 2014).  |
| 4.5                | Share Option Agreement dated as of July 26, 2013 between Trinity Biotech Public Limited Company and Rajnish Mittal (102,400 shares) (included as Exhibit 4.4 to our Registration Statement on Form S-8 (File No. 333-195232) filed with the SEC on April 11, 2014).   |
| 4.6                | Share Option Agreement dated as of July 26, 2013 between Trinity Biotech Public Limited Company and Kevin Lawson (102,400 shares) (included as Exhibit 4.5 to our Registration Statement on Form S-8 (File No. 333-195232), filed with the SEC on April 11, 2014).  |
| 4.7                | Credit Facilities Letter dated as of February 6, 2015 between Allied Irish Banks, p.l.c. and Trinity Biotech plc, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited, as Borrowers.   |
| 4.8                | Guarantee Letter to Allied Irish Banks, p.l.c. dated as of February 6, 2015 by Trinity Biotech plc, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited, as Borrowers.   |
| 4.9                | Fiomi Diagnostics AB Share Purchase Agreement dated as of February 28, 2012 (included as Exhibit 4(a) of our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on April 6, 2012).  |
| 4.10               | Agreement and Plan of Merger dated as of July 26, 2013 with Immco Diagnostics, Inc. (included as Exhibit 4.1 of our Annual Report on Form 20-F for the fiscal year ended December 31, 2013 (File No. 000- 22320), filed with th SEC on April 9, 2014).  |
| 4.11               | Lease agreement dated as of October 18, 2004 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of office premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.1 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 31, 2006).                                     |

| 4.12 | Lease agreement dated as of November 26, 2004 between Ronan O'Caoimh, Jonathon O'Connell and Jim Walsh with Trinity Biotech plc in respect of warehouse premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.2 to our to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on 31 March 2006). |
|------|---|
| 4.13 | Lease agreement dated as of December 20, 2007 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of warehouse premises in Bray, Co Wicklow, Ireland   |
| 4.14 | Lease agreement dated as of March 19, 2004 between Livers, LLC with Primus Corporation in respect of office premises in Kansas City, Missouri, U.S.A.   |
| 4.15 | Lease agreement dated as of May 30, 2001 between Lorrelle S. Johnson and Sharon L. Johnson with Clark Laboratories Inc in respect of office premises in Jamestown, New York, U.S.A.   |
| 4.16 | Lease agreement dated as of February 13, 2012 between Barco Inv. Inc with Mardx Diagnostics in respect of office premises in San Diego, California, U.S.A.  |
| 4.17 | Lease agreement dated as of December 1, 2007 between 60 Pineview LLC with Immco Diagnostics Inc in respect of office premises in Amherst, New York, U.S.A.  |
| 4.18 | Lab21 Business and Asset Purchase Agreement dated as of July 18, 2013.  |
| 4.19 | CDC Non-Exclusive Patent License Agreement dated as of May 22, 2012.  |
| 4.20 | The University of Texas System Materials License Agreement dated as of April 18, 2005.  |
| 4.21 | Inverness Medical Innovations, Inc. Patent License Agreement renewal dated as of August 3, 2006.  |
| 4.22 | National Institute of Health Non-Exclusive Patent License Agreement dated as of December 17, 1999.  |
| 8.1  | List of significant subsidiaries of Trinity Biotech plc (included as Item 18, note [29] to the consolidated financial statements in this Annual Report).  |
| 12.1 | Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |
| 12.2 | Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.  |
| 13.1 | Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 13.2 | Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 15.1 | Consent of Independent Registered Public Accounting Firm  |

#### **Strictly Private & Confidential**

5 February 2015

The Directors, Trinity Biotech PLC, IDA Business Park, Bray, Co Wicklow (the "Parent")

Cc:

Trinity Biotech Manufacturing Limited
Trinity Biotech Financial Services Limited
Benen Trading Limited
Immco Diagnostics Inc.
Trinity Biotech Inc
Clark Laboratories Inc.,
Mardx Diagnostics Inc
Primus Corporation

Dear Directors,

<u>WARNING:</u> If you do not meet the repayments on your credit agreement, your account will go into arrears. This may affect your credit rating, which may limit your ability to access credit in the future.

We are pleased to inform you that the Board of Allied Irish Banks, p.l.c. (the "Bank") has sanctioned certain credit facilities (together the "Facilities") to the Parent and certain of its subsidiaries as more particularly set out below (together the "Borrowers" and "Borrower" shall be construed accordingly), subject to the following terms and conditions (the "Facilities"), including but not limited to, the Events of Default, upon the occurrence of which the Bank shall be entitled to demand repayment of the sanctioned facility and to enforce all security given by the Borrower to the Bank:

In this Facility Letter capitalised terms which are defined in the Standard Terms and Conditions (as referred to in Section 3 below) forming part hereof shall have the meanings therein ascribed thereto.

### **SECTION 1**

#### The Facilities

## Facility 1:

**Method:** Uncommitted Revolver facility.

**Borrowers:** The Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited.

**Amount:** US\$10,000,000 (Ten million US Dollars)

**Purpose:** To finance working capital & other general corporate purposes.

The Borrowers shall not use any of Facility 1 for any purpose except that permitted hereunder. However, failure by a Borrower to comply with this Clause shall not prejudice any rights of the Bank, which shall not

be responsible for monitoring or ensuring the use or application by the Borrowers of Facility 1.

**Term:** The period ending on 30 November 2015.

**Availability:** Facility 1 shall be available for drawdown by the Borrowers in such amounts as may be agreed between the

Bank and the Borrowers as and when required during the Term. Each drawing under this Facility 1 will be

consolidated with that part of Facility 1already drawn.

**Availability Period:** Facility 1 is available for drawdown by the Borrowers up to 30 days prior to the expiry of the term applicable

to Facility 1.

**Repayment:** Facility 1 shall be repayable on demand.

Without prejudice to the right of the Bank to demand repayment thereof at any time, Facility 1 shall be

subject to review by 30 November 2015 or at any time at the Bank's discretion.

**Interest:** In the case of amounts drawn under Facility 1, interest periods shall be for a minimum one month period or

such other as may be agreed between the Borrower and the Bank.

Where the Borrower does not notify the Bank of its option prior to 11.00 a.m. on the first day of the interest period, an interest period of one month will be deemed to have been selected subject to availability of funds.

The interest rate payable on drawings under Facility 1 shall be at the rate of 2.50% per annum margin over the USD LIBOR cost of funds varying (currently 0.1735%), plus Reserve Asset Cost (as defined in the

Standard Terms and Conditions), for the appropriate interest period, if applicable.

Should the rate of interest applicable to funds sourced on the USD LIBOR fall below 0%, that rate shall be

taken to be 0% and no lower.

Facility 2:

**Method:** Overdraft

**Borrowers:** The Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services

Limited.

**Amount:** US\$2,000,000 (Two million US Dollars)

**Purpose:** To finance working capital.

The Borrowers shall not use any of Facility 2 for any purpose except that permitted hereunder. However, failure by a Borrower to comply with this Clause shall not prejudice any rights of the Bank, which shall not

be responsible for monitoring or ensuring the use or application by the Borrowers of Facility 2.

**Repayment:** Facility 2 shall be repayable on demand.

Without prejudice to the right of the Bank to demand repayment thereof at any time, Facility 2 shall be

subject to review by 30th November 2015 or at any time at the Bank's discretion.

**Interest:** Interest shall be payable on all sums drawn under Facility 2 at the AIB Global Treasury Services Overdraft

Rate varying, plus a margin of 0.10% (the "Overdraft Rate").

The AIB Global Treasury Services Overdraft Rate is calculated as one week USD LIBOR at 11.00am on the previous Thursday (i.e. adjustment for Bank Holidays will ensure setting provides spot value for Monday)

plus 0.9%, which may vary from time to time.

The AIB Global Treasury Services Overdraft Rate overdraft rate as of the date of this Facility Letter is 1.0368% per annum.

In addition to the Overdraft Rate, surcharge interest, at the rate of 12% per annum above the Overdraft Rate (subject to the application of the General Conditions (as defined below)) will apply to any unauthorised or excess borrowings on Facility 2 that the Bank may, in its absolute and sole discretion, permit from time to time.

In the event that the Bank shall permit such unauthorised or excess borrowings such permission shall not oblige the Bank to permit similar borrowings at any later time or times.

#### Facility 3:

Method:

Forward foreign exchange & contracts and/or interest rate swap contracts whereby a Facility 3 Borrower and the Bank shall from time to time agree on the delivery to one another of, respectively, different currencies or fixed and floating rates of interest payable on actual or notional amounts of principal.

**Borrowers:** 

The Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited.

Amount:

€1,016,000 (One million and sixteen thousand euro) by way of Credit Risk Equivalent (as defined below) on forward foreign exchange contracts.

**Purpose:** 

To assist the Borrowers in the management of their foreign exchange exposures.

The Borrowers shall not use any of Facility 3 for any purpose except that permitted hereunder. However, failure by a Borrower to comply with this Clause shall not prejudice any rights of the Bank, which shall not be responsible for monitoring or ensuring the use or application by the Borrowers of Facility 3.

#### **Utilisation:**

- (a) The Borrowers may from time to time apply to the Bank's Customer Treasury Services department to arrange forward foreign exchange contracts with the Bank. On receipt of such application the Bank will calculate the Credit Risk Equivalent of each such forward foreign exchange contract and provided that the aggregate (if any) of the Credit Risk Equivalent shall not exceed the amount referred to above and subject to the other terms and conditions hereof, the Bank and a Borrower of Facility 3 will then conclude the terms of the spot or forward foreign exchange contract then applied for by such Borrower.
- (b) In the event that the Bank shall determine that it shall not be agreeable to entering further forward foreign exchange or interest rate swap contracts with a Borrower of Facility 3 such determination shall not affect the obligations of the Borrowers on foot of outstanding forward foreign exchange contracts (if any).

### **Repayment**:

In the event that a Borrower shall fail at any time to comply with the terms of any forward foreign exchange contract or interest rate swap contract, then any and all losses incurred by the Bank (as certified in writing by the Bank) as a result of such failure (the "Delivery Loss") shall be payable by that Borrower on demand and the amount thereof may, at the option of the Bank, be debited to an account of that Borrower with the Bank.

In the event that the Bank shall terminate any then outstanding forward foreign exchange contract or interest rate swap contract as aforesaid, then the Bank, at its option, shall be further entitled to close out any or all other then existing treasury contracts with a Borrower, mark them to market

and net-off the amounts owing to and by such Borrower and the Bank respectively to each other and having taken account of the Delivery Loss a single net amount will be payable on demand by the party owing the greater amount. In the event that a Borrower shall be in default of any other obligations to the Bank and the Bank shall have made a demand for repayment thereof, then the Bank shall be entitled to close out any or all other then existing treasury contracts with that Borrower and (having taken account of the Delivery Loss) make or require payment of a single net amount as aforesaid. In the event that it shall be the Bank owing the greater amount as aforesaid, then the Bank shall be entitled to set-off and apply the net amount payable by it to a Borrower in settlement or reduction (as the case may be) of the other obligations in respect of which that Borrower shall be in default with the Bank.

A certificate of the Bank of any calculations herein shall be conclusive evidence thereof, save in the case of manifest error.

**Treasury Mandate:** 

A treasury mandate will be required to be completed in the event that the Bank's form of treasury mandate governing the conduct of treasury business shall not have been completed by a Borrower under Facility 3 and the Bank's Customer Treasury Services department will be in contact with you in that regard. Completion of the treasury mandate shall be a prerequisite to the entering into of contracts between the Bank and a Borrower under Facility 3.

Term:

Facility 3 shall be subject to review by 30th November 2015 or at any time at the Bank's discretion.

Credit Risk Equivalent:

In this Facility Letter, the term "Credit Risk Equivalent" shall mean such amount as the Bank, in its absolute discretion, shall determine, on the basis of the respective obligations of a Borrower and the Bank on foot of forward foreign exchange contracts or, as the case may be, interest rate swaps contracts applied for, the period of time within which such obligations shall be performed and such other factors as the Bank shall consider relevant, as being the proportion denominated in euros of the face value of each forward foreign exchange contract or swap contract which a Borrower under Facility 3 shall apply to the Bank to arrange as would constitute the loss to the Bank if such Borrower were not to perform its obligations on foot thereof. For the avoidance of doubt, a determination of any loss for the purpose of calculating Credit Risk Equivalent shall not be binding on the Bank for the purpose of calculating the Delivery Loss.

**Contracts:** 

Nothing herein shall require the Bank at any time or from time to time to enter into any forward foreign exchange or swap contracts with any Borrower under Facility 3.

Facility 4:

Facility: Leasing

**Lessee(s):** The Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited.

**Relevant Lender:** AIB Leasing Limited and/or the Bank (each a "**Relevant Lender**").

**Amount:** €2,000,000 (Two million euro)

**Documentation:** The terms and conditions of Facility 4 shall be governed by the documentation (the "**Leasing** 

**Documentation**") required to be signed by a Facility 4 Borrower by the Relevant Lender. The Leasing

Documentation to be in a form and substance satisfactory to the Relevant Lender.

**Pre-conditions:** Utilisation of Facility 4 will be subject to the satisfaction of such preconditions stipulated by the Relevant

Lender in addition to those Pre Conditions stated herein.

#### **Facility 5:**

Method:

Guarantee facility (the "Bank Guarantee Facility") to be availed of by means of guarantee(s), trade finance guarantee, standby letter(s) of credit, bond(s), indemnities or other contingent obligation(s) undertaken by the Bank to third parties which the Bank has heretofore issued and/or may from time to time issue on behalf of or at the request of a Borrower under Facility 5 in such form as the Bank may agree (each a "Bank Guarantee").

Facility 5 may also be utilised by means of guarantee(s), documentary credits, bonds or other contingent liabilities undertaken by the Bank to third parties on behalf of or at the request of a Borrower under Facility 5 which are issued by AIB Trade Finance (each a "**Trade Finance Guarantee/Letter of Credit**").

Any Trade Finance Guarantee/Letter of Credit shall be subject to separate AIB Trade Finance Terms and Conditions. In the event of any conflict between the AIB Trade Finance Terms and Conditions and the terms of this Facility Letter in relation to a Trade Finance Guarantee/Letter of Credit, the AIB Trade Finance Terms and Conditions shall prevail.

**Facility Limit:** 

€170,000 (One hundred and seventy thousand euro) which shall be the maximum aggregate exposure of the Bank in respect of <u>all</u> Bank Guarantees, Trade Finance Guarantees and/or Letters of Credit issued hereunder unless otherwise agreed by the Bank.

The Facility Limit set out above includes, but is not limited to, the following Bank Guarantees which the Bank has heretofore issued and/or may from time to time issue and, for the avoidance of doubt the Bank Guarantees referred to below may be amended or replaced from time to time with the agreement of the Bank:

• Bank Guarantee(s) in favour of the Revenue Commissioners in respect of the payment of VAT:

**Purpose:** 

To guarantee such contingent liabilities as may be agreed between the Borrowers and the Bank.

No Borrower under this Facility 5 shall utilise this Bank Guarantee Facility for any purpose except that permitted hereunder. However, failure by a Borrower to comply with this Clause shall not prejudice any rights of the Bank, which shall not be responsible for monitoring or ensuring the use or application by the Borrower of this Facility 5.

**Multiple Exposure:** 

The Borrowers acknowledge that the Bank's maximum exposure under any Bank Guarantee may be a multiple of the face value of that Bank Guarantee. The Borrowers hereby further acknowledge that in circumstances where the face value and the Bank's maximum exposure under any Bank Guarantee are different, for the purpose of fees, limit and the indemnity contained below that the Bank shall have reference to its maximum exposure under the relevant Bank Guarantee and not the face value of that Bank Guarantee.

Fees:

The Borrowers shall pay to the Bank a fee calculated at 1.0% per annum or part thereof (payable quarterly in arrears) on the Bank's maximum exposure under each Bank Guarantee. Such fee shall accrue from day to day, shall be calculated on the actual number of days elapsed and a 360 day year.

**Other Fees:** 

International Bank Guarantee: In respect of each International Bank Guarantee issued by the Bank under this Facility an issuance fee of 1.00% per annum of the Bank's maximum exposure under such International Bank Guarantee will apply and this fee will be charged quarterly in advance (minimum of €38 per quarter), together with any other fees applicable to the International Bank Guarantee (e.g. amendment fees etc.) as set out in the "Schedule of International Transaction Charges" as same may be amended from time to time, a current copy of

which is available at your local branch or on www.aib.ie. Please note that the relevant fees will be charged in advance for each full quarter irrespective of whether the Bank's exposure in respect of any International Bank Guarantee remains outstanding for the full quarter or only part thereof.

Standby Letters of Credit: In respect of each Letter of Credit issued by the Bank under this Facility, an issuance fee of 1.00% per annum of the Bank's maximum exposure under such Letter of Credit will apply and this fee will be charged quarterly in advance (minimum of €38 per quarter), together with any other fees applicable to the Letter of Credit (e.g. amendment fees etc.) as set out in the "Schedule of International Transaction Charges" as same may be amended from time to time a current copy of which is available at your local branch or on www.aib.ie. Please note that the relevant fees will be charged in advance for each full quarter irrespective of whether the Bank's exposure in respect of any Letter of Credit remains outstanding for the full quarter or only part thereof.

<u>Documentary Letters of Credit:</u> Any Documentary Letter of Credit shall be subject to the relevant fee and charge provisions set out for Outgoing Letters of Credit in the Bank's "Schedule of International Transaction Charges" as same may be amended from time to time, a current copy of which is available at your local branch or on www.aib.ie.

For the avoidance of doubt, all fees payable by any Borrower under this Clause entitled "Other Fees" shall be payable in addition to the fees outlined in the Clause entitled "Fees" for Facility 5.

Without prejudice to the preceding clauses, it is the Bank's present intention to review this Bank Guarantee Facility by 30<sup>th</sup> November 2015 or at any time at the Bank's discretion.

- (a) In the event of the Bank being called upon to make any payment under any Bank Guarantee, the Bank shall be entitled to make such payment on first demand.
- (b) The Borrowers shall not be entitled to query the correctness of any amount paid by the Bank under any Bank Guarantee and shall be obliged to immediately refund such amount, together with interest, to the Bank in accordance with the terms hereof.
- (c) Each of the Borrowers hereby agrees and undertakes:
  - to indemnify the Bank and to keep the Bank indemnified against all actions, proceedings, damages, costs, claims, demands, expenses or losses which the Bank may suffer or sustain by reason of or on account of the Bank having given a Bank Guarantee or otherwise in connection with the Facilities;
  - (ii) that its liability hereunder shall continue until the later of, the date on which the Bank's liability, either actual or contingent, under all Bank Guarantees shall have been discharged or the date on which any loan arising under sub-clause (v) hereof shall have been unconditionally discharged in full:
  - (iii) that any request made upon the Bank for payment of any sum of money under any Bank Guarantee shall be a sufficient authority to the Bank, without any notice to or consent from the Borrowers (or any of them) for making any such payment and it shall not be incumbent upon the Bank to enquire whether any such payment is in fact due;
  - (iv) that it shall on demand, provide and pay to the Bank cleared matching funds to meet any and all such payments made by the Bank under or in respect of any Bank Guarantee;
  - (v) without prejudice to the foregoing, the Bank shall be entitled to debit any of its accounts with the Bank (or, in the event of no such account being maintained by it with the Bank, an account specifically opened for such purpose and which the

#### **Operation:**

- Bank is hereby irrevocably authorised to open) with the amount of any and all payments made by the Bank under or in respect of any Bank Guarantee and to apply such funds in satisfaction of such payments in accordance with (c)(iv) above; and
- (vi) in the event that payment shall not be made by a Borrower on demand, then, without prejudice to the Bank's rights herein, interest shall be payable on the total amount due by a Borrower to the Bank at the rate of 5 per cent per annum over the cost to the Bank of one month matching funds on the appropriate Interbank market plus reserve asset cost if applicable. The rate shall be set on the date of payment by the Bank under any Bank Guarantee in accordance with normal banking practice and shall be reset at one monthly intervals thereafter.

The obligations of the Borrowers under the above Clause are continuing obligations and will extend to the ultimate balance of sums payable by the Borrowers (or any of them) in respect of any Bank Guarantee, regardless of any intermediate payment or discharge in whole or in part.

The obligations of the Borrowers under this Clause will not be affected by any act, omission, matter or thing which, but for this Clause, would reduce, release or prejudice any of its obligations under this Clause (without limitation and whether or not known to it or any other person) including:

- (i) any time, waiver or consent granted to, or composition with, any guarantor, obligor or any beneficiary under any Bank Guarantee or any other person;
- (ii) the release of any other guarantor or obligor or any other person under the terms of any composition or arrangement with any creditor or any member of a Borrower or the Group;
- (iii) the taking, variation, compromise, exchange, renewal or release of, or refusal or neglect to perfect, take up or enforce, any rights against, or security over assets of, any guarantor or obligor, any beneficiary under any Bank Guarantee or other person or any non-presentation or non-observance of any formality or other requirement in respect of any instrument or any failure to realise the full value of any security;
- (iv) any incapacity or lack of power, authority or legal personality of or dissolution or change in the members or status of a guarantor or obligor, any beneficiary under any Bank Guarantee or any other person;
- (v) any amendment (however fundamental) or replacement of this Facility Letter, any Bank Guarantee or any other document or security; or
- (vi) any unenforceability, illegality or invalidity of any obligation of any person under this Facility Letter, any Bank Guarantee or any other document or security; or any insolvency or similar proceedings.

The provisions of this Clause entitled "Operation" including in particular the Indemnity contained in the sub-paragraph (c), shall survive the termination, expiration or replacement of this Facility Letter.

### **SECTION 2**

The following terms and conditions shall apply to the Facilities, except to the extent that there shall be specific exclusion(s).

**Security:** 

The obligations of the Borrower to the Bank in respect of the Facilities shall be secured in a manner satisfactory to the Bank as follows:

#### **Existing Security Held:**

- (a) Cross Guarantees from the Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited dated 29 April 2010.
- (b) Counter Indemnity in favour of the Bank from the Parent, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited in respect of the Guarantee Facility of €170,000.

#### To be provided:

- (a) In respect of Facility 4, title to leased assets.
- (b) In respect of all Facilities, All Sums cross company guarantee and indemnity from the following:
  - (i) the Parent;
  - (ii) Trinity Biotech Manufacturing Limited;
  - (iii) Trinity Biotech Financial Services Limited;
  - (iv) Benen Trading Limited;
  - (v) Immco Diagnostics Inc.;
  - (vi) Trinity Biotech Inc;
  - (vii) Clark Laboratories Inc.;
  - (viii) Primus Corporation; and
  - (ix) Mardx Diagnostics Inc,

(collectively the "Guarantors" and each a "Guarantor").

The Parent and the Bank agree that any other Group company comprising (i) an individual company representing 5% or more ('a material subsidiary') and (ii) companies collectively representing 80% or more of (A) consolidated Gross Assets and (B) consolidated EBITDA ('material subsidiary group') shall accede to the guarantee and indemnity above. Any accession shall be on terms and on the basis of documentation satisfactory to the Bank.

<u>For the avoidance of doubt</u>, the Security to be provided, as described above, shall also secure such Limits afforded by the Bank from time to time in relation to iBusiness Banking and other electronic banking platforms for the amount stipulated by the Bank from time to time in the form of a Limits Letter. These Limits can be withdrawn at any time by the Bank at its sole discretion.

### AIB Corporate Banking Policy On Collateral

AIB Corporate Banking's policy on collateral is that, in order to secure a Borrower's obligations to the Bank, a Borrower may be required to provide such security which the Bank considers appropriate and reasonable having regard to the facility/ies sought and the nature, liquidity and value of the security.

Examples of such security include but is not limited to, a first/second legal mortgage/charge over specific suitable assets, a debenture creating a fixed and floating charge over the property and assets of the Borrower, a legal mortgage/charge over shares/instruments, a security assignment over rights such as intellectual property rights, receivables, agreements, etc., a charge/assignment over a bank account, an assignment of life policy/keyman insurance, a letters of undertaking and third party guarantees (corporate or personal as appropriate) which may be required to be supported by security from that third party.

If a Borrower is in default of the terms and conditions of this Facility Letter, the Bank is entitled to demand repayment of the facility/ies and to enforce all of this security.

At the request of a Borrower, the Bank will return to the Borrower any security, held by the Bank, when all facilities for which the security is pledged have been repaid.

#### **Conditions Precedent:**

The Bank shall not be obliged to provide the Facilities or any part thereof unless it has received, in each case in a form and substance satisfactory to the Bank and its advisers, each of the following:

- (a) A certified copy of the constitutional documents of each Borrower and each Guarantor (together the "**Obligors**" and each an "**Obligor**").
- (b) A certified copy of a resolution of the board of directors or, if applicable, a committee of the board of directors of each Original Obligor:
  - (i) approving the terms of, and the transactions contemplated by, this Facility Letter and any guarantee or security required to be provided in connection therewith (together the "**Finance Documents**" and each a "**Finance Document**") to which it is a party and resolving that it execute, deliver and perform the Finance Documents to which it is a party;
  - (ii) authorising a specified person or persons to execute the Finance Documents to which it is a party on its behalf:
  - (iii) authorising a specified person or persons, on its behalf, to sign and/or despatch all documents and notices (including, if relevant, any utilisation request) to be signed and/or despatched by it under or in connection with the Finance Documents to which it is a party; and
  - (iv) in the case of an Obligor, other than the Parent, authorising the Parent to act as its agent in connection with the Finance Documents.
- (c) If applicable, a certified copy of a resolution of the board of directors of the relevant company, establishing the committee referred to in paragraph (b) above.
- (d) If an Obligor is incorporated in Ireland, evidence that the Obligor has done all that is necessary to comply with Section 60 of the Companies Act 1963 in order to enable that Obligor to enter into the Finance Documents and perform its obligations under the Finance Documents.
- (e) If an Obligor is not incorporated in Ireland, such documentary evidence as legal counsel to the Bank may require, that such Obligor has complied with any law in its jurisdiction relating to its entry into of the Finance Documents.
- (f) A copy of a resolution signed by all the holders of the issued shares in each Guarantor incorporated in a jurisdiction other than Ireland, approving the terms of, and the transactions contemplated by, the Finance Documents to which the Guarantor is a party.
- (g) A copy of a resolution of the board of directors of each corporate shareholder of each Guarantor incorporated in a jurisdiction other than Ireland approving the terms of the resolution referred to in paragraph (f) above.

- (h) A certificate of the Parent (signed by two directors) confirming that borrowing or guaranteeing or securing, as appropriate, the Facilities would not cause any borrowing, guarantee, security or similar limit binding on any Obligor to be exceeded.
- A certificate of an authorised signatory of each Obligor incorporated in Ireland certifying that it and each of the other Obligors are members of a group of companies within the meaning of Section 155 of the Companies Act 1963 and for the purposes of Section 35 of the Companies Act 1990.
- The Finance Documents duly executed by each Obligor.
- (k) A utilisation request in relation to a Facility (where required by the Bank) in the form set out in the Schedule hereto.
- Such mandates (including, without limitation, the SEPA Mandate annexed hereto) and other account opening documentation as the Bank may require.
- (m) Legal Opinions from Counsel acceptable to the Bank for all non-Irish incorporated Obligors in relation to the entry by them into the Finance Documents to which they are a party, in a form acceptable to the Bank.
- Confirmation from the Parent that no Related Party Loans have been provided to or by any Obligor.
- (o) Clear searches in all appropriate registries against each Obligor.
- (p) A copy of any other Authorisation or other document, opinion or assurance which the Bank considers to be necessary or desirable (if it has notified the Parent accordingly) in connection with the entry into and performance of the transactions contemplated by any Finance Document or for the validity and enforceability of any Finance Document.

#### **Negative Covenants:**

By acceptance of the Facilities, the Borrowers hereby jointly and severally covenant with the Bank, that as long as any sums shall be owing to the Bank under the Facilities:

- No disposals shall be made by the Obligors outside the ordinary course of trading activities save for Permitted Disposals (as defined below).
- No acquisitions shall be made by the Obligors outside the ordinary course of trading activities save for Permitted Acquisitions (as defined below).

Positive Covenants: For so long as the Borrowers (or any of them) shall have any obligations to the Bank on foot of this Facility Letter or the Borrowers (or any of them) shall have the right to avail of the Facilities then the Obligors shall and the Parent shall procure that each of the Obligors shall comply with the following covenants:

- (1) (a) The Obligors will maintain insurances on or in relation to its business and assets with underwriters and insurance companies of repute against such risks of the kinds customarily insured against by, and in amounts reasonably and commercially prudent for, companies carrying on similar businesses and will ensure that such insurance policy contains such provisions for the protection of the Bank as the Bank may from time to time reasonably require.
  - (b) Any insurance required under this clause must be with an insurance company or underwriters acceptable to the Bank.

- (c) The Obligors will not do or permit anything to be done which may make void or voidable any such policy of insurance.
- (d) The Obligors will promptly pay all premiums and do all other things necessary to keep each policy of insurance in force.
- (e) The Obligors will, immediately on demand by the Bank, produce to the Bank the policy, certificate or cover note relating to any insurance policy and the receipt for the payment of the last premium.

If any Obligor fails to comply with any of the provisions of clauses (a) to (e), the Bank shall immediately be entitled (but not obliged) to effect or renew the insurances concerned at the expense of the Obligors.

- (2) pay promptly all debts, which are to be paid in priority to all other debts in a winding up and upon the appointment of a receiver on foot of, or upon the taking possession of property comprised in, a debenture secured by a floating charge; and
- (3) the claims of the Bank and its affiliates, against the Obligors under this Facility Letter, will rank at least *pari passu* with the claims of all its other unsecured and unsubordinated creditors, save those whose claims are preferred solely by any bankruptcy, insolvency, liquidation or other similar laws of general application.

### **Special Conditions:**

The provision and continued maintenance of the Facilities is conditional upon:

- (a) In the case of Facility 1 only, a minimum 30 consecutive days of nil drawing, until the 30th November 2015 review date.
- (b) In the case of Facility 2 only, a minimum (i) 30 consecutive days and (ii) 90 total days, of credit funds, until the 30th November 2015 review date.
- (c) All Group companies comprising (i) individual companies representing 5% or more and (ii) companies collectively representing 80% or more of (A) consolidated Gross Assets and (B) consolidated EBITDA shall be required to guarantee the obligations of the Borrowers under the Facilities at all times.
- (d) Notification to the Bank re any (i) enforcement action by any relevant government regulatory body (including, without limitation, the US Food & Drug Administration, the Irish Medicines Board and Health Canada) and/or (ii) failure to comply with any laws or regulations relevant to the Group's business.

#### Financial Information:

During the currency of the Facilities, the Parent shall furnish the following to the Bank:

- (a) Annual audited financial statements of the Group, to be provided to the Bank within 120 days subsequent to the Group's Financial Year End.
- (b) Annual budget for the Group to be provided 20 days prior to the Group's Financial Year End.
- (c) Quarterly accounts for the Group, to be provided to the Bank 45 days subsequent to each Quarter End (excluding the Financial Year End for the avoidance of confusion).
- (d) Such other information in relation to the Group and/or its business as the Bank may require from time to time.

(e) The Parent shall supply a compliance certificate (in such form as shall be agreed by the Bank and the Parent, each such certificate being a "Compliance Certificate") with each set of its annual financial statements and each set of its quarterly financial statements to be delivered by the Parent to the Bank pursuant to this clause entitled "Financial Information". Each Compliance Certificate shall, amongst other things, set out (in reasonable detail) calculations as to compliance with the financial covenants outlined in the clause entitled "Financial Covenants" in this Facility Letter. Each Compliance Certificate shall be signed by two directors of the Parent.

#### Financial Covenants:

At all times during the currency of the Facilities, the Parent shall procure that the following covenants will be complied:

- (a) the Group's consolidated Financial Indebtedness shall remain below two times (2.0x) Leverage; and
- (b) the Group's consolidated financial accounts shall report Tangible Net Worth of US\$35,000,000 (Thirty five million US Dollars) or above.

The financial covenants set out above shall be calculated in accordance with the Accounting Principles and tested (commencing on the first semi-annual reporting date) by reference to each of the financial statements and Compliance Certificates delivered pursuant to paragraphs (a) and (e) of the "Financial Information" clause above.

#### **Expenses and Fees:**

The Parent shall be liable to the Bank to account for:

- (a) any fee, charge, commission or expense (including legal fees) in respect of the Facilities including without limitation those which the Bank may incur in connection with the preservation, modification, amendment or release of its rights under this Facility Letter and/or the security required to be provided; and
- (b) any fee, charge, commission or expense (including legal fees) which the Bank may incur in connection with the enforcement or attempted enforcement of its rights under this Facility Letter or under the security required hereunder.

The Bank may debit any such fees, charges, commission or expenses from any one or more of the Borrowers' account(s) held with the Bank.

### **Indemnity:**

The Parent hereby agrees to indemnify the Bank against any liability, costs, damages, claims, demands, loss (including loss of profit), interest or expense of any nature whatsoever which the Bank may certify as incurred by the Bank as a consequence of:

- (a) the occurrence of any Event of Default hereunder; or
- (b) any repayment or prepayment of the Facilities or any part there of being made otherwise than on the last day of an interest period hereunder.

#### **SECTION 3**

## **Standard Terms** and Conditions:

The Facilities are further subject to the terms and conditions contained in the Standard Terms and Conditions, a copy of which is attached hereto. Acceptance by the Obligors of this Facility Letter shall be deemed to be an acknowledgement and acceptance of the Standard Terms and Conditions.

In the event of any inconsistency between the terms and conditions contained in the Standard Terms and Conditions and the terms and conditions of this Facility Letter, the terms and conditions of this Facility Letter shall prevail.

#### **SECTION 4**

#### **Events of Default:**

Strictly without prejudice to the demand nature of any of the Facilities, the Bank reserves the right to terminate its provision of Facilities hereunder and to call for immediate repayment in full of all monies outstanding hereunder, including interest and other charges, should any of the following events occur:

- (a) if a Borrower defaults in any payment of principal interest or any other sums payable hereunder when due: or
- (b) if an Obligor defaults in the performance of any other obligation, covenant, term or condition herein contained or contained in any other agreement entered into by an Obligor, any guarantee or any other party in connection with this Facility Letter (other than the payment of principal, interest or any other sums when due referred to in (a) above) and such default continues un-remedied for seven (7) days from the date thereof; or
- (c) if an order is made, proceedings are commenced, or an effective resolution is passed for the winding up of an Obligor, or a meeting is convened for the purpose of consideration of such a resolution other than for the purpose of reconstruction or amalgamation while solvent on terms which have been previously approved by the Bank in writing; or
- (d) if any loan, debt, guarantee or other obligation constituting indebtedness of an Obligor (whether to the Bank or to any other entity) becomes due prior to its specified maturity or is not paid when due or an Obligor is in breach of or in default under any agreement, deed or mortgage under or pursuant to which such indebtedness was incurred (whether or not steps are taken to enforce same), and provided that it shall not constitute an Event of Default if the aggregate amount of all such indebtedness is less than US\$500,000; or
- (e) if an Obligor convenes a meeting of or proposes or enters into any arrangement or composition for the benefit of its creditors; or
- (f) if a distress execution attachment or other process is levied or issued against any of an Obligor's property, assets or undertaking and is not discharged within fourteen (14) days from the date thereof; or
- (g) if a petition is presented for the appointment of an examiner (or analogous officer) to an Obligor; or
- (h) if an encumbrancer takes possession of, or a receiver, administrator or other similar officer is appointed in respect of, the whole or any part of an Obligor's property, undertaking and assets; or

- (i) if any representation or warranty made or reaffirmed pursuant to the Facilities proves at any time to be incorrect or inaccurate such that it is likely, in the opinion of the Bank (acting reasonably) to constitute a material adverse change in the business, assets or future prospects of the Group or is or are detrimental to the interests of the Bank; or
- (j) if an Obligor is unable to pay its debts within the meaning of Section 214 of the Companies Act 1963 or any statutory modification or re-enactment thereof; or
- (k) if an Obligor defaults in payment of any taxes due and payable (other than those being contested in good faith); or
- (l) if an Obligor ceases or threatens to cease to carry on its business or substantially the whole of its business without the prior written consent of the Bank; or
- (m) if this Facility Letter or any of the agreements entered into pursuant to the security requirements hereunder (including any guarantee) is or becomes (or is alleged to be) unlawful or unenforceable or ineffective in any respect or is repudiated by any person thereto in any respect; or
- (n) if any event or events shall happen or occur or be likely to happen or occur in relation to the business or affairs of an Obligor, which in the opinion of the Bank constitutes a material adverse change in its or their business, assets or future prospects or is or are detrimental to the interests of the Bank; or
- (o) if in the opinion of the Bank any change shall take place in any applicable law or regulation or in the interpretation thereof which shall make it unlawful for the Bank to maintain or give effect to its obligations hereunder; or
- (p) if the Parent ceases to be a listed company or if any person or group of persons acting in concert gains direct or indirect control of more than 29.99% of the shares in the Parent; or
- (q) if any Obligor (other than the Parent) ceases to be a direct or indirect subsidiary of the Parent.

#### **Other Facilities:**

The Facilities offered in this document are in substitution for and not in addition to the Facilities as set out on the Facility Letter dated 18<sup>th</sup> August 2014.

#### **Counterpart:**

This Facility Letter may be executed in any number of counterparts, each of which is an original and which together have the same effect as if each party had signed the same document.

#### **Standard Terms:**

The Facilities (save for any overdraft facility) are further subject to the terms and conditions contained in the Standard Terms and Conditions, a copy of which is attached hereto. In the event of any inconsistency between the terms and conditions contained in the Standard Terms and Conditions and the terms and conditions of this Facility Letter, the terms and conditions of this Facility Letter shall prevail.

## General Terms and Conditions:

The Facilities shall be further subject to the Bank's brochure on lending entitled 'General Terms and Conditions governing Business Lending' (the "General Conditions") a copy of which, effective from November 2013, is enclosed. Without prejudice to the generality of the brochure, we would draw your attention to Section V thereof, entitled 'Interest'.

Acceptance by the Borrowers of this Facility Letter shall be deemed to be an acknowledgement and acceptance of the Standard Terms and the General Conditions.

**Annual Review:** The Borrower is entitled to an annual review meeting with the Bank in relation to the Facilities and related

security.

**Applicable Law:** The Facility shall be governed by and construed in accordance with the laws of Ireland.

Acceptance: If the terms and conditions of the Facilities, including the terms of the Appendices, are acceptable to you, we

shall be obliged if you will so indicate by returning to us within twenty one (21) days:

(a) a certified copy of a resolution of your Board (draft enclosed), authorising the acceptance of the Facilities and the execution of this Facility Letter;

(b) the enclosed copy of this Facility Letter, duly accepted by the Borrowers; and

(c) the enclosed copy of this Facility Letter, acknowledged by the Guarantors.

We are pleased to have the opportunity of placing the Facilities before you.

Yours faithfully For and on behalf of **Allied Irish Banks, p.l.c.** 

/s/ Cathal O'Connor Cathal O'Connor Head of Healthcare AIB Corporate Banking Ireland /s/ Keith Fitzsimons Keith Fitzsimons Relationship Manager AIB Corporate Banking Ireland

## TO: Allied Irish Banks, p.l.c.

Accepted this 6th day of February 2015

For and on behalf of **Trinity Biotech plc** 

(in their capacity as Borrower)

/s/ Ronan O'Caoimh Director

/s/ Jim Walsh Director

For and on behalf of

Trinity Biotech Manufacturing Limited (in their capacity as Borrower)

/s/ Kevin Tansley **Director** 

/s/ Jim Walsh Director

For and on behalf of

**Trinity Biotech Financial Services Limited** 

(in their capacity as Borrower)

/s/ Kevin Tansley

/s/ Ronan O'Caoimh

Director

Director

## **GUARANTORS' ACKNOWLEDGEMENT**

We as guarantors of the within Facilities hereby acknowledge and accept the terms applicable thereto this 6th day of February 2015

For and on behalf of

**Trinity Biotech plc** 

(in their capacity as Guarantor)

/s/ Ronan O'Caoimh /s/ Jim Walsh **Director Director** 

For and on behalf of Trinity Biotech Manufacturing Limited (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Jim Walsh **Director Director** 

For and on behalf of

**Trinity Biotech Financial Services Limited** 

(in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

**Director Director** 

For and on behalf of **Benen Trading Limited** (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

**Director Director** 

For and on behalf of **Immco Diagnostics Inc** (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Jim Walsh Director Director

For and on behalf of **Trinity Biotech Inc** (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

Director Director

For and on behalf of Clark Laboratories Inc. (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

Director Director

For and on behalf of **Primus Corporation** (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

Director Director

For and on behalf of **Mardx Diagnostics Inc** (in their capacity as Guarantor)

/s/ Kevin Tansley /s/ Ronan O'Caoimh

Director Director

# Schedule

# Form of Utilisation Request

From: [ ] (as Borrower)

| To:  | Allied Irish Banks, p.l.c.  |  |
|------|---|--|
| Date | ed: [ ] 2015  |  |
| Dea  | ır Sirs   |  |
| Faci | ility Letter dated [ ] February 2015 issued by the Bank and addressed to Trinity Biotech PLC (the "Facility Letter")  |  |
| 1.   | We refer to the Facility Letter. This is a utilisation request. Terms defined in the Facility Letter have the same meaning in this utilisation request unless given a different meaning herein. |  |
| 2.   | We hereby request to drawdown € (INSERT NUMERICAL VALUE OF DRAWDOWN) (INSERT AMOUNT IN WORDS) from our US\$10,000,000 [Uncommitted Revolver, Facility 1 as documented in the Facility Letter].  |  |
| 3.   | Please transfer the amount to the following account:  |  |
|      | • [Trinity Biotech p.l.c.]  |  |
|      | Account: [Trinity Biotech p.l.c.]   |  |
|      | Sort Code: [ ]  |  |
|      | Account No: [ ]   |  |
|      | • IBAN: [ ]   |  |
|      | • IBIK: [ ]   |  |
| 4.   | We, the Directors of [Trinity Biotech p.l.c.], confirm that no Event of Default or potential Event of Default is continuing, unremedied or unwaived as at the date of this request.             |  |
| 5.   | This request is irrevocable.  |  |
|      | RECTOR 1 DIRECTOR 2 INT NAME] [PRINT NAME]  |  |

#### STANDARD TERMS AND CONDITIONS

#### 1. **DEFINITIONS**:

"Accounting Principles"

means generally accepted accounting principles, policies, standards and practices in Ireland including

IFRS.

"Bank"

means Allied Irish Banks, p.l.c., or any of its subsidiaries providing the Facilities (which term shall

include all or any of them).

"Business Day"

means a day on which the Bank's branches are generally open for business in Ireland.

"Borrower"

means the body corporate/company or other person/persons utilising the Facilities (or any part

thereof).

"Breakage Cost"

means the replacement cost to the Bank resulting from a Prepayment.

"Cost of Funds"

means in relation to a Facility, the cost to the Bank as determined by the Bank (expressed as a percentage per annum), given the nature of the Facility and prevailing market conditions, of raising

funds from external sources.

"EBIT"

means, in respect of any Relevant Period, the consolidated net income of the Group before:

- (a) any provision on account of taxation;
- (b) any interest (including capitalised interest), commission, discounts or other fees incurred or payable, received or receivable by any related party and or other permitted borrowings in respect of Indebtedness for Borrowed Money;
- (c) any amounts received or paid pursuant to the interest hedging arrangements entered into in respect of the Facilities;
- (d) any items treated as exceptional or extraordinary items, which will include, for the avoidance of doubt, any amount in respect acquisition costs;
- (e) any amount attributable to goodwill arising on the acquisition, any amount attributable to Pension Items.

"EBITDA"

means, for any relevant period, EBIT (see above) before any amount attributable to amortisation of intangible assets (including goodwill) and depreciation of tangible assets and amortisation, or the writing off of acquisition costs (to the extent, in each case, deducted in calculated EBIT).

"Environmental Laws"

means all present and future national, federal, state, local, foreign and supranational laws, rules or regulations, codes, ordinances, orders, decrees, judgements or injunctions issued, promulgated, approved or entered thereunder or other requirements of Governmental Authorities or the common law relating to health, safety, pollution or protection of the

environment, including without limitation laws relating to emissions, discharges, releases or threatened releases of pollutants, contaminants, chemicals or industrial, toxic or hazardous substances or wastes into the environment, including without limitation, land, air, surface water, ground water (land surface or sub-surface strata) or otherwise relating to the manufacture, processing, distribution, use, generation, treatment, storage, disposal, transport or handling of pollutants, contaminants, chemicals or industrial, toxic or hazardous substances, or wastes or underground storage tanks or emissions therefrom.

"Facilities"

means the banking facility or facilities agreed to be provided to or renewed, replaced or restructured on behalf of a Borrower by the Bank pursuant to the Offer Letter and Facility will mean any one of them as the context will require.

"Financial Indebtedness"

means any indebtedness for or in respect of:

- (a) Indebtedness for Borrowed Money;
- (b) any documentary or standby letter of credit or performance bond facility;
- (c) for the purposes of Cross Default only, any interest rate swap, currency swap, forward foreign exchange transaction, cap, floor, collar or option transaction or any other treasury transaction or any combination thereof or any other transaction entered into in connection with protection against or benefit from fluctuation in any rate or price (and the amount of the Financial Indebtedness in relation to any such transaction shall be calculated by reference to the mark-tomarket valuation of such transaction at the relevant time); and
- (d) any guarantee or indemnity issued in connection with any of the items referred to in paragraphs (a) to (c) above.

"Governmental Authority"

means any authority having power to make or enforce Environmental Laws or to issue licenses or other authorisations of any description which shall subject the conduct of any process (whether by manufacture or otherwise) to particular or general conditions and 'Governmental Authorities' shall be construed accordingly.

"Group"

Trinity Biotech plc and all subsidiaries.

"Interest Period"

means such period(s) by reference to which the Bank shall have agreed to fund a Facility.

"Leverage"

means the ratio of the Group's Financial Indebtedness deducted against cash held at bank, divided by EBITDA.

"Liquidity Requirement"

means any liquidity reserve ratio special deposit or similar requirements (or any other requirement having the same or similar purpose) of any Regulatory Authority.

"Margin"

means the rate per annum set out in the "Interest" clause of the Offer Letter payable over the cost to the Bank of funding a Facility.

"Market Disruption Event"

means:

- (a) at or about noon on the first day of the relevant Interest Period the Screen Rate is not available to determine EURIBOR or, if applicable, LIBOR for the relevant currency and Interest Period; or
- (b) before close of business on the first day of the relevant Interest Period, the cost to the Bank of obtaining matching deposits in the Relevant Interbank Market would be in excess of EURIBOR or, if applicable, LIBOR.

"Offer Letter"

means the facility letter (as same may be amended, restated, supplemented, extended, varied and/or renewed from time to time) issued by the Bank to Trinity Biotech plc and certain of its subsidiaries setting forth the terms and conditions of sanction in relation to the Facilities of which these Standard Terms and Conditions form part.

#### "Permitted Acquisitions"

means:

- (a) the acquisition, of (i) more than 50% of the share capital and voting rights of a limited liability company, where any minority shareholders do not have any right to veto any material decision in respect thereof or (ii) the business or assets of any entity (in whole or in part) or (iii) all or any of the remaining issued shares in any company or Joint Venture in which a member of the Group acquires shares after the date of this Agreement as a Permitted Joint Venture, provided that:
  - (i) no Event of Default has occurred and is continuing on the closing date of such acquisition and no Potential Event of Default would occur as a result of that acquisition (save that, notwithstanding any other provision of any Finance Document, during the period of 90 days commencing on the closing date of the relevant acquisition (the "Acquisition Clean-Up Period"), any circumstance relating exclusively to the Parent (or any of its subsidiaries acquired as part of the acquisition), business or assets acquired shall not constitute a Potential Event of Default including as a result of a breach of any applicable Representation in or Covenant in this document, provided that:
  - (ii) it is capable of remedy and reasonable steps are being taken to remedy it;
  - (iii) neither the Parent nor any of its Subsidiaries (in the case of a share acquisition, other than the acquired company or relevant member of the acquired group of companies) has knowingly procured or approved in writing the circumstances giving rise to it; and

- (iv) such circumstance is not reasonably likely to have a Material Adverse Effect, provided that, if the relevant circumstances are continuing on or after the end of the Acquisition Clean-Up Period, there shall be a breach of representation or warranty, breach of covenant or a Potential Event of Default, as the case may be, notwithstanding the above (and without prejudice to the rights and remedies of the Bank));
- the principal business of the company or business being acquired is similar to or complementary to the business carried on by a member of the Group and is located in an OECD country;
- (vi) the company or business being acquired does not have any liability material to the Group (taken as a whole) in relation to which the relevant vendor has not adequately indemnified, or given warranties to, the Group, or adequate insurance has not been obtained;
- (vii) the Borrower & Group will remain in compliance with its obligations under the Covenants & Financial Undertakings in this Offer Letter; and
- (viii) the proposed Permitted Acquisition (including the purchase price paid to the relevant vendors and the refinancing of the Financial Indebtedness of the acquired company or acquired business (the Total Purchase Price)), when aggregated with the Total Purchase Price of all other Permitted Acquisitions made during that Financial Year, (the Aggregate Sum) will not exceed US\$2,000,000 (Two million U.S. Dollars).
- (b) any other acquisition to which the Bank has given its prior written consent.

#### "Permitted Disposals"

#### means:

- (a) a disposal of stock in trade by a Group member in its ordinary course of trade and on arm's length terms;
- (b) by an Obligor to another Obligor if such Obligor is party to a legally valid, binding and enforceable Security Document which creates a first priority Encumbrance over all of its assets (or, if not all its assets, the assets being disposed of);
- (c) of an unencumbered asset by a member of the Group which is not an Obligor to another member of the Group;
- (d) for cash on arm's length terms of any surplus or obsolete assets not required for the efficient operation of the business of the Group by any Group member;

- (e) of cash where such disposal is not otherwise prohibited by this Offer Letter;
- (f) any asset on arm's length terms by a Group member which disposals are not within paragraph (i) to (iv) above and where the value of the net consideration received by a Group member in respect of any such disposal, which does not exceed US\$2,000,000(Two million US dollars) (or its equivalent); and
- (g) when aggregated with all other such disposals by members of the Group made in the same Financial Year does not exceed US\$2,000,000 (Two million US dollars (or its equivalent).

#### "Permitted indebtedness"

#### means:

- (a) all facilities from the Bank, including any affiliates, and specifically including AIB Leasing Limited; and
- (b) any financial indebtedness not falling within paragraph (a) above provided that the aggregate amount does not exceed US\$2,000,000 (Two million U.S. Dollars)(or its equivalent).

#### "Prepayment"

#### means:

- (a) if the Bank at its discretion agrees to allow full or partial out of course repayment or conversion of the Facility to another interest rate, or
- (b) if a Borrower makes payment following demand for payment by the Bank.

"Regulatory Authority"

means the Central Bank of Ireland, the Minister for Finance of Ireland and any other regulatory authority in or of Ireland or elsewhere having effect therein whether or not having the force of law.

"Relevant Interbank Market" means in relation to euro, the European interbank market and, in relation to any other currency, the London interbank market.

"Reserve Asset Cost"

means such additional percentage as the Bank shall conclusively determine to be necessary to compensate the Bank for the cost to the Bank (calculated by reference to circumstances existing on the first day of the relevant period) of making or maintaining a Facility for such relevant period by reason of the then current Liquidity Requirement.

#### "Screen Rate"

#### means:

- (a) in relation to LIBOR, the British Bankers' Association Interest Settlement Rate for the relevant currency and period; and
- (b) in relation to EURIBOR, the percentage rate per annum determined by the Banking Federation of the European Union for the relevant period,

displayed on the appropriate page of the Reuters screen. If the agreed page is replaced or service ceases to be available, the Bank may specify another page or service.

"Tangible Net Worth"

means at any time the aggregate of the amounts paid up or credited as paid up on the issued share capital of the Company (other than any redeemable shares) and the aggregate amount of the reserves of the Group including:

- (a) any amount credited to the share premium account;
- (b) any capital redemption reserve fund; and
- (c) any balance standing to the credit of the consolidated profit and loss account of the Group, but deducting:
- (d) any debit balance on the consolidated profit and loss account of the Group;
- (e) (to the extent included) any amount shown in respect of goodwill (including goodwill arising only on consolidation) or other intangible assets of the Group and interests of non-Group members in Group subsidiaries but after adding back any amortised goodwill and any transaction expenses in connection with the Acquisition amortised or written off;
- (f) (to the extent included) any amounts arising from an upward revaluation of assets made at any time after the date of Financial Year end 31st December 2013; and
- (g) any dividend or distribution declared, recommended or made by any member of the Group to the extent payable to a person who is not a member of the Group and such distribution is not provided for in the most recent financial statements,

and so that no amount shall be included or excluded more than once.

#### 2. PRECONDITIONS:

The Bank shall not be obliged to provide the Facilities or any part thereof unless: -

- (a) The Bank is satisfied that there shall have been no material adverse change in the business, assets or future prospects of a Borrower or of its parent/guarantor(s) (if appropriate) from that at the date hereof; and
- (b) All appropriate exchange control and other consents shall have been obtained and are in full force and effect; and
- (c) The Bank is satisfied that it is in a position to advance the Facilities having regard to the credit guidelines and exchange control regulations of any Regulatory Authority; and
- (d) The security requirements have been executed in a manner satisfactory to the Bank.

These preconditions are additional to any other terms and conditions precedent to the provision of the Facilities which have been agreed between a Borrower and the Bank.

## 3. NOTICE:

A Borrower shall give the Bank not less than three Business Days' notice in writing of its intention to avail of a Facility.

# 4. <u>INTEREST:</u>

- (a) The Interest Rate will be set on the date of first drawdown and shall be reset on the first day of each Interest Period.
- (b) In the event that any drawing shall occur other than on the first day of an Interest Period, (unless otherwise agreed between the Bank and a Borrower) the rate applicable to such drawing shall be determined on the relative drawdown date in accordance with the provisions hereof for a period expiring at the end of the then current Interest Period.
- (c) Where a Borrower has the option of selecting the duration of Interest Periods and does not notify the Bank of its option prior to 11.00 am on the day the interest rate falls to be determined, an Interest Period of 1 month shall be deemed to have been selected.
- (d) Interest shall be payable on the last day of each Interest Period and on the date of final repayment of the Facility, should such date differ from that quoted above save that where an Interest Period is for a period in excess of six months interest shall be payable at six monthly intervals and on the last day of the Interest Period.
- (e) Interest shall accrue from day to day (both before and after judgement) on the amount of the Facility, such interest to be calculated in arrears up to the last day of each Interest Period on the basis of 360 or 365 day year as determined in accordance with general banking practice.

#### 5. PREPAYMENT

- 5.1 Except where payment is being made immediately following demand by the Bank, the Borrower must serve at least three Business Days prior notice to the Bank of any proposed Prepayment of a Facility.
- **5.2** Prepayment will be subject to the payment by the Borrower of a Breakage Cost, to be calculated:
  - (i) where the period for which interest is fixed is less than one year or where the interest period is fixed for one year with no scheduled repayments during such one year period, using the following formula:

Breakage Cost =  $A \times U \times D\%$ , where:

"A" is the amount of the Prepayment and

"U" is the unexpired term of the fixed interest rate period, and

- "D" is the difference between the Cost of Funds applying to the Facility when the rate was fixed and the Cost of Funds applying at the time of Prepayment, for the amount of "A" for the term of "U".
- (ii) where the period for which interest is fixed is more than one year or where the interest period is for one year with scheduled repayments during such one year period, Breakage Cost will be calculated taking into account the following:
  - (a) the difference between the Cost of Funds applying to the Facility when the rate was fixed, and the Cost of Funds at the time of the Prepayment in the amount of the Prepayment, and

(b) associated cashflows for the remainder of the fixed rate term and applying a discount factor in accordance with standard net present value methodology.

Any Prepayment is treated as a permanent reduction and cannot be redrawn. Any such amount will shorten the repayment period but the Borrower must continue to make the repayments specified in the Offer Letter unless otherwise agreed.

# 6. MARKET DISRUPTION – EURIBOR/LIBOR LOANS:

- (a) If a Market Disruption Event occurs in relation to a Facility for any Interest Period, then the rate of interest on the Facility for the Interest Period shall be the percentage rate per annum which is the sum of:
  - (i) the Margin;
  - (ii) the rate which expresses as a percentage rate per annum the cost to the Bank of funding the Facility from whatever source it may reasonably select; and
  - (iii) the Reserve Asset Cost, if applicable to the appropriate Interest Period.
- (b) If a Market Disruption Event occurs and the Bank or the Borrower so requires, the Bank and the Parent shall enter into negotiations (for a period of not more than thirty days) with a view to agreeing a substitute basis for determining the rate of interest.

#### 7. INTEREST AND SURCHARGE INTEREST ON OVERDUE PAYMENTS:

In the event of interest or repayments not being paid on the due date, interest on the amount overdue shall be charged at the rate set out in the Offer letter and surcharge interest on the amount overdue shall be charged at the rate of 5% per annum. Such interest shall be payable on demand to the Bank.

IMPORTANT – OVERDUE INTEREST AND / OR SURCHARGE INTEREST WILL NOT BE PAYABLE IF SCHEDULED PAYMENTS ARE MADE ON TIME.

#### 8. GUARANTORS:

The Parent acknowledges that the Bank will, if required by its regulatory obligations, provide any guarantor(s) of the Facilities with a copy of the relevant Offer Letter, will notify them of any change(s) to the terms and conditions applying to such Facilities and will provide the guarantor(s) with a copy of the documentation effecting such change(s).

#### 9. RESERVE REQUIREMENTS:

If the cost to the Bank of making or maintaining any Facility increases as a result of the introduction of or change in any Liquidity Requirement or from any change in any law or regulation or the introduction of or increase in any tax (other than a change in the rate of corporation or other income tax), the Borrower shall pay to the Bank on demand that amount which the Bank shall conclusively determine as will compensate the Bank for such additional cost.

## 10. GROSSING UP:

All sums payable by a Borrower under any Facility, whether of principal, interest or otherwise shall be paid in the currency in which they are outstanding in full without any deduction, set off, counterclaim or withholding whatsoever. In the event of a Borrower being required by law to make any deduction or withholding from any payment to the Bank then such Borrower shall ensure that such deduction or withholding will not exceed the minimum legal liability therefor and shall forthwith pay to the Bank such additional amounts as will result in the receipt by the Bank of a net amount equal to the amount it would have received had no such deduction or withholding been required to be made.

#### 11. REPRESENTATIONS & WARRANTIES:

Each Borrower represents and warrants to the Bank that:-

- (i) It has full power, authority and legal right to utilise perform and comply with the terms and provisions of the Facilities;
- (ii) The execution and performance of the Facilities shall not contravene any agreement indenture or other instrument which is binding upon it;
- (iii) It is not in default of any of the terms and conditions of this or any other agreement;
- (iv) No material litigation is pending or threatened in relation to its business or likely to have an adverse effect on its business;
- (v) Full disclosure has been made to the Bank of all facts in relation to it and its business and affairs as are material and ought properly be made known to any person proposing to provide financial facilities to such Borrower.

These representations and warranties shall be deemed to be repeated at the beginning of each Interest Period.

#### 12. NEGATIVE COVENANTS:

By acceptance of the Offer Letter each Borrower covenants with the Bank that it shall not during the currency of the Facilities without the prior consent in writing of the Bank:

- (i) Create or agree to create or permit any mortgage, charge, or other encumbrance of any nature over any of its assets, subject to Permitted Indebtedness;
- (ii) Incur or agree to incur any financial indebtedness, subject to Permitted Indebtedness; and
- (iii) In the case of a body corporate, alter its Memorandum and Articles of Association in a manner prejudicial to the Bank.

#### 13. POSITIVE COVENANTS:

Each Borrower shall (i) keep all its property and assets insured against all risks as are normally covered in accordance with sound commercial practice and (ii) pay promptly all debts, which are to be paid in priority to all other debts in a winding up and upon the appointment of a receiver on foot of, or upon the taking possession of property comprised in, a debenture secured by a floating charge or in a bankruptcy or other insolvency proceeding, as the case may be.

#### 14. NON-BUSINESS DAYS

Any payment which would be due and payable on a non-Business Day, or on the 29th, 30th, or 31st day of a calendar month which does not include that date, will be deemed due and payable on the immediately preceding or immediately following Business Day, as the Bank in its discretion may determine.

## 15. ENVIRONMENTAL LAWS:

Each Borrower shall ensure that at all times it will comply with Environmental Laws and/or with any license(s) or other authorisation(s) issued in connection therewith by any Governmental Authority and each Borrower hereby indemnifies the Bank and agrees to keep the Bank indemnified against any and all actions, costs, demands, claims, losses or otherwise which the Bank may suffer or be put to by reason of breach or non-observance by it of Environmental Laws or of the terms of any license or other authorisation issued to it by any Governmental Authority.

# 16. **CERTIFICATION:**

A certificate of the Bank as to any amount payable under a Facility shall be final and binding on each Borrower save in the case of manifest error.

# **17. WAIVER:**

Each Borrower and each guarantor agrees and acknowledges that each of the terms and conditions set out in the Offer Letter are for the sole and exclusive benefit of the Bank. The Bank shall be entitled to waive any or all of these terms and conditions without the consent of the Borrower, the guarantor(s) or any other obligor being a party to the Offer Letter.

Furthermore, a waiver by the Bank of any of the terms or conditions shall not constitute a general waiver of such term or condition. No failure or delay by the Bank in exercising any right, power or privilege granted to it under the Offer Letter shall operate as a waiver thereof nor shall any single or partial exercise of any such right power or privilege preclude the further exercise of any such right, power or privilege. The rights and remedies herein provided are cumulative and not exclusive of any rights or remedies provided by law.

#### 18. **TIME:**

In the construction of the provisions herein relating to the payment of monies, time shall be of the essence of the contract.

#### 19. BENEFIT OF FACILITIES:

The benefit of the Facilities is personal to a Borrower and shall not be capable of assignment by a Borrower, in whole or in part, without the prior written consent of the Bank.

#### **20. ASSIGNMENT:**

The Bank reserves the right to assign, charge, transfer (by way of novation, securitisation or otherwise) or sub-participate all or part of the Facilities and any security held as collateral in respect thereof to any member of the Allied Irish Banks Group or to any third party, either within the State or elsewhere, without notice to or the prior consent of the Borrower.

The Bank will be entitled to give any proposed assignee, chargee, transferee or sub-participant such information as the Bank deems necessary relating to a Borrower, the Facilities and the security. The Borrower agrees to execute, at the cost of the Bank, any documentation (including without prejudice to the generality of the foregoing, any deed of novation) which the Bank requests it to execute in connection with any such assignment, charge, transfer, sub-participation or securitisation and in consideration of the Facilities and as security therefor, each Borrower irrevocably appoints the Bank to be its attorney for the purpose of the execution of any such documentation.

#### 21. DISCLOSURE OF INFORMATION:

The Bank may disclose information (including personal data) relating to the Borrower in the following circumstances:

(i) Where the disclosure is reasonably required in order to ensure the proper and efficient approval and performance of the Offer Letter by the Bank or by a third party engaged to assist the Bank in such performance (whether such a third party is an affiliate of the Bank or otherwise);

- (ii) To a third party to whom the Bank assigns, charges, transfers, sub-participates or otherwise disposes of (or may potentially do so) all or any of the rights and obligations under the Offer Letter;
- (iii) Where a Borrower has given its consent to the disclosure or where such consent has been given on behalf of that Borrower; or
- (iv) To the extent that the information is required to be disclosed by any applicable law or regulation.

#### **22. SET-OFF:**

The Bank shall be entitled to debit any of a Borrower's accounts with the Bank (or, in the event of no such account being maintained by it with the Bank, an account specifically opened for such purpose and which the Bank is hereby irrevocably authorised to open) with the amount of any and all amounts due and payable under the Offer Letter, including but not limited to, amounts due and payable in respect of interest and principal.

## 23. **CONSTRUCTION:**

- (a) If at any time any of the provisions of the Offer Letter is or becomes, or is declared to be invalid illegal or unenforceable in any respect under any law or for any reason whatsoever, the validity legality or enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- (b) Where one or more Borrowers avail of any of the Facilities under the Offer Letter, their respective obligations shall take effect as joint and several obligations and all references to the Borrower shall take effect as references to the said Borrowers or any of them.

## 24. AIB CORPORATE BANKING POLICY ON COLLATERAL:

AIB Corporate Banking's policy on collateral is that, in order to secure the Borrower's obligations to the Bank, the Borrower may be required to provide such security which the Bank considers appropriate and reasonable having regard to the facility/ies sought and the nature, liquidity and value of the security.

Examples of such security include but is not limited to, a first/second legal mortgage/charge over specific suitable assets, a debenture creating a fixed and floating charge over the property and assets of the Borrower, a legal mortgage/charge over shares/instruments, a security assignment over rights such as intellectual property rights, receivables, agreements, etc., a charge/assignment over a bank account, an assignment of life policy/keyman insurance, a letters of undertaking and third party guarantees which may be required to be supported by security from that third party.

The specific security required by the Bank in respect of the Facilities is set out in the Offer Letter to which these Standard Terms and Conditions are attached.

If a Borrower is in default of the terms and conditions of the Offer Letter, the Bank is entitled to demand repayment of the Facilities and to enforce all of this security.

At the request of a Borrower, the Bank will return to the Borrower any security, held by the Bank, when all Facilities for which the security is pledged have been repaid.

# 25. <u>SMALL AND MEDIUM ENTERPRISE APPEALS</u>. FACILITIES BETWEEN €1,000 AND €500,000

If the Bank has sanctioned facilities for an amount that is less that the amount for which the SME borrower had applied, or if a Borrower believes that the terms and conditions of the sanction are such that they cannot be accepted, or the Borrower is not willing to enter into an alternative repayment arrangement, the Borrower may submit a written appeal, outlining the basis of the appeal within 30 days to the Credit Appeals Officer, P.O. Box 11826, AIB, Bankcentre, Ballsbridge, Dublin 4.

If the Borrower's appeal is unsuccessful, a Borrower may, where applicable\*, refer the Bank's decision to the Credit Review Office established by the Minister for Finance

\* For more information see www.creditreview.ie

# **26. FURTHER ASSURANCE:**

Each Borrower shall promptly do all such acts or execute all such documents (including assignments, transfers, mortgages, charges, notices, instruments and any other documents) as the Bank may reasonably specify (and in such form as the Bank may require in favour of the Bank or its nominee(s)) to perfect the security stipulated in this Offer Letter (which may include the execution of a mortgage, charge, assignment, pledge, lien, encumbrance or other security interest over all or any of the assets which are, or are intended to be, the subject of this Offer Letter) or for the exercise of any rights, powers and remedies of the Bank provided by or pursuant to this Offer Letter or the security or arising by operation of law.

#### 27. NOTICES:

Any notice, demand, request or other communication in relation to a Facility may be delivered as follows: (i) by hand or by ordinary pre-paid post to the Borrower at the address of a Borrower last known to the Bank or to the Bank at the branch or business area of the Bank at which the Facility is domiciled; or (ii) by fax to a fax number provided for that purpose by the Borrower to the Bank or by the Bank to a Borrower; or (iii) by any electronic system used by both the Borrower and the Bank from time to time and capable of delivering and receiving such communication by use of access codes provided by a Borrower to the Bank or by the Bank to a Borrower. Such communication will be deemed to have been validly given or made when delivered by hand or twenty-four hours after dispatch by post, fax or other electronic system.

#### 28. APPLICABLE LAW:

The Offer Letter shall be governed by and construed in accordance with the laws of Ireland.

#### 29. FEES AND CHARGES:

All fees, charges, commission and expenses, legal and otherwise, including, without limitation, those incurred by the Bank in connection with the Facility (including the completion of the security) or the enforcement thereof (together with VAT thereon) shall be borne and paid by the Borrower. The same shall be payable whether or not the Facility is utilised in whole or in part. The Bank may debit any such fees, charges, commission or expenses from any one or more of a Borrower's account(s) held with the Bank even it this causes the said account(s) to be overdrawn.

# **SEPA Direct Debit Mandate**



#### **Unique Mandate Reference:**

(Unique Mandate Reference to be completed by Allied Irish Banks p.l.c)

By signing this mandate form, you authorise (a) Allied Irish Banks, p.l.c. to send instructions to your bank to debit your account and (b) your bank to debit your account in accordance with the instructions from Allied Irish Banks, p.l.c.

As part of your rights, you are entitled to a refund from your bank under the terms and conditions of your agreement with your bank. A refund must be claimed within 8 weeks starting from the date on which your account was debited. Your rights are explained in a statement that you can obtain from your bank.

|  | Direct Debit Mandate   |  |  |
|--|--|--|--|
| Please complete all fie  | lds below marked *   |  |  |
| * Name of Debtor (Account Holder)  |  |  |  |
| * Address of Debtor  | Line 1:  |  |  |
|  | Line 2:  |  |  |
|  | City/Postcode:   |  |  |
|  | Country:   |  |  |
| * BIC  |  |  |  |
|  |  |  |  |
| * IBAN   |  |  |  |
|  |  |  |  |
| Your BIC and IBAN are  | e printed on your bank statement. You can also request them directly from your bank.   |  |  |
| Type of repayment:<br>Name of Creditor:<br>Creditor Identifier:<br>Creditor Address: |  |  |  |
| Signature  |  |  |  |
| *  | *  |  |  |
| Date Mar<br>*  | ndate signed  *  Date Mandate signed  *  |  |  |
| Note: Your rights regar  | ding the above mandate are explained in a statement that you can obtain from your bank |  |  |

## Not part of the SEPA Direct Debit Mandate

# **Note:**

■ Where collecting from non AIB accounts you will be notified of your Unique Mandate Reference (UMR) prior to first collection.

- You must inform Allied Irish Banks, p.l.c. in writing if you wish to cancel this instruction.
- Banks may decline to accept instructions to pay direct debits on certain types of accounts.

# Please return this mandate to the Creditor

Allied Irish Banks, p.l.c., Registered Office, Bankcentre, Ballsbridge, Dublin 4. Registered in Ireland, Number 24173. Allied Irish Banks, p.l.c., is regulated by the Central Bank of Ireland.

Warning: as a guarantor of the credit facilities you will have to pay off the credit facilities, the interest and all associated charges if the Borrower does not. Before you sign this guarantee you should get independent legal advice.

## If you give security (collateral) to the Bank to support this guarantee:

- While the guarantee remains in force you may not dispose of property held by the Bank as security without the Bank's consent.
- If the Bank demands payment under the guarantee and you do not pay in full immediately, the Bank may dispose of the property held as security towards payment of your liability.

To: The Member or Members of the Allied Irish Banks Group named in the first part of the Schedule hereto (hereinafter called "the Bank" which term shall, where the context so admits or requires, include all or any of them)

In consideration of the Bank making or continuing advances or giving credit or otherwise affording banking facilities (including leasing facilities) or granting time for as long as and to the extent that the Bank may think fit to the party or parties named in the second part of the Schedule hereto (hereinafter together called "the Borrower")

We, the Company or Companies named in the third part of the Schedule hereto (hereinafter called "the Guarantor") hereby irrevocably guarantee payment to the Bank on demand of all moneys due by and liabilities of the Borrower to the Bank whether present or future actual or contingent and whether incurred solely severally or jointly and whether as principal or surety and whether alone or jointly with any other corporation or corporations person or persons or from or by any firm in which the Borrower may be a partner under whatever name and style including without prejudice to the generality of the foregoing:-

- (a) all sums due on account of moneys advanced or paid on any current or other account or in any manner and in any place wherever;
- (b) all sums due on foot of bills, notes, drafts, negotiable instruments, letters of credit, circular notes, guarantees, bonds, indemnities, interest rates swaps and other derivatives transactions, foreign exchange contracts or other transactions drawn, made, accepted, advised, endorsed, done, paid, entered into, discounted or given by the Bank with, for or for the benefit or accommodation of the Borrower (either alone or in conjunction as aforesaid) and all sums of money which the Borrower or the Bank may from time to time become liable to pay on foot of, or under any master agreement in relation to, any such bills, notes, drafts, letters of credit, circular notes, guarantees, bonds, indemnities, interest rate swaps and other derivatives transactions, foreign exchange contracts or other transactions as aforesaid;
- (c) in the case of the death, bankruptcy, dissolution, insolvency, receivership or liquidation of the Borrower all sums which would at any time have been owing to the Bank by the Borrower if such death, bankruptcy, dissolution, insolvency, receivership or liquidation had commenced at the time when the Bank received actual notice thereof and notwithstanding such death, bankruptcy, dissolution, insolvency, receivership or liquidation;
- (d) all moneys unpaid in respect of debentures or debenture stock of the Borrower held by or on behalf of the Bank;

- (e) in the event of the discontinuance by any means of this Guarantee and Indemnity all cheques, drafts, bills, notes, bonds, guarantees and negotiable instruments drawn by or for the account of the Borrower on the Bank or its agents and purporting to be dated on or before the date when such discontinuance becomes known to the Bank or its agents although presented to or paid by the Bank or such agents after that date and all liabilities of the Borrower to the Bank on such date whether certain or contingent and whether payable forthwith or at some future time or times and also all credits then established by the Bank for the Borrower;
- (f) interest on all such moneys due by and liabilities of the Borrower to the date of payment, at such rates as may be charged from time to time by the Bank, together with interest at the rates aforesaid on any unpaid interest and together with usual commission, banking charges and legal and other costs, charges and expenses (on a full indemnity basis) occasioned to the Bank by or incidental to this Guarantee and Indemnity including all expenses of enforcing or obtaining or endeavouring to enforce or obtain payment of all or any such monies as aforesaid;

#### AND IT IS HEREBY AGREED AND DECLARED as follows:-

- 1. (a) Any amount demanded under this Guarantee and Indemnity and for the time being unpaid shall bear interest (after as well as before judgement) from the date of that demand until receipt of that amount in full by the Bank in accordance with the following provisions:
  - i) to the extent that interest is payable by the Borrower on the liabilities in respect of which that demand has been made, the interest after that demand shall be at the same rates and payable on the same dates as interest is payable thereon by the Borrower; and
  - to the extent that interest is not so payable by the Borrower, then the interest after that demand shall be payable at the end of successive periods of 3 months beginning on the date of demand and the rate for each such period shall be the sum of 2 per cent per annum over the rate (as conclusively determined by the Bank) at which three month deposits in the currency and amount so demanded are offered to the Bank in the European or London Inter Bank Market as the case may be at or about 11 a.m. on the first day of the relevant period. If any such 3 month period would otherwise begin or end on a day on which a rate is not available, it shall instead begin or end (as the case may be) on the first business day thereafter.
  - (b) In the event of interest not being paid in accordance with paragraph (a) hereof, then, without prejudice to any other right of the Bank, from the date on which such interest was due for payment, such unpaid interest shall itself bear interest in accordance with the foregoing provisions of paragraph (a) hereof.
- 2. In the case of a contingent liability a demand may be made under this Guarantee and Indemnity by the Bank at any time (notwithstanding that the Bank has not at the time of such demand been called upon to make payment on behalf of or in respect of the Borrower) for an amount not exceeding the maximum possible amount (as determined by the Bank) of that liability but the Bank shall refund any excess promptly after that contingent liability has crystallised or ceased to exist.

