# 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, 2024**

**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)**

**Susan O'Connor**
**Interim 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 20 '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:

**359,193,482 Class 'A' Ordinary Shares (excluding Treasury Shares)**
(as of December 31, 2024)

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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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## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

As used herein, references to "we", "us", "Trinity Biotech" or the "Group" in this Annual Report on Form 20-F (the "Annual Report") shall mean Trinity Biotech plc and its subsidiaries. References to the "Company" in this annual report shall mean Trinity Biotech plc., the parent company. 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, 2024. 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, unless otherwise indicated.

## 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;
- statements of our plans and objectives;
- our ability to acquire or in-licence new product candidates;
- potential strategic relationships;

- the duration of our patent portfolio;
- the capabilities of our business operations;
- expected future economic performance;
- competition in our market; and
- assumptions underlying statements regarding us or our business.

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**

An investment in our securities involves a high degree of risk. Our business, financial condition or results of operations could be adversely affected by any of these risks. You should carefully consider the risks described below and, in the information, contained or incorporated by reference in this prospectus. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our American depositary shares ("ADSs") to decline, resulting in a loss of all or part of your investment.

***Risks Related to our Business and Industry***

- our ability to sell products could be adversely affected by competition from new and existing diagnostic products, and changing conditions in the diagnostic market.
- , including reductions in government funding and sector consolidation.
- changes in funding for staffing and operations of the FDA and other government agencies could negatively impact our business.
- our exclusion from one or more HIV testing algorithms, or a delay in the implementation of a HIV testing algorithm, could adversely affect our business and financial results.
- we have a history of losses from operations and negative cash flows from operating activities, which may continue in the future.
- we have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position.
- 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. Further our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase significantly.
- global trade issues including import and export license requirements, trade sanctions, tariffs and international trade disputes could increase our costs and have a material adverse effect on our business.
- failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.
- our ability to continue as a going concern depends on our ability to generate cash flows from operations and to conduct adequate financing activities. We expect we will require future additional capital.
- we may encounter difficulties in realizing the potential financial or strategic benefits of recent business acquisitions.
- we may be required to return the proceeds, plus interest and penalties, on loans received in 2021 under the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") as there are enquires as to whether our U.S. subsidiaries were eligible to receive some or all of the funds.
- our long-term success depends upon the successful development and commercialization of new products, particularly in the biosensor area.
- our products may in the future be subject to product recalls that could harm our reputation, business and financial results.
- the large amount of intangible assets and goodwill recorded on our balance sheet may lead to significant impairment charges in the future.
- changes in global economic conditions may have a material adverse impact on our results.
- 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 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.
- cybersecurity risks, including cyberattacks or data breaches, could disrupt our operations, compromise sensitive data, and adversely affect our business.
- our sales and operations are subject to the risks of fluctuations in currency exchange rates.
- any pandemic similar to the Covid-19 outbreak could significantly disrupt our operations and adversely affect our results of operations.

***Risks Related to Government Regulation***

- 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.
- 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.
- the FDA recently modified 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.
- if we are unable to obtain or fail to maintain regulatory approvals and clearances, 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.
- 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.
- we are subject to export controls and economic sanctions laws, anti-corruption, anti-bribery and similar laws and our customers and distributors are subject to import and export controls that could subject us to liability if we are not in full compliance with applicable laws.
- changes in healthcare regulation could affect our revenues, costs and financial condition.
- 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.
- compliance with regulations governing public company corporate governance and reporting is complex and expensive.

***Risks Related to Our Intellectual Property***

- we may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.
- our patent protection may not be sufficiently broad to compete effectively, the existing patents could be challenge, and trade secrets and confidential know-how could be obtained by competitors.
- 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.
- product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products, and 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.

***Risks Related to Ownership of our American Depository Shares***

- affiliates of Perceptive Credit Holdings III, LP (“Perceptive”) and MiCo IVD Holdings, LLC (“MiCo”) own approximately 9.6% and 12.5%, respectively, of the voting share capital of our Company (excluding ADS issuable with respect to warrants and a convertible note), which may give each of them significant influence over our management and affairs and may deter a change in control or other transaction that may be favorable to our shareholders.

- our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our ADSs and penny stock trading.
- the market price of our ADSs has been, and may continue to be, highly volatile.
- we expect we will need additional capital in the future.
- the conversion of our outstanding employee share options, any new employee share options and existing warrants would dilute the ownership interest of existing shareholders.
- it could be difficult for U.S. holders of our ADSs to enforce any securities laws claims against us, our officers or directors in Irish Courts.

**Risks Related to our Business and Industry**

***Our ability to sell products could be adversely affected by competition from new and existing diagnostic products, and changing conditions in the diagnostic market.***

We have invested in research and development but there can be no guarantees that our research and development ("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™, Afinion™, Architect™, FreeStyle Libre™), SD Biosensor (Standard Q), Bejing Wantai Biological Pharmacy (Wantai), Roche (Cobas, TinaQuant 3™), Bio-Rad (Variant 2™, Variant 2 Turbo™, D 100™, BioPlex 2200) Tosoh (G8™ and G11™), Arkray 8180™, Siemens DCA™, Sebia (Capyllaris 2™ and Capyllaris 3™), Shanghai Kehua Bio-Engineering (KHB), Euroimmun™, Guangzhou Wondfo Biotech Co., Ltd (Wondfo), Aesku™, Werfen, Copan™, Becton Dickenson™, Pointe Scientific, Dexcom ™ (G6, G7, Dexcom One, Stelo), Meril Life (MeriScreen™) 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 for new products, 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 the 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.

***Our ability to sell products could be adversely affected by reductions in government funding and sector consolidation.***

We are continuously monitoring the potential impact of the U.S. President's Executive Order on Reevaluating and Realigning United States Foreign Aid, and the resulting suspensions or termination of funding to HIV testing programs that utilize the Company's two rapid HIV tests. On January 20, 2025, the U.S. government paused, subject to certain exemptions, all new funding obligations and sub-obligations of funding of foreign assistance programs, pending a 90-day review of such foreign assistance programs. Although the U.S. government introduced a temporary waiver of the aforementioned funding pause for certain assistance, which the U.S. government later confirmed applied to funding for HIV testing under the President's Emergency Plan for AIDS Relief (PEPFAR), that waiver is temporary, and there can be no assurance that U.S. government funding for HIV programs that utilize the Company's rapid HIV tests will continue. Since the Executive Order, the Company has seen disruptions to ordering patterns and demand for our rapid HIV tests, and it remains unclear at this time what impact these changes will have on the timing and quantity of rapid HIV tests sold by the Company, and the receipt of funds for the sale of such tests. The outcome of the review aside from South Africa is that overall U.S. government spending will be cut by an estimated 15-20% for development-related programs. However, commodity procurement for HIV rapid tests outside of South Africa has been largely unaffected by these cuts. We continue to monitor the potential impact of these cuts closely, and countries affected are attempting to fill this gap from local and other funding sources.

***Changes in funding for, or disruptions to the staffing and operations of the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

Currently, federal agencies in the United States are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new products to be reviewed and/or approved, which would harm our business. Changes and cuts in FDA staffing also could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

A prolonged government shutdown or significant leadership, personnel, and/or policy changes, or other substantial modification in agency activities (including due to global health concerns or geopolitical factors) could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, government funding of other agencies on which our operations may rely, including those that fund research and development activities and clinical trials, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at agencies that fund our research and development activities and our clinical trials, or changes to such agencies' budgets, may negatively impact our operations and ongoing clinical trials and may limit our ability to seek additional funding in the future. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to whether and how the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the new administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new products.

***Our sales of point-of-care HIV tests in Africa are dependent on our inclusion in the applicable country's HIV testing algorithms and our exclusion from one or more of those HIV testing algorithms, or a delay in the implementation of a HIV testing algorithm, could adversely affect our business and financial results. Those HIV testing algorithms can be subject to legal challenges from market participants competitors or other stakeholders which can result in delays in the algorithm being implemented or the algorithm being revised to exclude the incumbent provider.***

Most countries in Africa have an established national HIV testing algorithm. The algorithm determines which provider's HIV point-of-care test will be used. The World Health Organisation has indicated that national HIV algorithms should contain a HIV screening test (A1) and two HIV confirmatory tests (A2 and A3). Our inclusion on a national HIV testing algorithm determines whether we will be able to sell HIV tests in that country. HIV testing algorithms are not updated annually and typically run for between five and seven years. Our Uni-gold HIV confirmatory test is included on many HIV testing algorithms throughout Africa and our newly launched HIV screening test, TrinScreen, succeeded in being added to Kenya's algorithm in 2023. In Kenya, the update to the HIV testing algorithm was challenged through the courts by a competitor and that legal challenge caused a delay in purchase orders being placed by the Kenyan health authorities under their revised algorithm. In 2024, another competitor began a court challenge in Kenya to the adopted HIV testing algorithm. Although we are not party to this court case, and the judge did not suspend procurement while the case is ongoing, it could have an adverse impact for us if the competitor succeeds in revising the current HIV testing algorithm. We understand that there were a number of hearings regarding this case during 2024, and we continue to monitor the ongoing court case. Legal challenges to the HIV testing algorithms from competitors, or other stakeholders, in any country in which we sell HIV tests could adversely affect our business and financial results.

***We have a history of losses from operations and negative cash flows from operating activities, which may continue in the future.***

We have incurred net losses and negative cash flows from operating activities in the past two years and we may not be able to achieve or maintain profitability or positive cash flow in the future. We have incurred losses of US$31.8 million and US$24.0 million in the years ended December 31, 2024 and 2023, respectively, and had negative cash flows from operating activities of US$4.2 million and US$11.6 million, respectively.

We expect to continue as a going concern. Our ability to continue as a going concern depends on our ability to generate cash flows from operations and to conduct adequate financing activities. We believe that we have access to sufficient cash reserves for our operating needs for at least the next twelve months from the date of this Annual Report. However, if negative cash flow from operating activities persists in the long run, cash resources may become insufficient to satisfy our on-going cash requirements.

Additional funding may not be available on acceptable terms, or at all. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. Further, as a result of geopolitical and macroeconomic events, including the Israel-Hamas and Russia-Ukraine wars, and the potential imposition or escalation of U.S. tariffs on imported medical and laboratory equipment, components, or raw materials, the global credit and financial markets have experienced volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

Expansion into new businesses may present operating and marketing challenges different from those we currently encounter, and we cannot assure that new business initiatives will be successful enough to justify the time, effort, and resources that we devote to them or ultimately achieve profitability. We initially announced the adoption of a transformation plan to improve the financial performance of our existing business in April 2024 and we continue to pursue and execute a strategic realignment of our continuing business. Although we have implemented or are in the midst of implementing a number of these cost-saving initiatives, including consolidating manufacturing, moving some manufacturing offshore to improve our operating margins, and moving significant aspects of our business support functions to a lower cost and centralized location, we cannot assure you that these efforts will be successful or that we can achieve our long-term profitability goals.

Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of the ADSs to decline.

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

As of December 31, 2024, we had total indebtedness of approximately US$101.6 million (carrying value under IFRS), consisting of a senior secured term loan (the "Term Loan" or "Credit Agreement") from Perceptive Credit Holdings III, LP ("Perceptive"), a convertible note issued to MiCo IVD Holdings, LLC. ("MiCo"), 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 had a total outstanding amount of US$75.5 million as of December 31, 2024. In connection with the third amendment and restatement of the credit agreement governing the Term Loan on December 23, 2024, we agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. On February 27, 2025, we entered into the fourth amended and restated credit agreement, which provided for an additional US$4.0 million increase to our outstanding Term Loan. In addition, a deferred consideration payment of US$5.0 million related to the acquisition of the biosensor assets of Waveform Technologies, Inc. ("Waveform") has been extended to November 2025. On May 14th , 2025, we entered into a fifth amendment to the Credit Agreement, which provided for an additional US$2.0 million in term loan funding, extended the maturity date of the Term Loan to July 27, 2026, and provided that interest payments for the months of April, May, and June 2025 will be paid-in-kind.

In May 2022, we received a US$45.2 million investment from MiCo. 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 our ADSs is at or above US$16.20 for any five consecutive NASDAQ trading days. Based on public filings, we understand that on December 17, 2024, MiCo was acquired by Dayli Trinity Holdings Limited as a result of a share purchase agreement with Mainstream Holdings Limited.

The convertible note is immediately repayable at par together with any accrued interest, if the Company or any of its material subsidiaries ceases or threatens to cease carrying on its business or a part of its business which is material to the Group. However, subject to the terms of an Investor Subordination Agreement between Perceptive and MiCo, MiCo may not, without the prior written consent of Perceptive, take any enforcement action with respect to the convertible note. Such enforcement actions include amongst other things any MiCo action to enforce payment of or to collect the whole or any part of the convertible note.

As a result of the debt we have incurred, 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 and 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 with Perceptive could result in a default under its terms and, if uncured, could result in action against our pledged assets.***

The Term Loan is secured by substantially all of our property and assets, including our equity interests in our subsidiaries. The credit agreement governing the Term Loan (the "Credit Agreement") contains financial covenants requiring that we (a) maintain agreed levels of unrestricted cash, which must be held in one or more accounts subject to the security interests of the lenders under the Credit Agreement, and (b) 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;
- 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 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.

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

Borrowings under our Credit Agreement are at a variable rate of interest and expose us to interest rate risk. On January 30, 2024, we entered into a second amended and restated senior secured term loan credit agreement which reduced the base rate of interest by 2.5% to 8.75%. The Term Loan accrues interest at an annual rate equal to 8.75% plus the greater of (a) Term SOFR (Secured Overnight Financing Rate) or (b) 4.0% per annum. On December 23, 2024, we amended the Credit Agreement, being third amended and restated senior secured term loan credit agreement, to draw down an additional $2.0 million and capitalized unpaid interest of approximately $3.3 million, bringing the total outstanding to $75.5 million. On February 27, 2025, we entered into a fourth amended and restated credit agreement, which provided for an additional US$4.0 million in term loan funding. On May 14th, 2025, we entered into a fifth amendment to the credit agreement, which provided for an additional US$2.0 million in term loan funding, extended the maturity date of the Term Loan to July 27, 2026, and provided that interest payments for the months of April, May, and June 2025 will be paid-in-kind. If interest rates 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, 2024, the total outstanding amount of our variable rate debt was US$75.5 million. The indebtedness increased by US$9.4 million to US$84.9 million between January 2025 and May 2025, following the fourth and fifth amendments to the Term Loan credit agreement, which included a US$6.0 million of total drawdowns and the capitalization of approximately US$3.4 million of accrued interest for the first four months of 2025.

Our anticipated annual cash interest expense on US$84.9 million variable rate debt at the current rate of approximately 12.75 percent would be approximately US$10.8 million. Every one percent increase in the interest rate results in additional annual interest payable of approximately US$0.8 million, based on the current amount of indebtedness.

***Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs, reduce the competitiveness of our products and otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

There is inherent risk, based on the complex relationships among the United States and the other countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The United States and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods, including medical devices and related components.

In 2025, President Trump signed a series of executive orders imposing various reciprocal tariffs, and other governments have imposed and may continue to impose retaliatory tariffs, trade restrictions or other trade barriers. Although we are an Irish company headquartered in Bray, Ireland, we derive a significant portion of our revenues from sales of our products in the United States. In addition, we conduct business globally and our operations and third-party suppliers span numerous countries outside the

While we cannot at this time predict the ultimate impact of such tariffs, we anticipate that our margins could be adversely affected depending on the scope and duration of the tariffs imposed.

Further, the continued threats of new or increased tariffs, sanctions, trade restrictions and trade barriers as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements, have had and may continue to have a generally disruptive impact on the global economy and, therefore, negatively impact revenues from sales of our products. Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant. In any event, further trade restrictions and export regulations, or new or increased tariffs, including further retaliatory measures, could increase our supply chain complexity and our manufacturing costs, decrease our margins, reduce the competitiveness of our products, or restrict our ability to sell our products, provide services or purchase necessary equipment and supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
While we cannot at this time predict the ultimate impact of such tariffs, we anticipate that our margins could be adversely affected depending on the scope and duration of the tariffs imposed.

Further, the continued threats of new or increased tariffs, sanctions, trade restrictions and trade barriers as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements, have had and may continue to have a generally disruptive impact on the global economy and, therefore, negatively impact revenues from sales of our products. Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant. In any event, further trade restrictions and export regulations, or new or increased tariffs, including further retaliatory measures, could increase our supply chain complexity and our manufacturing costs, decrease our margins, reduce the competitiveness of our products, or restrict our ability to sell our products, provide services or purchase necessary equipment and supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***Failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects. We may not succeed in our efforts to implement a comprehensive transformation plan to improve the financial performance of our existing business and realign our continuing business.***

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.

We initially announced the adoption of a transformation plan to improve the financial performance of our existing business in April 2024 and we continue to pursue and execute a strategic realignment of our continuing business. The plan has several key components, including:

- Reducing complexity and cost by consolidating our main manufacturing operations into a considerably smaller number of sites and also moving to an outsourced model for a significant amount of our less complex manufacturing activities;
- Reducing the cost of goods of many of our products by changing suppliers and negotiating new deals with existing suppliers;
- Continued market acceptance of our new TrinScreen™ HIV rapid point-of-care test;
- Simplifying our internal operations and optimizing and outsourcing some of our business support function locations; and
- Realigning our existing business portfolio to support our planned growth in the CGM space.

Although we have implemented or are in the midst of implementing a number of these cost-saving initiatives, including consolidating manufacturing, moving some manufacturing offshore to improve our operating margins, and moving significant aspects of our business support functions to a lower cost and centralized location, we cannot assure you that these efforts will be successful or that we can achieve our long-term profitability goals. A failure to achieve these goals will have a material adverse effect on our results of operations and financial condition.

***Our ability to continue as a going concern depends on our ability to generate cash flows from operations and to conduct adequate financing activities. 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 success of our research and product development efforts, in particular the significant development effort required to develop and commercialise the biosensor technology, including the continuous glucose monitoring technology acquired in January 2024;
- The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
- 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 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;
- The costs related to, and the success of, our operational efficiency focused activities;
- 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.

***We may encounter difficulties in realizing the potential financial or strategic benefits of recent business acquisitions. We expect to make additional acquisitions in the future that could disrupt our operations and harm our operating results.***

A significant part of our business strategy is to pursue acquisitions and other initiatives based on a strategy centered on adding complementary solutions to our portfolio—all while we seek to ensure our continued high quality of services and product delivery. We have made numerous acquisitions including the acquisition in 2024 of the biosensor assets of Waveform, and intend to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring ("CGM") product. During 2024 we also acquired Metabolomic Diagnostics which will grow our presence in the maternal health market, and we also entered the oncology space with the acquisition of Epicapture Limited.

Mergers and acquisitions of companies and assets are inherently risky and subject to many factors outside of our control and no assurance can be given that our future acquisitions will be successful and will not adversely affect our business, operating results, or financial condition. In the future, we may seek to acquire or make strategic investments in complementary businesses, technologies, services or products, or enter into strategic partnerships or alliances with third parties in order to expand our business. Failure to manage and successfully integrate such acquisitions could materially harm our business and operating results. Prior acquisitions have resulted in a wide range of outcomes, from successful introduction of new products technologies and professional services to a failure to do so. There can be no assurance that new product enhancements will be made in a timely manner or that pre-acquisition due diligence will have identified all possible issues that might arise with respect to such products. If we acquire other businesses, we may face difficulties, including:

- Difficulties in integrating the operations, systems, technologies, products, and personnel of the acquired businesses or enterprises;
- Diversion of management's attention from normal daily operations of the business and the challenges of managing larger and more widespread operations resulting from acquisitions;
- Integrating financial forecasting and controls, procedures and reporting cycles;
- Potential difficulties in completing projects associated with in-process research and development;
- Difficulties in entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions; and
- Insufficient revenue to offset increased expenses associated with acquisitions;

***In 2021, certain of our U.S. subsidiaries received loans which were subsequently forgiven under the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which they may not have been eligible to receive. If it is determined that the subsidiaries were ineligible to receive the loans, they may be required to return some or all of the proceeds, pay interest and may be subject to other penalties.***

In January 2021, two of our U.S. based subsidiaries applied for and received second round loans totaling approximately $1.8 million under the Paycheck Protection Program (the "PPP") of the CARES Act. In September 2021, the two subsidiaries applied for forgiveness of the loans and those loans were subsequently forgiven. While our subsidiaries believed at the time that they obtained the loans that they met all of the eligibility requirements under the CARES Act, they were notified by the U.S. Department of Justice ("DOJ") in late October 2024 that the two subsidiaries may have not been eligible to receive those loans since the eligibility requirements for second round loans differed from the first round loans in several ways, including the number of employees that an applicant, together with its affiliates, could employ to be eligible for a loan. We voluntarily conducted an internal review of the circumstances surrounding the loan process and have made a preliminary determination that due to changes in the guidelines for those loans, the two subsidiaries may have inadvertently not met the headcount eligibility criteria for the second round loans.

