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

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **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: 0-2022

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, County Wicklow, A98 H5C8, Ireland
(Address of principal executive offices)

John Gillard
Chief Financial Officer
Tel: +353 1276 9800
Fax: +353 1276 9888
IDA Business Park, Bray, County Wicklow, A98 H5C8, 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	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (each representing 4 'A' Ordinary Shares, par value US$0.0109)	**TRIB**	**NASDAQ Global Market**

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:

152,430,284 Class 'A' Ordinary Shares (excluding Treasury Shares)
(as of December 31, 2022)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form S-8 File Nos. 333-182279,333-195232 and 333-253070 and our Registration Statements on Form F-3 File Nos.333-239701, 333-267160 and 333-264992.

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PART II

PART III

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

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 consolidated financial statements appearing in this Annual Report 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 standards applied are those effective for accounting periods beginning January 1, 2022. 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. We present our consolidated financial statements in U.S. Dollars and except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "Euro" or "€" are to European Union Euro. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our competitive position and market opportunity, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Item 3.D. "*Risk Factors*" below.

Statements made in this Annual Report concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this Annual Report, you should read the document itself for a complete description of its terms, and the summary included herein is qualified by reference to the full text of the document which is incorporated by reference into this Annual Report.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are neither historical facts nor assurances of future performance. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to numerous risks and uncertainties some of which are beyond our control and are made in light of information currently available to us.

In some cases, these forward-looking statements can be identified by words or phrases such as "believe," "may," "will," "expect," "estimate," "could," "should," "anticipate," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the development of our products;
- the potential attributes and benefit of our products and their competitive position;
- our ability to successfully commercialize, or enter into strategic relationships with third parties to commercialize, our products;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- our ability to acquire or in-licence new product candidates;
- potential strategic relationships; and
- the duration of our patent portfolio.

We operate in an evolving environment. New risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the effect of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of important factors, including, without limitation, the important risk factors set forth in Item 3.D. "*Risk Factors*" of this Annual Report.

The forward-looking statements made in this Annual Report relate only to events or information as of the date on which the statements are made in this Annual Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Annual Report and the documents that we have filed as exhibits hereto completely and with the understanding that our actual future results or performance may be materially different from what we expect.

PART I

Item 1. *Identity of Directors, Senior Management and Advisers*

Not applicable.

Item 2. *Offer Statistics and Expected Timetable*

Not applicable.

Item 3. *Key Information*

A. Reserved

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary of Risk Factors

Investing in our shares involves a high degree of risk and uncertainty. You should carefully consider all of the information set forth in this Form 20-F, including the following summary of risk factors, when investing in our securities. These risks and uncertainties reflect the international scope of our company's operations and the highly regulated industry in which it operates. The risks and uncertainties presented below, which are discussed in more detail in the Risk Factors are reviewed on an annual basis and represent the principal risks and uncertainties faced by us at the time of compilation of this annual report on Form 20-F. During the course of 2023, new risks and uncertainties may materialise attributable to changes in markets, regulatory environments and other factors and existing risks and uncertainties may become less relevant, including the following:

Risks Related to our Business & Industry

- **Competition and trading conditions** - our ability to sell products could be adversely affected by competition from new and existing diagnostic products, changing conditions in the diagnostic market, including, inter alia, reductions in government funding and sector consolidation.
- **Borrowings** - we have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position. To the extent we are unable to repay our debt as it becomes due with cash on hand or from other sources, we will need to refinance our debt, sell assets or repay the debt with the proceeds from equity offerings in order to continue in business. Our ability to obtain additional funding may determine our ability to continue as a going concern. Failure to comply with the terms of the credit agreement for our term loan could result in a default under its terms and, if uncured, could result in action against our pledged assets. We are exposed to interest rate risk on some of our borrowings, which could cause our debt service obligations to increase significantly.
- **Capital structure** - we expect we will require future additional capital.
- **New product development** - our long-term success depends upon the successful development and commercialization of new products.
- **Supply chains** - significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results. We are dependent on third-party suppliers for certain critical components and the primary raw materials required for our test kits. Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.
- **Product recalls and claims** - our products may in the future be subject to product recalls that could harm our reputation, business and financial results. 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 regulatory agency enforcement actions. We may be subject to liability resulting from our products or services.
- **Financial impairment** - the large amount of intangible assets and goodwill recorded on our balance sheet may lead to significant impairment charges in the future.
- **Corporate strategy** - failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.
- **Global economic conditions** – changes in global economic conditions may have a material adverse impact on our results.
- **People** - 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.
- **Distributor network** - our revenues are highly dependent on a network of distributors worldwide. Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.
- **Cyber security** - 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.
- **Foreign exchange** - our sales and operations are subject to the risks of fluctuations in currency exchange rates.
- **Taxation** - tax matters, including disagreements with taxing authorities, the changes in corporate tax rates and imposition of new taxes could impact our results of operations and financial condition.
- **Acquisitions** - 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.
- **Pandemic impact** - the Covid-19 outbreak could significantly disrupt our operations and adversely affect our results of operations.
- **Environmental, Social and Governance** - increasing scrutiny and changing expectations from investors, lenders, customers and other market participants with respect to our Environmental, Social and Governance, or ESG, policies may impose additional costs on us or expose us to additional risks.

Risks Related to Government Regulations

- **Clinical trials** - clinical trials necessary to support future premarket submissions will be expensive and will require enrolment 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. If the third parties on whom we rely to conduct our pre-clinical studies and clinical trials and to assist in pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval or commercialize our products. The results of our clinical trials may not support our product candidate claims.

- **Regulatory compliance** - 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. 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.

- **Product approvals** - if we fail to maintain regulatory approvals and clearances our ability to commercially distribute and market these products could suffer. 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. Modifications to our products 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. Our laboratory business could be harmed from the loss or suspension of a licence or imposition of a fine or penalties under, or future changes in, the law or regulations of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), or those of other state or local agencies.

- **International regulations** - we face risks relating to our international sales and business operations, including regulatory risks, which could impact our current business operations and growth strategy.

- **Healthcare industry laws and public company regulations** - we are subject to various laws targeting fraud and abuse in the healthcare industry. Changes in healthcare regulation could affect our revenues, costs and financial condition. Compliance with regulations governing public company corporate governance and reporting is complex and expensive.

Risks Related to Our Intellectual Property

- **Proprietary rights** - we may be unable to protect or obtain proprietary rights that we utilise or intend to utilise.

- **Patent protection** – our patent protection may not be sufficiently broad to compete effectively, the existing patents could be challenged; and trade secrets and confidential know-how could be obtained by competitors. Our patent protection could be reduced or eliminated for non-compliance with various procedural requirements or due to changes in patent law. 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. Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

Risks Related to Ownership of our American Depository Shares (ADSs)

- **Significant shareholder -** MiCo IVD Holdings, LLC ("MiCo") currently owns approximately 29.3% of the voting share capital of our Company, which may give MiCo significant influence over our management and affairs and may deter a change in control or other transaction that may be favorable to our shareholders.

- **Information** - as a foreign private issuer we are exempt from a number of reporting requirements under the Exchange Act and are permitted to file less information with the SEC than a domestic U.S. reporting company.

- **Passive foreign investment company** - we may be classified as a passive foreign investment company, or PFIC, which would subject our U.S. investors to adverse tax rules.

- **Volatility** - the market price of our ADSs has been, and may continue to be, highly volatile. Future sales of our ADSs could reduce the market price of the ADSs.

- **Capital** - we expect we will need additional capital in the future.

- **Dilution** - the conversion of our outstanding employee share options, any new employee share options and existing warrants would dilute the ownership interest of existing shareholders.

- **Governed by Irish law** - it could be difficult for U.S. holders of ADSs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.

- **Dividends** - we have no plans to pay dividends on our ADSs, and you may not receive funds without selling the ADSs.

- **Voting rights of holders of ADSs** – the terms of the deposit agreement limit the voting rights of holders of ADSs.

- **NASDAQ listing standards** - our securities could be delisted from Nasdaq if we do not comply with Nasdaq's listing standards.

Risks Related to our Business & Industry

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. Our main competitors (and their principal products with which we compete) include: Premier (First response™), Chembio (Stat-Pak™, DPP HIV-Syphilis), Abbott (Determine™, SD BioLine™, Abon™, Acon™, Afinion™, Architect™), SD Biosensor, Wondf, Bejing Wanta, Roche TinaQuant 3™, Bio_Rad (Variant 2 Turbo™, D 100™, BioPlex 2200) Tosoh (G8™ & G11™) Arkray 8180™, Siemens DCA™, Sebia Capyllaris 2&3™, Bio-Rad Variant 2™, Sebia Capyllaris 2, Euroimmun™, Aesku™, Werfen, Copan™, Becton Dickenson™, Pointe Scientific and DiaSorin Liaison.

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 and adversely affect our results of operations, cash flow and business.

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 tests compete with products made by our competitors. Multiple competitors are making investments in competing technologies and products, and a number of our competitors have significantly 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 or other regulatory 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.

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position.

As of December 31, 2022, we had total indebtedness with a carrying value of approximately US$73.8 million, comprising a senior secured term loan ("Term Loan") from Perceptive Credit Holdings III, LP ("Perceptive"), a convertible note, a derivative liability related to warrants issued to Perceptive, lease liabilities and a residual amount owing for an exchangeable note which was almost completely retired in 2022. The Term Loan, which is repayable in January 2026, had a nominal outstanding amount of US$46.8 million at December 31, 2022. In February 2023, we entered into an amended and restated senior secured term loan credit agreement which allowed for an immediate US$5 million increase to our outstanding Term Loan and provided for a US$20 million facility to fund potential acquisitions. None of the US$20 million has been drawn down to date. The convertible note, which has a nominal outstanding amount of US$20 million, mandatorily converts into ADSs if the volume weighted average price of the Company's ADSs is at or above US$3.24 for any five consecutive trading days.

On April 27, 2023, we announced that we had closed the sale of our Fitzgerald Industries life sciences supply business, for cash proceeds of approximately US$30 million subject to customary adjustments. The Company has used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of its senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty. In connection with this transaction, we entered into an amendment to our senior secured term loan credit facility with Perceptive Advisors, which significantly reduces our minimum revenue covenants under that loan.

We may face further liquidity challenges if we are unable to meet obligations set forth in the Term Loan's credit agreement, including a financial covenant requiring that we achieve specified minimum total revenue amounts measured as of the end of each quarter. A breach of the minimum total revenue covenant or any other covenant in the credit agreement would result in a default under the credit agreement, which could enable the lender to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the credit agreement.

As a result, we may need to raise capital in one or more debt or equity offerings to fund our operations and obligations. There can be no assurance, however, that we will be successful in raising the necessary capital or that any such offering will be available to us on terms acceptable to us, or at all. If we are unable to raise additional capital that may be needed on terms in sufficient amounts or on terms acceptable to us, it could have a material adverse effect on our company. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our deliveries under our outstanding customer purchase orders or the development or commercialization of one or more of our products or one or more of our other research and development initiatives, sell assets and/or cease trading.

Our debt may:

- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our ability to use our cash flow or obtain additional financing for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- result in dilution to our existing shareholders in the event we issue equity to fund our debt obligations;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

To the extent we are unable to repay our debt as it becomes due with cash on hand or from other sources, we will need to refinance our debt, sell assets or repay the debt with the proceeds from equity offerings in order to continue in business. Additional indebtedness or equity financing may not be available to us in the future for the refinancing or repayment of existing debt, or if available, such additional debt or equity financing may not be available on a timely basis, or on terms acceptable to us and within the limitations specified in our then existing debt instruments. In addition, in the event we decide to sell additional assets, we can provide no assurance as to the timing of any asset sales or the proceeds that could be realized by us from any such asset sale. Our ability to obtain additional funding may determine our ability to continue as a going concern.

The failure to comply with the terms of the Credit Agreement could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders.

On December 15, 2021, the Company and certain of our subsidiaries, entered into the Credit Agreement, under which we obtained a US$81,250,000 senior secured term loan credit facility. The facility was conditioned on obtaining shareholder approval. Following shareholder approval in January 2022, the loan was drawn in full on January 27, 2022. In 2022, the Company made an early partial settlement of the term loan amounting to US$34,500,000. As at December 31, 2022, the Term Loan had a nominal outstanding amount of US$46,750,000. In February 2023, the Company entered into an amended and restated senior secured term loan credit agreement which allowed for an immediate US$5,000,000 increase to its outstanding Term Loan and provided for a US$20,000,000 facility to fund potential acquisitions. The Credit Agreement is secured by substantially all of our property and assets, including our equity interests in our subsidiaries. On April 27, 2023, the Company announced it had closed the sale of its Fitzgerald Industries life sciences supply business, for cash proceeds of approximately US$30 million subject to customary adjustments. The Company has used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of its senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty. In connection with this transaction, the Company has entered into an amendment to its senior secured term loan credit facility with Perceptive Advisors, which significantly reduces the Company's minimum revenue covenants under that loan.

The amended Credit Agreement also contains financial covenants requiring that we (a) maintain aggregate unrestricted cash of not less than US$2,000,000 at all times (effective from May 1, 2023 this limit increased to US$5,000,000), which must be held in one or more accounts subject to the security interests of the lenders under the Credit Agreement, and (b) commencing as of the end of the fiscal quarter ended June 30, 2023, achieve specified minimum total revenue requirements for the twelve months preceding each quarter end. In addition, the Credit Agreement contains covenants that restrict our ability to finance future operations or capital needs or to engage in other business activities. The Credit Agreement restricts the ability of our company and the restricted subsidiaries to, among other things:

- incur, assume or guarantee additional indebtedness; or
- repurchase capital stock;
- make other restricted payments, including paying dividends and making investments;
- create liens;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- enter into agreements that restrict dividends from subsidiaries;
- acquire another company or business or enter into mergers or consolidations;
- enter into certain inbound and outbound licenses of intellectual property, subject to certain exceptions; and
- enter into transactions with affiliates.

A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement. Upon an event of default under the Credit Agreement, the lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that we would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, we would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. If we were unable to pay such amounts due under the Credit Agreement, the lenders could proceed against the collateral securing the loan. Our inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

We expect we will 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 size of any repayment requirements for existing debt obligations;
- 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 licences;
- 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.

Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase significantly.

Borrowings under our senior secured Term Loan are at a variable rate of interest and expose us to interest rate risk. The Term Loan accrues interest at an annual rate equal to 11.25% plus the greater of (a) the Term SOFR Reference Rate and (b) one percent per annum. If interest rates continue to increase, our debt service obligations on the variable rate indebtedness will increase and our net income and cash flows, including cash available for servicing our indebtedness, would correspondingly decrease. As of December 31, 2022, the nominal amount of our variable rate debt was US$46.8 million. The indebtedness increased by US$5 million to US$51.8 million in February 2023, following an amendment to the Term Loan credit agreement. On April 27, 2023, the Company announced it had closed the sale of its Fitzgerald Industries life sciences supply business, for cash proceeds of approximately US$30 million subject to customary adjustments. The Company has used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of its senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty. Our anticipated annual cash interest expense on US$41.7 million variable rate debt at the current rate of 16 percent would be US$6.7 million. Every one percent increase in the interest rate results in additional annual interest payable of US$0.4 million, based on the current amount of indebtedness.

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. In the past, we have discontinued selling our Lyme Western Blot and HIV point-of-care tests in the U.S. due to changing market conditions which made those sales uncommercial. 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.

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, changing public health priorities 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.

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 new and enhanced 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 during its development phase after our investment of substantial time and money. During the fiscal years ended December 31, 2022, 2021 and 2020, we incurred US$4.5 million, US$6.8 million and US$6.9 million, respectively, in capitalised 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 we have to abandon a new product during its development phase, 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 U.S. is dependent in part on Food and Drug Administration ("FDA") clearance of products. If FDA clearance is delayed or not achieved for these products, it could have a material impact on the future growth of our business.

Similarly, future growth outside of U.S. is dependent on clearance of products by the relevant regulatory authorities in those countries.

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.

The trend towards managed care, together with healthcare reform of the delivery system in the U.S. and efforts to reform in Europe, has resulted in increased pressure on healthcare providers and other participants in the healthcare industry to reduce selling prices. Consolidation among healthcare providers and consolidation among other participants in the healthcare industry has resulted in fewer, more powerful groups, whose purchasing power gives them cost containment leverage. In particular, there has been a consolidation of laboratories. These industry trends and competitive forces place constraints on the levels of overall pricing, and thus could have a material adverse effect on our gross margins for products we sell in clinical diagnostic markets.

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. In 2022, we experienced significant disruption to our international supply chain which caused some disruption to operations. There can be no assurance that these disruptions will not continue or intensify in the future which may create significant challenges in fulfilling customer orders that we may not be able to overcome.

Although typically we do not plan to be dependent upon any one source for these critical components or raw materials, alternative sources of such raw materials or components with the characteristics and quality desired by us may not be available or commercially viable. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

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 ("MDR") requirements in the United States and comparable regulations worldwide, such as the Health Products Regulatory Authority ("HPRA"). 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 our 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.

We may be subject to liability resulting from our products or services.

We may be subject to claims for personal injuries or other damages if any of our products, services, 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; and
- Diversion of management time and attention;

We have global product liability insurance in place for our manufacturing subsidiaries up to a maximum of €6,500,000 (US$6,921,000) for any one accident, limited to a maximum of €6,500,000 (US$6,921,000) in any one-year period of insurance and is subject to a deductible. We also have professional indemnity insurance for the laboratory services business up to a maximum of US$5,000,000 for each claim and a U$7,000,000 aggregate limit. 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.

Our products may 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, a correction, a safety alert 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 labelling 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, modifications, design or labelling 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.

The large amount of intangible assets and goodwill recorded on our balance sheet may lead to significant impairment charges in the future.

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill and acquired indefinite life intangible assets are subject to impairment review on a periodic basis and whenever potential impairment indicators are present. Other long-lived assets are reviewed when there is an indication that an impairment may have occurred. The amount of goodwill and identifiable intangible assets on our consolidated balance sheet as of December 31, 2022, was US$35 million (2021: US$36 million) (2020: US$34 million). In 2022, we recorded total impairment charges of intangible assets of US$5 million (2021: US$4 million) (2020: US$15 million) as a result of our periodic impairment review. We may record further significant impairment charges in the future if there are changes in market conditions, a significant reduction in share price or other changes in the future outlook. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. Certain impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment charges could have a material adverse effect on our results of operations.

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 partly 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.

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

Uncertainty in global economic conditions may continue for the foreseeable future and intensify. The invasion of Ukraine by Russia has destabilised markets, increased volatility and created uncertainty, particularly in energy supply and energy prices. 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, refinance existing debts, or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding may 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 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.

Our success is dependent to a large extent upon the contributions of our key employees who in 2022 were Ronan O'Caoimh, our CEO and Chairman, who on October 3, 2022, was succeeded by Aris Kekedjian, and John Gillard, our CFO/Executive Director. The effectiveness of our senior leadership team generally, and any further transition as a result of these changes, could have a significant impact on our results of operations. Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions. 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.

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 and Kansas City, Missouri accounted for the majority of our revenues during the fiscal year ended December 31, 2022. 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. 2022 continued to see significant interruptions to international supply chains which may continue for some time to come. 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 fulfil 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, pandemics, 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 and/or services. 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/or 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 our or third-party manufacturing capabilities could materially and adversely affect our operating results.

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.

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

We currently distribute our 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 existing business unless suitable alternatives were quickly 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.

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. These risks increased as a result of the public health restrictions put in place due to Covid-19. 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.

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. We have been the victim of cyber-attacks but these have had no material impact on our operations. 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 personal information, including but not limited to employee or 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.

Section 3305 of FDORA (Food and Drug Omnibus Reform Act of 2022) aims to ensure cybersecurity of medical devices and requires manufacturers of cyber devices, when making a premarket submission to FDA, to provide a plan to monitor and address any post-market cybersecurity vulnerabilities; create and maintain procedures to ensure the device and related systems are cybersecure; provide a software bill of materials; and comply with any other requirements FDA may develop to ensure the device and related systems are cybersecure. This provision makes a failure to comply with these requirements a prohibited act. We have carried out the appropriate cybersecurity assessments for any of our relevant products in accordance with FDA, AAMI and ANSI requirements and standards in place at time of approval. We note that Section 3305 of FDORA does not apply to submissions made prior to the date of enactment.

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

A substantial portion of our operations are 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. In addition, in markets where we invoice in U.S. Dollars but where the local currency has weakened, we have been required to reduce our pricing in order to preserve our competitiveness. We have an exposure to the Canadian Dollar through our Canadian operations and to the Brazilian Real through our Brazilian subsidiary. We also have revenues and costs denominated in British Sterling.

The ongoing geopolitical uncertainty, inflation and central bank actions may lead to greater volatility in currency exchange rates globally. 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.

Tax matters, including disagreements with taxing authorities, the changes in corporate tax rates and imposition of new taxes could impact our results of operations and financial condition.

We are subject to regular reviews, examinations, and audits by tax authorities in a number of jurisdictions across the world with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position.

A significant portion of our business is located in the U.S. and is subject to income and other taxes in the U.S. and our operations, plans and results are affected by tax and other initiatives. Changes to the US tax code could have a significant impact on our profitability. Changes to the tax code could also affect our valuation of deferred tax assets and liabilities. Any such change in valuation would have a material impact on our income tax expense and deferred tax balances.

Future acquisitions and investments 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.

We have 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.

Public health emergencies, epidemics or pandemics, such as the emergence and spread of the Covid-19 pandemic, have the potential to significantly impact our operations through a decrease in demand for our products, interruption to business and a reduction in staff availability.

The Covid-19 pandemic has had a material impact on the healthcare industry and specifically the medical diagnostics sector in which we operate. The reduced but continuing uncertainty around the global pandemic could have an adverse effect on our operating results, cash flows, financial condition and/or prospects.

The global spread of Covid-19 and the public healthcare measures implemented by governments, such as quarantines and the temporary closure of businesses led and could again in the future lead to fewer patients presenting themselves for medical check-ups resulting in a fall in demand for certain of our products which may or may not be offset by increased demand within our Covid-19 related portfolio of products. Furthermore, funding allocated to combatting Covid-19 may result in a reduction or a postponement in the funding available for other diseases, conditions and disorders that our products are used to diagnose.

We operate in a labour-intensive industry where employees', contractors' and customers' activities can be adversely impacted by the availability of people to produce, manufacture or install our products. Covid-19 lead to the temporary closure of our manufacturing sites and associated furloughing of some staff. Furthermore, Covid-19 reduced our ability to visits customers and suppliers and required some of our staff to work from home in line with public health measures. Any significant loss of employee resources for a sustained period of time due to lockdown restrictions, self-isolation or sickness as a result of a public health emergency could impact our ability to produce, manufacture and deliver goods. Similarly, our customer facing activities could be adversely impacted by similar employee availability issues.

The situation with the Covid-19 pandemic remains fluid and uncertain at this time.

Increasing scrutiny and changing expectations from investors, lenders, customers and other market participants with respect to our Environmental, Social and Governance, or ESG, policies may impose additional costs on us or expose us to additional risks.

Companies across all industries are facing increasing scrutiny relating to their ESG policies. Investors, lenders and other market participants are increasingly focused on ESG practices and in recent years have placed increasing importance on the implications and social cost of their investments. The increased focus and activism related to ESG may hinder our access to capital, as investors and lenders may reconsider their capital investment allocation as a result of their assessment of our ESG practices. If we do not adapt to or comply with investor, lender or other industry shareholder expectations and standards, which are evolving, or if we are perceived to have not responded appropriately to the growing concern for ESG issues, regardless of whether there is a legal requirement to do so, we may suffer from reputational damage and the business, financial condition and the price of our company's ADS's could be materially and adversely affected.

Risks Related to Government Regulations

Clinical trials necessary to support future premarket submissions will be expensive and will require enrolment 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 future products under development, is 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 enrolment of patients who may be difficult to identify and recruit. Patient enrolment 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. Continuing public health measures against Covid-19 may increase the difficulty of conducting clinical trials.

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 and/or other regulatory authorities 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 enrolment 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 and/or other regulatory authorities 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 facilities 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 in-vitro diagnostic ("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.

In relation to World Health Organisation (WHO) qualification, our IVD clinical studies are required to meet all the requirements of the TSS-1: Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use. If we are not operating in compliance with this regulation, we could be subject to WHO enforcement action. In addition, our IVD clinical studies are required to meet the requirements of:

- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (2008);
- ICH Harmonised Guidelines - Integrated Addendum to ICH E6 (R2) Guideline for Good Clinical Practice (Nov 2016);
- ISO 20916:2019 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice;
- ISO 14155:2011: Clinical investigation of medical devices for human subjects – Good clinical practice.

If the third parties on whom we rely to conduct our pre-clinical studies and clinical trials and to assist in pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval 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 other regulatory 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.

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 or other relevant regulatory authorities. However, the FDA and/or the other relevant regulatory authorities could disagree and require us to stop promoting our products for those specific uses until we obtain clearance or approval for them. In addition, if the FDA or other relevant regulatory authorities determines that our promotional materials constitute promotion of an unapproved use, it could demand 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 ("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 IVD 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 provided notice that it intended to issue draft guidance to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. As part of developing this framework, the FDA issued draft guidance in October 2014 that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. 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 if 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 and the process can be costly. 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 labelling 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 labelling claims, the FDA allows us to make are limited, orders may decline and adversely affect our results of operations, cash flow and business.

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.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, regulatory 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 such as the HPRA in Ireland. 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 and maintaining 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 ("FDCA"), or is the subject of an approved premarket approval application ("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 labelling 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, many 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 inability 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 ("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. Furthermore, regulatory authorities, including the FDA, may not agree with our interpretation of its policies and regulations which may lead to enforced modifications, restrictions, discontinuation, etc. of some of our products, even if they were previously approved.

Our continued success is dependent on our ability to develop and market new or updated 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. Modifications made to our products may invalidate previously granted regulatory approvals which may lead to revised regulatory clearances, enforced modifications, restrictions, discontinuation, etc. of some of our products.

Additionally, changes in the FDA's review of certain clinical diagnostic products referred to as laboratory developed tests, which are tests developed by a single laboratory for use only in that laboratory, could affect some of our customers who use our Life Science instruments for laboratory developed tests. In the past, the FDA has chosen to not enforce applicable regulations and has not reviewed such tests for approval. However, the FDA has issued draft guidance that it may begin enforcing its medical device requirements, including premarket submission requirements, to such tests. Any delay in, or failure to receive or maintain, clearance or approval for our products could prevent us from generating revenue from these products and adversely affect our business operations and financial results.

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, such as the HPRA in E.U., impacts many aspects of our operations, and the operations of our suppliers and distributors, including manufacturing, labelling, 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 ("QSR"), which covers the methods and documentation of the design, testing, production, control, quality assurance, labelling, 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 and 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.

Other regulatory authorities have similar sanctions in their respective jurisdictions.

If any of these actions were to occur, they may 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.

For example, in August 2020, our subsidiary received a Warning Letter from FDA following an inspection of our subsidiary's Kansas City, Missouri manufacturing facility that took place in January and February 2020. We have taken voluntary remediation actions to correct the observations noted in the Warning Letter and on December 22, 2022, we received a close-out letter from FDA, noting that based on FDA's evaluation, it appears that the violations contained in the Warning Letter have been addressed.

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, labelling, 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 labelling, 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 countries may restrict our ability to sell products in those countries. 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.

Modifications to our products, 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 ultra² GeneSys Variant System and ultra² Resolution Variant System. The primary focus of the GeneSys Variant System 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 to both systems 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 with the ultra² GeneSys Variant System 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 filed new 510(k) notifications to obtain clearance for these indications. The FDA rejected our filing on the basis that the predicate device chosen did not meet their requirements. Additionally, the FDA asked us to withdraw the ultra² GeneSys Variant System from the market. A recall was conducted and has since been closed.

Additionally, in August 2020, we received a Warning Letter from the FDA. In the Warning Letter, FDA stated that we had made additional changes to the ultra² Resolution Variant System not covered within our existing 510(k). Accordingly, we conducted a voluntary recall of the ultra² Resolution Variant System. We have developed the Premier Resolution as a successor instrument to the ultra² Resolution Variant System and this has already been launched in various jurisdictions outside the United States. We submitted a 510(k) application for this successor instrument in 2022 which, if approved, will allow us to market this instrument in the United States.

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 are subject to export controls and economic sanctions laws, and our customers and distributors are subject to import controls that could subject us to liability if we are not in full compliance with applicable laws.

Certain of our products are subject to U.S. export controls and sanctions regulations and we would be permitted to export such solutions to certain destinations outside the U.S. only by first obtaining an export license from the U.S. government, or by utilizing an existing export license exception/General License, or after clearing U.S. government agency review. Obtaining the necessary export license or accomplishing a U.S. government review for a particular export may be time-consuming and may result in the delay or loss of sales opportunities.

Although we take precautions to prevent our products from being provided in violation of U.S. export control and economic sanctions laws, our products may have been in the past, and could in the future be, provided inadvertently in violation of such laws. If we were to fail to comply with U.S. export law requirements, U.S. customs regulations, U.S. economic sanctions or other applicable U.S. laws, we could be subject to substantial civil and criminal penalties, including fines, incarceration for responsible employees and managers and the possible loss of export or import privileges. U.S. export controls, sanctions and regulations apply to our distributors as well as to us. Any failure by our distributors to comply with such laws, regulations or sanctions could have negative consequences, including reputational harm, government investigations and penalties.

Changes or new versions of our products or changes in export and import regulations may create delays in the introduction of our products into international markets, prevent our distributors from deploying our products globally or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. In addition, any change in export or import regulations, economic sanctions or related legislation, shift in the enforcement or scope of existing regulations, or change in the countries, governments, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export or sell our products to, existing or potential international customers. Any decreased use of our principal products or limitation on our ability to export or sell such products would likely adversely affect our business, financial condition and operating results.

We are subject to anti-corruption, anti-bribery and similar laws, and non-compliance with such laws can subject us to criminal penalties or significant fines and harm our business and reputation.

We are subject to anti-corruption and anti-bribery and similar laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the Foreign Corrupt Practices Act, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the U.K. Bribery Act 2010 and other anti-corruption, anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly and prohibit companies and their employees and agents from promising, authorizing, making, offering, soliciting, or accepting, directly or indirectly, improper payments or other improper benefits to or from any person whether in the public or private sector. As we increase our international sales and business, our risks under these laws may increase. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, adverse media coverage and other consequences. Any investigations, actions or sanctions could adversely affect our business, results of operations and financial condition.

Changes in healthcare regulation could affect our revenues, costs and financial condition.

In the United States in recent years, there have been numerous initiatives at the federal and state level for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care Act, the Federal healthcare reform law enacted in 2010 (the "Affordable Care Act"). Similar reforms may occur internationally.

Third party payors, such as Medicare and Medicaid in the United States, have reduced their reimbursements for certain medical products and services. Our business is impacted by the level of reimbursement available for clinical tests from third party payors. In the United States payment for many diagnostic tests furnished to Medicare fee-for-service beneficiaries is made based on the Medicare Clinical Laboratory Fee Schedule (CLFS), a fee schedule established and adjusted from time to time by the Centers for Medicare and Medicaid Services (CMS). Some commercial payors are guided by the CLFS in establishing their reimbursement rates. Laboratories and clinicians may decide not to order or perform certain clinical diagnostic tests if third party payments are inadequate, and we cannot predict whether third party payors will offer adequate reimbursement for tests utilizing our products to make them commercially attractive. Legislation, such as the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act and the Middle Class Tax Relief and Job Creation Act of 2012, has reduced the payments for clinical laboratory services paid under the CLFS. In addition, the Protecting Access to Medicare Act of 2014 (PAMA) has made significant changes to the way Medicare will pay for clinical laboratory services, which has further reduced reimbursement rates.

Legislative and regulatory bodies are likely to continue to pursue healthcare reform initiatives in many forms and may continue to reduce funding in an effort to lower overall federal healthcare spending. The U.S. government recently enacted legislation that eliminated what is known as the "individual mandate" under the Affordable Care Act and may enact other changes in the future. The ultimate content and timing of any of these types of changes in other healthcare reform legislation and the resulting impact on us are impossible to predict. If significant reforms are made to the healthcare system in the U.S., or in other jurisdictions, those reforms may increase our costs or otherwise have an adverse effect on our financial condition and results of operations.

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

Our laboratory operated by our subsidiary 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 licence 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 licences to test specimens from patients residing in those states, and additional states may require similar licences in the future. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licences, certificates and authorisations, which could adversely affect our business and results of operations.

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 our subsidiary 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 payers 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. Often, to avoid the threat of treble damages and penalties under the False Claims Act, which in 2020 were $11,665 to $23,331 per false claim, companies will resolve allegations in a settlement without admitting liability to avoid the potential treble damages. Any such settlement could materially affect our business, financial operations, and reputation;

- 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 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 makes 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.

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.

Risks Related to Our Intellectual Property

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 licenced, and expect to continue to licence, 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 licence 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 licences or proprietary or patented technologies in the future, or that licences 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 licenced 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 a number of active patents, some with protection across multiple countries. These patents have remaining patent lives ranging from 5 years to 12 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-licence, 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 licenced 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 licenced or that we might obtain in the future. Similar changes could happen to patent laws outside of USA which would have the same consequences.

For example, the United States has 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 developed 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 licences 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 effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

If we need to obtain a licence as a result of litigation, we cannot predict whether any such licence 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 licences from third parties to advance our research or allow commercialisation of our products. We may fail to obtain any of these licences 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 licenced, we may have limited or no right to participate in the defence of any licenced 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 licence 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 ADSs.

Risks Related to Ownership of our ADSs

MiCo IVD Holdings, LLC ("MiCo") owns approximately 29.3% of the voting share capital of our Company, which may give MiCo significant influence over our management and affairs and may deter a change in control or other transaction that may otherwise be favorable to our shareholders.

MiCo owns 11.2 million of our ADSs, which represents approximately 29.3% of the outstanding voting share capital of our Company and, under the terms of the Company's Redeemable Unsecured Convertible Loan Note issued to MiCo (the "Convertible Note") and the purchase agreement for those ADSs, MiCo is entitled to nominate a total of four individuals, three of whom must be independent of MiCo, for consideration by the nomination committee of the board of directors of the Company for appointment as directors for as long as MiCo continues to hold qualifying amounts of ADSs or principal value of the Convertible Note or converted ADSs, as applicable. Because of its ownership interest and right to nominate directors, MiCo may have significant influence over our management and affairs and over matters requiring shareholder approval, including the election of directors and significant corporate transactions, such as a merger or other sale of our Company or our assets, for the foreseeable future. This concentration of ownership may also delay, deter or prevent a change in control, and may make some transactions more difficult or impossible to complete without the support of MiCo, regardless of the impact of such transactions on our other shareholders. The interests of MiCo may differ from the interests of other shareholders and thus result in corporate decisions that are disadvantageous to other shareholders. On December 8, 2022, MiCo filed an initial Schedule 13D with the Commission wherein they indicated that they had sought a management change in order to, in their purported opinion, turn around the operational and financial performance of the Company. MiCo had previously sought to convene an extraordinary general meeting of the Company's shareholders to effect such a change. In late October 2022, two of MiCo's representatives resigned from their positions on the board of directors of the Company, with Aris Kekedjian, the third director nominated by MiCo, remaining as a director of the Company (having become the Company's CEO) and no extraordinary general meeting was convened. The Company is currently in discussions with MiCo in an effort to resolve the differences between the parties. No assurance can be given that MiCo will not seek to cause a change in our management in the future.

We are a foreign private issuer under the rules and regulations of the SEC and are therefore exempt from a number of rules under the Exchange Act and are permitted to file less information with the SEC than a domestic U.S. reporting company, which reduces the level and amount of disclosure that you receive.

As a foreign private issuer under the Exchange Act, we are exempt from certain rules under the Exchange Act, including the proxy rules, which impose certain disclosure and procedural requirements for proxy solicitations. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic U.S. companies with securities registered under the Exchange Act; and are not required to comply with Regulation FD, which imposes certain restrictions on the selective disclosure of material information. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ADSs. Accordingly, you receive less information about our company than you would receive about a domestic U.S. company and are afforded less protection under the U.S. federal securities laws than you would be afforded in holding securities of a domestic U.S. company.

As a foreign private issuer whose ADSs are listed on the NASDAQ Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the NASDAQ Stock Market Rules. Among other things, as a foreign private issuer we may also follow home country practice with regard to, the composition of the board of directors, director nomination procedure, compensation of officers and quorum at shareholders' meetings. In addition, we may follow our home country law, instead of the NASDAQ Stock Market Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Accordingly, our shareholders may not be afforded the same protection as provided under NASDAQ's corporate governance rules. In addition, as foreign private issuer, we are not required to file quarterly reviewed financial statements. A foreign private issuer that elects to follow a home country practice instead of such requirements must submit to NASDAQ in advance a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws.

We may be classified as a passive foreign investment company, or PFIC, which would subject our U.S. investors to adverse tax rules.

U.S. holders of our ADSs may face income tax risks. Based on the composition of our income, assets (including the value of our goodwill, going-concern value or any other unbooked intangibles, which may be determined based on the price of the ordinary shares), and operations, we believe we will not be classified as a "passive foreign investment company", or PFIC, for the 2022 taxable year. However, because PFIC status is based on our income, assets and activities for the entire taxable year, it is not possible to determine whether we will be characterized as a PFIC for our current taxable year or future taxable years until after the close of the applicable taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in the current year and future years will depend on our income, assets and activities in each of those years and, as a result, cannot be predicted with certainty as of the date hereof. Furthermore, fluctuations in the market price of our ordinary shares may cause our classification as a PFIC for the current or future taxable years to change because the aggregate value of our assets for purposes of the asset test, including the value of our goodwill and unbooked intangibles, generally will be determined by reference to the market price of our shares from time to time (which may be volatile). The IRS or a Court may disagree with our determinations, including the manner in which we determine the value of our assets and the percentage of our assets that are passive assets under the PFIC rules. Therefore, there can be no assurance that we will not be a PFIC for the current taxable year or for any future taxable year. Our treatment as a PFIC could result in a reduction in the after-tax return to U.S. Holders (as defined below under Item 10E. "Additional Information – Taxation") of our ADSs and would likely cause a reduction in the value of such shares. A foreign corporation will be treated as a PFIC for U.S. federal income tax purposes if either (1) at least 75% of its gross income for any taxable year consists of certain types of "passive income," or (2) at least 50% of the average value of the corporation's gross assets produce, or are held for the production of, such "passive income." For purposes of these tests, "passive income" includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties that are received from unrelated parties in connection with the active conduct of a trade or business. If we are treated as a PFIC, U.S. Holders of ADSs would be subject to a special adverse U.S. federal income tax regime with respect to the income derived by us, the distributions they receive from us, and the gain, if any, they derive from the sale or other disposition of their ADSs. U.S. Holders should carefully read Item 10E. "Additional Information – Taxation" for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of ADSs.