- 3. In the event that payment by the Guarantor hereunder in respect of interest payable by the Borrower (whether pursuant to paragraph (f) above or Clause l) would or might attract a liability to tax in the hands of the Bank, even though such interest, if paid by the Borrower, would have been tax free, then, the obligations of the Guarantor in respect of such interest shall be to pay the amount thereof together with such additional amount as the Bank shall certify to be necessary to compensate for any taxation payable or chargeable on such interest by or against the Bank and all references to interest in this Guarantee and Indemnity shall be construed accordingly.
- 4. The Bank may at its sole discretion from time to time with or without the assent or knowledge of the Guarantor without in any case affecting this Guarantee and Indemnity or the liability of the Guarantor hereunder or being accountable for any loss occasioned thereby do any of the following things, that is to say:-
  - (a) determine, increase or vary any credit accommodation facility or accounts of the Borrower;
  - (b) deal with, accept, release, exchange, renew, vary, permit to lapse, abstain from perfecting or determine or discontinue or otherwise affect or relinquish the liability of any person or Company under all or any other guarantees or securities (whether primary or collateral) which the Bank may now or at any time hold from, for or on account of the Borrower or other company or person liable with the Borrower;
  - (c) grant time or other indulgence to or compound or make any other arrangements with the Borrower or with any person or Company liable on any account, bill, note or other security or guarantee held by the Bank;
  - (d) vote for or against any composition offered or made by the Borrower or any of the said person or company in any winding up, bankruptcy or arrangement matter whether outside or under the control of the Court, and value or give up therein any security;
  - (e) in the case of credits or facilities provided for two or more purposes of a different character vary the proportions of the respective credits allocated or applied for different purposes;
  - (f) subsequently obtain other persons or companies to enter into a guarantee and indemnity in the terms hereof or on such other terms as the Bank shall see fit;
  - (g) renew any bills, notes or other securities, whether negotiable or not;
  - (h) neglect or forbear to enforce repayment of any sums due by the Borrower to the Bank and (without prejudice to the generality of the foregoing) grant any indulgence or forbearance to or fail to assert or delay in asserting any right or remedy against the Borrower or any other person or company liable (whether contingently or otherwise) in respect of such sums as aforesaid or fail or delay in pursuing any right or remedies against the Borrower or such other person or company as aforesaid:
  - (i) amend add to or vary the terms of any agreement existing between the Borrower and the Bank from time to time;

- 5. This Guarantee and Indemnity shall be a continuing security and shall remain in force until determined by three months written notice actually received by the Bank from the Guarantor but such determination shall not affect the Guarantor's liability in respect of the Borrower's liabilities to the Bank at the date when the determination takes effect (including any new or additional liability incurred by the Borrower after receipt of the notice by the Bank but prior to its expiration).
- 6. This Guarantee and Indemnity shall apply to and secure any ultimate balance owing by the Borrower to the Bank and until this Guarantee and Indemnity has been determined and such balance has been paid in full (a) the Guarantor shall not be entitled to share in any security held or money received by the Bank on account of that balance or to stand in the place of the Bank in respect of any such security or money and (b) the Guarantor shall not take any step to enforce any right or claim against the Borrower in respect of any amount paid by the Guarantor to the Bank hereunder or have or exercise any rights as surety in competition with the Bank.
- 7. The Guarantor hereby warrants that the Guarantor has not and hereby covenants that it will not in respect of any sums hereby secured take from the Borrower either directly or indirectly without the prior written consent of the Bank, any promissory note, bill of exchange, mortgage, charge or other counter-security whether merely personal or involving a charge on any property whatsoever of the Borrower whereby the Guarantor or any person claiming through it by endorsement, assignment or otherwise would or might on the liquidation, dissolution or bankruptcy of the Borrower and to the prejudice of the Bank increase the proofs in such liquidation, dissolution or bankruptcy or diminish the assets distributable among the creditors of the Borrower. As regards any such counter-security as aforesaid which the Guarantor may have taken or may take with such consent as aforesaid, such counter-security shall be held on trust for the Bank and shall be a security to the Bank for the fulfilment of the obligations of the Guarantor hereunder and shall be forthwith deposited by the Guarantor with the Bank for that purpose and the Guarantor shall account to the Bank for all moneys at any time received by the Guarantor in respect thereof.
- 8. In addition to any other lien, right of set-off or other right to which the Bank may at any time be entitled (whether by agreement, operation of law or otherwise) (a) the Bank shall in respect of the Guarantor's liability hereunder have a lien on all securities documents or other property of the Guarantor at any time held by the Bank whether for safe custody, collection or otherwise; and (b) the Bank may at any time (both before and after any demand hereunder and without prior notice) set off any liability of the Borrower to the Bank (whether or not then due and payable) against any credit balance in any account(s) of the Guarantor with any office of the Bank (whether current or otherwise or subject to notice or not) and (c) may retain the whole or any part of such credit balance to meet the liability of the Guarantor to the Bank.
- 9. If this Guarantee and Indemnity is determined or a demand is made by the Bank hereunder or in the event of this Guarantee and Indemnity ceasing from any cause whatsoever to be binding as a continuing security on the Guarantor or its successors, the Bank shall be at liberty without thereby affecting its rights hereunder to open a fresh account or accounts and to continue any then existing account or accounts with the Borrower and no moneys paid into any such account or accounts by or on behalf of the Borrower and subsequently drawn out shall on settlement of any claim in respect of this Guarantee and Indemnity be appropriated or applicable in or towards or have the effect of payment of any part of the moneys due from the Borrower at the time of this Guarantee and Indemnity ceasing to be so binding unless the person or company paying in such monies shall at the time of such payment in writing direct the Bank specially so to appropriate the same.

- 10. This Guarantee and Indemnity shall be construed and take effect as a guarantee and indemnity of and in respect of the whole and every part of the principal moneys and other moneys hereby secured and accordingly the Guarantor shall not be entitled as against the Bank to any right of proof in the liquidation, insolvency or bankruptcy of the Borrower or other right of a surety discharging his liability in respect of the principal debt unless and until the whole of the principal moneys and other moneys hereby secured shall have first been completely discharged and satisfied AND further for the purpose of enabling the Bank to sue the Borrower or prove against its estate for the whole of the moneys secured as aforesaid or to preserve intact the liability of any other party the Bank may at any time place and keep for such time as it may think prudent any money received, recovered or realised on foot of this Guarantee and Indemnity to and at a separate or suspense account to the credit either of the Guarantor or such other person or persons or transactions (if any) as the Bank shall think fit without any intermediate obligation on the part of the Bank to apply the same or any part thereof in or towards discharge of the moneys hereby secured or any intermediate right on the part of the Guarantor to sue the Borrower or prove against his estate in the bankruptcy, insolvency or liquidation of the Borrower in competition with or so as to diminish any dividend or other advantage that would or might come to the Bank or to treat the liability of the Guarantor as diminished.
- 11. (a) This Guarantee and Indemnity shall not be discharged nor shall the Guarantor's liability be affected by reason of:-
  - (i) the death or other disability or any change in the constitution of the Borrower or any failure of or irregularity defect or informality in any security given by or on behalf of the Borrower or any other person or company in respect of all or any of the liabilities hereby guaranteed nor by any legal limitation, disability, incapacity or want of any borrowing powers of or by the Borrower or want of authority of any director, manager, official or other person appearing to be acting for the Borrower in any matter in respect of those liabilities.
  - (ii) any reduction occurring in or other arrangement being made relating to the Borrower's liabilities to the Bank as a result of any arrangement or composition, made pursuant to any of the provisions of the Companies (Amendment) Act, 1990.
  - (b) The liability of the Guarantor hereunder shall be as a sole or primary obligor and not merely as surety and shall not be impaired or discharged by reason of any matter act or omission whereby the liability of such Guarantor would not have been discharged if it had been a principal Borrower and the Guarantor hereby waives all and any of its rights as surety which may at any time be inconsistent with any of the provisions of these presents.
- 12. In addition to the guarantee contained herein and separate therefrom the Guarantor hereby irrevocably agrees to keep the Bank fully and effectively indemnified from and against all costs, claims, charges, damages, expenses and losses whatsoever arising out of or in connection with any transactions entered into by the Bank with the Borrower as hereinbefore specified or as a result of any disability, incapacity, irregularity, defect or informality specified in Clause 11(a).
- 13. (a) This Guarantee and Indemnity shall not be discharged nor shall the Guarantor's liability be affected by any amalgamation or merger of the Bank with any other company or any reconstruction of the Bank. Accordingly this Guarantee and Indemnity shall remain in full force and effect in favour of any company succeeding to the Bank's rights as a result of any such amalgamation, merger or reconstruction.

- (b) In the case where the Borrower is a partnership or firm this Guarantee and Indemnity shall apply to all moneys borrowed and liabilities incurred whether actual or contingent in the partnership's or firm's name until receipt by the Bank of actual notice of the dissolution or reconstitution of the partnership or firm. If, however, the dissolution or reconstitution be by reason only of the retirement or death of a partner or the introduction of a new partner or partners this Guarantee and Indemnity shall continue and apply to all moneys and liabilities incurred by or due to the Bank from the new partnership or firm thereby constituted as though there had been no change in the partnership or firm as previously constituted.
- (c) If the Guarantor or the Borrower is a company this Guarantee and Indemnity shall continue to be binding and effective as a continuing security notwithstanding the liquidation, absorption, amalgamation or reconstruction of the Borrower or the Guarantor.
- 14. No assurance security or payment given or made by the Borrower which may be avoided under enactments relating to bankruptcy or under Sections 286 and 288 of the Companies Act 1963, as amended by Sections 135 and 136 respectively of the Companies Act, 1990 or equivalent or analogous legislation in any other jurisdiction or any statutory modification or re-enactment thereof and no release settlement or discharge, which may have been given or made on the faith of any such assurance, security or payment shall prejudice or affect the Bank's right to recover from the Guarantor to the full extent of this Guarantee and Indemnity or the Bank's right to exercise the rights under Clause 8 (b) and (c) hereof.
- 15. The liquidation, insolvency or dissolution of the Borrower shall not affect or determine the Guarantor's liability hereunder but such liability shall continue in full force and effect until the Bank shall have been repaid all moneys due to the Bank from the Borrower immediately before the liquidation, insolvency or dissolution of the Borrower together with interest thereon.
- 16. The Bank shall be at liberty but not bound to resort for its own benefit to any other means of payment at any time and in any order it thinks fit without thereby diminishing the Guarantor's liability hereunder and the Bank may put this Guarantee and Indemnity in force either for the payment of the ultimate balance (together with interest thereon) after resorting to other means of payment or for the balance due at any time notwithstanding that other means of payment have not been resorted to and in the latter case without entitling the Guarantor to any benefit from such other means of payment so long as any moneys remain due to the Bank from the Borrower.
- 17. Any indebtedness of the Borrower now or hereafter held by the Guarantor is hereby subordinated to the indebtedness of the Borrower to the Bank and such indebtedness of the Borrower to the Guarantor if and only if the Bank so require shall be collected enforced and received by the Guarantor as trustee for the Bank and be paid over to the Bank on account of the indebtedness of the Borrower to the Bank but without reducing or affecting in any manner the Guarantor's liability under the provisions of this Guarantee and Indemnity.
- 18. (a) The moneys hereby guaranteed shall be due and payable to the Bank in the currency in which the moneys due to the Bank by the Borrower are denominated ("the denominated currency"), but without prejudice to this, if a

payment is made by the Guarantor in a currency other than the denominated currency ("the different currency") then, the Guarantor's obligations to the Bank will only be satisfied to the extent that the Bank may in accordance with normal banking procedures, on the business day following receipt of the different currency purchase in the appropriate Foreign Exchange Market, the denominated currency and if at the date of such purchase, the denominated currency so purchased falls short of the amount originally due to the Bank in the denominated currency, the Guarantor agrees as a separate obligation, to indemnify the Bank against any such shortfall.

- (b) In the event that the amount of the denominated currency is or has been calculated by reference to another currency ("the base currency") the Guarantor's obligation hereunder is to repay the full amount outstanding in the denominated currency even if due to fluctuations in the appropriate Foreign Exchange Market the amount of the denominated currency if reconverted at the date of demand hereunder in to the base currency would exceed the monetary limit in respect of principal hereby guaranteed.
- (c) Any amounts which the Bank recovers under any judgement of any Court against the Guarantor in respect of the Guarantor's liabilities hereunder shall as soon as is reasonably practicable be converted by the Bank (if necessary) into the currency or currencies of denomination of those liabilities for which such judgement was obtained. Should the proceeds of any such conversion produce amounts less than the amounts of those liabilities but the judgement has been wholly satisfied, then as a separate obligation (which shall not merge in the judgement) the Guarantor shall be liable to the Bank for the amount of any such deficiency. If the proceeds of any such conversion produce amounts in excess of the respective amounts of those liabilities then, notwithstanding any judgement as aforesaid, the Bank shall hold such excess to the Guarantor's order.
- (d) This Guarantee and Indemnity and the Bank's rights under it shall not be affected or prejudiced by the Bank permitting the Borrower to convert and/or reconvert any facility denominated in one currency into another currency or currencies.
- 19. All sums payable by the Guarantor hereunder shall be paid in full without any deductions, set off, counterclaim or withholding whatsoever and without any deduction for or on account of any present or future taxes, levies, imposts, duties, deductions or withholding or other charges of whatever nature imposed, levied, collected, withheld or assessed unless the Guarantor is compelled by law so to do. If the Guarantor shall be so compelled then the Guarantor shall ensure that such deduction or withholding will not exceed the minimum legal liability therefor and shall forthwith pay to the Bank such additional amounts as may be necessary in respect of its obligations hereunder in order that the net amounts received by the Bank after such taxes, levies, imposts, duties, deductions, withholdings or other charges shall equal the amounts due hereunder.
- 20. A certificate in writing signed by any officer of the Bank as to any rate of interest applicable hereunder and the amount of the liabilities of the Borrower to the Bank or the total amount recoverable under this Guarantee and Indemnity shall be conclusive evidence for all purposes against the Guarantor, except in case of manifest error.

- 21. The liability of any Guarantor hereunder shall not be affected by any failure by the Bank to take any security or by any invalidity of any security taken or by any existing or future agreement by the Bank as to the application of any advances made or to be made to the Borrower nor by the fact that this Guarantee and Indemnity is or may not be binding on any other Guarantor hereunder for any reason whatever.
- 22. This Guarantee and Indemnity shall be additional to any other guarantee or security at any time held from the Guarantor or any other person or company in respect of all or any of the liabilities hereby guaranteed.
- 23. Without prejudice to any other provision hereof the Bank shall be at liberty from time to time to enter, without the consent of the other or others of the Guarantors, into any arrangement with any one or more of the Guarantors for the discharge of its or their liability hereunder on any terms that the Bank may think fit, and any such discharge of the one or more of the Guarantors shall leave the liability of the other or others of the Guarantors unaffected and as effective as if such other as sole Guarantor or such others as joint and several Guarantors had alone signed this document.
- 24. If at any time any one or more of the provisions of this Guarantee and Indemnity is or becomes invalid, illegal or unenforceable in any jurisdiction in any respect, the validity, legality and enforceability of the remaining provisions hereof shall not in any way be affected or impaired thereby.
- 25. No delay by the Bank in exercising or the omission by the Bank to exercise any right, power or privilege shall impair such right, power or privilege or be construed as a waiver of such right, power or privilege nor shall any single or partial exercise of any right, power or privilege preclude any further exercise thereof or the exercise of any other right power or privilege. The rights and remedies herein provided are cumulative and not exclusive of any rights or remedies provided by law or otherwise.
- 26. (a) The legal costs and expenses of the Bank of and incidental to the negotiations leading to and the preparation and execution of this Guarantee and Indemnity as between Solicitor and client shall be paid by the Guarantor to the Bank on demand.
  - (b) The Guarantor shall pay to the Bank on demand all legal and other costs charges and expenses from time to time incurred by the Bank in any way in connection with this Guarantee and Indemnity or the enforcement or discharge thereof.
  - (c) All stamp and other duties payable on or in respect of these presents shall be payable by the Guarantor to the Bank on demand.
- 27. Where there is more than one person or company comprised in the term "Borrower" references to the Borrower shall where the context admits take effect as references to such persons or companies or any of them and where the Borrower is a firm shall include the person(s) from time to time constituting the firm whether or not under the same style or firm name.
- 28. If the Borrower be a committee or association or other unincorporated body which has no legal existence or which is under no legal liability to discharge obligations undertaken or purported to be undertaken by it or on its behalf this Guarantee and Indemnity shall be valid and binding upon the Guarantor notwithstanding that fact and as though the Guarantor was the principal Borrower or if there be more than one Guarantor as though the Guarantors were joint and several principal Borrowers.

- 29. (a) The expression "the Guarantor" when used herein shall mean, (where there is more than one Guarantor), all or any of such Guarantors and in this Guarantee and Indemnity the singular shall include the plural and vice versa, and the masculine shall include the feminine and neuter and vice versa.
  - (b) Where this Guarantee and Indemnity is executed by more than one company the agreements and obligations on the part of the Guarantor herein contained shall take effect as joint and several agreements and obligations and all references to the Guarantor shall take effect as references to the said companies or any of them and none of them shall be released from liability hereunder by reason of this Guarantee and Indemnity not being or ceasing to be binding as a continuing security on any other or others of them. This Guarantee and Indemnity shall be binding on the company or companies who has/have executed it notwithstanding the failure or refusal of any other company or companies to execute this Guarantee and Indemnity.
  - (c) Any reference in this Guarantee and Indemnity to Facility Letter, Agreement, Offer Letter, Finance Document or any other document whatsoever is a reference to such document as same may have been amended, supplemented, renewed, extended or replaced from time to time.
- 30. The amount hereby guaranteed shall be due and payable to the Bank on demand made in writing by an officer of or solicitor for the Bank and if sent by post may be addressed to the Guarantor at its registered office as herein written or at its address last known to the Bank and shall be effectual notwithstanding any change in address and shall be considered as duly made when sent (if by telex) or when delivered (if hand delivered) or on the next business day after posting (if posted) whether or not returned undelivered.
- 31. The Bank shall be entitled to assign the benefit of this Guarantee and Indemnity and all rights conferred upon the Bank hereby as and when it sees fit with or without notice to the Guarantor and this Guarantee and Indemnity may be enforced by any assignee and proceeded on in the same manner to all intents and purposes as if such assignee had been named herein instead of the Bank.
- 32. This Guarantee and Indemnity may be executed in any number of counterparts and all those counterparts taken together shall be deemed to constitute one in the same instrument.
- 33. This Guarantee and Indemnity shall be governed and construed in accordance with the Laws of the Republic of Ireland. In the event that the Guarantor is not resident in Ireland, the Guarantor hereby irrevocably submits to the non-exclusive jurisdiction of the High Court in the Republic of Ireland and hereby appoints the Borrower to be its attorney for the purposes of accepting on its behalf any summons, notice, order, judgement, demand or other legal document in respect of these presents or any matter arising thereout and any such service on such attorney shall be deemed to be a good service on the Guarantor.

**IN WITNESS** whereof the parties have executed this Guarantee and Indemnity as a deed and delivered same on the date first written below.

#### **SCHEDULE**

#### First Part

Name of Bank

#### ALLIED IRISH BANKS, p.l.c. of Bankcentre, Ballsbridge, Dublin 4, Ireland

#### **Second Part**

#### Name(s) and Address(es) of Borrower(s)

- 1. Trinity Biotech PLC (Company Number 183476) of IDA Business Park, Bray, Co Wicklow.
- 2. Trinity Biotech Manufacturing Limited (Company Number 239206) of IDA Business Park, Bray, Co Wicklow.
- 3. Trinity Biotech Financial Services Limited (Company Number 421486) of IDA Business Park, Bray, Co Wicklow.

# **Third Part**

## Name(s) and Registered Office(s) of Guarantor(s)

- 1. Trinity Biotech PLC (Company Number 183476) of IDA Business Park, Bray, Co Wicklow.
- 2. Trinity Biotech Manufacturing Limited (Company Number 239206) of IDA Business Park, Bray, Co Wicklow.
- 3. Trinity Biotech Financial Services Limited (Company Number 421486) of IDA Business Park, Bray, Co Wicklow.
- 4. Benen Trading Limited (Company Number 276238) of IDA Business Park, Bray, Co Wicklow.
- 5. Immco Diagnostics Inc. of 2711 Centreville Road, Suite 400, Wilmington, New Castle County, Delaware, 19808, United States of America.
- Trinity Biotech Inc of Corporation trust Centre, 1209 Orange Street, Wilmington, New Castle County, Delaware, 19808, United States of America.
- 7. Clarke Laboratories Inc of 80 State Street, Albany, New York, United States of America.
- 8. Mardx Diagnostics Inc of 5919 Farnsworth Court, Carlsbad, CA 92008.
- 9. Primus Corporation of 221, Bolivar Street, Jefferson City, MO 65101.

## DATED THIS SIXTH DAY OF FEBRUARY 2015

Present when the Common Seal of **TRINITY BIOTECH PLC** 

was affixed to this Deed and this Deed was delivered:

/s/ Ronan O'Caoimh Director

/s/ Kevin Tansley Director/Secretary

Present when the Common Seal of **TRINITY BIOTECH MANUFACTURING LIMITED** was affixed to this Deed and this Deed was delivered:

/s/ Jim Walsh Director

/s/ Kevin Tansley Director/Secretary

Present when the Common Seal of **TRINITY BIOTECH FINANCIAL SERVICES LIMITED** was affixed to this Deed and this Deed was delivered:

/s/ Ronan O'Caoimh Director

/s/ Kevin Tansley Director/Secretary Present when the Common Seal of **BENEN TRADING LIMITED** 

was affixed to this Deed and this Deed was delivered:

/s/ Ronan O'Caoimh Director

/s/ Kevin Tansley Director/Secretary

By: /s/ Kevin Tansley

Authorized officer or director

on behalf of IMMCO DIAGNOSTICS INC.

By: /s/ Kevin Tansley

Authorized officer or director

on behalf of TRINITY BIOTECH INC

By: /s/ Kevin Tansley

Authorized officer or director

on behalf of **CLARKE LABORATORIES INC** 

By: /s/ Kevin Tansley

Authorized officer or director

on behalf of MARDX DIAGNOSTICS INC

By: /s/ Kevin Tansley
Authorized officer or director
on behalf of **PRIMUS CORPORATION** 

#### BETWEEN

**RONAN O'CAOIMH** of Glencarrig, Delgany, County Wicklow and **JIM WALSH** of Ardvana, The Hill, Monkstown, Co. Dublin (hereinafter called "the Landlord") which expression shall where the context so admits include their respective successors in title, executors, administrators and assigns) of the one part **TRINITY BIOTECH MANUFACTURING LIMITED** having its registered office at IDA Business park, Bray, County Wicklow (hereinafter called "the Tenant" which expression shall where the context so admits include its successors in title and permitted assigns) of the other part and

#### WITNESSETH as follows:-

#### 1. **DEFINITIONS**

In these presents and in the Schedules hereto (save where the context otherwise requires or implies) the following words and expressions shall have the meanings assigned to them hereunder:-

- "Adjoining Property" means any land and/or buildings and/or air space adjoining or neighbouring (which includes overhead and which also includes the Retained Lands) the Demised Premises or any part thereof.
- **"the Building"** means all that and those the premises known as Trinity Biotech Building, IDA Business Park, Southern Cross Road, Bray, Co. Wicklow which for identification purposes is outlined in blue on plan 1 hereto together the appurtenances thereto and all additions thereon and includes the Landlord's Fit-out.
- "the Car Park" means the surface car park forming part of the Demised Premises and for the purposes of identification coloured yellow on Plan 1 attached hereto.
- "Conduits" means and includes all pipes, sewers, drains, gutters, watercourses, wires, cables (including fibre optic cables), channels, subways, ventilators, trunking, ducts, flues, conduits and all conducting media of whatsoever nature or kind.
- **"the Demised Premises"** means that part of the Estate outlined in red on Plan 1 attached hereto for identification purposes and includes the Building and the Car Park.
- **"Due Notice"** means at least 48 hours written notice given in accordance with the terms of this Lease where entry is required for inspection purposes and at least four weeks written notice given in accordance with the terms of this Lease where entry is required for the purposes of carrying out works to the Demised Premises and every case save in the case of emergency or where such works are minor in nature and will not cause disruption to the Tenant's business.

- "the Estate" means the lands comprised in folio 3533L County Wicklow which are comprised in the Superior Lease situate at the IDA Business Park, Bray, County Wicklow laid or to be laid out by the Landlord as a development the likely extent of which (without commitment) is shown on Plan No. 2 attached to this Lease and thereon surrounded by a green verge line together with any adjoining lands subsequently acquired within the Perpetuity Period and incorporated at the Landlords option as part of the Estate and the Tenant acknowledges that the Estate and the extent thereof may at the Landlords option be extended or reduced but not so as to adversely affect the Tenant's access to or the use and enjoyment of the Demised Premises.
- "the Estate Common Parts" means those parts of the Estate that consist of open spaces, water features, ponds, lakes, roads, footpaths, grass margins, landscaped areas, security huts or compounds, and any other area or any other structure used or intended to be used in common by the owners or occupiers of the Estate ( or any part thereof) but does not include the Demised Premises or any parts of the Estate which have been or are intended to be assured (whether by way of conveyance, assignment or by long lease) to any person other than a management company.
- "The Estate Service Charge" means the costs and expenses incurred by the Landlord in the provision to the Estate Common Parts of the services mentioned in the First Part of the Third Schedule hereto and ascertained in accordance with the provisions of the Second Part of the Third Schedule hereto.
- "Group Company" means any company related to either the Tenant within the meaning of Section 140(5) of the Companies (Amendment) Act 1990.
- **"the IDA Estate"** means the lands of the IDA known as the IDA Business Park, Bray, County Wicklow being the lands comprised in Folio 11934F County Wicklow but excluding the lands comprised in the Estate.
- "the Landlord's Fit-out" means the fit out works completed by the Landlord to the Building and set out in the Schedule from Basil Conroy & Co dated 17th October 2007 and attached hereto at Appendix 1
- "the Landlords Proportion of the IDA Service Charge" means the proportion of the costs and expenses set out at clause 3.3 and clause 3.4 of the First Schedule to the Superior Lease attributable to the Estate and payable from time to time by the Landlord.

- "Perpetuity Period" means the period commencing on the date of this Lease and ending at the expiration of twenty years from the date of the death of the last survivor of the issue now living of the late President of Ireland Eamon de Valera.
- "Plans" means the plans attached to this Lease.
- "the Prescribed Rate" means the monthly rate of interest that is equivalent to the rate of interest chargeable pursuant to Section 1080 of the Taxes Consolidation Act 1997 or such other monthly rate of interest as may from time to time be chargeable upon arrears of income tax.
- "the Retained Lands" means so much of the Estate that does not comprise the Demised Premises.
- "the Service Charge" means the Landlord's Proportion of the Estate Service Charge and the Landlord's Proportion of the IDA Service Charge.
- "the Service Yard" means the service yard forming part of the Estate and for the purposes of identification coloured orange on Plan 1 attached hereto
- "the Superior Lease" means the Lease dated the 2<sup>nd</sup> day of February 2000 and made between Industrial Development Agency (Ireland) of the one part and Ronan O'Caoimh, Jonathan O'Connell and Jim Walsh of the other part
- "Superior Lessor" means the person or entity entitled to the reversion expectant under determination of the Superior Lease.

## 2. **INTERPRETATION**

- **2.1** Where two or more persons are included in the expression "the Landlord" and/or "the Tenant" the covenants which are expressed to be made by the Landlord and/or the Tenant shall be deemed to be made by such persons jointly and severally.
- 2.2 Words importing the neuter gender include the masculine or the feminine gender (as the case may be) and words importing the masculine gender include the feminine gender and vice versa and words importing the singular number include the plural number and vice versa and words importing persons shall include firms companies and corporations and vice versa.
- 2.3 References to any right exercisable by the Landlord or any right exercisable by the Tenant in common with the Landlord shall be construed as including (where appropriate) the exercise of such right by and in common with all other persons authorised by the Landlord and their agents professional advisers prospective purchasers of any interest of the Landlord in the Demised Premises or in the Adjoining Property contractors workmen and others and all other persons having a like right.

- 2.4 Any reference to a Statute shall include any statutory extension or modification or re-enactment for the time being in force or any such Statute or any Orders Statutory Instrument Notices Regulations Directions Bye Laws Directives thereunder for the time being in force.
- 2.5 Any covenant by the Tenant not to do an act or thing shall be deemed to include an obligation not to permit such act or thing to be done.
- 2.6 The paragraph headings do not form part of this Lease and shall not be taken into account in the construction or interpretation thereof.
- 2.7 Any provision entitling the Landlord or others to enter the Demised Premises shall be subject to such persons complying with the Tenant's reasonable security and confidentiality requirements.

#### 3. **DEMISE**

In consideration of the yearly rents (and the increases thereof as hereinafter provided) and the covenants on the part of the Tenant and the conditions hereinafter reserved and contained the Landlord HEREBY DEMISES unto the Tenant ALL THAT AND THOSE the Demised Premises TOGETHER WITH the rights and easements specified in the First Schedule hereto EXCEPTING AND RESERVING the rights and easements specified in the Second Schedule hereto TO HOLD to hold the Demised Premises unto the Tenant from 1st July 2007 for the term of twenty five years YIELDING AND PAYING therefor and thereout during each of the first five years of the said term the yearly rent of €786,605.18 and thereafter during each of the successive periods of five years of which the first shall begin on the 1st July 2012 a rent equal to (a) the rent payable hereunder during the preceding period or (b) such revised rent as may from time to time be ascertained in accordance with the provisions in that behalf contained in the Fourth Schedule hereto (whichever shall be the greater) AND the rent in respect of each year of the said term is to be paid by direct debit by equal quarterly payments in advance on the 1st day of January, 1st day of April, 1st day of July and 1st day of October in every year without any deduction set off or counterclaim whatsoever.

AND ALSO PAYING BY WAY OF ADDITIONAL RENT the amount or amounts payable by the Tenant pursuant to the Tenant's covenant hereinafter contained in Clause 4.2 in respect of insurances effected from time to time by the Landlord such additional payments to be payable at the times and in the manner specified at the said Clause 4.2 AND ALSO PAYING BY WAY OF ADDITIONAL RENT the amount or amounts payable by the Tenant pursuant to the Tenant's covenant hereinafter contained in Clause 4.3 in respect of the provision or the procuring by the Landlord of the services hereinafter contained such additional payments to be payable at the times and in the manner hereinafter specified.

AND ALSO PAYING BY WAY OF ADDITIONAL RENT on demand all costs damages expenses losses costs and demands which the Landlord may from time to time incur in connection with or procuring the remedying of any breach by the Tenant of any of the covenants on the part of the Tenant herein contained having given the Tenant a reasonable opportunity of remedying such breaches.

#### 4. TENANT'S COVENANTS

The Tenant to the intent that the obligations may continue throughout the term hereby granted **HEREBY COVENANTS** with the Landlord as follows:-

#### **PAY RENT**

4.1 To pay the rent or increased rent hereby reserved or any sums payable thereunder on the days and in the manner herein prescribed without any deductions.

#### **INSURANCE PREMIUMS**

4.2 To pay to the Landlord from time to time within 21 days of demand without any deductions or abatement the amount or amounts expended by the Landlord in insuring the Demised Premises in accordance with clause 5.2hereunder.

#### **PAY FOR SERVICES**

- 4.3 To pay to the Landlord from time to time on demand without any deduction or abatement:
  - (a) 35.47% of the Estate Service Charge payment to be made in accordance with the provisions of the Third Part of the Third Schedule hereto;
  - (b) 35.47% of the Landlords Proportion of the IDA Service Charge.

**PROVIDED ALWAYS THAT** if the Building is extended or reduced (whether by way of sale or otherwise) the said percentage referred to in clause 4.3(a) and the percentage referred to in clause 4.3(b) shall be agreed as between the Landlord and the Tenant and in the absence of agreement determined by a chartered surveyor agreed and appointed by the Landlord and the Tenant or in the absence of agreement within three calendar months at the request of the Landlord by the President for the time being of the Society of Chartered Surveyors or any successor body.

**AND FURTHER PROVIDED ALWAYS** that if the gross area of the Estate less the Estate Common Parts shall be extended or reduced the Landlords Proportion of the Estate Service Charge shall be as agreed between the Landlord and the Tenant and in the absence of agreement determined by a Chartered Surveyor agree and appointed by the Landlord and the Tenant or in the absence of agreement within three calendar months at the request of the Landlord by the President for the time being of the Society of Chartered Surveyors or any successor body.

#### INTEREST ON ARREARS

4.4 If the Tenant shall fail to pay the rent hereinbefore reserved or any other sum reserved or made payable hereunder on the day and in the manner herein prescribed for the payment of same such unpaid rent or sum shall bear interest from the 14<sup>th</sup> day after day or days on which the same shall become due to the date of actual payment at the Prescribed Rate.

#### **PAY OUTGOINGS**

4.5 To pay and discharge all rates and taxes duties charges assessments impositions and outgoings whatsoever whether parliamentary parochial local or any other description which are now or may at any time hereafter be charged taxed assessed levied or imposed upon or payable in respect of the Demised Premises or on the owner or occupier in respect thereof notwithstanding any contract to the contrary except all Landlord's income and capital taxes, any tax referable to the receipt of the rent hereunder and any tax referable to a dealing in the reversion expectant on the determination of the term hereby created and to indemnify and keep indemnified the Landlord against or arising out of same or any expenses (legal or otherwise) in connection therewith to the extent that the Tenant is responsible.

#### **COMPLY WITH ENACTMENTS**

At all times during the said term to observe and comply in all respects with the provisions and requirements of any and every enactment for the time being in force or any orders or regulations thereunder for the time being in force and to do and execute or cause to be done and executed all such works as under or by virtue of any such enactment or any orders or regulations thereunder for the time being in force are or shall be properly directed or necessary to be done or executed upon or in respect of the Demised Premises or any part thereof whether by the Landlord, beneficial owner lessee tenant or occupier and at all times to keep the Landlord indemnified against all claims demands and liability in respect thereof and without derogating from the generality of the foregoing to comply with the requirements of any Local or other Statutory Authority European Community Regulations, the provisions of the Factories Act, 1955, Health Act, 1947, Office Premises Act, 1958, Housing Acts 1966 and 1969, the Safety in Industry Act, 1980, Fire Services Act, 1981, Waste Management Packaging (Amendment) Regulations 1998 and the order or orders of any Court of competent jurisdiction

# FIRE REQUIREMENTS

4.7 At all times during the said term to comply with all requirements of the appropriate Fire Authority, the insurers of the Demised Premises and the Landlord whether notified or directed to the Landlord or the Tenant in relation to fire precautions

#### **NUISANCE**

4.8 To pay to the Landlord all costs charges and expenses which may be reasonably and properly incurred by the Landlord in abating a nuisance in respect of the Demised Premises and to execute all such works as may be necessary for abating such a nuisance in obedience to a notice lawfully served by a Local or Public Authority or pursuant to any Court Order.

#### **REPAIRS**

Damage by any of the Insured Risks (as hereinafter defined in Clause 6.2 hereof if and so long only as Policy or Policies of insurance shall not have been vitiated or payment of the Policy monies withheld or refused in whole or in part by reason of any act neglect or default of the Tenant or the servants agents licensees or invitees of the Tenant or any other under-tenant or person under its or their control) and inherent structural defects excepted, to keep clean and tidy and to repair and keep in good order repair and condition from time to time and at all times during the term hereby created the Demised Premises and to maintain repair and keep in good working order and condition and the Conduits and all plant and machinery and systems installed in the Building including the central heating and air conditioning plant (if any), security systems, fire alarm systems the sprinkler system, lifts and lift machinery all boilers and all electrical and mechanical plant machinery equipment and apparatus

#### **DECORATE**

4.10 As often as is reasonably necessary and in any event not less than once every five years (whether determined by effluxion of time or otherwise) to decorate in a good and workmanlike manner with good materials and in colour schemes approved in advance by the Landlord in writing all parts of the Demised Premises requiring decoration.

## **MAINTAIN EXTERIOR**

- 4.11 (a) To keep all exterior parts of the Demised Premises including the Car Park and the Service Yard clean and tidy and free from weeds.
  - (b) To keep all landscaped areas properly cultivated and maintained preserving any trees and shrub in those areas
  - (c) To clean property as often as may be reasonably be required all windows and window frames and all other glass forming part of the Building.

# **PERMIT ENTRY**

4.12 To permit the Landlord, and/or the Superior Lessor their Surveyors and agents with or without workmen and others at all reasonable times after Due Notice (except in cases of emergency when no notice shall be required) to enter into and upon and remain on the Demised Premises and every part thereof and to take a plan of and examine the state of repair and condition of the same and to take inventories of the Landlord's fixtures to be yielded up at the expiration of the said term and within two calendar months (or sooner if possible and in any event within a reasonable period) after notice in writing to the Tenant of all defects and wants of reparation found on such examination shall have been given to repair and make good the same according to such notice and the covenants in that behalf herein contained and in case the Tenant shall make default in so doing it shall be lawful for the workmen or others to be employed by the Landlord to enter upon the Demised Premises (but without prejudice to the proviso for re-entry hereinafter contained) and repair and restore the same and all expenses incurred thereby shall on demand be paid by the Tenant to the Landlord and if not paid shall be recoverable by the Landlord as liquidated damages.

# **PERMIT WORKS**

4.13 To permit the Landlord and/or the Superior Lessors and their agents and workmen and other persons authorised by the Landlord with all necessary appliances at all reasonable times after Due Notice (except in cases of emergency when no notice shall be required) to enter upon the Demised Premises or any part thereof to execute repairs or alterations to or upon any Adjoining Property or to cleanse empty or repair any of the sewers watercourses drains or gutters belonging to the same the Landlord and others causing as little inconvenience as possible and the Landlord making good with all practicable speed all damage to the Demised Premises thereby occasioned.

# NOT TO DO ANYTHING TO INCREASE INSURANCE OR RENDER POLICY VOID

4.14 Not to do or omit or suffer to be done or omitted any act matter or thing whatsoever the doing or omission of which would make void or voidable the insurance of the Demised Premises or of the Landlord's fixtures and fittings therein or whereby the rate of premium thereupon may be increased.

## NOT TO OVERLOAD STRUCTURE

4.15 Not to do or permit or bring in or upon the Demised Premises anything which may throw on the Demised Premises or on any Adjoining Property any weight or strain in excess of that which such premises are capable of bearing with due margin for safety and in particular not to overload the floors or the electrical installations or the other services of in or to the Demised Premises nor suspend any excessive weight from the ceilings or walls stanchions or the structure thereof.

## NO BUILDINGS OR ALTERATIONS

- 4.16.1 Not to erect any new building or new structure on the Demised Premises or any part thereof nor to alter add to or change the height elevation or external architectural or decorative design or appearance of the Building nor to merge the Demised Premises with any Adjoining Property;
- 4.16.2 Not to alter divide cut maim injure or remove any of the principal or load-bearing walls floors beams or columns of the Demised Premises nor to make any other alterations or additions of a structural nature to the Demised Premises;
- 4.16.3 Not to make any alterations or additions to the Landlord's fixtures or to any of the Conduits without obtaining the prior written consent of the Landlord (such consent not to be unreasonably withheld or delayed);
- 4.16.4 Not to make any alterations or additions of a non-structural nature to the Demised Premises without obtaining the prior consent of the Landlord (which such consent not to be unreasonably withheld) but which consent shall not be required for periodic non structural alterations to office layouts not requiring a new fire safety certificate under the Building Regulations made under the Building Control Act 1990;
- 4.16.5 The Landlord may as a condition of giving consent under any of the said sub-clauses 4.16.3 and 4.16.4 require the Tenant to enter into such reasonable covenants as the Landlord shall require regarding the execution of any such works.

4.16.6 Where the Landlord is insuring any additions, alterations and/or improvements carried out or being carried out by the Tenant, in the event of the Tenant carrying out any alterations or additions to the Demised Premises which alterations or additions result in the increase in the cost of reinstating the Demised Premises to notify the Landlord of the increase in the reinstatement cost so as to enable the Landlord adjust the insurance cover accordingly and to pay to the Landlord any increased premium payable.

## REMOVE UNAUTHORISED STRUCTURES

4.17 On the request in writing of the Landlord or its agent forthwith to pull down and remove any building erection alteration or addition erected placed or made in breach of any of the foregoing covenants and if any portion of the Demised Premises has been altered pulled down or removed in breach of any of the foregoing covenants upon such request in writing as herein provided forthwith to amend restore replace or rebuild the Demised Premises according to the original plans and elevations thereof.

## **NUISANCE**

4.18 Not to do or permit not suffer to be done upon or in connection with the Demised Premises or any part thereof which shall or may be or become or cause a nuisance, damage, annoyance inconvenience disturbance injury or danger to the Landlord or the owners tenants or occupiers of any other part of the Estate and or the IDA Estate and not to permit suffer or allow any odours, vapours, steam, water, vibrations, noises or undesirable effects to emanate form the Demised Premises or from any equipment or installation therein and keep the Landlord fully and effectually indemnified against all actions, proceedings, damages, costs, expenses, claims or demands whatsoever arising out of or in consequence of any breach or non observance of this covenant to the extent that the Tenant is responsible.

# **OBSTRUCTION OF SEWERS**

4.19 Not to allow to pass into the Conduits serving the Demised Premises any noxious or deleterious effluent or other substance which will cause an obstruction or injure the said Conduits and in the event of any such obstruction or injury to make good as soon as practicable all such damage to the reasonable satisfaction of the Landlord's Surveyor.

## **NO SIGNS**

4.20 Not to fix or exhibit or permit to be affixed or exhibited to or upon any part of the exterior or interior so as to be visible from the exterior of the Demised Premises or of the external walls windows rails or fences thereof any pole flag aerial burglar alarm advertisement poster notice or other sign placard or thing whatsoever except such as subject to planning permission shall be approved in writing by the Landlord, or the Landlord's Surveyor such approval not to be unreasonably withheld.

## INFLAMMABLE GOODS AND NOISY MACHINERY

4.21 Not to have store or keep upon the Demised Premises or any part thereof any substance of an explosive or of an especially inflammable or dangerous nature or such as might increase the risk of fire or explosion or which might attach or in any way injure by percolation corrosion or otherwise the Demised Premises or the keeping or use whereof may contravene any statute or local regulation or bye-law and not to house or operate or permit to be housed or operated in or upon the Demised Premises or any part thereof any engine or machinery of any kind other than machines and which are not likely to cause any undue vibration or be or become a nuisance annoyance or disturbance to any other tenants or occupiers in any adjoining or neighbouring property.

## **USER**

- 4.22 (a) to use or permit the Building or any part thereof to be used for any purpose other for light manufacturing of pharmaceuticals and healthcare products and ancillary offices <u>AND</u> for no other purpose save with the Landlord's written consent which consent shall not be unreasonably withheld but it is hereby <u>AGREED AND DECLARED</u> that it shall be reasonable for the Landlord to refuse its consent on the grounds that such user would result in the Demised Premises being used for a use which would not be commercial or trade use.
- 4.22 (b) to use the Car Park for the purposes of providing car parking to the staff and visitors to the Building and for no other purposes whatsoever.
- 4.22 (c) to use the Service Yard for the purposes of making deliveries to and from the Building and for no other purposes whatsoever.
- 4.22 (d) to use any other parts of the exterior parts of the Demised Premises as access routes to and from the Building or as landscaped areas and for no other purposes whatsoever.

#### REFUSE

4.23 To remove and where appropriate dispose of all refuse generated out of the Tenant's use and occupation of the Demised Premises and in particular, to comply with the Waste Management (Packaging) (Amendment) Regulations 1998 and not to store refuse in any part of the Demised Premises where it would be visible for any part of the Estate

# **PROHIBITED USER**

4.24 Not at any time to use the Demised Premises or any part thereof or allow the same to be used for any entertainment or for any dangerous noisy noxious or offensive trade or business or occupation whatsoever or for a residence or for any illegal or immoral purposes nor permit any sale by auction to be held on the Demised Premises.

# LOCAL AUTHORITY REQUIREMENTS

4.25 At all times to comply with all requirements of the council or the relevant Local Authority in connection with the user of the Demised Premises for the purpose of the Tenant's business.

## **CONVEYANCING ACT NOTICES**

4.26 To pay to the Landlord all reasonable and proper costs charges and expenses (including legal costs and surveyor's fees) which may be incurred by it in the preparation and service of any notices and proceedings under Section 14 of the Conveyancing Act 1881 notwithstanding that forfeiture is avoided otherwise than by relief granted by the Court and in connection with the recovery or attempted recovery of arrears of rent or other sums due from the Tenant or in procuring the remedying of the breach of any covenant by the Tenant and in relation to any application for consent required or made necessary by this Lease whether or not the same is granted (except in cases where the Landlord is obliged not to unreasonably withhold its consent and the withholding of its consent is held to be unreasonable), or whether or not the application has been withdrawn and in relation to any application made by the Landlord at the request of Tenant and whether or not such application is accepted refused or withdrawn.

# NOT TO ASSIGN UNDERLET OR PART WITH POSSESSION

4.27 Save for Group Sharing where no consent shall be required if prior notice is given to the Landlord, not to assign transfer or underlet or part with possession or occupation of the Demised Premises or any part thereof or suffer any person to occupy the Demised Premises or any part thereof as a licensee but so that notwithstanding the foregoing the Landlord shall not unreasonably withhold its consent to an assignment of the entire of the Demised Premises or an underletting of the entire of the Demised Premises to an assignee or underlessee of good and sufficient financial standing and otherwise acceptable to the Landlord and subject to the following provisions or such of them as may be appropriate that is to say:-

- 4.27.1 The Tenant shall prior to any such assignment or under-letting apply to the Landlord and give all reasonable information concerning the proposed transaction and concerning the proposed assignee or under-lessee as the Landlord may require;
- 4.27.2 The Landlord's consent to any such assignment or underletting shall be given in writing and shall be given in such a manner as the Landlord shall reasonably decide and the Tenant shall pay the reasonable costs in connection with such consent:
- 4.27.3 In the case of an under-lease of the entire of the Demised Premises the same shall be at the then current market rent without any deduction whatsoever and the under-lessee shall if required by the Landlord enter into a direct covenant with the Landlord to perform and observe all the covenants (other than that for payment of the rent hereby reserved) and condition herein contained and every such under-lease shall also be subject to the following conditions that is to say that it shall contain:-
  - 4.27.3.1 an unqualified covenant on the part of the under-lessee not to under-lesse or part with or share the possession of the whole or part only of the premises hereby demised to the extent permitted by law;
  - 4.27.3.2 a covenant on the part of the under-lessee not to assign the premises thereby demised without obtaining the previous consent in writing of the Landlord under the Landlord's Lease (if any) and of the Landlord (which consent shall not be unreasonably withheld);
  - 4.27.3.3 a covenant condition or proviso under which the rent reserved by the under-lessee shall be reviewed every five years and the Review Dates as therein defined shall be the days which are the Review Dates in this Lease (notwithstanding that this provision may necessitate a first review before the expiration of five years from the commencement of the under-lease) but otherwise in the same terms as provided in this Lease subject to such variations are may be reasonably required having regard to the term of the under-lease.
  - 4.27.3.4 covenants and conditions in the same terms as nearly as circumstances admit as those contained in this Lease subject to such variations are may be reasonably required having regard to the term of the underlease.

- 4.27.4 In the case that any proposed under-lessee is a company the Landlord may require as a condition of its giving consent to the underlease that a guaranter satisfactory to the Landlord (acting reasonably) enter into a guarantee for payment of the rent and compliance with the covenants contained in the Lease in a form acceptable to the Landlord.
- 4.27.5 The Tenant shall enforce at the Tenants own expense the performance and observance of every such undertenant of the covenants provisions and conditions of the underlease and shall not at any time either expressly or by implication waive any breach of the same.
- 4.27.6 The Tenant shall not agree any reviewed rent with the undertenant nor any rent payable on any renewal thereof without the prior written consent of the Landlord (such consent not to be unreasonably withheld).
- 4.27.7 The Tenant shall not vary the terms or accept any surrender of any permitted underlease without the prior written consent of the Landlord (such consent not to be unreasonably withheld).
- 4.27.8 Within fourteen days of every such assignment or under-lease the Tenant shall give notice thereof in writing with particulars to the Landlord's Solicitors or Agents and shall furnish them with a true copy of such instrument and shall pay to the Landlord's Solicitor their reasonable legal costs and other expenses in connection with such an Assignment or Under-Lease.
- 4.27.9 The Tenant may share possession of the Demised Premises by way of non-exclusive licence with Group Companies provided that such licence shall not entitle the Group Companies to obtain any rights to a lease or a renewed lease under Landlord and Tenant legislation and such licence shall terminate on the termination of this lease for whatever reason whatsoever.

## NO OBSTRUCTION

4.28 Not to block up obstruct or enlarge any doorway passage window light or other easement or make any new window or other opening in the Demised Premises or in any manner obscure any grating window or opening therein giving light to or otherwise intended for the benefit of the Building or other premises and not to give permission for any new window light opening doorway path passage drain or other encroachment or easement to be made into or against or upon the Demised Premises which might be or grow to the damage annoyance or inconvenience of the Landlord **AND** in case any such

window light opening doorway path passage drain or other encroachment or easement shall be made to give immediate notice thereof to the Landlord immediately the same shall come to the notice of the Tenant and at the request and cost of the Landlord to adopt such means as may be reasonably required or deemed proper for preventing any such encroachment or the acquisition of any such easement.

## **PLANNING ACTS**

- 4.29 In relation to the Planning Acts (by which expression it is intended herein to designate The Planning & Development Act, 2000 –2002, any statutory modification or re-enactment thereof for the time being in force and any regulations or orders made thereunder and if applicable the Public Health Acts by which expression it is intended herein to designate the Local Government (Sanitary Services) Acts 1887 to 1964 and the Building Control Act, 1990 and any statutory modification or re-enactment thereof for the time being in force and any Regulations and Orders made thereunder) and excepting liability for the Tenant in respect of non-compliance existing at the commencement of the term hereby created:-
  - 4.29.1 Not to do or omit or permit to be done or omitted anything on or in connection with the Demised Premises the doing or omission of which shall be a contravention of the Planning Acts or of any notices orders licences consents permissions and conditions (if any) served made granted or imposed thereunder or under any enactment repealed thereby and to indemnify (as well after the expiration of the said term by effluxion of time or otherwise as during its continuance) and to the extent that the Tenant is responsible to keep indemnified the Landlord against all actions proceedings damages penalties costs charges claims and demands in respect of such acts and omissions or any of them and against the costs of any application for the Planning Permission and the works and things done in pursuance thereof;
  - 4.29.2 In the event of the Landlord giving written consent to any of the matters in respect of which the Landlord's consent shall be required under the provisions of this Lease or otherwise and in the event of permission from any Planning Authority or certificate from a Building Control Authority under the Planning Acts being necessary for any addition alteration or change in or to the Demised Premises or for the change of user thereof to apply at the cost of the Tenant to the Local and Planning and Building Control Authorities as the case may be for all consents and permissions and approvals and certificates which may be required in connection therewith and to furnish to the Landlord a copy of any such application and to give notice to the Landlord of the granting or

refusal (as the case may be) of all such consents and permission and approvals and certificates forthwith on the receipt thereof and to comply with all such consents and permissions and approvals and certificates and to complete the work in compliance with such consents permissions certificates and approvals and in compliance with Building Regulations (if applicable) and to furnish to the Landlord a Certificate of Compliance with the relevant permission approval consent certificate and Regulations duly completed by an Architect having qualifications reasonably satisfactory to the Landlord; and the Tenant will substantially comply with the Building Regulations and will also furnish the Landlord with copies of all Fire Safety Certificates issued and an Architect's certificate of Opinion that all such works have been carried out in substantial compliance with the plans lodged with the application for the Fire Safety Certificate as amended by any conditions imposed by the Building Control Authority together with an Architect's Certificate of Opinion that all such works are in substantial compliance with the Building Regulations.

- 4.29.3 To give notice forthwith to the Landlord of any notice order or proposal for notice or order served on the Tenant under the Planning and Development Acts and if so required by the Landlord to produce the same and to make or join in making such objections or representations in respect of any proposal as the Landlord may require;
- 4.29.4 To comply at its own cost with any notice or order served on the Tenant under the provisions of the Planning Acts to the extent that the Tenant is responsible for the issue of such notice or order;
- 4.29.5 If and when called upon so to do to produce to the Landlord or its Surveyor all such plans documents and other evidence as the Landlord may reasonably require in order to satisfy itself that the provisions of this sub-clause have been complied with in all respects.

## TO GIVE NOTICE

4.30 Within seven days of the receipt of notice of the same to give full particulars to the Landlord of any permission notice or order made given or issued to the Tenant by any Government Department or Local or Public Authority under or by virtue of any statutory power and if so required by the Landlord to produce such permission notice or order or proposal for a notice or order to the Landlord and also without delay to take all reasonable and necessary steps to comply with any such notice or order and also at the request of the Landlord to make or join with the Landlord in making objections or making representations against or in respect of any such notice order or proposal as aforesaid as the Landlord shall deem expedient.

## REVERSIONARY INTEREST

4.31 At all convenient hours in the daytime Due Notice to permit all prospective Purchasers or dealers in the reversionary interests of the Landlord by order in writing of the Landlord or its agents to view the Demised Premises without interruption but so that no undue interference is caused to the business of the Tenant subject to such persons complying with the Tenant's reasonable security and confidentiality requirements.

## **RE-LETTING SIGN**

4.32 To permit the Landlord and its agents and/or the Superior Lessor on Due Notice within six calendar months before the expiration or sooner determination of the said term to enter upon the Demised Premises and to fix and retain without interference upon any suitable part or parts thereof (but not in any position likely to interfere with the user of the Demised Premises) a Notice Board for re-letting or disposing of the same and not to remove or obscure the same and to permit all persons by order in writing of the Landlord or its agents to view the Demised Premises at all reasonable hours in the daytime without interruption.

# **INDEMNITY**

- 4.33 To indemnify and keep indemnified the Landlord against all and any expenses costs actions claims demands damages and other liabilities whatsoever in respect of the injury or death of any person or damage to any property howsoever to the extent that the Tenant is responsible arising directly or indirectly out of:-
  - 4.33.1 the state of repair or condition of the Demised Premises;
  - 4.33.2 the existence of any alterations thereto or to the state of repair or condition of such alteration;
  - 4.33.3 the user of the Demised Premises;
  - 4.33.4 any work carried out or in the course of being carried out to the Demised Premises by the Tenant its servants or agents sub-lessees or sub-tenants;
  - 4.33.5 anything now or hereafter attached to or projecting therefrom.

## **TO YIELD UP**

4.34 At the expiration or sooner determination of the said term quietly to yield up the Demised Premises together with all the Landlord's fixtures and all other fixtures and fastenings that now are or which during the said term shall be affixed or fastened thereto (except Tenant's or trade fixtures) in such repair and condition as shall be in accordance with the covenants of the part of the Tenant herein contained and in case any of the said fixtures and fittings shall be missing broken damaged or destroyed to forthwith replace them with others of a similar kind and of equivalent value (damage by any of the Insured Risks (as hereinafter defined in Clause 5.2 if and so long only as the policy or policies of insurance shall not have been vitiated or payment of the policy monies withheld or refused in whole or in part by reason of any act neglect of default of the Tenant or the servants agents licensees of the Tenant)excepted) and provided that the Tenant shall not be obliged to remove any alterations carried out to the Demised Premises with the Landlord's consent provided that such alterations are in a reasonable condition.

#### TO PAY STAMP DUTY AND VAT

4.35 To pay the Landlord the Stamp Duty on this Lease and the Counterpart thereof and subject to receipt of a valid Value Added Tax invoice to pay all Value Added Tax (if any) whether arising on the delivery hereof and/or whether arising on any payments to be made by the Tenant under or pursuant to this Lease unless otherwise agreed.

## **SAFETY FILE**

- 4.36 In relation to any work from time to time undertaken by or on behalf of the Tenant in on or to the Demised Premises or in the fitting out thereof to submit to the Landlord all such drawings designs specifications details and information as may be appropriate for the up-dating of the Safety File maintained by the Landlord in relation to the property comprising the Demised Premises whether alone or with other premises.
  - 4.36.1 In relation to any such work as is referred to in Clause 4.36.1 which shall require the preparation of a Safety File or Files ("the Tenant's Safety File") by or on behalf of the Tenant the Tenant shall open and maintain the Tenant's Safety File and shall ensure that copies of all entries and items which are or should be entered thereon shall forthwith be furnished to the Landlord and that on any assignment of the interest of the Tenant hereunder in the Demised Premises the Tenant's Safety File shall be delivered to the assignee and that on the determination (howsoever effected)of the term hereby granted the Tenant's Safety File shall be delivered to the Landlord.

4.36.2 Without prejudice to the Tenant's obligations to comply with The Safety, Health and Welfare at Work (Construction) Regulations, 1995 as amended from time to time ("the Regulations") the Tenant covenants that in the event that it is requested to do so by the Landlord, it will keep safely at the Demised Premises any Safety File given to it by the Landlord and will procure that the Safety File is updated to take account of any works carried out to the Demised Premises (including any fit out works carried out by the Tenant prior to the granting of this Lease) by the Tenant or any other party with the Tenant's authority. The Tenant further covenants that it will on Due Notice make the Safety File available to the Landlord for inspection and/or to any other person who requires to inspect it for the purpose of compliance by either the Landlord and/or such other person with any duties imposed on either of them pursuant to the Regulations and/or make the Safety File available for inspection by any prospective successor in title of the Landlord. The Tenant further covenants that it will, forthwith upon request being made of it by the Landlord, deliver up the Safety File to the Landlord at the end of term of this Lease.

#### REGULATIONS

4.37 The Tenant agrees to be bound by any reasonable regulations made by the Landlord or the Superior Lessor from time to time in respect of the management of the Estate.

## 5. <u>LANDLORDS COVENANTS</u>

#### THE LANDLORD HEREBY COVENANTS WITH THE TENANT;

# **QUIET ENJOYMENT**

5.1 That the Tenant paying the rent hereby reserved and performing and observing the several covenants and conditions and agreements herein contained and on its part to be performed and observed shall and may peaceably and quietly hold and enjoy the Demised Premises without interruption by the Landlord or its assigns or any purchaser claiming under or in trust for it.

## **INSURANCE**

5.2 SUBJECT to the Landlord being able to effect insurance against any one or more of the risks hereinafter specified AND SUBJECT always to such exclusions excesses and limitations as are normal and as may be imposed by the Landlord's insurers for the time being hereof to procure that the Demised Premises is insured in the name of the Landlord and all Landlord's fixtures and fittings therein or thereon including glass are kept insured in the full reinstatement cost (to be determined from time to time by the Landlord or its surveyor and including an inflationary factor subject to the Tenant's right to require the Landlord to insure for a higher amount than the full reinstatement cost as determined by the Landlord against damage by fire, explosion, lightning, impact, earthquake, aircraft, frost, floods, landslip, storm and tempest, terrorism, riot, civil commotion and malicious damage or bursting or overflowing of water tanks, apparatus or pipes, corrosion of pipes, melting of pipes, melting of cables and including demolition and site clearance expenses, architects and other fees and taxes in relation to the reinstatement of the Demised Premises and all stamp duties exigible on any building or like contract as may be entered into relative to the reconstruction reinstatement or repair of the Demised Premises or any part thereof resulting from the destruction loss or damage thereof or thereto from any of the perils aforesaid and public liability and three years loss of rent and Service Charge (subject to quotation) and against such other risks as the Landlord may from time to time reasonably consider prudent and desirable (all such perils and risks are herein called "the Insured Risks") and such risks may be covered by any policy or policies of insurance as the Landlord may reasonably consider appropriate.

# **RE-INSTATE**

5.3.1 In case the Demised Premises or access thereto or any parts thereof shall be destroyed or damaged by fire or from any of the Insured Risks then so as to render the Demised Premises unfit for use and occupation then (subject to the Landlord obtaining Planning Permission and all other necessary permits licences and approvals) and as often as shall happen to lay out all monies received in respect of such insurance as aforesaid (other than in respect of rent and Service Charge) (and making up any shortfall from its own funds) as soon as practical in or upon rebuilding repairing or reinstating the Demised Premises and access thereto in good and substantial manner unless the relevant policy shall have been vitiated or rendered less than fully effected by way, act, neglect, default or omission on the part of the Tenant or on the part of any person in or upon the Demised Premises with the Tenants authority PROVIDED ALWAYS that in the event of the Landlord being unable to reinstate the Demised Premises due to refusal of planning or other approvals consents or licences the Landlord having made all reasonable efforts to obtain same the Tenant agrees to surrender this Lease when called upon by the Landlord so to do and the Landlord agrees to accept a surrender of this Lease should the Tenant require.

- 5.3.2 The Landlord shall procure that either Tenant's interest will be noted on the Landlord's policy or a letter from the Landlord's insurers will be furnished waiving subrogation rights.
- 5.3.3 The Landlord shall procure that the Landlord's policies will contain a provision that the insurance is not invalidated by any change of occupancy of the Demised Premises without the knowledge of the Landlord provided that the Landlord shall immediately upon the same coming to its knowledge give notice to the insurers.

#### **SERVICES**

- 5.4.1 Subject to payment by the Tenant of the Service Charge as provided by Clause 4.3 to use its reasonable endeavours to procure the provision or making available of the services comprised in the Estate Service Charge.
- 5.4.2 The Landlord covenants to pay the Landlords Proportion of the IDA Estate Service Charge to the person entitled thereto forthwith it is received by the Landlord from the Tenant and will use its reasonable endeavours to procure the provision or making available to the services specified in the Superior Lease and will otherwise pay the rent and perform the covenants on the part of the lessee contained in the Superior Lease.
- 5.4.3 the Landlord shall not be responsible for any unavoidable delay or stoppage in connection with the provision of the services or for any loss, injury or damage sustained by the Tenant as a result of the temporary failure of the Landlord or its agents to provide the same or for any temporary omission to perform the same if such temporary failure, delay, stoppage or omission shall be due to any shortage of labour or materials, inclement weather or other cause not within the control of the Landlord but the Landlord shall nevertheless take all reasonable steps to remedy or make good any such failure, delay, stoppage or omission as aforesaid as soon as may be practicable;
- 5.4.4 if the Landlord shall fail to provide the services as hereinbefore provided the Tenant's sole remedy shall be an action to compel the Landlord to do so and the Landlord shall not be liable to the Tenant in respect of any loss, injury or damage which the Tenant shall sustain as a result of the failure of the Landlord's staff properly to carry out their duties unless the Tenant shall notify the Landlord in writing specifying the failure for which the Tenant complains and the Landlord shall after the expiration of twenty-one days from the receipt of the notice continue to neglect to provide said services in respect of which notices has been given by the Tenant;
- 5.4.5 the Landlord shall be entitled to cease to provide or to procure the provision of any of the services set forth in Part I of the Third Schedule if any services shall in the reasonable opinion of the Landlord cease to be for the benefit of the Tenant or the Estate or shall have become due to technological change or otherwise obsolete or redundant.

## **COMPLIANCE**

5.5 The Landlord covenants to procure compliance with all relevant laws relating to the Estate at its own cost where such a want of compliance existed at the commencement of the Term hereby created to the extent that the Tenant may be adversely affected by non compliance.

## **RIGHTS OF ENTRY**

- 5.6 In exercising any of the Landlord's rights of entry or other rights in relation to the Demised Premises the Landlord shall:-
- 5.6.1 take all necessary steps to ensure that as little damage is done to the Demised Premises and as little inconvenience is caused to the occupier or the business carried on therein as is reasonably practicable;
- 5.6.2 make good without delay any damage to the Demised Premises, or to the Tenant's fixtures and fittings and chattels, that may be caused in exercising such rights;
- 5.6.3 consider all reasonable alternatives not involving any materially greater cost and shall consult with the Tenant in that regard;
- 5.6.4 ensure insofar as it is reasonably practical that such rights of entry are exercised outside the hours when the Demised Premises is used for the purposes of the Tenant's business;
- 5.6.5 give to the Tenant Due Notice before entering the Demised Premises except in cases of emergency.
- 6. **PROVIDED ALWAYS** and it is hereby agreed and declared as follows:-

# **FORFEITURES**

- 6.1 If:-
- 6.1.1 the said rent or any interest on arrears of rent or any sum payable hereunder or any part thereof shall be unpaid for 14 days after any of the days hereinbefore appointed for payment whether the same shall have been lawfully demanded or not; or
- 6.1.2 any covenants on the Tenant's part herein contained shall not be observed and performed; or

- 6.1.3 the Tenant being an individual or a firm shall become a bankrupt or compound or arrange with his or its creditors or being a Company shall go into liquidation either compulsory or voluntary except for the purpose of reconstruction or amalgamation; or
- 6.1.4 he Tenant being a Company shall permit or suffer to be appointed a Receiver over its assets.
- 6.1.5 The Tenant being a Company shall permit or suffer an Examiner to be appointed over its assets.

**THEN** and in any of the said cases and at any time thereafter it shall be lawful for the Landlord or any person or persons authorised by the Landlord to enter upon the Demised Premises or any part thereof in the name of the whole and to repossess the same and enjoy the same as if this Lease had not been executed but without prejudice to any right of action or remedy on either party in respect of any antecedent breach of any of the covenants by the other herein contained.

## SUSPENSION OF RENT

6.2 If during the said term the Demised Premises or the Estate or any parts thereof shall be destroyed or damaged by any of the Insured Risks so as to be unfit for occupation or use and the policy or policies of insurance effected by the Landlord shall not have been vitiated or payment of the policy monies withheld or refused in whole or in part in consequence of any neglect or default of the Tenant its servants agents or licensees the rent and Service Charge hereby reserved and the obligations of the Tenant as to the maintenance and repair of the Demised Premises or a fair proportion thereof according to the nature and extent of the damage sustained shall be suspended until the Demised Premises shall have again been rendered fit for occupation or use by the Tenant or become accessible and any dispute concerning the provisions of this clause shall be determined by a single arbitrator in accordance with the provisions of the Arbitration Acts 1954 to 1998 or any statutory enactment in that behalf for the time being in force.

# **NO WARRANTY**

Nothing contained in this Lease shall be deemed to constitute any warranty by the Landlord that the Demised Premises or any part thereof are authorised under the Planning Acts or otherwise for use for any specific purposes other than the use as offices at the date of this Lease.

## **NOTICES**

6.4 <u>IN</u> addition to any other prescribed mode of service any Notices requiring to be served on the Tenant hereunder shall be validly served if left addressed or sent by post to the Tenant (or if there shall be more than one of them to any one or more of them) if an individual or individuals at the last known address or addressed of the Tenant or Tenants or any of them in Ireland and if a company at its registered office and any Notice required to be served on the Landlord shall be validly served if left or posted to on of the Landlords at his respective address set out above or if the Landlord is a limited company to the registered office of the Landlord or in either case to any substituted address nominated by the relevant party from time to time and notified to the other and any such Notices may be served by servants or agents and be served on servants or agents.

## APPLICABLE LAW

6.5 This Lease shall in all respects be governed by and interpreted in accordance with the laws of Ireland and the Tenant hereby irrevocably agrees that the Courts of Ireland are to have jurisdiction in all or any disputes which arise in connection with this Lease and that accordingly any suit, action or proceedings arising out of or in connection with this Lease may be brought in such Courts.

# **SEVERABILITY**

6.6 If any term or provision of this Indenture shall be held to be invalid or unenforceable in whole or in part for any reason then such term or provision or part shall to that extent be deemed not to form part of this Indenture but the validity and enforceability of the remainder of this Indenture shall not be affected.

#### **PERPETUITY**

6.7 If any term or provision of this Indenture would but for this provision be void in whole or in part under the rule against perpetuities then such term or provision or part shall to that extent be read and construed as if there had been included therein a restriction limiting the vesting of future interest in property thereby purported to be vested to the Perpetuity Period.

**IT IS HEREBY CERTIFIED** by the parties hereto that the premises hereby demised is situate in the Urban District of Bray.

<u>IT IS HEREBY FURTHER CERTIFIED</u> that Section 53 (Lease combined with Building Agreement for a dwellinghouse/apartment) of the Stamp Duties Consolidation Act 1999 does not apply to this instrument

IT IS HEREBY FURTHER CERTIFIED that the consideration for the Lease is wholly attributable to property which is not residential property and that the transaction effected by this Instrument does not form part of a larger transaction or of a series of transactions in respect of which the amount or value of the aggregate amount or value of the consideration to other than rent which is attributable to property which is not residential property exceeds €6,350.00

<u>IT IS HEREBY FURTHER CERTIFIED</u> the Tenant is a body corporate incorporated in a member state of the European Communities or other European State which is contracting party to the European Economic Area Agreement and having its registered office, central administration or principal place of business within the territory of those States.

**IN WITNESS** whereof the parties hereto have hereunto executed these presents the day and year first herein **WRITTEN** 

# FIRST SCHEDULE

- 1. Full right and liberty for the Tenant its permitted assigns and their permitted under-tenants its and their servants, agents, licensees and invitees and all other persons entitled in common with other persons who have or hereafter have the like right at all times hereafter by day or by night and for all purposes with or without vehicles to pass and re-pass along, over and upon (subject on to all regulations made from time to time in relation to traffic and to the use of the roadways forming part of the Estate) the roadways forming part of the Estate, and over the roads forming part of the IDA Estate.
- 2. The right subject to such rules and regulations as the Landlord may make from time to time make in accordance with the principles of good estate management to go pass and repass with or without vehicles over the Service Yard for the purpose of making deliveries of goods to the Demised Premises but not to obstruct any carparking spaces adjacent to the Service Yard.
- 2. The free passage and running water, soil, steam, air, electricity, radio, television, telegraphic, telephone, telecommunications, computer linking and other services and supplies to and from the Demised Premises through the Conduits which are now laid or within the Perpetuity Period shall be laid in, under, or through the Retained Lands and the Estate, so far as any of the same are necessary for the reasonable use and enjoyment of the Demised Premises.

# SECOND SCHEDULE

- 1. The free right of uninterrupted passage and running of water soil air gas electricity telephone and other services from and to any adjoining or neighbouring property through any Conduits which may at any time during the said term be through in over or under the Demised Premises or otherwise together with full right of access at all reasonable times on giving due notice in writing (except in cases of emergency) for the purposes of inspecting maintaining replacing and repairing the same the person or persons exercising such rights making good any damage thereby occasioned to the Demised Premises;
- 2. Full right and liberty on giving due notice in writing at all times during the said term to enter the demised Premises in order to maintain replace or relay electricity, post office, telecommunications or other cables, gas mains, water mains, sewers, drains, telecommunication systems, and all other services to and from the Adjoining Property the person or persons exercising such right making good any damage thereby occasioned to the Demised Premises;
- 3. Full right and liberty on giving due notice in writing at any time hereafter to execute works and make erections upon or to erect rebuild or alter any buildings or erections on the Adjoining Property and to use their Adjoining Property and buildings in such manner as they may think fit;
- 4. All rights easements and privileges now belonging to or enjoyed by any adjoining or neighbouring property;
- 5. All mines and minerals in or under the Demised Premises with full power of working and getting the same provided reasonable compensation is paid to the Tenant for any damage thereby occasioned to the Demised Premises;
- 6. The right to enter onto and remain on the Demised Premises for the purpose of performing any obligation or carrying out any work which the Landlord is obliged either to the Tenant and/or to any other party to perform or carry out whether under this Lease or otherwise.

#### THIRD SCHEDULE

#### FIRST PART

#### (Services in relation to the Estate Common Parts)

- 1. Procuring that the Estate Common Parts are kept and maintained in good order, repair and condition (including marking of car parking spaces) and all other services, matters things and facilities whatsoever, reasonably deemed neccessary for the running of the Estate.
- 2. Decorating, cleansing, regulating, lighting and insuring the Estate Common Parts
- 3. Discharging the costs of providing directional signs thereon, paying rates therefor and the provision of refuse collection therefrom and the costs of management thereof and the cost of providing security arrangements for the Estate.

#### SECOND PART

- 1. The amount of the Service Charge (by which is meant the Landlords Proportion of the Estate Service Charge and the Landlord's Proportion of the IDA Estate Service Charge) shall be ascertained and certified annually by a Certificate (hereinafter called "the Certificate") signed by an independent suitably qualified accountant appointed by the Landlord ("the Auditor") and the Landlord's managing agent as soon after the end of the Landlord's financial year as may be practicable and shall relate to such year in manner hereinafter mentioned.
- 2. The expression "the Landlords financial year" shall mean the period form 1<sup>st</sup> day of January to the 31<sup>st</sup> day of December (both days inclusive) or such other annual period as the Landlord may in its discretion from time to time determine as being that in which the accounts of the Landlord either generally or relating to the Estate shall be made up and shall notify the Tenant thereof.
- 3. The certificate shall state the total costs of providing the services set out in the First Part of this Schedule and the cost of the services comprised in the Superior Lease for the Landlord's financial year to which it relates and the proportion of the

Tenant's liability hereunder and the Certificate (or a copy thereof duly certified by the person by whom same is given) shall in relation to matters of fact be (in absence of manifest error) conclusive evidence for the purposes hereof of the matters which it purports to certify and shall (save in the case of manifest error) be final and binding on the parties hereto.

- 4. The Landlord shall make available for inspection upon request all receipts invoices and other documents to vouch the Certificate.
- 5. On the 1st day of January, the 1st day of April, the first day of July and the 1st day of October in every year of the term hereby granted the Tenant shall pay to the Landlord in advance such sums by equal quarterly instalments (hereinafter referred to as "the Advance Payments") as the Auditor and/or the Landlord and/or the Landlord's managing agent shall from time to time at the commencement of the Landlord's financial year certify as being fair and reasonable and on account of the Service Charge for the said financial year **PROVIDED ALWAYS** that in respect of the Landlord's financial year commencing on the 1st day of January 2005 and the subsequent years of the term hereby granted the Advance Payments shall be based on the actual Service Charge incurred or expended in the Landlord's preceding financial year or, at the Landlord's sole option, pending the ascertainment of the actual Service Charge for the preceding financial year shall be based on the amount of the Service Charge paid or payable by the Tenant during the preceding financial year, together with a reasonable additional sum not exceeding a sum equal to 2% (two per cent) plus the percentage increase in the Cost of Living Index (or should the said Index not be available then such reasonable increase as the Auditor and/or the Landlord may from time to time determine) from the date of the commencement of the preceding Landlord's financial year to the end of such year and any such interim payment shall be included as a credit for the purposes of calculating the balance of the Service Charge as specified in this Schedule and for the purposes of this Clause the said Certificate shall be final and binding on the parties hereto save in the case of manifest error.
- 6. As soon as practical after the end of each Landlord's financial year the Landlord shall furnish to the Tenant the Certificates in respect of that year due credit being given therein for Advance Payments made by the Tenant in respect of the said year and upon the furnishing of the Certificate there shall be paid by the Tenant to the Landlord on demand the balance of the Service Charge found to be payable or there shall be repaid by the Landlord to the Tenant any amount which may have been overpaid by the Tenant by way of Advance Payments as the case may require **PROVIDED ALWAYS** that the provisions of this subclause shall continue to apply notwithstanding the expiration or sooner determination of the term hereby granted but only in respect of the period to such expiration or sooner determination as aforesaid.

- 7. If any dispute or difference shall arise in respect of this Part of this Schedule, such dispute or difference shall be referred to the Auditor whose decision shall (in the absence of manifest error) be final and binding on the parties hereto in relation to matters of fact **PROVIDED** that if such dispute or difference shall relate to any manifest error or omission on the part of the Auditor or other disagreement or dispute with the Auditor then the same shall be referred to the decision of an independent auditor to be appointed by either party by mutual agreement or in default to be nominated at the request of either party by the President or the next available ranking officer for the time being of the Institute of Chartered Accountants in Ireland.
- 8. In the event of the Estate being altered, added to, extended or redeveloped, during the term hereby granted the Service Charge may be adjusted in such manner as the Auditor and/or the Landlord shall reasonably determine.

## **FOURTH SCHEDULE**

#### (Provisions as to Rent Revisions)

In this Schedule the word "Lessor" refers to the Landlord in the within Lease and the word "Lessee" refers to the Tenant in the within Lease.