During a January 28, 2025 videoconference among outside U.S. counsel engaged by us to respond to questions from the DOJ about those second round loans obtained by the two US subsidiaries, a lawyer employed by the DOJ raised, for the first time with us the question of whether our U.S. subsidiaries met the headcount eligibility criteria for approximately $4.0 million of first round of PPP loans they received in 2020, which were subsequently forgiven. The criteria for eligibility were different for the two rounds of loans, and we believe that the U.S. subsidiaries met the eligibility criteria for the first round of loans based on guidance issued by the Small Business Administration at the time of the application for the first round of loans. After further communication with the DOJ regarding those first found loans, representatives of the DOJ indicated to us that the government is unlikely to pursue claims related to those first round loans.

The DOJ has notified us that the U.S. government is considering the filing in court of a civil claim related to the second round of loans under which treble damages (up to a maximum amount of approximately $5.5 million) could be awarded if the government were to satisfy each of the essential elements of such a claim. We continue to review the circumstances surrounding the second round loans and are in the early stages of settlement discussions with the DOJ. Although we believe that the government's potential claims relating to the second round loans will be resolved for significantly less than treble damages, it is too early to predict a likely settlement outcome, or what the outcome would be in court if the matter is not settled by agreement. A negative outcome in court or a significant settlement may result in adverse publicity and damage to our reputation and have a material adverse effect on our results of operations and financial condition.

***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 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, 2024, 2023 and 2022, we incurred US$10.9 million, US$1.8 million and US$4.5 million, respectively, in capitalised R&D expenses. Included in the US$10.9 million in 2024, we capitalised borrowing costs of US$2.1 million, in line with IAS 23. Due to the acquisition of the biosensor technology of Waveform in January 2024, we expect to incur significantly higher costs related to our research and development activities for the foreseeable future.

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 the U.S. 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 and other changing conditions 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.

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

***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. Our biosensor business and our HB A1C business, both rely on a supply of raw materials to manufacture polymers, electronics and specialist engineered components. 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 other 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 export laws and import and customs regulations in many jurisdictions, 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 disruptions of a similar nature will not occur in the future which may create significant challenges in fulfilling customer orders that we may not be able to overcome.

The ongoing uncertainty regarding the upheaval to global trade from significant international tariff changes represents a significant and growing risk to our business and could materially increase our cost of goods sold, disrupt supply chains, and delay production or fulfilment schedules. 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 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 governed by the European In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746) with three 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. We 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$6,771,000) for any one accident, limited to a maximum of €6,500,000 (US$6,771,000) 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 US$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, 2024, was US$51 million (December 31, 2023: US$16 million) (December 31, 2022: US$35 million). During 2024, the Company made a number of acquisitions which significantly increased the Company's long-lived assets, which will be assessed for impairment each year. In the year ended December 31, 2024, we recorded total impairment charges of intangible assets of US$1.6 million (Year 2023: US$5.8 million) (Year 2022: US$4.6 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.

***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 and the Israel – Hamas war have 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.

The ongoing uncertainty regarding the upheaval to global trade from significant international tariff changes represents a significant and growing risk to our business and could materially increase our cost of goods sold, disrupt supply chains, and delay production or fulfilment schedules.

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.

***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, 2024. 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. 2024 continued to see 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. 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.

***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. In December 2023, our then CFO, John Gillard, was appointed CEO & President. Louise Tallon was appointed as CFO in August 2024. In April 2025, Louise Tallon was replaced by Susan O'Connor now serving as Interim CFO. In addition, during 2024 and early 2025 there were a number of changes to the Senior Management team reflecting the significant ongoing transformation and focus on new business areas.

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.

***Cybersecurity risks, including cyberattacks or data breaches, could disrupt our operations, compromise sensitive data, and adversely affect our business.***

We rely extensively on information technology systems and networks to securely process, transmit and store electronic information, including confidential and personal information relating to our employees, customers, and business operations. These systems are critical to the operation of our global business, including product manufacturing, distribution, research and development, clinical trials, customer service, and financial reporting.

Like many other companies, we are subject to increasing cybersecurity threats, including the risk of system breaches, ransomware, malware, phishing attacks, and other malicious activity. Security incidents, whether from external actors or internal sources, can result in operational disruption, shutdowns, corruption or loss of critical data and software, unauthorised access or disclosure of confidential information, and reputational harm.

We invest in technologies and processes designed to protect our information assets and mitigate cybersecurity threats. These include multi-factor authentication, data encryption, antivirus and endpoint protection, next-generation firewalls, cloud backups, end-user training (including simulated phishing exercises), and comprehensive policies for information security and data privacy. Despite these efforts, our IT systems and infrastructure may still be vulnerable to attack or breach due to the sophistication of threat actors, human error, equipment failure, or other disruptions.

We have experienced cyberattacks in the past, though none have had a material impact on our operations to date.

The age and configuration of our IT infrastructure varies by location, and our business continuity and disaster recovery capabilities may be less robust at certain sites. As a result, our ability to respond to or recover from a cybersecurity incident may be inconsistent across geographies.

A significant breach of our systems could result in the unauthorised disclosure of personal data, including personally identifiable information (PII) or protected health information (PHI), or other confidential business information. This could subject us to legal liability, regulatory penalties, breach notification requirements, and damage to our reputation, potentially resulting in loss of customers or revenue.

We are also subject to a complex and evolving regulatory landscape in data privacy and cybersecurity. Compliance with privacy and data protection laws, such as the EU's General Data Protection Regulation (GDPR), U.S. state-level privacy laws, and similar frameworks in other jurisdictions, may result in significant costs and operational changes. In particular, Section 3305 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) imposes specific cybersecurity obligations on manufacturers of certain medical devices. This includes maintaining processes for monitoring and remediating vulnerabilities, providing a software bill of materials, and ensuring continued security of the device and its related systems. A failure to comply with these requirements may constitute a prohibited act.

We have conducted appropriate cybersecurity assessments for relevant products in accordance with FDA, AAMI, and ANSI standards applicable at the time of approval. However, as the regulatory landscape continues to evolve, we may be required to make additional investments to maintain compliance and address emerging cybersecurity expectations for connected health technologies.

Cybersecurity incidents could also distract management or key personnel from core business operations and negatively impact our financial condition, results of operations, or business strategy.

***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.

***Public health emergencies, epidemics or pandemics, such as the emergence and spread of pandemics, such as Covid-19, 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 had a material impact on the healthcare industry and specifically the medical diagnostics sector in which we operate. The reduced but continuing uncertainty around global pandemics 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 or other pandemics, 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 visit 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.

***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.

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. The 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 (2013);
- 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; and
- ISO 14155:2020: 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.

***The FDA recently modified 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.***

Historically, 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 in vitro diagnostics ("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.

On September 29, 2023, the FDA proposed a new rule which was adopted on April 29, 2024, which amended the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. The FDA's ruling of April 29th, 2024, that significantly enhanced its regulatory authority over laboratory-developed tests (LDTs), which are developed and used within a single laboratory was overturned on March 31st, 2025. The U.S. District Court for the Eastern District of Texas vacated the FDA's final rule, stating that the FDA exceeded its authority under the Federal Food, Drug, and Cosmetic Act. This means that, for now, the FDA's new regulations will not go into effect, and laboratories will not need to obtain FDA clearance to market their LDTs. If the district court's decision stands, FDA's regulation of LDTs could be viewed as a legal nullity, as FDA could no longer regulate LDTs as medical devices under the ruling. This may mean that these LDTs would continue to be marketed solely under the Clinical Laboratories Improvement Act of 1967 (CLIA).

Ongoing compliance with FDA regulations increases the cost of conducting our business, and may subject us to heightened regulation by the FDA and penalties in the event of 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.

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. 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.

On September 29, 2023, the FDA proposed a new rule which was adopted on April 29, 2024, which amended the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory.

The FDA's ruling of April 29th, 2024, that significantly enhanced its regulatory authority over laboratory-developed tests (LDTs), which are developed and used within a single laboratory was overturned on March 31st, 2025. The U.S. District Court for the Eastern District of Texas vacated the FDA's final rule, stating that the FDA exceeded its authority under the Federal Food, Drug, and Cosmetic Act. This means that, for now, the FDA's new regulations will not go into effect, and laboratories will not need to obtain FDA clearance to market their LDTs. If the district court's decision stands, FDA's regulation of LDTs could be viewed as a legal nullity, as FDA could no longer regulate LDTs as medical devices under the ruling. This may mean that these LDTs would continue to be marketed solely under the Clinical Laboratories Improvement Act of 1967 (CLIA).

***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.

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.

***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 Medicare for All Act of 2021 (M4A) 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. ("Immco") 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 90$^{th}$ 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.

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 we operate. If any of such claims relate to our planned products, we intend to evaluate such claims and, if appropriate, seek a licence to use the protected technology. There can be no assurance that we would be able to obtain licences to use such technology or, obtain such licences on satisfactory commercial terms. If we or our suppliers are unable to obtain or maintain a licence to any such protected technology that might be used in our products, we could be prohibited from marketing such products. We could also incur substantial costs to redesign our products or to defend any legal action taken against us. If Trinity Biotech's products should be found to infringe protected technology, we could also be required to pay damages to the infringed party.

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. Patents have a life of up to 20 years, and we are generally filing new patents on an ongoing basis to protect our intellectual property. 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 the United States 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. The biosensor industry, including the CGM industry, is a highly innovative area with a number of industry participants developing intellectual property portfolios over many years. As such there can be no guarantee that the technology acquired from Waveform or further developed by us, will not infringe on other parties existing IP portfolios.

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 and Perceptive own approximately 12.5% and 9.6% respectively of the voting share capital of our Company, which may give each of these shareholders a 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 2.2 million of our ADSs, which represents approximately 12.5% of the outstanding voting share capital of our Company (15.8% on a fully diluted basis, including shares issuable upon conversion of the convertible note issued to MiCo). Based on public filings, we understand that on December 17, 2024, MiCo was acquired by Dayli Trinity Holdings Limited as a result of a share purchase agreement with Mainstream Holdings Limited. Under the terms of the MiCo convertible note and the purchase agreement for those ADSs, MiCo is entitled to nominate a total of up to 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.