The market price of our ADSs has been, and may continue to be, highly volatile, and such volatility could cause the market price of our ADSs to decrease and could cause you to lose some or all of your investment in our ADSs.

The stock market in general and the market prices of the ADSs on Nasdaq, in particular, are or will be subject to fluctuation, and changes in these prices may be unrelated to our operating performance. During the first quarter of 2023, the market price of our ADSs fluctuated from a high of $1.18 per ADS to a low of $0.87 per ADS, and the price of our ADSs continues to fluctuate. We anticipate that the market prices of our securities will continue to be subject to wide fluctuations. The market price of our securities may be subject to a number of factors, including:

- announcements of new products by us or others;
- announcements by us of significant acquisitions, disposals, strategic partnerships, in-licensing, joint ventures or capital commitments;
- the developments of the businesses and projects of our various subsidiaries;
- expiration or terminations of licences, research contracts or other collaboration agreements;
- public concern as to the safety of the products we sell;
- the volatility of market prices for shares of companies with whom we compete;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in revenues, gross profits and earnings announced by us;
- changes in estimates or recommendations by securities analysts, if the ADSs are covered by analysts;
- fluctuations in the share price of our publicly traded subsidiaries;
- changes in government regulations or patent decisions; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors may materially and adversely affect the market price of our securities and result in substantial losses by our investors.

We expect we will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

We expect we will require additional capital in the future. If we continue to incur losses, we will need significant additional financing, which we may seek through a combination of private and public equity offerings, debt financings, and asset sales, etc. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of any such offerings may include liquidation or other preferences that may adversely affect the then existing shareholders rights. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt or making capital expenditures. If we raise additional funds through collaboration, strategic alliance or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licences on terms that are not favorable to us.

Future sales of our ADSs could reduce the market price of the ADSs.

Substantial sales of our ADSs may cause the market price of our ADSs to decline. Sales by us or our security holders of substantial amounts of our ADSs, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ADSs.

The issuance of any additional ADSs, or any securities that are exercisable for or convertible into our ADSs, may have an adverse effect on the market price of our ADSs and will have a dilutive effect on our existing holders of ADSs.

The conversion of our outstanding share options and warrants would dilute the ownership interest of existing shareholders.

The total share options exercisable at December 31, 2022, as described in Item 18, Note 19 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 A Ordinary Shares. The exercise of the outstanding share options 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, if all of the vested and currently exercisable options outstanding at April 15, 2023 were exercised, the Company would have to issue 17,101,339 additional 'A' Ordinary Shares (4,275,335 ADSs). Similarly, at April 15, 2023, if all of the outstanding warrants to purchase 'A' Ordinary Shares were exercised, the Company would have to issue 10,000,000 'A' Ordinary Shares (2,500,000 ADSs). On the basis of 152,830,282 'A' Ordinary Shares outstanding at April 15, 2023, the exercise of both the share options and the warrants would effectively dilute the ownership interest of the existing shareholders by approximately 15%.

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. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state Court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be recognized or enforceable in Ireland. A judgment of the U.S. Courts will be enforced by the Irish Courts if the following general requirements are met:

- the debt is for a liquidated or defined sum;
- the procedural rules of the U.S. Court must have been observed and the U.S. Court must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule); and
- the judgment must be final and conclusive and the decree must be final and unalterable in the Court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. If the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that, in the meantime, the judgment should not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive.

However, the Irish Courts may refuse to enforce a judgment of the U.S. Courts which meets the above requirements for one of the following reasons:

- if the judgment is not for a debt or a definite sum of money;
- if the judgment was obtained or alleged to have been obtained by fraud;
- if the process and decision of the U.S. Courts were contrary to natural or constitutional justice under the laws of Ireland and if the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice;
- if the judgment is contrary to Irish public policy or involves certain United States laws which will not be enforced in Ireland or constitute the enforcement of a judgment of a penal or taxation nature;

- if jurisdiction cannot be obtained by the Irish Courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Irish Superior Courts Rules;

- there is no practical benefit to the party in whose favor the foreign judgment is made in seeking to have that judgment enforced in Ireland, or

- if the judgment is not consistent with a judgment of an Irish Court in respect of the same matter.

In addition, actions in the United States under U.S. federal securities laws could be affected under certain circumstances by the Foreign Tribunals Evidence Act 1856, which is the statute applicable in Ireland to obtaining evidence in aid of foreign civil proceedings, which may preclude or restrict the obtaining of evidence in Ireland or from Irish persons in connection with those actions.

We have no plans to pay dividends on our ADSs, and you may not receive funds without selling the ADSs.

We do not expect to pay any cash dividends on our ADSs for the foreseeable future. We currently intend to retain any additional future earnings to finance our operations and growth and, therefore, we have no plans to pay cash dividends at this time. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent on our earnings, financial condition, operating results, capital requirements, any contractual restrictions, and other factors that our board of directors deems relevant. Accordingly, you may have to sell some or all of the ADSs in order to generate cash from your investment. You may not receive a gain on your investment when you sell the ADSs and may lose the entire amount of your investment.

The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise your right to direct the voting of your Class A ordinary shares underlying the ADSs.

Holders of ADSs do not have the same rights as our registered shareholders. As a holder of the ADSs, you will not have any direct right to attend general meetings of our shareholders, cast any votes at such meetings or otherwise exercise the rights of registered shareholders set out in our articles of association or in Irish law. You will only be able to exercise the voting rights which attach to the Class A ordinary shares underlying the ADSs indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement with the depositary, you may vote only by giving voting instructions to the depositary, as the registered holder of the Class A ordinary shares underlying the ADSs. If the depositary asks for your instructions, then upon receipt of such voting instructions, it will try to vote the underlying Class A ordinary shares in accordance with these instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with instructions you give, but it is not required to do so. You will not be able to directly exercise any right to vote with respect to the underlying Class A ordinary shares unless you withdraw the shares underlying your ADSs and become the registered holder of such shares prior to the record date for the general meeting. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to enable you to withdraw the shares underlying the ADSs and become the registered holder of such shares prior to the record date for such general meeting to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. Where any matter is to be put to a vote at a general meeting, upon our instruction, the depositary will notify you of the upcoming vote and deliver our voting materials to you. We cannot assure you that you will receive the voting materials in time to ensure you can direct the depositary to vote the Class A ordinary shares underlying your ADSs in accordance with your instructions. In addition, the depositary and its agents are not responsible for failing to carry out your voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the shares underlying the ADSs are voted and you may have no legal remedy if the shares underlying the ADSs are not voted as you instructed.

Our securities could be delisted from Nasdaq if we do not comply with Nasdaq's listing standards.

Our ADSs are listed on the NASDAQ Capital Market under the symbol "*TRIB*." To continue to be listed on the NASDAQ Capital Market, we need to satisfy a number of conditions, including to maintain a minimum bid price of $1.00 per ADS and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. As of the date of this Annual Report on Form 20-F, we were in compliance with the Nasdaq continued listing requirements. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), if we fail to remain in compliance with the minimum bid price requirement we will be given 180 days to regain compliance. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice to us that our ADSs will be subject to delisting.

If our ADSs become subject to delisting, they would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our ADSs. This would adversely affect the ability of investors to trade our ADSs and would adversely affect the value of our ADSs. Delisting could also impair our ability to raise capital.

Item 4. Information on the Company

A. History and Development of the Company

We were incorporated in Ireland in 1992 as a private limited company and re-registered as a public limited company ("plc") in July of that year. In October 1992 we completed an initial public offering of our securities in the US and our ADS have traded on the Nasdaq Global Market since that time under the symbol "TRIB.".

The principal offices of our company are located at IDA Business Park, Bray, County Wicklow, Ireland. The Group has expanded its product base through internal development and acquisitions.

Our website address is https://www.trinitybiotech.com/ . The information contained on, or that can be accessed from, our website does not form part of this Annual Report. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as we, that file electronically, with the SEC at www.sec.gov.

B. Business Overview

Overview

We and our subsidiaries (the "Group") develop, acquire, manufacture and market 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. We are also a significant provider of raw materials to the life sciences and research industries globally through Fitzgerald Industries. Refer to Item 18, Note 28, Post Balance Sheet Events for more information on the sale of the Fitzgerald Industries in April 2023.

We market our portfolio of several hundred products to customers in approximately 100 countries around the world through our own sales force and a network of international distributors and strategic partners.

Organisational Structure

While our executive offices are located at Bray, Ireland, our research and development, manufacturing and marketing activities are principally conducted at the following:

- Trinity Biotech Manufacturing Limited, based in Bray, Ireland;
- Clark Laboratories Inc, based in Jamestown, New York;
- Primus Corporation, based in Kansas City;
- Biopool US Inc (trading as Trinity Biotech USA), based in Jamestown, New York;
- Immco Diagnostics Inc, based in Amherst and Buffalo, New York;
- Nova Century Scientific Inc, based in Burlington, Canada; and
- Trinity Biotech Brazil based in Sao Paulo, Brazil.

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.

Principal Markets

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

Point-Of-Care	Clinical Laboratory				
Infectious Diseases	**Infectious Diseases**	**Haemoglobin**	**Autoimmune**	**Clinical Chemistry**	**Blood Bank Screening**
UniGold	MarDx	Premier	ImmuBlot	EZ	Captia
Recombigen	FlexTrans	Ultra	ImmuGlo		
Trinscreen			ImmuLisa		
			OTOblot		

We also sell raw materials to the life sciences industry and research institutes globally through our wholly owned subsidiary, Benen Trading Ltd., trading as Fitzgerald Industries.

We sell our products through our direct sales organisations in the United States, Brazil and to an extent in the United Kingdom, France and Germany and then through our 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-Gold™ 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™ HIV. In Africa, Uni-Gold™ HIV has been used for many years in voluntary counselling and testing centers in the sub-Saharan region where it is a cornerstone to early detection and treatment intervention.

Trinscreen

In Africa, HIV testing typically involves using a point-of-care rapid test for screening followed by a different rapid test as the confirmatory test. Our Uni-Gold™ HIV product is a leading confirmatory HIV test in the African market.

Point-Of-Care is key to the growth of Trinity Biotech. Central to this growth is our new HIV screening test, TrinScreen HIV, which received World Health Organisation approval in February 2022. Trinity Biotech has not previously competed in the larger screening market, which is estimated to be valued at approximately US$150 million p.a. The screening market is addressed by few companies. TrinScreen should not significantly jeopardise our existing confirmatory business as it employs a different HIV antigen to the existing Uni-Gold™ HIV test. In other words, countries will be able to use both the TrinScreen HIV test and the Uni-Gold™ HIV test as part of their testing algorithm. Our strategy is to leverage the existing brand equity of Trinity Biotech in African markets to take market share in the screening market. This initiative will be supported by increased sales and marketing resources in the African market. Market opportunities for the TrinScreen HIV product also exist in other territories, in particular in emerging countries.

These point-of-care products will be sold through Trinity Biotech's sales and marketing organisation to a variety of customers including public health authorities, non-governmental organisations, clinical and reference laboratories directly in the United Kingdom, France and Germany and through independent distributors and strategic partners in other countries.

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;
- Glycated haemoglobin (for diabetes monitoring and diagnosis) and haemoglobin variants for the detection of haemoglobinopathies (haemoglobin abnormalities);
- Autoimmune diseases.

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

Infectious Diseases
Trinity Biotech manufactures kits for the detection of specialty and esoteric biomarkers of infectious diseases and other associated laboratory products. The products are used in processing patient samples whose results aid physicians in the diagnosis and clinical assessment of a broad range of infectious diseases. The key clinical laboratory disease areas that Trinity Biotech serves include:

- Sexually transmitted diseases, including Syphilis and Herpes;
- Markers for Epstein Barr, Measles, Mumps, Toxoplasmosis, Cytomegalovirus, Rubella, Varicella and other viral pathogens;
- Lyme disease; and
- SARS-CoV-2.

Trinity Biotech develops, manufactures and distributes products predominantly in enzyme-linked immunosorbent assay ("ELISA") format. As a complement to its product range, the company also offers third party automated processors to its customers.

Many of the products in our Infectious Diseases product line are FDA cleared for sale in the United States and CE marked in Europe. Products are sold in approximately 100 countries in total, 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 a variety of customers including public health authorities, clinical and reference laboratories directly in the U.S. and U.K. and through independent distributors and strategic partners in other countries.

Diabetes and Haemoglobinopathies

Trinity Biotech manufactures products for in-vitro diagnostic measurement of haemoglobin A1c ("HbA1c") used in the monitoring and diagnosis of diabetes, as well identifying those who are at a high risk of developing diabetes (pre-diabetic). The Premier Hb9210 uses boronate affinity technology to measure HbA1c which is a marker of a patient's average blood sugar control over the last 100 to 120 days. It is a highly accurate biomarker available for the diagnosis of diabetes and is a strong indicator of a diabetic's glycemic control. HbA1c is also used to identify those at risk of becoming diabetic; often referred to as impaired glucose tolerance. Additionally, HbA1c is used in the assessment of diabetes complications.

Trinity Biotech manufactures its own HbA1c instrument, the Premier Hb9210, which was launched in Europe and obtained FDA approval in late 2011. In Europe, Trinity Biotech distributes Premier Hb9210 through its partner A. Menarini. In the USA and Brazil, Trinity Biotech sells the Premier Hb9210 through its own direct sales organisations. In the rest of the world, Trinity sells the Premier Hb9210 through a network of distributors. The Premier's unique features, cost structure and core technology enable it to compete in most economies and settings.

Trinity Biotech also sells products for haemoglobin variants, through the Premier Resolution (CE cleared - meaning it can be sold in the EU). The Premier Resolution detects and identifies haemoglobinapothies. These are genetic defects that result in abnormal structure of the haemoglobin molecule. Haemoglobinapathies include sickle-cell diseases, alpha and beta thalassemia which are amongst the most common genetic disorders in the world.

Trinity Biotech has launched the Premier Resolution, its next generation Haemoglobinapothy Analyzer in Europe and the Middle East after undergoing rigorous and successful field trials. In 2022, we submitted a 510(k) clearance for the Premier Resolution to the FDA. The Premier Resolution uses an internally designed column as well as state of the art hardware and software.

Autoimmune Diseases

Autoimmune diseases are diseases that involve an abnormal immune response in which the immune system attacks the body's own cells and tissues.

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

- Immunofluorescence Assay ("IFA");
- Enzyme-linked immunosorbent ("ELISA");
- Western Blot ("WB"); and
- Line immunoassay ("LIA").

Many of Immco's products are FDA cleared for sale in the U.S. and CE marked in Europe. The Immco product line addresses the lower throughput, specialty 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.

In addition, Immco markets a panel of proprietary early markers for Sjögrens disease often referred to as "dry eye disorder".

The Immco products are sold through Trinity Biotech's sales and marketing organisation to clinical and reference laboratories directly in the USA and via distributors in other countries.

The diagnostic product line is complemented by Immco's New York State Department of Health licenced reference laboratory offering specialised services in diagnostic immunology, pathology and immunogenetics, and is marketed to U.S.-based reference laboratories and hospitals.

Clinical Chemistry

The speciality clinical chemistry business of Trinity Biotech includes reagent products such as ACE, bile acids, oxalate and glucose-6-phosphate dehydrogenase ("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 manufactures enzyme-linked immunosorbent assays ("ELISA"), for the detection of Syphilis and Malaria. These products are sold through distributors and are manufactured under original equipment manufacturer agreements for other major third party diagnostic companies. The business is not currently operating in the United States.

Sales and Marketing

Trinity Biotech sells its products 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 Diseases, Haemoglobins, Autoimmune and Clinical Chemistry products. Meanwhile the direct sales force in Brazil sells the company's haemogloblins product range.

Through its international sales and marketing organisation, which is located 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 approximately 100 countries.

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. This is a technology driven market with an emphasis on automation and emerging biomarkers. Trinity actively works on increasing automation for the clinical laboratory. Trinity seeks to bring novel biomarkers to market by licensing agreements with universities and innovative companies.

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

Research and Development

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 2022, a number of third-party consultants and contractors were engaged to assist with development projects, working principally on the Covid antigen projects. The total amount paid to these R&D consultants and contractors in 2022 was US$707,000 (2021: US$807,000).

Research and Products under Development

Trinity Biotech has research and development groups focusing separately on haemoglobin and infectious diseases products. During 2022, these groups were located in Ireland 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 (before amortization and impairment) incurred as at 31 December 2022:

Product Name	*2022* *US$'000*	*2021* US$'000	*Total project costs to December 31, 2022*[1] US$'000
Premier Instruments for A1c and haemoglobinopathies testing	1,904	2,538	37,828
HIV screening rapid test	379	1,488	12,619
COVID-19 tests[2]	1,378	1,320	3,165
Mid-tier haemoglobins instrument	484	303	1,093

[1] Cumulative costs to December 31, 2022 are shown before deduction of amortization and impairment losses.

[2] In 2022, the development expenditure on COVID tests related to a rapid COVID-19 antigen test which was approved for professional use in the EU during 2022. However, the demand for our COVID-19 portfolio of products is highly uncertain and very difficult to predict and in our experience the market has moved to over the counter ("OTC") rapid COVID-19 tests, for which this product is not yet approved. As such the Company's efforts to commercialise this test have been unsuccessful. In addition, pricing for rapid COVID-19 tests in the EU is relatively weak, with stronger pricing available in, for example, the US market, for which this product is not yet approved. Given the market outlook for rapid COVID-19 testing products and continued uncertainty regarding regulatory approval pathways in key markets, including the US, management has chosen to not immediately pursue further regulatory approvals but does intend to monitor these markets and regulatory pathways with a view to potentially seeking additional regulatory approvals. However, as the Company has no imminent plans to pursue these regulatory approvals, these intangible assets were written down to zero in 2022.

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.

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 these phases 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. 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:

Haemoglobin Development Group

Premier Hb9210 Instrument for Haemoglobin A1c Testing

A multi-generational product development plan focussed on improvements in our flagship Premier 9210 instrument has commenced. With phased launches planned across the next 18 months, the package of changes is expected to expand the target market, reduce instrument downtime and service cost, and significantly expand operating margins. New features are expected to include an enhanced column delivering up to three times the current injection capacity and stability, a reduced frequency of calibration, and an improved user interface and lab system integration.

Premier Resolution Instrument for Haemoglobin Variant Testing

We have developed the Premier Resolution instrument which is utilised for haemoglobin variant testing and is currently being rolled out in certain international markets outside of the USA. We continue to work closely with the FDA to gain clearance of our 510(k) submission for this instrument and we are planning the USA launch in 2023. Meanwhile, Premier Resolution continues to be enhanced with unique features such as lot specific gradients, an optimised internally designed column with extended column life, and a rapidly expanding on-board variant library.

Low to Medium throughput Haemoglobin instrument for A1c Testing

We are developing a low to medium throughput Haemoglobin A1c instrument with a view to targeting the market segment for testing volumes lower than the Premier Hb9210. We are targeting a launch date in the next two years.

Tri-stat instrument

In 2022, there was a strategic review of our Tri-stat instrument as part of a broader review of our haemoglobins product portfolio. In order to rationalise the haemoglobins product portfolio and to allow us to focus our resources on the higher growth products within that portfolio, management decided that Tri-stat sales would be restricted to only certain targeted partnerships. Further development of the instrument ceased at the end of the third quarter of 2022.

Point-of-Care Development Group

A syphilis point-of-care rapid test is also being developed using our existing lateral flow format. In 2022, other projects were prioritized, but it is expected this project will resume within the next one to two years.

Autoimmunity Development Group

IFA Smart Reader Project

We have been developing ScopeSmart, an automated IFA reader capable of performing image capture, pattern recognition and analysis on IFA slides. The development project was paused in 2022 as management reviewed other options, including the potential to proceed with a third-party reader instead of our own internally developed reader. Following this review, we determined that there were likely greater opportunities to capture more market share in a more capital efficient manner through partnering with a third-party reader manufacturer rather than pursuing an independent strategy. There is significant uncertainty if we will complete the project to develop our own in-house autoimmune smart reader but we may re-visit this decision in the future.

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 licensing arrangements including the following:

Immco entered into a licence agreement on January 19, 2012, and subsequently an amended licence agreement on June 14, 2018. The licence pertains to any product or service relating to identifying indicators of Sjogren's disease. The agreement is effective through January 21, 2036 and is worldwide in scope. Royalties are payable based on agreement in place.

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.

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 licensing arrangements disclosed under this subheading terminates on the date expiration or adjudication of invalidity or unenforceability of the last of the particular licenced patents covered by the respective agreement. 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 licenced. The total amount paid by Trinity Biotech under key licensing arrangements in 2022 was US$360,000 (2021: US$540,000).

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 Products Regulatory Authority (as the authority over Trinity Biotech in Europe), the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom 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 54% of Trinity Biotech's 2022 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

Many 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 products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. Other 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 or 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, labelling 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 U.S. 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 labelling, 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 process. 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. In February 2022, FDA published proposed regulation to update the Quality System Regulation to incorporate the international standard specific for medical device quality management systems (ISO 13485). If finalized, the quality management system requirements for FDA-regulated devices would be harmonized with the ISO 13485 standards.

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 labelled 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 ("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 non-invasive;
- 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 labelling 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, ("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;
- labelling 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 facilities with the FDA as medical device manufacturers. 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. In 2017, the FDA closed its pilot program for MDSAP (Medical Device Single Audit Program) and began accepting third party inspection reports from approved Auditing Organizations in lieu of conducting its own routine surveillance inspections. MDSAP audits are paid by the manufacturer and conducted annually. The FDA receives and reviews the MDSAP report and may respond to the manufacturer with its own inspection if it deems the facility is not in control. 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, ("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 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 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 the CLIA certificate for our Autoimmune Reference Laboratory, 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 supplies 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 provided notice that it intended to issue draft guidance to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. As part of developing this framework, the FDA issued draft guidance in October 2014 that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. 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. FDA issued a discussion paper on LDTs in January 2017 discussing possible approaches to oversight of LDTs.

Some products are for research use only ("RUO"), or for IUO. RUO and IUO products are not intended for human clinical use and must be properly labelled 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 Labelled 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, labelling 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 Imports/Exports

Products for export from the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate for Foreign Government ("CFG"). To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with QSR regulations at the time of the last FDA inspection. If the FDA determines that our facilities or procedures do not comply with the QSR regulations, it may refuse to provide such certificates until we resolve the issues to the FDA's satisfaction. Failure to obtain a CFG could inhibit our ability to export our products to countries that require such certificates.

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.

Foreign Corrupt Practices Act and Other Anti-Corruption Laws

The U.S. Foreign Corrupt Practices Act ("FCPA"), to which we are subject, prohibits corporations and individuals from engaging in bribery and corruption when dealing with foreign government officials and foreign political parties. It is illegal to corruptly offer, pay, promise, or authorize the giving of anything of value to any officer or employee of a foreign government or public international organization, political party, political party official, or political candidate, in an attempt to obtain or retain business or to otherwise improperly influence a person working in an official capacity on behalf of a foreign government or public international organization. Our present and future business has and will continue to be subject to the FCPA and various other laws, rules and/or regulations applicable to us as a result of our international sales. We also are subject to the FCPA's accounting provisions, which require us to keep accurate books and records and to maintain a system of internal accounting controls sufficient to assure management's control, authority, and responsibility over the company's assets. The failure to comply with the FCPA and similar laws could result in civil or criminal sanctions or other adverse consequences.

The laws to which we are subject as a result of our international sales also include the U.K. Bribery Act (the "Bribery Act"), which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

Healthcare Reform

The Protecting Access to Medicare Act of 2014 ("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 is 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 ("ACA"), 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 ("HHS"), has issued regulations to protect the privacy and security of individually identifiable health information, also known as protected health information ("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.

Federal Physician Payment Sunshine Act

The U.S. Physician Payment Sunshine Act requires certain manufacturers of drugs, biologics, devise and medical supplies to record any transfers of value to certain U.S. healthcare providers and U.S. teaching hospitals. These payments and transfers of value must be reported annually to CMS Open Payments. Sunshine Act reporting requirements were expanded in 2021 to include any payments and transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anaesthetists, and certified nurse-midwives. Failure to comply with Sunshine Act reporting requirements may result in civil monetary penalties of up to $100,000 for each knowing violation.

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 ACA, 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 licenced 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 licenced 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 licence, censure the holder of the licence 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. We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval (or pre-qualification or endorsement) from local regulators in such countries or international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. We generally pursue approval only in those countries that we believe have a significant market opportunity.

The International Organization for Standardization ("ISO") is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of the ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services. ISO 13485 certification indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution.

In the European Union (EU), diagnostic products are also categorized into four risk categories and the regulatory process, which is governed by the European In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746) with 3 of the product categories requiring review and approval by an independent company, known as a Notified Body, before the manufacturer can affix a CE mark to the product to declare conformity to the Regulation. The remaining product category, where - low patient and public health risk is presented, only require a self-certification process.

In the medical devices segment, the research and development process begins with research on a specific technology that is evaluated for feasibility and commercial viability. If the research program passes that hurdle, it moves forward into development. The development process includes evaluation, selection and qualification of a product design, completion of applicable clinical trials to test the product's safety and efficacy, and validation of the manufacturing process to demonstrate its repeatability and ability to consistently meet pre-determined specifications.

In the EU, medical devices are also categorized into different classes and the regulatory process, which is governed by the European Medical Device Regulation (Regulation (EU) 2017/745, requires each product to bear a CE mark to show compliance with the Regulation.

Some products require submission of a design dossier to the appropriate regulatory authority for review and approval prior to CE marking of the device. For other products, the company is required to prepare a technical file which includes testing results and clinical evaluations but can self-certify its ability to apply the CE mark to the product. Outside the U.S. and the EU, the regulatory requirements vary across different countries and regions.

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.

C. Organizational Structure

Please refer to Note 30 to our audited consolidated financial statements ("Group Undertakings") included elsewhere in this Annual Report for a listing of our significant subsidiaries, including name, country of incorporation, and proportion of ownership interest.

D. Property, Plants and Equipment

Our headquarters, manufacturing and research and development facilities as well as our sales offices are located in Bray Ireland. We have entered into a number of related party transactions with JRJ Investments ("JRJ"), a partnership currently owned by Mr Ronan O'Caoimh and Dr Walsh, directors of the Company, and directly with Mr O'Caoimh, to provide premises in Bray, Ireland. We entered into an agreement for a 25 year lease with JRJ effective from December 2003 for 15,780 square feet of offices at an annual rent of €381,000 (US$406,000). In 2007 we entered into a 25-year lease agreement with JRJ for a 43,860 square foot manufacturing facility in Bray, Ireland with an annual rent of €787,605 (US$838,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. In 2016, we entered into a 10-year lease with Mr. O'Caoimh for a warehouse adjacent to our leased manufacturing facility in Bray, Ireland. The warehouse is 16,000 square feet with an annual rent of €144,000 (US$153,000). In late 2020, the Group occupied some additional space adjoining the warehouse owned by Mr O'Caoimh. This was a short-term arrangement, and no payments were made for the additional space during 2020 and 2021. The Company vacated this space in 2021. In 2022, the rent payable to Mr O'Caoimh of US$90,000 was settled. See Item 7 – Major Shareholders and Related Party Transactions.

For the majority of 2022, we had six main manufacturing sites worldwide, five in the Americas (Amherst, Williamsville and Jamestown, NY, Kansas City, MO, and Extrema, Brazil), and one in Bray, Ireland. In November 2022 the number of manufacturing sites was reduced to five when we vacated the site located in Amherst and consolidated our Buffalo operations in the nearby existing Williamsville site. 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 registered and ISO certified facilities. As part of our ongoing commitment to quality, each Trinity Biotech facility was granted the latest ISO 13485 certification. This certification was granted by internationally recognised notified bodies. This 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 we will consistently manufacture products in a controlled manner. To achieve this certification, each Trinity Biotech facility performed an extensive review of the existing quality system and implemented any additional regulatory requirements.

The facilities at Jamestown, NY, Kansas City, MO and Bray, Ireland also achieved certification to the requirements of the Medical Device Single Audit Programme (MDSAP). The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. International regulatory authorities that are participating in the MDSAP include, US Food and Drug Administration, Therapeutic Goods Administration of Australia, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers.

Trinity Biotech USA operates from a 25,610 square foot FDA registered facility in Jamestown, New York. The facility was purchased in 1994. Additional warehousing space is rented in Jamestown, New York at an annual rental charge of US$203,000.

Primus Corp. operates from a 39,000 square foot facility in Kansas City, Missouri and an adjacent 13,500 square foot facility mainly used for warehousing. The leases on these properties run until 2025 and 2027 respectively and annual rents are US$133,000 and US$61,000 respectively.

For the majority of 2022, Immco Diagnostics Inc. operated from a 20,520 square foot facility in Amherst, New York and a 31,731 square foot facility in Williamsville, New York. The lease for the Amherst site expired in November 2022. In November 2022, we vacated the site located in Amherst, Buffalo and consolidated our Buffalo operations into the nearby site at Williamsville. The lease for the Williamsville site expires in 2034. The annual rent for the now vacated Amherst facility was US$259,000. The Williamsville facility's annual rent is currently US$405,000, rising to US$452,000 by 2029. An additional 5,120 square foot facility is owned by Trinity Biotech in Burlington, Canada.

Additional office and factory space is leased by the Group in Acton, Massachusetts, Sao Paulo, Brazil and Extrema, Brazil at an annual cost of US$104,000, US$11,000 and US$58,000 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, expand our existing facilities or outsource operations.

The following are the facilities where the Group currently manufactures products:

Bray, Ireland – Point-of-Care/HIV, 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. Viral Transport Media products are also manufactured at this facility.

Kansas City, Missouri – this site is responsible for the manufacture of the Group's haemoglobin range of products. It also carries out all of the Group's haemoglobin R&D activities.

Buffalo, New York – this site is responsible for the manufacture of autoimmune test kits along with its reference laboratory business.

Extrema, Brazil - this site is responsible for the manufacture of some of the haemoglobin range of products sold in Brazil.

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

Principal Capital Expenditure and Divestitures

Our principal capital expenditure in the last three financial years has been on developing new products internally. The amount capitalized for development projects has been US$4.5million, US$6.8 million, US$6.9 million for years ended December 31, 2022, 2021 and 2020 respectively. In 2023, we expect the capital expenditure on development projects will be in the range US$1,400,000 to US$2,400,000, however this remains subject to ongoing review.

Item 4A. ***Unresolved Staff Comments***

Not applicable.

Item 5. ***Operating and Financial Review and Prospects***

A. ***Operating Results***

Overview

We develop, manufacture and market 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 hundreds of different diagnostic products in approximately 100 countries. In addition, the Group manufactures its own diagnostic instrumentation. Through our Fitzgerald subsidiary, we are a provider of raw materials to the life sciences industry.

Our consolidated financial statements include the attributable results of Trinity Biotech plc and all its subsidiaries. This discussion covers the years ended December 31, 2022 and December 31, 2021 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.

We have relied on an exemption under the SEC's 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, 2022 as Trinity Biotech is a foreign private issuer and the financial statements have been prepared in accordance with IFRS as issued by the IASB.

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 significant revenue-generating products, carry out the necessary development work 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, 2022 and 2021 were impacted by impairment losses as a result of impairment reviews during the years ended December 31, 2022 and 2021 (See Item 18, Note 12).

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

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the discharge of liabilities in the normal course of business for the foreseeable future.

As reflected in the accompanying consolidated financial statements, for the years ended December 31, 2022 and 2021, we recorded a loss of US$41.0 million and a profit of US$0.9 million, respectively. In addition, for the years ended December 31, 2022 and 2021, we reported cash outflows of US$19.2 million and US$1.5 million, respectively. As of December 31, 2022, we had net current assets of US$29.3 million but had an accumulated deficit in equity attributable to the equity holders of the Company of US$2.2 million.

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the amendment and restatement of the term loan with Perceptive, and the divestiture of the Fitzgerald Industries life sciences supply business. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report, and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At the date of this report, the Group's liquidity position has substantially improved following the sale of its Fitzgerald life sciences business for cash proceeds of approximately $30 million (subject to customary adjustments). This transaction substantially improves the Group's capital structure by reducing gross debt by approximately US$10 million; with the balance of the proceeds (net of costs) providing significant capital for growth, transformation, and potentially further debt reduction. There are no material debt maturities until 2026.

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, the Brazilian Real and Canadian Dollar. Trinity Biotech's revenues are primarily denominated in US Dollars and its expenses are incurred principally in US Dollars, Euro and Brazilian Real. The weakening of the US Dollar could have an adverse impact on future profitability.

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 or Brazilian Real and the US Dollar may impact on the Group's Euro or Real monetary assets and liabilities and on Euro, Swedish Krona or Real expenses and consequently the Group's earnings.

Impact of Covid-19 Pandemic

Our revenues decreased by US$18.2 million or 19.6% in 2022 compared to 2021. The decrease is mainly due to lower sales of our COVID-19 focussed PCR Viral Transport Media products, as a result of the curtailing of large-scale PCR testing of the population in North America. Outside of our PCR Viral Transport Media products, the COVID-19 pandemic had an insignificant impact on our revenues in 2022, except for sales of infectious diseases products in China, where sales opportunities were hindered by a return to COVID-19 quarantine restrictions.

Covid-19 products

We developed three different Covid-19 diagnostic tests, namely a COVID-19 antibody test using an ELISA platform, a COVID-19 rapid antibody test and a rapid COVID-19 antigen test. To date we have not commercialised any of these tests. The antigen test is approved for professional use in the EU. However, the demand for our COVID-19 portfolio of products is highly uncertain and very difficult to predict and in our experience the market has moved to over-the-counter rapid COVID-19 tests, for which this product is not yet approved. As such the Company's efforts to commercialise this test have been unsuccessful. In addition, pricing for rapid COVID-19 tests in the EU is relatively weak, with stronger pricing available in, for example, the US market, for which this product is not yet approved. Given the market outlook for rapid COVID-19 testing products and continued uncertainty regarding regulatory approval pathways in key markets, including the US, management chose not to immediately pursue further regulatory approvals but does intend to monitor these markets and regulatory pathways with a view to potentially seeking additional regulatory approvals. We have no imminent plans to pursue these regulatory approvals.

Operations and Employee Safety

In response to the COVID-19 pandemic, we implemented health and safety policies to help safeguard our on-site employees and maintain business continuity, and these policies resulted in enhanced cleaning procedures, additional personal hygiene supplies and protective equipment. Where practical, we facilitated many employees to work remotely. Since the beginning of the pandemic, we have been able to maintain our operations without significant interruption. As the effects of the pandemic eased in 2022, some of these health and safety policies were relaxed where appropriate. Remote workers have been encouraged to attend our offices more frequently.

Supply Chains

In common with most companies, the pandemic caused delays in our supply chain, which have to a large extent been eliminated. We are continuously evaluating our supply chain to identify potential gaps and take steps intended to ensure continuity.

Outlook

The extent to which demand for our Covid-19 portfolio of products is sustained into 2023 and beyond is highly uncertain and very difficult to predict. Widespread public testing programmes for COVID-19 using PCR tests have largely been discontinued across North America. In 2022, PCR VTM revenues accounted for approximately 4% of total Group revenues. We expect the amount of our Covid-19 portfolio of products as a percentage of total Group revenues to diminish further in 2023.

Year ended December 31, 2022 compared to the year ended December 31, 2021

Revenues

Trinity Biotech's revenues for the year ended December 31, 2022 were US$74.8 million compared to revenues of US$93.0 million for the year ended December 31, 2021, which represents a decrease of US$18.2 million or 19.6%.

The decrease is mainly due to lower sales of our PCR Viral Transport Media ("VTM") products. In 2020-21, demand for VTM products was very strong with demand exceeding supply due to a limited worldwide manufacturing capacity. As the pandemic persisted, manufacturing capacity ramped up significantly with a consequent negative impact on selling prices. Excluding our Covid focused PCR VTM products, 2022 revenues of US$71.5 million were 1.0% lower than in 2021.

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

	Year ended December 31,		
	2022 US$'000	**2021 US$'000**	**% Change**
Revenues			
Clinical laboratory goods	58,294	74,700	(22.0%)
Clinical laboratory services	7,272	7,928	(8.3%)
Point-of-Care	9,213	10,337	(10.9%)
	74,779	**92,965**	**(19.6%)**

Clinical Laboratory Goods

Clinical Laboratory goods revenues decreased by US$16.4 million in 2022, which represents a decrease of 22.0%. The decrease is mainly due to lower sales of our PCR VTM product. The decrease is mainly due to lower sales volumes for our COVID-19 VTM products. While the outlook relating to COVID-19 products remains unpredictable, the Company has retained the capability to flex manufacturing volumes should market conditions warrant it.

Partly offsetting the reduction in revenues from our PCR VTM products was a continued strong performance in our haemoglobins product line, particularly for our diabetes products which recorded a year-on-year revenue increase of US$4.2m or 26.6%. The growth driver in this product line is the higher instrument installed base and continuing high incidence of diabetes, particularly in Asia and Latin America.

Fitzgerald Industries, our life science raw materials recorded single digit revenue growth in 2022. Autoimmune product revenues in 2022 recorded a slight decrease of US$0.2 million compared to 2021, mainly due to lower sales in Europe.

Clinical Laboratory Services

Our New York reference laboratory offers laboratory-testing services for autoimmune disorders, such as Sjogren's syndrome, hearing loss, celiac disease, lupus, rheumatoid arthritis and systemic sclerosis. Revenues for the laboratory decreased by 8.3% to US$7.3 million. While revenues for our proprietary Sjogren's syndrome test increased by 11% compared to 2021 these were offset by a reduction in testing for other disorders due to customer attrition. In addition, the laboratory has provided transplant testing services to a local healthcare provider for a number of years, however in early 2023 that healthcare provider informed the Company that it was moving to a different service provider and this will result in lost revenues for the laboratory beginning quarter 2, 2023.

Point-of-Care

Point-of-Care revenues decreased from US$10.3 million in 2021 to US$9.2 million in 2022, a decrease of US$1.1 million or 10.9%. This decrease reflected significant non-recurring bulk orders of HIV tests from Nigeria in 2021.

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,		
	2022 US$'000	2021 US$'000	% Change
Revenues			
Americas	40,176	57,799	(30.5%)
Asia/Africa	25,022	25,504	(1.9%)
Europe	9,581	9,662	(0.8%)
Total	**74,779**	**92,965**	**(19.6%)**

In the Americas, revenues decreased US$17.6 million or 30.5% mainly due to decreased sales of our VTM products which were used in the COVID-19 testing programs in U.S. and Canada. To a lesser extent, haemoglobin revenues were impacted by the discontinuation of sales of the Ultra II instrument reagents in U.S. in the early part of 2021.