- 1. The revised rent referred to in the within Lease in respect of any of the five year periods therein mentioned may be agreed at any time between the Lessor and the Lessee or (in the absence of agreement) be determined not earlier than the date of commencement of such period ("the Review Date") by an Arbitrator such Arbitrator to be nominated (in the absence of agreement between the parties) upon the application (made not more than three calendar months before or at any time after the Review Date) of either the Lessor or the Lessee by the Chairman (or other officer endowed with the functions of such Chairman) of
  - (a) the Society of Chartered Surveyors in the Republic of Ireland; or
  - (b) such body of Professional Surveyors or Valuers as (in the event of such Society not then being in existence) shall for the time being have undertaken in the Republic of Ireland the functions (in the activity of property valuation) currently performed by such Society or (should the Chairman or other officer as aforesaid be unwilling or unable to make the nomination) by the next Senior Officer of such Branch or Body who is willing and able to make the nomination (or in the event of there being no such Officer willing and able to make the nomination or should such Body not be in existence or not be readily identifiable) by the President (or other officer endowed with the functions of such President) of the Law Society of Ireland or (in the event of his being unwilling or unable to make the nomination) by the next Senior Officer of said Society who is willing and able to make the nomination

**AND** the revised rent so to be determined by the Arbitrator shall be such as in his opinion represents at the Review Date the full open market yearly rent for the demised premises let as a whole without fine or premium:-

- (i) on the basis of a letting with vacant possession thereof by a willing lessor to a willing lessee for a term (commencing on the Review Date) equal to that granted by the within-written Lease and subject to the provisions therein set forth (other than as to the amount of initial rent thereby reserved and the tenant's option for early termination but including these provisions in relation to review of rent) and
- (ii) on the assumption that at and until the Review Date all the covenants and conditions contained in the within Lease on the part of the Tenant shall have been fully performed and observed and that in the event of the Demised Premises having been destroyed or damaged the same shall then have been fully rebuilt repaired or reinstated (as the case may be) and

- (iii) having regard to other open market rental values current at the Review Date insofar as the Arbitrator may deem same to be pertinent to the matters under consideration by him **BUT** disregarding any affect on letting value of:-
  - (a) the fact that the Lessee has been in occupation of the demised premises
  - (b) the goodwill which shall have attached to the Demised Premises by reason of the business carried out thereat
  - (c) any increase in rental value of the Demised Premises attributable to the existence at the relevant Review Date of any works executed by and at the expense of the Lessee or any predecessor in title of the Lessee (or any party lawfully occupying the Demised Premises or any part thereof under the Lessee or any such predecessor) with the Lessor's consent in writing in on or to or in respect of the Demised Premises otherwise than in pursuance of an obligation on foot of the within Lease or any agreement therefore but excluding any fit out works carried out by the Tenant to the Demised Premises.
- (vi) The revised rent shall be based on the fact that the floor area of the Building is deemed to be 69,920.46 square feet and the Demised Premises is deemed to have 50 car parking spaces.
- 2. All such arbitrations as aforesaid shall be conducted in accordance with the provisions set forth in the Arbitration Acts 1954 and 1998 or in any Act or Statutory Rule or Order extending amending modifying or replacing the same for the time being in force.
- 3. If the Arbitrator shall relinquish his appointment or die or if it shall become apparent that for any reason he shall be unable or shall have become unfit or unsuited (whether because of bias or otherwise) to complete his duties, or if he shall be removed from office by court order, a substitute may be nominated in his place and in relation to any such nomination the procedures hereinbefore set forth shall be deemed to apply as though the substitution were a nomination de novo which said procedures may be repeated as many times as may be necessary.
- 4. If the revised rent in respect of any period ("the Current Period") shall not have been ascertained on or before the Review Date referable thereto rent shall continue to be payable up to the gale day next succeeding the ascertainment of the revised rent at the rate payable during the preceding period AND on such gale day the Lessee shall pay to the Lessor the appropriate instalment of the revised rent together with any shortfall between:

- (i) rent actually paid for any part of the Current Period and;
- (ii) rent at the rate of the revised rent attributable to the interval between the Review Date and such gale day (other than the said appropriate instalment if payable in arrear) and together further with interest on said shortfall such interest to be computed on a day to day basis at a rate per annum of 1% (one per centum) above EURIBOR.

For the purpose of this paragraph the revised rent shall be deemed to have been ascertained on the date when the same shall have been agreed between the parties or as the case may be on the date of the notification to the Lessee of the award of the Arbitrator.

- 5. If there should be in force at the commencement or during the currency of any particular relevant period any Statute or Order (directly or indirectly) prohibiting or restricting an increase of rent in respect of the demised premises the provisions of this Schedule and of the within Lease may nevertheless be invoked or reinvoked to determine the rent which would but for the said prohibition or restriction be payable during such relevant period but (if appropriate) the further implementation thereof shall be suspended in effect for such period as may be required by Law.
- 6. When and so often as the revised rent shall have been ascertained pursuant to the provisions herein set forth memoranda thereof shall thereupon be signed by or on behalf of the Lessor ad the Lessee and shall be annexed to the within Lease and its Counterpart and the parties shall bear their own costs in relation to the preparation and completion of such memoranda.

| SIGNED SEALED AND DELIVERED by RONAN O'CAOIMH in the presence of: |          |
|---|----------|
| SIGNED SEALED AND DELIVERED by JIM WALSH in the presence of:      |          |
| PRESENT when the COMMON SEAL of TRINITY MANUFACTURING LIMITED:    | Director |

Director

#### COMMERCIAL AND INDUSTRIAL LEASE AGREEMENT

THIS LEASE is made as of , 2004, between Livers, LLC a Missouri Limited Liability Company \_ ("Landlord"), with an address of 4621 E. 75th Terrace, Kansas City, Missouri, and Primus Corporation, a Missouri Corporation ("Tenant"), with an address of 4231 E. 75th Terrace, Kansas City, Missouri, who hereby agrees as follows:

- 1. <u>PREMISES</u>. Subject to the covenants and conditions of this Lease, Landlord leases to Tenant, and Tenant leases from Landlord, the premises (the "Premises") commonly known and numbered as 4231 E. 75<sup>th</sup> Terrace, in the City of Kansas City, County of Jackson, State of Missouri, and further described as: the 36,500 sq.ft. single-story office/warehouse building commonly known and numbered as 4231 E. 75<sup>th</sup> Terrace, Kansas City, Missouri 64132, together with the right of ingress and egress.
- 2. <u>USE OF PREMISES</u>. The Premises will be used only for: production and distribution of clinical diagnostic systems and reagents and related office uses (collectively, the "Permitted Use").
- 3. <u>TERM</u>. The term of this Lease (the "Term") is for five (5) years and no months, commencing on the 1st day of July, 2004, and ending on the 30th day of June, 2009.
- 4. <u>RENT PAYMENTS</u>. Tenant shall pay to Landlord an aggregate sum of Four Hundred Eighty-Nine Thousand Three Hundred Twenty-Seven AND 93/100s DOLLARS (\$489,327.93) as rent in monthly installments, each due and payable in advance without notice or demand at Landlord's above stated address, or at any other place Landlord designates in writing. The first monthly rent installment of \$8,364.58 will be paid at lease execution and all subsequent monthly rent installments will be due on the day of each succeeding month during the Term. The amount of each monthly rent installment will be as follows: July 1, 2004 September 30, 2004 \$4,182,29 per month October 1, 2004 June 30, 2009 \$8,364.58 per month
- 5. <u>SECURITY DEPOSIT</u>. Concurrently with its execution of this Lease, Tenant shall deliver to Landlord \$8,364.58 as security for the performance by Tenant of every covenant and condition of this Lease (the "Security Deposit"). Said Security Deposit may be co-mingled with other funds of Landlord and shall bear no interest. If Tenant shall default with respect to any covenant or condition of this Lease, including, but not limited to the payment of rent, Landlord may apply the whole or any part of such Security Deposit to the payment of any sum in default or any sum which Landlord may be required to spend by reason of Tenant's default. If any portion of the Security Deposit is so applied, Tenant, upon demand by Landlord, will deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount. Should Tenant comply with all of the covenants and conditions of this Lease, the Security Deposit or any balance thereof shall be returned to Tenant promptly after expiration of the term thereof.
- 6. <u>POSSESSION AT BEGINNING OF TERM</u>. Landlord shall use due diligence to give possession as nearly as possible at the beginning of the Term. Rent shall abate pro rata for the period of any delay in giving Tenant possession, but the Term will not be extended as a result of such delay. Tenant will make no other claim against Landlord for delay in obtaining possession.
- 7. <u>PROPERTY INSURANCE</u>. Tenant shall comply with all insurance regulations so the lowest property damage insurance and liability insurance rates may be obtained; and nothing shall be done or kept in or on the Premises by Tenant which will cause an increase in the premium for any such insurance on the Premises or on any building of which the Premises are a part or on any contents located therein, over the rate usually obtained for the proper use of the Premises permitted by this Lease or which will cause cancellation or make void any such insurance.

If, during the Term, the premiums for any property damage insurance maintained by Landlord with respect to the Premises are increased, or if the amount of property damage coverage that must be maintained with respect to the Premises is increased, then Tenant will pay to Landlord, as additional rent, the amount of all such increases in excess of the premium covering the Premises for the policy yea<u>r 2003</u> within thirty(30) days after receipt of Landlord's billing statement and demand for payment of the same. The amount payable by Tenant under this section will be pro rated on a per diem basis for the partial years, if any, in which this Lease commences and terminates.

Tenant shall maintain, at all times during the Term, adequate insurance on its personal property used, stored or kept in the Premises.

8. <u>INDEMNITY AND LIABILITY INSURANCE</u>. Tenant shall at all times indemnify, defend and hold Landlord harmless from all loss, liability, costs, damages and expenses that may occur or be claimed with respect to any person or persons, or property on or about the Premises or to the Premises resulting from

**Tenant's initials** 

Landlord's initials

any act done or omission by or through Tenant, its agents, employees, invitees or any person on the Premises by reason of Tenant's use or occupancy or resulting from Tenant's non use or possession of said property and any and all loss, cost, liability or expense resulting therefrom. Tenant shall maintain, at all times during the Term, comprehensive general liability insurance in a responsible insurance company, licensed to do business in the state in which the Premises are located and satisfactory to Landlord, properly protecting and indemnifying Landlord with single limit coverage of not less than \$1,000,000 for injury to or death of persons and for property damage. During the Term, Tenant shall furnish Landlord with a certificate or certificates of insurance covering such insurance so maintained by Tenant and naming Landlord and Landlord's mortgagees, if any, as additional insureds.

- 9. <u>ASSIGNMENT AND SUBLETTING</u>. Tenant shall not assign, transfer or encumber this Lease and shall not sublease the Premises or any part thereof or allow any other person to be in possession thereof without the prior written consent of Landlord, in each and every instance, which consent or consents shall not be unreasonably withheld. For the purpose of this provision, any transfer of a majority or controlling interest in Tenant (whether in one or more related or unrelated transactions), whether by transfer of stock, consolidation, merger, transfer of a partnership interest or transfer of any or all of Tenant's assets or otherwise, or by operation of law, shall be deemed on assignment of this lease. Notwithstanding any permitted assignment or subletting, Tenant shall at all times remain directly, primarily and fully responsible and liable for the payment of the rent herein specified and for compliance with all of its other obligations under the terms and provisions of this Lease.
- 10. <u>SIGNS AND ADVERTISEMENTS</u>. Tenant shall not place upon nor permit to be placed upon any part of the Premises, any signs, billboards or advertisements whatever, without the prior written consent of Landlord.
- 11. <u>CONDITION OF PREMISES AT BEGINNING AND END OF TERM</u>. Tenant acknowledges Tenant has inspected the Premises and, except as may be provided otherwise in the Lease and without abrogating Landlord's obligations under Paragraph 15 hereof. Tenant accepts the Premises in their present condition.

At the end of the Term, except for damage caused by fire or other perils, Tenant, at Tenant's expense, will (a) surrender the Premises in as good a condition as the Permitted Use will have reasonably permitted, subject to Tenant's obligations stated in Paragraphs 12 and 14 herein; (b) have removed all of Tenant's property from the Premises; (c) have promptly repaired any damage to the Premises caused by the removal of Tenant's Property; and (d) leave the Premises free of trash and debris and the building in "broom clean" condition.

- 12. MAINTENANCE AND REPAIR BY TENANT. Except for the obligations imposed upon Landlord in Paragraph 15 hereof, and except for damage resulting from an Insurable Loss, during the Term and at Tenant's sole cost and expense, Tenant will maintain and keep in good order, repair and condition and, when necessary, will replace all parts of the Premises (except those for which Landlord is expressly responsible under the terms of this Lease), including, but not limited to, dock bumpers and other dock equipment and apparatus, utility service lines from the point where they enter the building(s) of which the Premises are a part, interior walls, inside surfaces of exterior walls, fixtures, floor coverings, lighting fixtures, heating, ventilating, air-conditioning, plumbing, sprinkler system, glass, windows, doors, elevator, electrical and other mechanical equipment, appliances and systems, improvements made by and at the expense of Tenant and Tenant's property, including, but not limited to, Tenant's signs and advertisements. Tenant will police and keep the driveways, approaches, sidewalks, parking areas and adjacent alleys that are a part of the Premises clean, orderly, sightly, unobstructed and free from ice and snow and will keep railroad spur tracks that are a part of the Premises unobstructed. Tenant will regularly water, mow, trim, fertilize and otherwise maintain the lawn, shrubs, plants, trees and other landscaping of the Premises and will prevent water pipes in the Premises from freezing.
- 13. <u>LANDLORD'S RIGHT OF ENTRY</u>. Landlord or Landlord's agent may enter the Premises at reasonable hours to examine the same, to show the same to prospective lenders and purchasers, and to do anything Landlord may be required to do hereunder or which Landlord may deem necessary for the good of the Premises or any building of which they are a part; and, during the last <u>120</u> days of this Lease, Landlord may display a "For Lease" sign on and show the Premises.
- 14. <u>PARKING LOT MAINTENANCE</u>. Tenant shall be responsible for maintenance, cleaning, repainting, and repairs of the parking areas, driveways, sidewalks and approaches caused by placement or movement of trash containers, truck trailer dollies, trucks, etc. Tenant understands and agrees that no personal property shall be stored in the parking area or anyplace outside of the building without the prior written consent of Landlord.
- 15. MAINTENANCE AND REPAIR BY LANDLORD. Landlord, during the Term and at Landlord's sole cost and expense, will maintain and keep in good repair the roof, exterior walls (exclusive of inside surfaces and glass, windows and doors), gutters, down spouts, foundations and all other structural components of the building(s) of which the Premises are a part, all underground plumbing and sewer lines, and water, gas and electric service lines to the point where such service lines enter the building(s) of which the Premises are a part. Landlord will be under no obligation, and will not be liable for any failure, to make any repairs until and unless Tenant notifies Landlord in writing they are necessary, in which event Landlord will have a reasonable time after notice to make such repairs.

Tenant's initials

andlord's initials

- 16. <u>DAMAGE BY CASUALTY</u>. In case, during the Term or previous thereto, the Premises hereby let, or the building of which said Premises are a part, shall be destroyed or shall be so damaged by fire or other casualty as to become untenantable, then in such event, at the option of Landlord, the Term shall cease and this Lease shall become null and void from the date of such damage or destruction and Tenant shall immediately surrender said Premises and all interest therein to Landlord, and Tenant shall pay rent within said Term only to the time of such surrender; provided, however, that Landlord shall exercise such option to so terminate this Lease by notice in writing delivered to Tenant within thirty days after such damage or destruction. In case Landlord shall not so elect to terminate this Lease, this Lease shall continue in full force and effect and Landlord shall repair the Premises with all reasonable promptitude, placing the same in as good a condition as they were at the time of the damage or destruction, and for that purpose may enter said Premises and rent shall abate in proportion to the extent and duration of untenantability. In either event, Tenant shall remove all rubbish, debris, merchandise, furniture, equipment and other of its personal property, within five days after the request of Landlord. If the Premises shall be but slightly injured by fire or other casualty, so as not to render the same untenantable and unfit for occupancy, then Landlord shall repair the same with all reasonable promptitude, and in that case the rent shall not abate. Except as provided herein, no compensation or claim shall be made by or allowed to Tenant by reason of any inconvenience or annoyance arising from the necessity of repairing any portion of the building or the Premises, however the necessity may occur.
- 17. <u>PERSONAL PROPERTY</u>. Landlord shall not be liable for any loss or damage to any merchandise inventory, goods, fixtures, improvements or personal property of Tenant in or about the Premises, regardless of the cause of such loss or damage.
- 18. <u>ALTERATIONS.</u> Tenant shall not make any alterations or additions in or to the Premises without the prior written consent of Landlord. Tenant may install air-conditioning, back up power supplies, exterior landscaping and plumbing improvements at its own expense with Landlord's consent, which will not be unreasonably withheld.
- 19. <u>UTILITIES AND SERVICES</u>. Tenant shall furnish and pay for all electricity, gas, water, fuel, trash removal and any services or utilities used in or assessed against the Premises, unless otherwise herein expressly provided.
- 20. <u>LEGAL REQUIREMENTS</u>. Tenant shall comply with all laws, orders, ordinances and other public requirements now or hereafter affecting the Premises or the use thereof, including without limitation ADA, OSHA and like requirements, and indemnify, defend and hold Landlord harmless from expense or damage resulting from failure to do so.
- 21. <u>MULTIPLE TENANCY BUILDING</u>. If the Premises are a part of a multiple tenancy building, the responsibility of Tenant for reimbursements as called for in Paragraphs 7 and 23 of this Lease shall be a percentage of the total increase equal to the percentage of rentable floor space in said building occupied by Tenant. It is agreed Tenant occupies 100% ("Proportionate Share") of the floor space in the building for which the Premises are a part.

Landlord may, with written notice to Tenant, elect to perform and provide certain maintenance and services pertaining to the entire building or area of which the Premises are a part including, but not limited to, landscaping, trash removal, lawn maintenance, common area lighting, water, paving maintenance, maintenance to rail trackage and snow removal, and in such event Tenant shall reimburse Landlord for its Proportionate Share of said maintenance services within fifteen (15) days from the date of Landlord's notice of the amount so due hereunder.

Tenant agrees to conduct its business in a manner that will not be objectionable to other tenants in the building of which the Premises are a part, including noise, vibration, odor, trash or fumes. In the event Landlord receives complaints from other tenants in the building and determines, in its sole reasonable judgment, that Tenant is conducting its operations in a manner so as to be objectionable to other tenants, Tenant agrees, upon notice from Landlord thereof, to promptly modify the conduct of its operations to eliminate such objectionable operations.

- 22. <u>FIXTURES</u>. Except for Tenant's property and business fixtures, all buildings, repairs, alterations, additions, improvements, installations and other non-business fixtures installed or erected on the Premises, whether by or at the expense of Landlord or Tenant, will belong to Landlord and will remain on and be surrendered with the Premises at the expiration or termination of this Lease. However, at Landlord's option, Tenant shall remove Tenant's alterations or improvements prior to the expiration of this Lease and return the Premises to their original condition.
- 23. <u>INCREASE IN REAL ESTATE TAXES AND SPECIAL ASSESSMENTS</u>. In the event the real estate taxes and installments of special assessments, payable with respect to the Premises during any lease year shall be greater than the amount of such taxes and installments due and payable during the base year of 2003, in the amount of \$11,627.00 or the first fully assessed year, whether by reason of an increase in tax rate or an increase in the assessed valuation or otherwise, Tenant shall pay to Landlord the full amount of such increase as additional rent within thirty (30) days after notice that the same is due. Should Tenant occupy less than the whole of the property against which such taxes are assessed, Tenant's obligation hereunder shall be limited to its Proportionate Share of such increased taxes and special assessments.

**Tenant's initials** 

Landlord's initials

- 24. <u>EMINENT DOMAIN</u>. If the Premises or any substantial part thereof shall be taken under the power of eminent domain or be acquired for any public or quasi-public use or purpose, the Term shall cease and terminate upon the date when the possession of said Premises or the part thereof so taken shall be required for such use or purpose and without apportionment of the award, and Tenant shall have no claim against Landlord for the value of any unexpired Term. If any condemnation proceeding shall be instituted in which it is sought to take or damage any part of the Premises or the building of which the Premises are a part or the land under it, or if the grade of any street or alley adjacent to the Premises is changed by any legal authority and such change of grade makes it necessary or desirable to remodel the Premises to conform to the changed grade, Landlord shall have the right to cancel this Lease after having given written notice of cancellation to Tenant not less than ninety (90) days prior to the date of cancellation designated in the notice. In either of said events, rent at the then current rate shall be apportioned as of the date of the termination. No money or other consideration shall be payable by Landlord to Tenant for the right of cancellation and Tenant shall have no right to share in the condemnation award or in any judgment for damages caused by the taking or the change of grade. Nothing in this paragraph shall preclude an award being made to Tenant for loss of business or depreciation to and cost of removal of equipment or fixtures.
- 25. WAIVER OF SUBROGATION. As part of the consideration for this Lease, each of the parties hereby releases the other party hereto from all liability for damage due to any act or neglect of the other party (except as hereinafter provided) occasioned to property owned by said parties which is or might be incident to or the result of a fire or any other casualty against loss for which either of the parties is now carrying or hereafter may carry insurance; provided, however, that the releases herein contained shall not apply to any loss or damage occasioned by intentional acts of either of the parties hereto, and the parties hereto further covenant that any insurance they obtain on their respective properties shall contain an appropriate provision whereby the insurance company, or companies, consent to the mutual release or liability contained in this paragraph.
- 26. DEFAULT AND REMEDIES. In the event: (a) Tenant fails to comply with any term, provision, condition or covenant of this Lease; (b) Tenant deserts or vacates the Premises; (c) any petition is filed by or against Tenant under any section or chapter of the Federal Bankruptcy Act, as amended, or under any similar law or statute of the United States or any state thereof; (d) Tenant becomes insolvent or makes a transfer in fraud of creditors; (e) Tenant makes an assignment for benefit of creditors; or (f) a receiver is appointed for Tenant or any of the assets of Tenant, then in any of such events, Tenant shall be in default and Landlord shall have the option to do any one or more of the following: upon ten (10) days prior written notice, excepting the payment of rent or additional rent for which no demand or notice shall be necessary, in addition to and not in limitation of any other remedy permitted by law, to enter upon the Premises either with or without process of law, and to expel, remove and put out Tenant or any other persons who might be thereon, together with all personal property found therein; and, Landlord may terminate this Lease or it may from time to time, without terminating this Lease, rent said Premises or any part thereof for such term or terms (which may be for a term extending beyond the Term) and at such rental or rentals and upon such other terms and conditions as Landlord in its sole discretion may deem advisable, with the right to repair, renovate, remodel, redecorate, alter and change said Premises. At the option of Landlord, rents received by Landlord from such reletting shall be applied first to the payment of any indebtedness from Tenant to Landlord other than rent and additional rent due hereunder; second, to payment of any costs and expenses of such reletting, including, but not limited to, attorney's fees, advertising fees and brokerage fees, and to the payment of any repairs, renovation, remodeling, redecorations, alterations, and changes in the Premises; third, to the payment of rent and additional rent due and payable hereunder and interest thereon; and, if after applying said rentals there is any deficiency in the rent and additional rent and interest to be paid by Tenant under this Lease, Tenant shall pay any such deficiency to Landlord and such deficiency shall be calculated and collected by Landlord monthly. No such re-entry or taking possession of said Premises shall be constructed as an election of Landlord's part to terminate this Lease unless a written notice of such intention be given to Tenant. Notwithstanding any such reletting without termination, Landlord may at any time thereafter elect to terminate this Lease for such previous breach and default. Should Landlord at any time terminate this Lease by reason of any default, in addition to any other remedy it may have, it may recover from Tenant the worth at the time of such termination of the excess of the amount of rent and additional rent reserved in this Lease for the balance of the Term over the then reasonable rental value of the Premises for the same period. Landlord shall have the right and remedy to seek redress in the courts at any time to correct or remedy any default of Tenant by injunction or otherwise, without such resulting or being deemed a termination of this Lease, and Landlord, whether this Lease has been or is terminated or not, shall have the absolute right by court action or otherwise to collect any and all amounts of unpaid rent or unpaid additional rent or any other sums due from Tenant to Landlord under this Lease which were or are unpaid at the date of termination. In case it should be necessary for Landlord to bring any action under this Lease, to consult or place said lease or any amount payable by Tenant hereunder with an attorney concerning or for the enforcement of any of Landlord's rights hereunder, then Tenant agrees in each and any such case to pay to Landlord, Landlord's reasonable attorney's fees.

27. WAIVER. The rights and remedies of Landlord under this Lease, as well as those provided or accorded by law, shall be cumulative, and none shall be exclusive of any other rights or remedies hereunder or allowed by law. A waiver by Landlord of any breach or breaches, default or defaults of Tenant hereunder shall not be deemed on construed to be a continuing waiver of such breach or default nor as a waiver of or permission, expressed or implied, for any subsequent breach or default, and it is agreed that the acceptance by Landlord of any installment of rent subsequently to the date the same should have been paid hereunder, shall in no manner alter or affect the covenant and obligation of Tenant to pay subsequent installments of rent promptly upon the due date thereof. No receipt of money by Landlord after the termination of this Lease shall in any way reinstate, continue or extend the term above demised.

Tenant's initials

andlord's initials

- 28. TOXIC OR HAZARDOUS MATERIALS. Tenant shall not store, use or dispose of any toxic or hazardous materials in, on or about the Premises without the prior written consent of Landlord. Tenant, at its sole cost, will comply with all laws relating to Tenant's storage, use and disposal of hazardous or toxic materials. Tenant shall be solely responsible for and will defend, indemnify and hold Landlord, its agents and employees, harmless from and against all claims, costs and liabilities, including attorney's fees and costs, arising out of or in connection with the removal, clean up and restoration work and materials necessary to return the Premises, and any other property of whatever nature located on the Premises, to their condition existing prior to the appearance of toxic or hazardous materials on the Premises. Tenant's obligations under this paragraph will survive the termination of this Lease.
- 29. <u>REAL ESTATE COMMISSION</u>. Kessinger/Hunter & Co. the REALTOR identified in the "Agency Disclosure(s)" attached to and hereby incorporated into this Lease, is(are) the only real estate broker(s) involved in representing or procuring the parties to this Lease.

Upon complete execution of this Lease by both Landlord and Tenant, Landlord will pay the REALTOR a leasing commission of six percent (6%) pursuant to the agreement between Landlord and REALTOR.

Upon execution of any extensions or renewals of this Lease, or expansions of the Premises, a commission of two percent (2%) shall also be paid by Landlord to the above named REALTOR on all rentals to be received for any extensions or renewals of the Term and on all increases in the amount of rent due Landlord as a result of any enlargement of the Premises. If the Premises are purchased by Tenant during the Term, Landlord will pay such REALTOR a sales commission of four percent (4%).

Any party to this Lease through whom a claim to any broker's, finder's or other fee is made, contrary to the representations made above in this paragraph, shall indemnify, defend and hold harmless the other party to this Lease from any other loss, liability, damage, cost or expense including, without limitation, reasonable attorney's fees, court costs and other legal expenses paid or incurred by the other party, that is in any way related to such a claim.

- 30. <u>NOTICES</u>. Any notice hereunder shall be sufficient if sent by certified mail, addressed to Tenant at the Premises, and to Landlord where rent is payable.
- 31. <u>SUBORDINATION</u>. In the event Landlord holds title to said Premises by virtue of a lease, then this sublease is and shall remain subject to all of the terms and conditions of such underlying lease, so far as shall be applicable to the Premises. This Lease shall also be subject and subordinate in law and equity to any existing or future mortgage or deeds of trust placed by Landlord upon the Premises or the property of which the Premises form a part.
- 32. <u>SUCCESSORS.</u> The provisions, covenants and conditions of this Lease shall bind and inure to the benefit of the legal representatives, heirs, successors and assigns of each of the parties hereto, except that no assignment or subletting by Tenant without the written consent of Landlord shall vest any rights in the assignee or subtenant of Tenant.
- 33. <u>QUIET POSSESSION</u>. Landlord agrees, so long as Tenant fully complies with all of the terms, covenants and conditions herein contained on Tenant's part to be kept and performed. Tenant shall and may peaceably and quietly have, hold and enjoy the Premises for the Term aforesaid, it being expressly understood and agreed that the aforesaid covenant of quiet enjoyment shall be binding upon Landlord, its heirs, successors or assigns, but only during such party's ownership of the Premises. Landlord and Tenant further covenant and represent that each has full right, title, power and authority to make, execute and deliver this Lease.
- 34. <u>BANKRUPTCY</u>. Neither this Lease nor any interest therein nor any estate hereby created shall pass to any trustee or receiver in bankruptcy or to any other receiver or assignee for the benefit of creditors by operation of law or otherwise during the Term or any renewal thereof.
- 35. <u>HOLDING OVER</u>. If Tenant should remain in possession of the Premises after the expiration of this Lease term and without executing a new Lease, then, upon acceptance of rent by Landlord, such holding over shall be construed as a tenancy from month to month, subject to all the conditions, provisions and obligations of this Lease as existed during the last month of the term hereof, so far as applicable to a month to month tenancy, except that the monthly Base Rental amount shall be equal to one and one half the monthly Base Rental amount payable immediately prior to the expiration or termination of this Lease.
- 36. <u>ENTIRE AGREEMENT.</u> This Lease contains the entire agreement between the parties, and no modification of this Lease shall be binding upon the parties unless evidenced by an agreement in writing signed by Landlord and Tenant after the date hereof. If there be more than one Tenant named herein, the provisions of this Lease shall be applicable to and binding upon such Tenants, jointly and severally.
- 37. <u>ATTORNMENT</u>. Tenant shall attorn to any successor to Landlord upon request and to execute any documents reasonably required or appropriate to effectuate such an attornment, or the subordination aforesaid, upon written notice thereof, and Tenant does hereby make, constitute and irrevocably appoint Landlord as Tenant's attorney-in-fact and in Tenant's name, place and stead to execute all such documents in accordance therewith.

Tenant's initials

Landlord's initials

38. <u>ESTOPPEL CERTIFICATES</u>. Tenant shall at any time upon not less than ten (10) days' prior written notice from Landlord execute, acknowledge and deliver to Landlord or to any tender of or purchaser from Landlord a statement in writing certifying that this Lease is unmodified and in full force and effect (or if modified stating the nature of such modification) and the date to which the rent and other charges are paid in advance, if any, and acknowledging that there are not, to Tenant's knowledge, any uncured defaults on the part of Landlord or specifying such defaults if any are claimed. Any such statement may be conclusively relied upon by any prospective purchaser or encumbrancer of the Premises or of the business of Landlord.

# 39. ENVIRONMENTAL.

Immediately prior to the expiration of this Lease (or immediately after an earlier termination thereof), Tenant shall cause a Phase I Environmental report to be prepared, at Tenant's cost, and shall deliver the same to Landlord. Tenant shall be responsible and liable to cure any condition stated in the report, which constitutes a violation of any Environmental Law, at Tenant's sole cost and expense.

## 40. OPTION TO EXTEND TERM:

Tenant shall have one five-year option for a period beginning June 1, 2009 and ending May 38, 2014 to extend the term of the Lease on the same terms and conditions as set forth in this Lease except basic rental which shall be equal to the prevailing market rent for buildings of similar size, nature and location as 4231 E. 75th Terrace, KCMO. Written notice of intent to renew shall be given by Tenant to Landlord on or before November 30, 2008.

IN WITNESS WHEREOF, said parties hereunto subscribed their names. Executed in

originals.

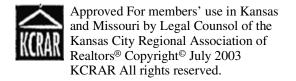
#### LANDLORD

By: <u>ILLEGIBLE</u> By: <u>ILLEGIBLE</u>

Title: Pres. Title: Pres.

Date: 3-19-04 Time: 1:30 PM Date: 3/19/04 Time: 3:00 PM

nant's initials Landlord's initials



#### AGENCY DISCLOSURE ADDENDUM

SELLER/LANDLORD: Livers, LLC, a Missouri Limited Liability Company

BUYER/TENANT: Primus Corporation, a Missouri Corporation

PROPERTY: 4231 E. 75th Terraco, Kansas City, Missouri

THE FOLLOWING DISCLOSURE IS MADE IN COMPLIANCE WITH MISSOURI AND KANSAS REAL ESTATE LAWS AND RULES AND REGULATIONS. APPLICABLE SECTIONS BELOW MUST BE CHECKED & COMPLETED FOR BOTH SELLER/LANDLORD & BUYER/TENANT.

Sollor/Landlord and Buyer/Tenant acknowledge that the real estate licensee involved in this transaction may be acting as agents of the Seller/Landlord, agents of the Buyer/Tenant, Transaction Brokers or Disclosed Dual Agents (Available only in Missouri). Licensees acting as an agent of the Seller/Landlord have a duty to represent the Seller's/Landlord's interest and will not be the agent of the Buyer/Tenant. INFORMATION GIVEN BY THE BUYER/TENANT TO A LICENSEE ACTING AS AN AGENT OF THE SELLER/LANDLORD WILL BE DISCLOSED TO THE SELLER/LANDLORD. Licensees acting as an agent of the Buyer/Tenant have a duty to represent the Buyer's/Tenant's interest and will not be an agent of the Seller/Landlord. INFORMATION GIVEN BY THE SELLER/LANDLORD TO A LICENSEE ACTING AS AN AGENT OF THE BUYER/TENANT WILL BE DISCLOSED TO THE BUYER/TENANT. LICENSEES ACTING IN THE CAPACITY OF A TRANSACTION BROKER ARE NOT AGENTS FOR EITHER PARTY AND DO NOT ADVOCATE THE INTERESTS OF EITHER PARTY. LICENSEES ACTING AS DISCLOSED DUAL AGENTS (available In Missouri only) ARE ACTING AS AGENTS FOR BOTH THE SELLER/LANDLORD AND THE BUYER/TENANT, and when acting as a Disclosed Qual Agent, a separate Dual Agency Disclosure Addendum is required. SELLER/LANDLORD AND BUYER/TENANT HEREBY ACKNOWLEDGE THAT THE REAL ESTATE BROKERAGE RELATIONSHIPS BROCHURE HAS BEEN FURNISHED TO THEM, AND THAT THE BROKERAGE RELATIONSHIPS WERE DISCLOSED TO THEM OR THEIR RESPECTIVE AGENTS AND/OR TRANSACTION BROKERS NO LATER THAN THE FIRST SHOWING, UPON FIRST CONTACT, OR IMMEDIATELY UPON THE OCCURRENCE OF ANY CHANGE TO THAT RELATIONSHIP.

# SELLER/LANDLORD AND BUYER/TENANT CONFIRMATION OF BROKERAGE AGENCY RELATIONSHIPS:

| A.                                     | Listing Licensee is functioning as:  |  |  |  |
|--|--|--|--|--|
| X                                      | Seller's/Landlord's Agent  |  |  |  |
|  | Designated Seller's/Landlord's Agent (In Kansas, Supervising Broker acts as a Transaction Broker)  |  |  |  |
|  | Disclosed Dual Agent, and SELLER/LANDLORD agree, if applicable, to sign a Disclosed Dual Agency Agreement. (Missouri Only)                       |  |  |  |
|  | Transaction Broker and SELLER/LANDLORD agrees, if applicable, to sign a Transaction Broker Agreement. Seller/ Landlord is not being represented. |  |  |  |
|  | SELLER/LANDLORD is not being represented.  |  |  |  |
| B. Selling Licensee is functioning as: |  |  |  |  |
|  | Buyer's/Tenant's Agent   |  |  |  |
|  | Seller's/Landlord's Agent  |  |  |  |
|  | Designated BUYER'S/TENANT'S Agent (In Kansas, Supervising Broker acts as a Transaction Broker)   |  |  |  |
|  | Designated Seller's/Landlord's Agent in Buyer's/Tenant's Purchase of the Property (In Kansas, Supervising Broker acts as a Transaction Broker)   |  |  |  |
|  | Disclosed Dual Agent, and BUYER/TENANT agree, if applicable, to sign a Disclosed Dual Agency Agreement (MO Only)                                 |  |  |  |
|  | Subagent   |  |  |  |
|  | Transaction Broker and BUYER/TENANT agrees, if applicable, to sign a Transaction Broker Agreement. Buyer/Tenant is not                           |  |  |  |

being represented.

■ BUYER/TENANT is not being represented.

# PAYMENT OF COMMISSION:

All brokerage fees, to include but not limited to broker commissions, broker administrative commissions and other fees shall be paid out of escrow at Closing as described in the terms of the respective agency agreements or other Seller/Buyer agreements. Sellers/Landlords and Buyers/Tenants understand and agree that Broker may be compensated by more than one party in the transaction.

# CAREFULLY READ THE TERMS HEREOF BEFORE SIGNING. WHEN SIGNED BY ALL PARTIES, THIS DOCUMENT BECOMES PART OF A LEGALLY BINDING CONTRACT. IF NOT UNDERSTOOD, CONSULT AN ATTORNEY BEFORE SIGNING.

Licensees also hereby certify that they are licensed to sell real estate in the state in which the Property is located.

| ILLEGIBLE<br>SELLER/LANDLORD                 | 3-19-04<br>DATE | ILLEGIBLE<br>BUYER/TENANT       | 3-19-04<br>DATE |
|--|-----------------|---------------------------------|-----------------|
| SELLER/LANDLORD                              | DATE            | BUYER/TENANT                    | DATE            |
| ILLEGIBLE LICENSEE ASSISTING SELLER/LANDLORD | 3-19-04<br>DATE | LICENSEE ASSISTING BUYER/TENANT | DATE            |

#### First Amendment to Base Lease

This First Amendment to Base Lease ("**Amendment**") is dated as of April 6, 2009. by and between Livers LLC. ("**Landlord**") and Trinity Biotech, dba Primus Inc. ("**Tenant**").

#### Recitals

- A. Landlord and Tenant entered into that certain lease dated March 19, 2004, the "Base Lease" and as hereafter amended from time to time. The terms set forth herein and not otherwise defined shall have the same definitions as set forth in the Base Lease.
- B. Landlord and Tenant desire to modify and amend certain provisions of the Base Lease, all as specifically set forth herein.

# Option to Extend Term

- 1. Tenant shall have a one-year option for a period beginning July 1, 2009 and ending May 31, 2010 to extend the term of the lease on the same terms and conditions of the Base Lease. The rate shall remain at \$8,364.58 per month through this First Amendment. Real Estate taxes as noted in Paragraph 23 of the Base Lease remain unchanged.
- 2. Tenant shall have four (4) one-year Amendment options thereafter to renew the lease under the same terms and conditions as in the Base Lease. Notice of intent to renew as noted in the Base Lease remains unchanged.
- 3. In the event the balance of the Amendment options as noted in (2) above are not exercised, the Tenant shall pay Landlord \$25,000 due upon written notice of termination.

## Alterations and Improvements Wording Amendment

1. Landlord proposes new language to Amend Base Contract as follows:

All work done by Tenant or its contractors shall be done in a first-class, workmanlike manner, using only high quality grades of materials and shall comply with all insurance requirements and all applicable laws and ordinances and rules and regulations of governmental departments or agencies. All alterations, improvements and additions to the Leased Premises, whether temporary or permanent in character, made or paid for by Landlord or Tenant shall become Landlord's property at the termination of this Lease and shall (unless Landlord requests their removal, which shall be done by Tenant in such a manner that the repair and restoration of the Leased Premises is made so that its condition is the same as it was prior to such alterations, improvements and additions) be relinquished to landlord in good condition, ordinary wear and tear excepted.

| I           | LANDLORD  |                                |        | TENANT      |                      |  |  |
|-------------|-----------|--------------------------------|--------|-------------|----------------------|--|--|
| LIVERS, LLC |           | TRINITY BIOTECH<br>CORPORATION |        | _dba PRIMUS |                      |  |  |
| By:         | ILLEGIBLE |                                | By:    | ILLEGIBLE   |                      |  |  |
| Title:      | President |                                | Title: | ILLEGIBLE   |                      |  |  |
| Date:       | 4-6-09    | Time <u>3:10 pm</u>            | Time:  | 4-7-09      | Time <u>10:30 am</u> |  |  |

#### Second Amendment to Base Lease

This Second Amendment to Base Lease ("Amendment") is dated as of December 8, 2009, by and between Livers LLC, ("Landlord") and Trinity Biotech, dba Primus Inc. ("Tenant").

#### Recitals

- A. Landlord and Tenant entered into that certain lease dated March 19, 2004, the "Base Lease" and as hereafter amended from time to time. The terms set forth herein and not otherwise defined shall have the same definitions as set forth in the Base Lease.
- B. Landlord and Tenant desire to modify and amend certain provisions of the Base Lease, all as specifically set forth herein.

# Option to Extend Term

- 1. Tenant shall have a one-year option for a period beginning July 1, 2010 and ending June 30, 2011 to extend the term of the lease on the same terms and conditions of the Base Lease. The rate shall remain at \$8,364.58 per month through this First Amendment. Real Estate taxes as noted in Paragraph 23 of the Base Lease remain unchanged. This lease shall automatically renew for one year unless Livers LLC is given a written 6 month prior notification to terminate the lease.
- 2. Tenant shall have four (3) one-year Amendment options thereafter to renew the lease under the same terms and conditions as in the Base Lease. Notice of intent to renew as noted in the Base Lease remains unchanged.
- 3. In the event the balance of the Amendment options as noted in (2) above are not exercised, the Tenant shall pay Landlord \$25,000 due upon written notice of termination.

# Alterations and Improvements Wording Amendment

1. Landlord proposes new language to Amend Base Contract as follows:

All work done by Tenant or its contractors shall be done in a first-class, workmanlike manner, using only high quality grades of materials and shall comply with all insurance requirements and all applicable laws and ordinances and rules and regulations of governmental departments or agencies. All alterations, improvements and additions to the Leased Premises, whether temporary or permanent in character, made or paid for by Landlord or Tenant shall become Landlord's property at the termination of this Lease and shall (unless Landlord requests their removal, which shall be done by Tenant in such a manner that the repair and restoration of the Leased Premises is made so that its condition is the same as it was prior to such alterations, improvements and additions) be relinquished to landlord in good condition, ordinary wear and tear excepted.

| L      | ANDLORD       | TENANT                      |             |
|--------|---------------|-----------------------------|-------------|
| L      | IVERS, LLC    | TRINITY BIOTECH CORPORATION | _dba PRIMUS |
| By:    | ILLEGIBLE     | By: ILLEGIBLE               |             |
| Title: | Manager       | Title: ILLEGIBLE            |             |
| Date:  | 8-26-10 Time: | Time: $8-26-10$             | Time:       |

# THIRD AMENDMENT TO BASE LEASE

THIS THIRD AMENDMENT TO BASE LEASE ("Agreement") is made this 9<sup>th</sup> day of May 2014, between Livers, LLC ("Landlord") and Primus Corporation, a Missouri corporation d/b/a Trinity Biotech ("Tenant").

#### **RECITALS**

- A. Pursuant to that certain Commercial And Industrial Lease Agreement dated March 19, 2004, as amended by First Amendment To Base Lease dated April 6, 2009 and Second Amendment to Base Lease dated December 8, 2009 (collectively, the "Lease"), Landlord demised to Tenant and Tenant leased from Landlord certain premises (the "Premises") that are more particularly described in the Lease and commonly known as 4231 E. 75th Terrace in Kansas City, Missouri.
- B. Landlord and Tenant desire to extend the term of the Lease and otherwise modify the Lease in accordance with the provisions of this Agreement.

NOW, THEREFORE, in consideration of mutual covenants and other good and valuable consideration, the legal sufficiency and receipt of which is hereby acknowledged, the parties hereto agree as follows:

- 1. Extension of Lease Term. Notwithstanding anything to the contrary contained in the Lease, effective retroactively as of November 1, 2013, the term of the Lease is hereby extended for a period of three years commencing on November, 1, 2013 and ending on October 31, 2016 (the "Extended Term"), on the same terms and conditions set forth in the Lease, as amended by this Agreement.
- 2. Option Period. Section 40 of the Lease and any other provisions of the Lease or any other correspondence between the parties that provide any right or option to Tenant to extend or renew the Lease are hereby deleted in their entirety. Provided that Tenant is not in default under the Lease, as herein amended, Tenant shall have the option to extend the Extended Term for the three year period commencing on November 1, 2016 and ending October 31, 2019 (the "Second Extended Term"), on the same terms and conditions set forth in the Lease, as amended by this Agreement. If Tenant shall so elect, it must do so by delivering written notice to Landlord exercising such option on or before March 31, 2016. If Tenant shall timely deliver the foregoing notice to Landlord on or before March 31, 2016, then the Lease shall be extended for the Second Extended Term. If the Landlord has not received the foregoing option notice from Tenant by March 31, 2016, then the Landlord may send a written notice to Tenant reminding them of their right to extend or terminate the Lease for the Second Extended Term. If the Tenant does not respond in writing within 30 days of receipt of this reminder notice from Landlord, then the Lease shall continue in full force and effect throughout the entire Second Extended Term.

- 3. <u>Rent.</u> Notwithstanding anything to the contrary contained in the Lease, (A) throughout the Extended Term, Tenant shall pay to Landlord, as rent, the sum of \$8,364.58 per month throughout the period from November 1, 2013 through June 30, 2015, and \$8,929.19 per month throughout the period from July 1, 2015 throughout the remainder of the Extended Term, and (B) throughout the Second Extended Term, if applicable, Tenant shall pay to Landlord, as rent, the sum of \$9,130.10 per month, all in the manner prescribed in the Lease.
- 4. **Repairs.** Section 12 of the Lease is hereby amended by adding the following new sentence to the end of Section 12: "All installations and replacements made by Tenant (but excluding any maintenance or repair work that does not include replacement items or new installations) shall be made using new, high quality commercial grades of materials, installed in a first class workmanlike manner, in compliance with all insurance requirements and in accordance with all applicable laws, codes and requirements of governmental authorities. Tenant shall provide Landlord with written notice prior to replacing any component of the Premises and permit Landlord to inspect such replacement work."
- 5. <u>Alterations</u>. Section 18 of the Lease (Alterations) and the paragraphs captioned "Alterations and Improvements Wording Amendment" in the First Amendment to Base Lease and Second Amendment to Base Lease are hereby deleted in their entirety and replaced with the following new Section 18 to the Lease:
- "18. ALTERATIONS. Tenant shall not make or permit any alterations, additions or improvements in the Premises without first submitting to Landlord plans and specifications therefor and obtaining Landlord's written approval thereof, which will not be unreasonably withheld. Subject to the preceding sentence, Tenant may install air-conditioning, back up power supplies, and plumbing improvements at its own expense. All alterations, additions or improvements made by Tenant shall be made using new, high quality commercial grades of materials, in a first class workmanlike manner, in compliance with all insurance requirements and in accordance with all applicable laws, codes and requirements of governmental authorities and the plans and specifications therefor approved in writing by Landlord. All alterations, additions and improvements to the Premises made or paid for by Landlord or Tenant shall become a part of the Premises and shall be surrendered to and owned by Landlord at the expiration of the Lease without any charge; provided, however, that Tenant shall, if Landlord requests, remove any such alterations, additions or improvements prior to the expiration or termination of the Lease in such a manner that the repair and restoration of the Premises is made so that its condition is the same as it was prior to such alteration, addition, or improvement. In all events, the Tenant shall surrender possession of the Premises and the alterations, additions and improvements that Landlord elects to retain in good condition, ordinary wear and tear excepted."

6. <u>Landlord's Work</u>. Notwithstanding anything within the Lease to the contrary, in consideration of the extension of the term of the Lease as provided herein, Landlord agrees to perform the following work ("*Landlord's Work*") at Landlord's cost without reimbursement by Tenant:

South Gravel Lot: Re-grade existing 13,400sf lot, furnish and install 2" overlay of AB3 rock/gravel; grade, furnish and install new 2,642sf "lay down" gravel pad (between existing gravel lot and receiving area concrete pad to its south edge) with 4" depth AB3 rock/gravel; machine compact both existing and new areas with grading equipment, and install temporary "indicator" striping.

Landlord shall perform Landlord's Work in accordance with a schedule agreed upon by Landlord and Tenant (with the understanding such schedule will provide for the completion of Landlord's Work not later than September 30, 2014).

7. Tenant's Work. Tenant acknowledges and agrees that it is responsible under the terms of the Lease to perform the work and maintenance items described below ("Tenant's Work"). With respect to the work specifically described below, Landlord agrees to perform such work at Tenant's expense as set forth below. Landlord does not assume any obligation or liability to perform any other work, maintenance or other obligations of Tenant under the Lease, nor does Landlord relieve or release Tenant from performing the same. Each component of Tenant's Work will be performed by Landlord during the calendar year indicated in each component (pursuant to a mutually agreed upon schedule, but in no event later than September 30<sup>th</sup>). Upon completion of each component of Tenant's Work, Tenant shall pay to Landlord the applicable amount described for each component of Tenant's Work within 15 days after Landlord's written request therefor. Tenant agrees that the amounts set forth for each component of Tenant's Work below are agreed to amounts and Tenant shall pay the stated amounts as required hereunder.

# Parking Area.

a) North Asphalt Lot—Prepare existing surface, overlay with new asphalt and restripe parking spaces:

|             | 2014  | \$11,495 |
|-------------|---|----------|
| bi-annual n | maintenance including sealant application and restriping: |          |
|             | 2016  | \$2,299  |
|             | 2018  | \$2,577  |

b) South Asphalt Lot—Resurface deteriorated 12' x 18' area, cold patch certain other areas, apply sealant and restripe entire "L" shaped area:

| 2014 \$5,2 |
|------------|
|------------|

bi-annual maintenance including sealant application and restriping:

| 2015 | \$3,025 |
|------|---------|
| 2017 | \$3,388 |
| 2019 | \$3,660 |

c) South Gravel Lot—annual grading maintenance with new rock not to exceed 27 tons/year:

| 2015 | \$1,536 |
|------|---------|
| 2016 | \$1,628 |
| 2017 | \$1,727 |
| 2018 | \$1,830 |
| 2019 | \$1,940 |

<u>Dock Drive Apron</u>. Remove the existing concrete slab on grade and replace it with a new 8" concrete drive (east of the two dock doors to the street), and repair the deteriorated asphalt street approach adjacent to such new concrete drive

Notwithstanding the foregoing, if Tenant shall deliver to Landlord its notice that waives and nullifies the Second Extended Term by March 31, 2016, then Tenant shall not be required to pay for (and Landlord shall not be required to perform) any of the foregoing components of work that are scheduled to be performed during the 2017, 2018 and 2019 calendar years.

Tenant has proposed to Landlord its concept for constructing a new lab area within the Premises and Landlord does not object to such concept plan, provided, however, that all alterations required in connection therewith shall be subject to Landlord's prior written approval of Tenant's plans and specifications for such improvements and Tenant's compliance with the terms and conditions set forth in Section 18 of the Lease (as amended herein) and other applicable terms of the Lease.

<sup>\*</sup> Landlord shall perform the Dock Drive Apron work in accordance with a schedule agreed upon by Landlord and Tenant (with the understanding such schedule will provide for the completion of such work not later than September 30, 2014).

- 8. **Brokers.** Section 29 of the Lease is hereby deleted in its entirety. Tenant represents and warrants to Landlord that it has had no dealings with any broker or agent in connection with this Agreement, EXCEPT M. DiCarlo llc, as Landlord's agent (whose commission shall be paid by Landlord), and Tenant agrees to indemnify and hold Landlord harmless from and against any and all claims, liabilities or expenses (including reasonable attorney's fees) imposed upon, asserted or incurred by Landlord as a consequence of any breach of this representation.
- 9. <u>Successors and Amendment</u>. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. The Lease, as herein amended, shall remain in full force and affect in accordance with its terms.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

| Landlord: | Livers, LLC |
|-----------|-------------|
|-----------|-------------|

By: /s/ Richard Livers Jr.

(Sign)

Name: Richard Livers Jr.

(Print)

Title: Manager of

Tenant: Primus Corporation, a Missouri corporation

d/b/a Trinity Biotech

By: /s/ Steven Schaefers

(Sign)

Name: Steven Schaefers

(Print)

Title: Director of Site Operations



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AGENCY DISCLOSURE ADDENDUM

SELLER/LANDLORD: Livers, LLC, a Missouri Limited Liability Company

BUYER/TENANT: Primus Corporation, a Missouri Corporation, d/b/a Trinity Biotech

PROPERTY: 4231 East 75th Terrace, Kansas City, MO 64132

Listing Licensee is functioning as:

THE FOLLOWING DISCLOSURE IS MADE IN COMPLIANCE WITH MISSOURI AND KANSAS REAL ESTATE LAWS AND RULES AND REGULATIONS. APPLICABLE SECTIONS BELOW MUST BE CHECKED & COMPLETED FOR BOTH SELLER/LANDLORD & BUYERITENANT.

Seller/Landlord and BuyerlTenant acknowledge that the real estate licensee involved in this transaction may be acting as agents of the Seller/Landlord, agents of the BuyerlTenant, Transaction Brokers or Disclosed Dual Agents (Available only in Missouri). Licensees acting as an agent of the Seller/Landlord have a duty to represent the Seller's/Landlord's interest and will not be the agent of the Buyer/Tenant. INFORMATION GIVEN BY THE BUYER/TENANT TO A LICENSEE ACTING AS AN AGENT OF THE SELLER/LANDLORD WILL BE DISCLOSED TO THE SELLER/LANDLORD. Licensees acting as an agent of the Buyer/Tenant have a duty to represent the Buyer's/Tenant's interest and will not be an agent of the Seller/Landlord. INFORMATION GIVEN BY THE SELLER/LANDLORD TO A LICENSEE ACTING AS AN AGENT OF THE BUYER/TENANT WILL BE DISCLOSED TO THE BUYER/TENANT. LICENSEES ACTING IN THE CAPACITY OF A TRANSACTION BROKER ARE NOT AGENTS FOR EITHER PARTY AND DO NOT ADVOCATE THE INTERESTS OF EITHER PARTY. LICENSEES ACTING AS DISCLOSED DUAL AGENTS (available in Missouri only) ARE ACTING AS AGENTS FOR BOTH THE SELLER/LANDLORD AND THE BUYER/TENANT, and when acting as a Disclosed Dual Agent, a separate Dual Agency Disclosure Addendum is required. SELLER/LANDLORD AND BUYER/TENANT HEREBY ACKNOWLEDGE THAT THE REAL ESTATE BROKERAGE RELATIONSHIPS BROCHURE HAS BEEN FURNISHED TO THEM, AND THAT THE BROKERAGE RELATIONSHIPS WERE DISCLOSED TO THEM OR THEIR RESPECTIVE AGENTS AND/OR TRANSACTION BROKERS NO LATER THAN THE FIRST SHOWING, UPON FIRST CONTACT, OR IMMEDIATELY UPON THE OCCURRENCE OF ANY CHANGE TO THAT RELATIONSHIP.

### SELLER/LANDLORD AND BUYER/TENANT CONFIRMATION OF BROKERAGE AGENCY RELATIONSHIPS:

| X  | Seller's/Landlord's Agent   |
|----|---|
|    | Designated Sellers/Landlord's Agent (In Kansas, Supervising Broker acts as a Transaction Broker)  |
|    | Disclosed Dual Agent, and SELLER/LANDLORD agree, if applicable, to sign a Disclosed Dual Agency Agreement. (Missouri Only)                      |
|    | Transaction Broker and SELLER/LANDLORD agrees, if applicable, to sign a Transaction Broker Agreement. Seller/Landlord is not being represented. |
|    | SELLER/LANDLORD is not being represented.   |
| B. | Selling Licensee is functioning as:   |
|    | Buyer's/Tenant's Agent  |
|    | Seller's/Landlord's Agent   |
|    | Designated BUYER'S/TENANT'S Agent (In Kansas, Supervising Broker acts as a Transaction Broker)  |
|    | Designated Seller's/Landlord's Agent in Buyer's/Tenant's Purchase of the Property (In Kansas, Supervising Broker acts as a Transaction Broker)  |
|    | Disclosed Dual Agent, and BUYER/TENANT agree, if applicable, to sign a Disclosed Dual Agency Agreement (MO Only)                                |
|    | Subagent  |
|    | Transaction Broker and BUYER/TENANT agrees, if applicable, to sign a Transaction Broker Agreement. Buyer/Tenant is not being represented.       |
| X  | BUYER/TENANT is not being represented.  |

#### **PAYMENT OF COMMISSION:**

All brokerage fees, to include but not limited to broker commissions, broker administrative commissions and other fees shall be paid out of escrow at Closing as described in the terms of the respective agency agreements or other Seller/Buyer agreements. Sellers/Landlords and Buyers/Tenants understand and agree that Broker may be compensated by more than one party in the transaction.

# CAREFULLY READ THE TERMS HEREOF BEFORE SIGNING. WHEN SIGNED BY ALL PARTIES, THIS DOCUMENT BECOMES PART OF A LEGALLY BINDING CONTRACT. IF NOT UNDERSTOOD, CONSULT AN ATTORNEY BEFORE SIGNING.

Licensees also hereby certify that they are licensed to sell real estate in the state in which the Property is located.

| ILLEGIBLE                          | 5-9-14 ILLEGIBLE                     | 5-8-14 |
|------------------------------------|--------------------------------------|--------|
| SELLER/LANDLORD                    | DATE BUYER/TENANT                    | DATE   |
|                                    |                                      |        |
| SELLER/LANDLORD                    | DATE BUYER/TENANT                    | DATE   |
|                                    |                                      |        |
| LICENSEE ASSISTING SELLER/LANDLORD | DATE LICENSEE ASSISTING BUYER/TENANT | DATE   |

#### LEASE AGREEMENT

THIS LEASE dated the 30 day of May, 2001, by and between:

LORRELLE S. JOHNSON and SHARON L. JOHNSON, of 3094 North Main Street Extension, Jamestown, New York 14701, hereinafter referred to as "Johnson."

and

CLARK LABORATORIES, INC (dba: TRINITY BIOTECH USA), of P.O. Box 1059, Jamestown, New York 14702-1059, hereinafter referred to as "Trinity Biotech."

#### WITNESSETH:

That Johnson hereby demises and leases unto Trinity Biotech and Trinity Biotech rents from the Johnsons for the term and upon the rental payments hereinafter specified, a portion of the building located at 2901 Girts Road, Jamestown, New York (the "Building"), such portion consisting of twenty thousand nine hundred ninety-five (20,995) square feet of the second floor of said Building as designated in Schedule "A" attached hereto and made a part hereof (the "Premises"), together all appurtenances thereto, including the non-exclusive use of all driveways, parking areas and lawns adjacent thereto (the "Common Areas") for access to the Premises.

1. <u>TERM</u>: The term of this rental agreement shall be for a period of five (5) years, commencing on the 1st day of July, 2001, and ending on the 30th day of June, 2006. The term of this rental agreement may be extended for up to two (2) additional terms of two (2) years each, at the election of Trinity Biotech, such election to be made by providing written notice to Johnson at least ninety (90) days prior to the expiration of the then current term.

2. <u>RENT</u>: The rent for the Premises shall be payable by Trinity Biotech to Johnson in equal monthly installments, due on or before the 1st day of each calendar month for the term hereof. payable at the offices of Johnson, or as may otherwise be directed by Johnson in writing:

From July 1, 2001 through June 1, 2006 – \$2,886.81/Month

From July 1, 2006 through June 1, 2008 - \$3,236.73/Month

From July 1, 2008 through June 1, 2010 – \$3,499.17/Month

- 3. <u>PEACEFUL POSSESSION</u>: Johnson covenants that Trinity Biotech, upon paying said rental and performing the covenants and conditions contained in this Lease Agreement, including the strict compliance of Trinity Biotech with any requirements in regard to the use and occupancy of the premises herein, that Trinity Biotech shall and may peaceably and quietly have, hold and enjoy the Premises for the term aforesaid.
- 4. <u>USE OF PREMISES</u>: Johnson acknowledges and agrees that Trinity Biotech intends to use the Premises for product assembly, equipment maintenance, and storage purposes, in connection with Trinity Biotech's business of manufacturing and distributing medical testing technology. Trinity Biotech covenants and agrees that Trinity Biotech shall obtain the prior written consent of Johnson for any uses of the premises that are materially different than those described in this paragraph, or, any uses which shall include the storage and/or use of any hazardous chemicals, substances or biological or biochemical or related materials, or any activities which shall require any administrative or governmental approvals or authorizations, the failure to obtain which would result in any penalty or liability to Johnson which consent shall not be unreasonably withheld.

- 5. SUB-LETTING AND ASSIGNMENT: Trinity Biotech shall not sublet the Premises, nor any portion thereof, nor shall this Lease Agreement be assigned by Trinity Biotech without the prior written consent of Johnson, such consent not to be unreasonably withheld; provided, however, that no such consent shall be necessary for an assignment of this agreement to a corporate affiliate having common ownership with Trinity Biotech, a wholly owned subsidiary of Trinity Biotech, or a successor by merger to Trinity Biotech.
- 6. <u>CONDITION OF PREMISES</u>: Trinity Biotech has examined the Premises and accepts it in its present condition, without any representations on the part of Johnson or its agents as to the present or future condition of Premises other than as provided herein. Trinity Biotech shall quit and surrender the Premises at the end of the demised term in as good condition as the reasonable use thereof will permit, except for ordinary wear and damage occurring during the term hereby demised.
- 7. <u>ALTERATIONS. IMPROVEMENTS AND MAINTENANCE</u>: Trinity Biotech shall not make any alterations, additions or improvements to the Premises without the prior written consent of Johnson; provided, however, that (a) such consent shall not be unreasonably witheld, and (b) Johnson has consented to those alterations, additions or improvements described in Schedule "B" attached hereto and made a part hereof which shall be at Trinity Biotech's Expense.

Trinity Biotech shall at its expense keep the Premises in good condition, and shall redecorate, paint and renovate the Premises as may be necessary to keep it in repair and good appearance. It is further understood that any electrical, mechanical, or structural repairs or

renovations which Trinity biotech shall deem necessary for its use of the Premises shall be subject to the written approval and consent of Johnson and will be completed in compliance with all building codes, as well as federal, state and local ordinances, regulations and statutes governing same. Failure to comply with any of these requirements shall be considered an immediate default pursuant to the terms of the Lease Agreement herein, and Johnson shall be entitled to any and all remedies set forth herein in regard to a default pursuant to the terms of this Lease Agreement.

Johnson shall, at their own expense, maintain, repair and, as provided herein, to replace, all exterior, mechanical and structural portions of the Building and the Common Areas and the Premises, including but not limited to, maintaining, repairing and replacing the roof, subfloor, exterior walls, ceilings, load-bearing columns, main sewer line, main water line, external electrical line, windows (other than as described in Schedule B), doors, loading platforms, loading docks, elevators, heating system (except any HVAC equipment installed by Trinity Biotech), plumbing system, electrical system, security system and sprinkler system. If Johnson fails to undertake such maintenance, repairs and replacements, the same may be done by Trinity Biotech at Johnson's expense. For purposes of this paragraph, Johnson shall be obligated to replace a system, component or portion of the Building only if the repair thereof cannot ensure that the system, component or portion will continue for the term of this agreement to function at least as well as it does as of the commencement date of this lease agreement.

- 8. MECHAN1C'S LIENS: In the event any mechanic's lien is filed against the premises as a result of the alterations, additions or improvements made by Trinity Biotech, and said lien is not paid or otherwise discharged within thirty (30) days after receipt of notice thereof by Trinity Biotech, Johnson at their option after thirty (30) days' notice to Trinity Biotech, may terminate this Lease and may pay the said lien, without inquiring into the validity thereof, and Trinity Biotech shall forthwith reimburse Johnson the total expense incurred by Johnson in discharging said lien, as additional rent due and owing herein.
- 9. <u>LIABILITY OF JOHNSON</u>: Johnson shall not be responsible for the loss of or damage to property, or injury to persons, occurring in or about the Premises, by reason of any existing or future condition, defect, matter or thing in Premises, or the property of which the Premises are a part, or for the acts, omissions or negligence of other persons or tenants in and about the said property.
- 10. <u>INDEMNIFICATION AND LIABILITY INSURANCE OF TRINITY BIOTECH</u>: Trinity biotech agrees to indemnify and hold harmless Johnson from and against all claims, demands, actions, controversies and suits, whether groundless or otherwise, liabilities, losses, damage, costs, charges, counsel fees and other expenses of every nature and character (collectively), "losses" arising out of or resulting from Trinity Biotech's use and occupancy of the Premises herein. Furthermore, Trinity Biotech shall keep in full force and effect during the term of this Lease a commercial liability insurance coverage in the amount of Two Million Dollars (\$2,000,000.00) in regard to its use and occupation of the Premises herein, and Trinity Biotech shall provide Johnson with proof of said commercial liability insurance coverage reflecting Johnson as an additional insured. Furthermore, said commercial liability insurance coverage shall provide that the insurance carrier be obligated to provide Johnson with at least thirty (30) days prior written notice of any cancellation of such commercial liability insurance coverage for non-payment or otherwise.

- 11. <u>UTILITIES</u>: The parties acknowledge that the utilities serving the Premises are or shall before the commencement of this lease be separately metered, and Trinity Biotech shall be responsible for payment of all utilities in regard to its use and occupancy of the Premises herein, including, but not limited to, electricity, gas and water. It is further understood that Johnson shall not be liable for any interruption or delay in any of the above services for any reason.
- 12. RIGHT TO INSPECT: Johnson, or their agents, shall have the right to enter the Premises with reasonable notice to Trinity Biotech, during normal working hours, to examine same, or to make such repairs, additions or alterations that it shall deem necessary for the safety, preservation or restoration of the improvements, or for the safety or convenience of the occupants or users thereof (there being no obligation, however, on the part of Johnson to make any such repairs, additions or alterations).
- 13. <u>DAMAGE BY FIRE, EXPLOSION, THE ELEMENTS OR OTHERWISE</u>: In the event of the destruction of the Premises or the building containing Premises by fire, explosion, the elements or otherwise during the term hereby created, or previous thereto, or such partial destruction thereof as to render the Premises wholly untenantable or unfit for occupancy, or should the Premises be so badly injured that same cannot be repaired within ninety (90) days from the happening of such injury, then the term hereby created shall, at the option of Johnson, cease and become null and void from the date of such damage or destruction, and Trinity Biotech shall immediately surrender Premises and all of Trinity Biotech's interest therein to Johnson, and shall

pay rent only pay rent only to the time of such surrender, in which event Johnson may re-enter and repossess the Premises thus discharged from this Lease and may remove all parties therefrom. Should the premised be rendered untenantable and unfit for occupancy, but yet be repairable within ninety (90) days from the happening of said injury, Johnson may enter and repair the same with reasonable speed, and the rent shall not accrue after said injury while the repairs are being made, but shall recommence immediately after said repairs shall be completed. But if the Premises shall be so slightly injured as not to be rendered untenantable and unfit for occupancy, then Johnson agrees to repair the same with reasonable promptness, and in that case the rent accrued and accruing shall not cease or terminate. Furthermore, Trinity Biotech shall immediately notify Johnson in case of fire or other damage to the Premises.

#### 14. CONDEMNATION

If all of the Premises are taken under the power of eminent domain or conveyed under threat of condemnation proceedings, or if only a part of the Premises are so taken or conveyed and Trinity Biotech shall determine that the remainder is inadequate or unsatisfactory for it purposes, which determination shall not be arbitrarily or capriciously made, then in either event, this Lease shall terminate effective as of the date Trinity Biotech is required to give up the right to occupy or use any of the Premises. The termination of this Lease as provided above shall not operate to deprive Trinity Biotech of the right to make claim against the condemning authority for any damages suffered by Trinity Biotech, but Trinity Biotech shall have no right to make any claim against Johnson because of such termination, nor shall Trinity Biotech have any claim to any of the damages awarded to Johnson by the condemning authority.

If the Premises shall be partially taken under the power of eminent domain or conveyed under threat of condemnation proceedings and if such partial taking shall not render the Premises inadequate or unsatisfactory for Trinity Biotech's purpose, then this Lease shall continue in full force and effect and the rent and any additional rent shall be proportionately reduced.

15. OBSERVATION OF LAWS, ORDINANCES. RULES AND REGULATIONS: Trinity Biotech agrees to observe and comply with all of the laws, ordinances, rules and regulations of the federal, state, county and municipal authorities applicable to the business to be conducted by Trinity Biotech in the Premises. Trinity Biotech agrees not to do or permit anything to be done in Premises or keep anything therein which will increase the rate of fire insurance premiums on the improvements or any part thereof, or on property kept therein, or which will obstruct or interfere with the rights of other tenants, or conflict with the regulations of the fire department or with any insurance policy upon said improvements or any part thereof. Furthermore, Trinity Biotech warrants and covenants that it will be in compliance with all federal, state or local laws regulations, ordinances or orders or requirements governing the use, manufacture, sale, registration, reporting, treatment, discharge, release, emission, storage or disposal of chemicals, hazardous materials, pollutants, contaminants, toxic waste or solid waste, or otherwise pertaining to protection of the environment or protection of the public and/or employee health, including, but not limited to all laws and regulations governing the generation, collection, discharge, or disposal of hazardous waste and II laws and regulations with regard to record keeping, notification and reporting requirements respecting hazardous waste.

# 16. ENVIRONMENTAL MATTERS.

- (a) Trinity Biotech will be solely responsible for and will defend, indemnify and hold Johnson, its agents, and employees harmless from and against any and all direct claims, costs, and liabilities, including attorney's fees and costs, arising out of or in connection with the cleanup or restoration of the Premises associated with the Trinity Biotech's, Trinity Biotech's agents, employees, contractors or invitees use of Hazardous Substances.
- (b) Johnson will be solely responsible for and will defend, indemnify, and hold Trinity Biotech, its agents, and employees harmless from and against any and all direct claims, costs, and liabilities, including attorney's fees and costs, arising out of or in connection with the removal, cleanup, or restoration of the Premises with respect to Hazardous Substances from any and all sources other than those Hazardous Substances introduced to the Premises by Trinity Biotech, Trinity Biotech's agents, employees, contractors or invitees.
- (c) "Hazardous Substances" shall mean asbestos in a friable state or condition, non- contained polychlorinated biphenyls ("PCBs"), petroleum or petroleum products, and any hazardous waste, toxic substance or related material defined or treated as a "hazardous substance" or "toxic substance" (or comparable term) in the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. 9601, et seq.) ("CERCLA"), the Hazardous Materials Transportation Act (49 U.S.C. 1801, et seq.), The Resource Conservation and Recovery Act (42 U.S.C. 6901, et seq.) ("RCRA"), or any other presently existing and applicable federal, state or local statute, law or ordinance, and any rules and regulations promulgated thereunder.
  - (d) The obligations of this section shall survive the expiration or other termination of this Lease.
- 17. <u>SIGNS</u>: No sign, advertisement or notice shall be affixed to or placed upon any part of the Premises by Trinity Biotech, except in such manner, and of such size, design and color as shall be approved in advance in writing by Johnson.

- 18. <u>SUBORDINATION OF MORTGAGES AND DEEDS OF TRUST</u>: This Lease is subject to and is hereby subordinated to all present and future mortgages. deeds of trust and other encumbrances affecting the Premises or the property of which Premises are a part, and Trinity Biotech agrees to execute and deliver upon demand such instruments subordinating this Lease to any such lien or encumbrance as shall be required by Johnson; provided, however, that so long as Trinity Biotech is not in default under this Lease, Trinity Biotech shall continue undisturbed in its possession and enjoyment of the Premises. Johnson shall furnish Trinity Biotech with a non-disturbance agreement, in form and content acceptable to Trinity Biotech, from all present and future mortgagees of the Premises.
- 19. <u>VIOLATION OF C</u>OVENANT: Incase of a violation by Trinity Biotech of any of the covenants, agreements and conditions of this Lease Agreement and upon failure to discontinue such violation within thirty (30) days after notice thereof, given to Trinity Biotech, this Lease shall thenceforth be terminated and Johnson may re-enter without further notice or demand. No waiver by Johnson of any violation or breach of condition by Trinity Biotech shall constitute or be construed as a waiver of any other violation or breach of condition, nor shall lapse of time after breach of a condition by Trinity Biotech before Johnson shall exercise its option under this paragraph operate to defeat the right of Johnson to declare this Lease null and void and to re-enter upon the Premises after said breach of violation.
- 20. <u>BANKRUPTCY</u>. <u>INSOLVENCY OR ASSIGNMENT FOR BENEFIT OF CREDITORS</u>: It is further agreed that if at any time during the term of this Lease Agreement Trinity Biotech shall make any assignment for the benefit of creditors, or be decreed insolvent or bankrupt according to law, or if a receiver shall be appointed for Trinity Biotech, then Johnson may, at their option, terminate this Lease, exercise of such option to be evidenced by notice to that effect served upon the assignee, receiver, trustee or other person in charge of the liquidation of the property of Trinity Biotech, but such tem1ination shall not release or discharge any payment of rent payable hereunder and then accrued, or any liability then accrued by reason of any agreement or covenant herein contained on the part of Trinity Biotech or Trinity Biotech's legal representatives.

- 21. <u>HOLDING OVER BY TRINITY BIOTECH</u>: In the event that Trinity Biotech shall remain in the Premises after the expiration of the term of this Lease without having executed a new written Lease with Johnson, such holding over shall not constitute or renew an extension of this Lease. Johnson may, at their option, elect to treat Trinity Biotech as one who has not removed at the end of its term, and there upon be entitled to all of the remedies against Trinity Biotech provided by law in that situation.
- 22. <u>INSTALLATION OF HVAC SYSTEM</u>: Trinity Biotech expressly agrees that if any HVAC system shall be installed, this shall be completed by Johnson Air Design, Inc., with the expense to be paid by Trinity Biotech.
- 23. <u>RIGHT OF FIRST REFUSAL FOR LEASED SPACE</u>: It is expressly agreed by and between the parties that, should the existing lease on any other portion of the second floor of the Building, including the approximately 8,183 square feet of the Building currently being leased to Zurn Industries and noted accordingly on Schedule A, be terminated or expire on its own terms, then, in that event, Johnson shall extend to Trinity Biotech a right of first refusal during the term of this Lease Agreement herein for the additional space upon the same terms and conditions as set forth in the Lease Agreement herein, and subject to the same rental charge per square foot as set forth in the Lease Agreement herein. Notwithstanding the above, Johnson may renew the existing lease with the Ellicott volunteer fire department, and in the event of such renewal, Trinity's right of first refusal shall be effective upon the termination or expiration of the renewed lease. It is expressly understood by and between the parties that from July 1, 2001 through June 30, 2006, the rental price shall be \$1.65 per square foot; from July 1, 2006 through June 30, 2008, the rental price shall be \$1.85 per square foot; and from July 1, 2008 through June 30, 2010, the rental price shall be \$1.97 per square foot.

- 24. <u>ENTIRE AGREEMENT</u>: This Lease sets forth all of the covenants, promises, agreements, conditions and undertakings between Johnson and Trinity Biotech concerning the Premises, and shall inure to the benefit of and be binding upon the respective parties hereto and their respective heirs, executors, administrators, successors in interest and assigns.
- 25. <u>CONSTRUCTION</u>: This Lease and all of its terms covenants and conditions shall be construed in accordance with the laws of the State of New York.
- 26. <u>NOTICES</u>: Any notice under this Lease must be served by certified or registered mail, postage pre-paid, return receipt requested, addressed to the parties at their respective address set forth at the beginning of this Lease, or at such other address as the parties may designate by written notice, effective three (3) days after the date of such mailing.
- 27. <u>MEMORANDUM OF LEASE</u>: It is acknowledged and agreed that Trinity Biotech may, but shall not be required to, prepare and file at its own expense a memorandum of this Lease Agreement in the office of the Chautauqua County Clerk, and Johnson agree to execute same upon request.

IN WITNESS WHEREOF, Johnson and Trinity Biotech have caused this Lease to be duly executed by their duly authorized representatives on the date and year first above written.

/s/ LORRELLE S. JOHNSON LORRELLE S. JOHNSON

/s/ SHARON L. JOHNSON SHARON L. JOHNSON

# CLARK LABORATORIES, INC. (dba: TRINITY BIOTECH, USA)

By: /s/ William H. Reese, Jr.

William H. Reese, Jr. Director of Corporat Finance STATE OF NEW YORK )
)SS:
COUNTY OF CHAUTAUQUA )

On the 1st day of June, 2001, before me, a Notary Public in and for said State, personally appeared LORRELLE S. JOHNSON and SHARON L. JOHNSON, personally known to me or proved to me on the basis of satisfactory evidence to be the individuals whose names are subscribed to the within instrument and acknowledged to me that they executed the same in their capacities, and that by their signatures on the instrument, the individuals, or the person upon behalf of which the individuals acted, executed the instrument, and that such individuals made such appearance before the undersigned in the State of New York.

Rachel 8 Nordine, 115000500 Notary Public, Stair. of New York Quahfled m

[ILLIGIBLE] Chautau11ua County

Notary Public My Commission Expires Aur.ust 17, 20N-

STATE OF NEW YORK )
SS:
COUNTY OF CHAUTAUQUA )

On the 1st day of June, 2001, before me, a Notary Public in and for said State, personally appeared William H Reese, as Director of Financial of Trinity Biotech USA, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their capacities, and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument, and that such individual(s) made such appearance before the undersigned in the State of New York.

Rachel B. Nordine, #5000500 Notary Pubhc, State of New York Quahhed m

/s/Rachel B Nordine Chautau11ua County

Notary Public vf.omm1 mn Exp11es August 17, 2Q))-.