Perceptive, our principal lender, owns 1.79 million of our ADSs which represents approximately 9.6% of the outstanding voting share capital of our Company. Perceptive also owns warrants to purchase an additional 2.5 million ADSs with an exercise price of US$0.80 per ADS. Because of its ownership interest and its position as the Company's principal lender, Perceptive may have significant influence over our management and affairs 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 Perceptive, regardless of the impact of such transactions on our other shareholders.

***The Nasdaq Global Select Market imposes listing standards on our ADSs that we may not be able to fulfill in the future, thereby leading to a possible delisting of our ADSs.***

As a listed Nasdaq Global Select Market company, we are subject to various listing standards. There can be no assurance that we will be able to meet all of the criteria necessary for Nasdaq to allow our ADSs to remain listed.

On March 19, 2025, we received two deficiency letters from the Listing Qualifications Department of Nasdaq (the "Staff"). One deficiency letter notified us that we are not in compliance with the minimum market value of publicly held shares ("MVPHS") requirement of the Nasdaq Listing Rules applicable to companies listed on the Nasdaq Global Select Market. For continued listing, companies are required to maintain a minimum MVPHS of $15 million. A failure to meet the minimum MVPHS requirement exists if the deficiency continues for a period of 30 consecutive business days. The other deficiency letter notified us that for the preceding 30 consecutive business days, the ADSs did not maintain a minimum closing bid price of $1.00 (the "Minimum Bid Price") per ADS, as required by Nasdaq Listing Rule 5450(a)(1).

In accordance with the Nasdaq Listing Rules, we have 180 calendar days from the date of the deficiency notices, or until September 10, 2025, to regain compliance with the minimum MVPHS requirement and the Minimum Bid Price requirement.

To regain compliance with the MVPHS requirement, the Company's MVPHS must exceed $15 million for a minimum of ten consecutive business days. If the Company does not regain compliance with the minimum MVPHS requirement by September 10, 2025, Nasdaq will provide written notification to the Company that its ADSs are subject to delisting. At that time, the Company may appeal the relevant delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules; however, there can be no assurance that the Company will satisfy the minimum MVPHS requirement or that any such appeal would be successful.

To regain compliance with the Minimum Bid Price requirement, the closing bid price of the Company's ADSs must meet or exceed US $1.00 for at least ten consecutive business days during the 180-calendar day cure period. In the event the Company does not regain compliance with the Minimum Bid Price Requirement in that period, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for MVPHS and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price and provide written notice to the Staff of our intention to cure the deficiency during the second compliance period. However, if it appears to the 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.

We also received deficiency letters from Nasdaq in 2023. In April 2023, Nasdaq notified us that we were not in compliance with the Minimum Bid Price requirement. To regain compliance and to facilitate investment from a broader pool of potential investors, we effected an ADS Ratio Change on February 23, 2024, pursuant to which the ADS to ordinary share ratio changed from one ADS representing four ordinary shares to one ADS representing 20 ordinary shares. We received another deficiency letter from Nasdaq in November 2023 notifying us that we were not in compliance with the MVPHS requirement at that time. Although Nasdaq determined in November 2024 that we had regained compliance with the MVPHS requirement, it did not preclude Nasdaq from monitoring our continued compliance and issuing the more recent deficiency letter regarding our current compliance with the MVPHS requirement.

If our ADSs are ultimately delisted from Nasdaq and we are unable to successfully transfer the listing of our ADSs to The Nasdaq Capital Market, our ADSs would likely then trade only in the over-the-counter market and the market liquidity of our ADSs could be adversely affected and their market price could decrease. If our ADSs were to trade on the over-the-counter market, selling our ADSs could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our ADSs and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

***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 NASDAQ, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the NASDAQ listing 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 listing 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 2024 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 2025, the market price of our ADSs fluctuated from a high of US$1.36 per ADS to a low of US$0.57 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 and additional ADSs issuable upon exercise of warrants 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 fact that substantial amounts of ADSs could be sold in the public market, whether or not sales have occurred or are occurring, could make it more difficult for the Company to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that it deems reasonable or appropriate.

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

The total share options exercisable as at March 31, 2025, are convertible into American Depository Shares (ADSs), 1 ADS representing 20 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 exercisable options outstanding at March 31, 2025 were exercised, the Company would have to issue 23,574,589 additional ordinary shares (1,178,729 ADSs). Similarly, if all of the outstanding warrants to purchase ordinary shares at March 31, 2025 were exercised, the Company would have to issue 51,200,000 A ordinary shares (2,560,000 ADSs). On the basis of 385,195,982 million A ordinary shares outstanding at March 31, 2025, the exercise of both the share options and the warrants would effectively dilute the ownership interest of the existing shareholders by approximately 16%.

***It could be difficult for U.S. holders of ADSs to enforce any securities laws claims against us, our officers or our 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, by way of separate action in Ireland, 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 U.S. 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, in certain circumstances 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.

***We have no plans to pay dividends on our ADSs, and ADS holders 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, ADS holders 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.

## 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 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. In January 2024, we entered into the biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. ("Waveform") and are currently developing a range of biosensor devices and related services, starting with a continuous glucose monitoring ("CGM") product.

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 by the following subsidiaries:

- Trinity Biotech Manufacturing Limited, based in Bray, Ireland;
- Konamite 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 Buffalo, New York;
- Trib Biosensors Inc, based in Wilsonville, Oregon;
- Nova Century Scientific Inc, based in Burlington, Canada;
- Trinity Biotech Brazil based in Sao Paulo, Brazil;
- Metabolomic Diagnostics Limited, based in Cork, Ireland; and
- EpiCapture Limited, based in Bray, Ireland.

***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 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.

In January 2024, the Company acquired the biosensor and Continuous Glucose Monitoring ("CGM") assets of privately held Waveform Technologies, Inc. ("Waveform"). We are currently developing the CGM device for optimization for broad adoption, evolving the technology to measure and analyse other valuable biomarkers and related datapoints. Our vision is to develop a portfolio of technologies that can offer users and clinicians valuable actionable health and wellness insights.

***Point-of-care***

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 HIV screening test, TrinScreen, 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. During December 2023, Trinity Biotech began commercial shipments of Trinscreen and this ramped up significantly in 2024.

***Clinical Laboratory***

We supply 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); and
- Autoimmune diseases.

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

*Infectious Diseases*

We manufacture 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 we serve include:

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

We also develop, manufacture and distribute products predominantly in enzyme-linked immunosorbent assay ("ELISA") format. As a complement to our product range, we also offer 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 our sales and marketing organisation to a variety of customers including public health authorities, clinical and reference laboratories.

*Diabetes and Haemoglobinopathies*

We manufacture 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 use in 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.

We manufacture our own HbA1c instrument, the Premier Hb9210, which was launched in Europe and obtained FDA approval in late 2011. In the USA and Brazil, we sell the Premier Hb9210 through our own direct sales organisations. In the rest of the world, we sell 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.

We also sell 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.

We have launched the Premier Resolution, our next generation Haemoglobinapothy Analyzer in Europe and the Middle East after undergoing rigorous and successful field trials. In August 2023, the Premier Resolution was approved by the FDA allowing the instrument to be sold in the U.S.

*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, we 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. The principal autoimmune conditions in this segment are Rheumatoid Arthritis, Vasculitis, Lupus, Celiac and Crohn's Disease, Ulcerative Colitis, Neuropathy, Hashimoto's Disease and Grave's Disease.

The Immco products are sold through our sales and marketing organisation to clinical and reference laboratories directly in the US 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.

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

*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*

We manufacture enzyme-linked immunosorbent assays, 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 U.S.

*Continuous Glucose Monitoring*

In January 2024, we acquired the biosensor and CGM assets of privately held Waveform Technologies, Inc. ("Waveform"). We are currently redeveloping the CGM technology with a view to developing an innovative CGM device and then evolve this platform technology to measure and analyse other valuable biomarkers and related datapoints. Our vision is to develop a portfolio of technologies that can offer users and clinicians valuable actionable health and wellness insights based upon what is happening in, on and around the body.

Waveform, a developer of novel and proprietary new technologies for diabetes care, received a CE Mark for its Cascade CGM in 2019, which was commercially available in Europe. The primary use of the device being to continuously monitor glucose in the human body. The Cascade CGM device and any subsequently developed sensor would be subject to regulatory oversight from the FDA and country specific regulatory authorities and would be subject to the same risks identified in the Government Regulation section of this Annual Report. Glucose in the blood diffuses from capillaries into the liquid between cells known as interstitial fluid. The Waveform CGM device is an electrochemical biosensor which detects the concentration of glucose in interstitial fluid by means of an enzyme immobilised at the surface of a sensor wire inserted into the skin. The action of the enzyme results in the generation of electrical current that is relayed to an attached transmitter where it is converted by a firmware algorithm into a blood glucose concentration. The transmitter then sends this blood glucose measurement to a smartphone or other device where the time within healthy range is tracked and the user alerted to risks of hypo- or hyperglycaemic episodes.

The Waveform CGM technology contains innovative and proprietary aspects with what we believe are important benefits. Significantly, the special composition of the sensor wire and the unique formulation of its protective outer membrane contribute to the ability to achieve needle-free insertion. Needle free insertion has numerous benefits including a reuseable applicator as no needle needs to be safely disposed. This, combined with a reusable transmitter which is also a feature of the acquired CGM technology, allows for two clear benefits. Firstly, it allows for a lower cost of production of the redesigned CGM product compared to the principal current CGM market players and secondly, it reduces the biological waste concerns associated with the currently marketed single-use disposable systems.

Additionally, we believe that this innovative platform technology will allow us to develop a broader suite of wearable biosensors to measure and analyse important health and wellness information. If successful, we intend to target other analytes and data points that represent markers of health and function and make these devices available more broadly around the globe.

The CGM technology acquired from Waveform was developed over many years and Waveform has granted a perpetual, worldwide, non-exclusive license to DexCom, Inc. and its affiliates, for some of the patents acquired by us, but to which we retain the right to use and exploit.

***Sales and Marketing***

We sell our products through our own direct sales force in the U.S. Our sales team in the U.S. 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 haemoglobins 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 several 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, Dexcom Inc., 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 and Development ("R&D") carried out by third parties*

Certain R&D activities of the Group are outsourced to third parties as required. These activities are carried out in the normal course of business with these companies. The total amount paid to these R&D consultants and contractors in 2024 was US$4,397,000 (2023: US$226,000). R&D activities carried out by third parties grew in 2024 as the Company engaged with external consultants regarding the development of our newly acquired CGM biosensor technology.