In Asia/Africa, revenues decreased by 1.9%, or US$0.5 million compared to 2021. The decrease is mainly due to lower Point-of-Care revenues in Africa reflecting significant non-recurring bulk orders of HIV tests from Nigeria in 2021 and lower sales of infectious diseases products to China due to strict public health quarantines which limited patients' ability to visit hospitals and clinics to get tested for diseases. This was largely offset by an increase in haemoglobins revenues in Asia. There was particularly strong demand for our diabetes products in Asia with year-on-year revenue growth of 36%. We continue to scale our commercial coverage in these markets where the increase in the incidence of diabetes and propensity for haemoglobin variants is at some of its highest rates and our boronate affinity technology has a particular competitive advantage.

In Europe, revenues decreased by US$0.1 million, or 0.8% compared to 2021. There were decreased revenues for autoimmune and clinical chemistry products, with the latter being caused by supply chain issues for a key raw material which limited our production output of the oxalate and G6PDH products. These decreases were largely offset by strong European demand for our haemoglobins products and for our life science business, Fitzgerald Industries.

Cost of sales, gross profit and gross margin

Total cost of sales decreased by US$2.2 million from US$54.9 million for the year ended December 31, 2021 to US$52.7 million, for the year ended December 31, 2022, a decrease of 3.9%. This resulted in a gross profit for 2022 of US$22.0 million compared to a gross profit for 2021 of US$38.1 million. The gross margin of 29.5% in 2022 compares to a gross margin of 41.0% in 2021.

The gross profit for the year ended December 31, 2022 reflects significant excess inventory and obsolescence charges of US$4.7m recorded in Q3 2022, consisting of the following:

i. VTM inventory write down (US$3.5 million) – as disclosed previously, we have not seen any evidence during the winter season of 2022-23 of significant peaks in demand for VTM products. This has led management to revisit our strategy of maintaining significant levels of raw materials inventory to meet demand peaks. Consequently, the value of inventory was written down in Q3, 2022 to our estimate of its net realisable value.

ii. Other inventory write down (US$0.9 million) - the value of certain excess raw materials and work in progress was written down in Q3, 2022 following a review and an update to our relevant quality assurance policy.

iii. Tri-stat inventory write down (US$0.3 million) - as disclosed previously, we undertook a strategic review of our Tri-stat instrument line as part of a broader review of our haemoglobins product portfolio. Management decided to limit sales of Tri-stat to certain targeted partnerships and as a consequence the value of this inventory was written down to reflect the revised outlook.

Excluding the effect of these significant excess inventory and obsolescence charges of US$4.7 million, the gross margin was 35.8% for fiscal year 2022, compared to 41.0% for the year ended December 31, 2021. The remainder of the reduction in gross margin in the year ended December 31, 2022 compared to year ended December 31, 2021 is largely due to sales mix changes, particularly the reduction in higher margin PCR VTM, inflationary increases in the price of raw materials and an under recovery of labour and overhead costs at three of our manufacturing facilities due to reduced production activity, partially driven by limited VTM production. To mitigate the impact of rising input costs, management implemented sales price increases where appropriate.

Other operating income

Other operating income decreased from US$4.7 million in the year ended December 31, 2021 to US$0.3 million in the year ended December 31, 2022. Other operating income in 2022 consist of government grants for R&D activities. In 2021, the US$4.7 million of Other operating income related to loan funding received in 2020 and 2021 under the U.S. government's Paycheck Protection Program ("PPP"). Six PPP loans received by the Company in 2020-21, totalling US$4.7 million, were forgiven during year ended December 31, 2021 and were therefore recognised as income in 2021. No funding was received under the U.S. government's PPP program in the year ended December 31, 2022.

Research and development expenses

Research and development expenses declined from US$4.5 million in the year ended December 31, 2021 to US$4.1 million when compared to the year ended December 31, 2022, a decrease of 8.0% mainly due to our lower headcount.

Selling, general and administrative expenses

Selling, general and administrative (SG&A) expenses increased from US$24.7 million in the year ended December 31, 2021 to US$29.2 million in the year ended December 31, 2022, an increase of US$4.5 million or 18.2%. The main reasons for this increase are as follows:

- The share-based payments expense was US$0.7m higher in 2022 compared to 2021, mainly due to share options granted during 2022. The majority of the options granted in 2022 are performance share options and are structured such that they are exercisable only if the market price for Company's ADSs exceeds certain levels ($3.00, $4.00 and $5.00 per ADS) during the life of the option. These performance share options align the goals of our team and our shareholders in the creation of shareholder value.
- With the lifting of COVID-related travel restrictions, we have tasked our sales and marketing teams to increase travel to customers and trade shows as we continue to revitalise our sales activities. Similarly, some key functional leaders based in Ireland have resumed visits to our overseas facilities as we seek to drive operational efficiencies. All of this has led to an approximately US$1.1 million increase in travel and promotional costs in 2022.
- Due diligence and other legal and professional fees increased by approximately US$0.8 million in 2022 as we took an active, but disciplined, approach to pursuing a pipeline of attractive M&A opportunities.
- Non-recurring professional fees, primarily associated with the debt refinancing, of US$0.6 million were expensed in 2022.
- Increased expected credit loss on trade receivables, with the majority of the increase due to one distributor.
- Higher recruitment fees in 2022 due to the hiring of more employees in senior management roles.

Impairment charges

The Company recognised impairment charges of US$5.8 million in the year ended December 31, 2022, compared to US$6.9 million for the year ended December 31, 2021.

It was determined that four internally developed products had a recoverable amount of zero and the total impairment charge for these was US$4.6 million. They comprise the following:

- Autoimmune smart reader (impairment charge US$1.3 million) - there is significant uncertainty whether the Company will complete the project to develop its own in-house autoimmune smart reader. While we may re-visit this decision in the future, in the interests of prudence we impaired the project's carrying value.
- Tri-stat instrument (impairment charge US$1.0 million) - following a strategic review of the Tri-stat instrument, it was decided that Tri-stat sales would be restricted to only certain targeted partnerships, and this led to an impairment in the carrying value of the Tri-stat intangible asset.
- COVID-19 antigen test on a rapid lateral flow format (impairment charge US$2.2 million) - this test is approved for professional use in the EU. However, the demand for our COVID-19 portfolio of products is highly uncertain and very difficult to predict and in our experience the market has moved to over the counter ("OTC") rapid COVID-19 tests, for which this product is not yet approved. As such the Company's efforts to commercialise this test have been unsuccessful. In addition, pricing for rapid COVID-19 tests in the EU is relatively weak, with stronger pricing available in, for example, the US market, for which this product is not yet approved. Given the market outlook for rapid COVID-19 testing products and continued uncertainty regarding regulatory approval pathways in key markets, including the US, management chose not to immediately pursue further regulatory approvals but does intend to monitor these markets and regulatory pathways with a view to potentially seeking additional regulatory approvals. As the Company has no imminent plans to pursue these regulatory approvals, under IFRS accounting rules these intangible assets were written down to zero.
- COVID-19 test on an ELISA format (impairment charge US$0.1 million) – this development project was written off because the market changed and there was no demand for a test on this format.

The impairment test on our cash-generating units performed as at June 30, 2022, identified an impairment loss of US$0.5 million in two cash-generating units, namely Biopool US Inc and Trinity Biotech Do Brasil. The impairment test on our cash-generating units performed as at December 31, 2022 identified an impairment loss of US$0.7 million in two cash-generating units, namely Clark Laboratories Inc and Trinity Biotech Do Brasil. For further details, see Item 18, Notes 11, 12 and 16.

Operating Loss

Operating loss for the year ended December 31, 2022 was US$16.8m, compared to an operating profit of US$6.6m in the year ended December 31, 2021. The reduction in profitability was mainly attributable to decreased revenues, lower gross margin, lower other operating income and higher indirect costs, partly offset by lower impairment charges.

Financial expenses

Financial expenses for current and comparative fiscal years are summarised in the table below.

	2022 US$'000	**2021 US$'000**
Loss on disposal of exchangeable notes	9.7	-
Penalty for early settlement of term loan	3.5	-
Term loan interest	9.8	-
Convertible note interest	0.7	-
Notional interest on lease liabilities for Right-of-use assets	0.7	0.8
Exchangeable note interest	0.4	4.6
Loan origination costs - term loan	-	1.6
Fair value movement for derivative asset	0.1	-
Total	**24.7**	**7.1**

Note: table contains rounded numbers

Financial expenses in the year ended December 31, 2022 were US$24.7 million compared to US$7.1m in the year ended December 31, 2021, an increase of US$17.6m. The increase is mainly due to two material non-recurring expenses incurred in 2022.

Firstly, we recorded a loss of US$9.7 million on the disposal of the exchangeable notes. In January 2022, the Company retired approximately US$99.7 million of the exchangeable notes. The accounting measure of total consideration for the retirement of the exchangeable Notes was US$92.9 million, consisting of cash consideration of US$86.7 million and the issuance of ADSs with a market value at the date of issue of US$6.2 million. The exchangeable notes were treated as a host debt instrument under IFRS with embedded derivatives attached. The embedded derivatives related to a number of put and call options which were measured at fair value in the Consolidated statement of operations. On initial recognition in 2015, the host debt instrument was recognised at the residual value of the total net proceeds of the bond issue less fair value of the embedded derivatives. Subsequently, the host debt instrument was measured at amortised cost using the effective interest rate method. At date of disposal, the carrying value of the extinguished exchangeable notes was US$83.2 million. As the IFRS measure of consideration was higher by US$9.7 million, the resulting loss on disposal was recorded as a once-off charge in the consolidated statement of operations in the year ended December 31, 2022.

Secondly, the Company made an early partial settlement of the senior secured term loan of US$34.5 million and in accordance with the Term Loan's credit agreement, there was an early repayment penalty of US$3.45 million.

The remaining increase in financial expenses is due to the debt re-financing which took place at the end of January 2022. Exchangeable notes with a fixed coupon rate of 4.0% were replaced by a senior secured term loan with a variable interest rate, which averaged 13% in the year. Cash interest payable on the term loan in the year ended December 31, 2022 was US$7.0 million, compared to US$4.0 million for the exchangeable notes in the year ended December 31, 2021. The accretion interest on the senior secured term loan was US$2.8 million in the year ended December 31, 2022 and this includes a one-off charge of US$2.1 million because the Company made an early partial settlement of the Term Loan, which resulted in an acceleration of the accretion interest expense. Additionally, there was a new convertible note issued in the second quarter and the financial expense for this instrument totaled US$0.7 million in 2022.

Financial income

Financial income for the year ended December 31, 2022 was US$0.3 million, relating to fair value adjustments of derivative financial instruments. In the year ended December 31, 2021, US$1.2 million of financial income was recorded relating to the decrease in the fair value of the embedded derivatives liability related to the exchangeable notes, the vast majority of which has since been retired.

Income tax credit

The Company recorded a tax credit on continuing operations of US$0.2 million for the year ended December 31, 2022 compared to a tax credit of US$0.2 million for the year ended December 31, 2021. The 2022 tax credit consists of US$0.3 million of current tax credit and US$0.1 million of a deferred tax charge. The 2021 tax credit consists of US$0.2 million of current tax credit and US$0.04 million of a deferred tax charge. For further details on the Group's tax charge please refer to Item 18, Note 7 and Note 13 to the consolidated financial statements.

(Loss)/profit from continuing operations

The loss for the year from continuing operations was US$41.0 million, compared to a profit of US$0.9 million in 2021.

Loss from discontinued operations

The Cardiac Point-of-Care operation was discontinued during the year ended December 31, 2016. Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item in the Statement of Operations. The loss on discontinued operations was US$7,000 in year ended December 31, 2022 (2021: US$54,000), which is mainly due to administrative expenses. For further details, see Item 18, Note 8.

Year ended December 31, 2021 compared to the year ended December 31, 2020

Revenues

In 2021, revenues decreased by 8.8% from US$102.0 million in 2020 to US$93.0 million. The decrease is mainly due to lower sales of our PCR VTM products. In 2020, demand for VTM products was exceptional while there was limited worldwide manufacturing capacity. As the pandemic has persisted, manufacturing capacity has ramped up significantly with a consequent negative impact on selling prices in 2021.

Trinity Biotech's revenues for the year ended December 31, 2021 were US$93.0 million compared to revenues of US$102.0 million for the year ended December 31, 2020, which represents a decrease of US$9.0 million or 8.8%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2021 US$'000	2020 US$'000	% Change
Revenues			
Clinical laboratory goods	74,700	84,280	(11.4%)
Clinical laboratory services	7,928	8,485	(6.6%)
Point-of-Care	10,337	9,215	12.2%
	92,965	**101,980**	(8.8%)

Clinical Laboratory Goods

Clinical Laboratory goods revenues decreased by US$9.6 million in 2021, which represents a decrease of 11.4%. The decrease is mainly due to lower sales of our PCR VTM. In 2020, demand for VTM products was exceptional while there was limited worldwide manufacturing capacity. As the pandemic has persisted, manufacturing capacity has ramped up significantly with a consequent negative impact on selling prices.

There was a significant reduction in demand for new orders of VTM from early 2021 as COVID-19 testing volumes dropped and customers utilised stockpiled product. While the situation relating to COVID-19 products remains very fluid, with the evolving impact of the new variants the Company has seen increased customer interest in VTM products over recent months and has resumed manufacturing VTM products, albeit in lower volumes compared to late 2020. The Company has retained the capability to flex manufacturing volumes should market conditions warrant it.

In 2021, there was a partial return towards more normalised level of Haemoglobins testing. While COVID-19 public health restrictions remained in place in 2021 in many markets, these restrictions were not as severe as in 2020. As a result, diabetic related testing revenues increased by almost 20% in 2021 and we are continuing to see increasing demand for these instruments and consumables as diabetic testing programmes continue their return to normalisation. Offsetting this increase was lower sales in our haemoglobinopathies products due to the recall of the Ultra II instrument in U.S. in the early part of 2021.

Fitzgerald Industries, our life science raw materials business and our clinical chemistry product line both recorded single digit revenue growth in 2021. Similarly, autoimmune product revenues in 2021 recorded single digit revenue growth compared to 2020, mainly due to a lessening of the impact of the Covid-19 pandemic.

Clinical Laboratory Services

Our New York reference laboratory offers laboratory-testing services for autoimmune disorders, such as Sjogren's syndrome, hearing loss, celiac disease, lupus, rheumatoid arthritis and systemic sclerosis. Revenues for the laboratory decreased by 6.6% to US$7.9 million. While revenues for our proprietary Sjogren's syndrome test increased by 46% compared to 2020 these were offset by a reduction in testing for other disorders due to fewer patients visiting their physicians for pandemic reasons and due to the ending of certain testing that was carried out for a high-volume customer.

Point-of-Care

Point-of-Care revenues increased from US$9.2 million in 2020 to US$10.3 million in 2021, an increase of US$1.1 million or 12.0%. This was driven by higher HIV sales in Africa. In 2020, HIV revenues were negatively impacted by logistical and testing constraints arising from COVID-19. Non-HIV point-of-care revenues, which mainly comprise a syphilis test sold in U.S., were broadly unchanged year on year.

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,		
	2021 US$'000	2020 US$'000	% Change
Revenues			
Americas	57,799	70,408	(17.9%)
Asia/Africa	25,504	22,567	13.0%
Europe	9,662	9,005	7.3%
Total	**92,965**	**101,980**	(8.8%)

In the Americas, revenues decreased US$12.6 million or 17.9% mainly due to decreased sales of our VTM products which were used in the Covid-19 testing programs in U.S. and Canada. To a lesser extent, haemoglobin revenues were impacted by the recall of the Ultra II instrument in U.S. in the early part of 2021, following an FDA warning letter in the prior year.

Asia/Africa revenues increased by 13.0%, or US$2.9 million compared to 2020. The increase is due i) to higher Point-of-Care revenues in Africa where logistical and testing constraints arose in 2020 due to Covid-19 and ii) an increase in haemoglobins revenues as there was a return to more normal diabetes testing schedules in China and our other Asian markets, in contrast to the disruptions that were seen in 2020 due to the pandemic.

In Europe, revenues increased by 7.3% or US$0.7 million, compared to 2020. The increase was due to higher haemoglobin A1c and infectious diseases revenues in the territory, mainly due to more patients attending their doctors for heath checks following the easing of the public healthcare emergency. Similar to Asia/Africa, there was an increase in haemoglobins instrument sales in Europe as customers that had postponed their instrument purchases in 2020 due to uncertainty created by the pandemic, returned to the market.

Cost of sales, gross profit and gross margin

Total cost of sales increased by US$1.5 million from US$53.4 million for the year ended December 31, 2020 to US$54.9 million, for the year ended December 31, 2021, an increase of 2.8%. This resulted in a gross profit for 2021 of US$38.1 million compared to a gross profit for 2020 of US$48.6 million. The gross margin of 41.0% in 2021 compares to a gross margin of 47.6% in 2020. Gross margin remains susceptible to product mix changes, geographic spread, currency fluctuations and product level variation. The reduction in the gross margin in 2021 compared to 2020 is mainly due to comparatively higher sales prices for VTM in 2020 caused by exceptionally high demand with prices and consequently gross margin reducing progressively during 2021. Lower margins were also recorded in our Fitzgerald life sciences supply business in 2021 compared to 2020 as we made a strategic decision to pursue larger volume orders that typically have lower pricing but are expected to add to overall profitability. Additionally, the receipt of government payroll supports in 2020 related to COVID-19 helped to increase the gross margin in 2020 and these supports were not claimed in 2021.

Other operating income

Other operating income increased from US$1.9 million in 2020 to US$4.7 million in 2021. In both years, this income almost entirely comprises income received under the U.S. government's Cares Act, principally its PPP and its Provider Relief Fund. All PPP loans received in 2020 and in 2021 have now been 100% forgiven by the U.S. government. Four PPP loans received in 2020, but not forgiven until 2021, totalling US$2.9m, were treated as short-term liabilities at December 31, 2020.

Research and development expenses

Research and development ("R&D") expenditures decreased from US$5.1 million in 2020 to US$4.5 million in 2021. The decrease in costs in 2021 is mainly due to the closure of an R&D centre located in Carlsbad, California in June 2020. For details of the Company's various R&D projects see "Research and Products under Development" below.

Selling, general and administrative expenses

Selling, general and administrative expenses (excluding impairment charges, closure costs, recognition of contingent asset and tax settlement) decreased from US$26.4 million in 2020 to US$24.7 million in 2021, which represents a decrease of 6.5%. In 2020, selling, general and administrative expenses were unusually low due to certain non-recurring savings, principally the furloughing of employees because of the pandemic and government payroll supports related to COVID-19. Despite neither of these savings occurring in 2021, a reduction in costs was recorded due to a cost saving program which saw headcount reduced by 7%, as well as lower performance-related pay due to lower revenues. Additionally, in 2021 a foreign currency gain was recorded on Euro-denominated lease liabilities while the equivalent foreign currency movement in 2020 was a loss.

The Group recorded a total share-based payments charge of US$1.1 million in 2021 compared to US$0.8 million in 2020. The increase of US$0.3 million in the total share-based payments expense is mainly due to a higher number of options being in their vesting period in 2021 compared to 2020 due to options granted in prior years. Share based payments included in selling, general and administrative expenses was US$1.1 million in 2021 and US$0.8 million in 2020. For further details, refer to Item 18, Note 19 to the consolidated financial statements.

Amortisation decreased from US$1.4 million for the year ended December 31, 2020 to US$0.9 million for the year ended December 31, 2021. The decrease of US$0.5 million is mainly due to the impairment recorded at December 31, 2020 which resulted in a lower carrying value for development projects and other intangible assets such as acquired technology, customer and supplier lists.

Recognition of contingent asset

In 2019, we disclosed a contingent asset of US$1.2 million which had not been recognised. It was in connection with the 2019 tax audit settlement and was payable by Darnick Company. This balance was settled in the year ended December 31, 2020 and was credited within selling, general and administrative expenses – recognition of contingent asset in 2020. The underlying amount was denominated in Euro. Due to a depreciation in the US Dollar between 2019 and 2020, the US Dollar equivalent amount increased from US$1.2 million to US$1.3 million.

Closure costs

In 2020, management decided to close a production facility in Carlsbad, California which specialised in Western Blot manufacturing. The last number of years had seen a steady migration of customers away from using the Western Blot testing format for diagnosing Lyme Disease in favour of alternative testing platforms. Production volumes declined steadily at the plant to the extent that it no longer made economic sense to continue. The plant was closed on June 30, 2020. Production of remaining products was transferred to other locations. The charge for closing the facility in 2020 was US$2.4 million which largely comprised redundancy costs, the write-off of inventory and the cost of exiting lease obligations.

Impairment charges

The Company recognized impairment charges of US$6.9 million in 2021. In 2020, the impairment charges were US$17.8 million. In accordance with the provisions of accounting standards under IFRS, a company is required to carry out impairment reviews in order to determine the appropriate carrying value of its net assets. A number of factors impacted this calculation including cash flow projections and net asset values across each of the Group's cash-generating units, the Company's share price at the date on which the impairment test is performed (in 2021, two tests were performed, one at June 30 and one at December 31) and the cost of capital. The impairment loss of US$5.0 million for Immco Diagnostics Inc. mainly comprised a write down of intangible assets. Trinity Biotech Do Brasil incurred an impairment loss of almost US$1.0 million (mainly comprising property, plant and equipment assets) in 2021 as this CGU continues to be impacted by the weakness of the Brazilian Real. Trinity Biotech Manufacturing Limited recorded an impairment loss of US$0.8 million relating to one development project intangible asset. Biopool US Inc. incurred an impairment loss of US$0.1 million in 2021, with a downward trend in non-Covid-19 related infectious disease revenues in U.S. being a major factor. For further details, see Item 18, Notes 11, 12 and 16.

Operating profit

The operating profit for continuing operations was US$6.6 million for the year, which compares to an operating profit of US$0.1 million for 2020.

Net financing expenses

Net financing expense was US$5.9 million for the year-end December 31, 2021 compared to US$6.7 million in 2020.

Financial income increased by US$1.2 million from US$0.04 million for the year-end December 31, 2020 to US$1.2 million in 2021. There was a decrease of US$33,000 in bank deposit interest mainly due to lower interest rates and an increase of US$1.2 million in the income arising from the revaluation of embedded derivatives at fair value.

Financial expenses increased by US$0.3 million to US$7.1 million during 2021 due to loan origination costs of US$1.7 million incurred in 2021 relating to the new term loan from Perceptive Advisors which was drawn down in 2022. Offsetting this an expense of US$1.2 million which arose in 2020 from revaluation of embedded derivatives at fair value. The equivalent revaluation in 2021 is a gain which is recorded in financial income.

Income tax credit

The Group recorded a tax credit on continuing operations of US$0.2 million for the year ended December 31, 2021 compared to a tax credit of US$0.6 million for the year ended December 31, 2020. The 2021 tax credit consists of US$0.2 million of current tax credit and US$0.04 million of a deferred tax charge. In 2020, the tax credit comprised US$0.4 million of current tax credit and US$0.2 million of a deferred tax credit. For further details on the Group's tax charge please refer to Item 18, Note 7 and Note 13 to the consolidated financial statements.

Profit/(loss) from continuing operations

The profit for the year from continuing operations was US$0.9 million, compared to a loss of US$6.0 million in 2020.

Loss from discontinued operations

The Cardiac Point-of-Care operation was discontinued during the year ended December 31, 2016. Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item in the Statement of Operations. The loss on discontinued operations is US$0.05 million in year ended December 31, 2021, which is mainly due to administrative expenses. The loss on discontinued operations is US$0.4 million in year ended December 31, 2020, which is mainly due to the unwinding of closure provisions and a change of estimate in relation to a tax receivable balance. For further details, see Item 18, Note 8.

B. ***Liquidity and Capital Resources***

The Group's capital structure is a mixture of debt and equity. In the first quarter of 2022, the Group re-financed its exchangeable notes debt by securing a term loan credit facility of US$81.3 million (the "Term Loan") from Perceptive. The re-financing improved the Group's capital structure by reducing gross debt by approximately US$19 million with the Group having no material debt maturities until 2026. As the Term Loan could be repaid, in part or in full, before the end of the four-year term, this gave the Group increased optionality regarding its future capital structure. In May 2022, the Group repaid just over 42% of the Term Loan (US$34.5 million) using the proceeds of an equity investment and the issuance of a 7-year convertible note.

Exchangeable notes

The Group originally issued US$115.0 million of 30-year exchangeable senior notes in 2015. The notes are senior unsecured obligations and accrue interest at an annual rate of 4%, payable semi-annually in arrears. In August 2018, the Group purchased US$15.1 million of the exchangeable notes. The nominal amount of the debt since this purchase had been US$99.9 million. The notes are convertible into ordinary shares of the parent entity at the applicable exchange rate, at any time prior to the close of business on the second business day immediately preceding the maturity date, at the option of the holder, or repayable on April 1, 2045. The conversion rate is 47.112 ADSs per $1,000 principal amount of notes, equivalent to an exchange price of approximately $21.88 per ADS. The notes include a number of non-financial covenants, all of which were complied with at December 31, 2022.

In December 2021, we entered into agreements with five holders of the exchangeable notes for the repurchase of approximately 99.7% of the outstanding notes. The agreements were conditioned on certain lending conditions being met and required shareholder approval, which was obtained in January 2022. In January 2022, we paid approximately US$86.7 million to the five note holders, using funds from a new term loan from Perceptive and the Company's own cash resources. We also issued a total of 5.3 million ADSs to the five note holders as partial consideration for the exchange of the notes. The remaining outstanding amount owing for exchangeable notes at December 31, 2022 is US$210,000.

Term loan with Perceptive

In December 2021, we and our subsidiaries entered into a US$81.3 million senior secured term loan credit facility with Perceptive. The Term Loan was drawn down in January 2022, when the necessary shareholder approvals were obtained.

The 48-month term loan will mature in January 2026 and accrues interest at an annual rate equal to 11.25% plus the greater of (a) one-month LIBOR (later changed to the Term SOFR Reference Rate effective from October 28, 2022) and (b) one percent per annum, and interest is payable monthly in arrears in cash. The term loan does not require any amortization, and the entire unpaid balance will be payable upon maturity. The term loan can be repaid, in part or in full, at a premium before the end of the four-year term.

In connection with the Term Loan, we agreed to issue warrants to Perceptive for 2.5 million of the Company's ADSs. The per ADS exercise price of the Warrants was US$1.30. The warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the Term Loan.

We made an early partial settlement of the senior secured term loan of US$34.5 million and in accordance with the Term Loan's credit agreement, there was an early repayment penalty of US$3.45 million. The remaining outstanding amount owing for the Term Loan at December 31, 2022 is US$46.8 million.

In February 2023, we announced that we and our subsidiaries had entered into an amended and restated senior secured term loan credit facility to allow for an immediate US$5 million increase to the outstanding Term Loan and provide for a US$20 million facility to fund potential acquisitions. In connection with the increased Term Loan facility, we agreed to reprice the 2,500,000 warrants originally issued under the Term Loan, with the Warrants now having a per ADS exercise price of US$1.071 compared to their initial per ADS exercise price of US$1.30.

On April 27, 2023, we announced that we had closed the sale of our Fitzgerald Industries life sciences supply business, for cash proceeds of approximately US$30 million subject to customary adjustments. The Company used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of its senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty. In connection with this transaction, the Company has entered into an amendment to its senior secured term loan credit facility with Perceptive Advisors, which significantly reduces the Company's minimum revenue covenants under that loan.

Investment from MiCo Ltd.

In May 2022, the Company announced a US$45.2 million investment from MiCo Ltd ("MiCo"). MiCo, a KOSDAQ-listed and Korea-based company, that is engaged in the biomedical business through its affiliate MiCo BioMed. The investment consisted of an equity investment of US$25.2 million and a seven-year, unsecured junior convertible note of US$20.0 million. The convertible note has an interest rate of 1.5% and interest is payable quarterly. The convertible note mandatorily converts into ADSs if the volume weighted average price of the Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days.

Leases

The Group entered into sale and leaseback arrangements in 2018 with Allied Irish Bank and Wells Fargo. In January 2022, the Group settled its outstanding lease liability with Allied Irish Bank. At December 31, 2022, the amount owed under the other remaining sale and leaseback arrangement was US$45,000. The Group also has lease liabilities relating to right-of-use assets with lease maturities between 1 and 11 years.

Cash and cash equivalents

At December 31, 2022, the cash and cash equivalents balance was US$6.6 million. In the future, the amount of cash generated from operations will depend on a number of factors which include the following:

- The ability of the Group to generate revenue growth from its existing product lines and 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.

Liquidity

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 and external financing. The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments.

The Directors are acutely aware of the relatively high cost of its borrowings and are focused on transforming the Group into a high growth business. The Company is actively examining the potential disposal of parts of its portfolio of businesses that are non-core to our future vision and strategy. Proceeds from these disposals may be used to fund repayments of the Group's debt and to fund investments with higher growth opportunities in strategically core areas.

Cash Flows

As at December 31, 2022, our consolidated cash and cash equivalents were US$6.6 million. The following table presents the major components of net cash flows used in and provided by operating, investing and financing activities.

	Year ended December 31,	
	2022	**2021**
	US$'000	**US$'000**
Net cash (used in) / generated by operating activities	(921)	13,238
Net cash outflow from investing activities	(5,977)	(8,691)
Net cash outflow from financing activities	(12,322)	(6,019)
Net decrease in cash and cash equivalents and short-term investments	(19,220)	(1,472)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 amounted to US$0.9 million (2021: inflow of US$13.2 million), a decrease of US$14.2 million. The decrease in net cash generated from operating activities of US$14.2 million is attributable to a decrease in operating cash flows before changes in working capital of US$16.6 million and a decrease in taxes received of US$1.6 million partially offset by a decrease in working capital outflows of US$4.1 million. The working capital outflow decrease, when compared to the prior year, is due to an increased inflow in trade and other payables of US$7.8 million and a decreased outflow associated with inventories of US$3.5 million partially offset by an increased cash outflow for trade and other receivables of US$7.2 million. The decrease in operating cash flows before changes in working capital is primarily driven by a lower operating profit compared to the prior year.

Investing Activities

Net cash outflows from investing activities for the year ended December 31, 2022 amounted to US$6.0 million (2021: US$8.7 million) which were principally made up as follows:

- Payments to acquire intangible assets of US$4.9 million (2021: US$6.9 million), 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$1.1 million (2021: US$1.8 million) incurred as part of the Group's investment programme for its manufacturing and distributing activities.

Financing Activities

Net cash outflows from financing activities for the year ended December 31, 2022 amounted to US$12.3 million (2021: US$6.0 million). This outflow is due to the payment of US$86.7 million for the retirement of the exchangeable Notes, the partial early settlement of the Term Loan plus a penalty of US$38.0 million, payments for lease liabilities of US$2.8 million, interest payments of US$7.9 million, refinancing costs US$2.4 million, partly offset by proceeds of issuance of shares of US$25.3 million and the draw down of the Term Loan of US$80.0 million (net of associated costs) and proceeds of US$20 million from the convertible note issued to MiCo. In 2021, the outflow was due to the payment of lease liabilities (US$3.0 million) and an interest payment on the exchangeable notes (US$4.0 million), refinancing costs (US$0.8m) partially offset by the receipt of loans in 2021 under the U.S. government's PPP (US$1.8 million).

C. Research and Development, Patents and Licences, etc.

For information on research and development, patents and licences see "Item 4. Information on the Company—Item 4.B Business overview."

D. Trend Information

In 2020 and 2021, the Company recorded combined revenues for our COVID-focused PCR Viral Transport Media products in excess of US$50 million, all of which related to North America. In 2022, our revenues for VTM products decreased to approximately US$3 million due to a significant scaling down of PCR testing programs for COVID-19 in North America and more competition. The demand for our COVID focused VTM products is highly uncertain and very difficult to predict.

The current indications are that public health policy has shifted away from large scale PCR testing of the population and instead the virus will be diagnosed by over-the-counter ("OTC") rapid antigen tests. The Company has developed an OTC rapid test for COVID-19 which has regulatory approval to be sold in the EU for professional use only. However, our efforts to commercialise this test have been unsuccessful. Pricing for rapid COVID-19 tests in the EU is relatively weak, with stronger pricing available in, for example, the US market, for which our product is not yet approved. Given the market outlook for rapid COVID-19 testing products and continued uncertainty regarding regulatory approval pathways in key markets, including the US, we have chosen to not immediately pursue further regulatory approvals but intend to monitor these markets and regulatory pathways with a view to potentially seeking additional regulatory approvals.

Excluding our COVID focused Viral Transport Media products, Group revenues in 2022 were 1.0% lower than in 2021. Haemoglobins is our largest product line in revenue terms, making up just under one third of our total Group revenues in 2022. We have seen continued strong performance in our haemoglobins product line in 2022, particularly for our diabetes products which recorded a year-on-year revenue increase of 26.6%. The growth driver in this product line is the higher instrument installed base and continuing high incidence of diabetes, particularly in Asia and Latin America. We expect revenues from this business to continue this growth trend driven by a higher instrument installed base and operational and strategic supply chain changes, which we expect will also drive margin increases.

Fitzgerald Industries, our life science raw materials business recorded single digit revenue growth in 2022, which is a typical result based on past trends. On April 27, 2023, we announced that we closed the sale of our Fitzgerald Industries life sciences supply business for cash proceeds of approximately US$30 million. For more information on this sale, refer to Item 18, Note 28. Autoimmune product revenues in 2022 recorded a slight decrease of US$0.2 million compared to 2021, mainly due to lower sales in Europe. Point-of-Care revenues, which mainly comprises sales of HIV lateral flow tests in Africa, decreased by US$1.1 million or 10.9%, reflecting significant non-recurring bulk orders of HIV tests from Nigeria in 2021. Revenues for our infectious diseases assays have been trending downwards for several years now, as the products in this portfolio are in the mature phase of their product life cycle. In 2022, the decrease for these products was approximately 23%, which was exacerbated by weak sales in China due to strict quarantine protocols enforced by public health officials to combat the spread of COVID-19.

E. 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

The Group recognises revenue when it transfers control over a good or service to a customer. Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group 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. Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods and services supplied to external customers, net of discounts and rebates and excluding sales taxes.

The core principle in IFRS 15 is a five-step model framework: 1) identify the contract(s) with a customer, 2) identify the performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations in the contract and 5) recognise revenue when (or as) the entity satisfies a performance obligation.

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 performance obligations to the customer in accordance with the shipping terms.

Some contracts oblige the Group to ship product to the customer ahead of the agreed payment schedule. For these shipments, a contract asset is recognised when control over the goods has transferred to the customer. The financing component is insignificant as invoicing for these shipments occurs within a short period of time after shipment has occurred and typically standard 30 day credit terms apply. Some contracts could be regarded as offering the customer a right of return. Due to the uncertainty of the magnitude and likelihood of product returns, there is a level of estimation involved in assessing the amount of revenue to be recognized for these types of contracts. In accordance with IFRS 15, when estimating the effect of an uncertainty on an amount of variable consideration to which the Group will be entitled, all information that is reasonably available, including historical, current and forecast, is considered.

The Group operates a licenced referenced laboratory in the US, which provides testing services to institutional customers and insurance companies. In the US, there are rules requiring all insurance companies to be billed the same amount per test. However, the amount that each insurance company pays for a particular test varies according to their own internal policies and this can typically be considerably less than the amount invoiced. We recognise lab services revenue for insurance companies by taking the invoiced amount and reducing it by an estimated percentage based on historical payment data. We review the percentage reduction annually based on the latest data. As a practical expedient, and in accordance with IFRS, we apply a portfolio approach to the insurance companies as they have similar characteristics. We judge that the effect on the financial statements of using a portfolio approach for the insurance companies will not differ materially from applying IFRS 15 to the individual contracts within that portfolio.

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.

The Group leases instruments to customers typically as part of a bundled package. Where a contract has multiple performance obligations and its duration is greater than one year, the transaction price is allocated to the performance obligations in the contract by reference to their relative standalone selling prices. For contracts where control of the instrument is transferred 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. Fair value is determined on the basis of standalone selling price. In the case where control of the instrument does not transfer to the customer, revenue is recognised on the basis of customer usage of the instrument. See also Note 1(v).

In obtaining these contracts, the Group incurs a number of incremental costs, such as sales bonus paid to sales staff commissions paid to distributors and royalty payments. NAs the amortisation period of these costs, if capitalised, would be less than one year, the Group makes use of the practical expedient in IFRS 15.94 and expenses them as they incur.

A receivable is recognised when the goods are delivered as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

The Group's obligation to provide a refund for faulty products under the standard warranty terms is recognised as a provision, see Note 21 for details.

Research and development expenditures -capitalized development costs

Under IFRS as issued by IASB, we write-off research and development expenditures as incurred, with the exception of expenditures 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.

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). 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, 2022 the carrying value of capitalised development costs was US$17.0 million (2021: US$17.7 million) (see Item 18, Note 12 to the consolidated financial statements). The decrease in 2022 was mainly due to impairment and amortization of US$5.1 million partly offset by additions of US$4.5 million.

Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment periodically while goodwill and indefinite lived assets are tested for impairment periodically, 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 a periodic basis. The recoverable amount of seven cash-generating units ("CGUs") is determined based on a value-in-use computation. Among other macroeconomic considerations, the impact of the COVID-19 pandemic has been factored into our impairment testing.

The value-in-use calculations use cash flow projections based on the 2023 projections for each CGU and a further four years projections using estimated revenue and cost average growth rates of between 0% and 5%. At the end of the five-year forecast period, terminal values for each CGU, based on a long term growth rate of 2%, 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 pre-tax discount rates used range from 16% to 24% (2021: 16% to 25%). Refer to Item 18, Note 12 for further information.

The cash flows have been arrived at taking into account the Group's financial position, its recent financial results and cash flow generation and the nature of the medical diagnostic industry, where product obsolescence can be a feature. However, expected future cash flows are inherently uncertain and are therefore liable to material change over time. The key assumptions employed in arriving at the estimates of future cash flows factored into impairment testing are subjective and include projected EBITDA margins, net cash flows, discount rates used and the duration of the discounted cash flow model. Significant under-performance in any of the Group's major CGUs may give rise to a material impairment which would have a substantial impact on the Group's income and equity.