### Third Addendum to Lease Agreement

This Third Addendum is dated this 1st day of October 2008, by and between

LORRELLE S. JOHNSON and SHARON L. JOHNSON, 3094 North Main Street Ext.Jamestown, New York 14701 (hereinafter referred to as the Johnsons), and

CLARK LABORATORIES, INC. (d/b/a TRINITY BIOTECH USA), P.O. Box 1059, Jamestown, New York 14702 (hereinafter referred to as Trinity Biotech).

#### **Recitals**

The parties hereto are parties to a certain Lease Agreement dated May 30, 2001, under which Trinity Biotech leased 29, 178 square feet of space from the Johnsons, a First Addendum to Lease Agreement under which Trinity Biotech leased additional space from the Johnsons on a month-to-month basis, a Second Addend um to lease agreement which changed certain terms of the lease.

It is intended that the Terms and Conditions of the underlying Lease Agreement, where not modified by the Addend ums to the Lease Agreement, will continue in full force and effect. It is also intended that the more current Addendums to the Lease Agreement shall amend the preceding Addendums thereto.

*Now*, Therefore, in consideration of the foregoing and upon the terms and conditions set forth herein, the parties agree as follows:

The first paragraph of the Lease Agreement will be replaced with the following:

The Johnsons hereby demise and lease to Trinity Biotech, and Trinity Biotech rents from the Johnsons, for the term and upon the rental payments hereinafter specified, all of the first floor and all of the second floor of the premises located at 2901 Girts Road in the Town of Ellicott, New York (the *Premises*), together with all appurtenances thereto, including the non-exclusive use of all drive-ways, parking areas, and lawns adjacent thereto (the Common *Area*) for access to the Premises.

Each paragraph of the Lease Agreement set forth below shall be replaced, in its entirety, with the following language:

2. <u>RENT</u>. The rent for the Premises shall be payable by Trinity Biotech to the Johnsons in equal monthly installments, due on or before the 1stday of each calendar month, for the term hereof, payable at the offices of the Johnsons, or as may otherwise be directed by the Johnsons in writing, as follows:

| July 1, 2006, through June 30, 2008  | \$9,602.43 per month |
|--------------------------------------|----------------------|
| July 1, 2008, through July 31, 2008  | 9,986.52 per month   |
| August 1, 2008 through June 30, 2009 | 10,431.14 per month  |
| July 1, 2009, through June 30, 2010  | 10,848.38 per month  |
| July 1, 2010, through June 30, 2011  | 11,282.31 per month  |
| July 1, 2011, through June 30, 2012  | 11,733.61 per month  |
| July 1, 2012, through June 30, 2013  | 12,202.96 per month  |
| July 1, 2013, through June 30, 2014  | 12,691.07 per month  |
| July 1, 2014, through June 30, 2015  | 13,198.72 per month  |
| July 1, 2015, through June 30, 2016  | 13,726.66 per month  |

# 29. OPTION TO LEASE ADDITIONAL SPACE. This paragraph intentionally deleted.

*In Witness Whereof*, the parties hereto have caused this Third Addendum to Lease Agree-ment to be duly executed by their duly authorized represe written.

| /s/ Lorrell S. Johnson                     |  |
|--|--|
| Lorrell S. Johnson                         |  |
| /a/ Chanan I I Jahasan                     |  |
| /s/ Sharon L. Johnson<br>Sharon L. Johnson |  |

CIARK LABORATORIES, INC.

(d/b/a TRINITY BIOTECH USA)

/s/ Beverly Isaman

| $\Gamma \gamma$ | ٦ <i>٨</i> ' | TE. | OE | λ/I | rw | VC | RK |
|-----------------|--------------|-----|----|-----|----|----|----|
|                 |              |     |    |     |    |    |    |

:SS.

### COUNTY OF CHAUTAUQUA:

On this day of October, 2008, before me, the undersigned, a notary public in and for said state, personally appeared **LORRELLE S. JOHNSON** and **SHARON L**. JOHNSON, personally known to me or proved to me on the basis of satisfactory evidence to be the individuals whose names are subscribed to the within instrument and acknowledged to me that they executed the same in their capacities, and that by their signatures on the instrument, the individuals, or the person upon behalf of which the individuals acted, executed the instrument.

| Notary Public |  |
|---------------|--|

STATE OF NEW YORK

:SS.

# COUNTY OF CHAUTAUQUA:

On this day of October, 2008, before me, the undersigned, a notary public in and for said state, personally appeared , personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her capacity, and that by his/her signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument.

| Notary Public |  |
|---------------|--|

# AIR COMMERCIAL REAL ESTATE ASSOCIATION STANDARD INDUSTRIAL/COMMERCIAL SINGLE-TENANT LEASE—NET

#### (DO NOT USE THIS FORM FOR MULTI-TENANT BUILDINGS)

#### 1. Basic Provisions ("Basic Provisions").

- 1.1 **Parties**: This Lease ("**Lease**"), dated for reference purposes only February 13, 2012, is made by and between Barco Inv. Inc. ("**Lessor**") and Mardx Diagnostics, a wholly owned subsidary of Trinity BioTech ("**Lessee**"), (collectively the "**Parties**," or individually a "**Party**").
- 1.2 **Premises:** That certain real property, including all improvements therein or to be provided by Lessor under the terms of this Lease, and commonly known as 5919 Farnsworth Court, located in the County of San Diego, State of California, and generally described as (describe briefly the nature of the property and, if applicable, the "**Project**", if the property is located within a Project) a freestanding R&D building that is approximately 21,436 square feet in size ("**Premises**"). (See also Paragraph 2)
- 1.3 **Term:** 3 years and 0 months ("**Original Term**") commencing July 1, 2012 ("**Commencement Date**") and ending June 30, 2015 ("**Expiration Date**"). (See also Paragraph 3)
  - 1.4 Early Possession: ("Early Possession Date"). (See also Paragraphs 3.2 and 3.3)
- 1.5 **Base Rent:** \$19,507.00 per month ("**Base Rent"**), payable on the 1st day of each month commencing July 1, 2012. (See also Paragraph 4)
- If this box is checked, there are provisions in this Lease for the Base Rent to be adjusted.
  - 1.6 Base Rent and Other Monies Paid Upon Execution Lease Commencement:
    - (a) **Base Rent:** \$19,507.00 for the period July 2012
    - (b) Security Deposit: \$17,200.00 ("Security Deposit"). (See also Paragraph 5) Already paid.
    - (c) **Association Fees:** \$ for the period
    - (d) **Other:** \$ for
    - (e) Total Due Upon Execution of this Lease: \$0.00.
  - 1.7 **Agreed Use:** Medical research, development, sales and all other legal related uses. (See also Paragraph 6)
  - 1.8 Insuring Party: Lessor is the "Insuring Party" unless otherwise stated herein. (See also Paragraph 8)
  - 1.9 **Real Estate Brokers:** (See also Paragraph 15)
- (a) **Representation:** The following real estate brokers (the "Brokers") and brokerage relationships exist in this transaction (check applicable boxes):

| Ц |   | re | presents Lesso | r excl | us1v | ely ("Le | ssor's Broker'');   |  |
|---|---|----|----------------|--------|------|----------|---------------------|--|
|   |   | re | presents Lesse | e excl | usiv | ely ("Le | ssee's Broker"); or |  |
|   | _ |    | DDE C          |        | 17   | . 3.6    | . 1 .1 T            |  |

- Cassidy Turley BRE Commercial—Kent Moore represents both Lessor and Lessee ("Dual Agency").
- (b) **Payment to Brokers:** Upon execution and delivery of this Lease by both Parties, Lessor shall pay to the Broker the fee agreed to in their separate written agreement (or if there is no such agreement, the sum of three or 3 % of the total Base Rent) for the brokerage services rendered by the Brokers.
- 1.10 **Guarantor.** The obligations of the Lessee under this Lease are to be guaranteed by N/A (**"Guarantor"**). (See also Paragraph 37)
  - 1.11 **Attachments.** Attached hereto are the following, all of which constitute a part of this Lease:
- an Addendum consisting of Paragraphs 49 through 53;

| Ц              | a plot plan depicting the Premises;         |  |  |  |
|----------------|---|--|--|--|
|                | a current set of the Rules and Regulations; |  |  |  |
|                | a Work Letter;                              |  |  |  |
|                | other (specify):                            |  |  |  |
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#### 2. Premises.

- 2.1 **Letting**. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. Unless otherwise provided herein, any statement of size set forth in this Lease, or that may have been used in calculating Rent, is an approximation which the Parties agree is reasonable and any payments based thereon are not subject to revision whether or not the actual size is more or less. **Note: Lessee is advised to verify the actual size prior to executing this Lease.**
- 2.2 Condition. Lessor shall deliver the Premises to Lessee broom clean and free of debris on the Commencement Date or the Early Possession Date, whichever first occurs ("Start Date"), and, so long as the required service contracts described in Paragraph 7.1(b) below are obtained by Lessee and in effect within thirty days following the Start Date, warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems ("HVAC"), loading doors, sump pumps, if any, and all other such elements in the Premises, other than those constructed by Lessee, shall be in good operating condition on said date and that the structural elements of the roof, bearing walls and foundation of any buildings on the Premises (the "Building") shall be free of material defects. If a non-compliance with said warranty exists as of the Start Date, or if one of such systems or elements should malfunction or fail within the appropriate warranty period, Lessor shall, as Lessor's sole obligation with respect to such matter, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, malfunction or failure, rectify same at Lessor's expense. The warranty periods shall be as follows: (i) 6 months as to the HVAC systems, and (ii) 30 days as to the remaining systems and other elements of the Building. If Lessee does not give Lessor the required notice within the appropriate warranty period, correction of any such non-compliance, malfunction or failure shall be the obligation of Lessee at Lessee's sole cost and expense.
- 2.3 Compliance. Lessor warrants that the improvements on the Premises comply with the building codes, applicable laws, covenants or restrictions of record, regulations, and ordinances ("Applicable Requirements") that were in effect at the time that each improvement, or portion thereof, was constructed. Said warranty does not apply to the use to which Lessee will put the Premises, modifications which may be required by the Americans with Disabilities Act or any similar laws as a result of Lessee's use (see Paragraph 50), or to any Alterations or Utility Installations (as defined in Paragraph 7.3(a)) made or to be made by Lessee. NOTE: Lessee is responsible for determining whether or not the Applicable Requirements, and especially the zoning, are appropriate for Lessee's intended use, and acknowledges that past uses of the Premises may no longer be allowed. If the Premises do not comply with said warranty, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, rectify the same at Lessor's expense. If Lessee does not give Lessor written notice of a non-compliance with this warranty within 6 months following the Start Date, correction of that non-compliance shall be the obligation of Lessee at Lessee's sole cost and expense. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Premises and/or Building, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Unit, Premises and/or Building ("Capital Expenditure"), Lessor and Lessee shall allocate the cost of such work as follows:
- (a) Subject to Paragraph 2.3(c) below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof, provided, however that if such Capital Expenditure is required during the last 2 years of this Lease and the cost thereof exceeds 6 months' Base Rent, Lessee may instead terminate this Lease unless Lessor notifies Lessee, in writing, within 10 days after receipt of Lessee's termination notice that Lessor has elected to pay the difference between the actual cost thereof and an amount equal to 6 months' Base Rent. If Lessee elects termination, Lessee shall immediately cease the use of the Premises which requires such Capital Expenditure and deliver to Lessor written notice specifying a termination date at least 90 days thereafter. Such termination date shall, however, in no event be earlier than the last day that Lessee could legally utilize the Premises without commencing such Capital Expenditure.
- (b) If such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor and Lessee shall allocate the obligation to pay for such costs pursuant to the provisions of Paragraph 7.1(d); provided, however, that if such Capital Expenditure is required during the last 2 years of this Lease or if Lessor reasonably determines that it is not economically feasible to pay its share thereof, Lessor shall have the option to terminate this Lease upon 90 days prior written notice to Lessee unless Lessee notifies Lessor, in writing, within 10 days after receipt of Lessor's termination notice that Lessee will pay for such Capital Expenditure. If Lessor does not elect to terminate, and fails to tender its share of any such Capital Expenditure, Lessee may advance such funds and deduct same, with Interest, from Rent until Lessor's share of such costs have been fully paid. If Lessee is unable to finance Lessor's share, or if the balance of the Rent due and payable for the remainder of this Lease is not sufficient to fully reimburse Lessee on an offset basis, Lessee shall have the right to terminate this Lease upon 30 days written notice to Lessor.
- (c) Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to non-voluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) immediately cease such changed use or intensity of use and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not, however, have any right to terminate this Lease.

- 2.4 **Acknowledgements.** Lessee acknowledges that: (a) it has been advised by Lessor and/or Brokers to satisfy itself with respect to the condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements and the Americans with Disabilities Act), and their suitability for Lessee's intended use, (b) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, and (c) neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease. In addition, Lessor acknowledges that: (i) Brokers have made no representations, promises or warranties concerning Lessee's ability to honor the Lease or suitability to occupy the Premises, and (ii) it is Lessor's sole responsibility to investigate the financial capability and/or suitability of all proposed tenants.
- 2.5 **Lessee as Prior Owner/Occupant.** The warranties made by Lessor in Paragraph 2 shall be of no force or effect if immediately prior to the Start Date Lessee was the owner or occupant of the Premises. In such event, Lessee shall be responsible for any necessary corrective work.

#### 3. Term.

- 3.1 **Term.** The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Paragraph 1.3.
- 3.2 **Early Possession.** If Lessee totally or partially occupies the Premises prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such early possession. All other terms of this Lease (including but not limited to the obligations to pay Real Property Taxes and insurance premiums and to maintain the Premises) shall, however, be in effect during such period. Any such early possession shall not affect the Expiration Date.

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- 3.3 **Delay In Possession.** Lessor agrees to use its best commercially reasonable efforts to deliver possession of the Premises to Lessee by the Commencement Date. If, despite said efforts, Lessor is unable to deliver possession by such date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease. Lessee shall not, however, be obligated to pay Rent or perform its other obligations until Lessor delivers possession of the Premises and any period of rent abatement that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to what Lessee would otherwise have enjoyed under the terms hereof, but minus any days of delay caused by the acts or omissions of Lessee. If possession is not delivered within 60 days after the Commencement Date, Lessee may, at its option, by notice in writing within 10 days after the end of such 60 day period, cancel this Lease, in which event the Parties shall be discharged from all obligations hereunder. If such written notice is not received by Lessor within said 10 day period, Lessee's right to cancel shall terminate. If possession of the Premises is not delivered within 120 days after the Commencement Date, this Lease shall terminate unless other agreements are reached between Lessor and Lessee, in writing.
- 3.4 **Lessee Compliance.** Lessor shall not be required to deliver possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Paragraph 8.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

#### 4. Rent.

- 4.1. **Rent Defined.** All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent ("Rent").
- 4.2 **Payment.** Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States on or before the day on which it is due, without offset or deduction (except as specifically permitted in this Lease). Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of \$25 in addition to any Late Charge and Lessor, at its option, may require all future payments to be made by Lessee to be by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent and Operating Expense Increase, and any remaining amount to any other outstanding charges or costs.
- 4.3 **Association Fees.** In addition to the Base Rent, Lessee shall pay to Lessor each month an amount equal to any owner's association or condominium fees levied or assessed against the Premises. Said monies shall be paid at the same time and in the same manner as the Base Rent.
- 5. Security Deposit. Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease, Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount due Lessor or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. If the Base Rent increases during the term of this Lease, Lessee shall, upon written request from Lessor, deposit additional moneys with Lessor so that the total amount of the Security Deposit shall at all times bear the same proportion to the increased Base Rent as the initial Security Deposit bore to the initial Base Rent. Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary, in Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 14 days after the expiration or termination of this Lease, if Lessor elects to apply the Security Deposit only to unpaid Rent, and otherwise within 30 days after the Premises have been vacated pursuant to Paragraph 7.4(c) below, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease.

#### 6. Use.

6.1 **Use.** Lessee shall use and occupy the Premises only for the Agreed Use, or any other legal use which is reasonably comparable thereto, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Lessor

shall not unreasonably withhold or delay its consent to any written request for a modification of the Agreed Use, so long as the same will not impair the structural integrity of the improvements on the Premises or the mechanical or electrical systems therein, and/or is not significantly more burdensome to the Premises. If Lessor elects to withhold consent, Lessor shall within 7 days after such request give written notification of same, which notice shall include an explanation of Lessor's objections to the change in the Agreed Use.

#### 6.2 Hazardous Substances.

(a) **Reportable Uses Require Consent.** The term "Hazardous Substance" as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any

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products, by-products or fractions thereof. Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lessee's expense) with all Applicable Requirements. "Reportable Use" shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use, ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

- (b) **Duty to Inform Lessor.** If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall immediately give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.
- (c) **Lessee Remediation.** Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee's expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.
- (d) Lessee Indemnification. Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys' and consultants' fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, or any third party (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance under the Premises from adjacent properties not caused or contributed to by Lessee's obligations shall include, but not be limited to, the effects of any contamination or injury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.
- (e) **Lessor Indemnification.** Lessor and its successors and assigns shall indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which result from Hazardous Substances which existed on the Premises prior to Lessee's occupancy or which are caused by the gross negligence or willful misconduct of Lessor, its agents or employees. Lessor's obligations, as and when required by the Applicable Requirements, shall include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.
- (f) **Investigations and Remediations.** Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to Lessee's occupancy, unless such remediation measure is required as a result of Lessee's use (including "Alterations", as defined in paragraph 7.3(a) below) of the Premises, in which event Lessee shall be responsible for such payment. Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor's agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor's investigative and remedial responsibilities.
- (g) **Lessor Termination Option.** If a Hazardous Substance Condition (see Paragraph 9.1(e)) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(d) and Paragraph 13), Lessor may, at Lessor's option, either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) if the estimated cost to remediate such condition exceeds 12 times the then monthly Base Rent or \$100,000, whichever is greater, give written notice to Lessee, within 30 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessor of Lessee's commitment to pay the amount by which the cost of the remediation of such Hazardous Substance Condition exceeds an amount equal to 12 times the then monthly Base Rent or \$100,000, whichever is greater. Lessee shall provide Lessor with said funds or

satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time provided, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 **Lessee's Compliance with Applicable Requirements.** Except as otherwise provided in this Lease, Lessee shall, at Lessee's sole expense, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to the such Requirements, without regard to whether such Requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving the failure of Lessee or the Premises to comply with any Applicable Requirements.

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6.4 **Inspection; Compliance.** Lessor and Lessor's **"Lender"** (as defined in Paragraph 30) and consultants shall have the right to enter into Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable notice, for the purpose of inspecting the condition of the Premises and for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see paragraph 9.1) is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (MSDS) to Lessor within 10 days of the receipt of a written request therefor.

#### 7. Maintenance; Repairs, Utility Installations; Trade Fixtures and Alterations.

# 7.1 Lessee's Obligations.

- (a) In General. Subject to the provisions of Paragraph 2.2 (Condition), 2.3 (Compliance), 6.3 (Lessee's Compliance with Applicable Requirements), 7.2 (Lessor's Obligations), 9 (Damage or Destruction), and 14 (Condemnation), Lessee shall, at Lessee's sole expense, keep the Premises, Utility Installations (intended for Lessee's exclusive use, no matter where located), and Alterations in good order, condition and repair (whether or not the portion of the Premises requiring repairs, or the means of repairing the same, are reasonably or readily accessible to Lessee, and whether or not the need for such repairs occurs as a result of Lessee's use, any prior use, the elements or the age of such portion of the Premises), including, but not limited to, all equipment or facilities, such as plumbing, HVAC equipment, electrical, lighting facilities, boilers, pressure vessels, fire protection system, fixtures, walls (interior and exterior), foundations, ceilings, roofs, roof drainage systems, floors, windows, doors, plate glass, skylights, landscaping, driveways, parking lots, fences, retaining walls, signs, sidewalks and parkways located in, on, or adjacent to the Premises. Lessee, in keeping the Premises in good order, condition and repair, shall exercise and perform good maintenance practices, specifically including the procurement and maintenance of the service contracts required by Paragraph 7.1(b) below. Lessee's obligations shall include restorations, replacements or renewals when necessary to keep the Premises and all improvements thereon or a part thereof in good order, condition and state of repair. Lessee shall, during the term of this Lease, keep the exterior appearance of the Building in a first-class condition (including, e.g. graffiti removal) consistent with the exterior appearance of other similar facilities of comparable age and size in the vicinity, including, when necessary, the exterior repainting of the Building.
- (b) **Service Contracts.** Lessee shall, at Lessee's sole expense, procure and maintain contracts, with copies to Lessor, in customary form and substance for, and with contractors specializing and experienced in the maintenance of the following equipment and improvements, if any, if and when installed on the Premises: (i) HVAC equipment, (ii) boiler, and pressure vessels, (iii) fire extinguishing systems, including fire alarm and/or smoke detection, (iv) landscaping and irrigation systems, (v) roof covering and drains, (vi) clarifiers (vii) basic utility feed to the perimeter of the Building, and (viii) any other equipment, if reasonably required by Lessor. However, Lessor reserves the right, upon notice to Lessee, to procure and maintain any or all of such service contracts, and if Lessor so elects, Lessee shall reimburse Lessor, upon demand, for the cost thereof.
- (c) **Failure to Perform.** If Lessee fails to perform Lessee's obligations under this Paragraph 7.1, Lessor may enter upon the Premises after 10 days' prior written notice to Lessee (except in the case of an emergency, in which case no notice shall be required), perform such obligations on Lessee's behalf, and put the Premises in good order, condition and repair, and Lessee shall promptly pay to Lessor a sum equal to 115% of the cost thereof.
- (d) **Replacement.** Subject to Lessee's indemnification of Lessor as set forth in Paragraph 8.7 below, and without relieving Lessee of liability resulting from Lessee's failure to exercise and perform good maintenance practices, if an item described in Paragraph 7.1(b) cannot be repaired other than at a cost which is in excess of 50% of the cost of replacing such item, then such item shall be replaced by Lessor, and the cost thereof shall be prorated between the Parties and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease, on the date on which Base Rent is due, an amount equal to the product of multiplying the cost of such replacement by a fraction, the numerator of which is one, and the denominator of which is 144 (ie. 1/144th of the cost per month). Lessee shall pay interest on the unamortized balance at a rate that is commercially reasonable in the judgment of Lessor's accountants. Lessee may, however, prepay its obligation at any time.
- 7.2 **Lessor's Obligations.** Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance), 9 (Damage or Destruction) and 14 (Condemnation), it is intended by the Parties hereto that Lessor have no obligation, in any manner whatsoever, to repair and maintain the Premises, or the equipment therein, all of which obligations are intended to be that of the Lessee. It is the intention of the Parties that the terms of this Lease govern the respective obligations of the Parties as to maintenance and repair of the Premises, and they expressly waive the benefit of any statute now or hereafter in effect to the extent it is inconsistent with the terms of this Lease.

### 7.3 Utility Installations; Trade Fixtures; Alterations.

(a) **Definitions.** The term "**Utility Installations**" refers to all floor and window coverings, air and/or vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, plumbing, and fencing in or on the Premises. The term "**Trade Fixtures**" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term "**Alterations**" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion. "**Lessee Owned Alterations and/or Utility** 

**Installations"** are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a).

(b) Consent. Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make non-structural Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating or removing the roof or any existing walls, will not affect the electrical, plumbing, HVAC, and/or life safety systems, and the cumulative cost thereof during this Lease as extended does not exceed a sum equal to 3 month's Base Rent in the aggregate or a sum equal to one month's Base Rent in any one year. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor, Lessor may, as a precondition to granting such approval, require Lessee to utilize a contractor chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with as-built plans and specifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor.

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(c) **Liens; Bonds.** Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 150% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same. If Lessor elects to participate in any such action, Lessee shall pay Lessor's attorneys' fees and costs.

# 7.4 Ownership; Removal; Surrender; and Restoration.

- (a) **Ownership.** Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per paragraph 7.4(b) hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lesse, become the property of Lessor and be surrendered by Lessee with the Premises.
- (b) **Removal.** By delivery to Lessee of written notice from Lessor not earlier than 90 and not later than 30 days prior to the end of the term of this Lease, Lessor may require that any or all Lessee Owned Alterations or Utility Installations be removed by the expiration or termination of this Lease. Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent.
- (c) **Surrender; Restoration.** Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof broom clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing, if this Lease is for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall completely remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or any third party (except Hazardous Substances which were deposited via underground migration from areas outside of the Premises, or if applicable, the Project) even if such removal would require Lessee to perform or pay for work that exceeds statutory requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Paragraph 7.4(c) without the express written consent of Lessor shall constitute a holdover under the provisions of Paragraph 26 below.

#### 8. Insurance; Indemnity.

8.1 **Payment For Insurance.** Lessee shall pay for all insurance required under Paragraph 8 except to the extent of the cost attributable to liability insurance carried by Lessor under Paragraph 8.2(b) in excess of \$2,000,000 per occurrence. Premiums for policy periods commencing prior to or extending beyond the Lease term shall be prorated to correspond to the Lease term. Payment shall be made by Lessee to Lessor within 10 days following receipt of an invoice.

#### 8.2 Liability Insurance.

- (a) Carried by Lessee. Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor as an additional insured against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than \$1,000,000 per occurrence with an annual aggregate of not less than \$2,000,000, an "Additional Insured-Managers or Lessors of Premises Endorsement" and contain the "Amendment of the Pollution Exclusion Endorsement" for damage caused by heat, smoke or fumes from a hostile fire. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "insured contract" for the performance of Lessee's indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. All insurance carried by Lessee shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only.
- (b) **Carried by Lessor.** Lessor shall maintain liability insurance as described in Paragraph 8.2(a), in addition to, and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

# 8.3 Property Insurance - Building, Improvements and Rental Value.

(a) **Building and Improvements.** The Insuring Party shall obtain and keep in force a policy or policies in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Premises. The amount of such insurance shall be equal to the full replacement cost of the Premises, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. If Lessor is the Insuring Party, however, Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee under Paragraph 8.4 rather than by Lessor. If the coverage is available and commercially appropriate, such policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. If such insurance coverage has a deductible clause, the deductible amount shall not exceed \$1,000 per occurrence, and Lessee shall be liable for such deductible amount in the event of an Insured Loss.

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- (b) **Rental Value.** The Insuring Party shall obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year with an extended period of indemnity for an additional 180 days ("Rental Value insurance"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12 month period. Lessee shall be liable for any deductible amount in the event of such loss.
- (c) **Adjacent Premises.** If the Premises are part of a larger building, or of a group of buildings owned by Lessor which are adjacent to the Premises, the Lessee shall pay for any increase in the premiums for the property insurance of such building or buildings if said increase is caused by Lessee's acts, omissions, use or occupancy of the Premises.

#### 8.4 Lessee's Property; Business Interruption Insurance.

- (a) **Property Damage.** Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility Installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed \$1,000 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations. Lessee shall provide Lessor with written evidence that such insurance is in force.
- (b) **Business Interruption.** Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils.
- (c) **No Representation of Adequate Coverage.** Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.
- 8.5 Insurance Policies. Insurance required herein shall be by companies duly licensed or admitted to transact business in the state where the Premises are located, and maintaining during the policy term a "General Policyholders Rating" of at least B+, V, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall, prior to the Start Date, deliver to Lessor certified copies of policies of such insurance or certificates evidencing the existence and amounts of the required insurance. No such policy shall be cancelable or subject to modification except after 30 days prior written notice to Lessor. Lessee shall, at least 30 days prior to the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may order such insurance and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same.
- 8.6 Waiver of Subrogation. Without affecting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be insured against herein. The effect of such releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.
- 8.7 **Indemnity.** Except for Lessor's gross negligence or willful misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, the use and/or occupancy of the Premises by Lessee. If any action or proceeding is brought against Lessor by reason of any of the foregoing matters, Lessee shall upon notice defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.
- 8.8 Exemption of Lessor from Liability. Lessor shall not be liable for injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether the said injury or damage results from conditions arising upon the Premises or upon other portions of the building of which the Premises are a part, or from other sources or places. Lessor shall not be liable for any damages arising from any act or neglect of any other tenant of Lessor nor from the failure of Lessor to enforce the provisions of any other lease in the Project. Notwithstanding Lessor's negligence or breach of this Lease, Lessor shall under no circumstances be liable for injury to Lessee's business or for any loss of income or profit therefrom.
- 8.9 **Failure to Provide Insurance.** Lessee acknowledges that any failure on its part to obtain or maintain the insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance

and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/ costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

### 9. Damage or Destruction.

#### 9.1 **Definitions.**

- (a) "Premises Partial Damage" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in 6 months or less from the date of the damage or destruction. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.
- (b) "Premises Total Destruction" shall mean damage or destruction to the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in 6 months or less from the date of the damage or destruction. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(c) "Insured Loss" shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a), irrespective of any deductible amounts or coverage limits involved.

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- (d) "Replacement Cost" shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.
- (e) "Hazardous Substance Condition" shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance as defined in Paragraph 6.2(a), in, on, or under the Premises which requires repair, remediation, or restoration.
- 9.2 Partial Damage Insured Loss. If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor's expense, repair such damage (but not Lessee's Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessee shall, at Lessor's election, make the repair of any damage or destruction the total cost to repair of which is \$10,000 or less, and, in such event, Lessor shall make any applicable insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to effect such repair, the Insuring Party shall promptly contribute the shortage in proceeds (except as to the deductible which is Lessee's responsibility) as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost insurance coverage was not commercially reasonable and available. Lessor shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the party responsible for making the repairs shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to: (i) make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect, or (ii) have this Lease terminate 30 days thereafter. Lessee shall not be entitled to reimbursement of any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Paragraph 9.3, notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.
- 9.3 **Partial Damage Uninsured Loss.** If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee's expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage. Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor of Lessee's commitment to pay for the repair of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.
- 9.4 **Total Destruction.** Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor's damages from Lessee, except as provided in Paragraph 8.6.
- 9.5 **Damage Near End of Term.** If at any time during the last 6 months of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an Insured Loss, Lessor may terminate this Lease effective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor's commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee's option shall be extinguished.

### 9.6 Abatement of Rent; Lessee's Remedies.

(a) **Abatement.** In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not to exceed the proceeds received from the Rental Value insurance. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

- (b) **Remedies.** If Lessor shall be obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lessee's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days thereafter, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.
- 9.7 **Termination;** Advance Payments. Upon termination of this Lease pursuant to Paragraph 6.2(g) or Paragraph 9, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor.
- 9.8 **Waive Statutes.** Lessor and Lessee agree that the terms of this Lease shall govern the effect of any damage to or destruction of the Premises with respect to the termination of this Lease and hereby waive the provisions of any present or future statute to the extent inconsistent herewith.

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# 10. Real Property Taxes.

- 10.1 **Definition.** As used herein, the term "**Real Property Taxes**" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, personal income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Premises or the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Building address and where the proceeds so generated are to be applied by the city, county or other local taxing authority of a jurisdiction within which the Premises are located. Real Property Taxes shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Premises, and (ii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease.
- 10.2 **Payment of Taxes.** In addition to Base Rent, Lessee shall pay to Lessor an amount equal to the Real Property Tax installment due at least 20 days prior to the applicable delinquency date. If any such installment shall cover any period of time prior to or after the expiration or termination of this Lease, Lessee's share of such installment shall be prorated. In the event Lessee incurs a late charge on any Rent payment, Lessor may estimate the current Real Property Taxes, and require that such taxes be paid in advance to Lessor by Lessee monthly in advance with the payment of the Base Rent. Such monthly payments shall be an amount equal to the amount of the estimated installment of taxes divided by the number of months remaining before the month in which said installment becomes delinquent. When the actual amount of the applicable tax bill is known, the amount of such equal monthly advance payments shall be adjusted as required to provide the funds needed to pay the applicable taxes. If the amount collected by Lessor is insufficient to pay such Real Property Taxes when due, Lessee shall pay Lessor, upon demand, such additional sum as is necessary. Advance payments may be intermingled with other moneys of Lessor and shall not bear interest. In the event of a Breach by Lessee in the performance of its obligations under this Lease, then any such advance payments may be treated by Lessor as an additional Security Deposit.
- 10.3 **Joint Assessment.** If the Premises are not separately assessed, Lessee's liability shall be an equitable proportion of the Real Property Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be conclusively determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available.
- 10.4 **Personal Property Taxes.** Lessee shall pay, prior to delinquency, all taxes assessed against and levied upon Lessee Owned Alterations, Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.
- 11. **Utilities and Services.** Lessee shall pay for all water, gas, heat, light, power, telephone, trash disposal and other utilities and services supplied to the Premises, together with any taxes thereon. If any such services are not separately metered or billed to Lessee, Lessee shall pay a reasonable proportion, to be determined by Lessor, of all charges jointly metered or billed. There shall be no abatement of rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

# 12. Assignment and Subletting.

## 12.1 Lessor's Consent Required.

- (a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively, "assign or assignment") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent.
- (b) Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of 25% or more of the voting control of Lessee shall constitute a change in control for this purpose.
- (c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale, acquisition, financing, transfer, leveraged buy-out or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the Net Worth of Lessee by an amount greater than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, whichever was or is greater, shall be considered an assignment of this Lease to which Lessor may withhold its consent. "Net Worth of Lessee" shall mean the net worth of Lessee (excluding any guarantors) established under generally accepted accounting principles.
- (d) An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1(c), or a noncurable Breach without the necessity of any notice and grace period. If Lessor elects to treat such unapproved

assignment or subletting as a noncurable Breach, Lessor may either: (i) terminate this Lease, or (ii) upon 30 days written notice, increase the monthly Base Rent to 110% of the Base Rent then in effect. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to 110% of the price previously in effect, and (ii) all fixed and non-fixed rental adjustments scheduled during the remainder of the Lease term shall be increased to 110% of the scheduled adjusted rent.

(e) Lessee's remedy for any breach of Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

### 12.2 Terms and Conditions Applicable to Assignment and Subletting.

- (a) Regardless of Lessor's consent, no assignment or subletting shall: (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary liability of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee.
- (b) Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach.

(c) Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.

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- (d) In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of Lessee's obligations under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor.
- (e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of \$500 as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Paragraph 36)
- (f) Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment or entering into such sublease, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.
- (g) Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Paragraph 39.2)
- 12.3 **Additional Terms and Conditions Applicable to Subletting.** The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:
- (a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's obligations any such excess shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor all Rent due and to become due under the sublease. Sublessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.
- (b) In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.
  - (c) Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor.
  - (d) No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.
- (e) Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

### 13. Default; Breach; Remedies.

- 13.1 **Default; Breach.** A "**Default**" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "**Breach**" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:
- (a) The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Paragraph 8.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism.
- (b) The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder, whether to Lessor or to a third party, when due, to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of 3 business days following written notice to Lessee.
- (c) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate, (v) a requested subordination, (vi) evidence concerning any guaranty and/or Guarantor, (vii) any document requested under Paragraph 42, (viii) material safety data sheets (MSDS), or (ix) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of 10 days following written notice to Lessee.

- (d) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 40 hereof, other than those described in subparagraphs 13.1(a), (b) or (c), above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.
- (e) The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "debtor" as defined in 11 U.S.C. §101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subparagraph (e) is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions.
  - (f) The discovery that any financial statement of Lessee or of any Guarantor given to Lessor was materially false.
- (g) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantor's becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantor's breach of its guaranty obligation on an anticipatory basis, and Lessee's failure, within 60 days following written notice of any such event, to provide written alternative assurance or security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

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- 13.2 **Remedies.** If Lessee fails to perform any of its affirmative duties or obligations, within 10 days after written notice (or in case of an emergency, without notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:
- (a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of the District within which the Premises are located at the time of award plus one percent. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall not waive Lessor's right to recover damages under Paragraph 12. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Paragraph 13.1 was not previously given, a notice to pay rent or quit, or to perform or quit given to Lessee under the unlawful detainer statute shall also constitute the notice required by Paragraph 13.1. In such case, the applicable grace period required by Paragraph 13.1 and the unlawful detainer statute shall run concurrently, and the failure of Lessee to cure the Default within the greater of the two such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.
- (b) Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.
- (c) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.
- 13.3 **Inducement Recapture.** Any agreement for free or abated rent or other charges, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "**Inducement Provisions**," shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an inducement Provision shall be immediately due and payable by Lessee to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this paragraph shall not be deemed a waiver by Lessor of the provisions of this paragraph unless specifically so stated in writing by Lessor at the time of such acceptance.
- 13.4 Late Charges. Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within 5 days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 10% of each such overdue amount or \$100, whichever is greater. The Parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for 3 consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.
- 13.5 **Interest.** Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor, when due as to scheduled payments (such as Base Rent) or within 30 days following the date on which it was due for non-scheduled payment, shall bear interest from the date when due, as to scheduled payments, or the 31st day after it was due as to non-scheduled payments. The interest ("**Interest**") charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law.

Interest is payable in addition to the potential late charge provided for in Paragraph 13.4.

# 13.6 Breach by Lessor.

- (a) **Notice of Breach.** Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall not be in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion.
- (b) **Performance by Lessee on Behalf of Lessor.** In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may elect to cure said breach at Lessee's expense and offset from Rent the actual and reasonable cost to perform such cure, provided however, that such offset shall not exceed an amount equal to the greater of one month's Base Rent or the Security Deposit, reserving Lessee's right to seek reimbursement from Lessor. Lessee shall document the cost of said cure and supply said documentation to Lessor.

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14. **Condemnation.** If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (collectively "Condemnation"), this Lease shall terminate as to the part taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than 10% of the Building, or more than 25% of that portion of the Premises not occupied by any building, is taken by Condemnation, Lessee may, at Lessee's option, to be exercised in writing within 10 days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within 10 days after the condemning authority shall have taken possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Condemnation awards and/or payments shall be the property of Lessor, whether such award shall be made as compensation for diminution in value of the leasehold, the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any compensation for Lessee's relocation expenses, loss of business goodwill and/or Trade Fixtures, without regard to whether or not this Lease is terminated pursuant to the provisions of this Paragraph. All Alterations and Utility Installations made to the Premises by Lessee, for purposes of Condemnation only, shall be considered the property of the Lessee and Lessee shall be entitled to any and all compensation which is payable therefor. In the event that this Lease is not terminated by reason of the Condemnation, Lessor shall repair any damage to the Premises caused by such Condemnation.

#### 15. Brokerage Fees.

- 15.1 **Additional Commission.** In addition to the payments owed pursuant to Paragraph 1.9 above, and unless Lessor and the Brokers otherwise agree in writing, Lessor agrees that: (a) if Lessee exercises any Option, (b) if Lessee acquires any rights to the Premises or other premises owned by Lessor and located within the same Project, if any, within which the Premises is located, (c) if Lessee remains in possession of the Premises, with the consent of Lessor, after the expiration of this Lease, or (d) if Base Rent is increased, whether by agreement or operation of an escalation clause herein, then, Lessor shall pay Brokers a fee in accordance with the schedule of the Brokers in effect at the time of the execution of this Lease.
- 15.2 **Assumption of Obligations.** Any buyer or transferee of Lessor's interest in this Lease shall be deemed to have assumed Lessor's obligation hereunder. Brokers shall be third party beneficiaries of the provisions of Paragraphs 1.9, 15, 22 and 31. If Lessor fails to pay to Brokers any amounts due as and for brokerage fees pertaining to this Lease when due, then such amounts shall accrue Interest. In addition, if Lessor fails to pay any amounts to Lessee's Broker when due, Lessee's Broker may send written notice to Lessor and Lessee of such failure and if Lessor fails to pay such amounts within 10 days after said notice, Lessee shall pay said monies to its Broker and offset such amounts against Rent. In addition, Lessee's Broker shall be deemed to be a third party beneficiary of any commission agreement entered into by and/or between Lessor and Lessor's Broker for the limited purpose of collecting any brokerage fee owed.
- 15.3 **Representations and Indemnities of Broker Relationships.** Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker or finder (other than the Brokers, if any) in connection with this Lease, and that no one other than said named Brokers is entitled to any commission or finder's fee in connection herewith. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

### 16. Estoppel Certificates.

- (a) Each Party (as "Responding Party") shall within 10 days after written notice from the other Party (the "Requesting Party") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the then most current "Estoppel Certificate" form published by the AIR Commercial Real Estate Association, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.
- (b) If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10 day period, the Requesting Party may execute an Estoppel Certificate stating that: (i) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party, not more than one month's rent has been paid in advance. Prospective purchasers and encumbrancers may rely upon the Requesting Party's Estoppel Certificate, and the Responding Party shall be estopped from denying the truth of the facts contained in said Certificate.
- (c) If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee and all Guarantors shall deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past 3 years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.
- 17. **Definition of Lessor.** The term "**Lessor**" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee's interest in the prior lease. In the event of a transfer of Lessor's title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by

Lessor. Except as provided in Paragraph 15, upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

- 18. **Severability.** The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.
- 19. **Days.** Unless otherwise specifically indicated to the contrary, the word "days" as used in this Lease shall mean and refer to calendar days.

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- 20. **Limitation on Liability.** The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor or its partners, members, directors, officers or shareholders, and Lessee shall look to the Premises, and to no other assets of Lessor, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor's partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction.
- 21. **Time of Essence.** Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.
- 22. No Prior or Other Agreements; Broker Disclaimer. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Premises. Brokers have no responsibility with respect thereto or with respect to any default or breach hereof by either Party. The liability (including court costs and attorneys' fees), of any Broker with respect to negotiation, execution, delivery or performance by either Lessor or Lessee under this Lease or any amendment or modification hereto shall be limited to an amount up to the fee received by such Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.

### 23. Notices.

- 23.1 **Notice Requirements.** All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or by facsimile transmission, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.
- 23.2 **Date of Notice.** Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 48 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantee next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices transmitted by facsimile transmission or similar means shall be deemed delivered upon telephone confirmation of receipt (confirmation report from fax machine is sufficient), provided a copy is also delivered via delivery or mail. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.
- 24. **Waivers.** No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent. The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of moneys or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

# 25. Disclosures Regarding The Nature of a Real Estate Agency Relationship.

- (a) When entering into a discussion with a real estate agent regarding a real estate transaction, a Lessor or Lessee should from the outset understand what type of agency relationship or representation it has with the agent or agents in the transaction. Lessor and Lessee acknowledge being advised by the Brokers in this transaction, as follows:
- (i) <u>Lessor's Agent.</u> A Lessor's agent under a listing agreement with the Lessor acts as the agent for the Lessor only. A Lessor's agent or subagent has the following affirmative obligations: <u>To the Lessor:</u> A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessor. <u>To the Lessee and the Lessor:</u> a. Diligent exercise of reasonable skills and care in performance of the agent's duties. b. A duty of honest and fair dealing and good faith. c. A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.
- (ii) <u>Lessee's Agent.</u> An agent can agree to act as agent for the Lessee only. In these situations, the agent is not the Lessor's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the

Lessor. An agent acting only for a Lessee has the following affirmative obligations. To the Lessee: A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessee. To the Lessee and the Lessor: a. Diligent exercise of reasonable skills and care in performance of the agent's duties. b. A duty of honest and fair dealing and good faith. c. A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(iii) Agent Representing Both Lessor and Lessee. A real estate agent, either acting directly or through one or more associate licenses, can legally be the agent of both the Lessor and the Lessee in a transaction, but only with the knowledge and consent of both the Lessor and the Lessee. In a dual agency situation, the agent has the following affirmative obligations to both the Lessor and the Lessee: a. A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either Lessor or the Lessee. b. Other duties to the Lessor and the Lessee as stated above in subparagraphs (i) or (ii). In representing both Lessor and Lessee, the agent may not without the express permission of the respective Party, disclose to the other Party that the Lessor will accept rent in an amount less than that indicated in the listing or that the Lessee is willing to pay a higher rent than that offered. The above duties of the agent in a real estate transaction do not relieve a Lessor or Lessee from the responsibility to protect their own interests. Lessor and Lessee should carefully read all agreements to assure that they adequately express their understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advice is desired, consult a competent professional.

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- (b) Brokers have no responsibility with respect to any default or breach hereof by either Party. The liability (including court costs and attorneys' fees), of any Broker with respect to any breach of duty, error or omission relating to this Lease shall not exceed the fee received by such Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.
- (c) Lessor and Lessee agree to identify to Brokers as "Confidential" any communication or information given Brokers that is considered by such Party to be confidential.
- 26. **No Right To Holdover.** Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, then the Base Rent shall be increased to 150% of the Base Rent applicable immediately preceding the expiration or termination. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee.
- 27. **Cumulative Remedies.** No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.
- 28. **Covenants and Conditions; Construction of Agreement.** All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.
- 29. **Binding Effect; Choice of Law.** This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located.
- 30. Subordination; Attornment; Non-Disturbance.
- 30.1 **Subordination.** This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "Security Device"), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as "Lender") shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving written notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.
- 30.2 **Attornment.** In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is subordinated (i) Lessee shall, subject to the non-disturbance provisions of Paragraph 30.3, attorn to such new owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of such new owner, this Lease shall automatically become a new Lease between Lessee and such new owner, upon all of the terms and conditions hereof, for the remainder of the term hereof, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and such new owner shall assume all of Lessor's obligations hereunder, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month's rent, or (d) be liable for the return of any security deposit paid to any prior lessor.
- 30.3 Non-Disturbance. With respect to Security Devices entered into by Lessor after the execution of this Lease, Lessee's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a "Non-Disturbance Agreement") from the Lender which Non-Disturbance Agreement provides that Lessee's possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises. Further, within 60 days after the execution of this Lease, Lessor shall use its commercially reasonable efforts to obtain a Non-Disturbance Agreement from the holder of any pre-existing Security Device which is secured by the Premises. In the event that Lessor is unable to provide the Non-Disturbance Agreement within said 60 days, then Lessee may, at Lessee's option, directly contact Lender and attempt to negotiate for the execution and delivery of a Non-Disturbance Agreement.
- 30.4 **Self-Executing.** The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.
- 31. **Attorneys' Fees.** If any Party or Broker brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon,

shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, "Prevailing Party" shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys' fees award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees reasonably incurred. In addition, Lessor shall be entitled to attorneys' fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach (\$200 is a reasonable minimum per occurrence for such services and consultation).

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- 32. **Lessor's Access; Showing Premises; Repairs.** Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through the Premises and/or other premises as long as there is no material adverse effect to Lessee's use of the Premises. All such activities shall be without abatement of rent or liability to Lessee.
- 33. **Auctions.** Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor's prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.
- 34. **Signs.** Lessor may place on the Premises ordinary "For Sale" signs at any time and ordinary "For Lease" signs during the last 6 months of the term hereof. Except for ordinary "for sublease" signs, Lessee shall not place any sign upon the Premises without Lessor's prior written consent. All signs must comply with all Applicable Requirements.
- 35. **Termination; Merger.** Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.
- 36. Consents. Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees with any determination made by the other hereunder and reasonably requests the reasons for such determination, the determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

### 37. Guarantor.

- 37.1 **Execution.** The Guarantors, if any, shall each execute a guaranty in the form most recently published by the AIR Commercial Real Estate Association, and each such Guarantor shall have the same obligations as Lessee under this Lease.
- 37.2 **Default.** It shall constitute a Default of the Lessee if any Guarantor fails or refuses, upon request to provide: (a) evidence of the execution of the guaranty, including the authority of the party signing on Guarantor's behalf to obligate Guarantor, and in the case of a corporate Guarantor, a certified copy of a resolution of its board of directors authorizing the making of such guaranty, (b) current financial statements, (c) an Estoppel Certificate, or (d) written confirmation that the guaranty is still in effect.
- 38. **Quiet Possession.** Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.
- 39. Options. If Lessee is granted an Option, as defined below, then the following provisions shall apply:
- 39.1 **Definition. "Option"** shall mean: (a) the right to extend the term of or renew this Lease or to extend or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase or the right of first refusal to purchase the Premises or other property of Lessor.
- 39.2 **Options Personal To Original Lessee.** Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting.
- 39.3 **Multiple Options.** In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised.

### 39.4 Effect of Default on Options.

(a) Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent is unpaid (without regard to whether notice thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given 3 or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period immediately preceding the exercise of the Option.

- (b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a).
- (c) An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.
- 40. **Multiple Buildings.** If the Premises are a part of a group of buildings controlled by Lessor, Lessee agrees that it will abide by and conform to all reasonable rules and regulations which Lessor may make from time to time for the management, safety, and care of said properties, including the care and cleanliness of the grounds and including the parking, loading and unloading of vehicles, and to cause its employees, suppliers, shippers, customers, contractors and invitees to so abide and conform. Lessee also agrees to pay its fair share of common expenses incurred in connection with such rules and regulations.

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- 41. **Security Measures.** Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties.
- 42. **Reservations.** Lessor reserves to itself the right, from time to time, to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, and to cause the recordation of parcel maps and restrictions, so long as such easements, rights, dedications, maps and restrictions do not unreasonably interfere with the use of the Premises by Lessee. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate any such easement rights, dedication, map or restrictions.
- 43. **Performance Under Protest.** If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay.

### 44. Authority; Multiple Parties; Execution.

- (a) If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each party shall, within 30 days after request, deliver to the other party satisfactory evidence of such authority.
- (b) If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.
- (c) This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.
- 45. **Conflict.** Any conflict between the printed provisions of this Lease and typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.
- 46. **Offer.** Preparation of this Lease by either Party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.
- 47. **Amendments.** This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.
- 48. Waiver of Jury Trial. THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.
- 49. **Mediation and Arbitration of Disputes.** An Addendum requiring the Mediation and/or the Arbitration of all disputes between the Parties and/or Brokers arising out of this Lease.  $\Box$  is not attached to this Lease.
- 50. Americans with Disabilities Act. Since compliance with the Americans with Disabilities Act (ADA) is dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee's use of the Premises requires modifications or additions to the Premises in order to be in ADA compliance, Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

### 51. Base Rent Schedule.

Months 1-12: \$19,507.00/Month/NNN Months 13-24: \$20,092.21/Month/NNN Months 25-36: \$20,694.98/Month/NNN

52. **Tenant Improvements:** Lessor will provide to Lessee a fifteen thousand dollar (\$15,000.00) allowance for the replacement of the exterior window weather stripping/caulking around the building windows. It will be Lessee's responsibility to hire the contractor and ensure the completion of the work.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

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<u>ATTENTION:</u> NO REPRESENTATION OR RECOMMENDATION IS MADE BY THE AIR COMMERCIAL REAL ESTATE ASSOCIATION OR BY ANY BROKER AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES. THE PARTIES ARE URGED TO:

- 1. SEEK ADVICE OF COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.
- 2. RETAIN APPROPRIATE CONSULTANTS TO REVIEW AND INVESTIGATE THE CONDITION OF THE PREMISES. SAID INVESTIGATION SHOULD INCLUDE BUT NOT BE LIMITED TO: THE POSSIBLE PRESENCE OF HAZARDOUS SUBSTANCES, THE ZONING OF THE PREMISES, THE STRUCTURAL INTEGRITY, THE CONDITION OF THE ROOF AND OPERATING SYSTEMS, AND THE SUITABILITY OF THE PREMISES FOR LESSEE'S INTENDED USE.

<u>WARNING:</u> IF THE PREMISES IS LOCATED IN A STATE OTHER THAN CALIFORNIA, CERTAIN PROVISIONS OF THE LEASE MAY NEED TO BE REVISED TO COMPLY WITH THE LAWS OF THE STATE IN WHICH THE PREMISES IS LOCATED.

The parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

| Executed at: ILLEGIBLE                  | Executed at: Carlsbad                                     |
|---|---|
| on 2-16-12                              | On: 2/14/12   |
| By LESSOR:                              | By LESSEE:  |
| Barco Inv. Inc.                         | Mardx Diagnostics, a wholly owned subsidiary of Trinity E |
| By: /s/ MICHAEL CASTLIE                 | By: /s/ IAN WOODWARDS                                     |
| Name Printed: MICHAEL CASTLIE           | Name Printed: IAN WOODWARDS                               |
| Title: V.P. BARCO INC                   | Title: CEO Mardx Diagnostics                              |
| By:                                     | By:   |
| By: Name Printed:                       | By: Name Printed:   |
| Title:                                  | Title:  |
| Address:                                | Address: 5919 Farnsworth Court                            |
|   | Carlsbad, CA 92008  |
| Telephone: ()                           | Telephone: (7 60) 929-0500                                |
| Facsimile: ()                           | Facsimile: ()   |
| Federal ID No                           | Federal ID No.  |
| BROKER:                                 | BROKER:   |
| Cassidy Turley BRE Commercial           |   |
| Attn: Kent Moore (CA Lic. 00933805)     | Attn:   |
| Title:                                  | Title:  |
| Address: 1000 Aviara Parkway, Suite 100 | Address:  |
| Carlsbad, CA 92011                      |   |
| Telephone: (760) 431-4224               | Telephone: ()   |
| Facsimile: (760) 454-3869               | Facsimile: ()   |
| Federal ID No.                          | Federal ID No.  |

NOTE: These forms are often modified to meet the changing requirements of law and industry needs. Always write or call to make sure you are utilizing the most current form: AIR COMMERCIAL REAL ESTATE ASSOCIATION, 700 So. Flower Street, Suite 600, Los Angeles, California 90017. (213) 687-8777. Fax No. (213) 687-8616

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Moore\5919FarnsworthCt-Mardx-STLN3

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### OPTION(S) TO EXTEND STANDARD LEASE ADDENDUM

Dated February 13, 2012

By and Between (Lessor) Barco Inv. Inc.

**By and Between (Lessee)** Mardx Diagnostics, a wholly owned subsidiary of Trinity BioTech

Address of Premises: 5919 Farnsworth Court Carlsbad, California

Paragraph 53

# A. OPTION(S) TO EXTEND:

Lessor hereby grants to Lessee the option to extend the term of this Lease for 1 additional 36 month period(s) commencing when the prior term expires upon each and all of the following terms and conditions:

- (i) In order to exercise an option to extend, Lessee must give written notice of such election to Lessor and Lessor must receive the same at least 6 but not more than 9 months prior to the date that the option period would commence, time being of the essence. If proper notification of the exercise of an option is not given and/or received, such option shall automatically expire. Options (if there are more than one) may only be exercised consecutively.
- (ii) The provisions of paragraph 39, including those relating to Lessee's Default set forth in paragraph 39.4 of this Lease, are conditions of this Option.
- (iii) Except for the provisions of this Lease granting an option or options to extend the term, all of the terms and conditions of this Lease except where specifically modified by this option shall apply.
- (iv) This Option is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and without the intention of thereafter assigning or subletting.
- (v) The monthly rent for each month of the option period shall be calculated as follows, using the method(s) indicated below: (Check Method(s) to be Used and Fill in Appropriately)

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the Base Rent shall be adjusted by the change, if any, from the Base Month specified below, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for (select one): 

CPI W (Urban Wage Earners and Clerical Workers) or CPI U (All Urban Consumers), for (Fill in Urban Area):

# All Items (1982 1984 100), herein referred to as "CPI".

b. The monthly rent payable in accordance with paragraph A.I.a. of this Addendum shall be calculated as follows: the Base Rent set forth in paragraph 1.5 of the attached Lease, shall be multiplied by a fraction the numerator of which shall be the CPI of the calendar month 2 months prior to the month(s) specified in paragraph A.I.a. above during which the adjustment is to take effect; and the denominator of which shall be the CPI of the calendar month which is 2 months prior to (select one):  $\Box$  the first month of the term of this Lease as set forth in paragraph 1.3 ("Base Month") or  $\Box$  (Fill in Other "Base Month"):

The sum so calculated shall constitute the new monthly rent hereunder, but in no event, shall any such new monthly rent be less than

the rent payable for the month immediately preceding the rent adjustment.

e. In the event the compilation and/or publication of the CPI shall be transferred to any other governmental department or bureau or agency of shall be discontinued, then the index most nearly the same as the CPI shall be used to make such calculation. In the event that the Parties cannot agree on such alternative index, then the matter shall be submitted for decision to the American Arbitration Association in accordance with the then rules of said Association and the decision of the arbitrators shall be binding upon the parties. The cost of said Arbitration shall be paid equally by the Parties.

| ☐ H. Market Rental Value Adjustment(s) (MRV) |
|--|
| a. On (Fill in MRV Adjustment Date           |
| <del>(s))</del>                              |
|  |

the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows:

1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the new MRV will be on the adjustment date. If agreement cannot be reached, within thirty days, then:

(a) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the Parties, or

(b) Beth Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:

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(i) Within 15 days thereafter, Lessor and Lessee shall each select an  $\Box$  appraiser or  $\Box$  broker ("Consultant" - check one) of their choice to act as an arbitrator. The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.

(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Premises is, and whether Lessor's or Lessee's submitted MRV is the closest thereto. The decision of a majority of the arbitrators-shall be binding on the Parties. The submitted MRV which is-determined to be the closest to the actual MRV shall thereafter be used by the Parties.

(iii) If either of the Parties fails to appoint an arbitrator within the specified 15 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, ie. the one that is NOT the closest to the actual MRV.

2) Notwithstanding the foregoing, the new-MRV shall not be less than the rent payable for the month immediately preceding the rent adjustment.

b. Upon the establishment of each New Market Rental Value:

1) the new MRV will become the new "Base Rent" for the purpose of calculating any further Adjustments, and

2) the first month of each Market Rental Value term shall become the new "Base Month" for the purpose of calculating any further Adjustments.

### **III. Fixed Rental Adjustment(s) (FRA)**

The Base Rent shall be increased to the following amounts on the dates set forth below:

| On (Fill in FRA Adjustment Date(s)): | The New Base Rent shall be: |  |  |
|--------------------------------------|-----------------------------|--|--|
| July 1, 2015                         | \$21,315.83                 |  |  |
| July 1, 2016                         | \$21,955.30                 |  |  |
| July 1, 2017                         | \$22,613.96                 |  |  |

#### **B. NOTICE:**

Unless specified otherwise herein, notice of any rental adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

## C. BROKER'S FEE:

The Brokers shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the Lease.

NOTICE: These forms are often modified to meet changing requirements of law and industry needs. Always write or call to make sure you are utilizing the most current form: AIR Commercial Real Estate Association, 800 W 6th Street, Suite 800, Los Angeles, CA 90017. Telephone No. (213) 687-8777. Fax No.: (213) 687-8616.

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#### SUBLEASE AGREEMENT

THIS SUBLEASE AGREEMENT, made and entered into on December 1, 2007 by and between 60 PINEVIEW LLC, organized and existing under and by virtue of the laws of the state of New York having its principal office at 60 Pineview Drive, Amherst, New York 14228 (the "Sublessor") and IMMCO DIAGNOSTICS, INC., organized and existing under and by virtue of the laws of the State of New York with its address at 60 Pineview Drive, Amherst, New York 14228 (the "Sublessee").

### **RECITALS**

- A. Pursuant to that certain Amended and Restated Lease Agreement dated as of February 28, 2001 (the "Lease Agreement"), Sublessor leases from the Amherst Industrial Development Agency (the "Agency") certain property located at 60 Pineview Drive, Amherst, New York 14228 (the "Property").
- B. Sublessor and the Agency entered into the Lease Agreement in connection with a Bond Inducement (the "Bond Inducement") for the construction of the building containing 15, ZOQ rentable square feet (the "Building") on the Property, pursuant to which the Agency issued and sold Industrial Development Bonds ("Bonds") ("Bond Financing") and in connection therewith acquired title to the Property and leased it and the Building to Sublessor.
- C. Sublessor desires to lease to Sublessee and Sublessee desires to hire from Sublessor the Building and the Property, on the terms and conditions set forth herein.
- NOW, THEREFORE, in consideration of the foregoing and the representations and agreements contained in the Sublease Agreement, the parties agree as follows:
- 1. Leased Premises. Sublessor hereby leases to Sublessee and Sublessee hires from Sublessor the premises located at 60 Pineview Drive, Amherst, New York (the "Leased Premises"), together with all of Sublessor's right, title and interest in and to all other improvements situated thereon and all easements, rights of way, licenses, agreements, privileges, hereditaments and appurtenances, if any, inuring to the benefit of such premises, upon the terms and conditions set forth in this Sublease Agreement. The Leased Premises are more particularly described on Exhibit A attached hereto and made apart hereof.
- 2. Term. The term of this Sublease Agreement shall be for One Hundred Twenty (120) months, which shall commence on December 1, 2007, and shall terminate on November 30, 2017. In the event that the Lease Agreement expires or is terminated prior to the expiration of the term of this Sublease Agreement, (i) this Sublease Agreement shall automatically become a direct lease between Sublessee and Sublessor, the holder of the Bonds (the "Bondholder"), the Agency or any other person or entity which may become the owner of the Property; (ii) such owner shall succeed to and assume and agree to perform all of the Sublessor's covenants, agreements and obligations under this Sublease Agreement and (iii) Sublessee's possession of the

Leased Premises will not be disturbed during the term of this Sublease Agreement. This Sublease shall continue in full force and effect in the event the Sublessor becomes the owner of the Property or in the event the Sublessor is no longer the Sublessor of the Property. In the event the Sublessor becomes the owner of the Property, this Sublease Agreement shall automatically and without any further action become the primary lease agreement. In such event, all references herein to "Sublessor" shall become "Landlord," all references to "Sublessee" shall become "Tenant," and all references to the Lease Agreement, Agency, Bond Inducement, Bonds, Bond Financing, Bondholder, Mortgage and Security Documents shall have no further force and effect.

3. Use. Sublessee's Use of the Premises. Sublessee shall occupy, use and operate the Leased Premises only for laboratory and office space. Sublessee acknowledges and agrees that the Premises will not be used for the retail sale of any goods or services. Sublessee will use the-Premises in a careful, safe and proper manner. Sublessee will not use or permit the Premises to be used or occupied for any purpose or in any manner prohibited by any applicable laws. Sublessee will not damage or suffer or permit damage to be committed in, on, or about the Premises, reasonable wear and tear excepted.

Sublessee shall at its own cost and expense promptly observe and comply in all material respects with all laws, ordinances, requirements, orders, directives, rules and regulations of the federal, state, county, municipal or town governments and of all governmental authorities affecting its occupancy of and conduct of its business at the Lease' Premises, Whether the same are in force at the commencement of the term of this Sublease Agreement or may in the future be passed, enacted or directed. Sublessor acknowledges that all construction performed hereunder shall comply in all material respects with all laws, ordinances, requirements, orders, directives, rules and regulations of the federal, state, county, municipal or town governments and of all governmental authorities affecting its occupancy of and conduct of its business at the Leased Premises, whether the same are in force at the commencement of the term of this Sublease Agreement or may in the future be passed, enacted or directed.

#### 4. Rent.

- a. As used herein, a Lease Year shall be each twelve-month period commencing on the date of the commencement of the term hereof or any anniversary thereof. If the term of this Sublease Agreement commences after January 1", the period from the commencement date through December 31st of that year shall be known as the "Initial Partial Lease Year" with all references to a Lease Year inclusive of the Initial Partial Lease Year and the Final Partial Lease Year.
- b. Sublessee covenants, guarantees and agrees to pay to Sublessor the rents as shown Exhibit C per square foot, per annum payable in equal monthly installments in advance without notice, demand, offset or deduction on the first day-of each month of the term.

- c. No payment by Sublessee or receipt by Sublessor of a lesser amount than that provided herein shall be deemed to be other than on account of the earliest stipulated rent; nor shall any endorsement or statement on any check or any letter accompanying any check or payment as rent be deemed as accord and satisfaction, and Sublessor may accept such check or payment without prejudice to Sublessor's right to recover the balance of such rent or pursue any other remedy provided herein.
- d. Late Pament. In the event that any payment of rent due hereunder shall not be paid by the fifth day after which it is due, a late charge of four (4%) percent for each dollar not paid may be charged by Sublessor with additional late fees of two (2%) percent of the outstanding balance per month beginning fifteen (15) days after the due date of any payment. This charge shall be in addition to and not in lieu of any other remedy Sublessor may have and is in addition to any reasonable fees and charges of any agents or attorneys Sublessor may employ as a result of any default in the payment of rent hereunder, whether authorized herein or by law. Any such "late charges" if not previously paid shall, at the option of Sublessor, be added to and become part of the succeeding rent payment to be made hereunder and shall be deemed to constitute additional rent.
- e. Upon the execution of the Sublease Agreement, Sublessee shall pay to Sublessor the amount of \$0.00 as partial prepayment of the base rent for the last month of the term hereof.
- f. In the event that the term commences after the first day of a month or expires prior to the last day of a month, rent for such month shall be prorated.
  - 5. Sublessee's Pro Rata Share of Taxes, Insurance and Other Expenses.
- a. Included in the rents shown in Exhibit C are Sublessee's pro rata share of Operating Expenses as defined herein, with the first twelve (12) months of occupancy defined as the "Base Year" for purposes of calculating and charging to the Sublessee any increase in the Base Year Operating Expenses. Commencing in the third year of the Lease term, Sublandlord will be entitled to charge as additional monthly rent the amount, if any, of its pro rata share of any expected increase for such expenses over the prior year. Sublessee shall pay to the Sublessor as additional monthly rent increases in its pro rata share of the following expenses collectively defined as "Operating Expenses" beyond the Base Year expense, which is included in the lease rate schedule in Exhibit C, (i) all state and locate real estate taxes and assessments, and payments in lieu thereof, and all other charges and assessments imposed upon the Property, (ii) all common utility costs including gas, water and electric, (iii) premiums for fire, rent liability, and other insurance maintained by Sublessor pursuant to Section 13(b) hereof, (iv) all Maintenance Expenses as defined herein, and (v) the cost of all services performed by Sublessor, including those set forth in Paragraph 3 of Exhibit D. Maintenance Expenses are defined as: ordinary repairs and maintenance (but excluding structural repairs and replacement and repairs and replacement to Building system which shall be performed by Sublessor at its sole cost and expense), landscaping, snow removal, trash removal and window cleaning including the cost of

Sublessor's services as defined in Paragraph 3 of Exhibit D. Sublessor shall initiate and prosecute proceedings for an abatement to real estate taxes for the Leased Premises following the request of Sublessee. Nothing in this Sublease Agreement shall be construed as placing upon Sublessee any obligation to pay any income tax, any transfer tax or documentary stamp tax, any inheritance tax, any capital gains tax, any franchise tax or any capital stock tax.

- b. Sublessee's pro rata share increase over the Base Year amount of the items enumerated in Section 5(a) (the "Operating Expenses") shall be payable pursuant to Subsection 5(b) as follows: (i) Sublessor shall provide to Sublessee Sublessor's estimate of the aggregate amount which will be incurred by Sublessor for the enumerated items during the applicable Calendar Year and shall compare said estimated expense to the Base Year expense. Beginning with January of the Calendar Year following the Commencement Date and each January of the Term thereafter, the rent shall be adjusted to reflect the estimate of Enumerated Items excess of the Base Year applicable to the current Calendar Year. As soon as reasonably possible after the completion of each Calendar Year, or, if the method set forth in this Subsection 5(b) is in effect for only part of a Calendar Year, Sublessor shall deliver to Sublessee a statement of the aggregate amount spent by Sublessor for the Enumerated Items during such Calendar Year or applicable part thereof less the Base Year portion included in Sublessee's lease rate. If the aggregate amount paid by Sublessee exceeds its actual pro rata share of said increase, Sublessor shall credit such excess against Sublessee's estimated payments toward its pro rata share increase of the cost of the Enumerated Items for the remaining Calendar Year, or-at Sublessor's' option, shall remit such excess to Sublessee. In the event the term of this Sublease Agreement has expired or been earlier terminated, then Sublessee shall be entitled to a refund of such excess from Sublessor (net of any amounts whatsoever which Lessee may still owe to Sublessor notwithstanding such expiration or early termination) within thirty (30) days after such date or expiration or earlier termination.
- c. In the event of a Final Partial Lease Year, the amount of Sublessee's pro rata share of the Enumerated Items of the Building payable to Sublessor for such year shall be prorated.
- d. Upon ten (10) days prior written notice to Sublessor, Sublessee shall have the right to examine all of Sublessor's records, books, statements, bills and other material evidencing operating costs incurred by Sublessor. If any such examination reveals an overpayment Lessee to Sublessor, Sublessee shall have the right to credit such overpayment against rent obligations next coming due and, in the event the term of this Sublease Agreement has expired or been earlier terminated, then Sublessee shall be entitled to a refund of such excess from Sublessor (net of any amounts whatsoever which Lessee may still owe to Sublessor not with standing such expiration or early termination) within thirty (30) days after such date or expiration or earlier termination.
- 6. A Sublessor's Services. Provided that Sublessee is not in default of any of the terms, conditions or provisions contained in this Sublease Agreement, Sublessor shall, during the term of this Sublease Agreement, and subject to Sublessee's obligation to pay its pro rata share thereof in accordance with Section 5, provide, as needed, exclusive of holidays, those services described in Exhibit D, attached hereto and made a part hereof.

7. Utilities. Sublessee shall be responsible for the cost of all gas, telephone service, electricity, and other utility services, excluding water, used in or to be supplied for the Leased Premises, including any deposits for meters and/or service. Sublessor shall hot be liable or responsible for any failure of any entity to supply such service or for any loss, damage or injury caused by or related to such service and in the event of such failure the Sublessee shall not be entitled to any cessation, abatement, reduction or offset of rent.

8. Maintenance and Repairs. Any guaranties and warranties shall inure for a period of time from contractors and/or manufacturers resulting from the initial construction, thereafter, Sublessee shall, at its sole expense, be responsible for maintaining the Leased Premises in a good, orderly and safe condition and state of repair and shall, to the reasonable satisfaction of Sublessor, make all repairs required to be made thereto (except those, if any, to be made by Sublessor pursuant to Exhibit D), including, without limitation, interior and exterior window cleaning and repairs or replacements to those components of the heating system, plumbing system, water system, electrical system, 'air conditioning system and carpeting and wall coverings which are located within the Leased Premises or serve Leased Premises exclusively. Sublessee shall be responsible for cleaning the Leased Premises and depositing trash in receptacles acceptable to Sublessor. Sublessor shall enter into a maintenance contract for the maintenance and repair of the heating, plumbing, water, electrical, and air conditioning systems. Sublessee shall also repair, at its sole expense, any damage to the Property, the Leased Premises, the Building or any appurtenances thereto caused by the misuse or negligence of Sublessee, its employees or invitees. Sublessee agrees to replace all broken glass with glass of the same size and quality of that broken. Sublessee shall not be entitled to any partial or total abatement of rent for periods during which repairs are required to be made, whether such repairs are the responsibility of Sublessor or Sublessee; provided, however, if the Leased Premises shall, for a period of three (3) consecutive business days, be untenantable (e.g., shall lack any service or operation which Sublessor is required to provide hereunder the lack of which adversely affects the continued operation in the ordinary course of Lessee's business),' then all fixed rent and additional rent and other amounts payable by Sublessee hereunder shall thereafter be abated in proportion to such untenantability until the day such service or operation is completely restored. Sublessee shall have no right of access to the roof of the Premises or the Building and shall not install, repair, place or replace any aerial, fan, air conditioner or other device on the roof of the Premises or the Building without the prior written consent of Sublessor, which will not be unreasonably withheld or delayed. Any aerial, fan, air conditioner or device installed without such written consent shall be subject to removal, at Sublessee's expense, without notice at any time. Sublessor shall repair at Sublessee's expense, any damage to the Building or roof resulting from the installation, repair, use, or replacement of any such air conditioner or other device. Sublessee may install, with Sublessor's consent, which shall not be unreasonably Withheld, antennas and microwave antennas so long as Sublessor is held harmless in the use and construction of the antennas and in the event the installation and use voids or impairs the roof warranty. Sublessee shall hold Sublessor harmless and be responsible for all costs and expenses.

- 9. Access to Leased Premises. Sublessee agrees that Sublessor, or Agency and the Bondholder, shall have such rights to enter upon the Leased Premises during normal business hours and upon giving Sublessee reasonable advance notice, including rights of ingress and egress, as shall be necessary to enable Sublessor, the Agency and the Bondholder to exercise its powers, rights, duties and obligations as are set forth in this Sublease Agreement and the Lease Agreement. Sublessor shall further have the right to enter into and grant licenses the right to enter the Leased Premises during Sublessee's normal business hours, or in the case of a bona fide emergency at any time, upon reasonable notice to Sublessee under the circumstances, for any purpose which the Sublessor may deem necessary, including, without limitation, for making structural repairs to the Building or the Leased Premises or any other repairs for which the Sublessor may be responsible, or for exhibiting the Leased Premises to prospective purchasers, mortgagees or tenants. In all cases of access as provided herein, such ingress and egress will be conducted so as to minimize interference with Sublessee's use of the Leased Premises and its conduct of business therein.
- 10. Quiet Enjoyment. Sublessor covenants that so long as Sublessee is not in default hereunder, it shall and may peaceably and quietly have, hold and enjoy the Leased Premises during the term of this Sublease Agreement and any renewal extension hereof, subject to the provisions hereof, of the Lease Agreement, an Indenture of Trust which shall serve the Bond (the "Mortgage") and all other documents used in connection with the Bond Financing (the "Security Documents") and any other mortgages, easements, restrictions or agreement to which the Leased Premises are now or shall hereinafter be subject.

#### 11. Alterations.

a. Sublessee shall make no structural alterations, additions or improvements in or to the Leased Premises without Sublessor's prior written consent which consent shall not be unreasonably withheld, conditioned or delayed. In the event that Sublessee makes any alterations, additions or improvements, they shall be made at Sublessee's sole expenses, and Sublessee shall, before making any such installations, alterations, additions or improvements, obtain all permits, approvals and certificates required by any governmental body or agency, and certificates of final approval thereof, and shall deliver promptly duplicates of all such permits, approvals and certificates to Sublessor. Sublessee agrees to carry, such workers' compensations, general liability, personal and property damage insurance as Sublessor may require subject to Paragraph 13 below. Sublessee shall compensate Sublessor for Sublessor's reasonable out of pocket expenses in reviewing any plans and/or specifications for any proposed alteration, addition, or improvement, whether or not Sublessor consents to the making of same if Sublessor's consent is required. Sublessee shall have the right, at any time and from time to time during the term of this Sublease Agreement, without notice to Sublessor and without the obligation to obtain Sublessor's consent or approval, or the consent or approval of the Agency, the Bondholder or any other third party, to make non-structural alterations, additions and improvements to the Leased Premises so long as the same does not (i) damage the basic structure '\_of the building or (ii) materially decrease the value of the Leased Premises as a whole.

b. Sublessee has no authority or power to cause or permit any lien or encumbrance, whether created by act of Sublessee, operation of law or otherwise, to be attached to or be placed upon the Leased Premises. Any lien or claim of lien filed against the Lease Premises for work claimed to have been done for, or for materials claimed to have been furnished to, shall, within twenty (20) days thereafter, be discharged by Sublessee, or, at the discretion of Sublessee, be bonded pursuant to [the New York Lien Law, at Sublessee's expense (but only if permitted by Mgrtgage the "Security Documents and any other mortgage which may encumber the Property). If Sublessee fails to discharge (or, if permitted, bond) any such liens, then Sublessor may, at its option, bond or discharge such lien, and the costs incurred by it in such discharge or bonding shall be due from Sublessee on demand and shall bear interest at ten Percent (10%) per annum.

12. Liability. Sublessee shall defend, indemnify and hold harmless Sublessor, the Bondholder and the Agency and its members, agents and employees from and against all causes of action, claims, damages, losses and expenses, including reasonable attorneys fees, resulting from or arising out of bodily injury or death, or damage to or destruction of property, or damage to the business of Sublessee in connection with Sublessee's use or occupancy of the Leased Premises or Property and caused by any act or negligence of Sublessee or its agents, contractors, employees, invitees or licensees, whether the same be asserted by third parties, Sublessee or Sublessee's agents, contractors, employees, invitees or licensees. The foregoing shall hold true except as arising out of the gross negligence or willful misconduct of the Sublessor, the Agency, the Bondholder and each of their respective partners, officers, agents and/or employees.

Moreover, the Sublessor, the Bondholder or the Agency shall not be liable for any damage or injury to the Leased Premises, to any property therein, to Sublessee, its agents, contractors, employees, invitees or licenses, arising from any use or condition of the Leased Premises or Property including, without limitation, any injury or damage to persons or property resulting from fire, explosion, collapse, falling plaster, steam, gas, electricity, water, rain or snow leaks from any pat of the Leased Premises or from the pipes, sprinklers, appliances or plumbing works or from the roof, street or subsurface or from any other place or by any dampness or by any other cause whatsoever and Sublessee shall defend, indemnify and hold Sublessor harmless from and against any and all causes of action, claims, damages, losses and expenses, including reasonable attorneys fees, caused by any act or negligence of Sublessee's agents, contractors, employees, invitees or licensees in connection therewith, except for damage or injury to the Leased Premises caused by the gross negligence or willful misconduct of the Sublessor, the Agency, the Bondholder and each of their respective partners, officers, agents and/or employees.