***Research and Products under Development***

Trinity Biotech has research and development groups focusing separately on product development in haemoglobins, infectious diseases and as a result of 2024 acquisitions, CGM, prostate cancer and pre-eclampsia. These groups are located in Ireland and the U.S. In addition to in-house activities, Trinity Biotech sub-contracts some research and development from time to time to independent researchers based in the U.S. and Europe.

***Principal Development Projects***

The following table sets forth 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 2024:

| ***Product Name*** | ***2024*** ***US$'000*** | ***2023*** ***US$'000*** | ***Total project costs to December 31, 2024[1]*** ***US$'000*** |
|---|---|---|---|
| Premier Instruments for A1c and haemoglobinopathies testing | 1,542 | 1,669 | 41,039 |
| Continuous Glucose Monitoring | 7,040 | - | 7,040 |

[1] Cumulative costs to December 31, 2024 is shown before deduction of amortization and impairment losses. Cumulative costs exclude amounts recognised as part of business combinations.

The costs in the preceding 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 consultant 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**

*Premier Hb9210 Instrument for Haemoglobin A1c Testing*

A product development plan focused on improvements in our flagship Premier 9210 instrument is ongoing. The package of changes aims to expand the target market, reduce instrument downtime and service cost, and significantly expand operating margins.

Our program to develop an improved, backward compatible column Diabetes HbA1c column system is now complete. The results of this development program have exceeded expectations, with our new column system now delivering up to four times the number of injections compared to the existing product. We are continuing the commercial launch of these new products.

*Premier Resolution Instrument for Haemoglobin Variant Testing*

We developed the Premier Resolution instrument which is utilised for haemoglobin variant testing. The instrument achieved 510(k) approval from the FDA in August 2023. The instrument has been sold in certain international markets outside of the U.S. for many years. 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.

**Point-of-care Development**

A combination HIV/Syphilis point-of-care rapid test is also being developed using our existing lateral flow format, we expect this project to restart in 2025.

**Continuous Glucose Monitoring Development**

In January 2024, we acquired the biosensor and CGM assets of Waveform. We are currently redeveloping the acquired CGM technology. The development work performed to date has focused on improving device performance and usability by refining the sensor design and redesigning the hardware and user workflow. Clinical trials with modified sensors performed in 2024 demonstrated significant improvements in signal quality, sensor accuracy and performance in the clinically important hypoglycemic range.

We have hired a number of research and development personnel and have engaged internationally recognised and reputable development consulting organisations to augment our internal CGM development function. We expect to continue to add to our biosensor and CGM research and development functions over time.

***Patents and Licences***

*Patents*

Due to the significant cost of putting patents in place for our wide range of products, many of our tests are not protected by specific patents. However, we believe that substantially all our tests are protected by proprietary know-how, manufacturing techniques and trade secrets.

As part of the Waveform asset acquisition, we acquired a CGM patent portfolio that includes numerous issued and pending patent applications in the U.S. and other parts of the world. We believe these patents to be of significant importance in establishing and protecting our proprietary rights in relation to our CGM business. Since the acquisition, one additional European patent has been granted, and a number of new provisional patent applications have been filed to protect novel inventions arising from the development programme.

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 we operate. If any of such claims relate to our planned products, we intend to evaluate such claims and, if appropriate, seek a licence to use the protected technology. There can be no assurance that we would be able to obtain licences to use such technology or, obtain such licences on satisfactory commercial terms. If we or our suppliers are unable to obtain or maintain a licence to any such protected technology that might be used in our products, we could be prohibited from marketing such products. We could also incur substantial costs to redesign our products or to defend any legal action taken against us. If Trinity Biotech's products should be found to infringe protected technology, we could also be required to pay damages to the infringed party.

*Licences*

We have 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, we entered into a licence agreement with a leading market participant, giving us a non-exclusive, worldwide licence to access 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, we obtained a non-exclusive commercial licence from the National Institutes 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 our non-performance. The key licensing arrangements, apart from the agreement entered into in 2013 which provides for the payment of a lump sum licence fee, require us to pay a royalty to the licence holder based on sales of the products which utilise the relevant technology being licenced. The total amount paid by us under key licensing arrangements in 2024 was US$142,000 (2023: US$210,000).

We acquired CGM technology from Waveform in January 2024. This technology has been developed over many years and Waveform has granted a perpetual, worldwide, non-exclusive license to Dexcom, Inc. and its affiliates, for some of the patents acquired by us, but to which we retain the right to use and exploit.

***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. 49% of Trinity Biotech's 2024 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. The FDA issued the Quality Management System Regulation (QMSR) Final Rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation (21 CFR Part 820), incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes. This final rule is the latest action taken by the FDA to promote consistency in the regulation of devices. This action will harmonize the FDA's CGMP regulatory framework with that used by other regulatory authorities.

The rule is effective February 2, 2026, two years after publication. Until then, manufacturers are required to comply with the QS regulation.

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 New York 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 proposed to 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 planned 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. On May 6, 2024, the FDA issued a final rule aimed at helping to ensure the safety and effectiveness of laboratory developed tests (LDTs). The rule amended the FDA's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory.

The FDA's ruling of April 29th, 2024, that significantly enhanced its regulatory authority over laboratory-developed tests (LDTs), which are developed and used within a single laboratory was overturned on March 31st, 2025. The U.S. District Court for the Eastern District of Texas vacated the FDA's final rule, stating that the FDA exceeded its authority under the Federal Food, Drug, and Cosmetic Act. This means that, for now, the FDA's new regulations will not go into effect, and laboratories will not need to obtain FDA clearance to market their LDTs. If the district court's decision stands, FDA's regulation of LDTs could be viewed as a legal nullity, as FDA could no longer regulate LDTs as medical devices under the ruling. This may mean that these LDTs would continue to be marketed solely under the Clinical Laboratories Improvement Act of 1967 (CLIA).

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 is 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, 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 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.

HIPAA's Security Rule and certain provisions of the HIPAA Privacy Rule and Breach Notification Rule apply to business associates of covered entities (i.e., entities that provide services to covered entities that may require access and use of protected health information on behalf of covered entities), and business associates are subject to direct liability for violation of these rules. In addition, a covered entity may be subject to criminal and civil penalties as a result of a business associate violating HIPAA, if the business associate is found to be an agent of the covered entity. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay and notification must also be made to the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) and, in certain situations involving large breaches, to the media. The OCR enforces the HIPAA Rules and performs compliance audits and investigations. In addition to enforcement by OCR, HIPAA authorizes state attorneys general to bring civil actions seeking either injunction or damages in response to HIPAA violations that impact state residents.

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.

There are numerous other laws, regulations and legislative and regulatory initiatives at the federal and state levels addressing privacy and security of personal information. We also remain subject to federal and state privacy-related laws that may be more restrictive or contain different requirements than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties. For example, the Federal Trade Commission, or FTC, uses its consumer protection authority to initiate enforcement actions against companies relating to their use and disclosure of personally identifiable information. Specifically, FTC has asserted authority and issued enforcement actions in response to actual or perceived unfair or deceptive practices by a company in the handling of consumer information. The FTC has also pursued enforcement actions against companies for violations of its Health Breach Notification Rule and the Children's Online Privacy Protection Act. Our use of personal information is also subject to our published privacy policies and notices.

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.

In addition, certain states also have laws and regulations related to payments and other transfers of value provided to healthcare professionals and entities. Similar to the federal law, certain states have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope. Certain states also mandate that device manufacturers implement compliance programs. Other states impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a company may violate one or more of the requirements, resulting in fines and penalties.

*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 $13,946 to $27,894 for each 7separate 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.

In the EU, the General Data Protection Regulation (GDPR) protects the rights of individuals regarding their personal data, including the right to access, correct, and erase their data. It also places a strong emphasis on data security and breach notification. Trinity Biotech has appointed a Data Protection Office (DPO) to lead and co-ordinate data compliance efforts. Organizations found violating GDPR can face fines up to 4% of their global annual revenue or €20 million, whichever is higher. Violations of the GDPR can arise from non-compliance with: data processing being lawful, fair, and transparent to the data subject; processing data for explicitly stated purposes; only collecting data that is absolutely necessary, accurate and contemporaneous; only storing data for as long as is required; any data processing ensures appropriate security, integrity, and confidentiality; and that the DPO is responsible to demonstrate GDPR compliance at all times.

*Environmental Regulation*

The process of designing, developing and manufacturing our products can involve the use of harmful and dangerous chemicals and materials. The use and handling of these dangerous substances is subject to federal, state and local laws and regulations in all the countries in which we operate. In the U.S., Trinity is subject to the Toxic Substances Act (TSCA) and Pollution Prevention Act (PCA) under the auspices of the Environmental Protection Agency (EPA). In Europe, the key environmental policy is written into Articles 11 and 191 to 193 of the Treaty on the Functioning of the European Union (TFEU) and specifically the Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) is the main EU law to protect human health and the environment from the risks that can be posed by chemicals. Failure to comply with these laws and regulations can result in financial penalties, restriction of operation and adverse publicity. The Trinity facility in Bray, Ireland is certified to ISO 14001. This is an internationally recognized standard for environmental management systems (EMS). This provides an externally assessed framework for improving resource usage, waste management and monitoring of environmental performance. Trinity uses their EMS to minimize environmental footprint and ensure compliance with relevant legal requirements.

**C. Organizational Structure**

Please refer to Note 32 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$421,000).

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 €787,000 (US$834,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. A rent review for this property became effective 1 July 2022 and, following an independent valuation, the annual rent increased to €1,050,000, with backdated rent accruing from that date. Included within overhead costs in cost of sales in 2024 is an amount of $659,000 in respect of backdated rent.

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$159,000). A rent review for this property became effective 1 July 2021 and, following an independent valuation, the annual rent increased to €170,560, with backdated rent accruing from that date. Included within overhead costs in cost of sales in 2024 is an amount of $93,000 in respect of backdated rent.

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

See Item 7 – Major Shareholders and Related Party Transactions.

We have six main manufacturing sites worldwide, five in the Americas (Buffalo and Jamestown, NY, Kansas City, MO, Wilsonville, OR and Extrema, Brazil), and one in Bray, Ireland. 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$221,000. This lease has recently been renewed effective 1 July 2025 for five (5) additional one-year rental periods.

TRIB Biosensors Inc. operates from a 26,000 square foot facility in Wilsonville, Oregon. We took over the lease for this facility in January 2024 as part of the Waveform transaction. The lease term was extended to December 2025 with an annual rent of US$363,000.

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 October 2025 and March 2027 with annual rents of US$137,000 and US$61,000 respectively.