The impairment testing performed during the year ended December 31, 2022 identified an impairment loss in three CGUs, namely Biopool US Inc, Clark Laboratories Inc, and Trinity Biotech Do Brasil totalling US$1.2 million. The impairment testing performed during the year ended December 31, 2021 identified an impairment loss in four CGUs, namely Trinity Biotech Manufacturing Limited, Biopool US Inc, Immco Diagnostics, and Trinity Biotech Do Brasil totalling US$6.9 million.

The impairment loss of US$0.4 million for Biopool US Inc. mainly comprised a write down of tangible assets and prepayments. A downward trend in non-Covid-19 related infectious disease revenues in U.S. was a major factor in this impairment. Trinity Biotech Do Brasil incurred an impairment loss of almost US$0.5 million (mainly comprising property, plant and equipment assets) in 2022 as this CGU continues to be impacted by the weakness of the Brazilian Real and low profitability. Clark Laboratories Inc. incurred an impairment loss of US$0.4 million in 2022 as this CGU manufactures and sells a range of infectious disease products which are in the mature stage of their product life cycle and accordingly the growth prospects are limited. For further details, see Item 18, Notes 11, 12 and 16.

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and the following sensitivity analysis has been performed:

- In the event that there was a reduction of 10% in the assumed level of future growth in revenue growth rate, which would represent a reasonably likely range of outcomes, there would be no additional impairment loss recorded at December 31, 2022.
- In the event there was a 10% increase 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 no additional impairment loss recorded at December 31, 2022.

In addition to impairment charges relating to the three CGUs, there were also specific impairment charges recorded in 2022 to write down the carrying value of four development projects to zero. These were recorded in intangible assets. The four impairments related to the Tri-stat instrument (US$1.0 million impairment charge), autoimmune smart reader (US$1.3 million), COVID-19 ELISA format assay (US$0.1 million) and COVID-19 rapid antigen test (US$2.2 million). Refer to Item 18, Note 12 for further information.

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 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. 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 2022, 2021 or 2020 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2022 our allowance for slow moving and obsolete inventory was US$16.3 million which represents approximately 42.0% of gross inventory value. At December 31, 2021 our allowance for slow moving and obsolete inventory was US$12.1 million, which represented approximately 29.3% of gross inventory value and at December 31, 2020 the provision was US$9.8 million, or approximately 24.5% of gross inventory value (see Item 18, Note 15 to the consolidated financial statements).

The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has increased between 2022 and 2021 due to significant increases in the provision for the following categories of inventory:

(i) VTM inventory – there was no evidence during the winter season of 2022-23 of significant peaks in demand for VTM products. This has led management to revisit the strategy of maintaining significant levels of raw materials inventory to meet demand peaks. Consequently, the provision for this inventory was increased by US$3.5 million in 2022 reflecting our estimate of its net realisable value.

(ii) Tri-stat inventory – the Company undertook a strategic review of our Tri-stat instrument line as part of a broader review of our haemoglobins product portfolio. Management decided to limit sales of Tri-stat to certain targeted partnerships and as a consequence the value of this inventory was written down by US$0.3 million to reflect the revised outlook.

(iii) Raw materials and work in progress failing to meet our revised quality policy - the value of certain excess raw materials and work in progress was written down by US$0.9 million in 2022 following a review and an update to our relevant quality assurance policy.

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$0.8 million at December 31, 2022 (2021: US$0.8 million) (2020: US$0.8 million) would result.

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.

Certain share options have been granted for which there is a condition that the options only become exercisable into ADSs when the market price of an ADS reaches a certain level. This is deemed to be a non-vesting condition. The term 'non-vesting condition' is not explicitly defined in IFRS 2, Share based Payment, but is inferred to be any condition that does not meet the definition of a vesting condition. The only condition for these options to vest is that the option holder continues service and there were no other conditions which would be considered non-vesting conditions. Non-vesting conditions are reflected in measuring the grant-date fair value of the share-based payment and there is no true-up in the measurement of the share-based payment for differences between the expected and the actual outcome of non-vesting conditions. If all service conditions are met, then the share-based payment cost will be recognized even if the option holder does not receive the share-based payment due to a failure to meet the non-vesting condition.

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.

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.

Senior secured term loan and related derivative balances

In 2022, the Company completed the drawdown of a senior secured term loan credit facility with Perceptive. The term loan is represented by three separate balances in our balance sheet. Firstly, included in Long Term liabilities is a Senior secured term loan balance, which, at initial recognition, comprised the principal loan amount of US$81.3 million less loan origination costs of US$3.6 million, less two derivative financial balances totalling US$1.7 million. This balance was reduced by an early partial settlement of the loan of US$34.5 million during 2022. The other two balances are a derivative financial asset and a derivative financial liability and these were initially recognised at fair value under IFRS 9. The derivative financial asset is valued at US$0.1m at December 31, 2022 and represents an estimate of the value to the Company of being able to repay the term loan early and potentially refinance at lower interest rate. The derivative financial liability is valued at US$1.6 million at December 31, 2022 and represents the fair value of the warrants issued to Perceptive. As part of the Credit Agreement, the Company agreed to issue warrants to Perceptive for 2.5 million of the Company's ADSs. The per ADS exercise price of the warrants was US$1.30 (this was revised to US$1.07 in 2023). The warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the term loan.

Litigation

From time to time we may be subject to various claims and contingencies in the ordinary course of business, including those related to litigation, business transactions, our intellectual property, regulatory compliance, employee-related matters and taxes, and others. When we are aware of a claim or potential claim, we assess the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, we will record a liability for the loss. In addition to the estimated loss, the recorded liability includes probable and estimable legal costs associated with the claim or potential claim. There is no assurance that such matters will not materially and adversely affect our business, financial position, and results of operations or cash flows.

Item 6. ***Directors, Senior Management and Employees***

A. Directors and Senior Management

Executive Officers and Directors

We are managed by a board of directors, which is currently comprised of five members, and our senior management. The following table presents information about our current executive officers, members of our board of directors and our senior management, including their ages. The term executive officer refers to any person in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the registrant. Executive officers of subsidiaries may be deemed executive officers of the registrant if they perform such policy making functions for the registrant.

Directors and Senior Management

Name	***Age***	***Title***
Directors		
Aris Kekedjian	57	Chairman and Chief Executive Officer
Ronan O'Caoimh	67	Founder & Director
Jim Walsh, PhD	64	Executive Director of Business Development
John Gillard	42	Chief Financial Officer, Company Secretary, Director
Tom Lindsay	65	Director
Senior Management		
Ian Wells, PhD	54	Vice President of Quality and Regulatory Affairs
Simon Dunne	49	Chief Accounting Officer
Gary Keating, PhD	50	Chief Technology Officer
Eibhlín Kelly	39	Chief Information Officer
Colm Molloy	52	Group Director of Human Resources and Culture
John Mee	59	Global Supply Chain Director
Nick O'Hare	50	Vice President of Global Commercial Operations and International Sales
Micheál Roche	63	Vice President of Global Health

Changes in Executive Officers and Board composition
James Merselis, Clint Severson and Kevin Tansley retired as directors on May 3, 2022. Seon Kyu Jeon, Aris Kekedjian and Michael Sung Soo Kim were appointed as directors on May 3, 2022. Seon Kyu Jeon and Michael Sung Soo Kim resigned as directors on October 24, 2022. Aris Kekedjian was initially appointed in a non-executive capacity and was appointed to replace Ronan O'Caoimh as Chief Executive Officer on October 3, 2022 and was appointed Chairman on September 30, 2022. Tom Lindsay was appointed as a director on October 25, 2022.

The executive officers, Fernando Devia and Sanjiv Suri left the Company during 2022 and Dan Goldsand left the Company in January 2023. Terence Dunne, moved to a part-time role in the Company in late 2022.

Directors

Aris Kekedjian, Chairman and Chief Executive Officer, joined the Board of Trinity Biotech in May 2022, initially in a non-executive capacity and was appointed to replace Ronan O'Caoimh as Chief Executive Officer on October 3, 2022. Mr Kekedjian was appointed as Chairman on September 30, 2022. Mr. Kekedjian spent 30 years in GE in several senior roles, including as GE's Chief Investment Officer and Global Head of Business Development. Mr. Kekedjian previously held roles as President & Chief Executive Officer at Icahn Enterprises, Senior Advisor to ECN Capital, and Independent Director of various public companies including Xerox Corporation, Finserv Acquisition Corp. and XPO Logistics, Inc. He received his undergraduate degree from Concordia University.

Ronan O'Caoimh, Director, 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. On May 3, 2022, Mr. O'Caoimh stepped down as Chairman and was replaced as Chairman by Seon Kyu Jeon. On October 3, 2022, Mr O'Caoimh stepped down as Chief Executive Officer. 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. 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. This arrangement ceased with effect from December 31, 2018 with Ronan O'Caoimh returning as an employee of the company.

Jim Walsh, PhD, Executive Director of Business Development, 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 Director of the Company. In October 2010, Dr Walsh rejoined the company as Chief Scientific Officer. Dr Walsh transferred from this position in 2015 and now provides strategic advice and technical diligence support, on a part time basis, with regards to the Company's business development activities. 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 is a director of a number of private Irish companies in the biotechnology and diagnostics sector, including EPONA Biotech since 2016, AllWorth Diagnostics since 2019 and AbacusLabs since 2020. Dr Walsh holds a PhD degree in Chemistry from University College Galway.

John Gillard, Chief Financial Officer, Company Secretary and Director, joined Trinity Biotech in November 2020 as Chief Financial Officer, Secretary to the Board of Directors and was appointed to the Board as Executive Director. Mr. Gillard is both a Chartered Accountant and Chartered Tax Advisor, having trained at PWC. Prior to joining Trinity Biotech, Mr. Gillard held a number of senior financial roles including from 2012 to 2016 at Alphabet Inc./Google, and from Nov 2016 to May 2020 at ION Investment Group. Since June 2020 Mr. Gillard has also acted as a business consultant. Mr. Gillard holds a Bachelor of Commerce degree from the National University of Ireland Galway and a Master's degree in Accounting from University College Dublin.

Tom Lindsay, Director, joined the Board as a non-executive director in October 2022. Mr. Lindsay has more than 35 years of sales and marketing leadership experience in the global medical diagnostics industry and was President of Alere Inc's (now Abbotts's) business in Africa for many years. Most recently, Mr Lindsay has provided consultancy services to several international in vitro diagnostics businesses. He currently serves as a non-executive director for Genedrive plc, a rapid, low-cost molecular diagnostics platform for the identification and treatment of a selection of infectious diseases.

Senior management

Ian Wells, Vice President of Quality and Regulatory Affairs, has served as Vice President of Quality and Regulatory Affairs of Trinity Biotech since September 2022. Dr. Wells has greater than 30 years' experience in the health care sector having worked in R&D, Operations and Quality/Regulatory for Zeneca, Johnson & Johnson, Ortho Clinical Diagnostics and Werfen. Dr. Wells graduated from Plymouth University and Technical University of Vienna with a BSc. in Chemistry (1993) and a PhD. in Chemometrics and Molecular Spectroscopy (1996). He is the co-author of Transforming Quality Organisations (published by BEP LLC, New York, April 2023).

Simon Dunne, Chief Accounting Officer, has served as our chief accounting officer since November 2007, having previously been our European CFO from November 2006. Prior to joining us, Mr. Dunne held various finance leadership positions with Misys plc and worked in the auditing division of PWC. He graduated from University College Dublin with a Bachelor of Commerce degree and is a Fellow of the Institute of Chartered Accountants Ireland.

Gary Keating, Chief Technology Officer, joined Trinity Biotech in October 2022 following a range of technical leadership roles in start-up and multinational diagnostics companies, including Transfer Manager at Abbott Diagnostics, R&D Manager at Diasorin Ireland, and CTO at HiberGene Ltd. Dr Keating graduated from the University of Ulster at Jordanstown with a BSc in Applied Biochemical Sciences in 1993 and earned a PhD in Applied Immunology from Dublin City University in 1998.

Eibhlín Kelly, Chief Information Officer, has served as Chief Information Officer of Trinity Biotech since September 2015. Previously, she served as Customer Services Manager at Lynq Limited between 2011 and 2015, and Service Delivery/Support Manager at Trinity Biotech between 2005 and 2011. She graduated with an honour's degree in Business Information Systems Development from Dublin Institute of Technology.

Colm Molloy, **Group Director of Human Resources and Culture**, has over 30 years Human Resources and Training experience and joined Trinity Biotech in January 2021. Prior to joining Trinity Biotech, he served as Head of Human Resources with Nuritas, a biotechnology company from 2019 to 2020. His previous roles included HR Director at Storm Technology from 2015 to 2019 and Head of Human Resources at Grant Thornton Ireland from 2011 to 2015. He is a Fellow of the Chartered Institute of Personnel and Development (CIPD) and a Graduate of the Marketing Institute of Ireland.

John Mee, Global Supply Chain Director has served in this position since joining Trinity Biotech in August 2022. Previous positions include Director of Supply Chain and Operations Consulting Services for EY, Supply Chain and Information System Manager for Glanbia Consumer Foods, Global inventory Planning Director for Grifols. John has held senior Supply Chain positions in Ireland and internationally. John holds an MSc in Supply Chain Management, an MSc in Manufacturing 4.0, a BSc in Data Analytics, is a qualified auditor (BS5750 Part 2), and a Certified Advanced Forecaster (Institute of Business Forecasting). John sits on the Executive Board of The Irish Exporters Association.

Nick O'Hare, Vice President of Global Commercial Operations and International Sales joined Trinity Biotech in January 2022. Prior to joining Trinity Biotech, Mr. O'Hare was a business consultant at hmR Ireland. In his career, he has held a range of senior roles in GSK, Roche Diagnostics, Novartis, IQVIA Ireland and PWC. Mr O'Hare has a primary degree in science from Dublin City University and also holds an MBA.

Mícheál Roche, Vice President of Global Health, joined Trinity Biotech in 2001. Prior to his current role as VP of Global Heath, he served as VP of HIV, Infectious Disease and Clinical Chemistry since October 2013. Earlier in his career, he worked for AB Biodisk and B. Braun Biotech. He graduated from the National University of Ireland with a Bachelor of Science degree and a master's degree in biotechnology.

Additional Information

There are no family relationships between any of the directors or members of senior management named above.

Our Memorandum and Articles of Association of the Company (the "Articles") provide for a board of directors of not less than four and not more than ten members with the exact number of directors, from time, to time, determined by either (i) a resolution of our board of directors or (ii) a vote of the shareholders at a general meeting or by way of written resolution.

Our board of directors is currently composed of five directors. Officers serve at the pleasure of the board of directors, subject to the terms of any agreement between the officer and us.

Pursuant to the terms of the Securities Purchase Agreement signed by Trinity Biotech plc and MiCo IVD Holdings LLC ("MiCo") on April 11, 2022 and the Redeemeable Unsecured Convertible Loan Note issued by the Company on May 3, 2022, MiCo have the right to nominate up to four individuals for consideration by the Nomination Committee of the Board of Directors for appointment to the Board of Directors, subject to certain minimum holding requirements. Three of MiCo's four nominees are required to meet the independence standards set out in the NASDAQ stock Market Rules at all times and at least one of those nominees must have substantial experience at a diagnostics testing business having annualised revenues of greater than US$1 billion. In considering MiCo's nominees, the Nomination Committee of the Board of Directors is required to take into consideration the need for the Company to retain its Irish tax status and status as a foreign private issuer under applicable federal securities laws.

We are not aware of any other arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any person referred to above was selected as a director or member of senior management.

B. Compensation

The 2022 remuneration scheme was approved by the Board of Directors.

Total directors and non-executive directors' remuneration, excluding pension and share options, for the year ended December 31, 2022 amounted to US$1,639,000. The pension charge for the year amounted to US$24,000. See Item 18, Note 9 to the consolidated financial statements. The split of directors' remuneration set out by director is detailed in the table below:

Director	*Title*	*Salary/Other payments/ Benefits US$'000*	*Performance related bonus US$'000*	*Transaction related bonus US$'000*	*Defined contribution pension US$'000*	*Total 2022 US$'000*	*Total 2021 US$'000*
Aris Kekedjian[1, 2]	Chairman and Chief Executive officer	262	125	—	—	387	—
Ronan O'Caoimh[1]	Executive Director	340	—	—	—	340	643
Jim Walsh	Executive Director	20	—	—	—	20	20
John Gillard [3]	Executive Director	452	183	204	24	863	593
Tom Lindsay[4]	Director	—	—	—	—	—	—
Kevin Tansley[5]	Former Director	19	—	—	—	19	60
Clint Severson[6]	Former Director	17	—	—	—	17	49
James Merselis[7]	Former Director	17	—	—	—	17	49
		1,127	308	204	24	1,663	1,414

[1] Aris Kekedjian was appointed as a director on May 3, 2022, initially in a non-executive capacity and on October 3, 2022 was appointed to replace Ronan O'Caoimh as Chief Executive Officer.
[2] Salary, other payments and benefits for Aris Kekedjian includes US$65,000 payable to him on commencement of employment as CEO and Chairman.
[3] John Gillard's transaction bonus was in relation to a financial transaction successfully completed during the year.
[4] Tom Lindsay was appointed as a director on October 25, 2022.
[5] Kevin Tansley retired as director on May 3, 2022.
[6] Clint Severson retired as director on May 3, 2022.
[7] James Merselis retired as director on May 3, 2022.

As at December 31, 2022 there was US$5,000 (2021: NIL) accrued by the Company to provide pension, retirement or similar benefits for the directors

In 2022, options to subscribe for up to 29,400,000 'A' ordinary shares (equivalent to 7,350,000 ADSs) were granted to the directors (2021: nil).

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

Compensation of Senior Management

Compensation of our executive officers is composed primarily of base salary and the payment of short-term and mid-term cash bonuses. Cash bonuses are generally tied to the achievement of financial performance indicators and strategic objectives, and they may vary as a percentage of base salary depending upon the level of responsibilities of the executive officer. Our executive compensation package is also complemented by long-term incentives in the form of stock options.

As previously set out by our Chairman and CEO, Mr. Aris Kekedjian and endorsed by our Board, one of our key priorities is to build a performance culture and drive ownership and accountability in the Company. A share-based compensation model that ensures shareholder alignment is regarded as core to this transformation and is currently in the process being rolled out to staff and senior management across the Company. To facilitate this shareholder aligned share-based compensation model for employees and senior management, on December 15, 2022, our Board approved an amendment to the Trinity Biotech Employee Share Option Plan 2020 (with the updated plan being the Company's 2023 Amended & Restated Plan) to increase the number of ordinary shares issuable under such plan by 30 million Class "A" ordinary shares (the equivalent to 7.5 million ADS). As this point in time, it is intended that these share-based compensation awards will be structured in a manner similar the options granted to our CEO, with a significant proportion of any awards being performance-based awards that only become exercisable if the market price of the Company's ADS reaches certain levels. These performance share-based compensation awards are intended to closely align the goals of our broader team with those of our shareholders in the creation of shareholder value. The majority of Mr. Kekedjian's options are performance share options and are structured such that they are exercisable only if the market price of the Company's ADSs increases to certain levels ($3.00, $4.00 and $5.00 per ADS) during the term of the option.

For the financial year ended December 31, 2022, our executive officers and directors, as a group (22 persons for 2022 including three executive officers that left the company during the year and one executive officer who moved to a part-time role during the year), received aggregate compensation of US$3,821,000 for services they rendered in all capacities during 2022, which amount includes base salary, commissions, bonuses, ex gratia payments and benefits in kind, excluding share options. The Board has appointed Korn Ferry, an internationally recognised consulting firm, to advise the Board on compensation matters for directors and senior management.

C. Board Practices

The Articles of Trinity Biotech provide that one third of the directors for the time being other than 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 each annual general meeting,but 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. 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. Subject as aforesaid, a retiring director shall be eligible for re-appointment and shall act as a director throughout the meeting at which he retires.

The Board has retained PWC to review and advise on the Company's existing corporate governance practices and structures to ensure they are appropriate and proportional for our company. We expect this process and any associated changes to be completed and implemented by the end of quarter 3, 2023.

The Board of Directors has established audit, remuneration and employee compensation committees. The Remuneration Committee consisted of Mr Clint Severson (committee chairman and lead director) and Mr James Merselis until the date of their resignation in May 2022. This Committee is responsible for approving executive directors' remuneration including bonuses and share option grants. The Board has appointed an internationally recognised independent consulting firm to advise the Board on compensation matters for directors and senior management.

The Audit Committee reviews the Group's annual and interim financial statements and reviews reports from management 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. Until May 2022, the Audit Committee comprised two non-executive directors of the Group, James Merselis (Committee Chairman) and Clint Severson. When these two directors retired in May 2022, they were replaced on the Audit Committee by non-executive directors Michael Sung Soo Kim and Aris Kekedjian (Committee Chairman). When Michael Sung Soo Kim resigned as a director in October 2022, he left the Audit Committee, and Aris Kekedjian left the audit committee on May 2, 2023. As a transitional arrangement, the Audit Committee now comprises solely the non-executive director, Tom Lindsay. The Board of Directors intend to appoint a second person to the Audit Committee once another suitably qualified non-executive director has joined the Board.

The Board of Directors has also formed an employee compensation committee currently comprises Mr Aris Kekedjian (Committee Chairman) and Mr. John Gillard. This committee is responsible for approving share-based compensation grants to employees of the Group, other than executive directors, pursuant to the terms of 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 'A' ordinary shares (7,500 ADRs) are approved by the Compensation Committee and subsequently ratified by the Board.

The Company also typically operates a Nomination Committee for appointments to the Board of Directors.

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.

Indemnification of Directors and Officers

Subject to exceptions, the Companies Act 2014 of Ireland, (the "Companies Act 2014") does not permit a company to exempt a director or certain officers from, or indemnify a director against, liability in connection with any negligence, default, breach of duty or breach of trust by a director in relation to the company.

The exceptions allow a company to: (a) purchase and maintain directors and officers insurance against any liability attaching in connection with any negligence, default, breach of duty or breach of trust owed to the company; and (b) indemnify a director or such other officer against any liability incurred in defending proceedings, whether civil or criminal, (i) in which judgment is given in his or her favor or in which he or she is acquitted or (ii) in respect of which an Irish Court grants him or her relief from any such liability on the grounds that he or she acted honestly and reasonably and that, having regard to all the circumstances of the case, he or she ought fairly to be excused for the wrong concerned.

The Articles includes a provision which, subject to the provisions of the Companies Act 2014 as aforesaid, entitles every present and former director and other officer of the Company to be indemnified out of the assets of the Company (other than any person (whether an officer or not) engaged by the Company as auditor) against any loss or liability incurred by him or her for negligence, default, breach of duty or breach of trust in relation to the affairs of the Company or otherwise incurred by him or her in the execution and discharge of his or her duties to the Company.

Under the Companies Act 2014 and the Articles, the Company may purchase and maintain directors' and officers' liability insurance, at the expense of the Company, for the benefit any of its present and former directors and other officers.

Limitation on Director Liability

Subject to exceptions, as described above, the Companies Act 2014 does not permit a company to exempt any director or certain officers from any liability arising from negligence, default, breach of duty or breach of trust against the company. One of the exceptions is that an Irish company is permitted to purchase and maintain directors' and officers' liability insurance, at the expense of the company, for the benefit of any of its present and former directors and other officers, including insurance against liability arising from the aforementioned matters.

Separately, in proceedings where negligence, default, breach of duty or breach of trust against a director has or may be established (or in anticipation of any such proceedings), an Irish Court has the power to grant a director or other officer relief from liability on the grounds that he or she acted honestly and reasonably and that, having regard to all the circumstances of the case, he or she ought fairly to be excused for the wrong concerned.

The Company has purchased directors' and officers' liability insurance which would indemnify the directors and officers against damages arising out of certain kinds of claims which might be made against them based on their negligent acts or omissions while acting in their capacity as such. In addition, certain of the Company's existing US-incorporated subsidiaries have entered into customary deeds of indemnity with our directors.

D. Employees

The following table details certain data on the average workforce of Trinity Biotech and its consolidated subsidiaries:

	Year Ended December 31, 2022		
	2022	**2021**	**2020**
Numbers of employees by geographic location			
United States	217	237	310
Ireland	146	211	199
United Kingdom	1	2	3
Brazil	34	27	31
Total workforce	**398**	**477**	**543**
Numbers of employees by category of activity			
Research scientists & technicians	30	41	52
Manufacturing/Operations	188	239	280
Quality Assurance	61	63	63
Finance/Administration	75	68	65
Sales & Marketing	44	66	83
Total workforce	**398**	**477**	**543**

We consider our employees the most valuable asset of our company. We offer competitive compensation and comprehensive benefits to attract and retain our employees. The remuneration and rewards include retention through share-based compensation and performance-based bonuses. We generally provide our employees with benefits and working conditions beyond the required minimums in each geographic and regulatory environment in which the Group operates.

We believe that an engaged workforce is key to maintaining our ability to innovate. We have been successful in integrating new employees into the business and keeping our employees engaged. Investing in our employees' career growth and development is an important focus for us. We offer learning opportunities and training programs including workshops, guest speakers and various conferences to enable our employees to advance in their chosen professional paths.

We are committed to providing a safe work environment for our employees. We took the necessary precautions in response to the Covid-19 outbreak, including offering employees flexibility to work from home where practical, mandatory social distancing requirements in the workplace (such as adding more space between workspaces) and provision of hand sanitizer to all employees, and improvement and optimization of our telecommuting system to support remote work arrangements.

E. Share Ownership

Beneficial Ownership of Executive Officers and Directors

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 Company's 2023 Amended & Restated 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, through its remuneration and employee compensation committees as the case may be. 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 'A' ordinary shares (7,500 ADRs) are administered by the employee compensation committee and subsequently ratified by the Board. 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 Board may accelerate the exercisability and termination of options.

As of April 15, 2023, our directors and executive officers as a group, then consisting of 13 persons, held options to purchase an aggregate of 40,627,336 'A' shares (10,156,834 ADS equivalent), having exercise prices ranging from US$0.19 per 'A' ordinary share (US$0.77 per ADS) to US$1.34 per 'A' ordinary share (US$5.35 per ADS) and expiration dates ranging from 2024 to 2029. Generally, the options vest over a two to four year period and have no performance conditions. One exception to this is that the majority of the options granted to Aris Kekedjian and John Gillard in the fourth quarter of 2022 are performance share options and are structured such that they are exercisable only if the market price of the Company's ADSs increases to certain levels (US$3.00, US$4.00 and US$5.00 per ADS) during the life of the option.

The following table sets forth certain information as of April 15, 2023, regarding the beneficial ownership by each of our directors and executive officers:

Name	Number of 'A' Ordinary Shares Beneficially Owned (1)	Percentage of Ownership (2)
Ronan O'Caoimh (3)	18,761,496	11.6%
Aris Kekedjian (4)	4,000,000	2.6%
Jim Walsh (5)	2,743,612	1.8%
John Gillard (6)	1,900,000	1.2%
Tom Lindsay	-	-
Simon Dunne (7)	240,000	*
Ian Wells	-	-
Eibhlín Kelly	-	-
Gary Keating	-	-
Colm Molloy	-	-
John Mee	-	-
Nick O'Hare	-	-
Mícheál Roche	-	-
Executive officers and directors as a group (13 persons)	27,645,108	16.3%

* Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Share options that have a performance condition related to the share price of the equity of the Company are deemed to be exercisable irrespective of whether the performance condition has been, or is expected to be, satisfied within 60 days of the date of this table. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.

(2) The percentages shown are based on 'A' Ordinary Shares issued and outstanding as of April 15, 2023.

(3) Represents (a) 9,724,160 'A' ordinary shares and (b) 9,037,336 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2023. Includes options issued to Darnick Company which in the past provided Trinity Biotech with the services of Mr. O'Caoimh as Chief Executive Officer.

(4) Represents 4,000,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2023.

(5) Represents (a) 1,393,612 'A' ordinary shares and (b) 1,350,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2023. Note that 1,393,612 'A' ordinary shares of Dr Walsh's shares are held in trust for the benefit of Dr Walsh's immediate family.

(6) Represents 1,900,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2023.

(7) Represents 240,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2023.

As of April 15, 2023, 40,387,336 (10,096,834 ADS equivalent) of the options outstanding were held by the directors of Trinity Biotech as follows:

Director/Company Secretary	Number of Options 'A' Shares	Number of Options ADS Equivalent	Exercise Price (Per 'A' Share)	Exercise Price (Per ADS)	Hurdle Price [2] (Per ADS)	Expiration Date of Options
Aris Kekedjian	8,000,000	2,000,000	0.27	1.07	None	03/10/2029
	4,000,000	1,000,000	0.27	1.07	$ 3.00	03/10/2029
	4,000,000	1,000,000	0.27	1.07	$ 4.00	03/10/2029
	4,000,000	1,000,000	0.27	1.07	$ 5.00	03/10/2029
John Gillard	600,000	150,000	0.67	2.69	None	23/10/2027
	1,400,000	350,000	0.27	1.09	None	25/03/2029
	3,200,000	800,000	0.29	1.14	None	19/12/2029
	1,600,000	400,000	0.29	1.14	$ 3.00	19/12/2029
	1,600,000	400,000	0.29	1.14	$ 4.00	19/12/2029
	1,600,000	400,000	0.29	1.14	$ 5.00	19/12/2029
Ronan O'Caoimh [1]	2,244,000	561,000	1.34	5.35	None	07/09/2024
	4,060,000	1,015,000	0.69	2.74	None	14/06/2026
	333,336	83,334	0.19	0.77	None	20/03/2027
	2,400,000	600,000	0.73	2.90	None	17/11/2027
Jim Walsh	750,000	187,500	1.34	5.35	None	07/09/2024
	600,000	150,000	0.19	0.77	None	20/03/2027

[1] Includes options issued to Darnick Company which in the past provided Trinity Biotech with the services of Mr. O'Caoimh as Chief Executive Officer.

[2] Share options with a hurdle price are structured such that they may only become exercisable into ADSs when the average closing price of the Company's ADSs, for ten trading days out of the thirty previous trading days, is equal to or greater than the relevant hurdle price of US$3.00, US$4.00 or US$5.00 per ADS (adjusted for any stock splits, reverse splits or equivalent reorganisations) during the life of the option. At April 15, 2023, none of the directors' share options with a hurdle price were exercisable as the hurdle price condition has not been achieved.

As of April 15, 2023 the following total options were outstanding:

	Number of 'A' Ordinary Shares Subject to Option	Range of Exercise Price per Ordinary Share	Range of Exercise Price per ADS
Total options outstanding	46,794,672	$ US0.19-US$1.34	$ US0.77-US$5.35

Item 7. ***Major Shareholders and Related Party Transactions***

A. Major Shareholders

As of April 15, 2023, Trinity Biotech has outstanding 152,830,284 'A' Ordinary shares (excluding treasury shares). Such totals exclude 46,794,672 shares issuable upon the exercise of outstanding options and 10,000,000 shares issuable upon the exercise of outstanding warrants.

The following table sets forth certain information regarding the beneficial ownership of our ordinary shares, as of April 15, 2023, by each person who we believe beneficially owns 5% or more of our outstanding ordinary shares and all of our directors and executive officers 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.

Name	Number of 'A' Ordinary Shares Beneficially Owned	Number of ADSs Beneficially Owned (1)	Percentage ownership (2)
MiCo IVD Holdings, LLC	44,759,388(3)	11,189,847	29.3%
All directors and officers as a group	27,645,108	6,911,277	16.3%
Perceptive Credit Holdings III, LP	10,000,000(4)	2,500,000	6.1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Share options that have a performance condition related to the share price of the equity of the Company are deemed to be exercisable irrespective of whether the performance condition has been, or is expected to be, satisfied within 60 days of the date of this table. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.

(2) The percentages shown are based on 'A' Ordinary Shares outstanding (excluding treasury shares).

(3) Based upon a Schedule 13D filed on December 8, 2022, by MiCo IVD Holdings, LLC with the SEC. The principal business address of MiCo IVD Holdings, LLC is 85 Orchard Road. Skillman, New Jersey 08558 United States.

(4) Based upon warrant agreement issued to Perceptive Credit Holdings III, LP in January 2022 in respect of 10,000,000 'A' Ordinary Shares (2,500,000 ADSs).

Significant Changes in the Ownership of Major Shareholders

To our knowledge, other than as disclosed in the table below there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2020.

The following shareholders have disclosed ownership above 5% since January 1, 2020 but their ownership is below 5% as at April 15, 2023 according to their Schedule 13G filings.

	Number of 'A' Ordinary Shares Beneficially Owned	Number of ADSs Beneficially Owned (1)	Percentage 'A' Ordinary Shares (2)	Percentage Total Voting Power	Date of Filing
Whitefort Capital Master Fund, LP	2,342,280	585,570	1.5%	1.5%	February 16, 2021
Highbridge Capital Management, LLC	675,064	168,766	0.4%	0.4%	April 14, 2022
Renaissance Technologies LLC	5,573,752	1,393,438	3.6%	3.6%	February 13, 2023
Stonehill Capital Management LLC	6,690,592	1,672,648	4.4%	4.4%	February 13, 2023
Paradice Investment Management, LLC	6,172,460	1,543,115	4.0%	4.0%	February 7, 2020

Major Shareholders Voting Rights

Our major shareholders do not have different voting rights.

B. Related Party Transactions

The following is a description of our related party transactions since January 1, 2022.

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, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland.

The Group entered into an agreement for a 25-year lease with JRJ effective from December 2003 for offices that adjacent to its then premises at IDA Business Park, Bray, Co. Wicklow, Ireland with an annual rent is €381,000 (US$406,000). Upward-only rent reviews are carried out every five years and there have been no increases arising from these rent reviews.

In 2007 the Group also entered into 25-year lease agreements with Mr O'Caoimh and Dr Walsh for a 43,860 square foot manufacturing facility in Bray, Ireland. The annual rent for the manufacturing facility is €787,000 (US$838,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. In 2016 the Group also entered into 10-year lease agreement with Mr O'Caoimh for a warehouse of 16,000 square feet adjacent to the leased manufacturing facility in Bray, Ireland. The annual rent for the warehouse is €144,000 (US$153,000). At the time, independent valuers advised the Group that the rent in respect of each of the leases represents a fair market rent. Upward-only rent reviews are carried out every five years and there have been no increases to date arising from these rent reviews, although a rent review of the 43,860 square foot facility is currently ongoing.

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 represented a fair and reasonable basis on which the Group could meet its ongoing requirements for premises. Dr Walsh has no ownership interest in the additional space adjoining the warehouse owned by Mr O'Caoimh and was therefore entitled to express an opinion on this arrangement.

In late 2020, the Group occupied some additional space adjoining the warehouse owned by Mr O'Caoimh. This was a short-term arrangement, and no payments were made for the additional space during 2020 and 2021. The Company vacated this space in 2021. In 2022, the rent payable to Mr O'Caoimh of US$90,000 was settled.

Indemnity Agreements

We have entered into customary agreements with each of our current directors and executive officers to indemnify them to the fullest extent permitted by law, subject to limited exceptions.

Related Person Transaction Policy

Our Board of Directors has adopted an interested party transaction policy, which governs the identification, reporting and approval of transactions with interested parties.

C. Interests of Experts and Counsel

Not applicable.

Item 8. ***Financial Information***

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See Item 18. "*Financial Statements*."

Export Sales

In the year ended December 31, 2022, the amount of our export sales (i.e., sales outside of Ireland) was approximately US$74,675,181 which represents 99.9% of our total sales.

Legal and Arbitration Proceedings

From time to time, we may be involved in various claims and legal proceedings related to claims arising out of our operations. We are not currently a party to any material legal proceedings, including any such proceedings that are pending or threatened, of which we are aware.

Dividend Policy

We have not paid a cash dividend on our ordinary shares or ADSs since 2015 and do not intend to pay cash dividends on our ADSs in the foreseeable future. Our earnings and other cash resources will be used to continue the development and expansion of our business. Any future dividend policy will be determined by our Board of Directors and will be based upon conditions then-existing, including our results of operations, financial condition, current and anticipated cash needs, contractual restrictions and other conditions.

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2022.

Item 9. ***The Offer and Listing***

A. Offer and Listing Details

Trinity Biotech's ADSs are listed on the NASDAQ Global Market under the symbol "TRIB" and the depositary bank for the ADSs is The Bank of New York Mellon.

B. Plan of Distribution

Not applicable.

C. Markets

Trinity Biotech's ADSs, each representing four ordinary shares, are listed on the NASDAQ Global Market under the symbol "TRIB" and the depositary bank for the ADSs is The Bank of New York Mellon.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Copies of our Articles are filed as Exhibit 1.1 to this Annual Report. The information called for by this Item 10.B. is included in Exhibit 2.1 to this Annual Report and is incorporated herein by reference.

Irish Law

Each of Trinity Biotech's principal subsidiary undertakings incorporated in Ireland (refer to Item 18, Note 30) is registered as a private company limited by shares under the Companies Act 2014. 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 in Ireland and are 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 accounting records. The shareholders have no statutory right to inspect the accounting records. The only financial records, which are open to the shareholders, are the statutory financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information regarding certain events relating to the Company (such as changes to share rights, changes to the board of directors etc). This information is filed with the Companies Registration Office in Ireland and is open to public inspection. The Articles permit ordinary shareholders to approve corporate matters in writing provided that the relevant resolution is signed by all the members for the time being entitled to vote and attend at general meeting. A general meeting can be convened by ordinary shareholders which hold not less than 50 per cent of the paid up share capital of the Company carrying the right of voting at general meetings of the Company. In addition, the directors of the Company are required to convene a general meeting forthwith upon the deposit of a requisition 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.

Directors have extensive and wide–ranging duties under Irish law. These arise from both common law and statute (principally the Companies Act 2014, which codified a number of key fiduciary duties). Our directors owe their duties individually and primarily to Trinity Biotech and not its shareholders (although there is a requirement that directors consider the interests of employees in addition to those of the company). Additionally, directors will also need to have regard to the interests of creditors, where a director believes, or has reasonable cause to believe, that a company is, or is likely to be, unable to pay its debts, or becomes aware of the company's insolvency. All of the directors have equal and overall responsibility for the management of the Company (although directors who also serve as employees will have additional responsibilities and duties arising under their employment agreements and may be expected to exercise a greater degree of skill and diligence than non-executive directors). Those duties include duties to act in good faith in the interests of Trinity Biotech, act honestly and responsibly in the conduct of the Company's affairs, act in accordance with the Company's Constitution and exercise their powers only for purposes allowed by law, not use the Company's property for their own or a third party's, benefit (unless duly authorised), not agree to restrict their power to exercise an independent judgment (subject to limited exceptions) and avoid conflicts of interests (unless they are properly released). A director must exercise the care, skill and diligence which would be exercised in the same circumstances by a reasonable person having the knowledge and experience that (a) may reasonably be expected of a person in the same position as the director and (b) which that particular director has. Other statutory duties include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed, maintaining certain registers and making certain filings as well as the disclosure of personal interests. 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 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 (where relevant) lead to the summary dismissal of the director, civil or criminal sanction from a Court, including penalties or imprisonment, and/or the imposition of orders restricting or disqualifying the director from acting as a director.