#### 13. Insurance.

a. Sublessee shall, at its sole option and expense, at all times during the term of this Sublease Agreement, either self-insure or maintain in force a policy or policies of (i) comprehensive public liability insurance, including liability for both bodily injury and property damage, against claims for loss of life, bodily injury and property damage occurring in, on or

about the Lease Premises or with respect to the operation of Sublessee in the Lease Premises, in which the limit of general liability coverage shall not be less than two million dollars (\$2,000,000) for combined single bodily injury: death, and property damage liability and (ii) fire, casualty and extended risk insurance covering Sublessee's property and inventory used or stored at the Leased Premises- If the Sublessee elects the Insurance Option, each policy of insurance shall be written by one or more insurance companies licensed to do business in the State of New York, shall name Sublessor, the Bondholder and the Agency as additional insured and as a certificate holder thereof, with express waivers and subrogation against Sublessor and the Bondholder and the Agency and shall provide that if the insurers cancel such insurance for any reason whatsoever, or the same is allowed to lapse or expire, or there be any reduction in amount, or any material change is made in the coverage, such cancellation, lapse, expiration, reduction of change shall not be effective as to Sublessor, the Bondholder and the Agency until thirty (30) days after receipt by the Sublessor, the Bondholder and the Agency of written notice thereof. A certificate of said insurance shall be delivered to Sublessor on or before the commencement of the term of this Sublease Agreement, and certificates with respect to all renewals, extensions or replacements thereof shall thereafter be furnished to Sublessor, the Bondholder and the Agency at least ten (10) days prior to the expiration or cancellation of any policies which they replace. Sublessee shall name Bondholder, Agency and Sublessor as additional insureds on all policies of liability insurance.

b. Subject to Sublessee's obligation to reimburse for Sublessee's pro rata share of the cost thereof in accordance with Section 5, Sublessor shall maintain during the term of this Sublease Agreement insurance policies providing coverage for (1) fire, casualty and extended risk for the Building for the full replacement value thereof, (ii) liability of Sublessor for personal injury and property damage caused by occurrences on or connected with the property, (iii) loss of rent by Sublessor during period for which rent is abated hereunder because bf fire or casualty damage, and (iv) such other insurance as the Agency or Bondholder may require.

14. Fire and Other Casual. In the event that the Leased Premises shall be rendered wholly untenantableby fire or other casualty, the Sublessor shall be entitled to the proceeds of all applicable insurance maintained by Sublessee, and may, at its option, (a) terminate the Sublease Agreement by giving Sublessee written notice thereof within thirty (30) days from the date of said damage or destruction, or (b) repair or replace the Leased Premises to substantially the same condition as prior to the damage or destruction to the Leased Premises, but Sublessor shall have no obligation to repair or replace any improvements, alterations or additions made by Sublessee. If the Sublessor fails to commence to repair the damage or destruction within ninety (90) days from the date of such damage or destruction or within thirty (30) days from the receipt of the insurance proceeds, whichever is later, or if the Leased Premises shall not-have been substantially replaced or repaired within one hundred eighty (180) days after date of damage or destruction or ninety (90) days after receipt of insurance proceeds whichever is later or if the casualty is of such a substantial nature that it includes more than 25% of the building area of the Leased Premises, Sublessee shall have the option, to be exercised by notice in writing to the Sublessor within thirty (30) days after such taking, to terminate this Sublease Agreement, Sublessee may, at its option, terminate this Sublease Agreement by giving written notice to Sublessor within fifteen (15) days after Sublessor's failure to commence or substantially complete said repairs Within the applicable time period. The rent herein required to be paid shall abate during the period of such untentability.

If the Leased Premises shall be damaged in part by fire or other casualty, but still remain partially tenantable, Sublessor shall repair the Leased Premises to substantially the same condition as prior to the damage to the extent of the proceeds of insurance available to Sublessor but Sublessor shall have no obligation to repair or replace any improvements, alterations or additions made by Sublessee- Sublessor shall commence repair of the damage or destruction within ninety (90) days from the date of occurrence or thirty (30) days from receipt of such insurance proceeds, whichever is later. During the period of such repairs and restorations, this Sublease Agreement shall continue in full force and effect, and Sublessee shall be required to pay rent herein reserved, abated by the percentage of area of the Lease Premises, to the extent that such abatement is covered by Sublessor's rent insurance (if any). If the portion remaining does not allow Sublessee to operate its business and Sublessee vacates the property, Sublessee shall be entitled to a full rent abatement.

In the event that any damage or destruction occurs during the last twelve (12) months of the initial term of this Sublease Agreement or any extension of the term, to the extent of fifty percent (50%) or more of the insurable value of the Leased Premises, Sublessor may, at its option, terminate this Sublease Agreement by giving notice of such election to Sublessee within thirty (30) days after such damage or destruction. In such event, Sublessor shall receive the proceeds of the Sublessee's insurance policies without obligations to rebuild or restore the Leased Premises, and Sublessee shall execute any waiver, which may be required of it by any insurer or Sublessor.

15. Eminent Domain. In the event that all or any portion of the Leased Premises shall be taken by any governmental authority under the exercise of its right of eminent domain or similar right (or by act in lieu thereof), all right, title and interest in and to any award granted (or sums paid in lieu thereof) shall belong entirely to Sublessor, and Sublessee hereby assigns to Sublessor all of its interest, title or claim, if any, in and to such award (or sums paid in lieu thereof), including but not limited to, any part of such award attributable to Sublessee's leasehold interest, if any. Nothing contained herein shall preclude Sublessee from seeking a separate award from the condemning authority for its moving expense and loss of any trade fixtures. In the event of a partial taking, rent shall be reduced as of the date of such taking by an amount that shall equitably reflect the portion of the property taken. If the taking is of such a substantial nature that (a) it includes more than 25% of the building area of the Leased Premises or (b) Sublessee cannot conduct its operations in the Leased Premises, Sublessee shall have the option, to be exercised by notice in writing to the Sublessor within thirty (30) days after such taking, to terminate this Sublease Agreement, or, if such taking be total, this Sublease Agreement shall terminate upon the taking. In the event that this Sublease Agreement is terminated pursuant to this Section 15, Sublessee shall not have any claim against Sublessor for the balance of the unexpired term of this Sublease Agreement If the portion remaining after such partial taking does not allow Sublessee to operate its business and Sublessee vacates the Property, Sublessee shall be entitled to a full rent abatement.

16. Subordination, Non-Disturbance and Attornment. This Sublease Agreement and Sublessee's rights under this Sublease shall be subject and subordinate to any mortgage, the Security Documents and to any other mortgage which now cucumbers or shall hereinafter encumber the Property, provided that any such subordination shall be expressly conditioned, upon the holder of any mortgage agreeing not to disturb Sublessee's rights hereunder so long as no Event of Default shall exist. This clause shall be self-operative and no further instrument of subordination need be required by any mortgagee or Sublessor. In confirmation of such subordination, however, Sublessee shall, at Sublessor's request, promptly execute any appropriate certificate or instrument that Sublessor may reasonably request. The Non-Disturbance and Attornment Agreement is provided herein and attached hereto as Exhibit F.

17. Estoppel Certificate. Each of Sublessee and Sublessor shall, from time to time, upon not 'less than fifteen (15) days prior to written request by the other party, execute, acknowledge and deliver to the requesting party a written Estoppel Certificate in such form as the requesting party may reasonably require, certifying that this Sublease Agreement is unmodified and in fiill force and effect (or if there have been modifications that the same is in full force and effect as modified and stating the modifications), that dates to which the rent and other charges have been paid, whether or not to the best of certifying party's knowledge, the requesting party is in default hereunder (and if so, specifying the nature of the default), and such other matters as may be required by the requesting party or the holder of any mortgage to which the Leased Premises are subject, it being intended that any such statement delivered pursuant to this Section 17 may be relied upon by a prospective purchaser of Sublessor's interest or mortgagee of Sublessor's interest or assignee of any mortgage or deed of trust upon Sublessor's interest in the Leased Premises or assignee of Sublessee's interest hereunder.

#### 18. Default.

a. Any one or more of the following events shall constitute and "Event of Default" hereunder: (i) if Sublessee fails to pay any installment of rent or additional rent within fifteen (15) days after it is due and within fifteen (15) days after written notice is given to Sublessee; (ii) if Sublessee fails to remedy a default by it with respect to any of the other covenants, conditions and agreements contained herein or in any rider, exhibit or other addendum hereto, Within forty-five (45) days after notice thereof and, in the event of any such alleged default in the obligation of Sublessee under this Sublease pursuant to clause (ii) of this paragraph, Sublessor will deliver to Sublessee within three (3) days of the occurrence, written notice listing the reasons for Sublessee's default and Sublessee wilhhave forty-five (45) days. following receipt of such notice to cure such alleged default or, in the event the alleged default cannot reasonably be cured within a forty-five (45) day period, to commence action and proceed diligently to cure such alleged default; or (iii) if a petition in bankruptcy is filed by Sublessee or if proceedings under any bankruptcy or debtor's relief law is filed are taken by or against Sublessee, or if Sublessee becomes insolvent or admits in writing its inability to pay its debts as

they become due, or if proceedings are taken by or against Sublessee seeking the appointment of a receive or similar relief, provided that in the event an involuntary petition is so"filed against Sublessee, there shall be no Event of Default unless the same is not dismissed within sixty(60) days after its filing.

b. If an Event of Default shall occur, Sublessor may, in addition to any other right or rights which Sublessor may have, serve a written three (3) days' notice of cancellation of the Sublease Agreement upon Sublessee, and upon the expiration of said three (3) days, this Sublease Agreement and the term hereunder shall end and expire as fully and completely as if the date of expiration of such three (3) day period were the day herein definitely fixed for the end and expiration of this Sublease Agreement and the term thereof, and Sublessee shall then quit and surrender the Subleased Premises to Sublessor, but Sublessee shall remain liable as hereinafter provided. If the three (3) day notice of cancellation shall have been given, and the term shall expire as aforesaid, or if any execution or attachment shall be issued against Sublessee or any of Sublessee's property where upon the Leased Premises shall be taken or occupied by someone other than Sublessee, then and in either of such events Sublessor may, without notice, re-enter the Leased Premises and dispossess Sublessee and the legal representative of Sublessee or other occupant of the Lease Premises by summary proceedings or otherwise, and remove their effects using such force for such purposes as may be necessary, without being liable for prosecution, without being deemed guilty of any manner of trespass, and without prejudice to any remedies for arrears of rent or other amounts payable under this Sublease Agreement or as a result of any preceding breach of covenants or conditions; and hold the Leased Premises as if this Sublease Agreement had not been made, but Sublessee shall remain liable hereunder as hereinafter provided.

c. In case of any such default, re-entry, expiration and/or dispossession by summary proceedings otherwise, (1) all rent, additional rent and other sums to be paid by Sublessee pursuant to this Sublease Agreement shall become due thereupon and paid up to the time of re-entry, dispossession and/or expiration, together with such reasonable expenses as Sublessor may incur for legal expenses, attorneys' fees, brokerage, and/or putting the Leased Premises in good order, (2) Sublessor may re-let the Leased Premises or any part or parts thereof, either in the name of Sublessor or otherwise, for a term or terms, which may at Sublessor's option be less than or exceed the period which would otherwise have constituted the balance of the term of this Sublease Agreement and may grant concessions of free rent and/or (3) Sublessee or the legal representatives of Sublessee shall also pay Sublessor as liquidated damages for the failure of Sublessee to observe and perform Sublessee's covenants herein contained, any deficiency between the rents and other sums hereby reserved and/or covenanted to be paid and the net amount, if any, of the rents collected on account of the lease or leases of the Lease Property for each month of the period which would otherwise have constituted the balance of the term of this Sublease Agreement. In computing such damages there shall be added to the said deficiency such reasonable expenses as Sublessor may incur in connection with re-letting, such as legal expenses, attorneys fees brokerage and for keeping the Leased Premises in good order. Sublessor, at Sublessor's option, may make such alterations, repairs, decorations and replacements as are reasonably necessary or desirable for the purpose of re-letting the Leased

Premises; and the making of such alterations and/or decorations shall not operate or be construed to release Sublessee from liability hereunder as aforesaid. Sublessor agrees to use commercially reasonable efforts to mitigate its damages from an Event of Default but neither the failure or refusal of Sublessor to re-let the Leased Premises or any part of parts thereof nor, in the event that the Leased Premises are re-let, the failure of Sublessor to collect the rent under such re-letting shall release or affect Sublessee's liability for damages, and Sublessor shall not in any way be liable for same, but, if Sublessor fails to collect such rent, Sublessee is hereby authorized to collect the same and apply the same to any indebtedness owing to Sublessor. Any such damages shall be paid in monthly installments by Lessee on the rent days specified in this Sublease Agreement and any suit brought to collect the amount of deficiency for any month or months shall not prejudice in any way the rights of Sublessor to collect the deficiency for any subsequent month or months by a similar proceeding. Any such action may be an action for the full amounts of all rents then due or to be due to, and all damages then suffered or to be suffered by Sublessor. Mention in this Sublease Agreement of any particular remedy shall not preclude Sublessor from resorting to any other remedy, in law or in equity. The foregoing remedies and rights of Sublessor are cumulative. Sublessee expressly waives any and all rights or redemption granted by or under any present or future laws in the event of Sublessee's eviction or dispossession for any cause. All costs incurred by Sublessor in collecting any amounts and damages owing by Sublessee pursuant to the provisions of this Sublease or to enforce any provision of this Sublease, including reasonable attomeys' fees from the date any such matter is turned over to an attorney, whether or not one or more actions are commenced by Sublessor wil also be recoverable by Sublessor from Sublessee.

- d. Notwithstanding anything to the contrary herein, so long as Vijay Kumar is the Chief Executive Officer of Sublessee, Sublessor shall not be entitled to declare or allege that an Event of Default has occurred and shall not be entitled to exercise its remedies under this Section 18.
- 19. Failure to Insist on Strict Performance. The failure of Sublessor to insist, if any one or more instances, upon a strict performance of any covenant term, provision or agreement of this Sublease Agreement shall not be construed as a waiver or relinquishment thereof, but the same shall continue and remain in full force and effect notwithstanding any law, usage or custom to the contrary. The receipt by Sublessor of rent with knowledge of the breach of any covenant or agreement hereunder shall not be deemed a waiver of the rights of Sublessor with respect to such breach, and no waiver by Sublessor of any provision hereof shall be deemed to have been made unless expressed in writing and signed by the Sublessor.
  - 20. Surrender of the Leased Premises.
- a. Sublessee shall, upon the termination of this Sublease Agreement, by lapse of time or otherwise, returnthe Leased Premises to Sublessor in as good condition as when received, loss by fire or other unavoidable casualty and reasonable wear and tear excepted. It is understood and agreed that the exception made as to "loss by fire or other unavoidable casualty" does not include damages, fires or casualties caused or contributed to by the act or neglect of Sublessee, its servants, agents, employees, invitees or licensees, and not compensated for by insurance. Sublessee shall surrender all keys to the Leased Premises and inform Sublessor of all combinations on locks,- safes and vaults therein.

- b. All installations, additions, fixtures and improvements in or upon the Leased Premises, whether placed there by Sublessor or Sublessee, including, without limitation, paneling, decoration, partitions, railings, carpeting and flooring, shall become the property of Sublessor and shall remain upon the Leased Premises at the termination of this Sublease Agreement without compensation, allowance or credit to the Sublessee; provided, however, that Sublessee shall have the option of removing any trade fixtures which it installed in or upon the Subleased Premises and which are not subject to the Mortgage or Security Documents prior to -the termination of this Sublease Agreement, but Sublessee shall remain responsible for repairing any damaged caused to the Leased Premises by such removal. Sublessee shall have no obligation to restore the Property for improvements made to the Leased Premises at the end of the Term. Sublessee shall remove all its equipment at the end of the Term.
- c. Any furniture, equipment, machinery or movable property owned by Sublessee and/or brought onto the Subleased Premises during the Lessee's occupancy there of and not removed at the termination of the Sublease Agreement, shall be deemed to have been abandoned by Sublessee and shall without any further act by Sublessee, be conclusively deemed to have been conveyed by Sublessee to Sublessor and may be sold by Sublessor or disposed of by Sublessor as it sees fit. Any amount realized upon any such sale shall be the property of Sublessor. If Sublessor has directed Sublessee to remove any or all of such property, Sublessee shall remain liable for the cost of its removal and/or the cost of restoring the Leased Premises after such removal.

The provisions of this Section 20 shall survive the termination or expiration of this Sublease Agreement.

21. Holding Over. Should Sublessee fail to vacate the Leased Premises at the termination hereof, such holding over shall operate and be construed to be a tenancy from month to month only, at a base monthly rental equal to the base monthly rental paid for the last month of the term of this Sublease Agreement plus twenty-five percent (25%) of such amount, unless otherwise agreed in writing, plus additional rent as provided herein and otherwise subject to the conditions, obligations and provisions of this Sublease Agreement. No such holding over or payment or acceptance of rent resulting therefrom shall constitute or be deemed reconfirmation or renewal of this Sublease Agreement. Nothing in this Section 21 shall be construed as a consent by Sublessor to the possession of the Leased Premises after the expiration or termination of this Sublease Agreement. Any such holdover tenancy that has the written consent of the Sublessor may be terminated immediately by Sublessor upon thirty (30) days notice.

# 22. Expenses and Attorneys Fees.

- a. Sublessee shall pay to Sublessor as additional rent hereunder all reasonable attorneys fees and expenses and all other expenses which may be incurred by Sublessor (to the extent that same are not paid to Sublessor pursuant to any insurance policies .maintained by Sublessee in accordance with this Sublease Agreement) in enforcing any of the obligations of Sublessee under this Sublease Agreement or in any other litigation or negotiation in which Sublessor shall become involved through or because of Sublessee's use or occupancy of the Leased Premises, any action or omission of the Sublessee, or the breach of any representations, warranties, covenants or agreements of Sublessee contained in or relating to this Sublease Agreement to the extent the Sublessee is determined to be liable.
- b. Sublessor shall pay to Sublessee all reasonable attorneys fees and expenses and all other expenses which may be incurred by Sublessee (to the extent that same are not paid to Sublessee pursuant to any insurance policies maintained by Sublessor in accordance with this Sublease Agreement) in enforcing any of the obligations of Sublessor under this Sublease Agreement or in any other litigation or negotiation in which Sublessee shall become involved through or because of Sublessor's action in conjunction with the Leased Premises, any action or omission of the Sublessor, or the breach of any representations, warranties, covenants or agreements of Sublessor contained in or relating to this Sublease Agreement to the extent the Sublessor is determined to be liable.
- 23. Obligations and Sublessee. If Sublessee fails to perform any of its obligations hereunder, Sublessor may (but shall not be obligated to) perform same, in such event, Sublessee shall reimburse Sublessor for the cost thereof, and said reimbursement shall be due and payable upon demand by Sublessor and shall bear interest at the highest lawful rate. As used herein, the term "highest lawful rate" means the rate of interest as defined in Paragraph 4(d) of this Agreement.
- 24. Assignment and Subletting. Sublessee shall not, without the prior written consent of Sublessor, have the right to assign this Sublease Agreement, or sublet, or encumber the Lease Premises in whole or in part, or permit any other person or entity to occupy or use same, except that the consent of Sublessor shall not be unreasonably withheld if the Sublessee shall assign this Sublease Agreement or sublet the Leased Premises to a tenant (i) whose use will notinterfere with or undermine the character of the Property, (ii) whose principals have a business reputation which is reasonably satisfactory to Sublessor, (iii) whose financial status and capacity will provide sufficient ability to perform under its agreement with Sublessee. No attempted assignment or subletting, whether with the consent of Sublessor or in Violation of this Section 24, shall relieve the Sublessee from liability for the payment of rent or other sums due hereunder, or from being bound by any of the terms, conditions, covenants and agreements of this Sublease Agreement and any assignment or sublease in violation of this Article 24 will be void. Notwithstanding anything to the contrary contained in this Sublease Agreement, the Sublessor's Consent shall not be required for an assignment of this Sublease Agreement or a sublease of all or any portion of the Leased Premises to an entity now or hereafter affiliated with Sublessee (including a subsidiary, affiliate or controlling cbrporation) or to any entity which may result from a merger or consolidation by or with the Sublessee, or to any entity to which Sublessee or its owners is selling all or substantially all of its assets or stock.

In the event that Sublessor consents to any proposed assignment, subletting, encumbrance, or granting of a right of use or occupancy, such consent shall not be deemed to be a consent to any other or further assignment, subletting, encumbrance or granting or granting of a right of use or occupancy.

Acceptance of rent from any other person or entity shall not be deemed as a waiver of any provisions of this Sublease Agreement or to be a consent to this Sublease Agreement or to the subletting, encumbrance or use or occupancy of the Leased Premises.

- 25. Broker. Sublessee and Sublessor agree that no broker brought about this 'Sublease Agreement.
- 26. Rules and Regulations. Sublessee agrees to follow all rules and regulations set forth in Exhibit E attached hereto and such reasonable rules and regulations as,may be promulgated from time to time by Sublessor with respect to the Building (provided any such new rules and regulations shall not unreasonably interfere with Sublessee's use of the Leased Premises) and the Property in accordance with the notice provisions of this Sublease Agreement.
  - 27. Use of Parking Lot. Sublessee shall have the exclusive right to use any and all parking areas located on the Property.
  - 28. Miscellaneous.
- a. This Sublease Agreement shall inure to the benefit of, and shall be binding upon, the Sublessor and the Sublessee and their respective successors and assigns.
  - b. This Sublease Agreement shall be governed by, and construed in accordance With, the laws of the State of New York.
- c. The Sublessee hereby waives the provisions of Section 227 of the New York Real Property Law or any Law of like import now or hereafter in effect.
- d. Notices. Any notice, request, demand, consent, approval, or other communication required or permitted under this Sublease must be in writing and will be deemed to have been given when sent by facsimile with receipt acknowledged, deposited with any nationally recognized overnight carrier that routinely issues receipts, or deposited in any depository regularly maintained by the United States Postal Service, postage prepaid, certified mail, return receipt requested, addressed to the party for whom it is intended at its address set forth in Section 38(0). Either Sublessor or Sublessee may add additional addresses or change its address for purposes of receipt of any such communication by giving ten (10) days prior written notice of such change to the other party in the manner prescribed in this Section.

- e. This Sublease Agreement shall completely and fully supersede all other prior understandings or agreements, both written and oral, between Sublessor and Sublessee relating to the terms and conditions of this Sublease including but not limited to, the rental of the Leased Premises.
- f. If any clause, provision, or section of this Sublease Agreement shall be ruled invalid by any court of competent jurisdiction, the invalidity of such clause, provision or section shall not affect any of the remaining provisions thereof.
- g. This Sublease Agreement may be simultaneously executed in several counterparts, each of which shall be an original and all of which shall constitute but one and the same instrument.
- h. Sublessee does hereby expressly waive all rights to trial by jury on any cause of action directly or indirectly involving the terms, covenants or conditions of this Sublease Agreement or the Lease Premises or any matters whatsoever arising out of or in any way connected with this Sublease Agreement.
- i. The provision of this Sublease Agreement relating to waiver of ajury trial and the right of redemption shall survive the termination or expiration of this Sublease Agreement.
  - j. Time of the Essence. Time is of the essence of each and every provision of this Sublease.
- k. Written Amendment Reguired. No amendment, alteration, modification of, or addition to the Sublease will be valid or binding unless-expressed in writing and signed by Sublessor and Sublessee. Sublessee agrees to make any modifications of the terms and provisions of this Sublease required or requested by any lending institution providing financing for the Building, provided that no such modifications will adversely affect Sublessee's rights and obligations under this Sublease.
- l. Notice of Sublessor's Default. In the event of any alleged default in the obligation of Sublessor under this Sublease, Sublessee will deliver to Sublessor within three (3) days of the occurrence, written notice listing the reasons for Sublessor's default and Sublessor will have thirty (30) days following receipt of such notice to cure such alleged default or, in the event the alleged default cannot be reasonably cured within a thirty (30) day period, to commence action and proceed diligently to cure such alleged default. A copy of such notice to Sublessor will be sent to any holder of a mortgage or other encumbrance on the Building of which Sublessee has been notified in writing, and any such holder will also have the same time periods to cure such alleged default

- 29. Construction. In this Sublease Agreement, unless the context otherwise requires:
- a. [The terms "hereby", "hereof", "hereto", "hereunder", and any other similar terms shall refer to this Sublease Agreement, and the term "hereafter" shall mean after, and the term "heretofore" shall mean before the date of the execution and delivery of this Sublease Agreement.
- b. Words of the masculine gender shall mean and include corrective words of the feminine and neuter genders and words importing the singular number shall mean and include the plural number and vice versa.
- c. Words importing persons shall include firms, associations, partnerships (including limited partnerships), trusts, corporations and other legal entities, including public bodies, as well as natural persons.
- d. Any heading preceding the texts of the several Sections of this Sublease Agreement, and any table of contents appended to copies hereof, shall be solely for convenience or reference and shall not constitute a part of this Sublease Agreement, nor shall they affect its meaning, construction or effect.
- 30. Force Majeure. This Sublease Agreement and the obligation of Sublessee to pay rent and additional rent hereunder and to perform all of the other covenants and agreements hereunder on the part of Sublessee to be performed shall not be affected, impaired or excused and Sublessor will not be in default under this Sublease or be liable to Sublessee or any other person for direct or consequential damage, or otherwise, for any failure to supply any heat, air conditioning, cleaning, lighting, security; for surges or interruptions of electricity; or for other services Sublessor has agreed to supply during any period when Sublessor uses reasonable diligence to supply such services. Sublessor will use reasonable efforts to diligently remedy any interruption in the furnishing of such services. Sublessor reserves the right temporarily to discontinue such times as may be necessary by reason of accident; repairs, alterations or improvements; strikes; lockouts; riots; acts of God; governmental preemption in connection with a national or local emergency; any rule, order, or regulation of any governmental agency; conditions of supply and demand that make any produce unavailable; Sublessor's compliance with any mandatory governmental energy conservation or environmental protection program, or any voluntary governmental energy conservation program at the request of or with consent or acquiescence of Sublessee; or any other happening beyond the control of Sublessor. Sublessor will not be liable to Sublessee or any other person or entity for direct or consequential damages resulting from the admission to or exclusion from the Building of any person. In the event of invasion, mob, riot, public excitement, strikes, lockouts, or other circumstances rendering such action advisable in Sublessor's sole opinion, Sublessor will have the right to prevent access to the Building during the continuance of the same by such means as Sublessor, in its sole discretion, may deem appropriate, including without limitation locking doors and closing parking areas and other common areas. Sublessor will not be liable for damages to person or property or for injury to, or interruption of, business for any discontinuance permitted under this Article 30, nor will such discontinuance in any way be construed as an eviction of Sublessee or cause an abatement of rent or operate to release Lessee from any of Sublessee's obligations under this Sublease. Force Majeure does not apply with respect to the tenant occupancy stipulation and penalties as contained in Paragraph 2.

- 31. Securifl Deposit. In addition to the sum to be paid by Sublessee pursuant to Section 4(0) hereof, Sublessee shall, upon execution of this Sublease Agreement, deliver to Sublessor the sum of \$0.00 (the "Security Deposit") as security for the full and faithful performance by Sublessee of all of the terms, covenants and conditions of this Sublease Agreement to be performed by Sublessee.
- 32. Memorandum of Lease. This Sublease Agreement shall not be recorded but at the request of either party, Sublessor shall execute a memorandum of Lease, which may be recorded in the Erie County Clerk's Office.
- 33. Representations and Warranties of Sublessee. Sublessee represents and warrants that the execution, delivery and performance of this Sublease Agreement and the consummation of the transactions herein contemplated have been duly authorized by the Sublessee (by all requisite corporate action on the part of the Sublessee, if the Sublessee is a corporation) and will not Violate any provision of law, any order of any court or agency of government, or the certificate of incorporation or by-laws of the Sublessee if a corporation, or any indenture, agreement or other instrument to which the Sublessee is a party or bywwhich it or any of its property is bound, or be in conflict with or result in a breach of or constitute (with due notice and/or lapse of time) a default under any such indenture, agreement or other instrument or result in the imposition of any lien, charge of encumbrance of any nature whatsoever.
  - 34. Sublessee's Covenants and Agreements in Connection with the Bond Financing.
- a. Sublessee acknowledges and agrees that all right, title and interest of pledged Sublessor in this Sublease Agreement, including all rentals, will be pledged and assigned by Sublessor as security for the payment of the bonds.
- b. Sublessee. agrees that this Sublease Agreement is expressly subordinated to the Lease Agreement, the Mortgage and Security documents and all extensions, modifications, menM ents and renewals thereof.
- c. Sublessee shall not create or permit the creation of any liens, encumbrance, mortgage or charge on this Sublease Agreement or any of its rights and interest in the Leased Premises except (i) as may be permitted by the Mortgage, the Lease Agreement and the Security Documents and (ii) with the consent of the Sublessee.
- d. Sublessee hereby acknowledges that neither the Agency nor the Bondholder shall be deemed the landlord of the Leased Premises for nay purpose and under no circumstances shall the Agency or the Bondholder be subject to any obligation or liability such.

- e. Sublessee covenants and agrees that it shall provide Sublessor with all reasonable information and documentation with respect to Sublessee or its use of the Leased Premises necessary to comply with the provisions and requirements of the Sublesse or any other documents related to Sublessor's Bond Financing.
- 35. Consent of Agency, Bondholder and Other Mortgages. This Sublease Agreement shall not become effective unless and until the Agency and Bondholder and the holder of any other mortgage which now encumbers the Property (if such mortgage requires the consent of such mortgagee to a lease or sublease of the Property) have consented to it in accordance with the provisions of the Sublease Agreement and such other mortgage (if applicable). Sublessor shall use its best efforts to obtain the consent of the Agency and Bondholder and such other mortgages (if applicable), but shall not be liable in the event that the Agency or the Bondholder or such other mortgages (if applicable), as a condition to its (or their) consent, provided that such modification does not alter the financial terms hereof or the rights or obligations of the parties hereunder. Sublessee covenants and agrees to cooperate with Sublessor in obtaining the consent of the Agency, the Bondholder and (if applicable), such other mortgage.
  - 36. Intentionally Omitted.
- 37. Sublease Agreement for Benefit of Agency and Bondholder. It is understood and agreed by the parties hereto that this Sublease Agreement is entered into in part for the benefit of the Agency and Bondholder, both of whom shall be entitled in the same manner as set forth in the Lease Agreement and the Mortgage to enforce performance and observance of this Sublease Agreement to the same extent as if they were parties signatory hereto. Whenever the consent of the Sublessor is required hereunder, the consent of the Agency, Bondholder and the holder of any other mortgage which encumbers the Property shall also be required by the Lease Agreement, the Mortgage, the Security Documents of any other mortgage which may encumber the Property.
- 38. Early Termination. In the event Sublessee or its owners sells or transfers substantially all of its assets or its stock to an unrelated party or entity, whether by merger, consolidation, sale or securities or otherwise, Sublessee may, at its'option, elect to terminate this Sublease Agreement by providing Sublessor with six (6) months advance notice of its intent to surrender the premises. After the sixth (6th) full calendar month, Sublessee shall no longer be obligated to fulfill its obligations under the terms of this Sublease Agreement. In the event that Sublessee exercises its right to early termination, Sublessee shall pay to Sublessor an early termination fee equal to six times the then currently monthly rent for the Leased Premises. Said early termination fee shall be due at the time Sublessee provides its notice to Sublessor of its early termination and shall be in lieu of payment of any rent for such six month period.

- 39. Construction. Sublessor shall construct the Leased Premises in accordance with the construction drawings, which shall incorporate Sublessee's specifications attached hereto as Exhibit B.
- 40. Arbitration. Any dispute between Sublessor and Sublessee arising out of the provisions of the Sublease, expecting the payment of base rent shall be submitted to arbitration in such a manner as the parties may agree upon, or if they cannot agree, in accordance with the rules of the American Arbitration Association.
- 41. Basic Lease Information Summary. As used in this Sublease, the following basic lease terms shall have the meanings ascribed thereto:

Sublease Date: December 1, 2007

b. Sublessee: Immco Diagnostics, Inc.

Sublessee's Address: 60 Pineview Drive

Amherst, New York 14228

d. Building Address: 60 Pineview Drive

Amherst, New York 14228

Leased Premises: 60 Pineview Drive

Amherst, New York 14228

f. Sublessee's Pro Rata Share of Building: 100%

g. Term: One Hundred Twenty (120) months beginning on the Commencement Date and expiring on the Expiration Date.

h. Commencement Date: December 1, 2007

Expiration Date: November 30, 2017

42. Exhibits. The following exhibits are attached to and made a part of this Sublease Agreement:

Exhibit A The Premises and Legal Description

Exhibit B Intentionally left blank

Exhibit C Sublease Rate Schedule

Exhibit D Sublessor's Services

Exhibit E Rules and Regulations

Exhibit F Subordination, Non-Disturbance and Attornment Agreement

- 43. Additional Definitions. As used in this Sublease, the following terms shall have the meanings ascribed thereto:
  - a. Additional Rent: Any amounts that this Sublease requires Sublessee to pay in addition to base rent.
- b. Building: The building and related improvements (including, without limitation, parking lots, walkways, driveways, fences and landscaping) of which the Premises are a part.

Land: The land on which the Building is located, which is described on Exhibit B.

d. Prime Rate: The rate of interest from time to time announced by Key Bank as its prime rate of interest.

Rent: The base rent and additional rent.

If any other provision of this Sublease contradicts any definition of this Article, the other provision will prevail.

# 44. Delivery of Premises:

- a. "Delivery of Possession" shall be deemed to occur when a permanent Certificate of Occupancy has been issued. Sublessor shall be deemed to have complied with its obligations hereunder notwithstanding that there may be insubstantial terms of construction, installation, finishing work or mechanical adjustments which do not unreasonably interfere with Sublessee's use and occupancy of the Premises.
- b. In the event that Delivery of Possession shall occur on a date other than the first day of a calendar month, the Expiration Date (unless sooner terminated as provided herein) shall be deemed to be the last day of the 120th month following the month in which Delivery of Possession occurs. Sublessee shall pay to Sublessor rent on a pro rata basis for any such partial month based upon the actual number of days remaining in such month from and after the date of Delivery of Possession. The commencement date of the Sublease shall be the date of Delivery of Possession or occupancy whichever comes first.

- c. Sublessee acknowledges that neither Sublessor nor its agents or employees have made any representations or warranties as to the suitability or fitness of the Premises for the conduct of Sublessee's business or for any other purpose, nor has Sublessor or its agents or employees agreed to undertake any alterations or construct any Sublessee improvements to the Premises except as expressly provided in this Sublease. Sublessee will execute a Commencement Date Certificate which shall be attached to this Sublease within fifteen (15) days of Sublessee's occupancy.
- d. If as a consequence of any act and/or omission of Sublessee, its agents, employees, representatives or contractors or the failure of Sublesseeto promptly comply with all requests and requirements of utility company servicing the Premises, the Delivery of Possession shall be delayed despite the application by Sublessor of due diligence (which shall not include overtime or weekend work), then in such event, Sublessor by written notice delivered to Sublessee, shall establish the Commencement Date as the date on which such date would have occurred pursuant to the provisions of this Sublease had it not been for said acts or omissions of Sublessee, and the period of the term shall be adjusted accordingly.

#### 45. Hazardous Materials:

- a. For purposes of this Sublease, "Hazardous Materials" means any explosives, radioactive materials, hazardous wastes, or hazardous substances, including without limitation substances defined as "hazardous substances" in the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. 9601-9657; the Hazardous Materials Transportation Act of 1975, 49 U.S.C. 1801-1812; the Resource Conservation and Recovery Act of 1976, 42 U.S.C. 6901-6987; or any other federal, state, or local statute, law, ordinance, code, rule, regulation, order, or decree regulating, relating to, or imposing liability or standards of conduct concerning hazardous materials, waste, or substances now or at anytime hereafter in effect (collectively, "Hazardous Materials Laws").
- b. Sublessee will not permit the Premises to be used or operated in a manner that may cause the Premises or the Building to be contaminated by any Hazardous Materials in violation of any Hazardous Materials Laws. Sublessee will immediately advise Sublessor in writing of (i) any and all enforcement, cleanup, remedial, removal, or other governmental or regulatory actions instituted, completed, or threatened pursuant to any Hazardous Materials Laws relating to any Hazardous Materials affecting the Premises; and (ii) all claims made or threatened by any third party against Sublessee, Sublessor, or the Premises relating to damage, contribution, cost recovery, compensation, loss or injury resulting from any Hazardous Materials on or about the Premises. Without Sublessor's prior written consent, Sublessee will not take any remedial action or enter into any agreements or settlements in response to the aforementioned contamination by any Hazardous Materials in, on, or about the Premises. Notwithstanding the foregoing, it is hereby acknowledged that in the normal course of Sublessee's occupancy and permitted use of the Leased Premises as an anatomic pathology and cytology laboratory, that Hazardous Materials will be used and stored in the Leased Premises and that Sublessee will provide MSDS forms as may be required by the Sublessor and any regulatory agencies before, during and after any construction phase.

- c. Sublessee will be solely responsible for and will defend, indemnify and hold Sublessor, its agents, and employees harmless from and against all claims, costs and liabilities, including attorneys' fees and costs, arising out of or in connection with Sublessee's breach of its obligations in this Article 45 during the term of this Sublease Agreement. Sublessee will be solely responsible for and will defend, indemnify, and hold Sublessor, its agents, and employees harmless from and against any and all claims, costs, and liabilities, including attorneys' fees and costs, arising out of or in connection with the removal, cleanup, and restoration work and materials necessary to return the Premises and any other property of whatever nature located on the Building to their condition existing prior to the appearance of Sublessee's Hazardous Materials on the Premises. Sublessee's obligations under this Article 45 will survive the expiration or other termination of this Sublease.
- 46. Sublessor's Rules and Regulations. Sublessee and its employees, agents, licensees and visitors will at all times observe faithfully, and comply strictly with, the rules and regulations set forth in Exhibit E. Sublessor may from time to time reasonably amend, delete, or modify existing rules and regulations, or adopt reasonable new rules and regulations for the use, safety, cleanliness, and care of the Premises and the Building, and the comfort, quiet,~ and convenience of occupants of the Building, provided that the same shall not unreasonably interfere with Sublessee's use of the Leased Premises. Modifications or additions to the rules and regulations will be effective upon thirty (30) days' prior written notice to Sublessee from Sublessor. In the event of any breach of any rules or regulations or any amendments or additions to such rules and regulations, Sublessor will have all remedies that this Sublease provides for default by Sublessee, and will in addition have any remedies available at law or in equity, including the right to enjoin any breach of such rules and regulations. Sublessor will not be liable to Sublessee for violation of such rules and regulations by any other tenant, its employees, agents, visitors, or licensees or any other person. In the event of any conflict between the provisions of this Sublease and the rules and regulations, the provisions of this Sublease will govern. The rules and regulations will be enforced in a non-discriminatory manner.
- 47. Sublessor's Consent: With respect to any provision hereof which provides for the consent or approval of Sublessor, said consent or approval shall be in writing and shall not be unreasonably withheld. Sublessee in no event shall be entitled to make any claim, and Sublessee hereby waives any claim for money damages, whether by way of set off, counterclaim, defense or otherwise, based upon any claim or assertion by Sublessee that Sublessor has unreasonably withheld or delayed any consent or approval. Sublessee's sole remedies shall be an action or proceeding to enforce any such provision, or for an injunction or declaratory judgment. All expenses reasonably incurred by Sublessor in reviewing and acting upon any request for consent hereunder, including but not limited to, attorneys' and architects' fees, shall be reimbursed by Sublessee to Sublessor, shall be deemed to constitute additional rent and shall be paid over to Sublessor on the first day of the month following demand therefor.

- 48. Sale of the Building: A sale, conveyance, or assignment of the Building will operate to release Sublessor from liability from and after the effective date of such sale, conveyance, or assignment upon all of the covenants, terms, and conditions of this Sublease, express or implied, except those liabilities that arose prior to such effective date, and, after the effective date of such sale, conveyance, or assignment, Sublessee will look solely to Sublessor's successor in interest in and to this Sublease. This Sublease will not be affected by any such sale, conveyance, or assignment and Sublessee will attorn to Sublessor's successor in interest to this Sublease, so long as such successor in interest assumes Sublessor's obligations under the Sublease from and after such effective date.
  - 49. Representations and Covenants of Sublessor.
- a. Sublessor warrants and represents to Sublessee as follows: (i) the Lease Agreement is in full force and effect, (ii) Sublessor has not received a notice of default or notice of termination with respect to the Lease Agreement, (iii) Sublessor is neither in default of nor has Sublessor breached any of its covenants, agreements or obligations under the Lease Agreement, (iv) to the best of Sublessor's knowledge, the Agency is neither in default of nor has the Agency breached any of its covenants, agreements or obligations under the Lease, (v) Sublessor's interest in the Lease Agreement has not been conveyed, transferred, assigned, pledged or otherwise encumbered, and (vi) all amounts due and payable by Sublessor under the Lease Agreement including any rent and additional rent have been paid through November 30, 2007.
- b. Sublessor shall, in its capacity as tenant under the Lease Agreement, perform and fulfill all of its covenants, obligations and agreements under the Lease Agreement in accordance with the provisions thereof, and shall not do anything which would cause the Lease to be terminated or forfeited. Sublessor shall indemnify and hold Sublessee harmless from and against any and all claims, liabilities, losses, damage, demands, expenses (including, without limitation, reasonable attorney's fees), actions and causes of action of any kind whatsoever by reason of any breach or default on the part of Sublessor or its employees or agents, in its capacity as tenant under the Lease Agreement, by reason of Which the Lease Agreement may be terminated or forfeited. Sublessor covenants that it will not enter into any agreement that will modify or amend the Lease Agreement so as to adversely affect Sublessee's right to use and occupy the Leased Premises or any other rights of Sublessee under this Sublease Agreement, or increase or materially affect the obligations of Sublessee under this Sublease Agreement. Further, Sublessor will promptly provide Sublessee with copies of all notices of default that Sublessor delivers to, or receives from, the Agency under the Lease Agreement.
- 50. Subordination of Landlord Lien. Sublessor acknowledges that Sublessee may, from time to time enter into, financing arrangements with lenders wherein Sublessee will grant to such lenders a security interest in all or a portion of Sublessee's personal property (referred to as "Collateral"). With respect to the Collateral, each of Sublessor and the Agency agrees that, during any period that a lender has a security interest in any of the Collateral, Sublessor and the

Agency disclaim any interest in the Collateral, waive any lien or security interest that they may have in the Collateral and agree not to levy upon the Collateral or to assert any claim against the Collateral. Each of Sublessor and the Agency agrees to execute any commercially reasonable instruments requested by a lender of Sublessee with respect to the foregoing.

# SUBLEASE AGREEMENT AS OF THE DATE FIRST WRITTEN HEREOF.

| Sublessor: 60 Pincview, LLC | Sublessee Immco Diagnostics, Inc. |  |
|-----------------------------|-----------------------------------|--|
| /s/ VIJAY KUMAR             | /s/ RAJNISH KR MITTAL             |  |
| Signature                   | Signature                         |  |
| VIJAY KUMAR                 | RAJNISH KR MITTAL                 |  |
| Name                        | Name                              |  |
|                             | CFO                               |  |
| Title                       | Title                             |  |

## DESCRIPTION OF FACILITY REALTY

#### LEGAL DESCRIPTION

ALL THAT TRACT OR PARCEL OF LAND situate in the Town of Amherst, County of Erie and State of New York, being part of Lot No. 82, Township 12, Range 7 of the Holland Land Company's Survey, bounded and described as follows:

BEGINNING at a point in the east line of Pineview Drive (50' wide) at its intersection with the south line of lands conveyed to MJR Associates as recorded in the Erie County Clerk's Office in Liber 10513 of Deeds at page 131, said point also being distant 402.56 feet southerly of the south line of North French Road, as measured along said east line of Pineview Drive; thence S 89° 59' 36" E along the said south line of MJR Associates a distance of 275-1 feet to the southeast corner thereof: thence N 01° 01' 09" W along the east line of said lands conveyed to MJR Associates a distance of 10.00 feet to the southwest corner of lands conveyed to William F- Swan as recorded in the Erie County Clerk's Office in Liber 6505 of Deeds at page 405,- thence S 87° 08' 26" E along said south line of William F. Swan a distance of 248.11 feet to a point in the west line of Sweet Home Road (66' wide); thence S 00° 17' 27" E along the west line of Sweet Home Road a distance of 100.00 feet to a point in the north line of lands conveyed to Howard Forman as recorded in the Erie County Clerk's Office in Liber 9502 of Deeds at page 306; thence N 87° 08' 26" W along said north line of Howard Forman a distance of 166.95 feet to the northwest corner thereof; thence S 00° 21' 52" E along the west line of said Howard Forman's lands a distance of 100.00 feet to the southwest corner thereof; thence N 87° 08' 26" W a distance of 357.7 feet to a point in the east line of Pineview Drive; thence N 00° 02' 32" E along the east line of Pineview Drive a distance of 176.24 feet to the point of beginning, containing 1.913 acres more or less.

# EXHIBIT C

# Lease Rate Schedule

| Year | Rate/SF   |
|------|---|
| 1-3  | \$3 55,200 annual payment or \$29,600 per month |
| 4    | \$366,000 annual payment or \$30,500 per month  |
|      | \$376,800 annual payment or \$31,400 per month  |
| 6    | \$388,200 annual payment or \$32,350 per month  |
|      | \$399,780 annual payment or \$33,315 per month  |
|      | \$411,780 annual payment or \$34,315 per month  |
| 9    | \$424,140 annual payment or \$35,345 per month  |
| 10   | \$436,860 annual payment or \$36,405 per month  |

# **EXHIBIT D**

## SUBLESSOR'S SERVICES

- 1. Repairs to and replacements of the foundation, roof and load bearing walls of the Building as needed in the reasonable judgment of Sublessor.
- 2. Repairs to -and replacements of the heating system, plumbing system, water system, electrical system, sprinkler system (if any) and air conditioning system serving the Leased Premises.
- 3. Snow plowing, parking lot lighting, striping and maintenance, landscaping, garbage removal, maintenance of fences (if any), lawn care, maintenance of Building exterior and Building sign (if any), general repairs and maintenance, site and building common utilities, cleaning and maintenance of any common hallways, walls and restrooms and other areas or facilities which service both the Leased Premises and other portions of the Building.

## **EXHIBIT B**

- 1. Sublessee shall not discharge or permit the discharge of any industrial waste, hazardous waste, or any other matter except for normal sanitary sewerage into the sewer facilities which serve or are used in connection with the Leased Premises-
- 2. Sublessee shall not, without the prior written consent of Sublessor which consent shall not be unreasonably with held, conditioned or delayed, install or permit the installation of any object, including, without limitation, any antenna, dish, sign, or transmission device on the roof or exterior walls of the Leased Premises or Building or in the yard or parking areas related thereto.
- 3. Sublessee shall not use, or permit the use of, the water, water closets and plumbing fixtures for any purposes other than those for which they were designed and constructed.
- 4. Sublessee shall not use, keep, or permit to be used or kept, any foul or noxious gas or other substance in or about the Leased Premises, or permit or suffer the Leased Premises to Sublessor, the Agency, the Bondholder or any occupants of the Building or Property by reason of noise, odors, and/or vibrations or by reason of interference in any ways with other tenants of the Property or Building or those having business therein.
- 5. Sublessee shall not exhibit, inscribe, paint or affix any sign, advertisement, notice or other document in or about the Leased Premises or the Building, or the surrounding areas, yards or parking lots or allow any such sign, advertisement, notice or other document to be so exhibited, inscribed, painted or affixed without first obtaining prior written consent of the Sublessor which consent shall not be unreasonably withheld, conditioned or delayed. In the event of any violations of the foregoing, Sublessor may remove same without any liability, and may charge the expense incurred by such removal to Sublessee.
- 6. Sublessee shall not mark, paint, drill into or in any deface any part of the Leased Premises or the Building. Sublessee shall not bore, cut or string Wire on or about the Leased Premises, Building or the surrounding areas, yards or parking lots or perm it same to be done without the prior written consent of the Sublessor.
- 7. Sublessor shall have the right to prohibit any advertising by Sublessee which, in Sublessor's reasonable opinion tends to impair the reputation of the Sublessor or the desirability of the Building or the Property, and upon written notice from Sublessor, Sublessee shall refrain from or discontinue such advertising.
- 8. Sublessee shall not bring or permit to be brought or kept in or on the Leased Premises, Building or surrounding yards, areas, or parking lots any inflammable, combustible or explosive or otherwise hazardous fluid, material chemical or substance or cause or permit any odors to penetrate in or emanate therefrom.

# Exhibit 4.18

402918-0001

# **DATED 18 July 2013**

\_\_\_\_\_

| TRINITY BIOTECH (UK) LIMITED          | (1) |
|---------------------------------------|-----|
| LAB21 LIMITED                         | (2) |
| LAB21 HEALTHCARE LIMITED              | (3) |
| MYCONOSTICA LIMITED                   | (4) |
| and                                   |     |
| TRINITY BIOTECH MANUFACTURING LIMITED | (5) |
|                                       |     |
| BUSINESS & ASSET PURCHASE AGREEMENT   |     |

MILLS & REEVE

## THIS AGREEMENT is made on 18 July 2013

#### **BETWEEN:**

- (1) **TRINITY BIOTECH (UK) LIMITED** (a company registered in England & Wales with registered number 8606499) whose registered office is at Botanic House, 100 Hills Road, Cambridge CB2 1PH ("**Buyer**");
- (2) **LAB 21 LIMITED** (a company registered in England & Wales with registered number 05382262) whose registered office is at 184 Cambridge Science Park, Cambridge CB4 0GA ("**Lab 21**");
- (3) **LAB 21 HEALTHCARE LIMITED** (a company registered in England & Wales with registered number 02957012) whose registered office is at 184 Cambridge Science Park, Cambridge CB4 0GA ("**Healthcare**");
- (4) **MYCONOSTICA LIMITED** (a company registered in England & Wales with registered number 05693850) whose registered office is at 184 Cambridge Science Park, Cambridge CB4 0GA ("**Myconostica**"); and
- (5) **TRINITY BIOTECH MANUFACTURING LIMITED** (a company registered in Ireland with registered number IE239206) whose registered office is at Bray Business Park, Bray, Co Wicklow, Ireland ("**TBML**").

## WHEREAS:

- (A) The Sellers (as defined below) are now and have for some time been carrying on the Businesses (as defined below).
- (B) Between them, the Sellers own the assets and employ the employees required for the operation and exploitation of the Businesses.
- (C) The Sellers have agreed to sell and transfer, and the Buyer has agreed to purchase, the Businesses (together with the Assets) on the terms and subject to the conditions of this Agreement and in particular on the basis of the representations, warranties, undertakings, agreements and indemnities set out in this Agreement.
- (D) TBML is party to this Agreement, inter alia, for the purposes of guaranteeing the obligations of the Buyer as provided for in clause 15.

# **NOW IT IS AGREED:**

# 1 <u>Definitions and interpretation</u>

- 1.1 In this Agreement unless the context otherwise requires:
  - "Accounts Date" means 31 December 2011;
  - "Assets" means the all the property, undertaking, rights and assets of the Businesses to be sold by the Sellers to the Buyer pursuant to clause 2.1;
  - "Associated Company" means any company which at the relevant time is:
  - (a) a holding company of any of the Sellers; or

- (b) a subsidiary or subsidiary undertaking of any of the Sellers; or
- (c) a subsidiary or subsidiary undertaking (other than any of the Sellers themselves) of any such holding company;
- "Bank" means Clydesdale Bank Plc;
- "Businesses" means businesses carried on by the Sellers associated with:
- (i) the development, manufacture, marketing and distribution of the following products: Syphilis RPR, TPHA and EIA, Malaria EIA, CMV EIA and HA, Mycassay Aspergillus, Mycassay Pneumocystis and MycXtra;
- (ii) the development, manufacture, marketing and distribution of the following products being developed under the Customer Contracts (as specifically provided for in such Customer Contracts) with Kras, Braf, DNA/RNA extraction from FFPE, hsa-mir-31-3p, and two further undefined assays under the BD Master Service Agreement (being a Contract); and
- (iii) exploitation of the know-how and capability to develop future protein and molecular based assays;
- "Business Day" means a day (other than a Saturday, Sunday or public holiday) on which banks in the City of London are ordinarily open for the transaction of normal banking business;
- "Business IPR" means all Seller IPR and all the Sellers' rights in the Relevant Third Party IPR;
- "Business Software" means any Software in which the Intellectual Property Rights are solely or jointly owned by the Sellers in the Businesses, including but not limited to all items identified as Business Software in Part C of Schedule 3;
- "Buyer's Solicitors" means Mills & Reeve LLP registered in England & Wales with number OC326165 of Botanic House, 100 Hills Road, Cambridge CB2 1PH;
- "Cambridge Property" means the Property at Unit 184 Phase 3, Cambridge Science Park, Milton Road, Cambridge as more particularly defined in the Lease of that Property;
- "Claims" means all rights and claims of the Sellers under any express or implied agreement, warranty, condition, representation, guarantee, indemnity or insurance policy subsisting at the Transfer Date whether express or implied in favour of the Sellers in relation to any of the Assets;
- "CA 2006" means the Companies Act 2006;
- "Completion" means completion of the sale and purchase of the Businesses and the Assets in accordance with clause 8;
- "Completion Payment" means the Consideration, less the Expected Creditor Payments, less the Exclusivity Payment;

"Confidential Information" means all commercial, technical, financial and other information of whatever nature and in whatever form (whether written, oral, visual, recorded, graphical, electronic or otherwise) relating to the Businesses and the Assets, which is, or may be, secret or confidential, including the Know-how, the Marketing Information and any third party know-how licensed to the Sellers under the Contracts;

"Consideration" means the aggregate consideration payable for the Assets as stated in clause 3;

#### "Contracts" means

- (a) the orders, engagements or contracts entered into prior to the Transfer Date by or on behalf of the Sellers with suppliers for the supply of goods or services in connection with the Businesses (including but not limited to the IT Contracts) which remain (in whole or in part) to be performed by the supplier (referred to in Part A of Schedule 5 and copies of which are attached to the Disclosure Letter) ("Supplier Contracts"); and
- (b) the IP Licences which continue in force (referred to in Part B of Schedule 5 and in the Disclosure Letter); and
- (c) the orders engagements or contracts entered into prior to the Transfer Date by or on behalf of the Sellers with customers for the sale of goods or provision of services by the Sellers in connection with the Businesses which remain in whole or in part or to be performed by the Sellers other than in relation to warranty or guarantee obligations or commitments of the Sellers and contracts with customers of the Businesses under which there are no orders which remain, as at the Transfer Date, to be performed by the Sellers (which contracts with customers taken together are referred to in this Agreement as "Customer Contracts") (referred to in Part C of Schedule 5 and copies of which are attached to the Disclosure Letter);

"Contractual Arrangement" means any agreement or commitment whether conditional or unconditional and whether by deed, under hand, and/or otherwise and any arrangement or understanding whether legally binding or not;

"Creditors" means the amounts payable (whether or not then due and payable) in respect of goods or services supplied to the Sellers in respect of the Businesses prior to the Transfer Date that are identified in Schedule 8 (and for the avoidance of doubt, the amounts payable by the Sellers which are not listed in Schedule 8 are not included within the definition of Creditors);

"Data Protection Legislation" means the DPA, the EU Data Protection Directive 95/46/EC, the Regulation of Investigatory Powers Act 2000, the Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2000 (SI 2000/2699), the Electronic Communications Data Protection Directive 2002/58/EC, the Privacy and Electronic Communications (EC Directive) Regulations 2003 and all applicable laws and regulations relating to processing personal data and privacy, including where applicable the guidance and codes of practice issued by the Information Commissioner;

"**Debts**" means the aggregate amount owing (whether or not then due and payable) to the Sellers at the Transfer Date in connection with the carrying on of the Businesses up to the Transfer Date;

- "Disclosure Document" means a disclosure document referred to as such in the Disclosure Letter;
- "Disclosure Letter" means the letter dated the same date as this Agreement in the agreed form from the Sellers to the Buyer disclosing certain matters in relation to the Warranties, together with all documents attached to it or listed in any schedule to it:
- "Domain Names" means the domain names listed in Schedule 3;
- "DPA" means the Data Protection Act 1998;
- "Employees" means the Lab21 Employees and the Healthcare Employees;
- "Employment Legislation" means legislation applying in England and Wales directly or indirectly affecting the relations (whether contractual or otherwise) between the Sellers and the Employees (whether individually or collectively) including the provisions of any EU treaty or Directive directly enforceable by any Employee against the Sellers;
- "Employment Liabilities" means all awards, claims, costs, damages, debts, demands, expenses, fines, penalties and all other liabilities of any nature (including professional fees and legal costs on an indemnity basis as defined in Rule 44.4(3) of the Civil Procedure Rules 1998) and any irrecoverable VAT.
- "Encumbrance" means any mortgage, charge, pledge, lien, hypothecation, assignment by way of security, option or obligation to grant an option, restriction, claim, right of pre-emption, right of first refusal, third party right or interest, other encumbrance or security interest of any kind (or an agreement or commitment to create any of them) or other preferential arrangement having similar effect;
- "Excluded Assets" means the assets excluded from the sale and listed in Part B of Schedule 1;
- "Excluded Employees" means any person other than the Employees;
- "Excluded Liabilities" means all the liabilities or obligations relating to the Businesses or Assets which are not expressed to be assumed by the Buyer and/or TBML under this Agreement and which are outstanding on, or accrued or referable to the period up to and including, the Transfer Date or arising by virtue of the sale and purchase recorded by this Agreement, including any and all liabilities in respect of National Insurance, PAYE, VAT or other taxation attributable to the Sellers in respect of the Businesses, the Assets or the Employees relating to the period ending on the Transfer Date and all bank and other overdrafts and loans owing by the Sellers (or either of them);
- "Exclusivity Payment" means the sum of £200,000 (two hundred thousand pounds) held by the Sellers' Solicitor pursuant to the terms of a solicitor's undertaking to the Buyer's Solicitors dated 28 June 2013;
- "Exclusivity Payment Balance" means the sum of £125,000 (being the Exclusivity Payment, less the £75,000 to be released to the Sellers on Completion in accordance with clause 8.2.3) to be held in accordance with an undertaking from the Sellers' Solicitors to the Buyer's Solicitor to come into effect on the date of this Agreement;

- "Expected Creditor Payments" has the meaning given to it in clause 10.4;
- "Financial Information" means the financial information appended to the Disclosure Letter comprising:
- (a) a an analysis of Sales; and
- (b) a summary of direct material costs incurred by the Sellers in connection with Sales;
- (c) a summary of costs and overheads attributable to use and occupation of the Properties for the Financial Period; and
- (d) a list of categories of all costs which have been incurred by the Sellers in connection with the carrying on of the Businesses during the Financial Period;
- "Financial Period" means the financial year of the Sellers ended 31 December 2012 and the period from 1 January 2013 to 30 June 2013;
- "Goodwill" means the goodwill and undertaking of the Sellers in relation to the Businesses and all trade names associated with the Businesses together with the exclusive right for the Buyer and/or TBML to represent itself as carrying on the Businesses in succession to the Sellers;
- "Healthcare Employees" means those persons listed in Part B of Schedule 4;
- "HMRC" means HM Revenue and Customs;
- "holding company" means a holding company as defined by section 1159 CA 2006 or a parent undertaking as defined by section 1162 CA 2006;
- "Independent Accountant" means a single independent chartered accountant or an independent firm of chartered accountants to be agreed upon by the Sellers and the Buyer or (in default of agreement within 10 Business Days) to be selected at the instance of either of them by the President for the time being of the Institute of Chartered Accountants in England and Wales;
- "Intellectual Property Rights" means any patents, supplementary protection certificates, registered trade marks and registered designs (including applications and the right to apply and to claim priority for any of the same in any country, region or jurisdiction in the world); rights in inventions; goodwill and all other rights in or relating to unregistered trade marks rights (including but not limited to any trade, brand or business names, product and packaging get-up and logos); unregistered design rights; copyright (including but not limited to copyright in computer software); rights in domain names; trade secrets and rights in confidential information and know-how; database rights; and all other intellectual property rights of a similar or corresponding nature in any country, region or jurisdiction in the world, all for the full term of the rights concerned and including all continuations, extensions and renewals of such rights;
- "IP Licence" means any licence, sub-licence, agreement, authorisation or permission, whether express or implied and whether or not in writing, to which the Sellers are a party, relating to the use, enjoyment and/or exploitation by the Sellers of any Third Party IPR or by any third party of any Business IPR;

**IT Contract**" means any arrangements and agreements relating to the IT Systems to which the Sellers are a party, including but not limited to Software Licences and any development agreements, escrow agreements, and support and maintenance agreements that relate to the IT Systems;

"IT Equipment" means any information and communications equipment owned by the Sellers and/or used by any of the Sellers in the Businesses, including but not limited to any of the following that are owned by the Seller and/or used by the Seller in the Businesses:

- (a) any computer (including but not limited to any server, desktop computer, laptop, computer component, printer, scanner, keyboard, screen, mouse or other peripheral) or other data processing and storage equipment; and
- (b) any communications or network equipment (including but not limited to telephones, fax machines, video and audio conferencing facilities, internet or broadband connection equipment, wifi or other wireless networking equipment and any associated cabling);

# "IT Servers" means:

- (a) the two servers at the Newmarket Property, namely:
  - (i) the purpose built unit, 2 GB of Ram, 64 bit windows 2008, 150GB hard disk space configured in raid, being a domain controller and a file and printer server; and
  - (ii) the Poweredge 1950 with 2GB of Ram, 64 bit windows 2008 and 75GB hard disk space configured in raid); and
- (b) the server at the Cambridge Property (Power Edge 710);

"IT Systems" means all information and communications technology systems owned by the Sellers and/or used by any of the Sellers in the Businesses or, including but not limited to the IT Equipment, the Business Software and the Third Party Software;

"Know-how" means all documentation and other media embodying any industrial, commercial and technical and accounts records and information and other information (wherever located) relating to the activities of the Businesses;

"Lab21 Employees" means those persons listed on Part A of Schedule 4;

"Landlord" means in respect of each of the Properties, the person or persons from time to time entitled to the reversion (whether immediate or not) expectant upon the termination of the Lease of the relevant Property;

"Lease Transfer Date" means in respect of each of the Properties, the later of:

- (a) the Transfer Date; and
- (b) the day which is five Business Days from, but not including, the date of the Licence granted in respect of that Property;

and "Relevant Lease Transfer Date" means the Lease Transfer Date for each one of the Properties;

- "Leased Assets" means those assets delivered to the Buyer on Completion and which have previously been in the possession or under the control of the Sellers by virtue of leasing, hire, hire purchase, and conditional sale agreements or sale and return agreements, details of which are referred to in Part D of Schedule 5 and the Disclosure Letter;
- "Leases" means the leases or underleases or licences brief particulars of which are listed in Part A of Schedule 2 under which any leasehold Properties are held;
- "Licence" means the consent of the Landlord authorising a transfer or an assignment of the residue of the term of a Property to the Buyer in accordance with and pursuant to the terms of the Lease, such consent being evidenced in a written, formal licence to assign by deed, dated and being obtained on reasonable terms, signed or executed by or on behalf of all of the parties to it;
- "Loaned Assets" means those assets used in the Businesses by the Sellers which have been loaned to the Sellers by customers, clients and other third parties for the purposes of product development and testing and which are required for the proper continuation of the Businesses as carried on by the Sellers at the Transfer Date details of which are referred to in Part E of Schedule 5 and the Disclosure Letter;
- "Marketing Information" means all documentation and other media embodying any information relating to the marketing of the Businesses including all customer names and lists and customer records, sales targets, sales statistics, marketing surveys and reports, marketing research and all advertising material, circulars, tradecards and promotional material;
- "Newmarket Property" means the Property at Unit 1 (a, b and c) Lanwades Business Park Kennett, Newmarket, Suffolk as more particularly defined in the Lease of that Property;
- "Oyster Bay Machine" means the automated EIA plate coating machine with serial number #0006292;
- "Part 1 Conditions" means the conditions in Part 1 of the Standard Commercial Property Conditions (Second Edition) and "Condition" means any one of them;
- "Part 2 Conditions" means the conditions in Part 2 of the Standard Commercial Property Conditions (Second Edition);
- "Personal Data" means personal data (as defined in the DPA) processed by the Seller in the conduct of the Businesses;
- "Plant and Equipment" means the fixed and loose plant, machinery and equipment, fittings and other chattels (including office equipment) owned and/or used by the Sellers in the Businesses whether or not situate at the Properties (including those listed in Part A of Schedule 1, but excluding the Excluded Assets);
- "**Properties**" means the leasehold properties specified in Part A of Schedule 2 but excluding in each case all items on the Properties which are comprised in the Plant and Equipment;
- "Records" means all files, records, documents, notebooks, books and accounts, statistics, surveys, blueprints, designs, drawings and specifications, relating to the Businesses or the Assets or the Employees including any such information recorded

or stored in writing or upon magnetic tape or disc or otherwise recorded or stored for reproduction whether by mechanical or electronic means and whether or not such reproduction will result in a permanent record of it being made other than those relating to the Excluded Assets;

- "Registered Seller IPR" means all Seller IPR that have been registered or that are applications for registration of Intellectual Property Rights or for registered Intellectual Property Rights;
- "Rent Deposit" means all amounts which become payable to Lab21 from time to time pursuant to the terms of the Rent Deposit Deed;
- "Rent Deposit Deed" means the rent deposit deed dated 29 September 2010 made between Lab21 and Siemens Healthcare Diagnostics Products Limited relating to Unit 184, Phase 3, Cambridge Science Park, Milton Road, Cambridge;
- "Relevant Third Party IPR" means all Third Party IPR licensed to the Sellers and used in the Businesses or the subject matter of which is used by the Sellers in the Businesses, including but not limited to all Intellectual Property Rights identified as Relevant Third Party IPR in Part B of Schedule 3;
- "Retained Third Party IPR" means the third party software, domain names, all Intellectual Property Rights solely or jointly owned by the Sellers which are listed in Part B of Schedule 1;
- "Sale Consents" means all consents or authorisations which are required (whether under their respective constitutional documents or otherwise) to be secured by the Sellers (or either of them) prior to the sale of the Businesses and the Assets and entry into this Agreement and the other documents to be entered into at Completion pursuant to it;
- "Sales" means sales made by the Sellers in connection with the carrying on of the Businesses in the Financial Period;
- "Sellers" means Lab21, Healthcare and Myconostica or any of them;
- "Seller IPR" means all Intellectual Property Rights solely or jointly owned by the Sellers and used in the Businesses, including but not limited to all items identified as Seller IPR in Schedule Part A of Schedule 3;
- "Sellers' Solicitors" means Pitmans LLP, 47 Castle Street, Reading, Berkshire RG1 7SR;
- "Shared Equipment" means the shared equipment referred to in Part B of Schedule 1;
- "Software" means computer programs (including but not limited to software applications, databases, operating systems, compilers, and firmware and any other computer programs embedded in any information or communications technology equipment) whether in source code or object code form, and including any accompanying user guides and/or manuals;
- "Software Licence" means any licence, sub-licence, agreement, authorisation or permission, whether express or implied and whether or not in writing, relating to the use, enjoyment and/or exploitation by the Sellers of any Third Party Software or by any third party of any Business Software;

- "**Stock**" means the stocks owned or used by the Sellers at the Transfer Date for the purpose of or in connection with the Businesses including goods or other assets purchased for resale, consumable stores, raw materials and components, work-in-progress, partly finished and finished goods (and including items supplied by a supplier subject to reservation of title);
- "subsidiary" means a subsidiary as defined by sections section 1159 CA 2006;
- "subsidiary undertaking" means a subsidiary undertaking as defined by section 1162 CA 2006;
- "Third Party IPR" means all Intellectual Property Rights not solely owned by the Sellers;
- "Third Party Software" means any Software used by the Sellers that is not solely owned by the Sellers, including but not limited to all items identified as Third Party Software in Part D of Schedule 3;
- "Trade Names" means those trade names used exclusively in connection with the Businesses (including those listed in Part E of Schedule 3) but excluding (for the avoidance of doubt) the names "Lab21" and "Lab21 Healthcare";
- "**Transfer Date**" means the close of business on 2013;
- "TSA" means the transitional services agreement in the agreed form between the Sellers and the Buyer;
- "TUPE" means the Transfer of Undertakings (Protection of Employment) Regulations 2006;
- "use" in the context of any Intellectual Property Rights means use of the subject matter of such rights including but not limited to any such use that would, without the consent of the owner of the Intellectual Property Rights, be an infringement or breach of such Intellectual Property Rights;
- "VAT" means value added tax in the United Kingdom chargeable under VATA;
- "VATA" means the Value Added Tax Act 1994;
- "Virus" means any software programme or code intended to destroy, interfere with, corrupt, or cause undesired effects on programme files, data or other information, executable code or application software macros, whether or not its operation is immediate or delayed, and whether such software programme is introduced wilfully, negligently or without knowledge of its existence;
- "Warranties" means the warranties and representations set out in Schedule 6; and
- "Websites" means the websites owned and/or operated by or on behalf of the Seller at the Domain Names and used in the Businesses, including but not limited to any content appearing at such websites.

- 1.2 In this Agreement unless the context otherwise requires:
  - 1.2.1 a document expressed to be "**in the agreed form**" means a document in a form which has been agreed by the parties on or before the date of this Agreement and for the purposes of identification signed or initialled by them or on their behalf by their solicitors;
  - 1.2.2 references to a clause or schedule are to a clause of, or a schedule to, this Agreement, references to this Agreement include its schedules and references in a schedule or part of a schedule to a paragraph are to a paragraph of that schedule or that part of that schedule;
  - 1.2.3 words importing the singular include the plural and vice versa and words importing a gender include every gender;
  - 1.2.4 descriptive headings to clauses, Schedules and paragraphs are inserted for convenience only, have no legal effect and shall be ignored in the interpretation of this Agreement;
  - 1.2.5 references to persons or companies will include any partnership, undertaking or other body of persons, whether incorporated or not incorporated and whether now existing or to be formed after the date of this Agreement;
  - 1.2.6 all agreements, obligations and liabilities (whether under warranties, representations, indemnities or otherwise) on the part of the Sellers or any two or more of the Sellers are joint and several and shall be construed accordingly;
  - 1.2.7 references to any enactment (meaning any statute or statutory provision, whether of the United Kingdom or elsewhere, any subordinate legislation (as defined by section 21(1) Interpretation Act 1978) and any other subordinate legislation made under any such statute or statutory provision) shall be construed as references to:
    - (i) any enactment which that enactment has directly or indirectly replaced (whether with or without modification); and
    - (ii) that enactment as re-enacted, replaced or modified from time to time, before or on the date of this Agreement, or after the date of this Agreement except to the extent that the liability of any party is thereby increased or extended:
  - 1.2.8 a reference to "**indemnify**" and "**indemnifying**" any person against any circumstance includes indemnifying and keeping him harmless from all actions, claims and proceedings from time to time made against him and all loss or damage and all payments, costs or expenses made or incurred by that person as a consequence of such circumstance which would not have arisen but for that circumstance.

# 2 Sale and purchase

2.1 The Sellers will sell to the Buyer and the Buyer (relying, as the Sellers acknowledge, on the representations, warranties, undertakings and indemnities of the Sellers (or any of them) referred to or contained in this Agreement) will buy as at the Transfer Date the Businesses as a going concern together with the following properties, rights and assets used, exercised or employed in the Businesses:

- 2.1.1 the Goodwill;
- 2.1.2 the Seller IPR;
- 2.1.3 the Know-how;
- 2.1.4 the Properties;
- 2.1.5 the Plant and Equipment, the Oyster Bay Machine and the IT Servers;
- 2.1.6 the benefit (but subject to the burden) of the Contracts;
- 2.1.7 the benefit (so far as the same can lawfully be assigned or transferred to or held in trust for the Buyer) of the Claims;
- 2.1.8 the Marketing Information;
- 2.1.9 the Records;
- 2.1.10 all rights, title and interests of Lab21 in and to the Rent Deposit; and
- 2.1.11 the Stock.
- 2.2 The Sellers shall sell the Assets with full title guarantee (unless otherwise specified in this Agreement) and free from any Encumbrance.
- 2.3 If any of the Stock is subject to any reservation of title in favour of any third party, the Sellers will not be deemed to sell such Stock with full title guarantee and the Sellers' right to possess, deal in and perfect the title to such Stock will pass to the Buyer to the greatest extent to which the Sellers are respectively able to pass them on and from Completion.
- 2.4 The Excluded Assets and the Excluded Liabilities are all excluded from the sale and purchase under this Agreement.
- 2.5 The Buyer will not be obliged to complete the purchase of any of the Assets unless the purchase of all the Assets is completed in accordance with this Agreement.
- 2.6 Notwithstanding that the Buyer shall purchase the Assets in accordance with the terms of this Agreement, the Sellers shall on Completion (and with the consent of the Buyer hereby given) transfer all rights title and interest in and to the following Assets to TBML:
  - 2.6.1 the Goodwill;
  - 2.6.2 the Seller IPR;
  - 2.6.3 the Know-how; and
  - 2.6.4 the benefit (but subject to the burden) of the Contracts.
- 2.7 The Sellers shall license the Buyer to use the product registrations referred to in Disclosure Document 16.1.1 until such time as the Buyer has done everything necessary to re-register such product registrations. The Buyer shall use all reasonable endeavours to obtain re-registration of such product registrations as soon as possible after Completion and in any event within 12 months thereafter (or where such re-registrations cannot in exceptional circumstances be secured within 12 months, such other period as the Buyer and/or TBML and the Sellers may agree).

# 3 Consideration

3.1 The Consideration for the sale of the Businesses and the Assets is £4,750,000 (four *million seven hundred and fifty thousand pounds*) which shall be allocated as follows:

| 3.1.1 | the Seller IPR, Know-how and all Goodwill which is specifically related to them;   | £4,599,996 |
|-------|--|------------|
| 3.1.2 | the benefit (but subject to the burden) of the Contracts and all Goodwill which is specifically related to such Contracts; | £1.00      |
| 3.1.3 | Properties;  | £1.00      |
| 3.1.4 | the Plant and Equipment, the Oyster Bay Machine and IT Servers;  | £100,000   |
| 3.1.5 | the Stock;   | £50,000    |
| 3.1.6 | all rights, title and interests of Lab21 in and to the Rent Deposit; and   | £1.00      |
| 3.1.7 | all other assets referred to in clause 2.1   | £1.00      |

# 4 <u>Capital Allowances</u>

4.1 The Sellers each agree to provide all information in their possession or control or that of their agents and will provide all cooperation and assistance that the Buyer may reasonably require to enable claims for capital allowances to be made and substantiated by the Buyer, including providing details and documentary evidence of the assessment of expenditure in respect of which capital allowances in respect of plant and machinery constituting fixtures have or could have been claimed by the Sellers, copies of claims for such allowances and the acceptance of such claims by HMRC provided always that the Buyer shall not disclose, without the consent of the Sellers, any such information which the Sellers provide on a confidential basis.

# 5 Value Added Tax

The parties agree that VAT will be chargeable in respect of the transfer of those Assets which are to be transferred to and acquired by the Buyer pursuant to the terms of this Agreement and in respect of the supply of such assets the Sellers shall issue the Buyer with a valid VAT invoice (or, if applicable, invoices) as soon as reasonably practicable after Completion, provided that the Buyer shall only be required to pay to the Sellers any amount in respect of such VAT within 5 Business Days prior to the date on which the Sellers are themselves required to account to HMRC in respect of such VAT and following receipt of a valid VAT invoice in respect of such amount. Should HMRC or the Buyer and the Sellers determine at any time after Completion that VAT was not chargeable on the sale of the Assets which are to be transferred to and acquired by the Buyer pursuant to the terms of this Agreement due to the applicability of the TOGC provisions contained in section 49 VATA and Article 5 of the Value Added Tax (Special Provisions) Order 1995 in relation to the supply of such Assets, then the Sellers shall promptly issue a credit note to the Buyer in respect of any VAT previously charged in connection with the supply of such Assets.