Immco operates from a 31,731 square foot facility in Buffalo, New York. The lease for the site expires in 2034. The annual rent for the facility is US$428,000. An additional 5,120 square foot facility is owned by Trinity Biotech in Burlington, Canada.

Trinity Biotech Brazil operates from office and factory space is leased in Sao Paulo, Brazil and Extrema, Brazil. The leases on these properties run have an annual cost of US$11,000 and US$57,000 respectively.

As part of the acquisition of Metabolomics Diagnostics Ltd, we acquired a lease for 2,300 square foot of office space in Cork, Ireland. The annual rent is US$21,600. This lease expired in 2023 and is currently rented on a rolling month-to-month basis.

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 and Clinical Chemistry products were manufactured at this site during 2024. Parts of the manufacturing process for Point-of-Care/HIV products is in the process of being transferred to a contract manufacturing partner, with production expected to commence in Q2 2025. Clinical Chemistry products continue to be manufactured in Bray. In 2025, certain manufacturing processes related to haemoglobin products began 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. In Q1 2025, in line with our consolidation strategy. significant aspects of the Group's autoimmune test kits manufacturing operations were transferred from the Buffalo site to Jamestown.

**Kansas City, Missouri** - this site is responsible for the manufacture of the Group's haemoglobin range of products and all haemoglobin R&D activities. During 2024 and early 2025, significant aspects of these manufacturing processes were transitioned to other Group manufacturing sites, in line with our strategy to consolidate operations and reduce complexity across our manufacturing footprint.

**Buffalo, New York** - this site is responsible for the manufacture of autoimmune test kits along with its reference laboratory business. In early 2025, consistent with our strategic focus on operational consolidation, significant aspects of the manufacturing processes were transitioned to other Group sites. Buffalo continues to operate as the Group's reference laboratory.

**Extrema, Brazil** - this site is responsible for the manufacture of certain haemoglobin products sold in Brazil. Manufacturing of the haemoglobin range will expand in 2025 as Kansas City production reduces.

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$8.6 million, US$1.8 million, US$4.5 million, for years ended December 31, 2024, 2023 and 2022 respectively. In 2025, we expect the capital expenditure on development projects will be in the range US$10 million to US$12 million, primarily driven by the advancement of our CGM and biosensor technologies and the advancement of a screening test for preeclampsia risk.

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

Not applicable.

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

***A. Operating Results***

***Overview***

We are commercial stage biotechnology company focused on diabetes management solutions and human diagnostics, including wearable biosensors. We develop, acquire, manufacture and market diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market and has recently entered the wearable biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. and intend to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product. Our products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. We sell our products directly in the United States, and Brazil and somewhat directly in Germany, France and the U.K. and through a network of international distributors and strategic partners in approximately 100 countries worldwide. This discussion covers the years ended December 31, 2024 and December 31, 2023 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, 2024 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 healthcare market is growing due to, among other reasons, lifestyle changes, the growing incidences of diabetes and other autoimmune and infectious diseases and as a consequence there is an increasing demand for rapid and continuous monitoring tests in a clinical and consumer 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, 2024 and 2023 were impacted by impairment losses as a result of impairment reviews during the years ended December 31, 2024 and 2023 (See Item 18, Note 12) and also as a result of restructuring costs and other once-off / exceptional costs (see Note 5) incurred in 2024.

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 we 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, 2024 and 2023, the Group recorded a loss of US$31.8 million and a loss of US$24.0 million, respectively. For the year ended December 31, 2024 we reported cash inflows of US1.7 million compared to cash outflows of US$2.8 million for 2023. As of December 31, 2024, we had net current assets of US$9.0 million but had an accumulated deficit in equity attributable to the equity holders of the Company of US$79.1 million.

We have made significant progress on a multi-year transformation plan aimed at improving profitability and simplifying our operating model. Key actions implemented include the consolidation and outsourcing of global manufacturing, closure of underutilized facilities, relocation of certain business support functions to lower-cost jurisdictions, and a reduction in overall headcount. These restructuring measures, largely completed by mid-2025, are expected to deliver significant annualized cost savings. Additionally, the Group retains further levers to manage liquidity if required, including deferring projected research and development spend.

A temporary decline in revenue occurred during the first four months of 2025, primarily due to transitional impacts associated with the Group's restructuring initiatives, including the consolidation of manufacturing operations and the transfer of Point-of-Care/HIV products to a third-party contract manufacturing partner. These initiatives have since progressed materially. Sales were also affected by reduced HIV test volumes resulting from uncertainty surrounding potential changes to U.S. foreign aid policy following a presidential executive order. In light of these temporary factors, the Group sought and received a formal waiver from Perceptive in respect of the Q1 2025 minimum revenue covenant, to ensure that no breach occurred under the Perceptive credit facility. In May 2025, the Group signed a buy-sell agreement with a contract manufacturing partner. We also have obtained World Health Organisation ("WHO") approval to commence assembly at the new site. It is expected that WHO approval for full production of our Trinscreen product to be received in July 2025, with approval for full production of our UniGold product expected in August 2025. The directors have alternative options and have prepared financial forecasts to address a scenario whereby WHO approval for production with our contract manufacturing partner takes longer than expected to achieve and the facility takes longer than expected to get up to full operational capacity. In such a scenario, management remain confident that all revenue covenants will be met through to 31 December 2025. In addition, the minimum revenue covenant thresholds for Q2, Q3 and Q4 2025 have been renegotiated to align with the Group's updated forecasts. Accordingly, management is confident in the Group's ability to maintain compliance with its debt covenants for the remainder of the going concern review period. Furthermore, Perceptive have a track record of supporting the Company and, when required, have provided covenant waivers and amendment of terms which indicates an appreciation of the Company's circumstances in terms of our transformational plan for the business and temporary declines in revenue. If a similar need were to recur in the foreseeable future, management are confident of their continued support.

We have also launched a strategic realignment review of our businesses in partnership with Barclays Bank. This process, is expected to make significant progress by the end of 2025 and may generate material capital proceeds that can be potentially used to reduce debt and support investment, including CGM investment.

In addition, the Group has continued to benefit from strong support from Perceptive, its principal lender and largest investor. On December 23, 2024, we entered into the third amendment and restatement of the credit agreement governing the Term Loan. As part of this agreement, an additional US$2.0 million of funding was made available to us. We also agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. In February 2025, we entered into a fourth amendment to the credit agreement, which provided for an additional US$4.0 million in term loan funding. On May 14, 2025, we entered into a fifth amendment to the credit agreement, which provided for a further US$2.0 million in funding, extended the maturity date of the Term Loan by six months from January 2026 to July 27, 2026, and confirmed that interest payments for the months of April, May, and June 2025 would be paid-in-kind. There are no material debt maturities until July 2026. These successive amendments demonstrate Perceptive's continued support and demonstrate their willingness to flex terms to preserve liquidity while the Company continues to execute its updated strategy, including its comprehensive transformation plan.

Under the fifth amendment to the credit agreement, the minimum liquidity covenant was reduced to US$1 million through to October 31, 2025, after which it reverts to US$3 million. While management is confident in the Group's ability to maintain compliance with this covenant, it is noted that the Group has planned significant R&D expenditure related to its CGM development program in the second half of 2025. However, the Group retains full discretion over the timing and phasing of these activities, which enables management to align expenditure with available funding and preserve liquidity if required.

In addition to lender support, our going concern forecasts include expected equity raises. These funds are expected to support ongoing CGM development activities. The Group has a strong track record of capital raising, including over US$7 million secured in 2024, and maintains active engagement with existing and potential investors. Management believes that the equity raise is achievable based on the Group's strategic focus and transformation progress to date.

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, The directors believe that, based on currently available information and reasonable assumptions, the Group will be able to continue its operations for at least the next 12 months from the year-end date, and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

***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***

Sales volumes for PCR Viral Transport Media ("VTM") products continued to decrease in 2024, down 32.8% on 2023 revenues due to a significant scaling down of PCR testing programs for COVID-19. The impact of COVID-19 in 2024 was otherwise insignificant on Group operations as quarantine restrictions were removed in most countries. Employees who worked remotely during large parts of the pandemic have returned to their respective offices, withs some hybrid working arrangements maintained. Health and safety policies implemented during the pandemic were relaxed where appropriate to allow for greater flexibility of Group operations without impacting employee health and safety.

As widespread public testing programmes for COVID-19 using PCR tests have largely been discontinued, we expect the amount of our COVID-19 portfolio of products as a percentage of total Group revenues to reduce further in 2025.

***Year ended December 31, 2024 compared to the year ended December 31, 2023***

***Revenues – continuing operations***

Our revenues from continuing operations for the year ended December 31, 2024 were US$61.6 million compared to revenues of US$56.8 million for the year ended December 31, 2023, which represents an increase of US$4.7 million or 8.3%.

The increase is mainly due to sales of our HIV screening test, TrinScreen HIV of US$10.0 million for the year offset by decreases in our clinical laboratory sales and sales in legacy haemoglobinopathies product.

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2024 US$'000 | 2023 US$'000 | % Change |
| **Revenues – continuing operations** | | | |
| Clinical laboratory goods | 39,372 | 42,288 | (6.9)% |
| Clinical laboratory services | 4,750 | 5,453 | (12.9)% |
| Point-of-Care | 17,433 | 9,091 | 91.8% |
| | **61,555** | **56,832** | **8.3%** |

*Clinical Laboratory Goods*

Clinical Laboratory goods revenues decreased by US$2.9 million in 2024, which represents a decrease of 6.9%. The movement is driven by decreases within our haemoglobin business, our COVID-19 VTM products and our Infectious Diseases products.

Sales in our haemoglobin business declined by US$1.1 million (5.2%) due primarily to the continued downward trend in revenues for our legacy haemoglobinopathies product, the Ultra II instrument. Our replacement for the Ultra II instrument, the Premier Resolution, obtained FDA approval in August 2023.

There was a decrease of US$0.4 million in sales for our COVID-19 VTM products as public health PCR testing programs for COVID-19 have largely been discontinued. We have retained the capability to flex manufacture volumes should market conditions warrant it.

Sales in our Infectious Diseases products have decreased by US$0.7 million which was primarily driven by two larger customers changing infectious disease technology platform.

*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 12.9% to US$4.8 million, due primarily to a reduction in transplant related testing volumes in full year 2024 compared to full year 2023. The laboratory had provided transplant testing services to a local healthcare provider for a number of years, however in early 2023 that healthcare provider informed us that it was moving to a different service provider and this resulted in lost revenues for the laboratory beginning in the second quarter of 2023.