C. Material Contracts

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

Term loan agreement with Perceptive Advisors

On December 15, 2021, the Company and its subsidiaries entered into a US$81.25 million senior secured term loan credit facility (the "Term Loan") with Perceptive Advisors ("Perceptive"), an investment manager with an expertise in healthcare. Proceeds from the Term Loan, along with existing cash and the issuance of new American Depository Shares ("ADS") in the Company, were used to retire the exchangeable notes in January 2022. The Term Loan will mature on the fourth anniversary of the drawdown date and accrues interest at an annual rate equal to 11.25% plus the greater of (a) one-month LIBOR (later changed to the Term SOFR Reference Rate effective from October 28, 2022) and (b) one percent per annum, and interest will be payable monthly in arrears in cash. The Term Loan does not require any amortization, and the entire unpaid balance will be payable upon maturity. The Term Loan can be repaid, in part or in full, at a premium before the end of the four-year term.

The drawdown of the Term Loan by the Company was subject to a number of conditions precedent including the repayment of at least 99.7% of the exchangeable notes and approval by the Company's shareholders of the Term Loan, an increase in the authorized share capital of the Company and the issuance of the Warrants. At the Extraordinary General Meeting held on January 25, 2022, the Company's shareholders approved all of the four resolutions put to the meeting, with each resolution being approved by at least 97% of votes cast. The term loan was drawn down on January 27, 2022. In May 2022, the Company made an early partial settlement of the term loan amounting to US$34,500,000.

In February 2023, the Company entered into an amended and restated senior secured term loan credit agreement which allowed for an immediate US$5,000,000 increase to its outstanding Term Loan and provided for a US$20,000,000 facility to fund potential acquisitions. In April 2023, the Company used approximately US$11 million of the proceeds of the sale of Fitzgerald Industries to repay approximately US$10.1 million of the Term Loan plus an approximately US$0.9 million early repayment penalty. In connection with this transaction, the Company entered into an amendment to its senior secured term loan credit facility with Perceptive Advisors, which significantly reduces the Company's minimum revenue covenants under that loan.

Warrant agreement with Perceptive Advisors

On December 15, 2021, the Company agreed, subject to drawdown of the Term Loan, to issue warrants exercisable for 2,500,000 of the Company's ADSs to Perceptive. The warrants were issued in January 2022 following the drawdown of the term loan. The per ADS exercise price of the Warrants is US$1.30, based on the lower of i) the 10-day volume weighted average price ("VWAP") for the Company's ADSs for the 10 business days prior to the Closing Date of the Credit Agreement for the Term Loan and ii) the 10-day VWAP for the Company's ADSs for the 10 business days prior to the drawdown date of the funding under the Term Loan. The Warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the Term Loan.

In February 2023, in connection with an increased Term Loan facility, the Company agreed to reprice the 2,500,000 warrants originally issued to Perceptive, with the Warrants now having a per ADS price of US$1.071.

Exchange agreement with certain holders of the Exchangeable Notes

On December 15, 2021, the Company entered into exchange agreements (the "Exchange Agreements") with five institutional investors that held approximately US$99,700,000 of the outstanding exchangeable notes, which are puttable by the holders to the Group, at par, in April 2022. Under the terms of this agreement each holder agreed to exchange their Notes at a discount to par with each holder receiving $0.87 of cash and the equivalent of $0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 10, 2021, discounted by 13%) per $1 nominal value of the Notes. The consummation of the Exchange Agreements was conditional upon (among other things) the approval by the Company's shareholders of the issuance of ADSs pursuant to the Exchange Agreements and certain matters related to the drawdown of the Term Loan. At the Extraordinary General Meeting held on January 25, 2022, the Company's shareholders approved all of the four resolutions put to the meeting, with each resolution being approved by at least 97% of votes cast. The Company retired the Notes owned by the five institutional investors on January 27, 2022.

MiCo Investment

In April 2022, the Company announced a US$45 million investment from MiCo, a KOSDAQ-listed and Korea-based company. The investment consisted of an equity investment of approximately US$25.2 million (11.2 million ADSs at a price of US$2.25 per ADS) and a seven-year, unsecured US$20 million junior convertible note, with a fixed interest rate of 1.5% and an ADS conversion price of US$3.24 per ADS. The convertible note mandatorily converts into ADS if the volume weighted average price of the Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days.

The chair of MiCo, Seon Kyu Jeon, along with Aris Kekedjian and Michael Sung Soo Kim joined the Board of Trinity Biotech after the investment completed. Existing directors Kevin Tansley, Clint Severson and James Merselis retired from the Board at the same time. In October 2022, Seon Kyu Jeon Jeon and Michael Sung Soo Kim resigned from the Board of Trinity Biotech.

Employment contract with Mr Aris Kekedjian

Mr. Aris Kekedjian was appointed as CEO with effect from October 3, 2022. As part of Mr. Kekedjian's compensation package he is entitled to a substantial share options package that is designed to align Mr. Kekedjian's interests with those of Trinity Biotech shareholders. Under the share options package, he is entitled to:

- Options to purchase 2 million ADS at an exercise price of US$1.071 (the closing price on 30 September 2022). The options will vest on a quarterly basis over 24 months from the date of commencement of employment.

- Options to purchase 3 million ADS which become exercisable in the event the closing price of the ADS reach certain levels for ten (10) trading days out of the thirty (30) previous trading days, of which: (i) options to purchase 1 million ADSs become exercisable if and when the closing price of the ADSs is equal to or greater than $3.00, (ii) options to purchase 1 million ADSs become exercisable if and when the closing price of the ADSs is equal to or greater than $4.00, and (iii) options to purchase 1 million ADSs become exercisable if and when the closing price of the ADSs is equal to or greater than $5.00, in each case adjusted for any stock splits, reverse splits or equivalent reorganisations. These options have an exercise price of US$1.071 and vest rateably over 3 years from the date of commencement of employment.

- Accelerated vesting of the share options in certain circumstances.

Sale of Fitzgerald Life Sciences business

On April 27, 2023, the Company announced it had closed the sale of its Fitzgerald Industries life sciences supply business, consisting of Benen Trading Ltd and Fitzgerald Industries International, Inc, to Biosynth for cash proceeds of approximately US$30 million subject to customary adjustments. The Fitzgerald life sciences supply business generated revenue of approximately US$12 million in the year ended December 31, 2022, and was EBITDA positive. The cash proceeds from Biosynth includes funding to Fitzgerald Industries to allow it repay intercompany loans owed to Trinity Biotech. Management determined that the life sciences supply business was no longer core to the Group's long-term strategy and pursued this transaction as part of its plan to transform into a high growth innovator in diabetes care and decentralised diagnostic solutions.

D. Exchange Controls

As an EU Member State, EU Council Regulations which implement EU and UN sanctions decisions automatically have direct effect in Irish law once they enter into force at EU level. Ireland does not currently operate an autonomous sanctions policy which departs from EU and UN sanctions decisions. At present EU Council Regulations prohibit financial transfers involving a number of persons, entities and bodies, which are subject to amendment on an ongoing, regular basis and currently include, but are not limited to: certain persons and activities in Afghanistan, Belarus, Bosnia & Herzegovina, Burundi, the Central African Republic, Democratic Republic of Congo, the Republic of Guinea, the Republic of Guinea-Bissau, Haiti, the Democratic People's Republic of Korea, Egypt, Eritrea, Iran, Iraq, Lebanon, Libya, Myanmar/Burma, Nicaragua, Russia, Syria, Somalia, South Sudan, Sudan, Tunisia, Turkey, Ukraine, Venezuela, Yemen, and Zimbabwe without the prior permission of the Central Bank of Ireland.

Under the Financial Transfers Act 1992 (the "1992 Act"), the Minister for Finance of Ireland may make provision for the restriction of financial transfers between Ireland and other countries. Financial transfers are broadly defined, and the acquisition or disposal of the ADRs, which represent shares issued by an Irish incorporated company, the acquisition or the disposal of Ordinary Shares and associated payments may fall within this definition. Dividends or payments on the redemption or purchase of shares and payments on the liquidation of an Irish-incorporated company would fall within this definition. Any orders made under the 1992 Act typically align with the EU and UN sanctions decisions as Ireland does not operate an autonomous sanctions policy at present.

Any transfer of, or payment in respect of, an ADS involving the government of any country that is currently the subject of EU or UN sanctions, any person or body controlled by any of the foregoing, or any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. The Company does not anticipate that orders made under the 1992 Act or EU or UN sanctions implemented into Irish law will have a material effect on its business.

E. 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 would 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 law as described 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 holder of such ADSs who a U.S. Holder (as defined below) is 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 tax resident of the U.S.; a corporation created or organised in or under the laws of the U.S. 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 U.S. and control by 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 or other persons 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 shares by vote or value, 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 that 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 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 income tax 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 ADSs 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 2022, it was 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 at the highest tax rate applicable to the U.S. Holder in the prior tax year or years to which it is allocated. 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 under the PFIC rules 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 be eligible to 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, would be treated as capital, and the interest penalty would not be imposed. This election is not made by Trinity Biotech, but by each U.S. Holder. In order for the U.S. Holder to maintain the election, Trinity Biotech must make available certain information, which Trinity Biotech may choose not to provide. U.S. Holders should contact their tax advisor for further information about the election.

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 PFIC 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 fallen below the U.S. Holder's 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. persons 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 ADSs.

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.

Irish 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 but the payment of dividends has subsequently been suspended (see section below on Dividend Policy). Up to 31 December 2019, the payment of a dividend was generally subject to dividend withholding tax ("DWT") at the standard rate of income tax in force at the time the dividend was paid (the applicable rate was 20% in 2019). However, the rate of DWT has increased to 25% in respect of dividends paid on or after 1 January 2020. Irish Revenue also plan to introduce a new "real time" collection system for DWT based on an individual's marginal income tax rate, however the introduction of this proposed system has been postponed at present. 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 40% depending on the individual's circumstances, excluding Pay Related Social Insurance ("PRSI") and the Universal Social Charge ("USC"). 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 USC of up to 8%, with a further 3% surcharge also arising on certain income in excess of €100,000 and a PRSI 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 (or a corporation resident in certain other countries with which Ireland has a double taxation treaty) 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), with such person or persons 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 recipient is the direct beneficial owner of the shares and is beneficially entitled to the dividend, and
- 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 in respect of expenditure incurred on ordinary shares or ADSs prior to 31 December 2002.

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 into 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 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 Global 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 tax-free threshold is determined by the amount of the current benefit and of previous benefits received within the group threshold since 5 December 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 does not dispose of the ordinary shares or ADSs within two years from the date of gift.

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. With effect from 9 October 2019, stamp duty at a rate of 7.5% applied in certain circumstances to the sale or transfer of shares which derive their value, or the greater part of their value, from non-residential property in Ireland. 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 (with a possible 14 day extension for online filings and payments). Late or inadequate payment of stamp duty may result in liability for interest, penalties, surcharge and fines.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the reporting requirements of the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act, and in accordance therewith, we file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K.

As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations is not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act and transactions in our equity securities by our officers and directors is exempt from reporting and the "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act.

In addition, we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

The SEC maintains an internet website that contains reports and other information regarding issuers that file electronically with the SEC. This annual report and the exhibits thereto and any other document we file pursuant to the Exchange Act may be viewed on the SEC's website at www.sec.gov and on our website at www.trinitybiotech.com. The information contained on our website is not incorporated by reference into this Annual Report.

The documents concerning our Company which are referred to in this Annual Report may also be inspected at our offices located at IDA Business Park, Bray, County Wicklow, Ireland.

I. Subsidiary Information

Not applicable.

Item 11. ***Quantitative 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 variable interest rates to which the Group is exposed would be an increase in the loss before tax for 2022 by approximately 1.1%.

Exchange rate sensitivity

At year-end 2022, the total net liability denominated in currencies other than the US Dollar, principally the Euro, Brazilian Real, Canadian Dollar, Swedish Krona and Great British Pound was US$6.8 million.

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 increasing or reducing the Group's 2022 year-end net worth by approximately US$0.7 million.

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, 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, 2022 the Group's borrowings were at a mixture of variable and fixed rates of interest. The senior secured term loan accrues interest at an annual rate equal to 11.25% plus the greater of (a) the Term SOFR Reference Rate and (b) one percent per annum. The exchangeable notes are at a fixed rate of interest of 4% and the convertible note is at a fixed rate of interest of 1.5%. The Group also has one remaining US Dollar denominated finance lease which expires in 2023. At December 31, 2022 the carrying value of the Group's indebtedness totalled US$73,769,000 (2021: US$99,156,000) (2020: US$102,625,000) at interest rates of 1.5% to 15.4% (2020: 4.00% to 5.51%).

In broad terms, a one-percentage point increase in interest rates would increase interest expense by US$468,000 (2021: increase in interest income of US$31,000).

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 and Brazilian Real denominated expenses as a result of the movement in the exchange rate between the US Dollar and those currencies. The Group did not engage in foreign currency hedging in 2022.

The Group had foreign currency denominated cash balances equivalent to US$3,722,000 at December 31, 2022 (2021: US$6,434,000).

Item 12. ***Description of Securities Other than Equity Securities***

A. Debt Securities

Not applicable.

B. Warrants and Rights

On December 15, 2021, the Company agreed to issue warrants exercisable for 2,500,000 of the Company's ADSs to Perceptive. The warrants were issued in January 2022 following the drawdown of the term loan. The per ADS exercise price of the Warrants was US$1.30, based on the lower of i) the 10-day volume weighted average price ("VWAP") for the Company's ADSs for the 10 business days prior to the Closing Date of the Credit Agreement for the Term Loan and ii) the 10-day VWAP for the Company's ADSs for the 10 business days prior to the drawdown date of the funding under the Term Loan. The Warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the Term Loan.

In February 2023, in connection with an increased Term Loan facility, the Company agreed to reprice the 2,500,000 warrants originally issued to Perceptive, with the Warrants now having a per ADS price of US$1.071.

C. Other Securities

Not applicable.

D. American Depositary Shares

Set forth below is a summary of certain provisions in relation to charges and other payments under the Deposit Agreement with the Bank of New York Mellon, as depositary, and the owners and holders from time to time of ADSs issued thereunder.

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.

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	Rate	By whom paid
(1) Issuance of ADSs upon deposit of ordinary shares.	Up to $10.00 per 100 ADSs (or portion thereof) issued.	Persons depositing ordinary shares or person receiving ADSs.
(2) Delivery of deposited securities against surrender of ADSs.	Up to $10.00 per 100 ADSs (or portion thereof) issued.	Persons surrendering ADSs for the purpose of 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 ADS	Person to whom distribution is made.
(5) Transfer of ADSs	Up to $1.50 per certificate for ADRs 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, 2022.

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, 2022.

Since Trinity Biotech is a non-accelerated filer, our auditor, Grant Thornton, an independent registered public accounting firm, is not required to issue an attestation report on the Group's internal control over financial reporting as of December 31, 2022.

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. ***Reserved***

16A. Audit Committee Financial Expert

Mr James Merselis was an independent director and a member of the Audit Committee until his resignation as a director in May 2022. Mr Tom Lindsay is an independent director who joined as a member of the Audit Committee in October 2022. Our board of directors has determined that Mr James Merselis and Mr Tom Lindsay meet the definition of an audit committee financial expert, as defined in Item 401 of Regulation S-K.

Management notes that due to changes in the composition of the Board of Directors, the Audit Committee now consists of only one director. However, the Board of Directors are seeking to recruit at least one additional suitably qualified independent director to join the Audit Committee in order to strengthen the internal control environment including the Committee's oversight of its external auditors.

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 December 31, 2022		*Year ended December 31, 2021*	
	US$'000	*%*	*US$'000*	*%*
Audit	1,064	92%	571	86%
Tax	89	8%	89	14%
Total	1,153		660	

Audit services include audit of our consolidated financial statements including interim 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 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.

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

None.

Share Buyback

Trinity Biotech did not purchase any of its own shares during 2022 or 2021.

16 F. Change in Registrant's Certifying Accountant

Not applicable.

16 G. Corporate Governance

NASDAQ Stock Market Rules and Home Country Practice

Under NASDAQ Stock Market Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the NASDAQ Stock Market Rules. A foreign private issuer that elects to follow a home country practice instead of any of such NASDAQ requirements must submit to NASDAQ, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. We provided NASDAQ with such a letter of non-compliance with respect to:

- Rule 5605(b)(1) - The Rule requiring maintaining a majority of independent directors. Instead, under Irish law and practice, we are not required to appoint a majority of independent directors.
- Rule 5605(b)(2) -The Rule requiring that our independent directors have regularly scheduled meetings at which only independent directors are present. Instead, we follow Irish law according to which independent directors are not required to hold executive sessions.
- Rule 5605(e) - The Rule regarding independent director oversight of director nominations process for directors. Instead, we follow Irish law and practice according to which our board of directors recommends directors for election/re-election by our shareholders.
- Rule 5635(c) - The requirement to obtain shareholder approval for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company (Rule 5635(b)), certain transactions other than a public offering involving issuances of a 20% or more interest in the company (Rule 5635(d)) and certain acquisitions of the stock or assets of another company (Rule 5635(a)). Instead, we follow Irish law and practice in approving such procedures, according to which Board approval may suffice in certain circumstances, depending on the extent existing general authorities to issue shares are in place.
- Rule 5605(c)(2) - The Rule requiring maintaining an audit committee consisting of at least three independent directors. Instead, we follow Irish law that requires that an audit committee have at least one independent director.
- Rule 5605(d)(2) - The Rule requiring a compensation committee consisting of at least two independent directors. We have had a compensation committee, which we referred to as the remuneration committee. We have engaged an international consultancy to advise the Board on Board and executive compensation.
- Rule 5620(c) - The Rule requiring a quorum of 33 1/3% at any meeting of shareholders (Rule 5620(c)). Instead, we follow the provisions of our Articles which require a quorum of 40%. If a quorum is not present within 30 minutes (or such longer time not exceeding one hour as the chairperson of the meeting may decide to wait) after the time appointed for the holding of the meeting a quorum is not present, or if during the meeting a quorum ceases to be present, the meeting, if convened on the requisition of shareholders, shall be dissolved and in any other case, shall stand adjourned to the same day in the next week or to such other day and at such other time and place as the chairperson (or, in default, the board of directors) may, subject to the provisions of the Companies Act 2014, determine. If at such adjourned meeting a quorum is not present within 15 minutes after the time appointed for holding it, the members present in person or by proxy shall be a quorum, but so that not less than two individuals shall constitute a quorum.

16 H. Mine Safety Disclosure

Not applicable.

16 I. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

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***

The audited consolidated financial statements as required under Item 18 are attached hereto starting on page 93 of this Annual Report. The audit report of Grant Thornton (PCAOB ID 1402), independent registered public accounting firm, is included herein preceding the audited consolidated financial statements.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Trinity Biotech plc

Opinion on the financial statements
We have audited the accompanying consolidated statements of financial position of Trinity Biotech plc and its subsidiaries (the "Company") as of December 31, 2022 and 2021, 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, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matters
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Impairment of goodwill and other long-lived assets valuation:

As at December 31, 2022 prior to impairment analysis, the goodwill and intangible assets of the Company totalled $39.9 million, property, plant and equipment of the Company totalled $6.4 million and prepayments of the Company totalled $2.4 million. The Company recognised $5.8 million impairment during the year ended December 31, 2022.

The Company's evaluation of the carrying value of goodwill for impairment involves the comparison of the recoverable amount of goodwill of each cash generating unit (CGU) to its carrying value. The Company used the value-in-use approach, which deploys a discounted cash flow model to estimate the recoverable amount.

This requires management to make significant estimates and assumptions related to discount rates, short-term forecasts of future revenues and margins, and long-term growth rates which drive net cash flows. Changes in these assumptions could have a significant impact on the recoverable amount, the amount of any impairment charge, or both.

We identified goodwill and other long-lived assets for certain CGUs as a critical audit matter because of the significant judgements made by management to estimate the recoverable value of certain CGUs and the difference between their recoverable amounts and carrying values. We focused on CGUs identified as sensitive by management and CGUs with a significant change in cash flow forecasts in the current year (collectively the "selected CGUs").

This required a high degree of auditor judgement and an increased extent of effort, when performing audit procedures to evaluate the reasonableness of management's estimates and assumptions as described above.

How the critical audit matter was addressed in the audit
Our audit procedures related to the assumptions, as described above, used by management to estimate the recoverable amounts of the selected CGUs included the following, among others:

- We evaluated the design effectiveness of controls over management's selection of the discount rates, short-term forecasts of future revenues and margins, and long-term growth rates used to determine the recoverable amount of each selected CGU.
- We compared the underlying cash flow forecasts against budgets and we evaluated management's ability to accurately forecast future revenues and margins by:
  - performing a look-back analysis and comparing actual results to management's historical forecasts; and
  - assessing the reasonableness of the impact of new products, new partnerships and other macroeconomic activity on short-term cash flows.
- We assessed the reasonableness of the valuation model used by the Company compared to generally accepted valuation practices and accounting standards.
- We tested the source information underlying the determination of the discount rates through use of observable inputs from independent external sources and we developed independent estimates and compared those to the discount rates selected by management.
- We developed independent estimates and compared those to the discount rates selected by management.
- We compared the long-term growth rates, used by management to grow cash flows in order to calculate a terminal value, to independent external sources to assess the reasonableness of these rates.

Accounting for capitalised development costs

As discussed in Note 12 to the financial statements, the Company capitalizes certain internal development costs related to the design, development and enhancement of the Company's products. The Company capitalized $4.5 million of internal development costs during the year ended December 31, 2022. We identified capitalization of development costs to be a critical audit matter.

The principal consideration for our determination that capitalized development cost is a critical audit matter is the degree of subjectivity involved in assessing which projects meet the capitalization criteria, based on the development stage of the project and the costs being capitalized.

How the critical audit matter was addressed in the audit
Our audit procedures related to the capitalization of research and development costs included the following, among others:

- We examined the supporting documents of internally generated development costs additions in the financial year to ensure they constituted development phase costs allowable for capitalization as stipulated by accounting standards.
- We tested the key assumptions used by management in concluding that development projects capitalized during the financial year demonstrate the required characteristics to permit capitalization, particularly the commercial and technical feasibility of on-going development projects.
- We conducted detailed discussions with senior project personnel in charge of the developments to understand their rationale for concluding on the appropriateness of capitalization of the development phase costs and, where necessary, challenged the underlying reasoning.
- We obtained a detailed understanding of the role of the employees in the development of the relevant projects whose salaries are capitalized.
- We evaluated the design effectiveness of management's control on costs capitalization and progress and likely outcome of on-going projects.

/s/ GRANT THORNTON

Dublin, Ireland

We have served as the Company's auditor since 2008.

DATE May 16, 2023

CONSOLIDATED STATEMENT OF OPERATIONS

	Notes	Year ended December 31 2022 Total US$'000	2021 Total US$'000	2020 Total US$'000
Revenues	2	**74,779**	**92,965**	**101,980**
Cost of sales		**(52,731)**	**(54,888)**	**(53,400)**
Gross profit		**22,048**	**38,077**	**48,580**
Other operating income	4	**343**	**4,672**	**1,860**
Research and development expenses		**(4,138)**	**(4,497)**	**(5,080)**
Selling, general and administrative expenses		**(29,166)**	**(24,683)**	**(26,390)**
Selling, general and administrative expenses – closure costs	9	**-**	**-**	**(2,425)**
Selling, general and administrative expenses – recognition of contingent asset	24	**-**	**-**	**1,316**
Impairment charges	5	**(5,839)**	**(6,944)**	**(17,779)**
Operating (loss)/profit		**(16,752)**	**6,625**	**82**
Financial income	6	**303**	**1,223**	**36**
Financial expenses	6	**(24,745)**	**(7,097)**	**(6,751)**
Net financing expense		**(24,442)**	**(5,874)**	**(6,715)**
(Loss)/profit before tax	9	**(41,194)**	**751**	**(6,633)**
Total income tax credit	2, 7	**192**	**178**	**620**
(Loss)/profit for the year on continuing operations	2	**(41,002)**	**929**	**(6,013)**
Loss for the year on discontinued operations	8	**(7)**	**(54)**	**(375)**
(Loss)/profit for the year (all attributable to owners of the parent)	2	**(41,009)**	**875**	**(6,388)**
Basic (loss)/profit per ADS (US Dollars) – continuing operations	10	(1.22)	0.04	(0.29)
Diluted (loss)/profit per ADS (US Dollars) – continuing operations	10	(1.22)	0.04	(0.29)
Basic (loss)/profit per 'A' ordinary share (US Dollars) –continuing operations	10	(0.30)	0.01	(0.07)
Diluted (loss)/profit) per 'A' ordinary share (US Dollars) – continuing operations	10	(0.30)	0.01	(0.07)
Basic (loss)/profit per ADS (US Dollars) – group	10	(1.22)	0.04	(0.31)
Diluted (loss)/profit per ADS (US Dollars) – group	10	(1.22)	0.04	(0.31)
Basic (loss)/profit per 'A' ordinary share (US Dollars) – group	10	(0.30)	0.01	(0.08)
Diluted (loss)/profit) per 'A' ordinary share (US Dollars) – group	10	(0.30)	0.01	(0.08)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Year ended December 31		
	Notes	*2022 US$'000*	*2021 US$'000*	*2020 US$'000*
(Loss)/profit for the year	2	(41,009)	875	(6,388)
Other comprehensive loss				
Items that will be reclassified subsequently to profit or loss				
Foreign exchange translation differences		(396)	(86)	(1,360)
Other comprehensive loss		(396)	(86)	(1,360)
Total Comprehensive (Loss)/profit (all attributable to owners of the parent)		**(41,405)**	**789**	**(7,748)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	At December 31 2022 US$'000	2021 US$'000
ASSETS			
Non-current assets			
Property, plant and equipment	11	5,682	5,918
Goodwill and intangible assets	12	35,269	35,981
Deferred tax assets	13	4,218	4,101
Derivative financial instruments	22	128	-
Other assets	14	139	207
Total non-current assets		**45,436**	**46,207**
Current assets			
Inventories	15	22,503	29,123
Trade and other receivables	16	15,753	16,116
Income tax receivable		1,834	1,539
Cash and cash equivalents	17	6,578	25,910
Total current assets		**46,668**	**72,688**
TOTAL ASSETS	2	**92,104**	**118,895**
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	18	1,963	1,213
Share premium	18	46,458	16,187
Treasury shares	18	(24,922)	(24,922)
Accumulated (deficit)/surplus	18	(26,695)	12,559
Translation reserve	18	(5,775)	(5,379)
Equity component of convertible note	18, 22	6,709	-
Other reserves	18	86	23
Total deficit		**(2,176)**	**(319)**
Current liabilities			
Income tax payable		28	22
Trade and other payables	20	15,375	15,127
Provisions	21	50	50
Exchangeable notes and other borrowings	22	210	83,312
Lease liabilities	23	1,676	1,980
Total current liabilities		**17,339**	**100,491**
Non-current liabilities			
Senior secured term loan	22	44,301	-
Derivative financial liability	22	1,569	-
Convertible Note	22	13,746	-
Lease liabilities	23	12,267	13,865
Deferred tax liabilities	13	5,058	4,858
Total non-current liabilities		**76,941**	**18,723**
TOTAL LIABILITIES	2	**94,280**	**119,214**
TOTAL EQUITY AND LIABILITIES		**92,104**	**118,895**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Share capital 'A' ordinary shares US$'000	*Share premium US$'000*	*Treasury Shares US$'000*	*Translation reserve US$'000*	*Equity Component of Convertible Note US$'000*	*Other reserves US$'000*	*Accumulated (deficit)/surplus US$'000*	*Total US$'000*
Balance at January 1, 2020	1,213	16,187	(24,922)	(3,933)	-	23	16,145	4,713
Loss for the period	-	-	-	-	-	-	(6,388)	(6,388)
Other comprehensive income	-	-	-	(1,360)	-	-	-	(1,360)
Total comprehensive loss	-	-	-	(1,360)	-	-	(6,388)	(7,748)
Share-based payments (Note 19)	-	-	-	-	-	-	816	816
Balance at December 31, 2020	**1,213**	**16,187**	**(24,922)**	**(5,293)**	**-**	**23**	**10,573**	**(2,219)**
Balance at January 1, 2021	1,213	16,187	(24,922)	(5,293)	-	23	10,573	(2,219)
Profit for the period	-	-	-	-	-	-	875	875
Other comprehensive loss	-	-	-	(86)	-	-	-	(86)
Total comprehensive profit/(loss)	-	-	-	(86)	-	-	875	789
Share-based payments (Note 19)	-	-	-	-	-	-	1,111	1,111
Balance at December 31, 2021	**1,213**	**16,187**	**(24,922)**	**(5,379)**	**-**	**23**	**12,559**	**(319)**
Balance at January 1, 2022	1,213	16,187	(24,922)	(5,379)	-	23	12,559	(319)
Loss for the period	-	-	-	-	-	-	(41,009)	(41,009)
Other comprehensive loss	-	-	-	(396)	-	-	-	(396)
Total comprehensive loss	-	-	-	(396)	-	-	(41,009)	(41,405)
Shares issued in the year (Note 18)	750	30,271	-	-	-	-	-	31,021
Shares to be issued	-	-	-	-	-	63	-	63
Equity component of convertible note (Note 18)	-	-	-	-	6,709	-	-	6,709
Share-based payments (Note 19)	-	-	-	-	-		1,755	1,755
Balance at December 31, 2022	**1,963**	**46,458**	**(24,922)**	**(5,775)**	**6,709**	**86**	**(26,695)**	**(2,176)**

CONSOLIDATED STATEMENT OF CASH FLOWS

	Notes	Year ended December 31, 2022 US$'000	2021 US$'000	2020 US$'000
Cash flows from operating activities				
(Loss)/profit for the year		(41,009)	875	(6,388)
Adjustments to reconcile net profit/(loss) to cash provided by operating activities:				
Depreciation	9,11	1,410	1,827	1,674
Amortisation	9,12	923	917	1,403
Income tax credit	7	(192)	(167)	(182)
Financial income	6	(303)	(1,223)	(36)
Financial expense	6	24,745	7,097	6,751
Share-based payments (net of capitalized amounts)	19	1,755	1,100	792
Foreign exchange gains on operating cash flows		(76)	(251)	(663)
Loss/(gain) on disposal or retirement of property, plant and equipment	9	2	(1)	30
Movement in inventory provision	15	7,391	5,589	5,059
Impairment of prepayments	5, 16	482	583	562
Impairment of property, plant and equipment	5, 11	733	2,508	1,795
Impairment of intangible assets	5, 12	4,624	3,853	15,422
Other non-cash items		269	(5,317)	(634)
Operating cash flows before changes in working capital		**754**	**17,390**	**25,585**
(Increase)/decrease in trade and other receivables		(966)	6,236	(2,489)
(Increase) in inventories		(877)	(4,406)	(3,419)
Increase/(decrease) in trade and other payables		181	(7,591)	4,994
Cash (used in)/generated from operations		**(908)**	**11,629**	**24,671**
Interest paid		-	(11)	(48)
Interest received		2	1	104
Income taxes (paid)/received		(15)	1,619	(972)
Net cash (used in)/generated by operating activities		**(921)**	**13,238**	**23,755**
Cash flows from investing activities				
Payments to acquire intangible assets		(4,876)	(6,879)	(6,990)
Acquisition of property, plant and equipment		(1,101)	(1,812)	(3,178)
Disposal of property, plant and equipment		-	-	(30)
Net cash used in investing activities		**(5,977)**	**(8,691)**	**(10,198)**
Cash flows from financing activities				
Issue of ordinary share capital including share premium (net of issuance costs)	18	25,336	-	-
Proceeds from shares to be issued		63	-	-
Net proceeds from senior secured term loan	22	80,015	-	-
Proceeds from convertible note issued	22	20,000	-	-
Expenses paid in connection with debt financing	22	(2,356)	(848)	-
Purchase of exchangeable notes	22	(86,730)	-	-
Repayment of senior secured term loan	22	(34,500)	-	-
Penalty for early settlement of term loan	22	(3,450)	-	-
Repayment of other loan		(23)	-	-
Interest paid on senior secured term loan		(6,424)	-	-
Interest paid on convertible note		(199)	-	-
Proceeds from Paycheck Protection loans		-	1,764	4,520
Interest paid on exchangeable notes	27	(1,293)	(3,996)	(3,996)
Payment of lease liabilities	27	(2,761)	(2,939)	(3,240)
Net cash used in financing activities		**(12,322)**	**(6,019)**	**(2,716)**
(Decrease)/increase in cash and cash equivalents and short-term investments		(19,220)	(1,472)	10,841
Effects of exchange rate movements on cash held		(112)	55	86
Cash and cash equivalents and short-term investments at beginning of year		25,910	27,327	16,400
Cash and cash equivalents and short-term investments at end of year	17	**6,578**	**25,910**	**27,327**

1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies adopted by Trinity Biotech plc ("the Company") and its subsidiaries (together the "the Group") are set out below.

i) General information

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 is a significant provider of raw materials to the life sciences and research industries globally. Trinity Biotech also operates a licenced reference laboratory that specializes in diagnostics for autoimmune diseases.

ii) 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 January 1, 2022. 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, in relation to the 2022 consolidated financial statements there are no differences regarding the effective date of new IFRS relevant to Trinity Biotech as issued by the IASB and as adopted by the EU. In relation to prior periods presented, none of the differences are relevant in the context of Trinity Biotech and the consolidated financial statements comply with IFRS both as issued by the IASB and as adopted by the EU.

iii) 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. Derivative financial instruments are also subsequently revalued and 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 29.

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At December 31, 2022, the Group had net current assets of US$29.3 million. At the date of this report, the Group's liquidity position has substantially improved following the sale of its Fitzgerald life sciences business for cash proceeds of approximately US$30 million (subject to customary adjustments). This transaction substantially improves the Group's capital structure by reducing gross debt by approximately US$10 million; with the balance of the proceeds (net of costs) providing significant capital for growth, transformation, and potentially further debt reduction. There are no material debt maturities until 2026.

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

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.

iv) 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.

v) 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
• Buildings	50 years
• Office equipment and fittings	10 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.

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

The Group considers whether a contract is or contains a lease. A lease is defined as 'a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration'. To apply this definition the Group assesses whether the contract meets three key evaluations which are whether:

- the contract contains an identified asset, which is either explicitly identified in the contract or implicitly specified by being identified at the time the asset is made available to the Group
- the Group has the right to obtain substantially all of the economic benefits from use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract
- the Group has the right to direct the use of the identified asset throughout the period of use. The Group assess whether it has the right to direct 'how and for what purpose' the asset is used throughout the period of use.

At lease commencement date, the Group recognises a right-of-use asset and a lease liability on the balance sheet. The right-of-use asset is measured at cost, which is made up of the initial measurement of the lease liability, any initial direct costs incurred by the Group, an estimate of any costs to dismantle and remove the asset at the end of the lease, and any lease payments made in advance of the lease commencement date (net of any incentives received).

The Group depreciates the right-of-use assets on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Group also assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Group measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available or the Group's incremental borrowing rate. Lease payments included in the measurement of the lease liability are made up of fixed payments (including in substance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised. Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in in-substance fixed payments. When the lease liability is remeasured, the corresponding adjustment is reflected in the right-of-use asset, or profit and loss if the right-of-use asset is already reduced to zero.

The Group has elected to account for short-term leases and leases of low-value assets using the practical expedients. Instead of recognising a right-of-use asset and lease liability, the payments in relation to these are recognised as an expense in profit or loss on a straight-line basis over the lease term. On the statement of financial position, right-of-use assets have been included in property, plant and equipment and lease liabilities have been included in separate lines within the current liabilities and non-current liabilities sections.
Leased assets - as lessor

The Group's accounting policy under IFRS 16 has not changed from the comparative period. As a lessor, the Group classifies its leases as either operating or finance leases. A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership of the underlying asset, and classified as an operating lease if it does not.

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)).

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

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, licenced, 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 at least 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.

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 capitalised.

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 in its intended market. The estimated useful lives are as follows:

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

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

The Group uses a useful economic life of 15 years for capitalised 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 several 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.

viii) Impairment

The carrying amount of the Group’s assets, other than inventories, accounts receivable, cash and cash equivalents, short-term investments 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 on 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. 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, 2021 and December 31, 2022. See Note 12.

In-process research and development (IPR&D) is tested for impairment on an annual basis, in the periodically and always at year end, 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.

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

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. 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.

x) Trade and other receivables

Trade receivables are amounts due from customers for products sold or services provided in the ordinary course of business. Trade and other receivables are stated at their amortised cost less impairment losses incurred. Cost approximates fair value given the short-term nature of these assets. The Group records the loss allowance as lifetime expected credit losses. These are the expected shortfalls in contractual cash flows, considering the potential for default at any point during the life of the financial instrument. Expected credit losses are recorded on all of trade receivables based on an assessment of the probability of default or delinquency in payments and the probability that debtor will enter into financial difficulties or bankruptcy.

xi) Trade and other payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business. Trade and other payables are stated at cost. Cost approximates fair value given the short term nature of these liabilities.

xii) Cash and cash equivalents

Cash and cash equivalents comprise cash balances and short-term deposits which are readily available at year-end. Deposits with maturities less than six months as at the year-end date are recognised as cash and cash equivalents and are carried at fair value when there is no expected loss in value on early termination. 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) Short-term investments

Short-term investments comprise short-term bank deposits which have maturities greater than six months as at the year-end date. Short-term deposits made for varying periods depending on the immediate cash requirements of the Group and earn interest at the respective deposit rates in place. Where restrictions are imposed by third parties, such as lending institutions, on short-term deposits held by the Group these are treated as financial assets in the financial statements.

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

xiv) 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.

Certain share options have been granted for which there is a condition that the options only become exercisable into ADSs when the market price of an ADS reaches a certain level. This is deemed to be a non-vesting condition. The term 'non-vesting condition' is not explicitly defined in IFRS 2, Share based Payment, but is inferred to be any condition that does not meet the definition of a vesting condition. The only condition for these options to vest is that the option holder continues service and there were no other conditions which would be considered non-vesting conditions. Non-vesting conditions are reflected in measuring the grant-date fair value of the share-based payment and there is no true-up in the measurement of the share-based payment for differences between the expected and the actual outcome of non-vesting conditions. If all service conditions are met, then the share-based payment cost will be recognized even if the option holder does not receive the share-based payment due to a failure to meet the non-vesting condition.