- 5.2 Subject to clause 5.4, the parties consider that no VAT will be chargeable in respect of the supply of those Assets which are to be transferred to and acquired by TBML pursuant to the terms of this Agreement on the basis that the sale of such Assets by the Sellers constitutes a supply of services made to a relevant business person outside the United Kingdom and accordingly agree that no amount in respect of VAT shall be payable by way of additional consideration payable for such Assets. The Buyer shall at the request of the Sellers provide its VAT number for the purposes of any dealings which the Sellers may have with HMRC in connection with the supply referred to in this clause 5.2.
- 5.3 The Buyer anticipates that it will be compulsorily required to register for VAT as a result of the acquisition of the Businesses and those of the Assets to be transferred to and acquired by the Buyer pursuant to the terms of this Agreement and has made an application to HMRC to be duly registered for the purposes of VAT with effect from Completion.
- 5.4 If HMRC determine that VAT is chargeable on the supply of any of the Assets in respect of which no VAT has been added to the consideration payable by the Buyer to the Sellers pursuant to the terms of this Agreement and notify the Sellers of such determination, then the Sellers will immediately on receipt of such notification issue to the Buyer or TBML (as appropriate) a valid VAT invoice in respect of the sale of those particular Assets ("Additional Vatable Assets") together with a copy of such notification from HMRC. Upon receipt of such invoice the Buyer or TBML (as appropriate) will pay to the Sellers the VAT charged on the sale of the Additional Vatable Assets provided that the Buyer or TBML (as appropriate) shall only be required to account to the Sellers in respect of such VAT within 5 Business Days prior to the date on which the Sellers are themselves required to account to HMRC in respect of such VAT. The Sellers will take such action and give such information and assistance as the Buyer and/or TBML may reasonably and promptly request to dispute or appeal any determination of HMRC referred to in this clause 5.4 provided that the Sellers shall not be required to take or allow an appeal to be taken beyond a decision of the First Tier Tribunal.

#### **6** Warranties

- 6.1 In consideration of the Buyer entering into this Agreement the Sellers warrant to the Buyer (for itself and as trustee for its successors in title):
  - 6.1.1 (subject to clause 6.2) in the terms of the Warranties; and
  - 6.1.2 that any Warranty which is qualified as being made "so far as the Sellers are aware" or "to the best of the knowledge, information and belief of the Sellers" or any similar expression has been so qualified after due diligent and careful enquiries by the Sellers of the following persons:
    - (i) Graham Mullis;
    - (ii) Susan Lowther;
    - (iii) Jacques Vidoret (in relation only to the Warranties at paragraph17 of Schedule 6);

- (iv) Denise Durkin (in relation only to the Warranties at paragraphs 13, 14 and 18 of Schedule 6);
- (v) Anthony Dyer (in relation only to the Warranties at paragraphs 3, 4, 5, 6, 7, 8, 9, 15, 19, 22 and 23 of Schedule 6):
- (vi) Anthony Cooke (in relation only to the Warranties at paragraphs 4, 5, 8, 10, 15, 16, 17 and 19 of Schedule 6); and
- (vii) Mike Annable (in relation only to the Warranties at paragraphs 3, 4, 7, 10 and 11 of Schedule 6) and that the Sellers have used all reasonable endeavours to ensure that all information given, referred to or reflected in that statement is accurate in all material respects.
- 6.2 The Warranties are qualified to the extent, but only to the extent, of the provisions of Schedule 7 and those matters fully and fairly disclosed in the Disclosure Letter and for this purpose "fully and fairly disclosed" means disclosed in such manner and in such detail as to enable a reasonable buyer to make an informed and accurate assessment of the matter concerned.
- 6.3 Each of the Warranties shall be construed as a separate and independent warranty and, save as expressly otherwise provided in this Agreement, shall not be limited by reference to any other Warranty or by any other provision of this Agreement and the Buyer shall have a separate claim and right of action in respect of each and every event, matter or circumstance which is inconsistent with, contrary to or otherwise a breach of any of the Warranties (as qualified by clause 6.2).
- 6.4 The Warranties shall not in any respect be extinguished or affected by Completion.
- 6.5 The Sellers agree with the Buyer that in the event of any claim being made against the Sellers whether under the Warranties or otherwise in connection with the sale of the Businesses or the Assets to the Buyer, the Sellers will not make any claim against any of the Employees on whom they may have relied before agreeing to any term of this Agreement or authorising any statement in the Disclosure Letter.

## 7 Restrictive covenants and Confidential Information

- 7.1 For the purpose of assuring to the Buyer the full benefit of and in consideration for the Buyer agreeing to buy the Businesses and the Assets on the terms of this Agreement, each of the Sellers undertakes to the Buyer and to TBML that they will not, and will procure that no Associated Company will, without the prior consent in writing of the Buyer and/or TBML whether directly, or indirectly and whether alone or in conjunction with any other person and whether as principal, shareholder, director, employee, agent, consultant, partner or otherwise:
  - 7.1.1 for a period of 2 years from the date of Completion carry on, be engaged, concerned or interested in any capacity (whether for reward or otherwise) in, provide any technical, commercial or professional advice to, or in any way assist any business which is or is about to be engaged in the manufacture, production, distribution, sale or supply of products or services which are competitive with or of the type supplied by the Businesses at Completion ("**Restricted Products or Services**") in competition with the Buyer and/or TBML;

- 7.1.2 for a period of 2 years from the date of Completion in relation to the Restricted Products or Services or any of them, solicit or canvass, accept orders from or otherwise deal with any person, firm, company or other organisation who was a customer of the Businesses or in the habit of doing business with the Sellers in relation to the Businesses at any time during the 2 years prior to Completion or at the date of Completion was in the process of negotiating or contemplating doing business with the Sellers in relation to the Businesses; or
- 7.1.3 for a period of 2 years from the date of Completion solicit or entice away or endeavour to solicit or entice away from the Businesses any person employed or otherwise engaged in the Businesses on the date of Completion, whether or not that person would commit any breach of his contract of employment by reason of his leaving the service of the Buyer or TBML.
- 7.2 Each of the Sellers undertakes with the Buyer and TBML that they will not (and shall procure that no Associated Company will) at any time after Completion without the express consent of the Buyer and/or TBML directly or indirectly, whether by itself, its employees or agents or otherwise howsoever:
  - 7.2.1 engage in any trade or business or be associated with any person firm or company engaged in any trade or business using the Trade Names or any name incorporating words used in the Trade Names or any similar name or names or any colourable imitation of them; or
  - 7.2.2 in the course of carrying on any trade or business, claim, represent or otherwise indicate any present association with the Businesses or, for the purpose of obtaining or retaining any business or custom, claim, represent or otherwise indicate any past association with the Businesses PROVIDED THAT the Sellers shall not be prevented from using the trade name "Lab21".
- 7.3 None of the restrictions contained in clauses 7.1 and 7.2 shall apply to the Sellers in the context of the proper performance by any of them of their duties pursuant to the terms of the TSA.
- 7.4 Each of the Sellers acknowledges that it has Confidential Information. Each of the Sellers further acknowledges that the disclosure of Confidential Information (whether directly or indirectly) to actual or potential competitors of the Businesses would place it at a competitive disadvantage and would do damage (whether financial or otherwise) to the Businesses. Each of the Sellers accordingly agrees to enter into the restrictions contained in clauses 7.5 to 7.8.
- 7.5 Each of the Sellers undertakes that it will not, and will procure that no Associated Company will, at any time after Completion:
  - 7.5.1 disclose any Confidential Information to any person except to those authorised by the Buyer and/or TBML to know;
  - 7.5.2 use any Confidential Information for their own purposes; or
  - 7.5.3 through failure to exercise all due care and diligence cause or permit any unauthorised disclosure of any Confidential Information.

- 7.6 The restrictions in clause 7.5 shall not apply:
  - 7.6.1 in respect of any of the Confidential Information which is in or becomes part of the public domain, other than through a breach of the obligations of confidentiality set out in this Agreement;
  - 7.6.2 to any of the Sellers to the extent that they are required to disclose Confidential Information by any applicable law, governmental order, decree, regulation, licence or rule or pursuant to the regulations of any securities exchange or regulatory or governmental body to which they are subject; or
  - 7.6.3 to any of the Sellers to the extent that they are required to use or disclose Confidential Information for the purposes of proper performance of their duties pursuant to the terms of the TSA.
- 7.7 The parties agree that each of the undertakings set out in this clause 7 are separate and severable and enforceable accordingly and if any one or more of such undertakings or part of an undertaking is held to be against the public interest or unlawful or in any way an unreasonable restraint of trade, the remaining undertakings or remaining part of the undertakings will continue in full force and effect and will bind the Sellers.
- 7.8 Each of the Sellers acknowledges that it has had the opportunity to take independent advice on the restrictions in clauses 7.1 to 7.6. While those restrictions are considered by the parties to be reasonable in all the circumstances, it is agreed that if any of those restrictions, by themselves or taken together, shall be adjudged to go beyond what is reasonable in all the circumstances for the protection of the legitimate interests of the Buyer and TBML but would be adjudged reasonable if part or parts of their wording were deleted or amended or qualified or their periods were reduced or the range of products or services or area dealt with by them were reduced in scope, then the relevant restriction or restrictions shall apply with such modification or modifications as may be necessary to make it or them valid and effective.

#### 8 Completion

- 8.1 The sale and purchase of the Businesses and the Assets will be completed at the offices of the Buyer's Solicitors or at such other place as the parties may agree immediately after the signing and exchange of this Agreement when the Sellers will deliver to the Buyer or TBML (as appropriate):
  - 8.1.1 all of the Assets which are capable of transfer by delivery whereupon the title to such Assets will pass to the Buyer (or pursuant to clause 2.6, TBML) by such delivery;
  - 8.1.2 the Leased Assets and the Loaned Assets (subject to the provisions of clause 13);
  - 8.1.3 the Contracts together with, where they have been requested by the Buyer or TBML and are available at Completion for exchange, duly executed agreements for the assignment or novation of them to the Buyer or TBML (as the Buyer shall direct), and all requisite consents and licences of any relevant third party, in each case in the agreed form;
  - 8.1.4 the Disclosure Letter;

- 8.1.5 an executed counterpart of the TSA;
- 8.1.6 the Records and the Marketing Information;
- 8.1.7 copies of all Sale Consents;
- 8.1.8 all mortgages, debentures or charges over the Assets (or any of them) duly vacated or (if the mortgages or charges also relate to other property) duly executed releases of the Assets from all mortgages, debentures or charges over the Assets (such releases to include confirmation that no steps have been taken to crystalise any floating charges contained therein) in the agreed form; and
- 8.1.9 the originals of all documents in the Sellers' possession constituting or evidencing the Employees' contracts of employment together with all National Insurance and PAYE records fully completed in respect of the Employees and showing that payments are up to date.
- 8.2 On Completion the Buyer shall:
  - 8.2.1 pay the sum of £2,900,000 (two million nine hundred thousand pounds) to the Bank in cash by way of CHAPS transfer from a clearing bank to such account as may have been communicated to the Buyer's Solicitors by the Bank (or its nominated advisers) for the purposes of receipt of such sum and payment of such sum to the Bank will be a good and sufficient discharge to the Buyer in respect of that sum and the Buyer will not be further concerned as to the application of the money so paid; and
  - 8.2.2 pay the sum of £1,442,752 (one million four hundred and forty two thousand seven hundred and fifty two pounds) in cash by way of a CHAPS transfer from a clearing bank to the client account of the Sellers' Solicitors (who will supply details on request) or by such other method as shall be agreed between the parties; and
  - 8.2.3 authorise the Sellers' Solicitors to release £75,000 from the Exclusivity Payment.
- 8.3 The Sellers' Solicitors are authorised to receive that part of the Completion Payment referred to in clause 8.2.2 and that part of the Exclusivity Payment referred to in clause 8.2.3 (and subject to its release in accordance with clause 10, the Exclusivity Payment Balance) on behalf of the Sellers and payment and/or release of such sums to them as provided for in clause 8.2 and in clause 10 will be a good and sufficient discharge to the Buyer and the Buyer will not be further concerned as to the application of the money so paid or its allocation as between the Sellers.
- 8.4 Within 30 Business Days following Completion the Sellers will:
  - 8.4.1 provide duly executed assignments of the Seller IPR and Goodwill to TBML together with:
    - (i) all documents of title, certificates, deeds, licences, agreements and other documents relating to them and (where registration in respect of any of them has been applied for but has not been obtained at the date of Completion) copies of the relevant applications; and

- (ii) all manuals, drawings, plans, documents and other materials and media on which the Know-how and the Confidential Information are recorded;
- 8.4.2 provide duly executed counterparts of any further documents which may be reasonably required by the Buyer and/or TBML to transfer or re-register any Seller IPR into the name of TBML in any jurisdiction where such Seller IPR may be registered;
- 8.4.3 make, or instruct an agent to make, the necessary applications to cause the rights in the Domain Names to be transferred by the relevant domain name registrar to the Buyer or TBML (or as the Buyer shall direct);
- 8.4.4 provide any supporting letters and documentation that may be required by the relevant domain name registrar in order to transfer the rights in any of the Domain Names to the Buyer or TBML (or as the Buyer shall direct); and
- 8.4.5 provide to the Buyer or TBML all the passwords and signed letters of instruction necessary to change the agent/tag holder together with any such further information as may be required to enable title to and control of the Domain Names to transfer to the Buyer or TBML.
- 8.5 The Sellers confirm and acknowledge to the Buyer that they have secured and obtained all Sale Consents and hereby indemnify the Buyer and TBML in connection with any and all actions, claims and proceedings from time to time made against the Buyer and/or TBML and all loss or damage and all payments, costs or expenses made or incurred by them as a consequence of any failure by the Sellers to secure or obtain any such Sale Consents.

### 9 Properties

- 9.1 The provisions of Part B of Schedule 2 will apply in relation to the Properties.
- 9.2 The Buyer will be responsible for the discharge of the Exit Liabilities (as defined in clause 9.4). Where the Leases have not been assigned to the Buyer prior to the establishment of the Exit Liabilities, then subject to receipt of the Rent Deposit pursuant to clause 9.3, the Buyer will pay the Exit Liabilities (using the Rent Deposit) to the relevant landlord as agent for the Sellers.
- 9.3 In connection with the Rent Deposit (which the parties acknowledge is an Asset the rights title and interest to which has been purchased by the Buyer pursuant to this Agreement), Lab21 undertakes to the Buyer that:
  - 9.3.1 it shall use all reasonable endeavours to procure that Siemens Healthcare Diagnostics Products Limited (as 'Landlord' under the Rent Deposit Deed) ("**Siemens**") shall pay the Rent Deposit to the Buyer as and when such amount becomes due and payable to Lab21 in accordance with the terms of the Rent Deposit Deed; or
  - 9.3.2 where Siemens pays the Rent Deposit to Lab21, Lab21 shall remit such amount to the Buyer immediately upon receipt.

- 9.4 The Buyer will use the Rent Deposit for the purposes of satisfying liabilities for dilapidations in respect of the Properties ("Exit Liabilities"). The Buyer undertakes to Lab21 to negotiate with the relevant landlords of the Properties with the objective, where possible, of minimising Exit Liabilities. In connection with such negotiations, the Buyer undertakes to Lab21 to:
  - 9.4.1 inform and consult with Lab21 in connection with the progress of such negotiations; and
  - 9.4.2 consider and take account of all reasonable proposals of Lab21 for minimising Exit Liabilities prior to taking agreeing the amount of the Exit Liabilities with any such landlord.
- 9.5 Where the negotiations with the relevant landlords of the Properties result in Exit Liabilities being less than the Rent Deposit Amount (a "Saving"), subject to receipt of the Rent Deposit pursuant to clause 9.3, the Buyer shall pay an amount equal to 50% of the Saving to Lab21, after deduction of reasonable third party costs and expenses incurred by the Buyer in agreeing Exit Liabilities with the relevant landlord.
- 9.6 Where Exit Liabilities exceed the Rent Deposit Amount, then subject to receipt of the Rent Deposit pursuant to clause 9.3, the Buyer shall use the full amount of the Rent Deposit for the purposes of satisfying such liabilities and acknowledges that it shall be responsible (without recourse to the Sellers) for settlement of Exit Liabilities.
- 9.7 For the purposes of this clause 9, "**Rent Deposit Amount**" shall mean the amount held by Siemens under the Rent Deposit Deed before any deductions for dilapidations.

### 10 Debts and Creditors

- 10.1 The Debts are excluded from the sale and purchase of the Businesses and shall be an Excluded Asset.
- 10.2 The Buyer shall, subject to the provisions of this clause 10, assume responsibility for and discharge the Creditors and shall indemnify the Sellers in respect of the same.
- 10.3 At the request of the Buyer, the Sellers shall, as agents and on behalf of the Buyer, settle amounts due to any of the Creditors which the Buyer requires the Sellers (or either of them) to discharge on its behalf, subject always to being placed in sufficient funds by the Buyer to discharge the amount(s) due to any such Creditor. Where a Seller agrees to discharge any such Creditor in accordance with this clause 10.3, it shall do so within 2 Business Days of being placed in funds by the Buyer for the purpose.
- 10.4 The Buyer and the Sellers acknowledge that the Completion Payment has been adjusted to take account of the amounts which the Sellers have disclosed to the Buyer as being payable to Creditors (being £207,248), with such amounts being specified in Schedule 8 ("Expected Creditor Payments").
- 10.5 The Buyer shall, as soon as possible following Completion, and in any event within 20 Business Days thereof, deliver to the Sellers an assessment (the "**Draft Assessment**") setting out:
  - 10.5.1 payments the Buyer has made to Creditors since the Transfer Date, together with details (where applicable) of where any such payments made have exceeded Expected Creditor Payments (due to Expected Creditor Payments or any of them having been understated by the Sellers) PROVIDED THAT no payments in excess of the Expected Creditor Payments shall be made by the Buyer without the prior agreement of the Sellers, such agreement not to be unreasonably withheld or delayed; and

10.5.2 payments to Creditors which the Buyer has agreed with the Creditors still need to be made by the Buyer to such Creditors:

(together "Required Creditor Payments").

- 10.6 The Sellers shall notify the Buyer within 5 Business Days of the later of receipt of the Draft Assessment or 5th August 2013 ("Review Period"), whether or not it accepts the Draft Assessment for the purposes of this Agreement. If the Sellers are satisfied with the content of the Draft Assessment, then the Consideration shall be adjusted as set out in clauses 10.8 to 10.10 (as applicable) and settled in accordance with clause 10.11. If within the Review Period the Sellers notify the Buyer that they object to the contents of the Draft Assessment, then the Buyer and the Sellers shall negotiate in good faith to attempt to agree such amendments to the Draft Assessment as may be deemed necessary. Where agreement is subsequently reached on the matter, then the Consideration shall be adjusted as set out in clauses 10.8 to 10.10 (as applicable) and settled in accordance with clause 10.11. If the Sellers and the Buyer fail to agree the Draft Assessment, the matter shall be referred to an Independent Accountant as provided for in clause 12.3 but by reference to this clause 10. The Draft Assessment when agreed or determined shall become the final assessment ("Final Assessment").
- 10.7 The Sellers and the Buyer shall use all reasonable endeavours to procure that all records, working papers and other information as may reasonably be required by the Buyer or the Sellers for the purposes of clauses 10.4 to 10.6 (inclusive) shall be made available to them on request.
- 10.8 Where in the Final Assessment the Expected Creditor Payments are found to have been correct and there does not require further adjustment in respect of such payments, then the Buyer shall promptly authorise the release of the Exclusivity Payment to the Sellers in full within 2 Business Days of such finding.
- Where in the Final Assessment (as approved or determined in accordance with clause 10.6) the value of Required Creditor Payments is found to be less than Expected Creditor Payments (the amount by which Expected Creditor Payments exceeds Required Creditor Payments being an "an Overprovision"), then the Buyer shall:
  - 10.9.1 promptly authorise the release of the full amount of the Exclusivity Payment Balance to the Sellers; and
  - 10.9.2 to the extent that it can satisfy the Overprovision in full, satisfy the Overprovision by applying a credit of against rent agreed by the Sellers to be payable to the Buyer for the six months commencing on the Transfer Date in respect of their occupation of the Cambridge Property for such period less any such rent paid since the Transfer Date (with such credit being applied evenly over the remainder of such six month period); and
  - 10.9.3 to the extent the Overprovision has not been satisfied in full by the provisions of clause 10.9.2, then the Buyer shall make an additional payment in cash to the Sellers to satisfy the remaining amount of the Overprovision ("Buyer's Additional Payment").

- 10.10 Where in the Draft Assessment (as approved or determined in accordance with clause 10.6) the value of Required Creditor Payments is found to exceed the value of Expected Creditor Payments, then the Buyer shall (subject to the Exclusivity Payment exceeding the value of such excess) be entitled to deduct an amount equal to the difference ("the Excess") from the Exclusivity Payment and shall promptly authorise the release of the remaining balance of the Exclusivity Payment to the Sellers, provided that if the value of the Excess exceeds the value of the Exclusivity Payment, the Exclusivity Payment shall be released to the Buyer in full and the Sellers shall promptly pay to the Buyer an amount equal to the difference between the Exclusivity Payment and the actual value of the Excess ("Sellers' Additional Payment").
- 10.11 Payment of the Buyer's Additional Payment or the Sellers' Additional Payment shall, as appropriate, be made by payment into the account of the Sellers' Solicitors specified pursuant to clause 8.2 or into such account as the Buyer' Solicitors shall nominate for the purpose (or into such other accounts as the Buyer and the Sellers may otherwise agree for the purpose).

### 11 Liabilities and apportionments

- 11.1 Save as otherwise expressly provided in this Agreement (including avoidance of doubt the assumption of the Exit Liabilities by the Buyer pursuant to clause 9.2 and the assumption of the Creditors by the Buyer pursuant to clause 10.2) and notwithstanding anything to the contrary contained in any agreement for the assignment or novation of any Contract to which the Sellers and the Buyer and/or TBML become a party on or after Completion (a "Contract Novation"), all profits and receipts of the Businesses and all losses, liabilities and outgoings in respect of the Businesses up to the Transfer Date shall belong to and be paid, borne and discharged by the Sellers and all profits and receipts of the Businesses and all losses, liabilities and outgoings of the Businesses after the Transfer Date shall belong to and be paid, borne and discharged by the Buyer, or where they may relate to any Contract, by TBML.
- 11.2 The parties agree to indemnify each other so as to give effect to the above sub-clause.
- 11.3 The Buyer (with the co-operation of the Sellers) shall cause a schedule of apportionments as at the Transfer Date to be prepared and agreed within 30 Business Days of the Transfer Date. That schedule shall show all expenses, outgoings, income, customer deposits, prepayments, accruals and similar items (including Employees' holiday pay) which relate to periods which extend both before and after the Transfer Date. Any net balance due in accordance with the schedule shall be paid to the party entitled to it within 5 Business Days after the amount due is agreed or determined. If the schedule of apportionments is not agreed within 30 Business Days of the Transfer Date, the matter shall be referred by either the Sellers or the Buyer (as the case may be) to the Independent Accountant who will act as an expert and not as an arbitrator and will ascertain and certify the amount (if any) payable by the Sellers to the Buyer or (as the case may be) the Buyer to the Sellers in accordance with the foregoing provisions of this clause 11. The decision of the Independent Accountant (which will be notified in writing to the Sellers and the Buyer) will be final and binding on the parties and his fees will be borne by the Sellers and the Buyer in such proportions as he may determine or, in the absence of any such

- determination, by the Sellers and the Buyer in equal shares. The Sellers and the Buyer will provide the Independent Accountant with such information and assistance as he may reasonably require for the purpose of resolving the dispute and ascertaining and certifying the amounts in question.
- Without prejudice to clause 11.1, nothing in this Agreement or contained in any Contract Novation will make the Buyer and/or TBML liable in respect of the Excluded Liabilities or anything done or omitted to be done by the Sellers up to the Transfer Date or in relation to the use of the Assets or the carrying on of the Businesses generally up to the Transfer Date, other than as may have been specifically assumed by the Buyer and/or TBML under this Agreement. The Sellers will indemnify the Buyer and TBML in full against any losses or damage to the Businesses or any liability (which liability will include all losses or costs, claims, expenses and damages including legal and other reasonable and properly incurred professional fees and expenses) which the Buyer and/or TBML may suffer or incur, directly or indirectly, as a result of anything done or omitted to be done by the Sellers including:
  - 11.4.1 any failure by the Sellers in the performance of any of the obligations of the Sellers falling due up to the Transfer Date under any of the Contracts; and
  - 11.4.2 any act, default or transaction of the Sellers or any circumstance occurring in respect of the use of the Assets or the carrying on of the Businesses up to the Transfer Date including those in any way relating to Contracts with customers entered into prior to the Transfer Date in respect of products sold and/or delivered or services rendered by the Buyer and/or TBML after the Transfer Date, as well as products sold and/or delivered or services rendered by the Sellers up to the Transfer Date, and so that where there are any claims by any third parties in respect of products sold and/or delivered or services rendered up to the Transfer Date the claims will be met in full by the Sellers.
- 11.5 Nothing in this Agreement will make the Sellers liable in respect of anything done or omitted to be done by the Buyer and/or TBML after the Transfer Date or in relation to the use of the Assets or the carrying on of the Businesses by the Buyer and/or TBML generally after the Transfer Date other than as may have been specifically assumed by the Sellers under this Agreement. The Buyer or TBML (as appropriate) will indemnify the Sellers in full against any losses or damage or any liability (which liability will include all losses or costs, claims, expenses and damages including legal and other reasonable and properly incurred professional fees and expenses) which the Sellers may suffer or incur as a result of anything so done or omitted to be done by the Buyer or TBML (as appropriate).
- Where at any time after the Transfer Date, the Sellers are the subject of a claim made by a customer of the Businesses in relation to the supply of defective products by the Sellers prior to the Transfer Date or services provided by the Sellers prior to the Transfer Date for which the Sellers are responsible pursuant to the provisions of clause 11.4 (a "Customer Claim") and the Sellers are, due to having sold the Businesses and the Assets pursuant to the terms of this Agreement, unable to provide replacement products or additional services requested by such customer for the purposes of satisfying any such Customer Claim, then the Sellers may make a request of the Buyer and/or TBML that it supply the Sellers with such replacement products or services as they may reasonably require in order to assist it in satisfying that Customer Claim PROVIDED THAT where the Buyer and/or TBML agrees to provide the Sellers with such replacement products or services, the Buyer and/or

TBML and the Sellers will negotiate in good faith to agree terms on which the Buyer and/or TBML will supply the same to the Sellers and the Buyer and/or TBML (as appropriate) shall be entitled, as a minimum, to charge the Sellers at cost for providing such products or services.

11.7 Notwithstanding any other provision in this Agreement the Seller shall not be liable for any repair or replacement costs relating to the Assets.

### 12 Contracts

- 12.1 Subject to the provisions of clause 11 and the other provisions of this clause 12 the Buyer and/or TBML will with effect from Completion adopt, perform and fulfil the Contracts.
- In so far as the benefit (subject to the burden) of any of the Contracts cannot be transferred by the Sellers to the Buyer or TBML except by way of an agreement or novation or with consent to the assignment from a third party then this Agreement will not operate to transfer the benefit of any such Contract and:
  - 12.2.1 the Sellers will, at their own expense when required to do so by the Buyer or TBML, use their respective best endeavours (with the co-operation of the Buyer or TBML) to procure that such Contracts are novated or assigned or consent is obtained as soon as is reasonably practicable (provided that the Buyer and/or TBML will not be obliged to make any payment, give any security or provide any guarantee as the basis for any such novation, assignment or consent);
  - 12.2.2 subject to clause 12.3, unless and until any such Contracts are novated or assigned or consent is obtained, the Sellers will continue their corporate existence, will hold the benefit of such Contracts upon trust for the Buyer and/or TBML absolutely and will account to the Buyer and/or TBML for any sums or any other benefits received by the Sellers in relation to such Contracts without any deduction or withholding of any kind;
  - subject to clause 12.3, the Buyer and/or TBML will, as the Sellers' agent, perform all the obligations of the Sellers relating to the period after the Transfer Date;
  - 12.2.4 subject to clause 12.3, unless and until any such Contracts are novated or assigned or consent is obtained the Sellers will act in accordance with the reasonable directions of the Buyer and/or TBML in all matters relating to such Contracts for so long as the Sellers are required and authorised so to do by the Buyer and/or TBML.
- 12.3 If notwithstanding the best endeavours of the Sellers pursuant to clause 12.2, the rights and obligations of the Sellers under any Contract sold to the Buyer or transferred to TBML cannot be transferred to the Buyer or TBML whether by way of novation or assignment or because any necessary consent is not forthcoming or is refused or otherwise not obtained on terms reasonably satisfactory to the Buyer and/or TBML within 20 Business Days of having been sought, then the Buyer and/or TBML will be entitled by notice in writing to the Sellers to require the Sellers either to terminate the relevant Contract or to exclude the same from the Assets whereupon the Sellers will indemnify the Buyer and/or TBML in full against any liability or obligation in respect of such Contract and all losses or costs, claims, expenses and damages (including legal and other professional fees and expenses) arising from such Contract or its termination or exclusion from this Agreement.

### 13 <u>Leased Assets, Loaned Assets and Software</u>

- 13.1 The Sellers shall allow the Buyer to take possession of the Leased Assets and the Loaned Assets upon Completion on terms that:
  - 13.1.1 the Buyer undertakes not to hold itself out as owner of the Leased Assets or the Loaned Assets nor to sell offer for sale, assign, charge or create any lien on such Leased Assets and Loaned Assets and to keep the Leased Assets and the Loaned Assets in its own possession and at its own expense (including any rentals or other similar charges due in respect of the period the Buyer has possession); and
  - 13.1.2 the Buyer undertakes that during such time as it is not the owner of the Leased Assets or the Loaned Assets it will at its own cost deliver possession of the Leased Assets to the Sellers immediately upon demand or to the owner of the Loaned Assets as and when required to do so by the owner(s) thereof.
- 13.2 The Sellers agree that, at the request of the Buyer made within a period of 60 days of Completion, they will use their respective reasonable endeavours to assist the Buyer in reaching satisfactory arrangements with the respective owners of the Leased Assets and (if required, the Loaned Assets). For the avoidance of doubt the Sellers shall not be under any obligation to make any payments to the owners or suppliers of any of the Leased Assets or the Loaned Assets in assisting the Buyer under this clause.
- 13.3 The Sellers acknowledge that, whilst the Buyer is not acquiring any right to the Q-Pulse system which includes Third Party Software, certain data contained within the Q-Pulse system forms part of the Records (being an Asset acquired by the Buyer under this Agreement). Accordingly, without prejudice to any other provision of this Agreement or the TSA, the Buyer and its agents will be entitled at any time on giving reasonable notice to have access to and take copies (in whatever format reasonably requested) of any and all Records which are stored on the Q-Pulse system.

### 14 **Employees**

- 14.1 The parties acknowledge that TUPE applies to the sale and purchase of the Businesses effected by this Agreement and accordingly the contracts of employment between the Sellers and the Employees (save for the provisions and rights relating to occupational pension schemes, if any, excluded by regulation 10 TUPE) shall transfer the Buyer with effect from the Transfer Date pursuant to TUPE.
- 14.2 Prior to the Transfer Date the Sellers shall;
  - 14.2.1 use reasonable endeavours to retain the services of each of the Employees and shall not dismiss any of the Employees without the Buyer's written consent which shall not be withheld in the case of serious misconduct;
  - 14.2.2 not make, propose or permit any change in their terms and conditions of employment or other arrangement of any of the Employees;

- 14.2.3 not replace any of the Employees or deploy any person other than those who are already assigned to the Businesses or materially increase the proportion of time any Employee or any other employee of the Sellers or any Associated Company spends working in connection with the Businesses (save in the case of such of the Employees where the increase is caused by the work done in relation to this Agreement); and
- 14.2.4 not increase or seek to increase the emoluments (excluding cost of living increases awarded in the ordinary course of business) payable to any of the Employees.
- 14.3 The Sellers have provided in Schedule 4 and the documents attached to the Disclosure Letter the employee liability information as required by regulation 11 TUPE in the time and manner stipulated by that regulation, informing the Buyer in writing immediately of any updates to that information.
- 14.4 The Sellers will in respect of the period on or before the Transfer Date:
  - pay all wages, salaries and other benefits of the Employees (including any contributions to retirement benefit schemes) and discharge all other financial obligations (including reimbursement of any expenses) owing to the Employees;
  - 14.4.2 procure that any loans or advances made to the Employees before the Transfer Date are repaid to them by the Transfer Date;
  - 14.4.3 account to the proper authority for all PAYE tax deductions and national insurance contributions payable in respect of the Employees; and
  - 14.4.4 pay the Buyer (as directed) within 14 days of the Transfer Date an amount which fairly reflects the progress of each of the Employees towards achieving any commission, bonus, profit share or other incentive payment payable after the Transfer Date wholly or partly in respect of a period before the Transfer Date.
- 14.5 The Sellers will discharge their obligations under clauses 14.4.1 and 14.4.3 on or before 25 July 2013. After the Transfer Date, the Sellers will pay the sums due under clause 14.4.1 and discharge the obligations under clause 14.4.3 until 31 July 2013 as the agent of the Buyer and at the Buyer's expense.
- 14.6 The Sellers shall indemnify the Buyer in full against all Employment Liabilities arising out of or connected with any claim or other legal recourse by:
  - 14.6.1 any of the Employees (whether on their own behalf or in their capacity as employee representatives) which relates to any actual or alleged act or omission of any of the Sellers or any Associated Company prior to the Transfer Date or any other event or occurrence prior to the Transfer Date save for where such act or omission results from complying with the instructions of the Buyer or the event or occurrence happens or occurs because of an act or omission or a prospective act or omission of the Buyer and/or;
  - 14.6.2 any employee representatives acting on behalf of any of the Employees which relates to any actual or alleged act or omission of any of the Sellers or any Associated Company prior to the Transfer Date or any other event or occurrence prior to the Transfer Date save for where such act or omission results from complying with the instructions of the Buyer or a failure by the Buyer to provide information required under regulation 13(4) of TUPE;

- 14.6.3 any claim or allegation by an Employee or any trade union, staff association or staff body recognised by the Sellers in respect of any of the Employees or any employee representatives acting on behalf of any of the Employees which relates to any actual or alleged failure by any of the Sellers to comply with regulation 13 of TUPE save where the Buyer has failed to comply with its obligations under regulation 13(4) of TUPE (where the reason for such failure does not relate to the acts or omissions of any of the Sellers); and
- 14.6.4 any material statement communicated to or material action taken by any of the Sellers or any Associated Company in respect of any of the Employees on or before the Transfer Date regarding the transfer effected by this Agreement which has not been agreed in advance with the Buyer.
- 14.7 The parties intend that TUPE shall apply only to the Employees and accordingly the Sellers undertake to indemnify the Buyer in full from all Employment Liabilities arising out of or in connection with:
  - 14.7.1 any contract of employment (including, without prejudice to the generality of the foregoing, the termination of it) with; or
  - 14.7.2 any obligation in relation to any matter whatsoever (whether arising before or after the Transfer Date) to

any person who is not an Employee where such contract or obligation is transferred to the Buyer under TUPE (or under any EC directive, regulation or other legislation having like effect) by the sale and purchase of the Businesses effected by this Agreement or is alleged by such person (or employee representative acting on behalf of such person) to have been so transferred.

- 14.8 The Buyer shall indemnify the Sellers in full against all Employment Liabilities arising out of or connected with:
  - 14.8.1 any actual or alleged act or omission of Buyer after the Transfer Date (or any other event or occurrence after the Transfer Date) in respect of any Employee (including but not limited to any liability which arises because an Employee's employment with the Buyer is deemed to include his previous continuous employment with the Sellers) save where such act or omission results from complying with the instructions of the Sellers;
  - 14.8.2 any claim or allegation by an Employee or any employee representatives acting on behalf of any of the Employees which relates to any actual or alleged failure by the Buyer to comply with its obligations under regulation 13(4) of TUPE save where the failure stems from the acts or omissions of any of the Sellers;
  - 14.8.3 any claim or allegation by any of the Employees (whether on their own behalf or in their capacity as employee representatives) that there has been or will be a substantial change in working conditions to their material detriment within regulation 4(9) of TUPE.

- 14.9 The following provisions shall apply in the event of any claim being made or threatened against the Buyer which involves or gives rise to or is likely to involve or give rise to an obligation or liability which the Sellers are required to discharge or in respect of which or any part of which the Sellers are required to reimburse or otherwise make any payment to or indemnify the Buyer under this clause:
  - 14.9.1 the Buyer shall notify the Sellers in writing immediately upon receipt by the Buyer or its otherwise becoming aware of the claim;
  - 14.9.2 the Buyer shall allow the Sellers and their professional advisers to investigate the matter or circumstances alleged to give rise to such claim and whether and to what extent any amount is payable in respect of such claim and for such purpose the Buyer shall give all such information and assistance including access to premises and personnel and the right to examine and copy or photograph any assets, accounts, documents and records as the Sellers or their professional advisers may reasonably request. The Sellers agree to keep all such information confidential and only to use it for the purposes of this clause;
  - 14.9.3 no admission of liability shall be made by or on behalf of the Buyer and the claim shall not be compromised, disposed of or settled without the prior written consent of the Sellers; and
  - 14.9.4 at their own cost the Sellers shall have the right to control, conduct or settle any such claim but shall consult fully with the Buyer as to the question of resisting, appealing, compromising or contesting it.
- 14.9 The provisions of clause 14.8 shall apply mutatis mutandis in respect of any claim which is made or threatened against the Sellers which involves or gives rise to or is likely to involve or give rise to an obligation or liability which the Buyer is required to discharge or in respect of which or any part of which the Buyer is required to reimburse or otherwise make any payment to or indemnify the Sellers under this clause and for such purposes all references in clause 14.9 to the Sellers shall be construed as references to the Buyer and vice versa.

### 15 TBML Guarantee

- 15.1 In consideration of the Sellers entering into this Agreement, at the request of the Buyer, TBML unconditionally and irrevocably guarantees to the Sellers, the due and punctual payment of all monies payable by the Buyer under this Agreement.
- 15.2 If the Buyer defaults on the payment of any amount due and payable to the Sellers under this Agreement, TBML shall immediately on demand by the Sellers unconditionally pay that amount to the Sellers in the manner prescribed in this Agreement as if it were the Buyer.
- 15.3 This guarantee is a continuing guarantee and shall extend to the ultimate balance of sums payable by the Buyer under this agreement, regardless of any intermediate payment or discharge in whole or in part. It shall not be affected by an act, omission, matter or thing which, but for this clause 15.3, would reduce, release or prejudice any of TBML's obligations under this clause 15 (without limitation and whether or not known to it or the Sellers).

- 15.4 If any payment by the Buyer, or any discharge given by the Sellers is avoided or reduced as a result of insolvency or any similar event, the liability of the Buyer and TBML shall continue as if the payment, discharge, avoidance or reduction had not occurred and the Sellers shall be entitled to recover the value or amount of that security or payment. TBML waives any right it may have of first requiring the Sellers (or any trustee or agent on its behalf) to proceed against or enforce any other rights or security or claim payment from any person before claiming from TBML under this clause 15.
- 15.5 Until all amounts which may be or become payable by the Buyer under or in connection with this Agreement have been irrevocably paid in full and unless the Sellers otherwise directs in writing, TBML shall not exercise any rights which it may have from or against the Buyer, its liquidator, an administrator, co-guarantor or any other person by reason of performance by it of its obligations under this clause 15.
- 15.6 The obligations of TBML shall be in addition to and independent of all other security which the Sellers may at any time hold in respect of any of the obligations of the Buyer under this Agreement.

#### 16 Information and access

- 16.1 Without prejudice to any other provision of this Agreement the Buyer and TBML and its agents will be entitled for a period of 6 years from Completion on giving reasonable notice to have access during normal business hours and to take copies (at its own expense) of any books documents or other records (including computer records) relating (whether wholly or partly) to the Businesses and the Assets and which have not been delivered to the Buyer.
- 16.2 The Sellers and their agents will, where necessary for the completion of their accounts or tax returns or for dealing with any claims or disputes relating to the use of the Assets or the carrying on of the Businesses up to the Transfer Date, be entitled for a period of 6 years from Completion on giving reasonable notice to have access during normal business hours and to take copies of (at their own expense) any of the Records.

#### 17 Future enquiries and assistance

- 17.1 The Sellers agree with the Buyer and TBML promptly to refer all enquiries relating to the Businesses to the Buyer and to assign to the Buyer and/or TBML (as appropriate) all orders relating to the Businesses which the Sellers may receive after Completion.
- 17.2 The Sellers will at the Buyer's and/or TBML's request and cost give to the Buyer and/or TBML (as appropriate) all reasonable assistance within the power of the Sellers to enable the Buyer and or TBML (as appropriate) to enforce the Claims or any of them.

#### 18 <u>Further assurance</u>

18.1 The parties agree that they will do or procure the doing of all such acts and things and execute or procure the execution of all such documents as may be required on or after Completion to vest in the Buyer or TBML legal and beneficial ownership of those of the Assets which are being acquired or transferred to them in accordance with this Agreement and otherwise to give effect to its terms.

### 19 Continuing effects of this Agreement

19.1 All provisions of this Agreement shall so far as they are capable of being performed or observed continue in full force and effect notwithstanding Completion except in respect of those matters then already performed and Completion shall not constitute a waiver of any of the Buyer's or TBML's rights in relation to this Agreement. All rights and remedies conferred on the Buyer or TBML under this Agreement are cumulative and are additional to, and not exclusive of, any rights or remedies provided by law or otherwise available at any time to the Buyer and/or TBML.

### 20 Announcements and confidentiality

- Save as (but only to the extent) expressly required by law or by any relevant regulatory, governmental or quasi-governmental authority all announcements by, or on behalf of any of the parties to this Agreement relating to the transactions contemplated by this Agreement or any matter ancillary to it and any disclosure of the terms of this Agreement (save as required by law) made by the Sellers shall be in terms previously approved in writing by the Buyer and/or TBML.
- 20.2 Each party shall at all times after the date of this Agreement keep and procure to be kept strictly confidential all information belonging to any of the other parties received or obtained as a result of entering into or performing this Agreement and any document in the agreed form which relates to:
  - 20.2.1 the subject matter and provisions of this Agreement;
  - 20.2.2 the negotiations relating to this Agreement; and
  - 20.2.3 each of the other parties

and shall neither use nor disclose any such information except for the purposes of the proper performance of this Agreement or with the prior written consent of the other parties. Where disclosure is made to any employee, consultant, adviser or agent, it shall be made subject to obligations equivalent to those set out in this Agreement and each party shall use its reasonable endeavours to procure that any such employee, consultant, adviser or agent complies with all those obligations. Each party shall be responsible to each of the other parties in respect of any disclosure or use of any such information belonging to the other parties by a person to whom disclosure is made. In this clause 20.2 disclosure includes disclosure in writing or by any other means.

- 20.3 The obligations of confidentiality in this clause 20 shall not extend to a party in respect of any matter which that party can show:
  - 20.3.1 is in or the public domain other than as a result of a breach of the obligations of confidentiality under this Agreement;
  - 20.3.2 was in that party's written records prior to the date of this Agreement and not subject to any obligations of confidentiality;
  - 20.3.3 was independently disclosed to that party by a third party entitled to disclose it;

- 20.3.4 is required to be disclosed for the purposes of stamping, by law of any relevant jurisdiction or for the purpose of any judicial or quasi-judicial proceedings;
- 20.3.5 is required by or for the purposes of any filing or registration by a party with any regulatory, governmental or quasigovernmental authority to which any party is subject or submits and wherever situated, (including the United Kingdom Listing Authority, the Land Registry and HM Revenue and Customs) and whether or not the requirement for information has the force of law; or
- 20.3.6 is disclosed on a strictly confidential, need to know basis to the employees, professional advisors, auditors and bankers of such party.

#### 21 Releases waivers etc by the Buyer/TBML

- 21.1 The Buyer and TBML may, in their discretion, in whole or in part release, compound or compromise, or waive its rights or grant time or indulgence in respect of, any liability of any the Sellers to them under this Agreement.
- 21.2 Subject to paragraph 1.2 of Schedule 7, neither the single or partial exercise or temporary or partial waiver by the Buyer or TBML of any right, nor the failure by the Buyer or TBML to exercise in whole or in part any right or to insist on the strict performance of any provision of this Agreement, nor the discontinuance, abandonment or adverse determination of any proceedings taken by the Buyer or TBML to enforce any right or any such provision shall (except for the period or to the extent covered by any such temporary or partial waiver) operate as a waiver of, or preclude any exercise or enforcement or (as the case may be) further or other exercise or enforcement by the Buyer or TBML of, that or any other right or provision.
- 21.3 The giving by the Buyer or TBML of any consent to any act which by the terms of this Agreement requires such consent shall not prejudice the right of the Buyer or TBML to withhold or give consent to the doing of any similar act.
- 21.4 The rights and remedies expressly provided for by this Agreement will not exclude any rights or remedies provided by law.

### 22 <u>Notices</u>

- Except as otherwise provided in this Agreement, every notice (including any request, demand, instruction, communication or other document) under this Agreement shall be in writing and shall be deemed to be duly given if it is addressed to the party to whom it is intended to be given at its authorised address and:
  - delivered by hand personally to the addressee (or, where the addressee is a corporation, any one of its directors or its secretary) or left in a letter box or other appropriate place for the receipt of letters at that address; or
  - 22.1.2 duly sent by prepaid first class post (or by airmail registered post if overseas); or
  - 22.1.3 duly transmitted to that address by facsimile transmission ("fax"),

and, in proving the giving or service of such notice, it shall be conclusive evidence to prove that the envelope containing such notice was addressed to the authorised address of the relevant party and delivered either to that address or into the custody of the postal authorities as a pre-paid first class post (or airmail registered post if overseas) letter, or that the notice was transmitted by fax to the fax number of the relevant party. The fact that the intended recipient of a notice shows that he did not receive the same, whether or not that fact was known to the giver of the notice, shall not derogate from the effectiveness in law of the service as provided by this clause 22.

- 22.2 Any notice duly given within the meaning of clause 22.1 shall be deemed to have been both given and received
  - 22.2.1 if it is delivered in accordance with clause 22.1.1, upon such delivery;
  - 22.2.2 if it is duly posted in accordance with clause 22.1.2, on the second (or, when sent by airmail, fifth) Business Day after the day of posting; or
  - 22.2.3 if it is transmitted by fax in accordance with clause 22.1.3, either upon receipt by the sender during business hours of the correct transmission report, or, if such report is received outside business hours, then at 10.00am on the Business Day following receipt of the correct transmission report.
- 22.3 No party shall attempt to prevent or delay the service upon it of any notice connected with this Agreement.
- 22.4 The provisions of this clause 22 will not apply, in the case of service of court documents, to the extent that such provisions are inconsistent with Part 6 of the Civil Procedure Rules.

#### 23 Entire Agreement

- 23.1 This Agreement (together with all documents which are required by its terms to be entered into by the parties or any of them) and all those terms of any other documents which this Agreement expressly preserves sets out the entire agreement and understanding between the parties in connection with the sale and purchase of the Businesses and the Assets and other transactions described in this Agreement and supersedes all previous understandings, agreements and arrangements between the parties or their respective advisers, or any of them, in relation to such transactions (whether express or implied, written or oral).
- 23.2 Nothing in this clause 23.2 shall operate to limit or exclude any liability or right which arises as a result of any fraudulent or dishonest act, omission or statement.

#### 24 Alterations

24.1 No purported alteration of this Agreement shall be effective unless it is in writing, refers to this Agreement and is duly executed by each party to this Agreement.

### 25 Severability

25.1 Each provision of this Agreement is severable and distinct from the others. The parties intend that every such provision shall be and remain valid and enforceable to the fullest extent permitted by law. If any such provision is or at any time becomes to any extent invalid, illegal or unenforceable under any enactment or rule of law, it shall to that extent be deemed not to form part of this Agreement but (except to that extent

in the case of that provision) it and all other provisions of this Agreement shall continue in full force and effect and their validity, legality and enforceability shall not be in any way affected or impaired, provided that the operation of this clause 25 would not negate the commercial intent and purpose of the parties under this Agreement.

25.2 If any provision of this Agreement is illegal or unenforceable as a result of any time period being stated to endure for a period in excess of that permitted by a regulatory authority, that provision shall take effect with a time period that is acceptable to the relevant regulatory authorities subject to it not negating the commercial intent of the parties under this Agreement.

### 26 <u>Counterparts</u>

26.1 This Agreement may be entered into in any number of counterparts and each of the executed counterparts, when duly exchanged or delivered, shall be deemed to be an original, but, taken together, they shall constitute one instrument.

#### 27 Payment of costs

Each of the parties shall be responsible for its respective legal and other costs incurred in relation to the negotiation, preparation, completion and implementation of this Agreement and all ancillary documents.

## 28 Successors and assigns

- 28.1 This Agreement shall be binding on and shall enure for the benefit of the successors in title of each party.
- 28.2 Save as provided in clause 28.3, none of the parties to this Agreement shall be entitled to assign the benefit of any rights under this Agreement.
- 28.3 The benefit of this Agreement (including the Warranties) shall be freely assignable by the Buyer (including to TBML) and, in the event of any such assignment, all references in this Agreement to the Buyer shall be deemed to include its assigns.

#### 29 Third Party Rights

- 29.1 Save as provided in clauses 29.2 and 29.3, no person who is not a party to this Agreement shall have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement, provided that no right or remedy of any such third party which exists or is available otherwise than by virtue of that Act shall be adversely affected by this Agreement.
- 29.2 TBML shall be entitled to enforce those terms of this Agreement insofar as they may related in any way to those of the Assets which are transferred to it pursuant to the terms of this Agreement.
- 29.3 Any person to whom the benefit of this Agreement is assigned by the Buyer pursuant to clause 28.3 shall have the right to enforce it.

## 30 Applicable law and submission to jurisdiction

30.1 This Agreement shall be governed by and construed in accordance with English law. Each party irrevocably agrees to submit to the exclusive jurisdiction of the courts of England over any claim or matter arising under or in connection with this Agreement.

**IN WITNESS** of which this Agreement has been executed as a Deed and delivered on the date stated at the beginning.

## Part A

# The Plant and Equipment

The plant and equipment listed attached (as replicated in Disclosure Document 8.1)

### Part B

#### The Excluded Assets

The following assets are excluded from the sale and purchase:

- 1 Cash-in-hand held as at the Transfer Date and at the bank (whether on current or deposit account) relating to the Businesses including uncleared cheques held at the Transfer Date.
- 2 Landlord's fixtures at the Properties.

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- (a) The orders, engagements or contracts entered into prior to the Transfer Date by or on behalf of the Sellers with suppliers for the supply of goods or services other than those referred to in Part A of Schedule 5 and the Disclosure Letter;
- (b) The IP Licenses other than those referred to in Part B of Schedule 5 and the Disclosure Letter;
- (c) The orders, engagements or contracts entered into prior to the Transfer Date by or on behalf of the Sellers with customers for the sale of goods or provision of services by the Sellers other than those referred to in Part C of Schedule 5 and the Disclosure Letter.
- 4. The Retained Third Party IPR listed overleaf.
- 5. The printers listed overleaf.
- 6. All IT Equipment (other than the IT Servers).
- 7. The telephone numbers of the Sellers listed in column A overleaf.
- 8. The retained product registrations listed overleaf:
- 9. The trade names "Lab 21" and "Lab 21 Healthcare".
- 10. All Shared Equipment listed overleaf.
- 11. The Debts.

### Part A

### The Properties

| No | Description   | Date of Lease          | Parties to<br>Lease   | Term and current rent        | Occupier(s) | Actual use                          |
|----|---|------------------------|---|------------------------------|-------------|-------------------------------------|
| 1  | Units 1 a, b and c<br>Lanwades Business<br>Park, Kennett,<br>Newmarket<br>Suffolk | 05/10/2006             | Gulbourne<br>Limited (1)<br>Newmarket<br>Laboratories<br>Limited (2)<br>Lab 21 Limited<br>(3) | 1/9/2006<br>to<br>31/8/2011  | The Sellers | Laboratories and associated offices |
| 1  |   | [Deed of<br>Variation] | Gulbourne<br>Limited (1)<br>Newmarket<br>Laboratories<br>Limited (2)<br>Lab 21 Limited<br>(3) |                              | The Sellers |                                     |
| 2  | Unit 184<br>Phase 3<br>Cambridge<br>Science Park<br>Milton Road<br>Cambridge      | 29/09/2010             | Siemens<br>Healthcare<br>Diagnostics<br>Products Limited<br>(1)<br>Lab 21 Limited<br>(2)      | 29/9/2010<br>to<br>21/3/2014 | The Sellers | Laboratories and associated offices |

### Part B

### **Property Provisions**

## 1 <u>Standard commercial property conditions</u>

- 1.1 The Part 1 Conditions are incorporated in this Agreement so far as they:
  - 1.1.1 apply to a sale by private treaty;
  - 1.1.2 are applicable to leasehold land;
  - 1.1.3 are not inconsistent with the other clauses in this Agreement or paragraphs in this Schedule; and
  - 1.1.4 have not been modified by the other clauses in this Agreement or paragraphs in this Schedule.
- 1.2 The Part 2 Conditions are not incorporated into Schedule.
- 1.3 The following Conditions shall not apply:
  - 1.3.1 Condition 1.1.4(a);

- 1.3.2 Condition 2;
- 1.3.3 Conditions 3.1, 3.2.1 and 3.3:
- 1.3.4 Conditions 6.1, 6.2, 6.3,6.4 and 6.6;
- 1.3.5 Condition 7;
- 1.3.6 Condition 8;
- 1.3.7 Condition 10;
- 1.3.8 Condition 11 and
- 1.3.9 Condition 12.
- 1.4 The Conditions shall be amended as follows:
  - 1.4.1 the definition of "conveyancer" in Condition 1.1.1(f) shall be construed as referring to the Buyer's Solicitors and/or the Seller's Solicitors, as the context requires;
  - 1.4.2 the definition of "completion date" in Condition 1.1.1(d) shall be construed as a reference to a Lease Transfer Date;
  - 1.4.3 Condition 1.1.3(b) shall read "in the case of the Seller, even though a mortgage remains secured on the Property, if the amount to be paid on completion enables the Property to be transferred free of all mortgages (except those to which the sale is expressly subject), or if the seller produces reasonable evidence that this is the case.
  - 1.4.4 Condition 9.1.1 shall read "If any plan or statement in the contract, or in written replies which the seller's conveyancer has given to any written enquiry raised by the buyer's conveyancer before the date of the contract, is, or was misleading or inaccurate due to any error or omission, the remedies available are as follows."

#### 2 Sale and purchase

Subject to paragraph 9 of this Schedule, the Sellers shall sell or procure the sale of such right, title and interest (if any) that the Sellers have in each of the Properties, to the Buyer.

## 3 <u>Vacant possession</u>

The Sellers shall sell or procure the sale of each of the Properties with vacant possession (subject as provided in paragraph 10 of this Schedule), to the Buyer, on the Relevant Lease Transfer Date.

### 4 <u>Deducing title</u>

4.1 Title to each of the Properties has been deduced to the Buyer's Solicitors before the date of this Agreement.

- 4.2 The deeds and documents of title for each of the Properties are listed in the Disclosure Letter and copies have been given to the Buyer's Solicitors.
- 4.3 The Buyer is deemed to have full knowledge of the title to each of the Properties and is not entitled to raise any objection, enquiry or requisition in relation to any of them.

### 5 <u>Title guarantee</u>

On the Relevant Lease Transfer Dates, the Sellers shall transfer or assign, or procure the transfer or assignment of the Lease of the relevant Property with full title guarantee except that the covenants implied by sections 3 and 4 of the 1994 Act shall be limited so that the Seller will have no liability under them for the consequences of any breach of the terms of the Leases relating to the physical condition of each of the Leasehold Properties.

### **6** Matters affecting the property

- 6.1 Each of the Properties are sold free from encumbrances other than:
  - 6.1.1 any matters disclosed in the Disclosure Letter;
  - 6.1.2 any matters discoverable by inspection of each of the Properties before the date of this agreement;
  - 6.1.3 any matters that the Sellers does not and could not reasonably know about;
  - 6.1.4 any matters disclosed or which would have been disclosed by searches and enquiries which a prudent buyer would have made before entering into this agreement
  - 6.1.5 public requirements;
  - 6.1.6 any matters which are unregistered interests which override registered dispositions under Schedule 3 to the Land Registration Act 2002 or (where title to any of the Leasehold Properties is not registered) are unregistered interests which override first registration under Schedule 1 to the Land Registration Act 2002.
- 6.2 The Buyer is deemed to have full knowledge of the matters referred to in this paragraph 6 and shall not raise any enquiry, objection, requisition or claim in respect of any of them.

#### 7 Transfer

The transfers or assignments of the Properties shall be in the forms annexed to this Agreement at Part E of this Schedule.

### 8 Completion

Completion of the sale and purchase of each Property shall take place on the Relevant Lease Transfer Date.

### 9 Landlord's consent

- 9.1 The provisions of this paragraph apply in respect of each Property.
- 9.2 Completion of the transfer or assignment of a Property is conditional on every Licence required under the relevant Lease.
- 9.3 On or before the Transfer Date, the Sellers shall apply for and use all reasonable endeavours to obtain every Licence but the Seller will not be obliged to seek any declaration of the Court that a Licence has been or is being unreasonably withheld. The Sellers shall pay all costs associated with obtaining, or seeking to obtain, each Licence.
- 9.4 The Buyer shall, without delay:
  - 9.4.1 supply all information, accounts and references as the Landlord any superior landlord or the Sellers may reasonably require in connection with an application for or consideration of any Licence;
  - 9.4.2 ensure that any amendments that the Buyer proposes to make to any form of Licence are communicated promptly to the Seller's Solicitors:
  - 9.4.3 supply, procure or enter into any guarantees, rental or other deposits, or other security for the performance of the tenant covenants of the Lease as may be required under the Lease or as the Landlord or any superior landlord may reasonably require;
  - 9.4.4 enter into any direct covenants with the Landlords as may be lawfully required under each Lease; and
  - 9.4.5 execute the Licences and any other documents providing security in the form reasonably required by the relevant Landlord and superior landlord and shall return all such documents duly executed to the Seller's Solicitors within 5 Business Days after each engrossment has been submitted to the Buyer's Solicitors.
- 9.5 In the event that a Licence has not been obtained for the Properties or either of them by the Transfer Date the provisions of paragraph 10 shall apply.
- 9.6 The Buyer shall register the assignment of each Lease within 5 Business Days of the Relevant Lease Transfer Date and shall at the same time send a copy of such registration to the Seller's Solicitors.
- 9.7 In the event that the Seller is required to provide an Authorised Guarantee Agreement as provided for in Section 16 of the Landlord and Tenant (Covenants) Act 1997 the Buyer will indemnify the Seller in respect of all liability arising under such agreements.
- 9.8 Upon completion of the assignment of the Cambridge Property the provisions of paragraph 10.6 shall apply.

### 10 Occupation

10.1 For the purposes of this clause:

- "Cambridge Facilities, Office and IT Recharge Schedule" means the schedule annexed at Part D of this Schedule;
- "Cambridge Licensed Area" means the Cambridge Property excluding the areas shown coloured blue and yellow on the plans ("the Plans") annexed at Part C of this Schedule;
- "Cambridge Facilities Costs" means projected cost of facilities for the Cambridge Property as shown on the Cambridge Facilities, Office and IT Recharge Schedule;
- "Cambridge Office and IT Costs" means the projected cost of office expenses, communications, IT expenses and commercial insurances as shown on the Cambridge Facilities, Office and IT Recharge Schedule;
- "Licensed Areas" means the Newmarket Property and the Cambridge Licensed Area;

10.3

- "Licence Period" means in respect of each Property the period from the Transfer Date to and including the Relevant Lease Transfer Dates for each Property;
- 10.2 Pending the Relevant Lease Transfer Dates the Buyer shall be entitled to occupy (i) Cambridge Licensed Area and (ii) the Newmarket Property in each case as a bare licensee only on a non-exclusive basis from the Transfer Date until the Relevant Lease Transfer Date.
  - 10.3.1 Whilst occupying the Licensed Areas, the Buyer shall be responsible for, and within five Business Days of written demand shall indemnify the Sellers against all sums payable by the tenant under the Leases due in respect of the Licensed Areas save to the extent that payment is made pursuant to the remaining provisions of this paragraph 10.3.
  - 10.3.2 The Buyer shall pay to the Sellers as from the Transfer Date in respect of the Newmarket Property during the Licence Period a licence fee equal to the rent payable under the Lease of £8,764.74 exclusive of VAT per month and all business rates water rates insurance premiums service charges utility costs and maintenance costs and VAT thereon.
  - 10.3.3 In respect of the Cambridge Property the Buyer shall during the Licence Period be primarily responsible for payment of all sums due under the Lease of the Cambridge Property and the Cambridge Facilities Costs (to the extent that they are not sums due under the Cambridge Lease) and Cambridge Office and IT Costs provided that the Sellers shall pay to the Buyer monthly in advance (and proportionately for any part of a month) by way of a contribution to such costs £21,022 per month from the Transfer Date to 31 December 2013 and then £12,613 per month from 1 January 2014 towards the Cambridge Facility Costs and £2,730 per month towards the Cambridge Office and IT Costs such payments to be made for so long as the Sellers remain in occupation of part of the Cambridge Property.
  - 10.3.4 During the Licence Period the Sellers shall permit the Buyer to have access to the Cambridge Licensed Area through the common parts of the Cambridge Property and to share the car parking area at the Cambridge Property.

- 10.4 The Buyer covenants with the Sellers that, whilst in occupation of the Licensed Areas, the Buyer shall observe and perform all the tenant covenants in the Leases in respect of such areas (other than (subject as provided in paragraph 10.3) the covenants relating to payment of the rents) and shall indemnify the Sellers against all proper costs, expenses, damages, proceedings and losses suffered or incurred by the Sellers arising from any breach, non-observance or non-performance of the tenant covenants in the Leases in relation to the Licensed Areas (other than (subject as provided in paragraph 10.3) the covenants relating to payment of the rents) by the Buyer.
- 10.5 This licence to occupy does not create, and is not intended to create, a demise and is personal to the Buyer. This licence cannot be assigned or otherwise transferred or dealt with and the Buyer shall not be entitled to share occupation of the Licensed Areas (or part thereof) with any other person, nor hold the Licensed Areas on trust for a third party save for a holding company or subsidiary of the Buyer.
- 10.6 As from the completion of the assignment of the lease of the Cambridge Property to the Buyer the Sellers shall permitted to continue to occupy the parts of the Cambridge Property shown coloured blue on the Plans as licensees subject to the Sellers continuing to pay to the Buyer for so long as they occupy such areas a licence fee equal to the sums payable pursuant to paragraph 10.3,3 above and during such period the Sellers shall be permitted to have access through the common parts of the Cambridge Property and to share the car parking area at the Cambridge Property.
- 10.7 For the avoidance of doubt there shall not be any duplication of payment pursuant to the provisions of this paragraph and the provisions of the TSA.

## Part C

# The Cambridge Licensed Area plans

## Part D

# Cambridge Facilities, Office and IT Recharge Schedule

Part E

# Deeds of Assignment

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### Part A - Seller IPR

- The Seller IPR which is registered or the subject of application for registration listed as attached (as replicated in Disclosure Document 16.1.1)
- 2 All unregistered trademarks forming part of the Seller IPR and listed as attached (as replicated in Disclosure Documents 16.1.2).
- The transferring product registrations listed as attached (as replicated in Disclosure Document 16.1.1); and
- The Domain Names listed as attached (as replicated in Disclosure Document 16.1.1).

### Part B – Relevant Third Party IPR

The patent licences listed as attached (as replicated in Disclosure Documents 16.1.3(a))

### Part C – Business Software

None

### Part D - Third Party Software

The third party software listed as attached (as replicated in Disclosure Document 16.1.3(b).

## Part E – The Trade Names

The trade names forming part or otherwise associated with the registered and unregistered trademarks listed in Part A above.

## Part A

# Lab21 Employees

Those persons listed attached

## Part B

## Healthcare Employees

Those persons listed attached

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### Part A

## **Supplier Contracts**

- Service Agreement Lab21/Excell commencing on 1 August 2005;
- Maintenance Service Agreement Lab21/ Excell commencing on 23 January 2008;
- Customer Order Lab21/Excell dated 28 November 2007;
- Service Agreement Myconostica/Professor David Dunning dated 19 September 2001;
- Supply Agreement Lab21/ BD Diagnostic Lee Labs dated 5 January 2012
- Supply Agreement Lab21/Pettingill Technology Ltd dated 5 January 2012
- Supply Agreement Lab21 Healthcare Ltd/Pettingill Technology Ltd dated 29 March 2010

Copies of the above mentioned Supplier Contracts are disclosed at Disclosure Document 10.1.

# Part B

# IP Licences

The Relevant Third Party IPR and the Third Party Software.

# Part C

# Customer Contracts

The contracts between the Sellers and the persons listed attached. Copies of such contracts are disclosed at Disclosure Document 10.2.

# Part D

# Leased Assets

The telephone equipment set out in a letter from Siemens dated 1 October 2009 (as set out in Disclosure Document 5.2.1)

# Part E

# **Loaned Assets**

Those listed attached (as replicated in Disclosure Document 5.2.2 where copies of relevant contracts are disclosed)

#### The Warranties

#### 1 Information

1.1 The information contained in Schedules 1, 2, 3, 4, 5 and 8 (inclusive) is true, complete and accurate in all respects.

#### **2** Powers and obligations of the Sellers

- 2.1 Each of the Sellers has full power under its constitution to execute, deliver and perform its obligations under this Agreement and to sell the Assets to the Buyer and has obtained the consent of any third party necessary.
- 2.2 The execution and delivery of, and the performance of the obligations of each of the Sellers under this Agreement has been duly authorised by all necessary corporate action on the part of the Sellers whether under their respective articles of association or otherwise.
- 2.3 This Agreement constitutes, and the other documents executed by each Seller which are to be delivered at Completion will, when executed, constitute legal, valid and binding obligations of each Seller enforceable in accordance with their respective terms.
- 2.4 The execution and delivery of, and the performance by each Seller of its obligations under, and compliance with the provisions of, this Agreement by such Seller will not:
  - 2.4.1 result in a breach of, or constitute a default under, any instrument to which such Seller is a party or by which such Seller is bound; or
  - 2.4.2 result in a violation of any law or regulation in any jurisdiction having the force of law or of any order, judgment or decree of any court or governmental agency or agreement to which such Seller is a party or by which such Seller is bound.
- 2.5 All consents, authorisations, licences or approvals of any of the Sellers' shareholders or of any governmental, administrative, judicial or regulatory body, authority or organisation which are required to authorise the execution, delivery, validity, enforceability or admissibility in evidence of this Agreement or the performance by the Sellers of their obligations under this Agreement have been obtained in advance of Completion.
- 2.6 The Sellers do not have and do not intend to acquire any interest, direct or indirect, in any business which has a close trading relationship with or which competes or is likely to compete with the Businesses.

#### **3** Financial Information

3.1 The Sales as represented to the Buyer in the Financial Information are a true and accurate representation of the total sales made by the Sellers in connection with the carrying on of the Businesses in the Financial Period.

- 3.2 The direct material costs incurred by the Sellers in connection with Sales as represented to the Buyer in the Financial Information are a true and accurate representation of the materials charged to the works orders relating to such costs.
- 3.3 The costs and overheads attributable to use and occupation of the Properties for the Financial Period and as represented to the Buyer in the Financial Information are a true and accurate representation of the total of the actual costs incurred by the Sellers of use and occupation of the Properties in the Financial Period.
- 3.4 The list of categories of the actual costs which have been incurred by the Sellers in connection with the carrying on of the Businesses during the Financial Period and included as part of the Financial Information is true, accurate and complete.

### 4 Records

- 4.1 All the Records (including all relating to invoices and other records required for VAT purposes (in so far as relevant)):
  - 4.1.1 have been fully, properly and accurately kept and completed;
  - 4.1.2 do not contain any material inaccuracies or discrepancies of any kind.
- 4.2 All the Records:
  - 4.2.1 give and reflect a fair view of the financial, contractual and trading position of the Businesses and of its plant and machinery, fixed and current assets and liabilities (actual and contingent), debtors and creditors and stock-in-trade and all other matters which would normally be expected to appear in them; and
  - 4.2.2 are exclusively owned by the Sellers and the means of access to them are under their direct control.
- 4.3 All documents which in any way affect the right, title or interest of the Sellers in or to any of the Assets and which attract stamp duty have been duly stamped within the requisite period for stamping.

### 5 Ownership and condition of assets

- 5.1 Each of the Assets is in the legal and beneficial ownership, possession and control of the Sellers, is free from any hire or hire-purchase agreement or agreement for payment on deferred terms or bill of sale or any encumbrance, equity or third party right or from any contract to grant the same and is not to any extent surplus to requirements.
- 5.2 In respect of the Leased Assets and the Loaned Assets:
  - 5.2.1 true and accurate particulars of all the contracts for the Leased Assets are attached to the Disclosure Letter;
  - 5.2.2 the Loaned Assets are detailed in the Disclosure Letter together with a summary of the terms on which they are loaned to the Sellers;
  - 5.2.3 the amount of the last rental payable under the Contract for such Leased Asset has been paid, and at the date of this Agreement no circumstance exists by virtue of which the lessor or the owner is or might be entitled to require an upward adjustment to the rental;

- 5.2.4 no circumstances have occurred which would entitle the lessor or the owner to terminate any contract for a Leased Asset;
- 5.2.5 no inquiry or investigation is being conducted by HMRC concerning the availability to the lessor of capital allowances in respect of the plant and machinery concerned.
- 5.3 The Assets (together with the Leased Assets and the Loaned Assets and the Excluded Assets) comprise all the assets now used in the Businesses.
- The lists contained in paragraphs 1 to 3 (inclusive) of Part A of Schedule 3 and in Part B of Schedule 3 include all patents, patent licences, trademarks and product registrations required by the Buyer for continuance of the Businesses in the manner that the Businesses were carried on by the Sellers at the Transfer Date.
- 5.5 Save as disclosed in the Disclosure Letter, the plant and equipment listed in Part A of Schedule 1 comprises all the plant and equipment which is required by the Buyer for continuance of the Businesses in the manner that the Businesses were carried on by the Sellers at the Transfer Date.
- 5.6 The Sellers have not acquired, or agreed to acquire, any asset on terms that title to that asset does not pass until full payment is made or all indebtedness incurred in connection with the acquisition of such asset is discharged.
- 5.7 The Assets, which are not situated at the Properties at Completion, are specified together with their actual location in the Disclosure Letter and are clearly identified as assets of the Sellers at such specified location.

#### 6 Stock

[Intentionally left blank]

## 7 <u>Creditors</u>

- 7.1 The Sellers are not obligated for any amount included in the Creditors otherwise than as the original debtor.
- 7.2 All amounts due from the Sellers and included amongst the Creditors relate to the Businesses, were properly incurred in the ordinary and usual course of business, are now due, owing and payable and where the Sellers are aware of any dispute these are referred to in the Disclosure Letter.

# 8 Plant and Equipment

- 8.1 The Plant and Equipment is completely and accurately recorded in Part A of Schedule 1.
- 8.2 All Plant and Equipment is in good repair and condition (fair wear and tear excepted) and in working order, has been properly serviced and maintained on a regular basis by competent personnel and complies with appropriate safety.

# 9 <u>Insurance</u>

- 9.1 All Assets of the Sellers in relation to the Businesses of an insurable nature are, and have at all material times been, insured in amounts equal to their full replacement value against fire and other risks normally insured against by persons carrying on the same class of business as the Sellers.
- 9.2 The Sellers have at all material times in respect of the Businesses and the Assets effected all insurances required by law to be effected by them.
- 9.3 All premiums due on the policies of insurance maintained by the Sellers in connection with the Businesses ("**Policies**") have been paid; all the other conditions of the Policies have been performed and observed; and none of the Policies has or may become void or voidable as a result of an act or omission of the Sellers.
- 9.4 No insurance claim for £10,000 or more is pending or outstanding in respect of the Businesses under any of the Policies and as far as the Sellers are aware there are no circumstances likely to give rise to any such claim.
- 9.5 No claims have been made by Employees in respect of industrial injury in the 2 years prior to the date of this Agreement and all recommendations, directions or requirements of any insurer or the Health and Safety Executive have been complied with in full.

#### 10 Material contracts

- 10.1 Copies of all Supplier Contracts are attached at the Disclosure Document 10.1.
- 10.2 Copies of all Customer Contracts are attached at the Disclosure Document 10.2.
- 10.3 Save as disclosed in the Disclosure Letter, the Customer Contracts are all the Contractual Arrangements with customers of the Businesses which are required by the Buyer for continuance of the Businesses in the manner that the Businesses were carried on by the Sellers at the Transfer Date.
- Other than the Contracts (and to the extent relevant, those Excluded Assets which comprise Contractual Arrangements) the Sellers are not party to any other Contractual Arrangements (other than supply agreements which are not being assumed by the Buyer under this Agreement) relating to the Businesses or the Assets which are material in relation to the Businesses or which the Buyer and or TBML would require to enable it to carry on the Businesses in the same manner as previously carried on by the Sellers: and for the purposes of this paragraph 10.4 the Sellers will be deemed to be party to a Contractual Arrangement if they are, or have agreed to become, entitled to benefit under such Contractual Arrangement or if they have obligations or liabilities or have agreed to assume obligations or liabilities under such Contractual Arrangement, in each case whether as an original party to the Contractual Arrangement or by virtue of assignment, novation or otherwise howsoever.
- 10.5 The Sellers are not involved in any dispute of any nature in connection with any Contract, there are no complaints or disputes of any nature which have been raised in relation to any Contract and there are no present circumstances of which the Sellers are aware which are likely to give rise to any such complaint or dispute.

# 11 Other business matters

- 11.1 There is attached to the Disclosure Letter a true, complete, accurate and up-to-date copy of the terms and conditions upon which the Businesses currently (and in the last twelve months) buy, sell and supply goods and services and otherwise trade; such terms and conditions apply to and govern all contracts and arrangements of purchase, sale and supply to which the Sellers are or have offered to become party in relation to the Businesses.
- 11.2 There are no special circumstances which might lead to a restriction or hindrance of supply of the services now supplied by the Businesses.
- During the 12 months ended on the Transfer Date there has been no substantial change in the basis or terms on which any person is prepared to enter into contracts or do business with the Sellers in respect of the Businesses (apart from normal price changes) and no contractual rights and obligations of the Sellers in relation to the Businesses will terminate by reason of this Agreement providing nothing in this warranty (or any other warranty) shall impose any liability on the Sellers for breach of warranty where the Contract requires the consent of the other party to the transfer of the Sellers' rights and liabilities.
- 11.4 The Businesses have not been materially and adversely affected by the loss during the two years ended on the Accounts Date of:
  - any important customer or source of supply, (being a customer or supplier which over a period of three months or more during those two years has accounted for 5 per cent. or more in value of the goods or services supplied by or to the Businesses during that period);
  - 11.4.2 an overall decrease in the value of orders received by or supplies made to the Businesses; or
  - by any abnormal factor not affecting similar businesses to a like extent and no such customer or supplier has given notice to the Sellers of an intention to cease or reduce trading with or supplies to the Businesses.
- 11.5 No supplier of the Businesses who is party to a Supplier Contract has:
  - 11.5.1 in the 6 months preceding the Transfer Date ceased supplying the Businesses; or
  - 11.5.2 (as a result of the acquisition of the Businesses by the Buyer or for any other reason) indicated to the Sellers that:
    - (i) it will cease supplying the Businesses; or
    - (ii) it may substantially reduce its supplies to the Businesses.

# 12 Effects of the Agreement

12.1 So far as the Sellers are aware (without having made due enquiry), the acquisition of the Businesses by the Buyer will not, and will not be likely to, affect the relationship between the Businesses and its customers, suppliers or the Employees.