*Point-of-Care*

Point-of-Care revenues increased by 91.8% from US$9.1 million in 2023 to US$17.4 million in 2024. Sales of our HIV screening test, TrinScreen HIV were US$10.0 million for the year (US$0.4 million in 2023) as we continued to see strong demand following our initial shipments in late 2023. This was partially offset by a decrease of 14.3% in other Point-of-Care revenues, primarily driven by decreased sales in our UniGold HIV range, primarily as a result of testing disruptions in two key markets, which we expect are temporary disruptions.

*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, | | |
|---|---|---|---|
| | 2024 US$'000 | 2023 US$'000 | % Change |
| **Revenues for continuing operations** | | | |
| Americas | 29,917 | 32,282 | (7.3)% |
| Asia/Africa | 24,775 | 18,909 | 31.0% |
| Europe | 6,863 | 5,641 | 21.7% |
| | | | |
| **Total** | **61,555** | **56,832** | **8.3%** |

In the Americas, revenues decreased US$2.4 million or 7.3%, primarily driven by lower sales in our haemoglobin business in Brazil, a full-year impact of reduced volumes in our New York reference laboratory, and a decline in demand for our COVID-19 VTM products. Sales in Brazil declined by US$0.8 million due to reduced demand for our legacy haemoglobinopathies instrument. Revenues from the New York laboratory declined by US$0.7 million, reflecting the full-year impact of the loss of transplant testing volumes beginning in the second quarter of 2023. In addition, COVID-19 VTM sales declined in the region as public health PCR testing programs continued to wind down.

In Asia/Africa, revenues increased by 31%, or US$5.9 million compared to 2023. The increase was primarily driven by strong growth in sales of our TrinScreen HIV screening test. TrinScreen continued to gain traction following its launch in late 2023, with significant uptake across key African markets. This increase was partially offset by a decline in sales of our UniGold HIV product range in Africa and modest reductions in revenues from our haemoglobin and infectious disease product lines within the Asia region

In Europe, revenues decreased by US$1.2 million, or 21.7% compared to 2023. The by higher demand from our main European distributor for haemoglobin products. This growth reflects stronger ordering within Western Europe year. The increase was supported by growth in our clinical chemistry product line across the region.

***Cost of sales, gross profit and gross margin***

Total cost of sales increased by US$2.7 million from US$37.4 million for the year ended December 31, 2023 to US$40.1 million, for the year ended December 31, 2024, an increase of 7.3%. This resulted in a gross profit for 2024 of US$21.4 million compared to a gross profit for 2023 of US$19.5 million. The gross margin of 34.8% in 2024 compares to a gross margin of 34.2% in 2023.

***Other operating (expense)/income***

Other operating income decreased from US$0.1 million for the year ended December 31, 2023 to negative US$1.79 million for the year ended December 31, 2024. This is due to the reversal of $1.8 million income from loan forgiveness of second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries recognised in 2020 which is currently the subject of a U.S. Department of Justice (DOJ) investigation. For further details, see Note 4.

The other operating income for 2024 relates to a transition services agreement with the acquirer of Fitzgerald Industries.

***Research and development expenses***

Research and development expenses increased from US$4.4 million for the year ended December 31, 2023 to US$4.5 million for the year ended December 31, 2024, an increase of 3.7% mainly due to lower capitalisation of payroll costs into product development intangible assets.

***Selling, general and administrative expenses***

Selling, general and administrative expenses decreased for the year ended December 31, 2024 by US$2.3 million to US$28.8 million when compared to the year ended December 31, 2023, representing a decrease of 7.5%. A significant element of the US$2.3 million decrease relates to:

i) a US$1.9 million decrease in salaries and related personnel costs, reflecting the impact of organisational realignment measures undertaken as part of the restructuring program.

ii) lower non-cash share-based payments expense of US$0.8 million mainly due to forfeitures and expirations.

***Impairment charges***

Impairment charges decreased from US$11.1 million for the year ended December 31, 2023 to US$1.4 million for the year ended December 31, 2024. There are a number of factors taken into account in calculating the impairment, including the Company's period-end share price, calculation of the cost of capital, and future projected cash flows for individual cash-generating units in the business. In addition, the Group examines individual development project assets for indicators of impairment.

The Company evaluated the value in use of each of its cash-generating units, which is defined as the present value of expected future cash flows. Where this value in use was determined to be less than the carrying amount of the respective unit's assets, excluding inventories, trade and other receivables, cash and cash equivalents, and deferred tax assets, an impairment was recognised.

Biopool US Inc's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.2 million).

Immco Diagnostics's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.1 million).

Clark Laboratories Inc's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.1 million).

Trinity Biotech do Brasil's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.2 million) and as at December 31, 2024 (US$0.2 million).

During the year the Company reassessed the carrying value of its current development projects. Specific impairments were recognized in respect of two projects totaling US$1.6 million.

During 2023, the Company fully impaired its investment in imaware, comprising US$0.7 million paid and US$0.8 million accrued but unpaid, under a total committed investment of $1.5 million. In 2024, the Company reversed US$0.8 million of the previously recognised impairment through profit or loss, corresponding to the accrued balance that was no longer payable under the terms of the investment agreement.

The impairment charges for the year ended December 31, 2023 related to impairment losses identified for two cash generating units, namely Immco Diagnostics Inc (US$10.8 million) and Trinity Biotech Do Brasil (US$0.3 million. For further details, see Item 18, Notes 11, 12, and 13.

***Restructuring Costs***

As part of a strategic initiative to enhance operational efficiency and align the Group's structure with its long-term objectives, we undertook a comprehensive business transformation during the year ended December 31, 2024. This program involved targeted measures aimed at improving operational profitability, streamlining our organizational structure, and consolidating certain business unit activities.

As a result, we incurred restructuring costs of US$4.2 million during 2024 (2023: US$nil), which were primarily related to personnel-related expenses, outsourcing of selected functions, site transfers, and stock-related adjustments. These costs are presented separately within Selling, General and Administrative expenses and are not expected to recur.

The restructuring activities are intended to deliver long-term cost savings and operational benefits, supporting the Group's strategy of focusing on core areas of growth and enhancing overall financial performance. For further details, see Item 18, Note 5 'Impairment, restructuring and once off costs'.

***Once-Off Costs***

During the year ended December 31, 2024, the Group incurred exceptional, non-trading costs totaling US$1.9 million (2023: US$nil). These costs were not related to the Group's ongoing operations and are not expected to recur.

Included within this amount was a charge of US$1.1 million relating to a non-refundable retainer fee paid to a corporate finance advisor in connection with a planned future equity raise, settled through the issuance of 650,000 American Depositary Shares ("ADSs").

***Operating Loss***

Operating loss for the year ended December 31, 2024 was US$21.2 million, compared to an operating loss of US$27.0 million in the year ended December 31, 2023. The lower loss was mainly attributable to increased revenues and gross margins, lower impairment charges and lower indirect costs, partly offset by restructuring costs and once off costs.

***Operating Loss excluding Impairment, Restructuring & Once-off costs***

Operating loss excluding Impairment, Restructuring & Once-off costs for the year ended December 31, 2024 was US$13.7 million, compared to US$15.9 million for the year ended December 31, 2023, reflecting the improvement in gross margins and the savings in indirect costs.

***Financial expenses***

Financial expenses in the year ended December 31, 2024 were US$9.6 million compared to US$11.1 million in the year ended December 31, 2024, a decrease of US$1.5 million, broken down as follows:

| | *Year ended December 31, 2024* | *Year ended December 31, 2023* |
|---|---|---|
| | *US$m* | *US$m* |
| Interest on senior secured term loan | 8.6 | 8.4 |
| Interest on convertible note | 1.2 | 1.1 |
| Penalty for early partial settlement of term loan | - | 0.9 |
| Lease interest | 0.6 | 0.6 |
| Interest payable on repayment of PPP loans | 0.3 | 0.0 |
| Capitalised borrowing costs | (2.1) | 0.0 |
| Other non-cash financial expense | 1.0 | 0.0 |
| Total | **9.6** | **11.1** |

*Note: table above contains rounded numbers*

The decrease of US$1.5 million in 2024 compared to 2023 is due to capitalization of borrowing costs and non-reoccurrence of early payment penalties, partially offset by costs associated with fair value remeasurement of embedded derivatives.

Interest on the senior secured term loan, comprising cash and non-cash interest, increased from US$8.4 million in 2023 to US$ 8.6 million for 2024 mainly due to a higher term loan balance. Interest on the convertible note, comprising cash and non-cash interest, increased from US$1.1 million in 2023 to US$1.2 million in 2024. An early repayment penalty of US$0.9 million was incurred in Q2, 2023 because of an early partial settlement of the term loan of US$10.1 million. During 2024, we capitalized borrowing costs totaling US$2.1 million into development costs (2023: US$nil). There was a net expense of US$1.0 million relating primarily to the fair value remeasurement of embedded derivatives.

In October 2024, the Company was notified that it is the subject of a U.S. Department of Justice (DOJ) investigation relating to second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries. At year-end, estimated interest of US$0.3 million was recorded in respect of the payable (see note 4 for further details).

***Financial income***

Financial income for the year ended December 31, 2024 was US$nil compared to US$1.2 million for the year ended December 31, 2023. In 2023, the financial income related to a fair value adjustment for the derivative liability related to warrants granted to the Group's principal lender.

***Income tax (expense)/credit***

The Company recorded a tax expense on continuing operations of US$486,000 for the year ended December 31, 2024 compared to a tax credit of US$59,000 for the year ended December 31, 2023. The 2024 tax credit consists of approximately US$285,000 of current tax charge and US$299,000 of a deferred tax credit. The 2023 tax credit consists of approximately US$264,000 of current tax charge and US$323,000 of a deferred tax credit. For further details on the Group's tax charge please refer to Item 18, Note 7 and Note 14 to the consolidated financial statements.

***Loss before tax from continuing operations***

The loss before tax for continuing operations for the year ended December 31, 2024 was US$31.2 million, in comparison to US$36.9 million for the year ended December 31, 2023.

***Profit/(Loss) from discontinued operations***

The discontinued operations comprise Fitzgerald Industries which was divested in April 2023 and the discontinued cardiac point-of-care business on the Meritas platform. Profit for the period from discontinued operations totalled US$12.9 million, largely attributable to the gain of US$12.7 million on the divesture of Fitzgerald Industries. The gain comprises proceeds of approximately US$30 million offset by transaction costs of US$1.3 million with net assets eliminated on disposal of US$16.3 million.