The expense in the consolidated 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.

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.

xv) Government grants and financial support

The Group received government-backed Covid-19 financial supports in the form of forgivable loans. Under IAS 20, Accounting for Government Grants, a forgivable loan from government is treated as a government grant when there is reasonable assurance that the terms for forgiveness of the loan will be met. Where a loan was received in the financial year but not yet forgiven within the financial year, the loan is treated as a current liability. The Group has opted to present government grant income for loans that have been forgiven as Other operating income in the consolidated statement of operations.

Grants that compensate the Group for expenses incurred such as research and development, employment and training are recognised as 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.

xvi) Revenue recognition

Goods sold and services rendered

The Group recognises revenue when it transfers control over a good or service to a customer. Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group 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. Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods and services supplied to external customers, net of discounts and rebates and excluding sales taxes.

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 performance obligations to the customer in accordance with the shipping terms.

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

Some contracts oblige the Group to ship product to the customer ahead of the agreed payment schedule. For these shipments, a contract asset is recognised when control over the goods has transferred to the customer. The financing component is insignificant as invoicing for these shipments occurs within a short period of time after shipment has occurred and standard 30 day credit terms typically apply. Some contracts could be regarded as offering the customer a right of return. Due to the uncertainty of the magnitude and likelihood of product returns, there is a level of estimation involved in assessing the amount of revenue to be recognized for these types of contracts. In accordance with IFRS 15, when estimating the effect of an uncertainty on an amount of variable consideration to which the Group will be entitled, all information that is reasonably available, including historical, current and forecast, is considered.

The Group operates a licenced referenced laboratory in the US, which provides testing services to institutional customers and insurance companies. In the US, there are rules requiring all insurance companies to be billed the same amount per test. However, the amount that each insurance company pays for a particular test varies according to their own internal policies and this can typically be considerably less than the amount invoiced. We recognise lab services revenue for insurance companies by taking the invoiced amount and reducing it by an estimated percentage based on historical payment data. We review the percentage reduction annually based on the latest data. As a practical expedient, and in accordance with IFRS, we apply a portfolio approach to the insurance companies as they have similar characteristics. We judge that the effect on the financial statements of using a portfolio approach for the insurance companies will not differ materially from applying IFRS 15 to the individual contracts within that portfolio.

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.

The Group leases instruments to customers typically as part of a bundled package. Where a contract has multiple performance obligations and its duration is greater than one year, the transaction price is allocated to the performance obligations in the contract by reference to their relative standalone selling prices. For contracts where control of the instrument is transferred 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. Fair value is determined on the basis of standalone selling price. In the case where control of the instrument does not transfer to the customer, revenue is recognised on the basis of customer usage of the instrument. See also Item 18, Note 1(v).

In obtaining these contracts, the Group incurs a number of incremental costs, such as sales bonus paid to sales staff commissions paid to distributors and royalty payments. As the amortisation period of these costs, if capitalised, would be less than one year, the Group makes use of the practical expedient in IFRS 15.94 and expenses them as they incur.

A receivable is recognised when the goods are delivered as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

The Group’s obligation to provide a refund for faulty products under the standard warranty terms is recognised as a provision, see Item 18, Note 21 for details.

Other operating income

Other operating income includes income for the provision of canteen services. This income has not been treated as revenue since the canteen activities are incidental to the main revenue-generating activities of the Group. Other operating income also includes government-backed Covid-19 financial supports and government grant income. The accounting policy for this income is described in Note 1 (xv).

xvii) 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.

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

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.

xviii) 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 Brazil, Canada and Sweden) principally operate. Thus, the functional currency of the Company and its subsidiaries (other than the Brazilian, Canadian and Swedish subsidiaries) is the US Dollar. The functional currency of the Brazilian entity is the Brazilian Real, the functional currency of the Canadian subsidiary, Nova Century Scientific Inc, is the Canadian Dollar and the functional currency of the Swedish subsidiary is the Swedish Kroner. 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 consolidated 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, Brazilian Real, Canadian Dollar 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, 2022.

xix) Hedging

The activities of the Group expose it primarily to changes in foreign exchange rates and interest rates. The Group uses derivative financial instruments, from time to time, 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.

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

xx) Exchangeable notes and derivative financial instruments

The Company's exchangeable notes are treated as a host debt instrument with embedded derivatives attached. On initial recognition, the host debt instrument is recognised at the residual value of the total net proceeds of the bond issue less fair value of the embedded derivatives. Subsequently, the host debt instrument is measured at amortised cost using the effective interest rate method.

The embedded derivatives are initially recognised at fair value and are restated at their fair value at each reporting date. The fair value changes of the embedded derivatives are recognised in the consolidated statement of operations, except for changes in fair value related to the Group's own credit risk, which are recorded in the statement of comprehensive income.

Where the exchangeable notes are redeemed early or repurchased in a way that does not alter the original conversion privileges, the consideration paid is allocated to the respective components and the amount of any gain or loss is recognised in the consolidated statement of operations.

xxi) Senior secured term loan

The senior secured term loan is initially recorded at the fair value of the consideration received net of: a) directly attributable transaction costs, b) the fair value at the date of issue of the warrants issued to the lender (see Note 1xxii) and c) the fair value of the option to prepay the loan at the date of issue (see Note 1xxii). Subsequent to initial recognition, the term loan is measured at amortised cost employing the effective interest methodology. Borrowing costs, including any penalties for early settlement of the loan, are recognised as an expense in the period in which they are incurred.

xxii) Warrants and loan prepayment option

The company issued warrants to Perceptive ("the warrants") which are exercisable into ADSs of the Company at a fixed exercise price. The Warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding. The warrants were issued to Perceptive in consideration of them entering into the term loan on the same date and Perceptive paid no other consideration to the company for the warrants issued.

A warrant contract might be accounted for as an equity instrument or a financial liability under IFRS depending on the terms of a warrant. A warrant contract that will or might be settled by an entity by delivering a fixed number of its own equity instruments, in exchange for a fixed amount of cash or another financial asset, is an equity instrument. As Perceptive has the option to choose a cashless exercise option, the Company will have to deliver a variable number of ADS, since the number of shares will vary depending on the ADS traded price. Even though the cashless exercise option is economically comparable to the cash exercise option, the fact that the company will issue a variable number of shares under the cashless exercise option results in one settlement alternative violating the 'fixed for fixed' requirement. The warrant contract therefore meets the definition of a financial liability and given the value of the warrant changes in response to the price of the Company's ADS, with no initial investment and settlement occurring in the future it meets the definition of a derivative liability under IFRS 9. The warrant is issued in a separate contract, is transferable independently of the term loan and can be exercised while the term loan remains outstanding. Therefore, the warrant is a separate instrument to the term loan.

The warrant contracts are initially recognised as a derivative liability at fair value and subsequently measured at fair value at each reporting period with any changes recognised in the consolidated statement of operations.

The Company has the option to prepay the senior secured term loan in whole or in part for an amount equal to the principal, accrued interest and prepayment premium. In accordance with IFRS 9, this option is separated from the term loan and is initially recognised as a derivative asset at fair value and subsequently measured at fair value at each reporting period with any changes recognised in the consolidated statement of operations.

xxiii) Convertible Note

The convertible note is accounted for as a compound financial instrument containing both an equity and liability element. The convertible note has a contractual obligation to deliver cash on redemption equal to the principal amount plus accrued interest and therefore has a liability component in line with the definition of a financial liability in IAS 32. The convertible loan note also has a conversion feature where it mandatorily converts into ADS if the volume weighted average price of the Company's ADSs is at a certain price for any five consecutive NASDAQ trading days or any other time at the discretion of the Noteholder. Where a derivative that will or may be settled other than by the exchange of a fixed amount of cash or another financial asset for a fixed number of the entity's own equity instruments, the conversion feature represents an equity component of the convertible note.

The equity component is measured as the residual amount that results from deducting the fair value of the liability component from the initial carrying amount of the instrument as a whole. There is no remeasurement of the equity element following initial recognition. The debt component is accounted for at amortised cost employing the effective interest methodology.

xxiv) 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.

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

xxv) 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 consolidated statement of operations except to the extent that it relates to items recognised directly in equity, in which case it is recognised in equity.

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 in the countries where the company and its subsidiaries operate and generate income 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.

xxvi) 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.

xxvii) 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.

xxviii) Finance income and costs

Financing expenses comprise interest costs payable on senior secured term loan, convertible note, leases and exchangeable notes along with non-recurring financing expenses such as penalty for early settlement of term loan and loss on disposal of exchangeable notes. 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 consolidated statement of operations as it accrues, using the effective interest method. Finance income also includes fair value adjustments for derivative assets and liabilities related to the senior secured term loan and to embedded derivatives associated with exchangeable notes.

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

xxvix) Treasury shares

When the Group purchases its own equity instruments (treasury shares), the costs, including any directly attributable incremental costs, are deducted from equity. No gain or loss is recognised in the consolidated 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.

xxx) 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.

xxxi) Profit or loss from discontinued operations

A discontinued operation is a component of the Group that either has been disposed of or is classified as held for sale. Profit or loss from discontinued operations comprises the post-tax profit or loss of discontinued operations and the post-tax gain or loss resulting from the measurement and disposal of assets classified as held for sale.

xxxii) 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

xxxiii) New IFRS Standards adopted as of January 1, 2022

The following standard amendments became effective for the Group as of January 1, 2022:

- Amendments to IFRS 3 Business Combinations – Reference to the Conceptual Framework
- Amendments to IAS 16 Property, Plant and Equipment – Proceeds before Intended Use
- Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets – Onerous Contracts – Costs of Fulfilling a Contract

The standard amendments did not result in a material impact on the Group's results.

xxxiv) Standards, amendments and interpretations to existing IFRS Standards that are not yet effective

At the date of authorisation of these financial statements, several new, but not yet effective, Standards and amendments to existing Standards, and interpretations have been published by the IASB or IFRIC. None of these Standards or amendments to existing Standards have been adopted early by the Group and no interpretations have been issued that are applicable and need to be taken into consideration by the Group at either reporting date. Management anticipates that all relevant pronouncements will be adopted for the first period beginning on or after the effective date of the pronouncement. New Standards, amendments and Interpretations not adopted in the current year have not been disclosed as they are not expected to have a material impact on the Group's consolidated financial statements.

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 - Ireland. 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:

Revenue *Year ended December 31, 2022*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Revenue from external customers	50,508	24,271	-	74,779
Inter-segment revenue	26,110	828	(26,938)	-
Total revenue	76,618	25,099	(26,938)	74,779

Revenue *Year ended December 31, 2021*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Revenue from external customers	67,249	25,716	-	92,965
Inter-segment revenue	49,059	2,517	(51,576)	-
Total revenue	116,308	28,233	(51,576)	92,965

2. SEGMENT INFORMATION (CONTINUED)

Revenue *Year ended December 31, 2020*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Revenue from external customers	77,688	24,292	-	101,980
Inter-segment revenue	59,304	1,095	(60,399)	-
Total revenue	136,992	25,387	(60,399)	101,980

ii) The distribution of revenue by customers' geographical area was as follows:

Revenue	*December 31, 2022* *US$'000*	*December 31, 2021* *US$'000*	*December 31, 2020* *US$'000*
Americas	40,176	57,799	70,408
Asia / Africa	25,022	25,504	22,567
Europe (including Ireland) *	9,581	9,662	9,005
	74,779	92,965	101,980

* 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, 2022* *US$'000*	*December 31, 2021* *US$'000*	*December 31, 2020* *US$'000*
Clinical laboratory goods	58,294	74,700	84,280
Clinical laboratory services	7,272	7,928	8,485
Point-of-Care	9,213	10,337	9,215
	74,779	92,965	101,980

iv) The group has recognised the following amounts relating to revenue in the consolidated statement of operations:

Revenue	*December 31, 2022* *US$'000*	*December 31, 2021* *US$'000*	*December 31, 2020* *US$'000*
Revenue from contracts with customers (a)	74,779	92,965	101,980
	74,779	92,965	101,980

2. SEGMENT INFORMATION (CONTINUED)

(v) Disaggregation of revenue from contracts with customers:

The Group derives revenue from the transfer of goods and services over time and at a point in time in the following geographical areas:

Timing of revenue recognition *Year ended December 31, 2022*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Rest of World Other* *US$'000*	*Total* *US$'000*
At a point in time	50,174	24,271	-	74,445
Over time	334	-	-	334
Total	50,508	24,271	-	74,779

Timing of revenue recognition *Year ended December 31, 2021*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Rest of World Other* *US$'000*	*Total* *US$'000*
At a point in time	66,806	25,716	-	92,522
Over time	443	-	-	443
Total	67,249	25,716	-	92,965

Timing of revenue recognition *Year ended December 31, 2020*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Rest of World Other* *US$'000*	*Total* *US$'000*
At a point in time	77,060	24,292	-	101,352
Over time	628	-	-	628
Total	77,688	24,292	-	101,980

(vi) The Group derives revenue from the transfer of goods and services over time and at a point in time based on customers' geographical area as follows:

Timing of revenue recognition *Year ended December 31, 2022*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	39,842	25,022	9,581	74,445
Over time	334	-	-	334
Total	40,176	25,022	9,581	74,779

Timing of revenue recognition *Year ended December 31, 2021*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	57,356	25,504	9,662	92,522
Over time	443	-	-	443
Total	57,799	25,504	9,662	92,965

2. SEGMENT INFORMATION (CONTINUED)

Timing of revenue recognition *Year ended December 31, 2020*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	69,780	22,567	9,005	101,352
Over time	628	-	-	628
Total	70,408	22,567	9,005	101,980

vii) The distribution of segment results by geographical area was as follows:

		Rest of World		
Year ended December 31, 2022	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
Result before impairment and unallocated expenses	(5,891)	(2,516)	(33)	(8,440)
Impairment charges	(2,331)	(3,508)	-	(5,839)
Result after impairment	(8,222)	(6,024)	(33)	(14,279)
Unallocated expenses *				(2,473)
Operating loss				(16,752)
Net financing expense (Note 6)				(24,442)
Loss before tax				(41,194)
Income tax credit (Note 7)				192
Loss for the year on continuing operations				(41,002)
Loss for the year on discontinued operations (Note 8)				(7)
Loss for the year				(41,009)

		Rest of World		
Year ended December 31, 2021	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
Result before impairment and unallocated expenses	9,276	5,084	(12)	14,348
Impairment charges	(6,088)	(856)	-	(6,944)
Result after impairment	3,188	4,228	(12)	7,404
Unallocated expenses *				(779)
Operating profit				6,625
Net financing expense (Note 6)				(5,874)
Profit before tax				751
Income tax credit (Note 7)				178
Profit for the year on continuing operations				929
Loss for the year on discontinued operations (Note 8)				(54)
Profit for the year				875

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World		
Year ended December 31, 2020	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Result before impairment and unallocated expenses	14,495	4,264	(71)	18,688
Impairment	(17,779)	-	-	(17,779)
Result after impairment	(3,284)	4,264	(71)	909
Unallocated expenses *				(827)
Operating profit				82
Net financing expense (Note 6)				(6,715)
Loss before tax				(6,633)
Income tax credit (Note 7)				620
Loss for the year on continuing operations				(6,013)
Loss for the year on discontinued operations (Note 8)				(375)
Loss for the year				(6,388)

* Unallocated expenses represent head office general and administration costs of the Group, which cannot be allocated to the results of any specific geographical area.

viii) The distribution of segment assets and segment liabilities by geographical area was as follows:

		Rest of World		
As at December 31, 2022	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Assets and liabilities				
Segment assets	41,779	37,695	-	79,474
Unallocated assets:				
Income tax assets (current and deferred)				6,052
Cash and cash equivalents and short-term investments				6,578
Total assets as reported in the Group balance sheet				92,104
Segment liabilities	58,307	30,845	42	89,194
Unallocated liabilities:				
Income tax liabilities (current and deferred)				5,086
Total liabilities as reported in the Group balance sheet				94,280

		Rest of World		
As at December 31, 2021	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Assets and liabilities				
Segment assets	45,891	41,453	1	87,345
Unallocated assets:				
Income tax assets (current and deferred)				5,640
Cash and cash equivalents and short-term investments				25,910
Total assets as reported in the Group balance sheet				118,895
Segment liabilities	12,382	101,927	25	114,334
Unallocated liabilities:				
Income tax liabilities (current and deferred)				4,880
Total liabilities as reported in the Group balance sheet				119,214

ix) 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 and derivative financial instruments), by geographical area was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Rest of World – Ireland	21,180	22,617
Americas	19,910	19,489
	41,090	42,106

2. SEGMENT INFORMATION (CONTINUED)

x) The distribution of depreciation and amortisation by geographical area was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Depreciation:			
Rest of World – Ireland	128	204	127
Americas	1,282	1,662	1,587
	1,410	1,866	1,714
Amortisation:			
Rest of World – Ireland	123	69	32
Americas	800	848	1,371
	923	917	1,403

xi) The distribution of share-based payment expense by geographical area was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Rest of World – Ireland	632	1,072	722
Americas	1,123	28	70
	1,755	1,100	792

See Note 19 for further information on share-based payments.

xii) The distribution of taxation (expense)/credit by geographical area was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Rest of World – Ireland	284	540	293
Rest of World – Other	(4)	(2)	(8)
Americas	(88)	(360)	335
	192	178	620

xiii) During 2022 and 2020 there were no customers generating 10% or more of total revenues. In 2021, one customer accounted for more than 10% of total revenues.

xiv) The distribution of capital expenditure by geographical area was as follows:

	December 31 2022 US$'000	*December 31, 2021 US$'000*
Rest of World – Ireland	2,443	3,826
Rest of World – Other	-	-
Americas	4,370	4,776
	6,813	8,602

3. EMPLOYMENT

The average number of persons employed by the Group is as follows:

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
Research and development	30	41	52
Administration and sales	119	134	148
Manufacturing and quality	249	302	343
	398	477	543

Employment costs charged in the consolidated statement of operations for continuing operations are analysed as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Wages and salaries	23,608	26,561	26,187
Social welfare costs	2,036	2,403	2,195
Pension costs	352	352	447
Share-based payments	1,755	1,100	792
Restructuring Cost	274	270	388
Recognition of contingent asset (Note 24)	-	-	(1,316)
	28,025	30,686	28,693

Employment costs are shown net of capitalisations and Irish government wage subsidies. Total employment costs, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2022 amounted to US$28,848,000 (2021: US$33,366,000) (2020: US$33,347,000). Total share-based payments, inclusive of amounts capitalised in the balance sheet, amounted to US$1,755,000 for the year ended December 31, 2022 (2021: US$1,111,000) (2020: US$816,000). See Note 19 for further details.

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$352,000 (2021: US$352,000) (2020: US$447,000). The pension accrual for the Group at December 31, 2022 was US$44,000 (2021: US$47,000), (2020: US$47,000).

4. OTHER OPERATING INCOME

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Government supports - COVID-19	7	4,668	1,840
Government grants	333	-	-
Other income	-	-	17
Rental income from premises	3	4	3
	343	4,672	1,860

4. OTHER OPERATING INCOME (CONTINUED)

In 2020, the Company received an interest-free loan received under the Canada Emergency Business Account ("CEBA"). The CEBA loans were provided by the Canadian Government to mitigate the financial impact of the Covid-19 outbreak. This interest-free loan was repaid in the year ended December 31, 2022 and an amount of CAD$10,000 (US$7,000) was forgiven, which has been recognised as income. In 2021 and 2020, government supports - COVID-19 comprised funding received under the U.S. government's Cares Act, specifically its Paycheck Protection Program and its Provider Relief Fund. Six Paycheck Protection Program ("PPP") loans received by the Company, amounting to US$4,668,000 were forgiven during 2021 and recognised as Other Operating Income in that year. Two PPP loans received by the Company in 2020, amounting to US$1,615,000 were forgiven during 2020 and recognised as Other Operating Income. In addition, in 2020 the Company received US$225,000 under the U.S. government's Provider Relief Fund and recognised as Other Operating Income. No funding was received under the Provider Relief Fund in either 2021 or 2022.

5. IMPAIRMENT CHARGES

In accordance with IAS 36, *Impairment of Assets*, the Group carries out periodic impairment reviews of the asset valuations. A number of factors impacted this calculation including the Company's market capitalization during the year ended 31 December 2022, the cost of capital, cash flow projections and net asset values across each of the Company's cash-generating units.

The impact of the above items on the consolidated statement of operations for the year ended December 31, 2022, December 31, 2021, December 31, 2020 was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Selling, general & administration expenses			
Impairment of PP&E (Note 11)	733	2,508	1,795
Impairment of goodwill and other intangible assets (Note 12)	4,624	3,853	15,422
Impairment of prepayments (Note 16)	482	583	562
Total impairment loss	**5,839**	**6,944**	**17,779**

6. FINANCIAL INCOME AND EXPENSES

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Financial income:			
Non-cash financial income	303	1,220	-
Interest income	-	3	36
	303	1,223	36
Financial expense:			
Interest on leases (Note 27)	(657)	(815)	(896)
Loss on disposal of exchangeable notes (Note 22, 27)	(9,678)	-	-
Penalty for early partial settlement of senior secured term loan (Note 22)	(3,450)	-	-
Cash interest payable on senior secure term loan	(7,039)	-	-
Cash interest payable on convertible note	(199)	-	-
Cash interest on exchangeable notes	(296)	(3,996)	(3,996)
Loan origination costs	-	(1,638)	-
Non-cash interest on exchangeable notes	(84)	(648)	(643)
Non-cash interest on senior secured term loan	(2,772)	-	-
Non-cash interest on convertible note	(495)	-	-
Non-cash financial expense	(74)	-	(1,216)
Other	(1)	-	-
	(24,745)	(7,097)	(6,751)
Net Financing Expense	(24,442)	(5,874)	(6,715)

For more information on the senior secured term loan, convertible note and exchangeable notes, refer to Note 22, Interest-Bearing Loans and Borrowings.

7. INCOME TAX CREDIT

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Current tax (credit)/expense			
Irish Corporation tax	(331)	(511)	(480)
Foreign taxes (a)	(5)	296	179
Adjustment in respect of prior years	61	-	(152)
Total current tax credit	(275)	(215)	(453)
Deferred tax credit (b)			
Origination and reversal of temporary differences (see Note 13)	321	620	48
Origination and reversal of net operating losses (see Note 13)	(238)	(583)	(215)
Total deferred tax charge/(credit)	83	37	(167)
Total income tax credit on continuing operations in statement of operations	(192)	(178)	(620)
Tax charge on discontinued operations (see Note 8)	-	12	438
Total tax credit	(192)	(166)	(182)

(a) In 2022, the foreign taxes relate primarily to USA and Canada.

(b) In 2022, there was a deferred tax charge of US$109,000 (2021: charge of US$118,000) (2020: credit of US$444,000) recognised in respect of Ireland and a deferred tax credit of US$26,000 (2021: credit of US$81,000) (2020: credit of US$397,000) recognised in respect of overseas tax jurisdictions.

Effective tax rate	*December 31, 2022*	*December 31, 2021*	*December 31, 2020*
(Loss)/profit before taxation – continuing operations (US$'000)	(41,194)	751	(6,633)
As a percentage of (loss)/profit before tax:			
Current tax %	(0.67)%	(28.63)%	(6.83)%
Total (current and deferred) %	(0.47)%	(23.70)%	(9.35)%

7. INCOME TAX CREDIT (CONTINUED)

The following table reconciles the applicable Republic of Ireland statutory tax rate to the effective total tax rate for the Group:

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
Irish corporation tax	(12.5)%	12.5%	(12.5)%
Effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised (a)	11.66%	49.63%	24.13%
Effect of tax rates on overseas earnings	(7.76)%	(0.22)%	(9.92)%
Effect of Irish income taxable at higher tax rate	4.17%	98.68%	5.92%
Adjustments in respect of prior years	0.15%	(0.01)%	(10.66)%
R&D tax credits	(0.81)%	(79.22)%	(11.00)%
Other items (b)	4.62%	(105.06)%	4.68%
Effective tax rate	(0.47)%	(23.70)%	(9.35)%

(a) No deferred tax asset was recognised because there was no reversing deferred tax liability in the same jurisdiction reversing in the same period and insufficient future projected taxable income in the same jurisdiction.

(b) Other items comprise items not chargeable to tax and expenses not deductible for tax purposes. This was a significant number in 2021 because the US$4.7 million income from the Paycheck Protection Program loans was not chargeable for tax purposes. There is no Paycheck Protection Program income in 2022. In 2022, other items mainly relate to the loss on disposal of the exchangeable notes.

The distribution of (loss)/profit before taxes by geographical area was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Rest of World – Ireland	(19,768)	1,862	296
Rest of World – Other	(33)	3,939	3,304
Americas	(21,393)	(5,050)	(10,233)
	(41,194)	751	(6,633)

At December 31, 2022, the Group had unutilised net operating losses for continuing operations as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Rest of World – Ireland	62,731	68,132	78,700
Rest of World – Other	448	1,000	2,185
Americas	12,778	4,761	4,313
	75,957	73,893	85,198

7. INCOME TAX CREDIT (CONTINUED)

At December 31, 2022, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Rest of World – Ireland – unused tax losses	7,489	9,272	12,514
Rest of World – Other – unused tax losses	124	279	546
Americas – unused tax losses	3,163	5,891	1,466
Americas – unused tax credits	4,658	3,368	2,862
Unrecognised deferred tax asset	15,434	18,810	17,388

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.

8. LOSS FOR THE YEAR ON DISCONTINUED OPERATION

In 2016, management decided to cease the development of Cardiac point-of-care tests on the Meritas platform. These products were being developed by the Group's subsidiary Fiomi Diagnostics ("Fiomi") located in Sweden.

Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item (net of related taxes) on the face of the consolidated statement of operations. The discontinued operation had no revenues since commencement as the products were still in their development phase. In 2022, administrative expenses of US$7,000 were incurred.

8. LOSS FOR THE YEAR ON DISCONTINUED OPERATION (CONTINUED)

The operating loss for the Cardiac point-of-care tests operation in Sweden and the loss on re-measurement of its assets and liabilities are summarised as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Administrative expenses	(7)	-	-
Closure provision	-	(42)	127
Foreign currency translation reserve	-	-	(64)
Tax expense	-	(12)	(438)
Total loss	(7)	(54)	(375)
Loss for the year from discontinued operations	**(7)**	**(54)**	**(375)**

Basic loss per ordinary share – discontinued operations

Basic loss per ordinary share for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$7,000 (2021: loss US$54,000) (2020: loss US$375,000) for the financial year by the weighted average number of 'A' ordinary shares in issue. As at December 31, 2022, this amounted to 134,939,327 shares (2021: 83,606,810 shares) (2020: 83,606,810 shares), see note 10 for further details.

Diluted loss per ordinary share – discontinued operations

Diluted loss per ordinary share for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$7,000 (2021: loss US$54,000) (2020: loss US$375,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 134,939,327 (2021: 83,606,810 shares) (2020: 83,606,810 shares), see note 10 for further details. Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. Therefore, diluted loss per ADS in accordance with IFRS is equal to basic earnings per ADS.

Loss 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 loss per ADS for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$7,000 (2021: loss US$54,000) (2020: loss US$375,000) for the financial year by the weighted average number of ADS in issue of 33,734,832 (2021: 20,901,703) (2020: 20,901,703), see note 10 for further details.

Diluted loss per ADS for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$7,000 (2021: loss US$54,000) (2020: loss US$375,000) for the financial year, by the diluted weighted average number of ADS in issue of 33,734,832 (2021: 20,901,703) (2020: 20,901,703), see note 10 for further details.

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
Basic loss per ADS (US Dollars) – discontinued operations	0.00	0.00	(0.02)
Diluted loss per ADS (US Dollars) – discontinued operations	0.00	0.00	(0.02)
Basic loss per 'A' share (US Dollars) – discontinued operations	0.00	0.00	0.00
Diluted loss per 'A' share (US Dollars) – discontinued operations	0.00	0.00	0.00

8. LOSS FOR THE YEAR ON DISCONTINUED OPERATION (CONTINUED)

Cash flows

The cash flows attributable to discontinued operations are as follows:

	December 31, 2022 US$000	*December 31, 2021 US$000*	*December 31, 2020 US$000*
Cash flows from operating activities	(10)	(40)	(22)

There were no cash flows from investing or financing activities attributable to discontinued operations for the years ended December 31, 2022, 2021 or 2020.

9. (LOSS)/PROFIT BEFORE TAX

The following amounts were charged / (credited) to the statement of operations:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Directors' emoluments (including non- executive directors):			
Remuneration	1,639	1,391	2,020
Pension	24	24	41
Share based payments	1,707	986	678
Auditor's remuneration			
Audit fees	888	580	558
Tax fees	89	77	146
Depreciation (Note 11)[1]	1,410	1,827	1,674
Amortisation (Note 12)	923	917	1,403
Loss/(profit) on the disposal of property, plant and equipment	2	(1)	30
Selling, General and Administrative Expenses – Closure Costs	-	-	2,425
Net foreign exchange differences	(1,210)	(789)	583

[1] In 2022, no depreciation was capitalised to research and development projects (2021: US$38,000) (2020: US$40,000).

Selling, General and Administrative Expenses – Closure Costs - in early 2020, management decided to close a production facility in Carlsbad, California facility which specialized in Western Blot manufacturing. The preceding number of years had seen a steady migration of customers away from using the Western Blot testing format for diagnosing Lyme in favour of alternative testing platforms. Production volumes declined steadily at the plant to the extent that it no longer made economic sense to continue. The plant was closed on June 30, 2020. Production of remaining products was transferred to other locations in the Group. The charge for closing the facility was US$2,425,000 which comprised redundancy costs, the write-off of inventory, the cost of exiting lease obligations and other costs associated with the closure of the facility.

10. (LOSS)/EARNINGS PER SHARE

Basic (loss)/earnings per ordinary share

Basic (loss)/earnings per ordinary share is calculated by dividing the net (loss)/earnings attributable to owners of the parent of US$41,009,000 (2021: profit of US$875,000) (2020: loss of US$6,388,000) by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year. Basic (loss)/earnings per ordinary share from continuing operations is calculated by dividing the loss from continuing operations attributable to owners of the parent of US$41,002,000 (2021: profit of US$929,000) (2020: loss of US$6,013,000) by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year.

As at December 31, 2022, the number of 'A' ordinary shares for the purposes of the calculation of basic (loss)/earnings per share are 134,939,327 shares (2021: 83,606,810 shares) (2020: 83,606,810 shares).

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
'A' ordinary shares	134,939,327	83,606,810	83,606,810
Basic (loss)/earnings per share denominator	134,939,327	83,606,810	83,606,810
Reconciliation to weighted average (loss)/earnings per share denominator:			
Number of 'A' ordinary shares at January 1 (Note 18)	96,162,410	96,162,410	96,162,410
Weighted average number of 'A' ordinary shares issued during the year	51,332,517	-	-
Weighted average number of treasury shares	(12,555,600)	(12,555,600)	(12,555,600)
Basic (loss)/earnings per share denominator	134,939,327	83,606,810	83,606,810

Diluted (loss)/earnings per ordinary share

Diluted (loss)/earnings per ordinary share is calculated by dividing the net (loss)/earnings attributable to owners of the parent by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year, plus the weighted average number of 'A' ordinary shares that would be issued on the conversion of all the dilutive potential 'A' ordinary shares into 'A' ordinary shares. As the potentially dilutive instruments were anti-dilutive in all periods presented, basic (loss)/earnings per 'A' ordinary share and diluted (loss)/earnings per 'A' ordinary share are equivalent.

The following potential 'A' ordinary shares are anti-dilutive and are therefore excluded from the weighted average number of 'A' ordinary shares for the purposes of calculating diluted (loss)/earnings per 'A' ordinary share.

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
Potentially Dilutive Instruments:			
Issuable on exercise of options (Note 19)	44,814,672	18,727,990	19,485,990
Issuable on exercise of warrants to Perceptive (Note 22)	10,000,000	-	-
Issuable on conversion of Exchangeable notes (Note 22)	38,391	18,263,254	18,263,254
Issuable on conversion of Convertible notes (Note 22)	24,691,358	-	-
Total number of potentially dilutive instruments excluded from the weighted average number of 'A' ordinary shares in calculating dilutive (loss)/earnings per 'A' ordinary share	79,544,421	36,991,244	37,749,244

Of the 'A' ordinary shares issuable on exercise of options, 16,800,000 are contingently issuable as their issue is contingent upon satisfaction of specified performance conditions in addition to the passage of time. The conditions governing their exercisability have not been satisfied as at the end of the reporting period.

Subsequent to the end of the reporting period, the following ordinary share transactions or potential ordinary share transactions occurred:

10. (LOSS)/EARNINGS PER SHARE (CONTINUED)

- Options over 3,000,000 'A' ordinary shares were granted, of which 1,400,000 are contingently issuable as their issue is contingent upon satisfaction of specified performance conditions in addition to the passage of time.
- Options over 280,000 'A' ordinary shares lapsed unexercised.
- 400,000 'A' ordinary shares were issued on the exercise of options.
- Warrants over 10,000,000 'A' ordinary shares held by Perceptive were repriced from an exercise price of $0.325 per 'A' ordinary share to $0.268 per 'A' ordinary share.

(Loss)/earnings per ADS

Trinity Biotech's ADS to 'A' ordinary share ratio is 1 ADS: 4 'A' ordinary shares.

Basic (loss)/earnings per ADS is calculated by dividing the (loss)/earnings attributable to owners of the parent of US$41,009,000 (2021: profit of US$875,000) (2020: loss of US$6,388,000) by the weighted average number of ADS in issue, net of any Treasury Shares, during the year. Basic (loss)/earnings per ADS from continuing operations is calculated by dividing the (loss)/earnings of US$41,002,000 (2021: profit of US$929,000) (2020: loss of US$6,013,000) by the weighted average number of ADS in issue, net of any Treasury Shares, during the year.

As at December 31, 2022, the number of ADS for the purposes of the calculation of basic (loss)/earnings per ADS were 33,734,832 ADS (2021: 20,901,703 ADS) (2020: 20,901,703 ADS).

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
ADS	33,734,832	20,901,703	20,901,703
Basic (loss)/earnings per ADS denominator	33,734,832	20,901,703	20,901,703
Reconciliation to weighted average (loss)/earnings per ADS denominator:			
Number of ADS at January 1 (Note 18)	24,040,602	24,040,602	24,040,602
Weighted average number of shares issued during the year*	12,833,129	-	-
Weighted average number of treasury shares	(3,138,899)	(3,138,899)	(3,138,899)
Basic (loss)/earnings per ADS denominator	33,734,832	20,901,703	20,901,703

Diluted (loss)/earnings per ADS

Diluted (loss)/earnings per ADS is calculated by dividing the net (loss)/earnings attributable to owners of the parent by the weighted average number of ADS in issue, net of any Treasury Shares, during the year, plus the weighted average number of ADS that would be issued on the conversion of all the dilutive potential ADS into ADS. As the potentially dilutive instruments were anti-dilutive in all periods presented, basic (loss)/earnings per ADS and diluted earnings per ADS are equivalent.

The following potential ADS are anti-dilutive and are therefore excluded from the weighted average number of ADS for the purposes of calculating dilutive (loss)/earnings per ADS.

	December 31, 2022	*December 31, 2021*	*December 31, 2020*
Potentially Dilutive Instruments:			
Issuable on exercise of options (Note 19)	11,203,668	4,681,998	4,871,498
Issuable on exercise of warrants to Perceptive (Note 22)	2,500,000	-	-
Issuable on conversion of Exchangeable notes (Note 22)	9,598	4,565,814	4,565,814
Issuable on conversion of Convertible notes (Note 22)	6,172,840	-	-
Total number of potentially dilutive instruments excluded from the weighted average number of ADS in calculating dilutive (loss)/earnings per ADS	19,886,106	9,247,812	9,437,312

10. (LOSS)/EARNINGS PER SHARE (CONTINUED)

Of the ADS issuable on exercise of options, 4,200,000 are contingently issuable as their issue is contingent upon satisfaction of specified performance conditions in addition to the passage of time. The conditions governing their exercisability have not been satisfied as at the end of the reporting period.

Subsequent to the end of the reporting period, the following ordinary share transactions or potential ordinary share transactions occurred:

- Options over 750,000 ADS were granted, of which 350,000 are contingently issuable as their issue is contingent upon satisfaction of specified performance conditions in addition to the passage of time.
- Options over 70,000 ADS lapsed unexercised.
- 100,000 ADS were issued on the exercise of options.
- Warrants over 2,500,000 ADS held by Perceptive were repriced from an exercise price of $1.30 per ADS to $1.071 per ADS.

11. PROPERTY, PLANT AND EQUIPMENT

	Land & Buildings US$'000	*Leasehold Improvements US$'000*	*Computer & Office Equipment US$'000*	*Plant & Equipment US$'000*	*Total US$'000*
Cost					
At January 1, 2021	24,287	2,670	4,309	33,839	65,105
Additions	46	126	144	1,392	1,708
Disposals or retirements	-	(186)	(255)	(2,410)	(2,851)
Exchange adjustments	1	(18)	2	(484)	(499)
At December 31, 2021	24,334	2,592	4,200	32,337	63,463
At January 1, 2022	24,334	2,592	4,200	32,337	63,463
Additions	379	93	362	1,100	1,934
Disposals or retirements	-	-	(25)	(42)	(67)
Reallocations/ reclassifications	-	-	(2)	2	-
Exchange adjustments	(31)	16	5	286	276
At December 31, 2022	24,682	2,701	4,540	33,683	65,606
Accumulated amortisation and Impairment losses					
At January 1, 2021	(19,629)	(1,884)	(3,946)	(31,099)	(56,558)
Charge for the year	(628)	(149)	(115)	(974)	(1,866)
Disposals or retirements	-	186	255	2,410	2,851
Impairment losses	(1,196)	(279)	(98)	(935)	(2,508)
Exchange adjustments	21	(5)	(46)	566	536
At December 31, 2021	(21,432)	(2,131)	(3,950)	(30,032)	(57,545)
At January 1, 2022	(21,432)	(2,131)	(3,950)	(30,032)	(57,545)
Charge for the year	(414)	(133)	(214)	(649)	(1,410)
Disposals or retirements	-	-	22	43	65
Impairment losses	(48)	(4)	(31)	(650)	(733)
Exchange adjustments	9	(16)	(5)	(289)	(301)
At December 31, 2022	(21,885)	(2,284)	(4,178)	(31,577)	(59,924)
Carrying amounts					
At December 31, 2022	2,797	417	362	2,106	5,682
At December 31, 2021	2,902	461	250	2,305	5,918

The assets of the Group are pledged as security for the senior secured term loan from Perceptive Advisors.

11. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

Right-of-use assets

Additional information on the right-of-use assets by class of assets is as follows:

	Carrying amount At December 31, 2022 US$000	*Depreciation Charge Year ended December 31, 2022 US$000*	*Impairment Charge Year ended December 31, 2022 US$000*
Buildings	2,482	(398)	(48)
Computer equipment	217	(40)	-
Plant and Equipment, vehicles	-	(17)	(200)
	2,699	(455)	(248)

	Carrying amount At December 31, 2021 US$000	*Depreciation Charge Year ended December 31, 2021 US$000*	*Impairment Charge Year ended December 31, 2021 US$000*
Buildings	2,549	(609)	(1,089)
Computer equipment	23	(5)	-
Plant and Equipment, vehicles	-	-	-
	2,572	(614)	(1,089)

Income from sub-letting right-of-use buildings amounted to US$3,000 in the year ended December 31, 2022 (2021: US$3,000).

Right-of-Use assets at 31 December 2022	*No. of Right-of-Use leased assets*	*Range of remaining term in years*	*Average remaining lease term (years)*	*No. of Leases with extension options*	*No. of Leases with options to purchase*	*No. of leases with variable payments linked to index*	*No. of leases with termination options*
Building	9	1 to 11	5	2	-	-	-
Vehicle	20	0.4 to 3	2	-	20	-	20
I.T. and office equipment	5	4	4	-	-	-	-

Right-of-Use assets at 31 December 2021	*No. of Right-of-Use leased assets*	*Range of remaining term in years*	*Average remaining lease term (years)*	*No. of Leases with extension options*	*No. of Leases with options to purchase*	*No. of leases with variable payments linked to index*	*No. of leases with termination options*
Building	11	1 to 12	3	1	-	2	-
Vehicle	16	1 to 3	2	-	16	-	16
I.T. and office equipment	2	1 to 5	4	-	-	-	-

11. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

The details of the impairment review are described in Note 12. When an impairment loss is identified in a cash-generating unit, it must be first allocated to reduce the carrying amount of any goodwill allocated to the cash-generating unit and then to the other assets of the unit pro rata on the basis of the carrying amount of each asset in the unit. In this manner, an impairment loss of US$733,000 was allocated to property, plant and equipment as at December 31, 2022 (2021: US$2,508,000). The recoverable amount of property, plant and equipment was determined to be the value in use of each cash-generating unit.

Assets held under operating leases (where the Company is the lessor)

The Company has 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, 2022 and 2021 is US$Nil following full write down of the assets due to group impairment (refer to Note 12). Depreciation charged on these assets in 2022 amounted to US$34,000 (2021: US$27,000).

Property, plant and equipment under construction

There were no assets under construction included in property, plant and equipment at December 31, 2022 (2021: US$Nil).

12. GOODWILL AND INTANGIBLE ASSETS

	Goodwill *US$'000*	*Development costs* *US$'000*	*Patents and licenses* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
Cost					
At January 1, 2021	79,182	128,977	8,947	33,311	250,417
Additions	-	6,771	102	21	6,894
Disposals or retirements	-	(14,576)	(342)	(134)	(15,052)
Exchange adjustments	-	1	-	-	1
At December 31, 2021	79,182	121,173	8,707	33,198	242,260
At January 1, 2022	79,182	121,173	8,707	33,198	242,260
Additions	-	4,475	22	382	4,879
Exchange adjustments	-	(64)	-	-	(64)
At December 31, 2022	79,182	125,584	8,729	33,580	247,075
Accumulated amortisation and Impairment losses					
At January 1, 2021	(66,591)	(115,533)	(8,790)	(25,643)	(216,557)
Charge for the year	-	(482)	(7)	(428)	(917)
Disposals or retirements	-	14,573	342	132	15,047
Impairment losses	(54)	(2,053)	(106)	(1,640)	(3,853)
Exchange adjustments	-	1	-	-	1
At December 31, 2021	(66,645)	(103,494)	(8,561)	(27,579)	(206,279)
At January 1, 2022	(66,645)	(103,494)	(8,561)	(27,579)	(206,279)
Charge for the year		(479)	(9)	(435)	(923)
Impairment losses	-	(4,623)	-	(1)	(4,624)
Exchange adjustments	-	20	-	-	20
At December 31, 2022	(66,645)	(108,576)	(8,570)	(28,015)	(211,806)
Carrying amounts					
At December 31, 2022	12,537	17,008	159	5,565	35,269
At December 31, 2021	12,537	17,679	146	5,619	35,981

Included within development costs are projects with a carrying value of US$6,982,000 which were not amortised in 2022 (2021: US$7,994,000) (2020: US$6,980,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at the end of the financial year. As at December 31, 2022 these projects are expected to be completed during the period from January 1, 2023 to December 31, 2025 at an expected further cost of approximately US$1,100,000.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

The following represents the costs incurred during each period presented for each of the principal development projects:

Product Name	2022 US$'000	2021 US$'000
Premier Instruments for A1c and haemoglobinopathies testing	1,904	2,538
COVID-19 tests	1,378	1,320
Mid-tier haemoglobins instrument	484	303
HIV screening rapid test	379	1,488
Tri-stat point-of-care instrument	163	245
Uni-gold raw material stabilisation	42	144
Autoimmune Smart Reader	82	550
Other projects	43	183
Total capitalised development costs	**4,475**	**6,771**

Other intangible assets

Other intangible assets consist primarily of acquired customer and supplier lists, trade names, website and software assets.

Amortisation

Amortisation is charged to the consolidated 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 a periodic basis and whenever there are indicators of impairment. Specific assets are assessed for impairment when there are indicators of impairment. If any such indication exists, the Company estimates the recoverable amount of the asset.

The recoverable amount of seven CGUs is determined based on a value-in-use computation at June 30 and December 31. Among other macroeconomic considerations, the impact of the COVID-19 pandemic has been factored into our impairment testing. The value-in-use calculations use cash flow projections based on the 2023 projections for each CGU and a further four years projections using estimated revenue and cost average growth rates of between 0% and 5%. At the end of the five year forecast period, terminal values for each CGU, based on a long-term growth rate of 2%, 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 pre-tax discount rates used range from 16% to 24% (2021: 16% to 25%).

Sources of estimation uncertainty

The cash flows have been arrived at taking into account the Group's financial position, its recent financial results and cash flow generation and the nature of the medical diagnostic industry, where product obsolescence can be a feature. However, expected future cash flows are inherently uncertain and are therefore liable to material change over time. The key assumptions employed in arriving at the estimates of future cash flows factored into impairment testing are subjective and include projected EBITDA margins, net cash flows, discount rates used and the duration of the discounted cash flow model. Significant under-performance in any of the Group's major CGUs may give rise to a material impairment which would have a substantial impact on the Group's income and equity.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Specific asset impairment charges

In the year ended December 31, 2022, four internally developed intangible assets were fully impaired, as shown in the table below.

Asset name	*Entity*	*2022 US$'000*
Rapid COVID-19 antigen test	Trinity Biotech Manufacturing Ltd	2,214
Autoimmune smart reader	Trinity Biotech Manufacturing Ltd	1,265
Tri-stat instrument	Primus Corp.	1,024
COVID-19 ELISA test	Trinity Biotech Manufacturing Ltd	120
Total		4,623

The rapid COVID-19 test is approved for professional use in the EU. However, as previously disclosed by the Company, the demand for our COVID-19 portfolio of products is highly uncertain and very difficult to predict and in our experience the market has moved to over the counter ("OTC") rapid COVID-19 tests, for which this product is not yet approved. As such the Company's efforts to commercialise this test have been unsuccessful. In addition, pricing for rapid COVID-19 tests in the EU is relatively weak, with stronger pricing available in, for example, the US market, for which this product is not yet approved. Given the market outlook for rapid COVID-19 testing products and continued uncertainty regarding regulatory approval pathways in key markets, including the US, the Company has chosen to not immediately pursue further regulatory approvals but does intend to monitor these markets and regulatory pathways with a view to potentially seeking additional regulatory approvals. As the Company has no imminent plans to pursue these regulatory approvals, this development project was written down from US$2,214,000 to zero in 2022. For similar reasons, the carrying value of our internally developed COVID-19 ELISA test was fully impaired and the impairment charge for this project was US$120,000.

The development project for the autoimmune smart reader was paused in 2022 as management reviewed other options, including the potential to proceed with a third-party reader instead of our own internally developed reader. Following this review, we determined that there were likely greater opportunities to capture more market share in a more capital efficient manner through partnering with a third-party reader manufacturer rather than pursuing an independent strategy. There is significant uncertainty if we will complete the project to develop our own in-house autoimmune smart reader and thus while we may re-visit this decision in the future, in the interests of prudence the project's carrying value of US$1,265,000 was impaired to zero.

In 2022, there was a strategic review of our Tri-stat instrument as part of a broader review of our haemoglobins product portfolio. In order to rationalise the haemoglobins product portfolio and to allow us to focus our resources on the higher growth products within that portfolio, management decided that Tri-stat sales would be restricted to only certain targeted partnerships, and this led to the carrying value for the Tri-stat intangible asset of US$1,024,000 being written down to zero.

In the year ended December 31, 2021, there was a specific asset impairment charge related to the carrying value of the intangible asset for the COVID-19 antibody rapid test, which was written off in full. This product development was an asset of Trinity Biotech Manufacturing Limited and the impairment charge recorded for this asset was US$856,000.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Impairment tests of cash-generating units

The impairment tests performed at June 30, 2022 and at December 31, 2022 identified an impairment loss in three CGUs, Clark Laboratories Inc, Trinity Biotech Do Brasil and Biopool US Inc. The table below sets forth the impairment loss recorded for each of the CGU's, comprising both the specific asset impairment charges (as per the above table) and the impairments arising from the CGU impairment tests:

	December 31, 2022 US$'000	***December 31, 2021 US$'000***
Trinity Biotech Manufacturing Limited	3,599	856
Primus Corp	1,024	-
Trinity Biotech Do Brasil	454	956
Clark Laboratories Inc.	407	-
Biopool US Inc.	355	153
Immco Diagnostics Inc	-	4,979
Total impairment loss	**5,839**	**6,944**

The table below sets forth the breakdown of the impairment loss for each class of asset:

	***December 31, 2022* US$'000**	***December 31, 2021 US$'000***
Goodwill and other intangible assets	4,624	3,853
Property, plant and equipment (see Note 11)	733	2,508
Prepayments (see Note 16)	482	583
Total impairment loss	**5,839**	**6,944**

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and the following sensitivity analysis has been performed:

- In the event that there was a reduction of 10% in the assumed level of future growth in revenue growth rate, which would represent a reasonably likely range of outcomes, there would be no additional impairment loss recorded at December 31, 2022.
- In the event there was a 10% increase 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 no additional impairment loss recorded at December 31, 2022.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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 periodically, 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:

Fitzgerald Industries	*December 31, 2022*	*December 31, 2021*
Carrying amount of goodwill (US$'000)	12,591	12,591
Discount rate applied (real pre-tax)	15.77%	19.66%
Excess value-in-use over carrying amount (US$'000)	7,432	3,496
% EBITDA would need to decrease for an impairment to arise	31.28%	18.15%
Long-term growth rate	2.0%	2.0%

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, 2022 US$'000*	*December 31, 2021 US$'000*
Fitzgerald Industries International CGU		
Fitzgerald trade name	970	970
RDI trade name	560	560
Primus Corporation CGU		
Primus trade name	365	365
Immco Diagnostic CGU		
Immco Diagnostic trade name	2,069	2,069
Total	**3,964**	**3,964**

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.

In 2021, an impairment loss of US$869,000 was allocated against the Immco Diagnostic trade name as the carrying value of the CGU's net assets exceeded its discounted future cashflows.

13. 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	
	2022 US$'000	*2021 US$'000*	*2022 US$'000*	*2021 US$'000*	*2022 US$'000*	*2021 US$'000*
Property, plant and equipment	229	477	(5)	(11)	224	466
Intangible assets	-	-	(3,950)	(3,969)	(3,950)	(3,969)
Inventories	423	620	-	-	423	620
Provisions	2,194	1,871	-	-	2,194	1,871
Tax value of loss carry-forwards	1,254	1,016	-	-	1,254	1,016
Other items	118	117	(1,103)	(878)	(985)	(761)
Deferred tax assets/(liabilities)	4,218	4,101	(5,058)	(4,858)	(840)	(757)

The deferred tax asset in 2022 is mainly due to deductible temporary differences relating to provisions, loss carry-forwards, property, plant and equipment and the elimination of unrealised intercompany inventory profit. In 2022, the deferred tax asset increased by US$117,000 mainly due to an increase in deductible temporary differences principally attributable to provisions and loss carry-forwards.

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 US. The deferred tax liability increased by US$200,000 in 2022, principally because of other items.

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, 2022 and at December 31, 2021 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.

Most temporary differences are expected to reverse after 2024.

Movement in temporary differences during the year

	Balance January, 1 2022 US$'000	*Recognised in income US$'000*	*Balance December 31, 2022 US$'000*
Property, plant and equipment	466	(242)	224
Intangible assets	(3,969)	19	(3,950)
Inventories	620	(197)	423
Provisions	1,871	323	2,194
Tax value of loss carry-forwards	1,016	238	1,254
Other items	(761)	(224)	(985)
	(757)	(83)	(840)

13. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

	Balance January, 1 2021 US$'000	*Recognised in income US$'000*	*Balance December 31, 2021 US$'000*
Property, plant and equipment	724	(258)	466
Intangible assets	(4,072)	103	(3,969)
Inventories	750	(130)	620
Provisions	2,159	(288)	1,871
Tax value of loss carry-forwards	433	583	1,016
Other items	(714)	(47)	(761)
	(720)	(37)	(757)

Unrecognised deferred tax assets

Deferred tax assets have not been recognised by the Group in respect of the following items, which have not been tax effected:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Capital losses	8,293	8,293
Net operating losses	75,957	73,893
US alternative minimum tax credits	1,906	1,704
Other temporary timing differences	38,960	21,301
US state credit carryforwards	2,753	1,664
	127,869	106,855

14. OTHER NON-CURRENT ASSETS

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Finance lease receivables (see Note 16)	84	151
Other assets	55	56
	139	207

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 16.

15. INVENTORIES

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Raw materials and consumables	12,094	13,650
Work-in-progress	3,948	5,546
Finished goods	6,461	9,927
	22,503	29,123

The assets of the Group, including inventories have been pledged as security for the term loan from Perceptive Advisors.

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$16,274,000 (2021: US$12,063,000) (2020: US$9,781,000). Cost of sales in 2022 includes inventories expensed of US$45,340,000 (2021: US$49,299,000) (2020: US$48,342,000).

The movement on the inventory provision for the three-year period to December 31, 2022 is as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Opening provision at January 1	12,063	9,781	6,716
Charged during the year	7,391	5,589	5,179
Utilised during the year	(3,180)	(3,307)	(1,994)
Released during the year	-	-	(120)
Closing provision at December 31	16,274	12,063	9,781

During 2022, US$Nil (2021: US$Nil) (2020: US$120,000) of inventory provision relating to net realisable value was released to the statement of operations following a current year review of inventory usage.

16. TRADE AND OTHER RECEIVABLES

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Trade receivables, net of impairment losses	12,620	13,290
Prepayments	1,932	1,945
Contract assets	739	739
Value added tax	43	-
Finance lease receivables	86	142
Grant receivable	333	-
	15,753	16,116

Trade receivables are shown net of an impairment losses provision of US$2,691,000 (2021: US$2,986,000) (2020: US$3,922,000) (see Note 26). Prepayments are shown after impairment charges of US$482,000 (2021: US$583,000) (2020: US$562,000) (see Note 5).

16. TRADE AND OTHER RECEIVABLES (CONTINUED)

Long-term contract receivable

(i) Finance lease commitments – Group as lessor

The Group leases instruments as part of its business. Future minimum receivables with non-cancellable terms are as follows:

	December 31, 2022 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	180	6	86
Between one and five years (Note 14)	173	6	84
	353	12	170

	December 31, 2021 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	292	11	142
Between one and five years (Note 14)	310	11	151
	602	22	293

The Group classified future minimum lease receivables between one and five years of US$84,000 (2021: US$151,000) as Other Assets, see Note 14. Under the terms of the lease arrangements, no contingent rents are receivable.

(ii) Operating lease commitments – Group as lessor

The Group leases instruments under operating leases as part of its business.

Future minimum rentals receivable under non-cancellable operating leases are as follows:

	December 31, 2022 US$'000	
	Instruments	Total
Less than one year	1,589	1,589
	1,589	1,589

16. TRADE AND OTHER RECEIVABLES (CONTINUED)

(ii) Operating lease commitments – Group as lessor

	December 31, 2021 US$'000	
	Instruments	Total
Less than one year	3,953	3,953
Between one and five years	171	171
	4,124	4,124

17. CASH AND CASH EQUIVALENTS

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Cash at bank and in hand	6,578	22,790
Short-term deposits	-	3,120
Cash and cash equivalents	6,578	25,910

18. CAPITAL AND RESERVES

Share capital

	December 31, 2022 Class 'A' Ordinary shares '000s	*December 31, 2021 Class 'A' Ordinary shares '000s*
In thousands of shares		
In issue at January 1	96,162	96,162
Issued for cash (a)	47,492	-
Issued as consideration for Exchangeable Notes purchase (b)	21,332	-
At period end	164,986	96,162

	December 31, 2022 ADS	*December 31, 2021 ADS*
In thousands of ADSs		
Balance at January 1	24,041	24,041
Issued for cash	11,873	-
Issued as consideration for Exchangeable Notes purchase	5,333	-
At period end	41,247	24,041

18. CAPITAL AND RESERVES (CONTINUED)

The amounts in the tables above are inclusive of Treasury Shares. The number of Treasury Shares is as follows:

	December 31, 2022 Class 'A' Treasury shares '000s	*December 31, 2021 Class 'A' Treasury shares '000s*
In thousands of shares		
Balance at January 1	12,556	12,556
Purchased during period	-	-
At period end	12,556	12,556

	December 31, 2022 Class 'A' Treasury shares '000s	*December 31, 2021 Class 'A' Treasury shares '000s*
In thousands of ADSs		
Balance at January 1	3,139	3,139
Purchased during period	-	-
At period end	3,139	3,139

(a) During the year ended December 31, 2022, the Company issued 47,492,000 'A' Ordinary shares for a consideration of US$25,707,000 settled in cash. The Company incurred US$606,000 in connection with the issues of shares. The total shares issued for cash comprises 44,759,000 'A' Ordinary shares issued to MiCo and 2,733,328 'A' Ordinary from the exercise of employee share options. For more information on the investment by MiCo, refer to Note 22.

(b) During the year ended December 31, 2022, the Company issued 21,332,000 'A' Ordinary shares, with a market value of US$6,133,000, as partial consideration for the purchase of Exchangeable Notes. The Company incurred US$213,000 in connection with this issue of shares. For more information on the purchase of Exchangeable Notes, refer to Note 22.

Translation reserve

The 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.

Other reserves

Other reserves comprise the hedging reserve of US$23,000 and shares to be issued of US$63,000. 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. The hedging reserve is shown within Other Reserves in the Consolidated Statement of Financial Position. Shares to be issued as at December 31, 2022 have been issued in 2023.

18. CAPITAL AND RESERVES (CONTINUED)

Equity component of Convertible Note

In May 2022, the Company announced the successful closure of a US$45.2 million investment from MiCo Ltd ("MiCo"). MiCo, a KOSDAQ-listed and Korea-based company. The investment consisted of an equity investment of US$25.2 million and a seven-year, unsecured junior convertible note of US$20.0 million. The convertible note mandatorily converts into ADSs if the volume weighted average price of the Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days. The convertible loan is accounted for as a compound financial instrument containing both an equity and liability element. The equity component of the convertible note is US$6.7 million. There is no remeasurement of the equity element following initial recognition.

Treasury shares

During 2022, the Group did not purchase any 'A' Ordinary shares (2021: nil) (2020: nil) 'Treasury shares'.

19. SHARE OPTIONS

Options

Under the terms of the Company's Employee Share Option Plans, options to purchase 44,814,672 'A' Ordinary Shares (11,203,668 ADS's) were outstanding at December 31, 2022. Under these Plans, options are granted to officers and employees of the Group at the discretion of the Compensation Committee (designated by the Board of Directors), under the terms outlined below.

In the past, share options were granted to consultants of the Group and, where this was the case, the Group measured the fair value of the services provided by these consultants by reference to the fair value of the equity instruments granted. This approach was adopted in these cases as it was impractical for the Group to reliably estimate the fair value of such services. There are no outstanding options for consultants at December 31, 2022.

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 Board and Remuneration Committee at the date of grant of the options (usually the date of approval by the Compensation Committee) and it is generally over a two to four-year period.

Non-vesting conditions

In 2022, share options were granted to certain directors for which there is a condition that the options only become exercisable into ADSs when the market price of an ADS reaches a certain level. This is deemed to be a non-vesting condition. The term 'non- vesting condition' is not explicitly defined in IFRS 2, *Share based Payment*, but is inferred to be any condition that does not meet the definition of a vesting condition. The only condition for these particular options to vest is that the director continues service and there were no other conditions which would be considered non-vesting conditions. Non-vesting conditions are reflected in measuring the grant-date fair value of the share-based payment and there is no true-up in the measurement of the share-based payment for differences between the expected and the actual outcome of non-vesting conditions. If all service conditions are met, then the share-based payment cost will be recognized even if the director does not receive the share-based payment due to a failure to meet the non-vesting condition.

19. SHARE OPTIONS (CONTINUED)

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.

The number and weighted average exercise price of share options per ordinary share is as follows:

	Share Options 'A' Ordinary Shares	*Weighted-average exercise price US$* Per 'A' Ordinary Share	*Range US$* Per 'A' Ordinary Share
Outstanding January 1, 2020	12,303,990	1.31	0.46 –4.36
Granted	9,100,000	0.38	0.19 –1.10
Exercised	-	-	-
Expired / Forfeited	(1,918,000)	2.14	0.19-4.21
Outstanding at end of year	19,485,990	0.79	0.19-4.36
Exercisable at end of year	7,959,323	1.27	0.66-4.36
Outstanding January 1, 2021	19,485,990	0.79	0.19-4.36
Granted	-	-	-
Exercised	-	-	-
Expired / Forfeited	(758,000)	1.07	0.19-4.21
Outstanding at end of year	18,727,990	0.78	0.19-4.36
Exercisable at end of year	13,401,322	0.93	0.19-4.36
Outstanding January 1, 2022	18,727,990	0.78	0.19-4.36
Granted	29,400,000	0.27	0.27-0.29
Exercised	(2,733,328)	0.19	0.19-0.19
Expired / Forfeited	(579,990)	1.87	0.69-4.36
Outstanding at end of year	44,814,672	0.47	0.19-2.43
Exercisable at end of year	14,138,004	0.89	0.19-2.43

19. SHARE OPTIONS (CONTINUED)

	Share Options 'ADS' Equivalent	Weighted-average exercise price US$ Per 'ADS'	Range US$ Per 'ADS'
Outstanding January 1, 2020	3,075,998	5.24	1.83 - 17.45
Granted	2,275,000	1.52	0.77 - 4.41
Exercised	-	-	-
Expired / Forfeited	(479,500)	8.56	0.77 - 16.84
Outstanding at end of year	4,871,498	3.15	0.77-17.45
Exercisable at end of year	1,989,831	5.08	2.64 -17.45
Outstanding January 1, 2021	4,871,498	3.15	0.77-17.45
Granted	-	-	-
Exercised	-	-	-
Expired / Forfeited	(189,500)	4.28	0.76 - 16.84
Outstanding at end of year	4,681,998	3.12	0.76 - 17.44
Exercisable at end of year	3,350,331	3.72	0.76 –17.44
Outstanding January 1, 2022	4,681,998	3.12	0.76 - 17.44
Granted	7,350,000	1.09	1.07-1.14
Exercised	(683,332)	0.77	0.77-0.77
Expired / Forfeited	(144,998)	7.48	2.76 - 17.44
Outstanding at end of year	11,203,668	1.88	0.77-9.73
Exercisable at end of year	3,534,501	3.56	0.77-9.73

In 2022, 2,733,328 share options were exercised in 2022 at an average share price of US$0.28 or US$1.13 per ADS at the date of exercise. There were no share options exercised during 2021 or 2020.

The opening share price per 'A' Ordinary share at the start of the financial year was US$0.36 or US$1.43 per ADS (2021: US$0.95 or US$3.81 per ADS) (2020: US$0.27 or US$1.07 per ADS) and the closing share price at December 31, 2022 was US$0.25 or US$0.99 per ADS (2021: US$0.36 or US$1.43 per ADS) (2020: US$0.95 or US$3.81 per ADS). The average share price for the year ended December 31, 2022 was US$0.30 per 'A' Ordinary share or US$1.22 per ADS.

A summary of the range of prices for the Company's share options for the year ended December 31, 2022 follows:

	Outstanding			Exercisable		
Exercise price range	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.19-US$0.99	39,546,672	0.35	6.10	8,930,004	0.59	4.05
US$1.00-US$1.74	4,988,000	1.34	1.78	4,928,000	1.34	1.74
US$1.75- US$2.43	280,000	2.43	0.15	280,000	2.43	0.15
	44,814,672			14,138,004		

19. SHARE OPTIONS (CONTINUED)

	Outstanding			Exercisable		
Exercise price range	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.77-US$3.96	9,886,668	1.39	6.10	2,232,501	2.37	4.05
US$4.00-US$6.94	1,247,000	5.37	1.78	1,232,000	5.38	1.74
US$6.95- US$9.73	70,000	9.73	0.15	70,000	9.73	0.15
	11,203,668			3,534,501		

The weighted-average remaining contractual life of options outstanding at December 31, 2022 was 5.58 years (2021: 4.35 years).

A summary of the range of prices for the Company's share options for the year ended December 31, 2021 follows:

	Outstanding			Exercisable		
Exercise price range	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.19-US$0.99	13,000,006	0.48	3.54	7,960,004	0.55	2.92
US$1.00-US$2.05	5,228,000	1.34	0.79	4,941,334	1.35	0.99
US$2.06- US$2.99	439,984	2.53	0.03	439,984	2.53	0.04
US$3.00 -US$4.36	60,000	4.17	0.00	60,000	4.17	0.00
	18,727,990			13,401,322		

	Outstanding			Exercisable		
Exercise price range	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.77-US$3.96	3,250,002	1.94	3.54	1,990,001	2.19	2.92
US$4.00-US$8.20	1,307,000	5.36	0.79	1,235,334	5.40	0.99
US$8.24- US$11.96	109,996	10.13	0.03	109,996	10.13	0.04
US$12.00 -US$17.45	15,000	16.67	0.00	15,000	16.67	0.00
	4,681,998			3,350,331		

19. SHARE OPTIONS (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$1,755,000 was charged to the statement of operations in 2022, (2021: US$1,100,000) (2020: US$792,000) split as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Share-based payments – cost of sales	-	5	12
Share-based payments – selling, general and administrative	1,755	1,095	780
Total – continuing operations	1,755	1,100	792
Share-based payments – discontinued operations	-	-	-
Total	1,755	1,100	792

No share-based payments expense was capitalised in intangible development project assets during the year. In 2021, US$11,000, (2020: US$24,000) of share-based payments was capitalised in intangible development project assets. The total share-based payments charge gross of any capitalisations for 2021 was US$1,111,000 (2020: US$816,000).

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 Black-Scholes model. The following are the input assumptions used in determining the fair value of share options granted in 2022, 2021 and 2020:

	Key management personnel 2022	**Other employees 2022**	**Key management personnel 2021**	**Other employees 2021**	**Key management personnel 2020**	**Other employees 2020**
Weighted average fair value at measurement date per 'A' share / (per ADS)	US$0.19 / (US$0.77)	- / -	- / -	- / -	US$0.20 / (US$0.80)	US$0.27 / (US$1.08)
Total 'A' share options granted / (ADS's equivalent)	29,400,000 / (7,350,000)	- / -	- / -	- / -	8,480,000 / (2,120,000)	620,000 / (155,000)
Weighted average share price per 'A' share / (per ADS)	US$0.27 / (US$1.09)	- / -	- / -	- / -	US$0.38 / (US$1.52)	US$0.48 / (US$1.96)
Weighted average exercise price per 'A' share / (per ADS)	US$0.27 / (US$1.09)	- / -	- / -	- / -	US$0.38 / (US$1.52)	US$0.48 / (US$1.96)
Weighted average expected volatility	76.79%	-%	-%	-%	66.98%	65.89%
Weighted average expected life	6.82	-	-	-	4.34	4.35
Weighted average risk-free interest rate	3.59%	-%	-%	-%	0.44%	0.42%

19. SHARE OPTIONS (CONTINUED)

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.

20. TRADE AND OTHER PAYABLES

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Trade payables	6,205	6,763
Accruals and other liabilities	8,585	7,595
Payroll taxes	368	398
Employee related social insurance	103	130
Deferred income	114	141
Deferred government grants	-	69
Other payables	-	31
	15,375	15,127

Included in trade and other payables at December 31, 2022 was US$176,000 (2021: US$Nil) relating to contracted licence payments.

Other payables

Other payables at December 31, 2021 related to an interest-free loan received under the Canada Emergency Business Account ("CEBA"). The CEBA loans were provided by the Canadian Government to mitigate the financial impact of the Covid-19 outbreak. This interest-free loan was repaid and partly forgiven in the year ended December 31, 2022. For more information, refer to Note 4.

21. PROVISIONS

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Product warranty provision	50	50
	50	50

During 2022 and 2021 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, 2022 represents the estimated cost of product warranties, the exact amount which cannot be determined. US$50,000 represents management's best estimate of these obligations at December 31, 2022.

22. INTEREST-BEARING LOANS AND BORROWINGS

The carrying value of interest-bearing loans, borrowings and related balances is as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Current liabilities		
Exchangeable senior notes	210	83,312
Total	210	83,312

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Non-Current liabilities		
Senior secured term loan	44,301	-
Derivative financial liability	1,569	-
Convertible Note	13,746	-
Total non-current liabilities	59,616	-

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Non-Current assets		
Derivative financial asset	128	-
Total non-current assets	128	-

Exchangeable senior notes

In January 2022, the Company retired approximately US$99.7 million of the Exchangeable Notes as part of a debt re-financing. This represented approximately 99.7% of the total Exchangeable Notes. Consideration was in cash and an issue of 'A' Ordinary shares. The cash paid was US$86.73 million with each holder that was party to the agreement receiving US$0.87 of cash per US$1 nominal value of the Exchangeable Notes. The shares consideration was 5,333,000 ADSs (21,332,000 'A' Ordinary shares) representing the equivalent of US$0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 10, 2021, discounted by 13%) per US$1 nominal value of the Exchangeable Notes, as partial consideration for the exchange of the Exchangeable Notes. The shares consideration is valued at US$6.1 million based on market price on the date of issue.

The Exchangeable Notes were treated as a host debt instrument under IFRS with embedded derivatives attached. The embedded derivatives related to a number of put and call options which were measured at fair value in the consolidated statement of operations. On initial recognition in 2015, the host debt instrument was recognised at the residual value of the total net proceeds of the note issue less fair value of the embedded derivatives. Subsequently, the host debt instrument was measured at amortised cost using the effective interest rate method.

At date of disposal, the carrying value of the extinguished Exchangeable Notes was US$83.2m. As the IFRS measure of consideration was higher by US$9.7 million, the resulting loss on disposal was recorded as a financial expense in the year ended December 31, 2022. The remaining nominal value of the Exchangeable Notes at December 31, 2022 is US$210,000 and this is shown within Current Liabilities.

22. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

The movement in the Exchangeable Notes balance was as follows:

	December 31, 2022 US$000	*December 31, 2021 US$000*
Balance at January 1	(83,312)	(82,664)
Accretion interest	(83)	(648)
Repaid to Note holders	86,730	0
Shares issued to Note holders as consideration	6,133	0
Loss on disposal	(9,678)	0
Liability	(210)	(83,312)

During the year ended December 31, 2022, the Company acquired two new debt liabilities, as follows:

(i) Senior secured term loan

The Company and its subsidiaries entered into a US$81.3 million senior secured term loan credit facility in December 2021 (the "Term Loan") with Perceptive Credit Holdings III, LP ("Perceptive", an investment manager with an expertise in healthcare. The Term Loan was drawn down in January 2022, when the necessary shareholder approvals were obtained. The term loan is secured by a charge over the Group's assets. The 48-month term loan will mature in January 2026 and accrues interest at an annual rate equal to 11.25% plus the greater of (a) one-month LIBOR (later changed to the Term SOFR Reference Rate effective from October 28, 2022) and (b) one percent per annum, and interest is payable monthly in arrears in cash. The term loan does not require any amortization, and the entire unpaid balance will be payable upon maturity. In connection with the Term Loan the Company agreed to issue warrants to Perceptive for 2.5 million of the Company's ADSs. The per ADS exercise price of the Warrants was US$1.30. In February 2023, in connection with an increased Term Loan facility, the Company agreed to reprice the 2,500,000 warrants originally issued to Perceptive, with the Warrants now having a per ADS price of US$1.071. The warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the Term Loan.

At the discretion of the Company, the Term Loan can be repaid, in part or in full, at a premium before the end of the four-year term. In May 2022, the Company repaid US$34.5 million of the term loan principal and incurred an early payment penalty of approximately US$3.5 million, which has been recorded as a financial expense in the year ended December 31, 2022.

In accordance with IFRS accounting standards, the Term Loan is represented by three separate balances in the statement of financial position. US$44.3 million is shown in non-current liabilities as a senior secured term loan. At initial recognition, the balance comprised the principal loan amount of US$81.25 million less loan origination costs of US$3.6 million, less two derivative financial balances totaling US$1.7 million to give a balance of US$76.0 million. During the year ended December 31, 2022 accretion interest of US$2.8 million was accrued and the repayment of US$34.5 million reduced the liability to leave a closing carrying value of US$44.3 million. The early repayment of a portion of the Term Loan necessitated an accretion interest adjustment of US$2.1 million in the year ended December 31, 2022, recognised as a financial expense, to discount the revised expected future cash flows for the loan.

The other two balances related to the Term Loan are: a) a derivative financial asset and b) a derivative financial liability. The fair value of the derivative financial asset is estimated at US$128,000 at December 31, 2022 and represents the value to the Company of being able to repay the Term Loan early and potentially refinance at a lower interest rate. The fair value of the derivative financial liability is estimated at US$1,569,000 at December 31, 2022 and represents the fair value of the warrants issued to Perceptive. The fair value remeasurement for these two derivative financial balances resulted in a net financial income of US$0.2m being recognised in the consolidated statement of operations.

22. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

(ii) 7-year convertible note

In May 2022, the Company announced a US$45.2 million investment from MiCo Ltd ("MiCo"). MiCo, a KOSDAQ-listed and Korea-based company, is engaged in the biomedical business through its affiliate MiCo BioMed. The investment consists of an equity investment of US$25.2 million and a seven-year, unsecured junior convertible note of US$20.0 million. The convertible note has an interest rate of 1.5%. The convertible note mandatorily converts into ADSs if the volume weighted average price of the Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days. For further details on the convertible note, refer to the Company's Form 6-K filings with the SEC on April 11, 2022.

The convertible loan note is accounted for as a compound financial instrument containing both an equity and liability element. The debt component is accounted for at amortised cost in accordance with IFRS 9. At December 31, 2022, the carrying value of the convertible note's debt component was US$13.7 million and accretion interest of US$0.5 million has been recognised as a financial expense in the year ended December 31, 2022. The equity component of the convertible note is US$6.7 million and has been recorded in the equity section of the statement of financial position as Equity component of convertible note. There is no remeasurement of the equity element following initial recognition.

The movement in the Term Loan and the 7-year convertible notes in the year ended December 31, 2022 is summarised as follows:

	Senior secured term loan US$000	*7-year Convertible Note US$000*
Balance at January 1, 2022	-	-
Principal amount loaned	(81,250)	(20,000)
Loan origination costs	3,551	40
Derivative financial liability at date of issue	1,872	-
Derivative financial asset at date of issue	(202)	-
Equity component at date of issue	-	6,709
Accretion interest	(2,772)	(495)
Cash repayment of principal	34,500	-
Non-current liability at December 31, 2022	(44,301)	(13,746)

The movement in the derivative financial liability in the year ended December 31, 2022 was as follows:

	US$000
Balance at January 1, 2022	-
Derivative financial liability at date of issue of Term Loan	(1,872)
Fair value adjustments in the period	303
Non-current liability at December 31, 2022	(1,569)

The movement in the derivative financial asset in the year ended December 31, 2022 was as follows:

	US$000
Balance at January 1, 2022	-
Derivative financial asset at date of issue of Term Loan	202
Fair value adjustments in the period	(74)
Non-current asset at December 31, 2022	128

23. LEASE LIABILITIES

The Group has leases for some of its manufacturing plants, all warehouses, offices, motor vehicles and some IT equipment. With the exception of short-term leases and leases of low-value underlying assets, each lease is reflected on the balance sheet as a right-of-use asset (net of any depreciation and/or impairment) and a lease liability. Variable lease payments which do not depend on an index or a rate (such as lease payments based on a percentage of Group sales) are excluded from the initial measurement of the lease liability and asset. The Group classifies its right-of-use assets in a consistent manner to its property, plant and equipment (see Note 11).

Each lease generally imposes a restriction that, unless there is a contractual right for the Group to sublet the asset to another party, the right-of-use asset can only be used by the Group. Leases are either non-cancellable or may only be cancelled by incurring a substantive termination fee. Some leases contain an option to purchase the underlying leased asset outright at the end of the lease, or to extend the lease for a further term. The Group is prohibited from selling or pledging the underlying leased assets as security. For leases over office buildings and factory premises the Group must keep those properties in a good state of repair and return the properties in their original condition at the end of the lease. Further, the Group must insure items of property, plant and equipment and incur maintenance fees on such items in accordance with the lease contracts.