- 12.2 The execution of this Agreement and the observance and performance of its provisions will not:
  - result in a breach of any Contract, law, regulation, order, judgment, injunction, undertaking, decree or other like imposition to or by which the Sellers are party or are bound, or entitle any person to terminate or avoid any Contract to which the Sellers are party;
  - 12.2.2 result in the loss or impairment of or any default under any licence, authorisation or consent required by the Sellers for the purpose of the Businesses; or
  - 12.2.3 result in the creation, imposition, crystallisation or enforcement of any encumbrance whatsoever on any of the Assets.
- 12.3 There is no Contract to which the Sellers are party in respect of the Businesses which depends on the continuation of the connection (whether as an officer of any of the Sellers or otherwise) of any person with the Sellers.

#### 13 **Employees**

- 13.1 The Employees comprise all persons employed or engaged in any capacity by the Sellers in relation to the Businesses at the date of this Agreement or who has or may have a statutory or contractual right to return to work or be re-instated or reengaged by any of the Sellers in the Businesses.
- 13.2 Schedule 4 shows the following information in relation to each Employee namely:
  - 13.2.1 name;
  - 13.2.2 their job title;
  - 13.2.3 their current remuneration (including any guaranteed overtime, bonus, commission or profit sharing arrangements, share and other incentive schemes and any other non-cash benefits which the Sellers are obliged to provide to them whether now or in the future);
  - 13.2.4 their date of commencement of employment or appointment to office and the commencement date of any previous employment with which such employment is continuous;
  - 13.2.5 the type of contract concerned (including whether full or part-time, and whether permanent, fixed-term, temporary or casual);
  - 13.2.6 the notice period required to be given by the Sellers and by the individual concerned, or, if the contract is for a fixed term, the expiry date and details of any previous renewals;
  - 13.2.7 whether or not a member of any pension scheme;
  - 13.2.8 if working or paid outside England and Wales, details of the relevant arrangements including the country concerned and the governing law of the relevant contract;

- 13.2.9 if currently absent from work for any reason (for example secondment, maternity or adoption leave, suspension or ill health) details of the relevant arrangements;
- 13.2.10 date of last increase in salary; and
- 13.2.11 whether or not their employment was at any time transferred under TUPE to the Sellers, to any predecessor of the Sellers or to any previous owner of the whole or part of the Businesses or of the Assets

and such information is complete and correct in all respects.

- 13.3 Complete and up-to-date copies of the following documents are attached to the Disclosure Letter:
  - 13.3.1 contracts or particulars of employment or service agreements applying to each of the Employees;
  - 13.3.2 all policies, handbooks and other documents relating to the engagement, management or dismissal of any Employees;
  - 13.3.3 so far as the Sellers are aware details of any unwritten agreements or arrangements which may affect any Employees;
  - 13.3.4 any collective or workforce agreements or similar arrangements relating to the Employees and details of any disputes under them;
  - 13.3.5 details where they exist of all trade union or other employee representatives, with, in the case of union representatives, the name of the union they represent;
  - 13.3.6 any correspondence with the Health and Safety Executive within the last six years concerning the Sellers or the Businesses:
  - 13.3.7 any correspondence with HMRC within the past six years concerning the Sellers or the Businesses;
  - 13.3.8 any correspondence with the Equality and Human Rights Commission or the Information Commissioner within the past three years concerning the Sellers or the Businesses; and
  - 13.3.9 details of any equality monitoring carried out by the Sellers within the last three years.
- 13.4 All contracts of employment between the Sellers and the Employees disclosed in the Disclosure Letter contain the entirety of the terms and conditions upon which the Employees are employed.
- 13.5 Save as disclosed in the Disclosure Letter the Sellers have not:
  - 13.5.1 offered and will not offer prior to Completion to employ or engage any person;
  - 13.5.2 made, agreed or proposed or entered into negotiation or received any request for any change in the terms of employment or engagement of any Employees.

- 13.6 All Employees requiring a work permit, certificate of sponsorship or other permission to work in the United Kingdom have a current and appropriate work permit, certificate or other permission and all other necessary permissions to remain in the United Kingdom.
- 13.7 The Sellers have in relation to all Employees:
  - 13.7.1 materially complied with Employment Legislation;
  - 13.7.2 maintained adequate up-to-date records regarding their service and engagement; and
  - 13.7.3 materially complied so far as they are aware with all contractual obligations towards them.
- 13.8 None of the Employees has given or received notice to terminate their employment and none of the Employees has given notice to the Sellers that he objects to becoming employed by the Buyer and the Sellers know of no circumstances (including Completion) which the Buyer is not also aware of which could give rise to such a notice.
- 13.9 There is no amount due to or in respect of any Employee which is in arrear and unpaid other than his salary for the month current at the date of this Agreement and in respect of the reimbursement of expenses and none of them is entitled to accrued but unpaid holiday pay or holiday leave accrued but not taken in respect of the Employees' current or previous holiday year. There are no amounts owing to the Sellers by any of the Employees.
- 13.10 So far as the Sellers are aware no dispute or litigation of any nature is threatened or pending in relation to any of the Employees or any other individuals engaged by the Sellers (whether brought by or on behalf of the Employees or such individuals or by a third party) nor have any statutory questionnaires been served on the Sellers and there are no present circumstances (including Completion) which are likely to give rise to any such dispute or litigation or to the service of such questionnaires.
- 13.11 Within a period of one year preceding the date of this Agreement:
  - 13.11.1 the Sellers have not given notice of any redundancies to the Secretary of State for Employment or started consultations with any independent trade union or unions under Part IV Trade Union and Labour Relations (Consolidation) Act 1992 and the Sellers have not failed to comply with any obligation under such Part IV; and
  - 13.11.2 the Sellers have not been a party to any relevant transfer as defined in TUPE and the Sellers have not failed to comply with any duty to inform and consult any independent trade union or employee representatives.
- 13.12 The Sellers have not recognised or done any act which might be construed as recognition of a trade union nor are any steps being taken by employees, workers or other representatives to ensure trade union recognition and there is no collective bargaining agreement or other arrangement (whether binding or not) between the Sellers and any trade union or other body representing their employees.
- 13.13 There are no Employees who have been absent due to sickness leave for more than 3 months in the 12 month period ending on the date of this Agreement.

- 13.14 There is no obligation outstanding to give any bonus, incentive or perquisite or to make any payment or provide any perquisite under any option, incentive or profit sharing scheme to all or any of the Employees.
- 13.15 Full particulars of any Employees who have at any time been the subject of a relevant transfer under TUPE while engaged in the Businesses (or any part of the Businesses) are attached to the Disclosure Letter and no such employees are entitled as a consequence to any terms and conditions of employment (including but not limited to rights relating to redundancy or early retirement) different from or more favourable than those enjoyed by employees of an equivalent grade or seniority who have not been the subject of such a transfer.
- 13.16 There are no incentive schemes or other incentive arrangements (including without limitation, any long term incentive plan, any share option arrangement, commission, profit sharing or bonus scheme) established by any of the Sellers, any Associated Company or any other person pursuant to which any of the Employees are entitled to any kind of benefit on or after the Transfer Date (whether as a result of the transactions provided for in this Agreement or otherwise).

#### 14 Pensions

- 14.1 In this paragraph 14 these definitions apply:
  - "Benefits" means pensions, allowances, lump sums or other like benefits payable on retirement or on death or during periods of sickness or disablement;
  - "Pension Arrangement" means any agreement, arrangement, custom or practice (whether legally enforceable or not) for the payment of or contribution towards any Benefits; and
  - the "Schemes" include each arrangement disclosed in the Disclosure Letter in relation to this paragraph 14.
- 14.2 Other than the Schemes there is no Pension Arrangement in operation for the benefit of any current or former employees of the Sellers or for the benefit of any of their dependents and no assurance has been given to any such persons about the introduction of any Pension Arrangement.
- 14.3 All material details of the Schemes have been given to the Buyer including copies of:
  - 14.3.1 all current booklets, announcements and other explanatory literature issued to Employees who are members of the Scheme and copies of material letters or other documents relating to arrangements for individual members or groups of members:
  - a list of all Employees of the Seller who are members of the Schemes together with all particulars of them necessary to establish the benefits payable or contingently payable to or in respect of them under the Scheme;
  - 14.3.3 a list of all Employees who will become eligible to join the Schemes upon the satisfaction of any conditions of eligibility; and
  - 14.3.4 a list of all contributions payable to the Schemes and the basis on which they are calculated.

- 14.4 All insurance premiums payable in respect of the Schemes which are due for payment have been paid.
- 14.5 No notice has been received by the Sellers (or either of them) claiming that they have discriminated against, or in relation to, any Employee on grounds of age, sex, disability, marital status, hours of work, fixed-term or temporary agency worker status, sexual orientation, religion or belief in providing Benefits.
- 14.6 Since 30 August 1993, no Employee has had his contract of employment transferred to any Seller from another employer in circumstances where the Transfer of Undertakings (Protection of Employment) Regulations 1981 or 2006 (as appropriate) applied to the transfer of his contract of employment.
- 14.7 Prior to 1 October 2012, the Sellers have facilitated access for those Employees who were not members of the Seller's Scheme to a designated stakeholder scheme as was required by section 3 of the Welfare Reform and Pensions Act 1999 including:
  - 14.7.1 undertaking the necessary consultation process with the Employees in selecting the stakeholder scheme; and
  - 14.7.2 designating the stakeholder scheme,

and so far as the Sellers are aware, there are no circumstances which could result in any penalty for failure to comply with that Act or regulations made under it becoming payable by any Seller.

## 15 The Properties

- 15.1 The Sellers are the legal and beneficial owner of the Properties and are in occupation of the whole of each of the Properties for the purpose of the Businesses and no other person is in occupation of the whole or any part of the Properties.
- 15.2 The information set out in Schedule 2 is true and complete and accurate at the date of this Agreement and the actual use of the Properties stated in Schedule 2 corresponds to the actual use to which the Properties are in fact put.
- 15.3 The Sellers' title to each of the Properties is good and marketable and the Sellers possess all documents of title needed to deduce their title to the Properties.
- 15.4 In respect of the Properties and stamp duty or stamp duty land tax:
  - 15.4.1 where a document of title gave rise to a land transaction for the purposes of stamp duty land tax:
    - (i) either a land transaction return complete and accurate in all material respects was delivered in respect of that document or the Sellers have sufficient documentation (which for land transactions effected before 12 March 2008 includes an SDLT60 signed by the purchaser) as evidence that no such return was required;
    - (ii) there is no potential or outstanding obligation to make an additional land transaction return to HMRC as a result of the following:

- (A) in respect of a lease during the first five years of the term:
  - 1) the settlement or determination of any rent review or any other provision for varying the rent;
  - 2) the settlement or determination of any contingent, uncertain or unascertained rents;
- (B) any contingent, uncertain or unascertained consideration.
- 15.5 As far as the Sellers are aware there is appurtenant to each of the Properties all rights and easements necessary for the carrying on there of the Businesses and their reasonable use and enjoyment of Properties.
- 15.6 All the documents in the possession of the Sellers relating to the title to the Properties have been produced to the Buyer's Solicitors for inspection prior to the date of this Agreement.
- 15.7 Except as revealed by the copy documents supplied to the Buyer's Solicitors, the Properties are free from:
  - 15.7.1 any mortgage, charge, rent-charge, lien, encumbrance or other third party right in the nature of security and no such matter exists which is capable of registration against any of the Properties;
  - 15.7.2 any Land Charge registered under the Land Charges Act 1972, a Local Land Charge as defined in section 1 Local Land Charges Act 1975, a Land Registry caution, inhibition, notice or restriction;
  - 15.7.3 incumbrances with the exception of:
    - (i) those discoverable by a reasonably careful inspection of any Property before the date of this Agreement;
    - (ii) those about which the Sellers do not know and about which the Sellers could not reasonably be expected to know;
    - (iii) matters disclosed in any documents of title produced to the Buyer's Solicitors;
    - (iv) matters mentioned in the Disclosure Letter.
    - (v) matters that would be disclosed by searches and enquiries which would be carried out in respect of the Properties by a prudent purchaser
- 15.8 The Sellers are entitled to possession of the whole of each of the Properties and there are no circumstances known to the Sellers which would entitle any landlord or any other person to exercise any powers of entry or right to forfeiture or right to take possession or which would otherwise restrict or terminate the continued sole and exclusive possession or occupation of each of the Properties by the Sellers.
- 15.9 The Sellers have paid all rent or licence fees and all other outgoings which have become due and been demanded in respect of each of the Properties.

- 15.10 To the best of the knowledge and belief of the Sellers they have performed and observed all their obligations under all covenants, conditions, agreements, statutory requirements, planning consents, byelaws, orders and regulations affecting any of the Properties, its use and any business of the Sellers there carried on. No notice of any breach of any such matter has been received.
- 15.11 With regard to the use of each of the Properties:
  - 15.11.1 this is specified in Schedule 2;
  - 15.11.2 it does not contravene the Town and Country Planning Act 1990 (as amended);
  - 15.11.3 there are no outstanding enforcement notices, stop notices, enforcement proceedings or appeals in respect of any "development" at the Properties as that term is defined in section 55 Town and Country Planning Act 1990;
  - 15.11.4 any planning permission regulating the use is not stated to be limited to use by a particular person;
  - 15.11.5 no planning permission is suspended or remains unimplemented in whole or in part; and
  - 15.11.6 the Sellers have not submitted a planning application which awaits determination.
  - 15.11.7 so far as the Sellers are aware there are no proposals of any local or other authority for the compulsory acquisition of any of the Properties.
- 15.12 Where the operation of the Businesses at the Properties requires a statutory licence any such licence is in force and the Sellers have not received any notice of breach of a term of any such licence.
- 15.13 The written replies given by or on behalf of the Sellers to enquiries raised by the Buyer's Solicitors in respect of any of the Properties are true and accurate in all respects and not misleading.
- 15.14 No solicitors other than the Sellers' Solicitors are instructed by or on behalf of the Sellers in connection with any matter relating to any of the Properties except for this Agreement and the Disclosure Letter.
- 15.15 Since the Accounts Date the Sellers have not acquired or disposed of or agreed to acquire or dispose of the whole or any part of or any interest in any land or buildings, nor will they acquire or dispose of the whole or any part of or any interest in any land or buildings without the prior written consent of the Buyer.
- 15.16 No option to tax under Part 1 of Schedule 10 VATA has been made by the Sellers or by any associate of the Sellers (within the meaning of paragraph 3 of Schedule 10 VATA) which has effect or has ever had effect in relation to the whole or any part of the Properties.
- 15.17 The obligations on the part of the tenant in the Rent Deposit Deed have been observed and performed including but not limited to payment of the Initial Deposit (as defined in the Rent Deposit Deed) in full.

# 16 <u>Intellectual Property Rights</u>

- 16.1 Disclosure Documents 16.1.1 to 16.1.3 (inclusive) set out a complete and accurate list sufficient for the purpose of identification of each of the following:
  - all Intellectual Property Rights that have been registered or that are applications for registration of Intellectual Property Rights or for registered Intellectual Property Rights, by or on behalf of the Sellers (Disclosure Document 16.1);
  - 16.1.2 all unregistered Intellectual Property Rights solely or jointly owned by the Sellers and used by the Sellers in the Businesses and that are material to the Businesses (Disclosure Document 16.1.2); and
  - 16.1.3 all Third Party IPR licensed to the Sellers or the subject matter of which is used by the Sellers for any purpose in the Businesses(Disclosure Document 16.1.3(a)).
- 16.2 The Sellers have, as part of the Records free of any Encumbrance, complete, accurate and up to date records enabling identification of all Business IPR.
- 16.3 The Business IPR constitute all of the Intellectual Property Rights that are necessary or desirable for the current and planned future operation of the Businesses.
- 16.4 Other than pursuant to the IP Licences disclosed under paragraph 16.21 below and other than pursuant to the Contracts, the Sellers have not granted and are not obliged to grant any IP Licence, option (whether exercisable as a matter or right or contingent on the passage of time or the occurrence of some event) for an IP Licence or other Encumbrance in respect of any Business IPR and the Sellers are not obliged (whether now or contingent on the passage of time or the occurrence of some event) to assign any Intellectual Property Rights used in the Businesses to any third party.
- 16.5 All Seller IPR is legally and beneficially owned solely by the Sellers free from and clear of any Encumbrance.
- 16.6 The Sellers are the sole owners of all rights (including but not limited to the right to apply for patents) in all inventions made by their employees that are used in, or relate to, the Businesses.
- Any works copyright in which forms part of the Seller IPR have been independently created by the Sellers' employees in the course of their employment by the Sellers and are original works.
- 16.8 All Seller IPR are fully valid, subsisting and enforceable and nothing has been done or omitted to be done by which they may cease to be fully valid, subsisting and enforceable.
- 16.9 The Sellers have in their possession all documents and things free of any Encumbrance necessary to establish the Sellers' ownership of the Seller IPR and to prove the subsistence of the Seller IPR. All such items and things (including without limitation any relevant Know-how) are clearly and fully documented as part of the Records.
- 16.10 The Seller IPR are, where capable of registration, registered in the sole names of the Sellers in the jurisdictions shown in Schedule 3 Part A.

- 16.11 All moral rights in respect of the Seller IPR have been irrevocably waived in favour of the Sellers and their successors in title.
- 16.12 Save in respect of any Excluded Assets, the Registered Seller IPR listed referred to in Schedule 3 and in Disclosure Documents 16.1.1 and 16.1.2 are all the registered Intellectual Property Rights relating to the Businesses of which the Sellers are legal or beneficial owner together with all applications for the registration of such Intellectual Property Rights or for such registered Intellectual Property Rights that the Sellers have made or caused to be made.
- 16.13 The Sellers are the sole registered proprietor (or, where relevant, sole applicant for registration) of all the Registered Seller IPR.
- 16.14 The Seller have taken all steps required up to the date of Completion for the prosecution and maintenance of the Registered Seller IPR.
- 16.15 [Intentionally omitted].
- 16.16 All renewal, registration, prosecution or other official fees, charges or dues that have become due for payment in respect of any Registered Seller IPR, and all fees or charges of any person payable in connection with the prosecution or maintenance of any Registered Seller IPR have been paid in full and in due time.
- 16.17 The Sellers have not been notified that there is any fact or matter (including any act or omission of any of the Sellers) that might result in any registration of any of the Registered Seller IPR, either in whole or in part, being revoked, invalidated or rendered unenforceable or, in the case of applications for registration forming part of the Registered Seller IPR, that might prejudice the prospects of registration as filed.
- 16.18 The Sellers have in their possession free of any Encumbrance, as part of the Records, all documents and records that have arisen in the course of the prosecution of any application for registration of all Registered IPR.
- 16.19 The Sellers are and will be, unless any IP Licence is properly terminated by reason of the Sellers being in breach thereof, fully entitled under valid and subsisting IP Licences to use all Relevant Third Party IPR for all purposes for which the Relevant Third Party IPR has been or is being used by the Sellers in the Businesses or that are necessary or desirable for the current and planned future operation of the Businesses.
- 16.20 The Sellers are properly registered in the relevant jurisdictions shown in Disclosure Document 16.1.1 in respect of all Seller IPR registered in such jurisdictions.
- 16.21 Particulars of all IP Licences are set out in Disclosure Document 16.1.1(a) and (b).
- 16.22 The Sellers have not been notified that they are in material breach of any IP Licence.
- 16.23 None of the Sellers has received any notice terminating any IP Licence or terminating, restricting or altering any right granted under any IP Licence, and no other party to any IP Licence is entitled without the consent of the Sellers to terminate, restrict or alter or give a valid notice of termination, restriction or alteration of any IP Licence.

- 16.24 The fact that the Sellers have proposed to or have entered into this Agreement, the performance by the Sellers of any obligation pursuant to this Agreement or consequent on the Sellers entering into this Agreement or any other matter or thing consequent on the Sellers entering into this Agreement will not entitle any other party to an IP Licence to terminate any IP Licence or to terminate, restrict or alter any right granted to the Sellers under any IP Licence (other than where any such IP Licence prevents assignment without the consent of the other party).
- 16.25 There are and have been no claims, disputes or proceedings arising or threatened under any IP Licence.
- 16.26 Whether in the carrying on of the Businesses or otherwise, the Sellers at the date of this Agreement and at any time within the past six years:
  - 16.26.1 so far as the Sellers are aware do not infringe and have not infringed any Third Party IPR;
  - 16.26.2 are not breaching and have not breached any obligations of confidence owed to any third party;
  - 16.26.3 do not engage and have not engaged in activities that constitute or have constituted passing off or actionable unfair competition in any jurisdiction;
  - 16.26.4 do not acquiesce, induce or procure, and have not acquiesced, induced or procured, any of the activities referred to in paragraphs 16.26, 16.26.1 and 16.26.2 above; and
  - 16.26.5 as a result of any of the activities referred to in paragraphs 16.26, 16.26.1 and 16.26.2 above, have or had any obligation to pay any royalty, fee, fine, compensation, damages, account of profits or any other sum whatsoever, or been or become subject to any restriction or limitation on its activities.
- 16.27 So far as there Sellers are aware there is no, nor has there been, at any time during the past six years, any:
  - 16.27.1 misappropriation, unauthorised use or infringement by any person of any of the Seller IPR;
  - 16.27.2 any breach by any third party of any obligations of confidence owed to the Sellers;
  - 16.27.3 any misappropriation or misuse of any Confidential Information; or
  - 16.27.4 activities that constitute or constituted passing off or actionable unfair competition in respect of which the Sellers do or may have a claim against any person.
- 16.28 None of the Seller IPR are the subject of any existing, pending or threatened proceedings (other than the normal prosecution to grant of any application for registration) or claim for opposition, cancellation, revocation, rectification, transfer, licence of right, whether in whole or in part, or relating to title, or any similar proceedings or claim anywhere in the world and none of the Sellers is aware of any circumstances that might result in any such proceedings or claim.

- 16.29 The Sellers have not made any threat, whether express or implied, to bring proceedings for infringement of Intellectual Property Rights that is actionable by virtue of applicable legislation.
- 16.30 The Sellers have not been notified that any person has made or is entitled to make any claim arising under:
  - 16.30.1 sections 77 to 84 of the Copyright, Designs and Patents Act 1988; or
  - 16.30.2 sections 40 and 41 of the Patents Act 1977,
  - or under similar legislation in any jurisdiction, in respect of any Seller IPR.
- 16.31 The Confidential Information and all information that is of a type that the Sellers could reasonably have been expected to maintain confidential has been kept secret and is under the Sellers' lawful possession and under their sole control.
- 16.32 The Sellers have not disclosed or permitted, agreed to, undertaken or arranged the disclosure to any person other than the Buyer or TBML of any Confidential Information or information that is of a type that the Sellers could reasonably have been expected to maintain confidential (including but not limited to any unpublished or confidential Business IPR and the Sellers are not obliged to make any such disclosure, except properly and in the ordinary course of business and pursuant to a written obligation of confidence that is valid and enforceable).
- 16.33 The Sellers are not party to any confidentiality agreement or other agreement which is outside the ordinary course of business or any obligation or duty that imposes on any of them a material restriction on the use of or disclosure of any information in its possession other than confidentiality agreements details of which are set out in the Disclosure Letter.

## 17 Information Systems

- 17.1 The IT Servers are legally and beneficially owned solely by the Sellers free from and clear of any Encumbrance. The Sellers are entitled to use the IT Systems for all purposes necessary to carry on the Businesses.
- 17.2 The IT Servers:
  - 17.2.1 have been and are being properly and regularly maintained;
  - 17.2.2 function consistently and accurately;
  - 17.2.3 do not contain any software Virus;
  - 17.2.4 include firewalls and up-to-date anti-Virus software; and
  - 17.2.5 will not need replacing in whole or in part for at least four years from Completion.
- 17.3 Full details of the Sellers' disaster recovery plan in respect of the IT Servers are set out in the Disclosure Letter.
- 17.4 The Sellers have possession or control of the source code of all Business Software and, save as set out in the Disclosure Letter, all Third Party Software.

- 17.5 Complete and accurate copies of all escrow agreements to which the Sellers are a party in respect of the Third Party Software are attached to the Disclosure Letter.
- 17.6 The Domain Names are the only Internet domain names owned and used in the Businesses by the Sellers or used by the Sellers in the Businesses, whether in the Businesses or otherwise.
- 17.7 The Sellers are the sole registered proprietor or owner, free of any Encumbrance, of the Domain Names. All the Domain Names are validly registered in the names of the Sellers.
- 17.8 None of the Domain Names are the subject of any claim or pending or threatened proceedings for transfer, cancellation or otherwise anywhere in the world. None of the Sellers is aware of any circumstances that might result in any such proceedings.
- 17.9 All Intellectual Property Rights in the Websites are legally and beneficially owned solely by the Sellers free from and clear of any Encumbrance.

#### 18 Data Protection

- 18.1 So far as the Sellers are aware, the Sellers comply with and have not breached the Data Protection Legislation.
- 18.2 So far as the Sellers are aware, the Sellers in the conduct of the Businesses:
  - 18.2.1 comply with and have not breached the principles set out in the DPA in respect of the Personal Data;
  - 18.2.2 process the Personal Data fairly and lawfully, have notified the subjects of the Personal Data of the purposes for which they process their Personal Data, and have not processed the Personal Data for any other purposes;
  - 18.2.3 have ensured (and have procedures for ensuring) that the Personal Data is adequate, relevant, not excessive, accurate, up to date and not kept for longer than is necessary; and
  - 18.2.4 comply with and have not breached the Data Protection Legislation when carrying out any direct marketing.
- 18.3 So far as the Sellers are aware, if any third party processes Personal Data on behalf of the Sellers, the Sellers have entered into a written contract with such third party confirming that it will only act on the instructions of the Sellers and requiring it to comply with obligations relating to security measures equivalent to those imposed on the Sellers by the DPA.
- 18.4 So far as the Sellers are aware, the Sellers either do not transfer Personal Data outside the European Economic Area and the Disclosure Letter sets out complete and accurate particulars of any transfers of Personal Data outside the European Economic Area and the steps taken by the Sellers to comply with the Data Protection Legislation in respect of such transfers.
- 18.5 The Sellers have maintained an accurate and up to date registration with the Information Commissioner's Office in respect of their processing of Personal Data as required by the DPA.

- 18.6 None of the Sellers has received a notice, letter or complaint from the Information Commissioner's Office relating to the conduct of the Businesses and so far as the Sellers are aware there are no circumstances that are likely to give rise to any such notice, letter or complaint being served given or made in the future.
- 18.7 So far as the Sellers are aware, no individual has been awarded compensation from the Sellers under the DPA relating to the conduct of the Businesses, no such claim is outstanding and so far as the Sellers are aware there are no circumstances likely to give rise to any claim for compensation being made.
- 18.8 So far as the Sellers are aware, the Sellers have complied with all requests from the subjects of the Personal Data for access, changes to or deletions of the Personal Data and no such requests are outstanding.

# 19 General legal compliance

- All necessary licences, consents, permits and authorities (public and private) have been obtained by the Sellers to enable the Businesses to be carried on effectively in the places and in the manner in which the Businesses are now carried on. There is no reason of which the Sellers are aware why any of them should be suspended, cancelled or revoked. Save in respect of any licences, consents, permits and authorities forming part of thr Excluded Assets, there are no other licences, consents, permits and authorities (public and private) necessary to be obtained by the Buyer and/or TBML to enable it to carry on the Businesses effectively in the places and manner in which the Businesses are now carried on. Enclosed with the Disclosure Letter are copies of all such licences, consents, permits and authorities.
- 19.2 The Sellers have not been notified that they have not conducted the Businesses in accordance with all applicable laws and regulations of the United Kingdom (including the Consumer Credit Act 1974 and the Bribery Act 2010).
- 19.3 None of the Sellers' officers, (during the course of his duties in relation to the Businesses) has committed or omitted to do any act or thing in contravention of any law, order, regulation or the like in the United Kingdom.

#### 20 Litigation

- 20.1 The Sellers nor any person for whose acts or defaults the Sellers may be contractually or vicariously liable is involved in any capacity in any litigation, arbitration, prosecution or other legal proceedings or in any investigation, enquiry, proceedings or hearings before any statutory, governmental, administrative or regulatory body, department, board or agency in respect of the Businesses or any of the Assets and no such matters are pending or threatened against the Sellers in respect of the Businesses or any of the Assets and the Sellers are not aware of any circumstances which are likely to give rise to any such matter.
- There is no outstanding judgment, order, decree, arbitral award or decision of any court, tribunal, arbitrator or governmental agency against the Sellers in respect of the Businesses or any of the Assets.
- 20.3 The Sellers are not a party to any subsisting undertaking given to any court or third party arising out of any proceedings of the kind described in paragraph 20.1.

# 21 Insolvency

- 21.1 No order has been made and no resolution has been passed for the winding up of any of the Sellers or for a provisional liquidator to be appointed in respect of any of the Sellers and no petition has been presented which remains outstanding and no meeting has been convened for the purpose of winding up any of the Sellers and none of the Sellers has been a party to any transaction which could be avoided in a winding up.
- 21.2 No administrator has been appointed by court order or any other means in respect of any of the Sellers, no notice has been served of an intention to appoint an administrator in respect of any of the Sellers and no petition for such an order has been presented in respect of any of the Sellers.
- 21.3 No receiver or administrative receiver has been appointed in respect of any of the Sellers or in respect of all or any part of their assets.
- 21.4 No voluntary arrangement has been proposed under Part I Insolvency Act 1986 in respect of any of the Sellers and none of the Seller has made or proposed any arrangement or composition with its creditors or any class of them.
- 21.5 None of the Sellers is insolvent or unable to pay or has no reasonable prospect of being able to pay its debts nor could any of the Sellers be deemed to be unable to pay its debts within the meaning of section 123 Insolvency Act 1986 and none of the Sellers has received a written demand pursuant to section 123(a) Insolvency Act 1986 or stopped paying its debts as they fall due.
- 21.6 No circumstances have arisen which entitle any court or a creditor to appoint a receiver and/or manager or administrative receiver or which entitle any court to make a winding-up order and none of the Sellers has taken or suffered any similar or analogous action in consequence of debt.
- 21.7 No distress, execution or other process has been levied, applied for or threatened in respect of any of the Assets.
- 21.8 No composition in satisfaction of the debts of any of the Sellers or scheme of arrangement of any of their affairs or compromise or arrangement between any of them and their creditors and/or members or any class of their creditors and/or members has been proposed, sanctioned or approved.
- 21.9 No disqualification order has at any time been made pursuant to the provisions of the Company Directors Disqualification Act 1986 against any former or current of the Sellers.

# 22 Taxation and grants

- 22.1 All documents in the possession of or under control of the Sellers or to the production of which the Sellers are entitled which are necessary to establish the title of the Sellers to any of the Assets and which attract stamp duty in the UK or elsewhere have been properly stamped and no such documents which are outside the UK would attract stamp duty if they were brought into the UK.
- 22.2 Neither HMRC nor any other fiscal or regulatory authority has operated or agreed to operate any special arrangement (being an arrangement which is not based on relevant legislation or any published practice) in relation to the tax affairs of the Businesses.

- 22.3 The Sellers have complied in all material respects with all statutory provisions, rules, regulations, orders and directions in relation to the Businesses concerning PAYE (including the deduction of income tax in relation to the Construction Industry Scheme, casual labour and employee benefits) and National Insurance contributions (both primary and secondary contributions) including the making on time of accurate returns, deductions and payments and the proper maintenance and preservation of records and the Sellers have not been given any penalty, notice or warning regarding the same.
- 22.4 Neither HMRC nor any other fiscal or other regulatory authority has conducted any investigation into the Businesses (or any part of them) and none of the Sellers nor any of their agents has received any written notification that any such investigation is pending or threatened. At the date of this Agreement no dispute exists between the Sellers and any such authority in relation to the Businesses nor are there any circumstances in existence which may give rise to such a dispute.
- 22.5 There is no outstanding HMRC charge (as defined in section 237 Inheritance Tax Act 1984) over any of the Assets and there are in existence no circumstances by virtue of which any such power as mentioned in section 212 Inheritance Tax Act 1984 could be exercised in relation to any of the Assets.
- Full particulars of all grants, subsidies, payments or allowances from any government authority, body or agency (whether supra-national, national, regional or local) relating to the Businesses are set out in the Disclosure Letter and none of them will at any time be or become repaid or repayable.

#### 23 VAT

- 23.1 The Sellers are registered persons for the purposes of VATA under the registration numbers:GB860459805 (Lab 21) 637992485 (Healthcare) 878574947 (Myconistica).
- 23.2 The Sellers have in all material respects maintained and obtained at all times complete, correct and up-to-date records, invoices and other documents (as the case may be) appropriate or requisite for the purposes of all legislation relating to VAT, has preserved such records, invoices and other documents in such form and for such periods as are required by such legislation and is not subject to any condition imposed by HMRC under paragraph 6 Schedule 11 VATA.
- 23.3 None of the Assets are or could be subject to the VAT Capital Goods Scheme provided for in Part XV of the Value Added Tax Regulations 1995.
- 23.4 The Sellers have not made and do not make exempt supplies for VAT purposes (except such exempt supplies as may be disregarded in calculating the amount of input tax for which the Sellers may claim a credit or repayment under sections 24 or 25 VATA) and the Sellers have not been and will not be denied credit for any input tax by reason of the operation of section 26 VATA in respect of the Businesses or otherwise.

# **24** Competition matters

24.1 The Sellers conduct, and have conducted the Businesses fully in accordance with the requirements of all applicable competition laws (whether of the UK, EU, or other jurisdiction) and have not infringed such requirements nor been investigated for any alleged non-compliance or infringement nor given any undertakings in connection therewith.

For the purposes of paragraph 24.1, the term "**competition laws**" includes any applicable rules dealing with state aid, public procurement, or anti-dumping, and the requirements of any special regulatory regime to which the Sellers may be subject in relation to the Businesses.

# 25 **Guarantee**

25.1 There is not now outstanding in respect of the Businesses any guarantee or agreement for indemnity or for suretyship given by or for the accommodation of the Businesses otherwise than by the Sellers and all such guarantees or agreements have been disclosed in the Disclosure Letter.

#### Schedule 7

#### Provisions for the protection of the Sellers

#### 1 Time Limits

- 1.1 No claim against the Sellers for breach of the Warranties shall be brought by the Buyer unless notice in writing of such claim (specifying in reasonable detail with supporting evidence the event, matter or default which gives rise to the claim and an estimate of the amount claimed) has been given to the Sellers within 24 months from the date of this Agreement.
- 1.2 Clause 21 of this Agreement is without prejudice to the time limits in paragraph 1.1 (for which purposes time shall be of the essence) and all references in clause 21 to:
  - 1.2.1 any right shall include any power, right or remedy conferred by this Agreement on, or provided by law or otherwise available to, the Buyer; and
  - 1.2.2 any failure to do something shall include any delay in doing it.
- 1.3 Any claim that is made shall (if it has not been previously satisfied, settled or withdrawn) be deemed to have been waived or withdrawn on the expiration of 12 months after the expiration of the relevant period in paragraph 1.1 unless court proceedings in respect of it shall then have been commenced against the Sellers (or either of them). For the purposes of this paragraph court proceedings shall not be deemed to have been commenced unless they have been both issued and served on the Sellers (or either of them).

#### 2 Threshold

2.1 The Sellers shall not be liable for any claim unless the amount of the claim, when aggregated with all other claims made on the same occasion or previously, is equal to or exceeds £100,000 (one hundred thousand pounds) (in which case the Sellers shall be liable for the whole amount of all the claims and not simply the excess).

#### 3 Aggregate maximum

3.1 The total joint and several liability of the Sellers in respect of all claims shall not exceed £4,750,000 (*four million seven hundred and fifty thousand pounds*).

### 4 **Specific limitations**

- 4.1 The Sellers will have no liability in respect of any claim for a breach of the Warranties (a "Claim"):
  - 4.1.1 to the extent that it arises or is increased as a result of:
    - (i) any legislation not in force at Completion or any change in law or administrative practice having retrospective effect which comes into force after Completion;
    - (ii) any voluntary act of the Buyer and/or TBML after Completion; or

(iii) any increase after the date of this Agreement in the rates of taxation in force at Completion.

# 5 Recovery from third parties

- 5.1 Where the Buyer becomes entitled to recover from some other person (including any fiscal or taxation authority or body) any sum in respect of any matter or event which could give rise to a Claim, the Buyer (as appropriate) shall:
  - 5.1.1 inform and consult with the Sellers;
  - 5.1.2 consider and take account of all reasonable proposals of the Sellers prior to taking or omitting to take any action;
  - 5.1.3 (should the Buyer or TBML consider in its sole discretion that it would not have a detrimental effect on its profitability (excluding management time involved in making such Claim), reputation or goodwill), recover that sum before making such Claim, and any sum recovered will reduce the amount of such Claim after deduction of all reasonable costs and expenses of recovery.
- 5.2 If the Sellers pay the Buyer sum to settle or discharge a Claim and the Buyer subsequently recovers whether by payment, discount, credit, relief or otherwise from any third party (including any tax authority) a sum which is referable to the Claim then:
  - 5.2.1 the Buyer will repay the Sellers immediately the amount recovered from the third party less any reasonable costs and expenses incurred in recovering the same; or
  - 5.2.2 if the figure resulting under paragraph 5.2.1 above is greater than the amount paid by the Sellers to settle or discharge the relevant Claim, then the Buyer is only obliged to repay to the Sellers such amount as is equivalent to the sum paid by the Sellers in settlement or discharge of that Claim.

# 6 No double recovery

6.1 The Buyer is not entitled to recover damages or otherwise obtain payment, reimbursement or restitution more than once in respect of the same loss or liability.

## 7 Contingent Liabilities

7.1 Without prejudice to paragraph 1, if any potential Claim arises as a result of a contingent or unquantifiable liability of the Buyer, the Sellers will not be obliged to pay any sum in respect of the potential Claim until the liability either ceases to be contingent or becomes quantifiable.

# 8 Third party claims

- 8.1 If the Buyer becomes aware that matters have arisen which will or are likely to give rise to a Claim, the Buyer will:
  - 8.1.1 give notice to the Sellers within 90 days of any relevant third party claim or any circumstance giving or likely to give rise to a relevant third party claim coming to its notice or to the notice of the Buyer;
  - 8.1.2 disclose to the Sellers such information and documents as the Buyer deems appropriate and relating to the potential Claim or the matters which will or are likely to give rise to the potential Claim (subject always to the Buyer being able to withhold such information in circumstances where it constitutes Confidential Information and disclosure of such information could be detrimental effect on the profitability, reputation or goodwill of the Buyer);
  - 8.1.3 if requested by the Sellers, and upon agreement by the Buyer, give the Sellers and its professional advisers reasonable access to:
    - (i) the personnel of the Buyer in order to interview the personnel; and
    - (ii) any relevant premises, accounts, documents and records within the possession or control of the Buyer in order to, at the Sellers' own expense, examine and (where legitimate to do so) photograph such premises or take copies of such accounts, documents and records;
  - 8.1.4 should the Buyer consider in its sole discretion that it would not have a detrimental effect on its profitability (excluding management time involved in making such Claim), reputation or goodwill or on the business relationship with the relevant third party, consider all reasonable proposals of the Sellers to avoid, resist, contest, defend, compromise or remedy the potential Claim or the matters which will or are likely to give rise to such Claim and in each case on the basis that the Sellers will indemnify the Buyer for all reasonable costs incurred as a result of such a request by the Sellers.
- 8.2 The Buyer shall not, for the avoidance of doubt, be bound by the provisions of paragraph 8.1 as a condition precedent of bringing any Claim and any failure by the Buyer to adhere to the provisions of paragraph 8.1 shall not in any way prejudice the ability of the Buyer to bring any such Claim.

# 9 Mitigation

9.1 Nothing in this Schedule 7 will in any way restrict or limit the Buyer's common law duty to mitigate its loss.

#### 10 Successful claims deemed to constitute a reduction in Consideration

10.1 The satisfaction by the Sellers of any claim shall be deemed to constitute a reduction in the Consideration.

# 11 <u>Exclusion of rights of set-off</u>

11.1 None of the Sellers shall be entitled to set off any sum due to it from the Buyer against any sum due to the Buyer from that Seller under or in relation to this Agreement and all such sums shall be paid free and clear of any deductions save for any which are required by law.

# 12 <u>Limitation of liability</u>

12.1 Nothing in this Schedule 7 or in any other provisions of this Agreement will operate so as to exclude or limit the liability of any of the Sellers to the extent that any claim for breach of any of the Warranties arises by reason of any fraud or dishonest, reckless or wilful misstatement or omission by or on behalf of any of the Sellers.

# Schedule 8

The Creditors

Listed as attached

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| Signed as a deed by <b>TRINITY BIOTECH</b> ( <b>UK</b> ) <b>LIMITED</b> acting by a director in the presence of: | )<br>)<br>)          |
|--|----------------------|
|  | Director's signature |
|  | Director's name      |
| Witness' signature:  |                      |
| Witness' name:   |                      |
| Witness' address:  |                      |
|  |                      |
|  |                      |
| Witness' occupation:   |                      |
| Signed as a deed by <b>LAB21 LIMITED</b> acting by a director in the presence of:                                | )<br>)<br>)          |
|  | Director's signature |
|  | Director's name      |
| Witness' signature:  |                      |
| Witness' name:   |                      |
| Witness' address:  |                      |
|  |                      |
|  |                      |
| Witness' occupation:   |                      |

| Signed as a deed by <b>LAB21 HEALTHCARE LIMITED</b> acting by a director in the presence of: | )<br>)<br>)          |
|--|----------------------|
|  | Director's signature |
|  | Director's name      |
| Witness' signature:  |                      |
| Witness' name:   |                      |
| Witness' address:  |                      |
|  |                      |
|  |                      |
| Witness' occupation:   |                      |
| Signed as a deed by MYCONOSTICA LIMITED acting by a director in the presence of:             | )<br>)<br>)          |
|  | Director's signature |
|  | Director's name      |
| Witness' signature:  |                      |
| Witness' name:   |                      |
| Witness' address:  |                      |
|  |                      |
|  |                      |
| Witness' occupation:   |                      |

| Signed as a deed by TRINITY BIOTECH MANUFACTURING LIMITED acting by a | )                         |
|---|---------------------------|
| director in the presence of:  | )                         |
|   | )<br>Director's signature |
|   | Director's name           |
|   | -                         |
| Witness' signature:   |                           |
| Witness' name:  |                           |
| Witness' address:   |                           |
|   |                           |
| Witness' occupation:  |                           |
|   |                           |

# AGREED FORM DOCUMENTS

Disclosure Letter and index of disclosed documents

Deed of release from Clydesdale Bank

**TSA** 

Financial Information (as defined)

#### PUBLIC HEALTH SERVICE

#### PATENT LICENSE AGREEMENT-NONEXCLUSIVE

#### **COVER PAGE**

Patent License Number: A198-11

Serial Number(s) of Licensed Patent(s):

US Patent 8,148,057, entitled, "Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", issued 4/3/2012, claiming priority to US Provisional Patent Application No. 60/693,120, filed 6/21/2005, inventor, Arnold Castro.

US Patent Application Serial No. 13/421,681, entitled, "Methods, Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", filed 3/15/2012, claiming priority to US Provisional Patent Application No. 60/693,120, filed 6/21/2005, inventors, Arnold Castro and Robert George.

PCT Patent Application Serial No. PCT/US06/024117 entitled, "Methods, Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", filed 6/20/2006, and related foreign applications, inventors, Arnold Castro and Robert George. [CDC Ref. No 1-010-05].

Licensee: Trinity Biotech Manufacturing Limited

IDA Business Park Southern Cross Road

Bray Co. Wicklow Ireland

CRADA Number (if applicable): NCHHSTP-C1D11426-00

Additional Remarks: This royalty rate is for use in Trinity's dual Trep/Non-Trep Syphilis rapid test. The treponemal (total antibody) + non-treponemal assay essentially is a combination screen and confirmation test. In accordance with fair government practices, this technology is being licensed at the same rates as previous licenses.

Public Benefit (s): Development of a point of care test that can quickly detect both treponomal and nontreponomal antigens.

This Patent License Agreement, hereinafter referred to as the "**Agreement**," consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Modifications), Appendix E (Benchmarks), Appendix F (Commercial Development Plan), and Appendix G (Example Royalty Report). The Parties to this **Agreement** are:

- 1) The National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "**PHS**," agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and
- 2) The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

Trinity Biotech Manufacturing Limited (1-010-05)
Patent License Agreement - Non-Exclusive #A198-11

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#### PHS PATENT LICENSE AGREEMENT-NONEXCLUSIVE

#### PHS and Licensee agree as follows:

#### 1. BACKGROUND

- 1.01 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.
- 1.02 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the United States Government, owns intellectual property rights claimed in any United States and/or foreign patent applications or patents corresponding to the assigned inventions **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.
- 1.03 The Secretary of HHS has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.
- 1.04 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.05 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, and/or marketable products for public use and benefit.

#### 2. DEFINITIONS

- 2.01 "Benchmarks" mean the performance milestones that are set forth in Appendix E.
- 2.02 "Commercial Development Plan" means the written commercialization plan attached as Appendix F.
- 2.03 "First Commercial Sale" means the initial transfer by or on behalf of Licensee of Licensed Products or the initial practice of a Licensed Process by or on behalf of Licensee in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.
- 2.04 "Government" means the Government of the United States of America.
- 2.05 "Licensed Fields of Use" means the field(s) of use identified in Appendix B.
- 2.06 "Licensed Patent Rights" shall mean:
  - a) Patent applications including provisional patent applications and PCT patent applications, and/or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;
  - b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; and iv) any reissues, reexaminations, and patent term extensions;

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- c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign applications and patents to a) and b) above, including those listed in Appendix A.
  - **Licensed Patent Rights** shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in a) above.
- 2.07 "Licensed Process(es)" means processes which, in the course of being practiced would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.08 **"Licensed Product(s)"** means tangible materials which, in the course of manufacture, use, offer to sell, sale, or importation would, in the absence of this **Agreement**, infringe one or more claims of the **Licensed Patent Rights** that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.09 "Licensed Territory" means the geographical area identified in Appendix B.
- 2.10 "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of Licensee, and from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by Licensee, and on its payroll, or for the cost of collections.
- 2.11 **"Practical Application"** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

#### 3. GRANT OF RIGHTS

- 3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, and to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.
- 3.02 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**.

### 4. SUBLICENSING

4.01 **Licensee** has no right to sublicense.

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## 5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.01 Prior to the **First Commercial Sale, Licensee** agrees to provide **PHS** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.
- 5.02 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

### 6. ROYALTIES AND REIMBURSEMENT

- 6.01 **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this **Agreement** becomes effective.
- 6.02 **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year. The minimum annual royalty due for the first calendar year of this **Agreement** may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
- 6.03 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.
- 6.04 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C and Appendix E.
- 6.05 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing the earned royalty and payments in any given country on the earliest of the dates that a) the application has been abandoned and not continued, b) the patent expires or irrevocably lapses, or c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.06 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights.**
- 6.07 On sales of **Licensed Products** by **Licensee** to affiliated parties or on sales made in other than an arm's-length transaction, the value of the **Net Sales** attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.
- 6.08 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay to **PHS**, as an additional royalty, within sixty (60) days of **PHS's** submission of a statement, and request for payment to **Licensee**, an amount equivalent to such patent expenses previously incurred by **PHS**.
- 6.09 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** on or after the effective date of this **Agreement, PHS**, at its sole option, may require **Licensee:** 
  - 1. to pay **PHS** on an annual basis, within sixty (60) days of **PHS's** submission of a statement, and request for payment, a royalty amount equivalent to all such patent expenses incurred during the previous calendar year(s); or
  - 2. to pay such expenses directly to the law firm employed by **PHS** to handle such functions. However, in such event, **PHS** and not **Licensee** shall be the client of such law firm.

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6.10 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any **Licensed Patent Rights** upon ninety (90) days written notice to **PHS** and owe no payment obligation under Paragraph 6.09 for patent-related expenses incurred in that country after the effective date of such written notice.

# 7. PATENT FILING, PROSECUTION, AND MAINTENANCE

- 7.01 **PHS** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights.**
- 7.02 Pursuant to statute 15 U.S.C. §3710c(a)(l)(A)(i), **PHS** may use royalty payments as calculated in Appendix C, in whole or in part, to pay some or all of the patent costs of the **Licensed Patent Rights.**

#### 8. RECORD KEEPING

- 8.01 Licensee agrees to keep accurate and correct records of Licensed Products made, used, sold, or imported and Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due PHS. Such records shall be retained for at least five (5) years following a given reporting period, and shall be available during normal business hours for inspection at the expense of PHS by an accountant or other designated auditor selected by PHS for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall only disclose to PHS information relating to the accuracy of reports and payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then Licensee shall reimburse PHS for the cost of the inspection at the time Licensee pays the unreported royalties, including any late charges as required by Paragraph 9.08 of this Agreement. All payments required under this Paragraph shall be due within thirty (30) days of the date PHS provides Licensee notice of the payment due.
- 8.02 Licensee agrees to conduct an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the Licensed Product or Licensed Processes are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of Licensee during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the Government, the amount of royalty funds owed to the Government under this Agreement, and whether the royalty amount owed has been paid to the Government and is reflected in the records of the Licensee. The audit shall also indicate the PHS license number, product, and time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to PHS on completion. Licensee shall pay for the entire cost of the audit.

#### 9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.01 Prior to signing this **Agreement, Licensee** has provided to **PHS** the **Commercial Development Plan** at Appendix F, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix E.
- 9.02 Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, marketing, importing, and sales during the preceding calendar year, as well

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as plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any such annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under **this Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written consent by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if such request is supported by a reasonable showing by **Licensee** of diligence in **its** performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of practical application as defined in 37 CFR 404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

- 9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix C and/or Appendix E and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrence.
- 9.04 Licensee shall submit to PHS within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each such royalty report, Licensee shall submit payment of the earned royalties due. If no earned royalties are due to PHS for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of Licensee and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine Net Sales made under Article 6 to determine royalties due.
- Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "CDC/Technology Transfer" and shall reference the licensing agreement number assigned by the Centers for Disease Control and Prevention (CDC). All such payments shall be sent to the following address: CDC, Financial Management Office, P.O. Box 15580, Atlanta, GA 30333 or by wire transfer. To ensure timely and accurate payment processing, please be sure to include the invoice number (if applicable), tax ID number, and/or a copy of the invoice with your payment. Also, please send a copy/confirmation of such payment to the following address: CDC, Technology Transfer Office, 4770 Buford Highway NE, MailStop K-79, Atlanta, GA 30341. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by Licensee. The royalty report required by Paragraph 9.04 of this Agreement shall accompany each such payment and a copy of such report shall also be mailed to PHS at its address for notices indicated on the Signature Page of this Agreement.
- 9.06 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign governments.
- 9.07 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

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9.08 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of such records by the **PHS** under the Freedom of Information Act, 5 U.S.C. § 552 shall be subject to the predisclosure notification requirements of 45 CFR § 5.65(d).

## 10. PERFORMANCE

- 10.01 **Licensee** shall use its reasonable best efforts to bring the License Products and Licensed Processes to Practical Application. "Reasonable best efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** at Appendix F and performance of the **Benchmarks** at Appendix E.
- 10.02 Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use its reasonable best efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

### 11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.01 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.
- In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against **PHS**, **PHS** agrees to notify **Licensee** that an action alleging invalidity has been brought. **PHS** does not represent that it will commence legal action to defend against a declaratory action alleging invalidity. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such declaratory judgment action. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action. Upon **Licensee's** payment of all costs incurred by the **Government** as a result of **Licensee's** joinder motion or other action, these actions by **Licensee** will not be considered a default in the performance of any material obligation under this **Agreement**.

#### 12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.01 **PHS** offers no warranties other than those specified in Article 1.
- 12.02 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.
- 12.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.
- 12.04 **PHS** does not represent that it will commence legal actions against third parties infringing the **Licensed Patent Rights.**

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12.05 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by or on behalf of **Licensee**, directors, employees, or third parties of any **Licensed Patent Rights**, or b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**. **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

### 13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

- 13.01 This **Agreement** is effective when signed by all parties and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.
- 13.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement,** including but not limited to the obligations listed in Paragraph 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice, and pursue outstanding amounts owed through procedures provided by the Federal Debt Collection Act.
- 13.03 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee's** receipt of written notice.
- 13.04 **Licensee** shall have a unilateral right to terminate this **Agreement** and/or any licenses in any country by giving **PHS** sixty (60) days written notice to that effect.
- 13.05 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**: 1) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the **Licensed Products** or **Licensed Processes**; 2) has not achieved the **Benchmarks** as may be modified under Paragraph 9.02; 3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license agreement; 4) has committed a material breach of a covenant or agreement contained in the license; 5) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences; 6) cannot reasonably satisfy unmet health and safety needs; or 7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived. In making this determination, **PHS** will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.02. Prior to invoking this right, PHS shall give written notice to Licensee providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS's** concerns as to the previous items 1) to 7). If **Licensee** fails to alleviate **PHS's** concerns as to the previous items 1) to 7) or fails to initiate corrective action to **PHS's** satisfaction, **PHS** may terminate this **Agreement**.
- 13.06 **PHS** reserves the right according to 35 U.S.C. § 209(d)(3) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee.**

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- 13.07 Within thirty (30) days of receipt of written notice of **PHS's** unilateral decision to modify or terminate this **Agreement, Licensee** may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.08 Within ninety (90) days of termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (e.g., full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of the destruction thereof.

# 14. GENERAL PROVISIONS

- 14.01 Neither Party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any such term or condition by **Licensee.**
- 14.02 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights,** and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.03 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.04 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.05 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.06 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party. Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 14.07 This **Agreement** shall not be assigned by **Licensee** except a) with the prior written consent of **PHS**, such consent not to be withheld unreasonably; or b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this Agreement. **Licensee** shall notify **PHS** within ten (10) days of any assignment of this Agreement by **Licensee**, and Licensee shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this Agreement within thirty (30) days of such assignment.

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- 14.08 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
- 14.09 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. PHS neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **PHS** patent rights in such countries.
- 14.11 By entering into this **Agreement, PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement. Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government, PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of NIH, CDC, **PHS**, or HHS or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written consent of **PHS**.
- 14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.
- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Paragraphs 8.01, 9.06-9.08, 12.01-12.05, 13.07, 13.08, and 14.12 of this **Agreement** shall survive termination of this **Agreement**.

SIGNATURES BEGIN ON NEXT PAGE

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# PHS PATENT LICENSE AGREEMENT-NONEXCLUSIVE

#### SIGNATURE PAGE

| For <b>PHS</b> : |
|------------------|
|------------------|

/s/ David Holmes
Signature of Authorized PHS Official
Date

David Holmes, Ph.D.

Director, Division of Laboratory Policy and Practice

Centers for Disease Control and Prevention

Mailing Address for Notices: Technology Transfer Office

Centers for Disease Control and Prevention

4770 Buford Highway

Mailstop K-79

Atlanta, Georgia 30341 USA

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by

/s/ Pat Vaughan \_\_\_\_\_\_\_\_14<sup>th</sup> May 2012

Signature of Authorized Official Dat

Pat Vaughan, Ph.D.

VP of R&D

Official and Mailing Address for Notices: Trinity Biotech Manufacturing Limited

IDA Business Park Southern Cross Road

Bray

Co. Wicklow

Ireland

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

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# APPENDIX A—Patent(s) or Patent Application(s)

## **Patent(s) or Patent Application(s):**

US Patent 8,148,057, entitled, "Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", issued 4/3/2012, claiming priority to US Provisional Patent Application No. 60/693,120, filed 6/21/2005, inventor, Arnold Castro.

US Patent Application Serial No. 13/421,681, entitled, "Methods, Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", filed 3/15/2012, claiming priority to US Provisional Patent Application No. 60/693,120, filed 6/21/2005, inventors, Arnold Castro and Robert George.

PCT Patent Application Serial No. PCT/US06/024117 entitled, "Methods, Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies", filed 6/20/2006, and related foreign applications, inventors, Arnold Castro and Robert George. |CDC Ref. No. 1-010-05|.

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# APPENDIX B—Licensed Field(s) of Use and Territory

# **Licensed Field(s) of Use:**

For in vitro diagnostic use in Licensee's dual Trep/Non-Trep Syphilis rapid test.

# **Licensed Territory:**

In all countries where claims of the Licensed Patent Rights exist.

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## APPENDIX C—Royalties

## **Royalties:**

Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty in the amount of five thousand (\$5,000) dollars.

**Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty of Five Thousand (\$5,000) dollars; the first such payment will be due **January 1, 2013**.

**Licensee** agrees to pay **PHS** earned royalties on **Net Sales** by or on behalf of **Licensee** of five percent (5%).

Royalty will be reduced to two and a half percent (2.5%) of **Net Sales** on **Licensed Products** sold in countries classified as low-income and lower-middle-income economies by the World Bank (www.worldbank.org). Classification will be reassessed at the beginning of each calendar year.

**Licensee** shall be entitled to a one-half percent (0.5%) credit against the earned royalty rate for each percent (1%) of royalty **Licensee** must pay to third party licensors for the manufacture and sale of **Licensed Products**. Said reduction, however, shall not reduce the royalty rate for Net Sales of **Licensed Products** to below two and one-half percent (2.5%) in high-income and middle-income economies and the royalty will not be reduced below one and a quarter percent (1.25%) in low-income and lower-middle-income economies.

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# APPENDIX D-Modifications

PHS and Licensee agree to the following modifications to the Articles and Paragraphs of this Agreement:

6.08 Deleted.

6.09 Deleted.

6.10 Deleted.

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# APPENDIX E—Benchmarks and Performance

**Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

None.

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### APPENDIX F—Commercial Development Plan

**Licensee** shall expend reasonable efforts and resources to carry out the development and marketing plan submitted with **Licensee's** application for a license and to bring the **Licensed Patent Rights** to the point of practical application as defined in Title 37 of the Code of Federal Regulations, Section 404.3(d). **Licensee** shall offer **Licensed Products** for sale within eighteen (18) months of the Effective Date of this **Agreement** unless this period is extended by mutual agreement of the parties. **PHS** shall not unreasonably withhold approval of any request by **Licensee** to extend this period if such request is supported by evidence of reasonable efforts by **Licensee** to bring the **Licensed Patent Rights** to practical application, including any reasonable and diligent application for regulatory approvals required by any **Government** agency.

The research involves development of a visually read, qualitative immunochromatographic test for detecting both Treponemal and non-Treponemal antibodies on the same device. With this configuration the assay will simultaneously screen for the presence of anticardiolipin antibodies and confirm the results by the detection of antibodies to *T. pallidum*. The test results could be obtained in 15 to 20 minutes in point of care settings and patients can be counseled as to whether they have active infection that would require treatment.

The design of the rapid lateral flow test device will be used with whole blood or serum/plasma samples.

This assay will be unique in its ability to simultaneously test for both non-Treponemal and Treponemal antibodies. If successful, this test will provide testing opportunities where current test methods could not be performed. It will allow patients to be advised of infection status and to be treated in a single visit to a clinic.

### **Proposed components:**

Configuration: Lateral Flow device.

Control line: Possibly anti-Human 1g or other blood marker

Trep line: R17 proteins or equivalent.
Non-Trep: Modified cardiolipin molecule
Cardiolipin/Lecithin/Cholesterol

Time: 15 - 20 minutes for POC.

Sample: Whole blood, serum/plasma 5 -20 ul for POC

#### **Methods:**

### First phase: Development of non-Treponemal test.

The first phase of research is focusing on the development of the assay for the reagin or non-Treponemal antibodies.

Traditionally, non-Treponemal assays detect antibodies reactive to cardiolipin present in a mixture containing cholesterol and lecithin (VDRL antigen). This antigen is not easily bound to nitrocellulose membranes devices and it is disrupted and released from the membrane by detergents frequently used as blocking agents. In the cardiolipin molecular structure there are no other reactive groups that can readily link cardiolipin to proteins, latex particles, or to nitrocellulose. The long fatty acid ester groups in cardiolipin imparts a high degree of hydrophobicity to the molecule and makes it difficult to bind cardiolipin to polar surfaces such as nitrocellulose or ELISA plates.

The first objective of this research is to investigate methods to attach the micelle produced when an alcoholic preparation of cardiolipin, lecithin and cholesterol is diluted 1:10 in buffered saline. The micelle is (CDC method) enabling it to bind to nitrocellulose CDC is initiating a patent application for a proprietary method of modifying the VDRL antigen. "Methods, Immunoassays and Devices for Detection of Anti-Lipoidal Antibodies" U.S. Patent Application No. 11/993,213. – Training by CDC complete and development ongoing at Trinity Biotech

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- 2. CDC will instruct Trinity in the preparation of the micelle antigen using the CDC invention "Composition and Methods for Detecting Syphilis Using Synthetic Antigens. U.S. Patent Application No. 10/009,698. Training by CDC complete and development ongoing at Trinity Biotech
- 3. Investigate the modified antigen for its ability to detect all stages of syphilis infections with a high degree of sensitivity and specificity.
- 4. Work is currently underway at Trinity Biotech (since 2011) to apply the nitrocellulose bound cardiolipin and latex bound cardiolipin into a lateral flow assay to detect non-treponemal antibodies. Prototypes were generated in Q1 2012 and further refinement continues into Q2 and Q3 2012.

# **Second phase:** Development of Treponemal test.

Concurrently, and independent of the CDC technology, the second phase of research is focusing on the development of a sensitive and specific assay for Treponemal antibodies. There is substantial published data available which is related to the attachment of antigens of protein in nature to nitrocellulose. This assay is based on *T. pallidum* recombinant antigens, Tp17 and possibly Tp47. Prototypes have been developed Q1 2012 and are soon to enter verification and validation Q2 2012.

#### Third phase:

<u>Third phase</u>: Combining the Treponemal and non-Treponemal antigens on the same device for the dual POC test. This work is

due to start in Q3 2012 and continue for approximately 6 months.

### **Fourth phase:**

Fourth phase: Conduct medium scale test studies using stored sera from CDC serum bank with both documented and non-

documented cases of syphilis in Q4 2012.

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### APPENDIX G - EXAMPLE ROYALTY REPORT

# Required royalty report information includes:

- CDC TTO license reference number (A198-11)
- · Reporting period
- Catalog number and units sold of each Licensed Product (Please separate items by country)
- Gross Sales per catalog number per country
- Total Gross Sales (Summarized by country)
- Itemized deductions from Gross Sales
- Earned Royalty Rate and associated calculations
- · Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

\*\* In addition, a sample product and/or product packaging is to be sent on the first report and each time the product packaging is re-designed. \*\*

# **Example:**

A198-11: Trinity Biotech Manufacturing Limited: Reporting Period: January 2012 through December 2012

| Country        | Product Name             | Catalog/Item# | Units Sold | Item Price (US\$) | Gross Sales (US\$) |  |
|----------------|--------------------------|---------------|------------|-------------------|--------------------|--|
| Australia      | A                        | 123ABC        | 250        | 100.00            | 62,500             |  |
| Australia      | A                        | 456DEF        | 32         | 75.00             | 16,500             |  |
| Australia      | A                        | 789GHI        | 25         | 50.00             | 15,625             |  |
| TOTAL          |                          |               | 307        |                   | 94,625             |  |
| Comment        | D 1 (N                   | G . 1 . W     | W 44 G 11  | T. D. (TIGA)      | a al arab          |  |
| Country        | Product Name             | Catalog/Item# | Units Sold | Item Price (US\$) | Gross Sales (US\$) |  |
| USA            | В                        | 010JKL        | 0          | 79.00             | 0                  |  |
| TOTAL          |                          |               | 0          |                   | 0                  |  |
| G              |                          | G . 3 . 7     | ** ** **   | T. D. (7704)      | a a a arab         |  |
| Country        | Product Name             | Catalog/Item# | Units Sold | Item Price (US\$) | Gross Sales (US\$) |  |
| United Kingdom | C                        | 011MNO        | 57         | 80.00             | 57,125             |  |
| United Kingdom | C                        | 012PQR        | 12         | 25.00             | 1,500              |  |
| TOTAL          |                          |               | 62         |                   | 58,625             |  |
|                |                          |               |            |                   |                    |  |
|                | Grand Total Gross Sales  |               |            | 153,250           |                    |  |
|                | Less Deductions:         |               |            | •                 |                    |  |
|                | Freight                  |               |            | 3,000             |                    |  |
|                | Returns                  |               |            | 7,000             |                    |  |
|                | Total Net Sales:         |               | 143,250    |                   |                    |  |
|                | Royalty Rate             |               | 8%         |                   |                    |  |
|                | Royalty Due              |               | 11,460     |                   |                    |  |
|                | Less Creditable Payments |               |            | 10,000            |                    |  |
|                | Net Royalty Due:         |               |            | 1,460             |                    |  |

Sample product packaging included? Y or N

Trinity Biotech Manufacturing Limited (1-010-05) Patent License Agreement - Non-Exclusive #A198-11



# PATENT LICENSE AGREEMENT

THIS AGREEMENT ("**Agreement**") is between the Board of Regents ("**Board**") of The University of Texas System ("**System**"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, and Trinity Biotech, Incorporated, a Missouri corporation having a principal place of business located at 1930 Business Center Drive, Saint Louis, Missouri 63114, USA ("**Trinity**").

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#### RECITALS

- A. **Board** owns certain **Patent Rights** and **Technology Rights** related to **Licensed Subject Matter**, which were developed at The University of Texas Health Science Center at Houston ("**University**"), a component institution of **System**.
- B. **Board** desires to have the **Licensed Subject Matter** developed in the **Licensed Field** and used for the benefit of **Trinity**, the **Inventor**, **Board**, and the public as outlined in **Board's** Intellectual Property Policy.
- C. Trinity desires to obtain a license from **Board** to practice **Licensed Subject Matter**.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties agree as follows:

### 1. EFFECTIVE DATE

This **Agreement** is effective as of April 18th, 2005 ("**Effective Date**").

#### 2. DEFINITIONS

As used in this **Agreement**, the following terms have the meanings indicated:

- 2.1 "Affiliate" means:
  - a. any business entity at least 50% owned by **Trinity**, or
  - b. any business entity that owns at least 50% of **Trinity**, or
  - c. any business entity that is at least 50% owned by a business entity that owns at least 50% of **Trinity**, or
  - d. any business entity in which **Trinity** has a controlling share.
- 2.2 "Actively Attempting to Commercialize" means an effective, ongoing and active research, development, manufacturing, marketing or sales program as appropriate, directed toward obtaining regulatory approval, and/or production and/or Sales of Licensed Products or Sales of a product incorporating Licensed Products or a part thereof, in any jurisdiction, and where Trinity has provided plans acceptable to University, in its sole discretion, to Commercialize Licensed Subject Matter in Licensed Territory.
- 2.3 "Commercialize" means having Sales of Licensed Products, or Sales of products incorporating Licensed Products or parts thereof.
- 2.4 "**Inventor**" means Dr. Steven J. Norris or any person specifically under Dr. Norris's direction in his capacity as a principal investigator at **University**.

Patent License Agreement between the Board of Regents of The University of Texas System and Trinity Biotech, Inc.

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- 2.5 "Licensed Field" means the use of Licensed Subject Matter to make, have made, use and Sell a protein or antibody-based human diagnostic test for Lyme disease.
- 2.6 "Licensed Product" means any product or Service comprised or derived from Licensed Subject Matter; or which utilizes Licensed Subject Matter in its development; or any products with which Licensed Subject Matter is combined, attached, packaged, retrofitted, marketed, or Sold.
- 2.7 "Licensed Subject Matter" means protein and antibody based inventions covered by Patent Rights or Technology Rights for use within Licensed Field.
- 2.8 "Licensed Territory" means worldwide
- 2.9 "Net Sales" means the gross revenues received by Trinity or its Affiliates, as the case may be, from the Sale of Licensed Products or performance of a Service with in the Licensed Territory, less:
  - a. Sales and/or use taxes actually paid;
  - b. Import and/or export duties actually paid;
  - c. Non-reimbursed outbound transportation prepaid or allowed; and
  - d. Amounts allowed or credited due to returns.

Such deductions shall only arise from **Trinity's** expenses incurred in **Selling** a **Licensed Product** within the **Licensed Territory** and shall not exceed the original billing or invoice amount.

- 2.10 "Patent Rights" means Board's rights in information or discoveries covered by the University's patent(s) or patent applications in the Licensed Territory, which are listed in Exhibit A, for:
  - a. "VMP-Like Sequences of Pathogenic Borrelia"; and
  - b. "VMP-Like Sequences of Pathogenic Borrelia Species and Strains"; and
  - c. any patent(s) issuing from the foregoing applications; and
  - d. any reissue, extension, revival or reexamination of the foregoing patent(s).
- 2.11 "Patent Territory" means Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Spain, Sweden, Switzerland and The United States of America.
- 2.12 "Sale, Sold or Sell" means the transfer or disposition of a Licensed Product for value to a party other than Trinity.
- 2.13 "Service" means Trinity's or its Affiliate's performance of in-house testing using Licensed Subject Matter. For calculating Net Sales, Service shall not include Trinity's or its Affiliate's use of Licensed Subject Matter to perform quality assurance testing for any Licensed Product.

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2.14 "Technology Rights" means Board's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, trade secrets, drawings or data created by Inventor at UTHSC-H, before the Effective Date, relating to Patent Rights, which are not covered by Patent Rights but which are necessary for practicing the invention covered by Patent Rights.

#### 3. WARRANTY: SUPERIOR-RIGHTS

- 3.1 Except for the rights, if any, of the Government of the United States, as set forth below, **Board** represents and warrants its belief that (i) it is the owner of the entire right, title, and interest in and to **Licensed Subject Matter**, (ii) it has the right to grant licenses thereunder, and (iii) it has not knowingly granted licenses thereunder to any other entity that would restrict rights granted to **Trinity** except as stated herein.
- 3.2 **Trinity** understands that the **Licensed Subject Matter** may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This **Agreement** is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this **Agreement**, the terms of the Government agreement, applicable law or regulation shall prevail.
- 3.3 **Trinity** understands and acknowledges that **Board**, by this **Agreement**, makes no representation as to the operability or fitness for any use, safety, efficacy, ability to obtain regulatory approval, patentability, and/or breadth of the **Licensed Subject Matter** or **Materials**. **Board**, by this **Agreement**, also makes no representation as to whether there are any patents now held, or which will be held, by others or by **Board** in the **Licensed Field**, nor does **Board** make any representation that the inventions contained in **Patent Rights** or **Materials** do not infringe any other patents now held or that will be held by others or by **Board**.
- 3.4 **Trinity**, by execution hereof, acknowledges, covenants and agrees that it has not been induced in any way by **Board**, **System**, **University** or its employees to enter into this **Agreement**, and further warrants and represents that (i) it has conducted sufficient due diligence with respect to all items and issues pertaining to this Article 3 and all other matters pertaining to this **Agreement**; and (ii) **Trinity** has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and agrees to accept all risks inherent herein.

### 4. LICENSE

4.1 **Board** hereby grants to **Trinity** a royalty-bearing, non-exclusive license under **Licensed Subject Matter** to manufacture, have manufactured, use, distribute, **Sell**, offer to **Sell**, import, lease, loan or otherwise **Commercialize Licensed Products** in **Trinity's** ordinary course of business, within the **Licensed Territory** for use within **Licensed Field**. This grant specifically excludes the right to (i) sublicense, (ii) cross-license, and (iii) transfer any rights granted herein.

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This grant is subject to any rights held by the Government of the United States as set forth in Paragraph 3.2, the payment by **Trinity** to **University** of all consideration as provided herein, and is further subject to the following rights retained by **University** and **Board** to:

- a. Publish the general scientific findings from research related to **Licensed Subject Matter** subject to the terms of Section 12, Confidential Information; and
- b. Use Licensed Subject Matter for research, teaching and other educationally-related purposes; and
- c. Grant other licenses to **Licensed Subject Matter**.
- 4.2 **Trinity** may extend the license granted herein to any **Affiliate** provided that the **Affiliate** consents in writing to be bound by this **Agreement** to the same extent as **Trinity**.
- 4.3 **Trinity** shall at all times use commercially reasonable efforts develop, manufacture or have others manufacture, seek and obtain any necessary governmental approval, and actively promote, **Sell** and distribute **Licensed Products** in the **Licensed Territory** in only lawful ways and to the extent commercially reasonable.
- 4.4 **Trinity** shall use commercially reasonable efforts to develop and market **Licensed Products** for **Sale** in the **Licensed Territory** according to the timetables set-forth below.
  - a. Within nine (9) months after the Effective Date, Trinity shall develop a Licensed Product; and
  - b. Within twelve (12) months after the **Effective Date**, **Trinity** shall offer for **Sale** or **Sell** a **Licensed Product**.
- 4.5 To assist **Trinity's** development of **Licensed Products**, **University**, through its **Inventor**, shall provide to **Trinity** the following ("**Materials**"):
  - a. Five micrograms of its expression vector for Borrelia burgdorferi Vls protein (VlsE1-His); and
  - b. Ten milligrams of its purified, recombinant Borrelia burgdorferi VlsE1-His protein.

Such **Materials** shall be provided within 14 days after **University's** receipt of **Trinity's** payment indicated in Paragraph 5.1.a.

### 5. PAYMENTS AND REPORTS

- 5.1 In consideration of rights granted by **Board** to **Trinity** under this **Agreement**, **Trinity** will pay **Board** the following (all dollar amounts are in United States Dollars):
  - a. A non-refundable, non-creditable license documentation fee in the amount of seventy thousand dollars (\$70,000). Such fee shall be due and payable within fourteen (14) days after the **Effective Date**.

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- b. An annual non-creditable license management fee in the amount of two thousand five hundred dollars (\$2,500), due and payable on each anniversary of the **Effective Date** beginning on the first anniversary; and
- c. A running royalty equal to four percent (4%) of **Net Sales** of a **Licensed Product**.
- d. A non-refundable, non-creditable amount of thirty thousand dollars (\$30,000) upon:
  - (i) achieving five million dollars (\$5,000,000) of gross, aggregate income from **Sales** of all **Licensed Products** in the United States of America; and
  - (ii) achieving five million dollars (\$5,000,000) of gross, aggregate income from **Sales** of all **Licensed Products** in EPO member countries; and
  - (iii) achieving ten million dollars (\$10,000,000) of gross, aggregate income from **Sales** of all **Licensed Products** in the United States of America
  - (iv) achieving ten million dollars (\$10,000,000) of gross, aggregate income from **Sales** of all **Licensed Products** in EPO member countries

(The parties agree that each payment under Sections 5.1(d) shall only be due and paid once during the **Term** of this **Agreement**.)

- 5.2 **Trinity** shall pay **University** ten thousand dollars (\$10,000) of **University's** prior expenses incurred by for filing, prosecuting, enforcing and maintaining **Patent Rights** in the **Licensed Territory**, through the **Effective Date**. Such amount shall be due and payable within thirty (30) days after this **Agreement** is executed by **Trinity**.
- 5.3 For expenses incurred after the Effective Date and subject to Section 5.3(b):
  - a. **Trinity** shall pay twenty percent (20%) of all future expenses incurred by **University** for filing, patent office prosecution, and maintaining **Patent Rights** in the **Patent Territory** ("**Expenses**"), for so long as this **Agreement** remains in effect. Since this **Agreement** is non-exclusive, if the percent reimbursement for future **Expenses** made under all license agreements for **Patent Rights** in the **Patent Territory** exceeds one hundred percent (100%), then during the period in which such percent reimbursements exceed one hundred percent (100%), the percentage due from **Trinity** shall be decreased proportionately so that the percent reimbursement does not exceed 100%. **University** will invoice **Trinity** on a regular basis beginning with expenses incurred by **University** after the **Effective Date**. The invoiced amounts will be due and payable by **Trinity** within thirty (30) days after receipt of invoice from **University**.
  - b. If the amount owed by **Trinity** under Section 5.3(a) exceeds \$10,000 during any year of this **Agreement**, then **Trinity** may elect to carry forward the amount in excess of \$10,000 to the following year. Subject to the foregoing, any amount carried forward hereunder shall be (i) added to the legal fees due during the following year and (ii) paid with the March 31 quarterly report, up to the \$10,000 cap.