Lease liabilities

Lease liabilities are payable as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Current liabilities		
Lease liabilities related to Right of Use assets	1,631	1,878
Sale and leaseback liabilities	45	102
	1,676	1,980
Non-Current liabilities		
Lease liabilities related to Right of Use assets	12,267	13,790
Sale and leaseback liabilities	-	75
	12,267	13,865

	December 31, 2022 US$'000 Lease liabilities related to Right of Use assets			*December 31, 2022 US$'000 Sale and leaseback Liabilities*		
	Minimum lease payments	Interest	Principal	Minimum lease payments	Interest	Principal
Less than one year	2,249	618	1,631	46	1	45
In more than one year, but not more than two	2,240	561	1,679	-	-	-
In more than two years but not more than five	5,739	1,217	4,522	-	-	-
more than five years	6,968	902	6,066	-	-	-
	17,196	3,298	13,898	46	1	45

23. LEASE LIABILITIES (CONTINUED)

	December 31, 2021 US$'000 Lease liabilities related to Right of Use assets			*December 31, 2021 US$'000 Sale and leaseback Liabilities*		
	Minimum lease payments	Interest	Principal	Minimum lease payments	Interest	Principal
Less than one year	2,575	697	1,878	109	7	102
In more than one year, but not more than two	2,175	621	1,554	77	2	75
In more than two years but not more than five	5,985	1,469	4,516	-	-	-
more than five years	8,992	1,272	7,720	-	-	-
	19,727	4,059	15,668	186	9	177

Lease payments not recognised as a liability

No short-term lease expenses were incurred for the year ended December 31, 2022. Payments made under such leases are expensed on a straight-line basis. In addition, certain variable lease payments are not permitted to be recognised as lease liabilities and are expensed as incurred.

Terms and debt repayment schedule

The terms and conditions of outstanding interest-bearing loan and borrowing at December 31, 2022 are shown in the table below. A Euro-denominated sale and leaseback liability, which had a maturity date in 2023, was settled in full in 2022.

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	USD	5.51%	2023	45	45

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2021 are as follows:

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	Euro	4.53%	2023	65	65
Sale and leaseback liabilities	USD	5.51%	2023	111	111
Total				176	176

The total paid in respect of lease liabilities in the year ended December 31, 2022 was US$2,761,000 (2021: US$2,938,000).

24. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has capital commitments authorised and contracted for of US$Nil as at December 31, 2022 (2021: US$440,000).

(b) ***Leasing Commitments***

The Group's leasing commitments are shown in Note 23.

24. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(c) ***Bank Security***

The Credit Agreement for the senior secured term loan is secured by substantially all of our property and assets, including our equity interests in our subsidiaries, refer to Note 22.

At December 31, 2022, the Group's sale and leaseback borrowings were at fixed rates of interest and consisted of USD denominated borrowings, refer to Note 23. The bank providing the financing has a charge over the equipment for which the borrowing pertains.

(d) ***Group Company Guarantees***

Pursuant to the provisions of Section 357, Irish Companies Act, 2014, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, Trinity Research Limited and Trinity Biotech Financial Services Limited subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2022 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 357, Irish Companies Act, 2014. 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) ***Contingent Asset***

In the 2019 financial statements, a contingent asset of US$1,231,000 was disclosed in connection with the 2019 tax audit settlement payable by Darnick Company. This balance was settled in the year ended December 31, 2020 and has been credited to the Statement of Operations within Selling, General and Administrative Expenses. The underlying amount was denominated in Euro. Due to a depreciation in the US Dollar since 2019, the US Dollar equivalent amount increased from US$1,231,000 to US$1,316,000. The settlement amount received by the Company was US$177,000 more than the balance owed and this overpayment was recorded as a related party current liability for the benefit of Ronan O'Caoimh as at December 31, 2020. The amount was settled by the Group in January 2021. There are no contingent assets as of December 31, 2022 (2021: US$Nil).

(f) ***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, 2022. However, if the income were to become repayable, the maximum amounts repayable as at December 31, 2022 would amount to US$3,259,509 (2021: US$3,095,000).

To mitigate the financial impact of the Covid-19 outbreak, the Group availed of governmental supports. In 2020, the Group received US$4.5 million of Paycheck Protection Program ("PPP") loans and in 2021, a further US$1.8 million of PPP loans were received. All of the loans received to date under the program have been forgiven by the US government before December 31, 2022 and therefore no liability for these loans exists at December 31, 2022.

(g) ***Other Contingencies***

The Company has other contingencies primarily relating to claims and legal proceedings, onerous contracts, product warranties and employee related provisions. The status of each significant claim and legal proceeding in which the Company is involved is reviewed by management on a periodic basis and the Group's potential financial exposure is assessed. If the potential loss from any claim or legal proceeding is considered probable, and the amount can be reliably estimated, a liability is recognised for the estimated loss. Because of the uncertainties inherent in such matters, the related provisions are based on the best information available at the time; the issues taken into account by management and factored into the assessment of legal contingencies include, as applicable, the status of settlement negotiations, interpretations of contractual obligations, prior experience with similar contingencies/claims, and advice obtained from legal counsel and other third parties. The Group expects the majority of these provisions will be utilised within one to three years of the balance sheet date; however due to the nature of the legal provisions there is a level of uncertainty in the timing of settlement as the Group generally cannot determine the extent and duration of the legal process.

25. 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 following is a description of our related party transactions since January 1, 2022.

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, to provide premises at IDA Business Park, Bray, County Wicklow, Ireland.

The Group entered into an agreement with JRJ for a 25-year lease commencing in December 2003 for offices that were adjacent to its then premises at IDA Business Park, Bray, County Wicklow, Ireland with an annual rent of €381,000 (US$406,000). Upward-only rent reviews are carried out every five years and there have been no increases arising from these rent reviews.

In 2007, the Group entered into a 25-year lease agreement with Mr O'Caoimh and Dr Walsh for a 43,860 square foot manufacturing facility in Bray, Ireland with an annual rent of €787,000 (US$838,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. In 2016, the Group also entered into a 10-year lease agreement with Mr O'Caoimh for a warehouse of 16,000 square feet adjacent to the leased manufacturing facility in Bray, Ireland. The annual rent for the warehouse is €144,000 (US$153,000). At the time, independent valuers advised the Group that the rent in respect of each of the leases represented a fair market rent. Upward-only rent reviews are carried out every five years and there have been no increases to date arising from these rent reviews, although a rent review for the 43,860 square foot facility is currently ongoing.

In late 2020, the Group occupied some additional space adjoining the warehouse owned by Mr O'Caoimh. This was a short-term arrangement, and no payments were made for the additional space during 2020 and 2021. The Company vacated this space in 2021. In 2022, the rent payable to Mr O'Caoimh of US$90,000 was settled.

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 were entered into represented a fair and reasonable basis on which the Group could meet its ongoing requirements for premises. Dr Walsh has no ownership interest in the additional space adjoining the warehouse owned by Mr O'Caoimh and was therefore entitled to express an opinion on this arrangement.

Compensation of key management personnel of the Group

During the year ended December 31, 2022, the key management personnel of the Group were made up of the executive directors; Mr. Ronan O'Caoimh, Dr Jim Walsh, Mr. John Gillard and Mr. Aris Kekedjian. For the year ended December 31, 2021, the key management personnel of the Group were made up of the executive directors; Mr. Ronan O'Caoimh, Dr Jim Walsh, Mr. John Gillard and Mr. Kevin Tansley. Compensation for the year ended December 31, 2022 of these personnel is detailed below:

	December 31, 2022 *US$'000*	December 31, 2021 *US$'000*
Short-term employee benefits	1,074	1,065
Performance related bonus	512	227
Post-employment benefits	24	24
Share-based compensation benefits as calculated under IFRS 2	1,690	965
	3,300	2,281

25. RELATED PARTY TRANSACTIONS (CONTINUED)

The amounts disclosed in respect of directors' emoluments in Note 9 includes non-executive directors' fees of US$53,000 (2021: US$98,000) and share-based compensation benefits of US$17,000 (2021: US$61,000). Total directors' remuneration is also included in "employment" (Note 3) and "(Loss)/profit before tax" (Note 9). The performance bonuses for Mr. Kekedjian and Mr. Gillard in respect of fiscal year 2022 have been accrued as at December 31, 2022.

Directors' interests in the Company's shares and share option plan

	'A' Ordinary Shares	*Share options*
At January 1, 2022	9,077,713	16,738,000
Shares of retired director	(626,600)	-
Options of retired director	-	(2,924,000)
Shares purchased during the year	2,666,664	(2,666,664)
Shares sold during the year	-	-
Granted	-	29,400,000
Expired / forfeited	-	-
At December 31, 2022	11,117,777	40,547,336

	'A' Ordinary Shares	*Share options*
At January 1, 2021	9,077,713	17,394,000
Shares of retired director	-	-
Options of retired director	-	(656,000)
Shares purchased during the year	-	-
Shares sold during the year	-	-
Granted	-	-
Expired / forfeited	-	-
At December 31, 2021	9,077,713	16,738,000

Rayville Limited, an Irish registered company, which was wholly owned by three executive directors and certain other former executives of the Group, owned all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries, and these 'B' shares were surrendered through Trinity Research Limited in 2021. 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. All liabilities in relation to Rayville Limited and Trinity Research Limited were extinguished as at December 31, 2021 and December 31, 2022.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT

Capital Management

The Group's policy is to maintain a strong capital base to maintain investor, creditor and market confidence and to sustain future development of the business. The Board of Directors monitors (loss)/earnings per share as a measure of performance, which the Group defines as (loss)/profit after tax divided by the weighted average number of shares in issue.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Fair Values

The table below sets out the Group's classification of each class of financial assets/liabilities, their fair values and under which valuation method they are valued:

	Note	*Level 1 US$'000*	*Level 2 US$'000*	*Total carrying amount US$'000*	*Fair Value US$'000*
December 31, 2022					
Loans and receivables at amortised cost					
Trade receivables	*16*	12,620	-	12,620	12,620
Cash and cash equivalents	*17*	6,578	-	6,578	6,578
Finance lease receivable	*14, 16*	170	-	170	170
		19,368	-	19,368	19,368
Liabilities at amortised cost					
Senior secured term loan	22	-	(44,301)	(44,301)	(44,301)
Convertible note	22	-	(13,746)	(13,746)	(13,746)
Exchangeable note	*22*	(210)	-	(210)	(210)
Lease liabilities	*23*	(13,943)	-	(13,943)	(13,943)
Trade and other payables (excluding deferred income)	*20*	(15,261)	-	(15,261)	(15,261)
Provisions	*21*	(50)	-	(50)	(50)
		(29,464)	(58,047)	(87,511)	(87,511)
Fair value through profit and loss (FVPL)					
Derivative liability - warrants	*22*	-	(1,569)	(1,569)	(1,569)
Derivative asset – prepayment option	*22*	-	128	128	128
		-	(1,441)	(1,441)	(1,441)
		(10,096)	(59,488)	(69,584)	(69,584)

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.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

	Note	*Level 1 US$'000*	*Level 2 US$'000*	*Total carrying amount US$'000*	*Fair Value US$'000*
December 31, 2021					
Loans and receivables at amortised cost					
Trade receivables	*16*	13,290	-	13,290	13,290
Cash and cash equivalents	*17*	25,910	-	25,910	25,910
Finance lease receivable	*14, 16*	293	-	293	293
		39,493	-	39,493	39,493
Liabilities at amortised cost					
Exchangeable note[1]	*22*	-	(83,312)	(83,312)	(83,312)
Lease liabilities	*23*	(15,845)	-	(15,845)	(15,845)
Trade and other payables (excluding deferred income)	*20*	(14,986)	-	(14,986)	(14,986)
Provisions	*21*	(50)	-	(50)	(50)
		(30,881)	(83,312)	(114,193)	(114,193)
Fair value through profit and loss (FVPL)					
Exchangeable note bond call option	*22*	-	-	-	-
Exchangeable note equity conversion option	*22*	-	-	-	-
		-	-	-	-
		8,612	(83,312)	(74,700)	(74,700)

The valuation techniques used for instruments categorised as level 2 are described below:

The fair values of the options associated with the exchangeable notes are calculated in consultation with third-party valuation specialists due to the complexity of their nature. There are a number of inputs utilised in the valuation of the options, including share price, historical share price volatility, risk-free rate and the expected borrowing cost spread over the risk-free rate.

Financial Risk Management

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. 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.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

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, 2022	*Note*	*Effective interest rate*	*Total US$'000*	*6 mths or less US$'000*	*6 –12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*> 5 years US$'000*
Cash and cash equivalents	*17*	0.00%	6,578	6,578	-	-	-	-
Lease receivable	*14,16*	4.0%	170	46	41	49	34	-
Exchangeable note	*22*	4.8%	(210)	-	-	-	-	(210)
Senior secured term loan[1]	*22*	15.4%	(44,301)	-	-	-	(44,301)	-
Convertible note[2]	*22*	1.5%	(13,746)	-	-	-	-	(13,746)
Lease payable on Right of Use assets	*23*	5.0%	(13,898)	(812)	(819)	(1,679)	(4,522)	(6,066)
Lease payable on sale & leaseback transactions	*23*	5.0%	(45)	(35)	(10)	-	-	-
Total			(65,452)	5,777	(788)	(1,630)	(48,789)	(20,022)

[1] The senior secured term loan is a variable instrument which bears interest at an annual rate equal to 11.25% plus the greater of (a) one-month Term SOFR Reference Rate and (b) one percent per annum.

[2] The convertible note is a fixed rate instrument which bears a fixed rate of interest of 1.5% per annum.

[3] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045.

As at December 31, 2021	*Note*	*Effective interest rate*	*Total US$'000*	*6 mths or less US$'000*	*6 -12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*> 5 years US$'000*
Cash and cash equivalents	*17*	0.01%	25,910	25,910	-	-	-	-
Lease receivable	*14,16*	4.0%	293	81	61	89	62	-
Exchangeable note[1]	*22*	4.8%	(83,312)	-	-	-	-	(83,312)
Other borrowings		0%	(31)	-	(31)	-	-	-
Lease payable on Right of Use assets	*23*	5.0%	(15,668)	(973)	(905)	(1,554)	(4,516)	(7,720)
Lease payable on sale & leaseback transactions	*23*	5.0%	(177)	(51)	(51)	(75)	-	-
Total			(72,985)	24,967	(926)	(1,540)	(4,454)	(91,032)

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$Nil (2021: US$31,000) as, at December 31, 2022 the Company holds no funds in interest-bearing accounts; while the annual impact on the interest expense would be an increase of US$467,500 (2021: nil) on the costs of servicing the senior secured term loan.

In accordance with the UK Financial Conduct Authority's announcement in March 2021, LIBOR benchmark rates were discontinued after 31 December 2022. The Group's cash flows were affected by the interest rate benchmark reform. The senior secured Term Loan originally varied by reference to one-month LIBOR. During 2022, LIBOR was replaced by the Term SOFR Reference Rate as part of the inter-bank offer rate reform. This change did not have a material financial impact.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Interest rate profile of financial assets / liabilities

The interest rate profile of financial assets/liabilities of the Group was as follows:

	December 31, 2022 US$'000	*December 31, 2021 US$'000*
Variable rate instruments		
Cash at bank and in hand	6,578	22,790
Short-term deposits	-	3,120
Variable rate financial liabilities (senior secured term loan)	(44,301)	-
	(37,723)	25,910
Fixed rate instruments		
Fixed rate financial liabilities (exchangeable note)	(210)	(83,312)
Fixed rate financial liabilities (convertible note)	(13,746)	-
Fixed rate financial liabilities (borrowings)	-	(31)
Fixed rate financial liabilities (lease payables)	(13,943)	(15,844)
Financial assets (short-term deposits and short-term investments)	-	3,121
Financial assets (lease receivables)	170	293
	(27,729)	(95,773)

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, 2022 or December 31, 2021 would not affect profit or loss. 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, 2022 and December 31, 2021 as all fell due within 6 months.

Liquidity risk

The following are the contractual maturities of financial liabilities, including estimated interest payments:

As at December 31, 2022 US$'000	*Carrying amount US$'000*	*Contractual cash flows US$'000*	*6 mths or less US$'000*	*6 mths – 12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*>5 years US$'000*
Financial liabilities							
Trade & other payables	15,261	15,261	15,261	-	-	-	-
Lease payable on Right of Use assets	13,898	17,196	1,120	1,130	2,240	5,739	6,967
Lease payable on sale & leaseback transactions	45	46	36	10	-	-	-
Senior secured term loan	44,301	69,519	4,194	3,595	7,190	54,540	-
Convertible note	13,746	21,900	150	150	300	900	20,400
Exchangeable notes	210	397	4	4	8	24	357
	87,461	124,319	20,765	4,889	9,738	61,203	27,724

[1] The contractual cash flows of interest on the senior secured term loan is estimated based on the prevailing interest rate at December 31, 2022

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

As at December 31, 2021 *US$'000*	*Carrying amount* *US$'000*	*Contractual cash flows* *US$'000*	*6 mths or less* *US$'000*	*6 mths – 12 mths* *US$'000*	*1-2 years* *US$'000*	*2-5 years* *US$'000*	*>5 years* *US$'000*
Financial liabilities							
Trade & other payables	15,127	15,127	15,127	-	-	-	-
Lease payable on Right of Use assets	15,668	15,668	973	905	1,554	4,516	7,720
Lease payable on sale & leaseback transactions	177	177	51	51	75	-	-
Other borrowings	31	31	-	31	-	-	-
Exchangeable notes [1]	83,312	99,900	-	-	-	-	99,900
Exchangeable note interest	999	93,906	1,998	1,998	3,996	11,988	73,926
	115,314	224,809	18,149	2,985	5,625	16,504	181,546

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045.

Foreign exchange risk

The majority of the Group's activities are conducted in US Dollars. 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. There were no forward contracts in place as at December 31, 2022 or December 31, 2021.

Foreign currency 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:

As at December 31, 2022	*EUR* *US$'000*	*GBP* *US$'000*	*SEK* *US$'000*	*CAD* *US$'000*	*BRL* *US$'000*	*Other* *US$'000*
Cash	700	199	5	2,061	756	-
Trade and other receivable	1,001	27	-	950	1,443	-
Trade and other payables	(3,481)	(5)	(6)	(473)	(662)	-
Lease liabilities	(9,024)	-	-	-	(277)	-
Total exposure	(10,804)	221	(1)	2,538	1,260	-

As at December 31, 2021	*EUR* *US$'000*	*GBP* *US$'000*	*SEK* *US$'000*	*CAD* *US$'000*	*BRL* *US$'000*	*Other* *US$'000*
Cash	327	115	5	4,617	1,370	-
Trade and other receivable	464	58	-	488	1,538	-
Trade and other payables	(2,456)	(28)	(11)	(166)	(629)	-
Lease liabilities	(10,629)	-	-	-	(139)	-
Total exposure	(12,294)	145	(6)	4,939	2,140	-

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Sensitivity analysis

A 10% strengthening of the US Dollar against the Euro at December 31, 2022 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 US$'000
December 31, 2022	
Euro	982
December 31, 2021	
Euro	780

A 10% weakening of the US Dollar against the Euro at December 31, 2022 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 US$000
December 31, 2022	
Euro	(1,200)
December 31, 2021	
Euro	(953)

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, the Group's exposure to credit risk arises from default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments. The Group's management considers that all of the above financial assets that are not impaired or past due for each of the 31 December reporting dates under review are of good credit quality.

The Group maintains cash and cash equivalents 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 approximate their fair value.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (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 December 31, 2022 US$'000	*Carrying Value December 31, 2021 US$'000*
Third party trade receivables (Note 16)	12,620	13,290
Finance lease income receivable (Note 16)	170	293
Cash and cash equivalents (Note 17)	6,578	25,910
	19,368	39,493

The maximum exposure to credit risk for trade receivables and finance lease income receivable by geographic location is as follows:

	Carrying Value December 31, 2022 US$'000	*Carrying Value December 31, 2021 US$'000*
United States	6,061	5,822
Euro-zone countries	1,183	1,072
United Kingdom	67	118
Other regions	5,479	6,571
	12,790	13,583

The maximum exposure to credit risk for trade receivables and finance lease income receivable by type of customer is as follows:

	Carrying Value December 31, 2022 US$'000	*Carrying Value December 31, 2021 US$'000*
End-user customers	7,365	6,923
Distributors	4,630	6,220
Non-governmental organisations	795	440
	12,790	13,583

Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

26. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Impairment Losses

The ageing of trade receivables at December 31, 2022 is as follows:

	Gross 2022 US$'000	*Impairment 2022 US$'000*	*Expected Credit Loss Rate 2022 %*	*Gross 2021 US$'000*	*Impairment 2021 US$'000*	*Expected Credit Loss Rate 2021 %*
Not past due	8,341	-	-%	8,461	-	-%
Past due 0-30 days	1,622	-	-%	2,423	1	0.1%
Past due 31-120 days	1,564	23	1.5%	1,981	97	4.9%
Greater than 120 days	3,783	2,668	70.5%	3,011	2,888	73.0%
	15,310	2,691	-	15,876	2,986	-

The movement in the allowance for impairment in respect of trade receivables during the year was as follows:

	2022 US$'000	*2021 US$'000*
Balance at January 1	2,986	3,922
Charged to costs and expenses	1,240	76
Amounts written off during the year	(1,535)	(1,012)
Balance at December 31	2,691	2,986

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.

27. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES

The changes in the Group's liabilities arising from financing activities can be classified as follows:

	Note	*Borrowings & derivative financial instruments US$'000*	*Lease liabilities US$'000*
Balance at January 1, 2022	*20,22,23*	83,343	15,845
Cash-flows:			
Principal amount loaned – term loan		81,250	
Principal amount loaned – convertible note		20,000	-
Loan origination costs paid		(3,591)	-
Interest paid for term loan		(6,424)	-
Interest paid for convertible note		(199)	
Interest paid for exchangeable notes		(1,293)	
Repayment of exchangeable notes		(86,730)	
Repayment of term loan		(34,500)	
Repayment of CEBA loan		(23)	(2,761)
Penalty paid for early settlement of term loan		(3,450)	-
Non-cash:			
Interest charged		7,914	-
Penalty for early settlement charged		3,450	-
Shares issued as consideration for purchase of Exchangeable Notes		(6,133)	-
Equity component of convertible note at date of issue		(6,709)	-
Derivative financial asset at date of issue		202	-
Loss on disposal of Exchangeable Notes		9,678	-
Additions (related to Right of Use assets)		-	830
Exchange adjustment		-	(628)
Loan forgiven		(7)	-
Accretion interest		3,351	657
Fair value of derivative liability - warrants		(303)	-
Balance at December 31, 2022	*22,23*	59,826	13,943

27. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES (CONTINUED)

	Note	Borrowings & derivative financial instruments US$'000	Lease liabilities US$'000
Balance at January 1, 2021	*20, 22,23*	84,065	18,741
Cash-flows:			
Interest paid		(3,996)	(11)
Repayment		-	(2,939)
Non-cash:			-
Interest charged		3,996	-
Additions (related to Right of Use assets)		-	71
Exchange adjustment		-	(820)
Accretion interest		648	803
Fair value	*6*	(1,370)	-
Balance at December 31, 2021	*22,23*	83,343	15,845

28. POST BALANCE SHEET EVENTS

Strategic Partnership with imaware™.

On January 9, 2023, a subsidiary of the Company entered into a strategic partnership with imaware, Inc. ("imaware") that combines their built-to-partner digital health platform with Trinity Biotech's advanced reference laboratory facilities to power the Digital Health Industry with at-home and remote testing programs. A subsidiary of the Company entered into a 5-year agreement to become the lab testing partner for imaware, starting later in 2023. In connection with the arrangement, a subsidiary of the Company committed to make a US$1.5 million convertible note investment in imaware. Our New York reference laboratory will have additional capacity for the increased testing volumes resulting from this strategic partnership since an existing customer, a local healthcare provider to whom our laboratory has provided transplant testing services, informed the Company recently that it was moving to a different service provider.

Amendment and restatement of Term Loan

On February 21, 2023, the Company and certain of its subsidiaries entered into an amended and restated senior secured term loan credit facility with Perceptive. The amendment to the Term Loan allows for an immediate US$5.0 million increase to its outstanding term loan and provides for a US$20 million facility to fund potential acquisitions.

In connection with the increased Term Loan facility, the Company agreed to reprice the 2,500,000 warrants originally issued to Perceptive under the Term Loan, with the Warrants now having a per ADS price of US$1.071 compared to their initial per ADS exercise price of US$1.30. The financial impact of the repricing of the warrants is not yet known.

TrinScreen HIV's inclusion in the new Kenyan HIV testing algorithm

On March 22, 2023, the Kenyan Ministry of Health announced the adoption of a new HIV rapid testing algorithm. This new algorithm establishes Trinity Biotech's TrinScreen HIV as the screening testing. The Kenyan HIV screening programme is one of the largest in Africa, with an estimated annual number of screening tests of between 7 million and 9 million. Trinity Biotech has been preparing for large scale manufacturing of TrinScreen HIV at its automated WHO standard, ISO13485 certified lateral flow test facility in Bray, Ireland and the Company expects to scale workforce capacity at the facility in the second quarter of 2023 as orders ramp up.

28. POST BALANCE SHEET EVENTS (CONTINUED)

Divestiture of Fitzgerald Life Sciences business and partial repayment of term loan

On April 20, 2023, the Company announced it had entered into an agreement to sell its Fitzgerald Industries life sciences supply business, consisting of Benen Trading Ltd and Fitzgerald Industries International, Inc, to Biosynth for cash proceeds of approximately US$30 million subject to customary adjustments. The Fitzgerald life sciences supply business generated revenue of approximately US$12 million in the year ended 31 December 2022, and was EBITDA positive. The cash proceeds from Biosynth includes funding to Fitzgerald Industries to allow it repay intercompany loans owed to Trinity Biotech. The Fitzgerald Industries life sciences supply business is included in the Rest of World - Ireland segment in the Company's segmental disclosures.

Management considered that life sciences supply was no longer core to the Group's refined long-term strategy and pursued this transaction as part of its plan to transform into a high growth innovator in diabetes care and decentralised diagnostic solutions.

On April 27, 2023 the Company announced it had closed the sale of Fitzgerald Industries. The Company has used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of its senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty. In connection with this transaction, the Company has entered into an amendment to its senior secured term loan credit facility with Perceptive Advisors, which significantly reduces the Company's minimum revenue covenants under that loan.

29. 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 12 contains information about the assumptions and the risk factors relating to goodwill impairment. Note 19 outlines information regarding the valuation of share options. Note 22 outlines the valuation techniques used by the Company in determining the fair value of the Group's interest-bearing loans and borrowings. In Note 26, 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:

Revenue Recognition

No revenue is recognised if there is uncertainty regarding recovery of the consideration due at the outset of the transaction. We make a judgement as to the collectability of invoiced sales based on an assessment of the individual debtor taking into account past payment history, the probability of default or delinquency in payments and the probability that debtor will enter into financial difficulties or bankruptcy.

Some customer contracts could be regarded as offering the customer a right of return. Due to the uncertainty of the magnitude and likelihood of product returns, there is a level of estimation involved in assessing the amount of revenue to be recognized for these types of contracts. In accordance with IFRS 15, when estimating the effect of an uncertainty on an amount of variable consideration to which the Group will be entitled, all information that is reasonably available, including historical, current and forecast, is considered.

29. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

We operate a licenced reference laboratory in New York, USA that specializes in diagnostics for autoimmune diseases. The laboratory provides testing services to two types of customers. Firstly, institutional customers, such as hospitals and commercial diagnostic testing providers, and secondly insurance companies on behalf of their policyholders. The revenue recognition for services provided to insurance companies requires some judgement. In the US, there are rules requiring all insurance companies to be billed the same amount per test. However, the amount that each insurance company pays for a particular test varies according to their own internal policies and this can typically be considerably less than the amount invoiced. We recognise lab services revenue for insurance companies by taking the invoiced amount and reducing it by an estimated percentage based on historical payment data. We review the percentage reduction annually based on the latest data. As a practical expedient, and in accordance with IFRS, we apply a portfolio approach to the insurance companies as they have similar characteristics. We judge that the effect on the financial statements of using a portfolio approach for the insurance companies will not differ materially from applying IFRS 15 to the individual contracts within that portfolio.

At December 31, 2022 US$114,000 (2021: US$141,000) (2020: US$4,445,000) of revenue was deferred in accordance with IFRS15. For further information, refer to Note 20.

Research and development expenditure – capitalized development costs

Under IFRS as issued by IASB, the Group writes 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. For further information, refer to Note 12.

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).

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, 2022 the carrying value of capitalised development costs was US$17,008,000 (2021: US$17,679,000) (see Item 18, Note 12 to the consolidated financial statements). The decrease in 2022 was mainly as a result, an impairment charge of US$4,623,000 and amortisation of US$479,000, partially offset by additions of US$4,475,000.

Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment periodically while goodwill and indefinite lived assets are tested for impairment at least 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.

29. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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.

The impairment testing performed during the year ended December 31, 2022 identified an impairment loss in three CGUs, namely Biopool US Inc, Clark Laboratories Inc, and Trinity Biotech Do Brasil totalling US$1.2 million. For further information, refer to Note 12.

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 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. 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 2022, 2021 or 2020 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2022 our allowance for slow moving and obsolete inventory was US$16.3 million which represents approximately 42.0% of gross inventory value. At December 31, 2021 our allowance for slow moving and obsolete inventory was US$12.1 million which represented approximately 29.3% of gross inventory value and at December 31, 2020 the provision was US$9.8 million, or approximately 24.5% of gross inventory value. The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has increased between 2022 and 2021 due to significant increases in the provision for the following categories of inventory:

(i) VTM inventory – there has been no evidence during the winter season of 2022-23 of significant peaks in demand for VTM products. This has led management to revisit the strategy of maintaining significant levels of raw materials inventory to meet demand peaks. Consequently, the provision for this inventory was increased by US$3.5 million in 2022 reflecting our estimate of its net realisable value.

(ii) Tri-stat inventory – the Company undertook a strategic review of our Tri-stat instrument line as part of a broader review of our haemoglobins product portfolio. Management decided to limit sales of Tri-stat to certain targeted partnerships and as a consequence the value of this inventory was written down by US0.3 million to reflect the revised outlook.

(iii) Raw materials and work in progress failing to meet our revised quality policy - the value of certain excess raw materials and work in progress was written down by US$0.9 million in 2022 following a review and an update to our relevant quality assurance policy.

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$0.8 million at December 31, 2022 (2021: US$0.8 million) (2020: US$0.8 million) would result. For further information, refer to Note 15.

29. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

Going Concern

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At December 31, 2022, the Group had net current assets of US$29.3 million. At the date of this report, the Group's liquidity position has substantially improved following the sale of its Fitzgerald life sciences business for cash proceeds of approximately US$30 million (subject to customary adjustments). This transaction substantially improves the Group's capital structure by reducing gross debt by approximately US$10 million; with the balance of the proceeds (net of costs) providing significant capital for growth, transformation, and potentially further debt reduction. There are no material debt maturities until 2026.

30. GROUP UNDERTAKINGS

The consolidated financial statements include the financial statements of Trinity Biotech plc and the following principal subsidiary undertakings:

Name and registered office	*Principal activity*	*Principal Country of incorporation and operation*	*Group % holding*
Trinity Biotech Manufacturing Limited IDA Business Park, Bray County Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland	100%
Trinity Research Limited IDA Business Park, Bray County Wicklow, Ireland	Research and development	Ireland	100%
Benen Trading Limited IDA Business Park, Bray County Wicklow, Ireland	Trading	Ireland	100%
Trinity Biotech Manufacturing Services Limited IDA Business Park, Bray County Wicklow, Ireland	Dormant	Ireland	100%
Trinity Biotech Luxembourg Sarl 1, rue Bender, L-1229 Luxembourg	Investment and provision of financial services	Luxembourg	100%
Trinity Biotech Inc Girts Road, Jamestown, NY 14702, USA	Holding Company	U.S.A.	100%
Clark Laboratories Inc Trading as Trinity Biotech (USA) Girts Road, Jamestown NY14702, USA	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Mardx Diagnostics Inc 5919 Farnsworth Court Carlsbad CA 92008, USA	Dormant	U.S.A.	100%
Fitzgerald Industries International, Inc 2711 Centerville Road, Suite 400 Wilmington, New Castle Delaware, 19808, USA	Management services company	U.S.A.	100%
Biopool US Inc (trading as Trinity Biotech Distribution) Girts Road, Jamestown NY14702, USA	Sale of diagnostic test kits	U.S.A.	100%
Primus Corporation 4231 E 75th Terrace Kansas City, MO 64132, USA	Manufacture and sale of diagnostic test kits and instrumentation	U.S.A.	100%

30. GROUP UNDERTAKINGS (CONTINUED)

Name and registered office	*Principal activity*	*Principal Country of incorporation and operation*	*Group % holding*
Phoenix Bio-tech Corp. 1166 South Service Road West Oakville, ON L6L 5T7 Canada.	Dormant	Canada	100%
Fiomi Diagnostics Holding AB Dag Hammarskjöldsv 52A SE-752 37 Uppsala Sweden	Holding Company	Sweden	100%
Fiomi Diagnostics AB Dag Hammarskjöldsv 52A SE-752 37 Uppsala Sweden	Discontinued operation	Sweden	100%
Trinity Biotech Do Brasil Comercio e Importacao Ltda Rua Silva Bueno 1.660 – Cj. 101/102 Ipiranga Sao Paulo Brazil	Sale of diagnostic test kits	Brazil	100%
Trinity Biotech (UK) Ltd Mills and Reeve LLP Botanic House 100 Hills Road Cambridge, CB2 1PH United Kingdom	Sales & marketing activities	UK	100%
Immco Diagnostics Inc 60 Pineview Drive Buffalo NY 14228, USA	Manufacture and sale of autoimmune products and laboratory services	U.S.A.	100%
Nova Century Scientific Inc 5022 South Service Road Burlington Ontario Canada	Manufacture and sale of autoimmune products and infectious diseases	Canada	100%
Trinity Biotech Investment Ltd PO Box 309 Ugland House Grand Cayman KY1-1104 Cayman Islands	Investment and provision of financial services	Cayman Islands	100%

31. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on May 16, 2023.

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/ Mr Aris Kekedjian
Mr Aris Kekedjian
Director/
Chief Executive Officer

Date: May 16, 2023

By: /s/ Mr John Gillard
Mr John Gillard
Company secretary/
Chief Financial Officer

Date: May 16, 2023

Item 19 ***Exhibits***

Exhibit No.	Description of Exhibit
1.1	Memorandum and Articles of Association of Trinity Biotech plc (as altered by Special Resolution dated September 30, 2022).
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 filed on January 15, 2004 and incorporated herein by reference).
2.1	Description of Rights of Securities Registered under Section 12 of the Securities and Exchange Act of 1934
4.1	Trinity Biotech plc Employee Share Option Plan 2017 and Trinity Biotech Share Option Plan 2020 (included as Exhibit 4.3 and 4.4 to our Registration Statement on Form S-8, filed on February 12, 2021 and incorporated herein by reference).
4.2	Trinity Biotech plc Employee Share Option Plan 2013 (included as Exhibit 4.1 to our Registration Statement on Form S-8 filed on April 11, 2014 and incorporated herein by reference).
4.3	Trinity Biotech plc Employee Share Option Plan 2011 (included as Exhibit 4 to our Registration Statement on Form S-8 filed on June 22, 2012 and incorporated herein by reference).
4.4	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, County Wicklow, Ireland (included as Exhibit 4b.1 to our Annual Report on Form 20-F filed on March 31, 2006 and incorporated herein by reference).
4.5	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, County Wicklow, Ireland (included as Exhibit 4b.2 to our Annual Report on Form 20-F filed March 31 2006 and incorporated herein by reference).
4.6	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, County Wicklow, Ireland (included as Exhibit 4.13 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.7	CDC Non-Exclusive Patent Licence Agreement dated as of May 22, 2012 (included as Exhibit 4.19 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.8	Inverness Medical Innovations, Inc. Patent Licence Agreement renewal dated as of August 3, 2006 (included as Exhibit 4.21 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.19	National Institute of Health Non-Exclusive Patent Licence Agreement dated as of December 17, 1999 (included as Exhibit 4.22 to our Report on Form 6-K filed on March 25, 2015 and incorporated herein by reference).
4.10	Credit Agreement and Guaranty Dated as of December 15, 2021 Among Trinity Biotech, Inc., Fitzgerald Industries International, Inc., Clark Laboratories, Inc. (D/B/A Trinity Biotech (USA)), Biopool U.S., Inc. (D/B/A Trinity Biotech Distribution), Primus Corporation, Mardx Diagnostics, Inc. and Immco Diagnostics, Inc. as the Borrowers, Trinity Biotech PLC and Certain of its Subsidiaries as Guarantors and Perceptive Credit Holdings III, LP, as Administrative Agent (included as Exhibit 99.2 to our Report on Form 6-K , filed on December 16, 2021 and incorporated herein by reference).
4.11	Form of Exchange Agreement with Holders of Exchangeable Senior Notes. (included as Exhibit 99.3 to our Report on Form 6-K, filed on December 23, 2021 and incorporated herein by reference).
4.12	Form of Warrant Certificate to purchase American Depositary Shares of Trinity Biotech plc (included as Exhibit 99.1 to our Report on Form 6-K filed on December 23, 2021 and incorporated herein by reference).
4.13	Securities Purchase Agreement between Trinity Biotech Plc and MiCo IVD Holdings, LLC dated April 11, 2022 (included as Exhibit 99.2 to our Report on Form 6-K filed on April 11, 2022 and incorporated herein by reference).
4.14	Convertible Loan Note (included as Exhibit 99.3 to our Report on Form 6-K filed on April 11, 2022 and incorporated herein by reference).

4.15	Amended and Restated Credit Agreement and Guaranty dated February 21, 2023 Among Trinity Biotech, Inc., Fitzgerald Industries International, Inc., Clark Laboratories, Inc. (D/B/A Trinity Biotech (USA)), Biopool U.S., Inc. (D/B/A Trinity Biotech Distribution), Primus Corporation, Mardx Diagnostics, Inc. and Immco Diagnostics, Inc. as the Borrowers, Trinity Biotech PLC and Certain of its Subsidiaries as Guarantors and Perceptive Credit Holdings III, LP, as Administrative Agent (included as Exhibit 4.10 to our Report on Form 6-K filed on February 22, 2023 and incorporated herein by reference).
4.16	First Amendment to Warrant Certificate to purchase American Depositary Shares of Trinity Biotech plc dated February 21, 2023 (included as Exhibit 4.12.1 to our Report on Form 6-K filed on February 22, 2023 and incorporated herein by reference).
4.17	Employment agreement between Aris Kekedjian and Trinity Biotech Inc. dated October 3, 2022.
4.18	Share Purchase Agreement in respect of Benen Trading Limited and Fitzgerald Industries International Inc., dated as of April 20, 2023 (included as Exhibit 4.15 to our Report on Form 6-K filed on April 24, 2023 and incorporated herein by reference).
4.19	First Amendment, dated as of April 20, 2023, to Amended and Restated Credit Agreement and Guaranty, dated as of February 21, 2023 (included as Exhibit 4.10.1 to our Report on Form 6-K filed on April 24, 2023 and incorporated herein by reference).
8.1	List of significant subsidiaries of Trinity Biotech plc (included as Item 18, note 30 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
101.INS	XBRL Instance Document (The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).