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- 5.4 During the term of this **Agreement** and for three (3) years thereafter, **Trinity** agrees to keep complete and accurate records of its and its **Affiliate's Sales** and **Net Sales** of **Licensed Products** under the license granted in this **Agreement** in sufficient detail to enable the royalties payable hereunder to be determined. **Trinity** agrees to permit **Board** or its representatives, at **Board's** expense, to periodically examine its books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report required under this **Agreement**. If the amounts due to **Board** are determined to have been underpaid by five percent (5%) or greater, **Trinity** will pay the cost of the examination and accrued interest at the prime rate, as published by the United States Federal Reserve Bank, New York, New York on the date quarterly due date for which the payment was due plus three percent (3%).
- 5.5 Within thirty (30) days after March 31, June 30, September 30, and December 31, beginning immediately after the **Effective Date**, **Trinity** shall deliver to **Board** a true and accurate written report, even if no payments are due **Board**, giving the particulars of the business conducted by **Trinity** and its **Affiliate(s)**, during the preceding three (3) calendar months under this **Agreement** as are pertinent to calculating payments hereunder. This report will include at least:
  - a. The total quantities of **Licensed Products** produced;
  - b. The total **Sales** separately listed by country;
  - c. The calculation of royalties and amounts payable thereon;
  - d. The total royalties computed and due **Board**; and,
  - e. All other amounts due **University** herein.
  - Simultaneously with the delivery of each report, **Trinity** shall pay to **Board** the amount, if any, due for the period of each report.
- 5.5 On or before each anniversary of the **Effective Date**, irrespective of having a first **Sale** or offer for **Sale**, **Trinity** shall deliver to **Board** a written report summarizing **Trinity's** efforts and accomplishments during the preceding year in diligently commercializing **Licensed Subject Matter** in the **Licensed Territory** and **Trinity's** commercialization plans for the upcoming year.
- 5.6 All amounts payable herein by **Trinity** shall be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind. When **Licensed Product** is **Sold** for monies other than United States dollars, the earned royalties first will be determined in the foreign currency in the country in which such **Licensed Products** were sold, and then converted into equivalent United States funds. The exchange rate will be that rate established by the United States Federal Reserve Bank, New York, New York on the last day of the reporting period, and will be quoted in the continental terms method of quoting exchange rates (local currency per United States dollar). All royalty payments which are not paid by **Trinity** by the thirty-first (31st) day after each quarterly payment date shall bear interest at the Prime Rate of the United States Federal Reserve Bank, New York, New York plus three percent (3%). Such interest payments shall be calculated from the quarterly due dates until the payment is received by **University**. **University** is a tax-exempt organization under the laws of the State of Texas and of the United States and shall be solely responsible for any taxes that may hereafter be levied upon the payments to **Board**. Payments shall be made by check payable to The University of Texas Health Science Center at Houston, and mailed to **University** at the address set forth in Section 14.2, or made via electronic

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funds transfer to: Bank Name: JP Morgan Chase Bank; Bank Account #: ; ABA Routing #: ; Account Name: The University of Texas Health Science Center at Houston. In the event of a wire transfer, **Trinity** shall promptly notify **University** in writing of such transfer.

5.7 No payments due or royalty rates owed under this **Agreement** will be reduced as a result of co-ownership of **Licensed Subject Matter** by **Board** and another party, including, but not limited to, **Trinity**.

#### 6. TERM AND TERMINATION

- 6.1 The term of this **Agreement** is from the **Effective Date** to the full end of the term or terms for which **Patent Rights** have not expired, unless otherwise terminated as provided herein. Notwithstanding the foregoing, if only **Technology Rights** are licensed and no **Patent Rights** are applicable, the term of this **Agreement** shall be for fifteen (15) years from the **Effective Date**, after which **Virotech** shall have a non-exclusive, royalty free license to **Technology Rights**.
- 6.2 Any time after three (3) years from the **Effective Date**, **Board** and **University** have the right to terminate this license in any national political jurisdiction in the **Licensed Territory** if **Trinity**, within ninety (90) days after receiving written notice from **University** of intended termination, fails to provide written evidence, satisfactory to **University**, that **Trinity** or an **Affiliate** has **Commercialized** or is **Actively Attempting to Commercialize** a licensed invention in such jurisdiction(s).
- 6.3 Subject to any rights that survive termination, this **Agreement** will earlier terminate in its entirety:
  - a. automatically if **Trinity** becomes bankrupt or insolvent and/or if the business of **Trinity** is placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of **Trinity** or otherwise; or
  - b. upon thirty (30) days written notice from **University** if **Trinity** breaches or defaults on its obligation to make payments (if any are due) or reports, in accordance with the terms of Article 5 hereunder, unless, before the end of the thirty (30) day period, **Trinity** has cured the default or breach and so notifies **Board**, stating the manner of the cure: or
  - c. upon sixty (60) days written notice from **University** if **Trinity** breaches or defaults on any other obligation under this **Agreement**, unless, before the end of the sixtieth (60) day period, **Trinity** has cured the default or breach and so notifies **Board**, stating the manner of the cure; or
  - d. upon sixty (60) days written notice from **Trinity** if **University** materially breaches or defaults on its other obligation under this **Agreement**, unless, before the end of the sixtieth (60) day period, **University** has cured the default or breach and so notifies **Trinity**, stating the manner of the cure; or

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- e. at any time by mutual written agreement between **Trinity**, **University** and **Board**, upon one hundred eighty (180) days written notice to all parties and subject to any terms herein which survive termination; or
- f. under the relevant provisions of Paragraphs 6.2 if invoked.
- 6.4 If **Trinity** is current in its payments under Section 5 herein, then **Trinity** may terminate this **Agreement** by providing **Board** one hundred eighty (180) days written notice. Such termination shall become effective on the one-hundred eightieth (180<sup>th</sup>) day after **Board** receives such written notice.
- 6.5 If this **Agreement** is terminated for any cause:
  - a. nothing herein will be construed to release either party of any obligation matured prior to the effective date of the termination; and
  - b. after the effective date of the termination, **Trinity** may **Sell** all **Licensed Products** and parts thereof it has on hand at the date of termination, if **Trinity** pays running royalties thereon and any other amounts according to the terms of Article 5; and
  - c. **Trinity** covenants and agrees to be bound by the provisions of Articles 10 (Indemnification), 11 (Use of **Board** and **University** Name), and 12 (Confidential Information) of this **Agreement**; and
  - d. all data, prototypes, derivatives of data, designs or **Materials**, and accompanying rights thereto, provided to **Trinity** by **Inventors**, will be returned to **University** at **Trinity**'s expense.

### 7. INFRINGEMENT

- 7.1 If **Trinity** is notified of any patent held by a third party that **Trinity** reasonably believes would be infringed by the continued **Sale** of **Licensed Products**, or by the use of **Licensed Products** by its customers, or of the possible infringement by a third party of the **Patent Rights** granted hereunder, **Trinity** agrees to promptly notify **Board** of same in writing.
- 7.2 **Trinity**, at its expense, may enforce any patent licensed hereunder against third party infringement within the **Licensed Field** and **Licensed Territory**, and shall be entitled to retain recoveries from such enforcement. If legally required to do so, **Board** and **University** agree to be named parties in any litigation instituted by **Trinity** to enforce **Patent Rights**. **Trinity** agrees to pay **Board** a royalty as set forth above on any monetary recovery (after deduction of **Trinity's** third-party, documented, unrecovered reasonable legal expenses incurred exclusively from such suit) if the monetary recovery is for damages based on sales of an infringing product or a reasonable royalty in lieu thereof. If **Trinity** does not file suit against a substantial infringer of a patent within six (6) months of knowledge thereof, then **Board** and **University**, at their sole discretion and expense, may enforce any patent licensed hereunder on behalf of themselves and **Trinity**, with **Board** retaining all recoveries from such enforcement.

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- 7.3 In any infringement suit or dispute, the parties agree to cooperate fully with each other. At the request and expense of the party bringing suit, the other party will permit access to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.
- 7.4 **Trinity** may request that **Board** join the prosecution of an infringer. If **Board** agrees, then **Trinity** and **Board** shall jointly enforce against infringement by third parties and shall be entitled to retain any recovery from such enforcement. After deducting **Trinity's** and **Board's** third-party, documented, unrecovered reasonable legal expenses incurred exclusively from such suit, any remaining recovery shall be divided equally.

#### 8. ASSIGNMENT

Except in connection with the sale of substantially all of **Trinity's** assets to a third party, this **Agreement** may not be assigned by **Trinity** without the prior written consent of **Board**, which will not be unreasonably withheld.

#### 9. PATENT MARKING AND MAINTENANCE

- 9.1 **Trinity** shall permanently and legibly mark all products and documentation manufactured or **Sold** by **Trinity** or its **Affiliates** pursuant to this **Agreement** with a patent notice as may be permitted or required under Title 35, United States Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for **Licensed Products** accordingly.
- 9.2 **Board** shall use reasonable efforts to obtain and maintain **Patent Rights** in the **Patent Territory**, including payment of maintenance fees and, where appropriate, preparing, filing, and prosecuting patent applications.

### 10. INDEMNIFICATION

**Trinity** agrees to hold harmless and indemnify **Board**, **System**, **University**, its Regents, officers, employees and agents from and against any claims, demands, or causes of action whatsoever, or costs of suit or reasonable attorney's fees, including without limitation those costs arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the license granted hereunder by **Trinity**, its officers, **Affiliates** or their officers, employees, agents or representatives.

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#### 11. USE OF BOARD AND UNIVERSITY NAME

Trinity may not use the name of University, System, or Board without express written consent.

#### 12. CONFIDENTIAL INFORMATION AND PUBLICATION

- 12.1 **Board** and **Trinity** each agree that all information contained in documents marked "confidential" and forwarded to one by the other (i) are to be received in strict confidence, (ii) used only for the purposes of this **Agreement**, and (iii) not disclosed by the recipient party, its agents or employees without the prior written consent of the other party, except to the extent that the recipient party can establish competent written proof that such information:
  - a. was in the public domain at the time of disclosure;
  - b. later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns;
  - c. was lawfully disclosed to the recipient party by a third party having the right to disclose it;
  - d. was already known by the recipient party at the time of disclosure;
  - e. was independently developed by the recipient, as evidenced by written documentation; or
  - f. is required by law or regulation to be disclosed.
- 12.2 Each party's obligation of confidence hereunder shall be fulfilled by using at least the same degree of care with the other party's confidential information as it uses to protect its own confidential information. This obligation shall exist while this **Agreement** is in force and for a period of three (3) years thereafter.

### 13. PATENTS AND INVENTIONS

- 13.1 If after consultation with **Trinity**, both parties agree that a patent application should be filed for **Licensed Subject Matter**, **Board** will prepare and file the appropriate patent applications, and **Trinity** will pay the cost, according to Section 5.1(g) above, of searching, preparing, filing, prosecuting and maintaining same. If **Trinity** notifies **Board** that it does not intend to pay the costs of an application, or if **Trinity** does not respond or make an effort to agree with **Board** on the disposition of rights in the subject invention, then **Board** may file an application at its own expense and **Trinity** will have no rights to such invention.
- 13.2 **Board** will provide **Trinity** a copy of any patent application for which **Trinity** has paid the costs, according to Section 5.1(g) above, of searching, preparing and filing, as well as copies of any documents received or filed with the respective patent office during the prosecution thereof ("**Notice**"). Should **Trinity** decline to support a particular patent application in a particular country, **Trinity** shall so notify the **University** in writing within thirty (30) days after receiving **Notice** and **Trinity** shall thereafter have no further rights hereunder in that particular patent application in that particular country.

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#### 14. ALTERNATE DISPUTE RESOLUTION

Any dispute or controversy arising out of or relating to this **Agreement**, its construction or its actual or alleged breach may be decided by mediation. If the mediation does not result in a resolution of such dispute or controversy, it may be decided by an appropriate method of alternate dispute resolution, including without limitation, arbitration, conducted in the city of Houston, Texas in accordance with the Licensing Agreement Arbitration Rules of the American Arbitration Association. The arbitration panel will include members knowledgeable in the evaluation of protein and antibody-based technologies. Judgment upon the award rendered may be entered in the highest court or forum having jurisdiction, state or federal. The provisions of this Article 14 will not apply to decisions on the validity of patent claims or to any dispute or controversy as to which any treaty or law prohibits such arbitration. The decision of the arbitration must be sanctioned by a court of law having jurisdiction to be binding upon and enforceable by the parties. The use of any method of alternative dispute resolution will not be construed by either party in a manner that would adversely affect the other party's rights in court. Nothing in this section will prevent one party from resorting to judicial proceedings if good faith efforts to resolve a dispute have been unsuccessful or if injunctive relief is necessary to prevent serious and irreparable harm to one party or third parties.

### 15. GENERAL

- 15.1 This **Agreement** constitutes the entire and only agreement between the parties for **Licensed Subject Matter** and all other prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by a written document signed by both parties.
- 15.2 Any notice required by this **Agreement** shall be given by prepaid, first class, certified mail, return receipt requested, addressed to:

The University of Texas Health Science Center at Houston Office of Technology Management 7000 Fannin Street, Suite 720 Houston, Texas 77030 FAX: 713.500.0331 PHONE: 713.500.3369

Patent License Agreement between the Board of Regents of The University of Texas System and Trinity Biotech, Inc.

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## with copy to:

Board of Regents The University of Texas System 201 West 7th Street Austin, Texas 78701 ATTENTION: Office of General Counsel FAX: 512.499.4523

### or in the case of **Trinity** to:

Trinity Biotech, Inc. 1930 Business Center Drive St. Louis , Missouri 63114 USA ATTENTION: FAX: PHONE:

or other addresses as may be given from time to time under the terms of this notice provision.

- 15.3 **Trinity** shall comply with all applicable federal, state, and local laws and regulations in connection with its activities pursuant to this **Agreement**.
- 15.4 This **Agreement** will be construed and enforced in accordance with the laws of the United States of America and of the State of Texas.
- 15.5 Failure of **Board** to enforce a right under this **Agreement** will not act as a waiver of that right or the ability to later assert that right relative to the particular situation involved.
- 15.6 Headings are included herein for convenience only and shall not be used to construe this **Agreement**.
- 15.7 If any part of this **Agreement** is for any reason found to be unenforceable, all other parts nevertheless remain enforceable.

# (Remainder of Page Intentionally Blank)

Patent License Agreement between the Board of Regents of The University of Texas System and Trinity Biotech, Inc.

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IN WITNESS WHEREOF, parties hereto have caused their duly authorized representatives to execute this Agreement.

# Board of Regents of The University of Texas System

By: /s/ Kevin Dillon T. Kevin Dillon Executive Vice President for Finance and Business Affairs The University of Texas Health Science Center at Houston

Date: 4/12/05

Trinity Biotech, Inc.

By: /s/ Jim Walsh (Typed Name) (Typed Title)

Date: 4/18/05

Approved as to Content:

By: /s/ Bruce D. Butler Bruce D. Butler, Ph.D. Assistant Vice President for Research and Technology Date: 4/12/05

Read and Understood:

By: /s/ Steven Norris Steven J. Norris, Ph.D. Inventor

Date: 4/12/05

Patent License Agreement between the Board of Regents of The University of Texas System and Trinity Biotech, Inc.

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# Exhibit A

| Patent Title  | UTHSC-H<br>File Number | Type of Application  | Filing Date   | Serial Number   | Issue Date / Number          |
|---|------------------------|--|---------------|---|------------------------------|
| VMP Like Sequences of Pathogenic Borrelia                           | 1996-0001              | US Provisional   | Feb 21, 1996  | 60/012,028  | N.A.                         |
|   | 1996-0001              | U.S. Nationalization of<br>PCT Patent Application<br>Number<br>PCT/US97/02952              |               | 09/125,619  | Aug 20, 2002<br>6,437,116    |
|   | 1996-0001              | Continuation of U.S.<br>Patent Number<br>6,437,116   | May 10, 2002  | 10/143,024  | May 25, 2004<br>6,740,744    |
|   | 1996-0001              | Continuation of U.S.<br>Patent Number<br>6,437,116   | Aug 16, 2002  | 10/222,566  | April 13, 2004<br>6,719,983  |
|   | 1996-0001              | Continuation of U.S.<br>Patent Number<br>6,437,116   | May 24, 2004  | 10/852,555  | Notice of allowance received |
| VMP Like Sequences of<br>Pathogenic Borrelia                        | 1996-0001              | PCT Conversion of US<br>Provisional Application<br>Number 60/012,028                       | Feb 21, 1997  | PCT/US97/02952  | N.A.                         |
|   | 1996-0001              | EPO Nationalization of<br>PCT Conversion of<br>PCT Application<br>Number<br>PCT/US97/02952 | Oct 26, 1998  | 97,914,794.9<br>EPO Publication<br>Number: EP894143<br>Publication Date:<br>Aug. 8, 1997          | Pending                      |
| VMP-Like sequences of<br>Pathogenic Borrelia Species<br>and Strains | 2003-0002              | US Provisional   | Dec 20, 2002  | 60/435,077  | N.A.                         |
|   | 2003-0002              | PCT Conversion of US<br>Provisional Application<br>Number 60/435,077                       | Dec. 22, 2003 | PCT/US03/47782<br>PCT Publication<br>Number:<br>WO04/058181<br>Publication Date:<br>July 15, 2004 | Pending                      |

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#### PATENT LICENSE AGREEMENT

This PATENT LICENSE AGREEMENT (the "Agreement") is entered into as of August 3, 2006, by and between Inverness Medical Innovations, Inc., a corporation organized and existing under the laws of Delaware (hereinafter called "Inverness"), and Trinity Biotech PLC, a corporation organized and existing under the laws of the Republic of Ireland (hereinafter called "Trinity").

Inverness and one of its affiliates and Trinity are parties to a Settlement Agreement and Mutual Release dated as of the date set forth above (the "Settlement Agreement") pursuant to which certain litigation was settled and, among other conditions, the parties agreed that Inverness would license or sub-license to Trinity certain patents. Trinity desires to acquire a limited, nonexclusive license under those patents on the terms set forth herein. In consideration of the promises and mutual covenants herein contained and contained in the Settlement Agreement, Inverness and Trinity agree as follows:

## Section 1. Definitions.

"Affiliate" shall mean shall mean any entity that controls, is controlled by, or is under common control with a party hereto. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of a majority of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of a majority of the equity interest with the power to direct the management and policies of such non-corporate entities.

"Charlton Field" shall mean sale through any channels for use by licensed professional health-care providers (including hospitals, physicians acting as such and licensed professional health-care centers).

"Charlton Patents" shall mean the following, to the extent Controlled by Inverness or its Affiliates: (i) U.S. Patent Nos. 5,714,389, 5,989,921, and 6,485,982; (ii) U.S. Patent Application No. 11/035,047; (iii) any continuations or divisionals of such patents and patent applications, whether such continuations or divisionals are filed before or after the Effective Date; and (iv) any foreign counterparts of the patents and patent applications described in sub-paragraphs (i)-(iii) above.

"Control" shall mean the ability of a party to grant a license or sublicense under any Patent Rights without violating the terms of any agreement or other arrangement with any Third Party.

"Current Patents" shall mean the following, to the extent owned or Controlled by Inverness or its Affiliates: (i) U.S. Patent Nos. 6,352,862; 6,534,320; 5,622,871; 5,656,503; 6,187,598; 4,956,302; 6,627,459; and 5,120,643; (ii) U.S. Patent Application Nos. 09/780,351; 10/990,946; 09/944,389; 10/328,402; 10/456,771, and 10/328,403; (iii) any continuations or divisionals of such patents and patent applications, whether such continuations or divisionals are filed before or after the Effective Date; and (iv) any foreign counterparts of the patents and patent applications described in sub-paragraphs (i)-(iii) above.

"Effective Date" shall mean the date on which this Agreement is executed by the party which lasts executes this Agreement.

"Existing Products" shall mean the Trinity products listed on Exhibit B, provided such products are manufactured by Trinity or any Trinity Subsidiary.

"Future Patents" shall mean: (a) any continuation-in-part of the Current Patents, and any foreign counterparts of any such continuation-in-part; (b) any continuation-in-part of the Charlton Patents and any foreign counterparts of such continuation-in-part, provided that the inclusion of this sub-paragraph (b) in this definition of Future Patents shall not be construed to grant any license to Charlton Patents outside the Charlton Field; and (c) any other Patent Rights in respect of which Inverness acquires ownership or Control after the Effective Date and that would be infringed by Trinity's (including Trinity Subsidiaries) making, using, offering for sale, importing or selling Licensed Products.

"Future Product" means any diagnostic product that is first commercially sold after the Effective Date:

- (a) the manufacture, use, sale or importation of which would, but for the licenses granted herein, infringe at least one claim of the Current Patents or Charlton Patents; and
  - (b) that is manufactured by Trinity or any Trinity Subsidiary; and
- (c) that is "Developed or Substantially Developed" by Trinity or any Trinity Subsidiary, where "Developed or Substantially Developed" means that all or substantially all of the technical product development man/hours required to take the product from conception to market were spent by employees or individuals engaged as contractors by Trinity or a Trinity Subsidiary;

but excluding the following:

- (d) any diagnostic products for women's healthcare applications, including without limitation pregnancy hormone (hCG) and ovulation (LH);
- (e) any cardiac tests, cardiovascular risk assessment tests or diagnostic product designed to test for cardiovascular disease other than D-dimer test products;
- (f) any product acquired by Trinity or any Trinity Subsidiary after the Effective Date (and the parties agree, without limitation of the foregoing, that where a product had been sold to an arms-length purchaser in the United States of America or a member country of the European Union on or before being acquired by Trinity or such Trinity Subsidiary, such product has been acquired, and not Developed or Substantially Developed by Trinity); and
- (g) any product Developed or Substantially Developed before the Effective Date by a Third Party that is acquired by Trinity or a Trinity Subsidiary, or that otherwise becomes a Trinity Subsidiary, after the Effective Date.

For the avoidance of doubt, the parties agree that the exclusion set forth in sub-paragraph (f) of this definition of Future Product is not intended to limit the scope of sub-paragraph (c), but rather provides an example of a product that was not "Developed or Substantially Developed" by Trinity or a Trinity Subsidiary.

"HIV Products" shall mean Licensed Products used to test for the presence of HIV.

"Kang Patents" shall mean U.S. Patent Nos. 6,737,277, 6,541,277, 6,506,612, 6,027,943, 5,728,587, 5,559,041, and 5,252,496, any continuations, continuations-in-part or divisionals of the foregoing patents, and any foreign equivalents of any of the foregoing.

"LDC Countries" shall mean those countries set forth on Exhibit A attached hereto.

"<u>Licensed Product</u>" shall mean (a) Existing Products; and (b) Future Products, but, with respect to Future Patents, only to the extent set forth in Section 2.3.

"Net Sales" shall mean the amount invoiced by Trinity or Trinity Subsidiaries on sales of the Licensed Products less:

(a) customary trade, quantity or cash discounts actually allowed and taken; (b) amounts repaid or credited by reason of rejection or return of the Licensed Products and amounts paid by reason of late delivery of Licensed Products; (c) commissions paid to brokers or government imposed rebates; and (d) to the extent separately stated on purchase orders, invoices or other documents of sale, taxes levied and/or other governmental charges made as to production, sale, transportation, delivery or use of the Licensed Products. Notwithstanding the foregoing definition, if Licensed Products are transferred for less than fair market value (for example as part of a "bundle" of products or as a "loss leader"), Net Sales attributable to such Licensed Products shall be no less than their fair market value, which shall be calculated based on the sales price of comparable Licensed Products sold separately in the same market.

"Non-Retail Field" shall mean products sold through any distribution channels other than the Retail Field.

"Patent Rights" shall mean (a) any patents, pending patent applications, any patents issuing therefrom worldwide, and all provisional rights with respect to patent applications, (b) any substitutions, divisionals, patents of addition, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, term extensions (under applicable patent law or regulation or other law or regulation), and certificates of invention of any patents or patent applications described in clause (a); and (c) all rights in any of the foregoing.

"Retail Field" shall mean products sold to consumers through retail distribution channels for use by a consumer without the supervision of any health care professional.

"Third Party" shall mean any person or entity other than Trinity and Trinity Subsidiaries, or Inverness and Inverness Affiliates.

"Third Party Mark" shall mean any trademark, trade name or trade dress, all right, title and interest (including all goodwill) in which is wholly owned by any Third Party.

"Trinity HIV Product" shall mean the FDA approved Trinity Unigold Lateral Flow HIV Test.

"Trinity Mark" shall mean any trademark, trade name or trade dress, all right, title and interest (including all goodwill) in which is wholly owned by Trinity or any Trinity Subsidiary.

"Trinity Subsidiary" shall mean a corporation, company or other entity: (a) more than fifty percent (50%) of whose outstanding shares or securities (representing the right to vote for the election of directors or other managing authority) are owned or controlled, directly or indirectly, by Trinity, or a corporation, company or other entity that is subsequently formed by Trinity during the term of the Agreement, which corporation, company or other entity does not include assets from a Third Party, but such corporation, company or other entity shall be deemed to be a Trinity Subsidiary only so long as such ownership or control exists; or (b) which does not have outstanding shares or securities, as may be the case in a partnership, joint venture or unincorporated association, but more than fifty percent (50%) of whose ownership interest representing the right to make the decisions for such corporation, company or other entity is owned or controlled, directly or indirectly, by Trinity, or a corporation, company or other entity that is subsequently formed by Trinity during the term of the Agreement, but such corporation, company or other entity shall be deemed to be a Trinity Subsidiary only so long as such ownership or control exists.

# Section 2. Lateral Flow Licenses.

- 2.1 <u>License to Lateral Flow Patents</u>. Subject to the terms and conditions of this Agreement, Inverness grants to Trinity (including Trinity Subsidiaries) a non-exclusive, non-transferable (except as set forth in Section 11 below), non-sublicensable, worldwide, royalty-bearing license, under the Current Patents and Future Patents to make, use, offer for sale, import and sell: (a) Licensed Products sold by Trinity under a Trinity Mark (and no Third Party Mark) in the Non-Retail Field; (b) HIV Products sold by Trinity under a Trinity Mark (and no Third Party Mark) in the Retail or Non-Retail Field; and (c) HIV Products sold by Trinity to any Third Party for re-sale in the Retail or Non-Retail Field by such Third Party under a Third Party Mark owned by such Third Party ("Re-Branded HIV Products").
- 2.2 <u>License to Charlton Patents</u>. Subject to the terms and conditions of this Agreement, Inverness grants to Trinity (including Trinity Subsidiaries) a non-exclusive, non-transferable (except as set forth in Section 11 below), non-sublicensable, worldwide, royalty-bearing license, under the Charlton Patents to make, use, offer for sale, import and sell: (a) Licensed Products sold by Trinity under a Trinity Mark (and no Third Party Mark) in the Charlton Field; (b) HIV Products sold by Trinity under a Trinity Mark (and no Third Party Mark) in the Charlton Field; and (c) HIV Products sold by Trinity to any Third Party for re-sale by such Third Party as Re-Branded HIV Products in the Charlton Field.
- 2.3 <u>Limitations on Licenses as to Future Patents</u>. The licenses granted in Sections 2.1 and 2.2 grant licenses to Future Patents: (a) for Existing Products; and (b) for Future Products, but only with respect to claims in the Future Patents that are infringed by the making, using, selling or importing of any Existing Product. Otherwise, Inverness grants no right or license to any Future Patents under this Agreement, including without limitation any license to any Future Patent except as described in the foregoing sentence.

- 2.4 Have Made Restrictions and Exception. The licenses granted in Sections 2.1 and 2.2 shall not permit Trinity to have Licensed Products made by any Third Party, with the following exceptions: (a) at any time during the Term with respect to HIV Products sold by Trinity for final sale in any country that is a member of the Economic Community of West African States as at the Effective Date, Trinity may have any part of the manufacturing process from the uncut nitrocellulose sheet stage onwards conducted by a contract manufacturer located in Nigeria; and (b) after the third anniversary of the Effective Date, Trinity may subcontract the manufacture of any HIV Products to any contract manufacturer. Trinity shall execute a written sublicense with any contract manufacturer which shall be subject to Trinity's rights and obligations under the terms of this Agreement, and shall provide a copy of the sublicense agreement to Inverness within 30 days' after execution. Trinity shall ensure that any such sublicense agreement contains terms that are at least as protective of the Current Patents, Charlton Patents and Future Patents as the terms set forth herein, and contains no terms that would be in violation of the license grant set forth in this Agreement, and, with respect to such sublicense agreement, shall cause any contract manufacturer to assume and perform all of the covenants and obligations of Trinity to Inverness contained in this Agreement, to the extent applicable to such contract manufacturer's exercise of its sublicense rights. Upon termination of this Agreement as provided herein, any sublicense agreement shall thereupon automatically terminate, and Trinity shall cause any sublicense agreements to provide for such termination. Except as set forth above or in Section 11, Trinity shall otherwise have no right to sublicense, transfer or assign any right or license granted by Section 2.1 or 2.2, and any purported sublicense, transfer or assignment shall be void.
- 2.5 <u>Use of Distributors</u>. The restrictions in Section 2.1, 2.2 and 2.4 on transfer and sub-licensing of license rights shall not prohibit Trinity or Trinity Subsidiaries from distributing Licensed Products under a Trinity Mark through any distributor that is granted only the right to offer for sale and sell Licensed Products under such Trinity Mark where such products and their packaging are not modified by the distributor from the form in which the products and packaging are shipped by Trinity or the Trinity Subsidiary, nor shall such restrictions prevent third parties that purchase HIV Products from Trinity (including Trinity Subsidiaries) for re-sale as Re- Branded HIV Products from selling such Re-Branded HIV Products under the same packaging and Third Party Mark (any such distributor a "Distributor"). Inverness acknowledges that Distributors include distributors that sell Licensed Products on commission as well as distributors that purchase Licensed Products from Trinity (including Trinity Subsidiaries) for resale for the distributor's own account.
- 2.6 Section 365(n). The licenses granted under this Section 2 shall be treated as licenses of rights to "intellectual property" (as defined in Section 101(56) of Title 11 of the United States Code, as amended (the "Bankruptcy Code")) for purposes of Section 365 (n) of the Bankruptcy Code. The parties agree that Trinity may elect to retain and may fully exercise all of its rights and elections under the Bankruptcy Code provided that it abides by the terms of this Agreement.

- 2.7 <u>Marking</u>. To the extent commercially feasible and consistent with prevailing business practices, Trinity and Trinity Subsidiaries shall mark all Licensed Products in accordance with applicable patent-marking laws of the jurisdiction in which such Licensed Products are manufactured, used or sold.
- 2.8 Kang Patents. Trinity acknowledges that this Agreement does not and shall not grant any right or license to the Kang Patents.
- 2.9 <u>Reservation of Rights</u>. Except as expressly set forth herein, this Agreement does not grant to Trinity or Trinity Subsidiaries any right, title, interest, ownership or license, by implication, estoppel or otherwise, to any Patent Rights owned or Controlled by Inverness. Inverness retains the unqualified right to exploit the Current Patents, Charlton Patents and any Future Patents, and to develop, make, have made, use, sell, have sold, lease, or import Licensed Products.

## Section 3. Not Used.

# Section 4. Royalties and Payment.

- 4.1 <u>Royalties Payable</u>. Trinity (and/or Trinity Subsidiaries) shall pay royalties to Inverness in respect of Net Sales invoiced after the Effective Date as follows:
- (i) With respect to Net Sales in LDC Countries, 1% of Net Sales invoiced on or before December 31, 2008, and 2% of Net Sales invoiced thereafter;
- (ii) With respect to Net Sales of HIV Products in the Retail Field worldwide but excluding LDC Countries, \$2.00 per unit of Licensed Product (with each unit being a single diagnostic test) or 10% of Net Sales for such unit, whichever is greater; and
- (iii) With respect to all other Net Sales, 5% of Net Sales invoiced on or before December 31, 2008, and 8.5% of Net Sales invoiced thereafter.
- 4.2 <u>Royalty Increase on Change of Control</u>. In the event of any Change of Control (as defined in Section 11), the royalties payable pursuant to Section 4.1(iii) above shall increase to 10% of Net Sales, whether such Net Sales are invoiced before or after December 31, 2008.
- 4.3 <u>Royalty Conditions</u>. The above royalties shall be payable on a Licensed Product-by-Licensed Product basis. The royalty term for each Licensed Product shall continue until the date when the last to expire of the Current Patents, Charlton Patents or Future Patents (if any) covering such Licensed Product expires. In the event that more than one Current Patent, Charlton Patent or Future Patent (if any) is applicable to any Licensed Product subject to royalties under this Section 4, then only one royalty shall be paid to Inverness in respect of such Licensed Product. Furthermore, in no event shall more than one royalty be due hereunder with respect to any Licensed Product.
- 4.4 <u>Interest</u>. Trinity (and/or Trinity Subsidiaries) shall be liable for interest on any overdue royalty payment commencing on the date such royalty payment becomes due, at an annual rate which is the greater of eight percent (8%) and one percentage point higher than the

prime interest rate as quoted by the head office of Citibank, N.A., New York, at the close of banking on such date, or on the first business day thereafter if such date falls on a non-business day. If such interest rate exceeds the maximum legal rate in the jurisdiction where a claim therefor is being asserted, the interest rate shall be reduced to such maximum legal rate.

4.5 <u>Underpayments</u>. In the event an audit under the provisions of Section 5.6 identifies an underpayment of royalties by Trinity, Trinity shall pay an amount equal to such underpayment within sixty days of Inverness's written request following such audit. Such amounts shall be subject to interest under the provisions of Section 4.4.

# Section 5. Royalty Accruals, Records, Reports and Other Information.

- 5.1 <u>Royalty Accrual</u>. Royalties shall accrue when a Licensed Product is first sold or otherwise transferred for value by Trinity or a Trinity Subsidiary to a Third Party (including, except as otherwise agreed in writing by Inverness, sold or otherwise transferred to Inverness or any Inverness Affiliate).
- 5.2 <u>Currency Conversion</u>. Trinity shall pay all royalties and other payments due hereunder in United States dollars. All royalties for an accounting period in respect of Net Sales billed and received in other currencies shall be converted into United States dollars at the exchange rate for bank transfers from such currency to United States dollars as quoted by the head office of Citibank, N.A., New York, at the close of banking on the last day of such accounting period (or the first business day thereafter if such last day shall be a non-business day).
- 5.3 Quarterly Report and Payment. Within thirty (30) days after the end of each calendar quarter during the Term, Trinity shall furnish to Inverness a written report containing the information specified in Section 5.4 and shall pay to Inverness all royalties accrued hereunder for such calendar quarter.
- 5.4 Content of Reports. Trinity's written reports shall be certified by an officer of Trinity and shall contain for each type of Licensed Product upon which a royalty has accrued (i) a description of said Licensed Product, (ii) the quantity of such Licensed Product sold or otherwise transferred during the accounting period, (iii) the price at which the Licensed Product was sold, (iv) the region (LDC Country or other than LDC Country) in which it was sold, (v) Net Sales attributable to each of the Licensed Products during such accounting period and (vi) the calculation of royalties and the total royalties due Inverness. In the event no royalties are due, Trinity's report shall so state.
- 5.5 <u>Verification of Licensed Products</u>. For the purpose of determining whether products offered for sale or otherwise marketed by Trinity (including Trinity Subsidiaries) and not identified by Trinity as Licensed Products in the reports delivered pursuant to Section 5.4 should be considered Licensed Products, Trinity shall, within thirty (30) days of a written request by Inverness for confirmation that any such product is not a Licensed Product (such request to include the basis on which Inverness believes the product is a Licensed Product), provide to an independent outside patent attorney selected by Inverness and reasonably acceptable to Trinity, which patent attorney shall at Trinity's request enter into a confidentiality agreement reasonably

acceptable to Trinity as a condition precedent to receiving such materials containing terms consistent with the provisions of Section 9, evidence that the product does not in fact infringe any Current Patent, Charlton Patent or any Future Patent. Such patent attorney shall only disclose his/her conclusions regarding whether the products that are the subject of Inverness's request should be characterized as Licensed Products, including the basis for such conclusion, but shall not disclose the materials provided by Trinity without Trinity's prior written consent, except to the extent that the disclosure is necessary to provide the basis for the conclusion regarding infringement. Such patent attorney shall simultaneously provide Trinity and Inverness with a copy of any such conclusions.

- 5.6 <u>Records and Audit</u>. Trinity (including Trinity Subsidiaries) shall establish and maintain complete and accurate records in sufficient detail to permit the determination of Licensed Products subject to this Agreement, the royalties due Inverness, and the accuracy of the information in Trinity's written reports.
- (a) Such records shall include, but not be limited to, detailed records supporting the information provided under Section 5.4 which, if applicable, shall be kept in accordance with generally accepted accounting principles ("GAAP").
  - (b) Such records shall be kept for two years following the reporting period to which they pertain.
- (c) Upon Inverness's written request for an audit, Trinity will permit an independent certified public accounting firm of recognized standing, selected by Inverness and reasonably acceptable to Trinity, together with a limited number of such independent legal and technical support personnel as Inverness deems necessary which personnel are reasonably acceptable to Trinity, to examine, during ordinary business hours, records, materials, and manufacturing processes of Trinity for the purpose of verifying the accuracy of the royalty reports and payments by Trinity. The audit shall be limited to pertinent books and records for any calendar year ending not more than twenty-four (24) months prior to the date of such request. Such audit right shall not be exercised more than once in any calendar year. The accounting firm and legal and technical firm employees shall sign confidentiality agreements reasonably acceptable to Trinity as a condition precedent to their audit, which shall contain terms consistent with the provisions of Section 9. Trinity may designate competitively sensitive information which such auditor may not disclose to Inverness; provided, however, that such designation shall not encompass the auditor's conclusions. The accounting firm shall disclose to Inverness only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies.
- (d) Such requested audit shall be restricted to an audit of those records, materials, and manufacturing processes reasonably related to Licensed Products, Current Patents, Charlton Patents and Future Patents (if any). Accordingly, such records and materials shall include the records specified in this Section 5.6 and other general financial information to the extent necessary to provide a cross-check for the amount of royalties reported. Such financial information shall include, but not be limited to, records on the total revenue derived from Licensed Products for the accounting period with documentation supporting the non-payment of royalty on that portion of the total revenue which Trinity claims should not be included in Net Sales, records of sales of products that were bundled with Licensed Products, and records pertaining to Licensed Products that were transferred for below fair market value.

- (e) Trinity shall provide its full cooperation in such audit.
- (f) Inverness shall pay the cost of such audit. However, in the event that the audit reveals underpayment of five percent (5%) or more of the royalties which should have been paid for the accounting periods being audited, then Trinity shall pay for the cost of such audit.

### Section 6. Option To Distribute.

- 6.1 Grant of Option. Trinity hereby grants Inverness the option to serve as the exclusive distributor of the Trinity HIV Product in the Retail Field in the United States, subject to the parties' negotiation of a mutually acceptable distribution agreement (the "Option"). Inverness shall exercise the Option by delivering to Trinity written notice of its intention to exercise the Option during the period beginning on the Effective Date and ending on the six-month anniversary of the Effective Date (the "Option Period"), after which such Option shall expire. In the event that Inverness exercises the Option within the Option Period, Trinity shall use its best efforts to negotiate in good faith with Inverness the terms of a mutually acceptable distribution agreement. Trinity shall negotiate with Inverness for not less than three (3) months after exercise of the Option (unless the parties conclude an agreement within that period). During the Option Period and such negotiation period, Trinity shall not appoint any Third Party to distribute the Trinity HIV Product in the United States. If the parties are unable to reach mutually agreeable terms within the three month period, the parties hereby agree to submit the matter to a third party mediator, and to work with such mediator in good faith to arrive at a resolution for a period of up to 30 days from appointment of the mediator.
- 6.2 <u>Inverness Credit</u>. If Inverness exercises the Option and the parties enter into an agreement within 9 months after the Effective Date pursuant to which (a) Trinity appoints Inverness as the exclusive distributor of the Trinity HIV Product in the Retail Field in the United States (that is, neither Trinity nor any Trinity Subsidiary nor any Third Party may distribute the Trinity HIV Product in the Retail Field in the United States); and (b) Inverness agrees not to distribute or sell any other HIV diagnostic tests in the Retail Field in the United States during the term of such agreement, then Trinity agrees that Inverness may withhold and retain 20% of the amounts otherwise due to Trinity in each payment period under such distribution agreement, until Inverness has withheld and retained a total of \$1 million in such payments.

# Section 7. Term of Agreement; Termination.

- 7.1 <u>Term</u>. The term of this Agreement shall be from the Effective Date hereof until the last to expire of the Current Patents, Charlton Patents or Future Patents, unless it is sooner terminated in accordance with this Section 7 (the "Term").
- 7.2 <u>Termination for Trinity Convenience</u>. Trinity may terminate this Agreement at any time on written notice to Inverness. Such termination shall be effective on the date such notice is mailed.

- 7.3 <u>Termination for Breach</u>. If either party shall breach any material provision of this Agreement, and such failure has not been cured within sixty (60) days after written notice from the non-breaching party specifying the nature of such failure, the non-breaching party shall have the right to terminate this Agreement on written notice to the breaching party.
- 7.4 <u>Termination on Insolvency</u>. If any party enters any involuntary bankruptcy, insolvency, receivership, dissolution, or similar proceeding which continues for thirty (30) days from filing, or any voluntary bankruptcy, insolvency, receivership, dissolution, liquidation, or similar proceeding, or otherwise fails to be able to pay its debts as and when they fall due, the other party may terminate this Agreement on written notice to such party.
- 7.5 <u>Termination for Patent Challenge</u>. If Trinity or any Trinity Subsidiary shall challenge the validity of any of the Current Patents, Charlton Patents or Future Patents before any court or governmental agency, then this Agreement and the licenses granted herein shall terminate immediately without notice.
- 7.6 Effect of Termination. No termination of this Agreement shall relieve either party of any obligation or liability accrued hereunder prior to such termination (including unpaid royalties), or rescind or give rise to any right to rescind anything done by Trinity or any payments made or other consideration given to Inverness hereunder prior to the time such termination becomes effective, and such termination shall not affect in any manner any rights of either party arising under this Agreement prior to such termination. The provisions of Sections 5 (with respect to sales made through the effective date of termination), 7.6, 8, 9, 10, 11 and 12.3-12.8 shall survive any termination or expiration of this Agreement in accordance with their respective terms.

#### Section 8. Warranty, Disclaimers, Indemnification, Insurance and Limitation of Liability.

- 8.1 Mutual Representations and Warranties: Each Party represents and warrants that:
  - (a) it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
  - (b) this Agreement constitutes a valid and binding agreement, enforceable against it in accordance with its terms; and
- (c) the execution, delivery and performance of this Agreement does not violate any law, statute, ordinance, rule or regulation, or any judgment, injunction, order, writ or decree of any court, arbitrator, or governmental entity by which such Party or any of its assets or properties may be bound, and does not conflict with or result in the breach or termination of any license, permit, approval, consent, franchise, lease, contract, or other instrument or agreement by which such party is bound.

- 8.2 <u>Inverness Warranty</u>. Inverness represents and warrants that:
- (a) it has the full right and power to grant the licenses set forth in Section 2 and Section 3, and that there are no outstanding agreements, assignments, or encumbrances inconsistent with the provisions of such licenses or with any other provisions of this Agreement;
- (b) as at the Effective Date, the Current Patents and Charlton Patents include all Patent Rights owned or Controlled by Inverness or Inverness Affiliates that are used in, useful or necessary for the manufacture, use, sale or importation of Licensed Products, and Inverness and Inverness Affiliates have not taken any action to exclude from the Current Patents or Charlton Patents any such Patent Rights; and
- (c) to the best of the Inverness's knowledge, all Patent Rights licensed hereunder are valid and enforceable, and all patents, if any, issuing on any of the pending patent applications of the Patent Rights will be valid and enforceable.
- 8.3 <u>Disclaimer</u>. Inverness does not represent or warrant that the Current Patents or Charlton Patents are applicable to any particular Licensed Product. Inverness also makes no other representations or warranties, express or implied, and hereby disclaims the implied warranties of merchantability, fitness for a particular purpose or non-infringement of third party rights. Inverness disclaims and Trinity assumes any liability in respect of any infringement of patents or other rights of Third Parties due to Trinity's operation under the license herein granted. Without limiting the disclaimer, Inverness specifically disclaims any representation, warranty or implication that the licenses granted hereby are sufficient for Trinity to make, use, lease, import, sell and otherwise transfer Licensed Products.
- 8.4 Indemnification. Trinity shall indemnify, defend, and hold harmless Inverness and its Affiliates and their directors, officers, employees and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon any of the Indemnitees by any Third Party in connection with any claims, suits, actions, demands or judgments arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning any product, process, or service that is made, used, or sold pursuant to the exercise by Trinity (including Trinity Subsidiaries) of any right or license granted under this Agreement. To receive the benefit of indemnification the Indemnitees must (i) provide Trinity with prompt written notice within twenty (20) days of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement; (ii) cooperate fully with Trinity in such defense; and (iii) permit Trinity to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal, and settlement). Trinity agrees, at its own expense, to provide attorneys reasonably acceptable to Inverness to defend against any such claim. In the event that Inverness has rejected Trinity's choices of counsel three (3) consecutive times, then Trinity, in its sole decision, shall select counsel acceptable to Trinity. Notwithstanding the provision of Section 8.4(iii), any Indemnitee shall have the right to retain its own counsel, at the expense of Trinity, if representation of such Indemnitee by the counsel retained by Trinity would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel. Trinity agrees to keep Inverness informed of the progress in the defense and disposition of such claim and to consult with Inverness with regard to any proposed settlement. Trinity shall

have no obligation to indemnify any Indemnitee in connection with any settlement made without Trinity's written consent. The foregoing indemnification obligations shall not apply to the extent that a court of competent jurisdiction determines that applicable losses arose as a result of any Indemnitee's negligence or intentional misconduct.

8.5 <u>Insurance</u>. Trinity shall maintain insurance or self-insurance that is reasonably adequate to fulfill any potential obligation to the Indemnitees, but in any event not less than one million dollars (\$1,000,000) for injuries to any one person arising out of a single occurrence and two million dollars (\$2,000,000) for injuries to all persons arising out of a single occurrence. Trinity shall provide Inverness, upon request, with written evidence of such insurance or self-insurance. Trinity shall continue to maintain such insurance or self-insurance after the expiration or termination of this Agreement during any period in which Trinity continues to make, use, or sell a product that was a Licensed Product under this Agreement, and thereafter for a period of five (5) years.

8.6 <u>Limitation of Liability</u>. EXCEPT FOR BREACHES OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER AND FOR VIOLATIONS OF ANOTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND FOR DAMAGES CAUSED BY A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, WHETHER OR NOT THE PARTY ALLEGEDLY CAUSING THE DAMAGE HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THIS SECTION 8.6 SHALL NOT BE CONSTRUED TO LIMIT TRINITY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 8.4 HEREOF.

#### Section 9. Confidentiality.

- 9.1 <u>Definition</u>. In this Agreement, "Confidential Information" means any material non-public information disclosed by one party ("Disclosing Party") to the other ("Recipient"), including without limitation any trade secrets, any written information marked "confidential", any technical or product information, any information relating to the business strategies or plans of such party, and, with respect to Trinity, any information which Inverness obtains from Trinity's fulfillment of its obligation under Sections 5.3, 5.5 or 5.6
- 9.2 <u>Obligations</u>. The Recipient shall: (a) not disclose the Disclosing Party's Confidential Information to third parties; (b) not use the Disclosing Party's Confidential Information for any purpose other than for the purposes permitted under this Agreement, provided that the Recipient retains the right to use such information in a court of law, in arbitration, or in other similar proceedings to establish its rights under this Agreement; and (c) limit access to the Disclosing Party's Confidential Information to those of its personnel for whom such access is reasonably necessary for the purposes permitted under this Agreement. The above mentioned limitations shall not apply to Confidential Information which (i) was in the possession of the Recipient prior to disclosure hereunder; (ii) was in the public domain at the time of disclosure or later became part of the public domain without breach of the confidentiality obligations herein contained; (iii) was disclosed by a Third Party without breach of any

obligation of confidentiality owed to the Disclosing Party; (iv) is the subject of a subpoena or other validly issued administrative or judicial process requesting disclosure of such Confidential Information; <u>provided</u>, that the Recipient provides prompt notice to the Disclosing Party and permits the Disclosing Party to contest or narrow such request for disclosure, and thereafter complies with such subpoena or other process; or (v) was independently developed by the Recipient without reference to the Disclosing Party's Confidential Information.

#### Section 10. Patent Prosecution and Enforcement.

10.1 <u>Prosecution</u>. Inverness and its Third Party licensors shall retain all right, in their absolute discretion, to control the prosecution (or failure to prosecute) all Patent Rights included within the Current Patents, Charlton Patents and Future Patents. Neither party nor any of its Affiliates (including Inverness Subsidiaries) shall be required hereunder to file any patent application, or to secure any patent or patent rights, or to maintain any patent in force, or to provide copies of patent applications to the other party or its Affiliates, or to disclose any inventions described or claimed in such patent applications.

10.2 <u>Enforcement</u>. Trinity shall promptly inform Inverness if and when it becomes aware of any Third Party infringement of any of the Current Patents, Charlton Patents or any Future Patents. Inverness shall not have any obligation hereunder to institute any action or suit against third parties for infringement of any such Patent Rights or to defend any action or suit brought by a Third Party which challenges or concerns the validity of any such Patent Rights. In addition, Trinity shall not have any right to institute any action or suit against third parties for infringement of any of the Current Patents, Charlton Patents or any Future Patents.

#### Section 11. Assignment.

Trinity (including Trinity Subsidiaries) shall not assign, transfer or grant any right under any of the Current Patents, Charlton Patents or Future Patents whether by agreement, operation of law (as in the case, by way of example, of a Change of Control as hereinafter defined; it being understood that the result of a Change of Control shall be determined in accordance with the following sentence), or otherwise. If, after the Effective Date (a) Trinity is acquired by any Third Party, whether by stock acquisition, merger, consolidation or otherwise (including whether or not Trinity survives as a separate corporation or legal entity as a result of such acquisition), (b) Trinity enters into a transaction in which the outstanding voting stock of Trinity is converted into cash, securities, or other property, or (c) any person, entity or group (within the meaning of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended) acquires the majority of the voting power of the voting stock of Trinity, or (d) Trinity sells all or substantially all of the assets of Trinity (any of the foregoing a "Change of Control"), then with automatic effect on occurrence of such Change of Control (the "Change of Control Event") and without any action required of Inverness, the licenses granted in Sections 2.1 and 2.2 of this Agreement shall thenceforth be limited to Licensed Products which, at the time that Trinity first entered into discussions with a Third Party leading to such Change of Control Event: (i) have been commercially released (that is, have been sold by Trinity or Trinity Subsidiaries as finished products to Third Parties in arms' length transactions); or (ii) have already been substantially developed, by employees employed by, or individuals engaged as subcontractors by, Trinity or a Trinity Subsidiary.

#### Section 12. Miscellaneous.

12.1 Communications and Notices. Payment shall be made by electronic funds transfer. Payments shall be deemed to be made on the date of electronic funds transfer. Any notice or other communication required or permitted to be made or given to either party hereto pursuant to this Agreement shall be sent to such party by facsimile (such notice to be effective when sent, if confirmed by registered airmail or registered or certified mail) or by registered airmail (except that registered or certified mail may be used where delivery is in the same country as mailing) (such mailed notice to be effective on the date which is three (3) business days after the date of mailing), postage prepaid, addressed to it at its address set forth below, or to such other address as it shall designate by written notice given to the other party. The addresses are as follows:

For electronic funds transfers of payments:

To an Inverness account notified in writing to Trinity.

For mailing to Inverness:

Inverness Medical Innovations, Inc. Attention: Office of the General Counsel 51 Sawyer Road Waltham MA 02453 **USA** 

For facsimile transmission to Inverness:

Inverness Medical Innovations, Inc. Attention: Office of the General Counsel

Facsimile: (781) 647 3939

For mailing to Trinity:

Trinity Biotech plc Attention: Chief Financial Officer Southern Cross Road Bray, Co. Wicklow, Ireland Facsimile: +353 1 2769883

12.2 No Publicity. Nothing contained in this Agreement shall be construed as conferring any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark or other designation of either party hereto (including any contraction, abbreviation or simulation of any of the foregoing). Each party hereto agrees not to use or refer to this Agreement or any provision thereof in any promotional activity, without the express written approval of the other party.

- 12.3 Amendments; Entire Agreement. This Agreement will not be binding upon the parties until it has been signed herein below by or on behalf of each party, in which event it shall be effective as of the Effective Date. No amendment or modification hereof shall be valid or binding upon the parties unless made in writing and signed. This Agreement and any schedules or exhibits hereto or thereto, together with the related Settlement Agreement, embody the entire understanding of the parties with respect to the subject matter hereof and merge all prior discussions between them, and neither of the parties shall be bound by any conditions, definitions, warranties, understandings or representations with respect to the subject matter hereof other than as expressly provided herein. In the event of any conflict or contradiction between the terms of this Agreement and the Settlement Agreement, this Agreement shall control.
- 12.4 Compliance with Laws. Trinity shall comply with all local, state, federal, and international laws and regulations relating to the development, manufacture, use, and sale of Licensed Products. Trinity expressly agrees to comply with the following: (i) Trinity shall obtain all necessary approvals from U.S. regulatory authorities and any similar governmental authorities of any foreign jurisdiction in which Trinity intends to make, use, or sell Licensed Products; and (ii) Trinity shall comply with all United States laws and regulations controlling the export of commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit, or require a license for, the export of certain types of commodities and technical data to specified countries. Trinity hereby gives written assurance that it will comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or any Trinity Subsidiary, and that it will indemnify, defend, and hold Inverness harmless (in accordance with Article 8.4) for the consequences of any such violation.
- 12.5 <u>Headings</u>. The heading of the several Sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
- 12.6 <u>Severability</u>. If any Section of this Agreement is found by competent authority to be invalid, illegal or unenforceable in any respect for any reason, the validity, legality and enforceability of any such Section in every other respect and the remainder of this Agreement shall continue in effect.
- 12.7 <u>Disclosure of Agreement</u>. The parties and each of their respective counsel, and other agents, agree that the negotiations concerning and the terms of this Agreement, including the Agreement, shall be strictly confidential, and shall not be released or disclosed by any party or their counsel in any way to any person, entity, or form of media (including but not limited to written/published media, television, radio or electronic media), unless required by law or by an order of a court of competent jurisdiction. In the event that either party is served with a request or order requiring disclosure of the terms of this Agreement, it shall provide the other party with prompt notice thereof, provided however that the terms of the Agreement may be disclosed

without notice on a confidential basis to an attorney, auditor, insurance agent or carrier, or other person having a legitimate business need to know such information; provided that the disclosing party ensures that such persons shall be subject to obligations to use such information solely for such purposes.

12.8 Governing Law; Venue. This Agreement shall be construed, and the legal relations between the parties hereto shall be determined, in accordance with the law of the Commonwealth of Massachusetts, United States of America, without reference to its conflicts of law principles. Any claim arising under this Agreement and any action to enforce the terms of this Agreement may be brought only in a state or federal court sitting in Massachusetts and the parties consent to jurisdiction over them by state and federal courts sitting in Massachusetts, and waive any objection to Massachusetts as a convenient forum or venue for any action arising under this Agreement. Before either party may initiate litigation, the chief executive officers of the respective parties shall meet and confer in good faith in an effort to resolve any claims or disputes arising under this Agreement.

[Remainder of page left intentionally blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly signed as of the date first above written.

|                     | Inverness Medical Innovations, Inc. |  |
|---------------------|-------------------------------------|--|
| Witness             | Ву                                  |  |
|                     | Title                               |  |
|                     | Trinity Biotech PLC                 |  |
| Witness (ILLEGIBLE) | By (ILLEGIBLE)                      |  |
|                     | Title CFO                           |  |

#### **EXHIBIT A**

#### LESS DEVELOPED COUNTRIES

Afghanistan Malawi Algeria Maldives Angola Mali Bangladesh Mauritania Belize Mauritius Benin Micronesia Bhutan Mongolia Morocco Botswana Mozambique Burkina Faso Myanmar Burundi Namibia Cameroon Cape Verde Nepal Central Africa Rep. Nicaragua Niger Chad Nigeria Comoros North Korea Congo Cote d'Ivoire Pakistan Cuba Papua New Guinea

Cuba Papua New Djibouti Philippines Dominica Rwanda Egypt Samoa

Equatorial Guinea Sao Tome & Principe

Equatorial Guinea Sao Fonic & Frini Eritrea Senegal Ethiopia Seychelles Fiji Sierra Leone Gabon Solomon Islands Gambia Somalia Ghana Sudan

Ghana Sudan
Guatemala Suriname
Guinea Swaziland
Guinea-Bissau Syrian Arab Rep.
Guyana Tanzania
Haiti Timor

Honduras Togo
Iran-Islamic Rep. of Tonga
Iraq Tunisia
Jordan Tuvalu
Kenya Uganda
Kiribati Vanuatu

Laos Vietnam
Lebanon West Bank and Gaza

Lesotho Yemen
Liberia Zaire
Libya Zambia
Madagascar Zimbabwe

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#### PUBLIC HEALTH SERVICE

#### PATENT LICENSE AGREEMENT-NONEXCLUSIVE

#### **COVER PAGE**

For PHS internal use only:

Patent License Number: L-165-99/0

Serial Number(s) of Licensed Patent(s) and/or Patent Application(s): 06/602,945; 06/602946; 06/643,729; 06/785,638;

07/117,937

Licensee: Trinity Biotech Plc

Cooperative Research and Development Agreement (CRADA) Number (if applicable): N/A

Additional Remarks: Trinity Biotech currently manufactures all of its HIV test kits in Ireland. It is currently Trinity Biotech's intention to continue manufacturing HIV test kits for worldwide distribution from its Irish manufacturing site. However, any new plant, built by Trinity Biotech, for production of HIV test kits for sale in the United States, must be built in the United States, as stated in the U.S. Manufacturing Waiver dated November 3, 1999, a copy of which is included in Appendix G.

Public Benefit(s): N/A

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) and/or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Modifications), Appendix E (Benchmarks), Appendix F (Commercial Development Plan) and Appendix G (U.S. Manufacturing Waiver). The Parties to this **Agreement** are:

- 1) The National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**DHHS**"); and
- 2) The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "Licensee".

#### CONFIDENTIAL

PHS Patent License Agreement-(*Nonexclusive*)- L-165-99/0 Trinity Biotech Plc Final 11/23/99 Model 980611 Page 1 of 18

#### PHS PATENT LICENSE AGREEMENT-NONEXCLUSIVE

#### PHS and Licensee agree as follows:

#### 1. BACKGROUND

- 1.01 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.
- 1.02 By assignment of rights from PHS employees and other inventors, DHHS, on behalf of the United States Government, owns intellectual property rights claimed in any United States and/or foreign patent applications or patents corresponding to the assigned inventions. DHHS also owns any tangible embodiments of these inventions actually reduced to practice by PHS.
- 1.03 The Secretary of **DHHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.04 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.05 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, and/or marketable products for public use and benefit.

#### 2. DEFINITIONS

- 2.01 "Benchmarks" mean the performance milestones that are set forth in Appendix E.
- 2.02 "Commercial Development Plan" means the written commercialization plan attached as Appendix F.
- 2.03 **"First Commercial Sale"** means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.
- 2.04 "Government" means the Government of the United States of America.
- 2.05 "Licensed Fields of Use" means the fields of use identified in Appendix B.
- 2.06 "Licensed Patent Rights" shall mean:
  - a) Patent applications (including provisional patent applications and PCT patent applications) and/or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;
  - b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; iv) priority patent application(s) of a) above; and v) any reissues, reexaminations, and extensions of all such patents;
  - c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign and U.S. patent applications and patents to a) and b) above, including those listed in Appendix A.

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- **Licensed Patent Rights** shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in a) above.
- 2.07 "Licensed Process(es)" means processes which, in the course of being practiced would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.08 "Licensed Product(s)" means tangible materials which, in the course of manufacture, use, sale, or importation would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.09 "Licensed Territory" means the geographical area identified in Appendix B.
- 2.10 "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of Licensee or its sublicensees, and from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by Licensee, or sublicensees, and on its payroll, or for the cost of collections.
- 2.11 **"Practical Application"** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

#### 3. GRANT OF RIGHTS

- 3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.
- 3.02 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**.

#### 4. <u>SUBLICENSING</u>

4.01 **Licensee** has no right to sublicense.

#### 5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.01 Prior to the **First Commercial Sale, Licensee** agrees to provide **PHS** reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.
- 5.02 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

#### **CONFIDENTIAL**

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#### 6. ROYALTIES AND REIMBURSEMENT

- 6.01 **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this **Agreement** becomes effective.
- 6.02 **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year. The minimum annual royalty due for the first calendar year of this **Agreement** may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
- 6.03 Licensee agrees to pay PHS earned royalties as set forth in Appendix C.
- 6.04 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.
- 6.05 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that a) the application has been abandoned and not continued, b) the patent expires or irrevocably lapses, or c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.06 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights.**
- 6.07 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arm's-length transaction, the value of the **Net Sales** attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.
- 6.08 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay to **PHS**, as an additional royalty, within sixty (60) days of **PHS**'s submission of a statement and request for payment to **Licensee**, an amount equivalent to such patent expenses previously incurred by **PHS**.
- 6.09 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** incurred by **PHS** on or after the effective date of this **Agreement**, **PHS**, at its sole option, may require **Licensee:** 
  - (a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS**'s submission of a statement and request for payment, a royalty amount equivalent to all such patent expenses incurred during the previous calendar year(s); or
  - (b) to pay such expenses directly to the law firm employed by **PHS** to handle such functions. However, in such event, **PHS** and not **Licensee** shall be the client of such law firm.

Under exceptional circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights.** In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain such patent applications or patents and shall provide to **PHS** copies of each invoice associated with such services as well as documentation that such invoices have been paid.

#### **CONFIDENTIAL**

PHS Patent License Agreement-(*Nonexclusive*)- L-165-99/0 Trinity Biotech Plc Final 11/23/99 Model 980611 Page 4 of 18 6.10 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any **Licensed Patent Rights** upon sixty (60) days written notice to **PHS** and owe no payment obligation under Article 6.09 for patent-related expenses incurred in that country after the effective date of such written notice.

#### 7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.01 **PHS** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights.** 

#### 8. RECORD KEEPING

- 8.01 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. Such records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection at the expense of **PHS** by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any late charges as required by Paragraph 9.07 of this **Agreement**. All payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.
- 8.02 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Product** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalty funds owed to the **Government** under this **Agreement**, and whether the royalty amount owed has been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

#### REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.01 Prior to signing this **Agreement, Licensee** has provided to **PHS** the **Commercial Development Plan** at Appendix F, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application.** This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement.** Based on this plan, performance **Benchmarks** are determined as specified in Appendix E.
- 9.02 Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. PHS also encourages these reports to include information on any of Licensee's public service activities that relate to the Licensed Patent Rights. If reported progress differs from that projected in the Commercial Development Plan and Benchmarks, Licensee shall explain the reasons for such differences. In any such annual report, Licensee may propose amendments to the Commercial Development Plan, acceptance of which by PHS may not be denied unreasonably. Licensee agrees to

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provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under this **Agreement. Licensee** may amend the **Benchmarks** at any time upon written consent by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if such request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

- 9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix E and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.
- 9.04 Licensee shall submit to PHS within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each such royalty report, Licensee shall submit payment of the earned royalties due. If no earned royalties are due to PHS for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of Licensee and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine Net Sales made under Article 6 to determine royalties due.
- 9.05 Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, PA 15251-6120. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee.** The royalty report required by Paragraph 9.04 of this **Agreement** shall accompany each such payment, and a copy of such report shall also be mailed to **PHS** at its address for notices indicated on the Signature Page of this **Agreement.**
- 9.06 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign governments.
- 9.07 Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.08 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of such records by the PHS under the Freedom of Information Act (FOIA), 5 U.S.C.' 552 shall be subject to the predisclosure notification requirements of 45 CFR' 5.65(d).

#### 10. PERFORMANCE

- 10.01 **Licensee** shall use its reasonable best efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application.** "Reasonable best efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** at Appendix F and performance of the **Benchmarks** at Appendix E.
- 10.02 Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use its reasonable best efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

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#### 11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.01 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.
- 11.02 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against **PHS**, **PHS** agrees to notify **Licensee** that an action alleging invalidity has been brought. **PHS** does not represent that it will commence legal action to defend against a declaratory action alleging invalidity. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such declaratory judgment action. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action. Upon **Licensee's** payment of all costs incurred by the **Government** as a result of **Licensee's** joinder motion or other action, these actions by **Licensee** will not be considered a default in the performance of any material obligation under this **Agreement**.

#### 12. <u>NEGATION OF WARRANTIES AND INDEMNIFICATION</u>

- 12.01 **PHS** offers no warranties other than those specified in Article 1.
- 12.02 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.
- 12.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.
- 12.04 PHS does not represent that it will commence legal actions against third parties infringing the Licensed Patent Rights.
- 12.05 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of: a) the use by or on behalf of **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**; or b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**. **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

#### 13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

- 13.01 This **Agreement** is effective when signed by all parties and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.
- 13.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Article 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding amounts owed through procedures provided by the Federal Debt Collection Act.

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- 13.03 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee's** receipt of written notice.
- 13.04 **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving **PHS** sixty (60) days written notice to that effect.
- 13.05 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**: 1) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**; 2) has not achieved the **Benchmarks** as may be modified under Paragraph 9.02; 3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license **Agreement**; 4) has committed a material breach of a covenant or agreement contained in the license; 5) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences; 6) cannot reasonably satisfy unmet health and safety needs; or 7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived. In making this determination, **PHS** will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.02. Prior to invoking this right, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS's** concerns as to the previous items 1) to 7) or fails to initiate corrective action to **PHS's** satisfaction, **PHS** may terminate this **Agreement.**
- 13.06 **PHS** reserves the right according to 35 U.S.C.' 209(f)(4) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee.**
- 13.07 Within thirty (30) days of receipt of written notice of **PHS**'s unilateral decision to modify or terminate this **Agreement, Licensee** may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.08 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of the destruction thereof.

#### 14. GENERAL PROVISIONS

- 14.01 Neither Party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any such term or condition by **Licensee.**
- 14.02 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights,** and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement.**

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- 14.03 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.04 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.05 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.06 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party. Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 14.07 This **Agreement** shall not be assigned by **Licensee** except: a) with the prior written consent of **PHS**, such consent not to be withheld unreasonably; or b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**. **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**, and **Licensee** shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within thirty (30) days of such assignment.
- 14.08 **Licensee** agrees in its use of any PHS-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
- 14.09 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S. **Government** or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **PHS** patent rights in such countries.

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- 14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of NIH, CDC, **PHS**, or **DHHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written consent of **PHS**.
- 14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.
- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Paragraphs 8.01, 9.06-9.08, 12.01-12.05, 13.07, 13.08, and 14.12 of this **Agreement** shall survive termination of this **Agreement**.

#### SIGNATURES BEGIN ON NEXT PAGE

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#### PHS PATENT LICENSE AGREEMENT—NONEXCLUSIVE

#### SIGNATURE PAGE

| For <b>PHS</b> :   |                   |          |  |  |
|--|-------------------|----------|--|--|
| /s/ Jack Spiegel   |                   | 12/17/99 |  |  |
| Jack Spiegel, Ph.D.  |                   | Date     |  |  |
| Director, Division of Technology Develope  | ment and Transfer |          |  |  |
| Office of Technology Transfer  |                   |          |  |  |
| National Institutes of Health  |                   |          |  |  |
| Mailing Address for Notices:   |                   |          |  |  |
| Office of Technology Transfer  |                   |          |  |  |
| National Institutes of Health  |                   |          |  |  |
| 6011 Executive Boulevard, Suite 325  |                   |          |  |  |
| Rockville, Maryland 20852-3804 U.S.A.  |                   |          |  |  |
| For <b>Licensee</b> (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of <b>Licensee</b> made or referred to in this document are truthful and accurate.): |                   |          |  |  |
| by: /s/ Jim Walsh  | 3/12/99           |          |  |  |
| Signature of Authorized Official   | Date              |          |  |  |
|  |                   |          |  |  |
| /s/ Jim Walsh  |                   |          |  |  |
| Printed Name   |                   |          |  |  |
| DIRECTOR COO   |                   |          |  |  |
| Title  |                   |          |  |  |
|  |                   |          |  |  |

Official and Mailing Address for Notices:

Dr. James Walsh Chief Operating Officer Trinity Biotech Plc IDA Business Park Southern Cross Rd. Bray Co. Wicklow Ireland

Phone: 353-1-2769800 Fax: 353-1-2769888

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C." 3801-3812 (civil liability) and 18 U.S.C. 1001 (criminal liability including fine(s) and/or imprisonment).

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#### **APPENDIX A—Patent(s) or Patent Application(s)**

#### **Patent(s) or Patent Application(s):**

USPA SN 06/602,945, filed April 23, 1984, (USPN 4,520,113, issued May 28, 1985) "Serological Detection of Antibodies to HTLV-III in Sera of Patients with AIDS and Pre-AIDS Conditions"

USPA SN 06/602,946, filed April 23, 1984, (USPN 4,647,773, issued March 3, 1987) "Method of Continuous Production of Retrovirus (HTLV-III) from Patients with AIDS and Pre-AIDS"

USPA SN 06/643,729, filed August 24, 1984, (USPN 4,652,599, issued March 24, 1987) "Method of Continuous Production of Retrovirus (HTLV-III) from Patients with AIDS and Pre-AIDS Using Permissive Cells"

USPA SN 06/785,638, filed October 8, 1985, (USPN 4,708,818, issued November 24, 1987) "Human Immunodeficiency Viruses Associated with Acquired Immune Deficiency Syndrome (AIDS), A Diagnostic Method for AIDS and Pre-AIDS and a Kit Therefor"

USPA SN 07/117,937, filed November 5, 1987, (USPN 5,135,684, issued August 4, 1992) "Human Immunodeficiency Viruses Associated with Acquired Immune Deficiency Syndrome (AIDS), A Diagnostic Method for AIDS and Pre-AIDS and a Kit Therefor"

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#### APPENDIX B—Licensed Fields of Use and Territory

#### **Licensed Fields of Use:**

Development, manufacture and sales of immunodiagnostic products for detection of HIV-1 antibodies.

### **Licensed Territory:** Worldwide

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#### **APPENDIX C—Royalties**

#### **Royalties:**

**Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of Ten Thousand Dollars (\$10,000). Half of this amount shall be due on December 31, 1999. The other half shall be due on December 31, 2000.

Licensee agrees to pay to PHS a nonrefundable minimum annual royalty in the amount of Ten Thousand Dollars (\$10,000).

Licensee agrees to pay PHS earned royalties on Net Sales by or on behalf of Licensee as follows:

Six Percent (6%) of Net Sales of all Licensed Products made or sold in the Licensed Territory.

Licensee agrees to pay PHS benchmark royalties as follows:

None.

**Licensee** agrees to pay **PHS** Twenty Eight Thousand Five Hundred Thirty Dollars (\$28,530) for Earned Royalties on sales of **Licensed Products** between January 1, 1992 and December 31, 1998 as calculated below using an earned royalty rate of 6%. Half of this amount shall be due upon signing of this **Agreement.** The other half shall be due on December 31, 1999.

| Year  | Net sales | Net HIV-1 sales | Royalty @ 6% |
|-------|-----------|-----------------|--------------|
| 1992  | 0         | 0               | 0            |
| 1993  | 20,000    | 10,000          | 600          |
| 1994  | 88,000    | 44,000          | 2,640        |
| 1995  | 210,000   | 105,000         | 6,300        |
| 1996  | 90,000    | 45,000          | 2,700        |
| 1997  | 188,000   | 94,000          | 5,640        |
| 1998  | 355,000   | 177,500         | 10,650       |
| Total | 951.000   | 475,500         | 28,530       |

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#### **APPENDIX D—Modifications**

PHS and Licensee agree to the following modifications to the Articles and Paragraphs of this Agreement:

(New)

2.12 Combined Product means a product that contains a Licensed Product along with at least one other active component or ingredient not covered by the Licensed Patent Rights.

(New)

- 2.13 If the **Licensee** sells a **Combined Product**, the **Net Sales** for purposes of earned royalty determination under Article 6 shall be the market price of the **Licensed Product** content of the **Combined Product** when sold separately. If the **Licensed Product** is not sold separately, then **Net Sales** upon which a royalty is paid shall be the greater of (a) the market price at which the **Licensed Product** reasonably could be sold as a separate item, or (b) **Net Sales** of the **Combined Product** multiplied by a factor 1/x where x is the number of active components or ingredients contained in the **Combined Product** up to a maximum of x=3.
- 5.01 Deleted in its entirety.

(Amended)

6.01 **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this **Agreement** becomes effective according to the payment schedule in Appendix C.

(Amended)

- 6.02 **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C <u>beginning</u>

  <u>January 1, 2000</u>. The minimum annual royalty is due and payable, <u>half on June 30</u>, the other half on <u>December 31</u> on

  <del>January 1</del> of each calendar year and may be credited against any earned royalties due for sales made in that year. The
  minimum annual royalty due for the first calendar year of this **Agreement** may be prorated according to the fraction of
  the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
- 6.08 Deleted in its entirety.
- 6.09 Deleted in its entirety.
- 6.10 Deleted in its entirety.
- 8.02 Deleted in its entirety.

(Amended)

9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix E and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

(Amended)

13.01 This **Agreement** is effective <u>as of January 1, 1992</u>, when signed by all parties and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

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#### **APPENDIX E—Benchmarks and Performance**

**Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

None.

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#### **APPENDIX F—Commercial Development Plan**

The Commercial Development Plan shall be as described in Licensee's Application for License to Public Health Service Inventions.

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#### APPENDIX G-U.S. Manufacturing Waiver



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service National Institutes of Health

Office of Technology Transfer National Institutes of Health 6011 Executive Boulevard Rockville, MD 20852

November 3, 1999

Dr. James Walsh COO Trinity Biotech Plc IDA Business Park Southern Cross Rd. Bray, Co. Wicklow Ireland

SUBJECT: Trinity Biotech Plc Request for a Waiver of the U.S. Manufacturing Requirement for Production of HIV Test Kits—OTT Ref. No. L-165-99/0

#### Dear Dr. Walsh:

I am pleased to inform you that the NIH Office of Technology Transfer (OTT) has granted Trinity Biotech Plc's request for a waiver of the U.S. manufacturing requirement for the production of HIV test kits. Based on a review of information supplied by your company, OTT concluded that it will not be commercially feasible for Trinity to produce its rapid HIV test kits in the United States. A condition of this waiver is that any new plant built by Trinity, for production of HIV test kits for sale in the United States, must be built in the United States.

We look forward to completing the nonexclusive license agreement associated with this waiver request. Thank you for your interest in NIH technology.

Sincerely,

/s/ Jack Spiegel

Jack Spiegel, Ph.D.

Director, Division of Technology Development and Transfer

cc

Kathleen Sybert, NCI

#### **CONFIDENTIAL**

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#### CERTIFICATION PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

- I, Ronan O'Caoimh, certify that:
- 1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the company and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the company's auditors and the audit committee of the company's board of directors:
- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2015

#### /s/ RONAN O'CAOIMH\*

Ronan O'Caoimh

Chief Executive Officer

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

### CERTIFICATION PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

- I, Kevin Tansley, certify that:
- 1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the company and have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the company's auditors and the audit committee of the company's board of directors:
- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2015

/s/ KEVIN TANSLEY \*

Kevin Tansley

Chief Financial Officer

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronan O'Caoimh, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

## /s/ RONAN O'CAOIMH \* Ronan O'Caoimh Chief Executive Officer

March 25, 2015

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by Trinity Biotech plc for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin Tansley, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

## /s/ KEVIN TANSLEY\* Kevin Tansley Chief Financial Officer

March 25, 2015

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by Trinity Biotech plc for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

#### **Consent of Independent Registered Public Accounting Firm**

We have issued our reports dated March 25, 2015, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Trinity Biotech plc on Form 20-F for the year ended December 31, 2014. We hereby consent to the incorporation by reference of said reports in the following Registration Statements of Trinity Biotech plc:

| Form Type | File Number | <b>Effective Date</b> |
|-----------|-------------|-----------------------|
| Form S-8  | 333-7762    | 10/10/1997            |
| Form S-8  | 333-124384  | 4/28/2005             |
| Form S-8  | 333-166590  | 5/6/2010              |
| Form S-8  | 333-182279  | 6/22/2012             |
| Form S-8  | 333-195232  | 4/11/2014             |

/s/ GRANT THORNTON Dublin, Ireland

March 25, 2015