Following negotiations, a settlement agreement was finalised prior to December 31, 2024 and subsequently signed in January 2025. Under the terms of the settlement, the Company agreed to pay Biosynth US$150,000 in full and final settlement of all post-completion claims. Accordingly, a provision of US$150,000 has been recorded in the consolidated financial statements as at December 31, 2024, see Note 22. The settlement fully resolves all disputes related to the sale of Fitzgerald Industries, and no further liabilities are expected to arise.

For further details, see Item 18, Note 8.

***Year ended December 31, 2023 compared to the year ended December 31, 2022***

***Revenues – continuing operations***

Our revenues from continuing operations for the year ended December 31, 2023 were US$56.8 million compared to revenues of US$62.5 million for the year ended December 31, 2022, which represents a decrease of US$5.7 million or 9.1%.

The decrease is mainly due to lower sales of our PCR Viral Transport Media ("VTM") products (US$1.8 million), lower laboratory services revenue (US$1.8 million) following the loss of our transplant testing service contract and haemoglobins revenues were 8% lower due to the continued decrease in revenues for our legacy haemoglobinopathies product, the Ultra II instrument and due to the deferral of year end shipments of products at sub-optimal pricing as we renegotiated contract terms with a key customer in line with the new management team's focus on profitability.

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2023 US$'000 | 2022 US$'000 | % Change |
| **Revenues – continuing operations** | | | |
| Clinical laboratory goods | 42,288 | 46,036 | (8.1)% |
| Clinical laboratory services | 5,453 | 7,272 | (25.0)% |
| Point-of-Care | 9,091 | 9,213 | (1.3)% |
| | **56,832** | **62,521** | **(9.1)%** |

*Clinical Laboratory Goods*

Clinical Laboratory goods revenues decreased by US$3.7 million in 2023, which represents a decrease of 8.1%. The decrease is mainly due to a decrease of US$1.8 million in sales for our COVID-19 VTM products as public health PCR testing programs for COVID-19 have largely been discontinued. We have retained the capability to flex manufacture volumes should market conditions warrant it. The remainder of the decrease in clinical laboratory goods revenues is largely due to our haemoglobin business, sales of which declined by 8% due to the continued downward trend in revenues for our legacy haemoglobinopathies product, the Ultra II instrument and due to the deferral of shipments in the fourth quarter of 2023 of products at sub-optimal pricing as we renegotiated contract terms with a key customer. In Q1, 2024, we agreed upon revised terms. Our replacement for the Ultra II instrument, the Premier Resolution, obtained FDA approval in August 2023.

*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 25.0% to US$5.5 million. The laboratory had provided transplant testing services to a local healthcare provider for a number of years, however in early 2023 that healthcare provider informed us that it was moving to a different service provider and this resulted in lost revenues for the laboratory beginning in the second quarter of 2023. This decrease was partly offset by higher services revenue for our proprietary Sjogren's syndrome test which increased by 3% in 2023 compared to 2022.

*Point-of-Care*

Point-of-Care revenues decreased 1.3% from US$9.2 million in 2022 to US$9.1 million in 2023. There was a slight decrease in sales of HIV tests in Africa which was largely offset by an increase in revenues for the syphilis point-of-care test in U.S. Included in our HIV point-of-care revenues is US$0.4m for our new Trinscreen test, which commenced its first shipments in December 2023.

*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, | | |
|---|---|---|---|
| | 2023 US$'000 | 2022 US$'000 | % Change |
| **Revenues for continuing operations** | | | |
| Americas | 32,282 | 35,557 | (9.2)% |
| Asia/Africa | 18,909 | 20,401 | (7.3)% |
| Europe | 5,641 | 6,563 | (14.0)% |
| | | | |
| **Total** | **56,832** | **62,521** | **(9.1)%** |

In the Americas, revenues decreased US$3.3 million or 9.2%, mainly due to a US$1.8 million decrease in sales of our VTM products which were used in the COVID-19 testing programs in U.S. and Canada. The other main contributor to the drop in revenues in Americas was a US$1.8 million decrease in revenues for our New York laboratory due to the loss of a transplant testing service contract. Offsetting these decreases was strong growth in our haemoglobins business, particularly in Brazil, where revenues increased by 13% in 2023 compared to 2022.

In Asia/Africa, revenues decreased by 7.3%, or US$1.5 million compared to 2022. The decrease was primarily due to lower haemoglobins revenues in Asia. In 2022, there was particularly strong demand for our diabetes products in Asia with year-on-year revenue growth in 2022 of 36%, boosted by high instrument sales. Haemoglobins revenues in Asia decreased in 2023 compared to 2022 due to lower number of instruments sold and due to the deferral of year end shipments of haemoglobins products at sub-optimal pricing as we renegotiated contract terms with a key customer in line with our new management team's focus on profitability.

In Europe, revenues decreased by US$0.9 million, or 14.0% compared to 2022. The decrease was mainly caused by lower demand from our main European haemoglobins distributor due to customer attrition in their installed base following tendering processes in Western Europe.

***Cost of sales, gross profit and gross margin***

Total cost of sales decreased by US$7.9 million from US$45.3 million for the year ended December 31, 2022 to US$37.4 million, for the year ended December 31, 2023, a decrease of 17.4%. This resulted in a gross profit for 2023 of US$19.5 million compared to a gross profit for 2022 of US$17.3 million. The gross margin of 34.2% in 2023 compares to a gross margin of 27.6% in 2022.

The gross profit for the year ended December 31, 2022 reflected significant excess inventory and obsolescence charges of US$4.7 million recorded in Q3 2022, consisting of VTM inventory write down (US$3.5 million) Tri-stat inventory write down (US$0.3 million) and other inventory write downs (US$0.9 million). The remainder of the reduction in gross margin in the year ended December 31, 2023 compared to year ended December 31, 2022 is largely due to sales mix changes, inflationary increases in the price of raw materials which cannot always be passed onto customers in the form of higher prices due to contract terms.

***Other operating income***

Other operating income decreased from US$0.3 million for the year ended December 31, 2022 to US$0.1 million for the year ended December 31, 2023. The other operating income for 2023 relates to a transition services agreement with the acquirer of Fitzgerald Industries. The income for 2022 consisted of government grants in relation to R&D activities and there was no equivalent in 2023.

***Research and development expenses***

Research and development expenses increased from US$4.1 million for the year ended December 31, 2022 to US$4.4 million for the year ended December 31, 2023, an increase of 6% mainly due to lower capitalisation of payroll costs into product development intangible assets.

***Selling, general and administrative expenses***

Selling, general and administrative expenses increased for the year ended December 31, 2023 by US$4.2 million to US$31.2 million when compared to the year ended December 31, 2022, representing an increase of 15.5%. A significant element of the US$4.2 million increase relates to:

i) technical advisory, legal and professional fees were higher in 2023 compared to 2022 by US$1.6 million primarily due to costs associated with the acquisition of the biosensor assets of Waveform (which closed in January 2024) and other corporate development and corporate finance activities as we continue to assess strategic opportunities for inorganic growth and balance sheet optimization,

ii) an increase of US$1.5 million in foreign exchange losses largely relating to the accounting requirement to mark to market euro-denominated lease liabilities for right-of-use assets, and

iii) higher non-cash share-based payments expense of US$0.3 million mainly due to the full year effect of options granted in 2022.

***Impairment charges***

Impairment charges increased from US$5.8 million for the year ended December 31, 2022 to US$11.1 million for the year ended December 31, 2023. There are a number of factors taken into account in calculating the impairment, including the Company's period-end share price, calculation of the cost of capital, and future projected cash flows for individual cash-generating units in the business. In addition, the Group examines individual development project assets for indicators of impairment.

The impairment charges for the year ended December 31, 2023 relate to Immco Diagnostics Inc (US$10.8 million) and Trinity Biotech Do Brasil (US$0.3 million). As the Company has previously reported, Immco's laboratory had for a number of years provided transplant testing services to a local healthcare provider. However, in early 2023 that healthcare provider informed Immco that it was moving to a different service provider, and this resulted in lost revenues for the laboratory beginning in the second quarter of 2023. Additionally, the expected level of laboratory services revenue arising from its proposed partnership with imaware, Inc ("imaware") did not materialise. As a result, Immco's value in use, defined as the present value of its future cash flows, fell below the value of the carrying amount of its assets, other than inventories, accounts receivable, cash and cash equivalents and deferred tax assets as at June 30, 2023 (US$10.7 million) and at December 31, 2023 (US$0.1 million).

Included within the Immco impairment is a full impairment of the financial assets associated with the Group's investment in imaware. To date the Group has paid US$0.7 million of a proposed US$1.5 million investment to imaware. As the investment agreement provided for a total investment of US$1.5 million, this amount was recognised in the balance sheet as at March 31, 2023. Given the uncertainty over the future of imaware's performance and thus the value of this investment, management decided to impair the entire US$1.5 million at June 30, 2023. The Group has not to date paid the additional US$0.8 million to imaware which remains on our balance sheet as an accrued payable.

Similarly, Trinity Biotech do Brasil's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2023 (US$0.1 million) and as at December 31, 2023 (US$0.2 million).

The impairment charges for the year ended December 31, 2022 related to impaired intangible assets relating to R&D projects (US$4.6 million) and impairment losses identified for three cash generating units, namely Trinity Biotech Do Brasil (US$0.5 million), Clark Laboratories Inc. (US$0.4 million) and Biopool US Inc (US$0.4 million). For further details, see Item 18, Notes 11, 12, and 13.

***Operating Loss***

Operating loss for the year ended December 31, 2023 was US$27.0 million, compared to an operating loss of US$19.3 million in the year ended December 31, 2022. The higher loss was mainly attributable to decreased revenues, lower other operating income, higher impairment charges and higher indirect costs, partly offset by a higher gross margin.

***Financial expenses***

Financial expenses in the year ended December 31, 2023 were US$11.1 million compared to US$24.7 million in the year ended December 31, 2022, a decrease of US$13.6 million, broken down as follows:

| | *Year ended December 31, 2023* | *Year ended December 31, 2022* |
|---|---|---|
| | *US$m* | *US$m* |
| Interest on senior secured term loan | 8.4 | 9.8 |
| Interest on convertible note | 1.1 | 0.7 |
| Penalty for early partial settlement of term loan | 0.9 | 3.5 |
| Lease interest | 0.6 | 0.7 |
| Loss on disposal of exchangeable notes | 0.0 | 9.7 |
| Interest on exchangeable notes | 0.0 | 0.4 |
| Other non-cash financial expense | 0.0 | 0.1 |
| Total | **11.1** | **24.7** |

*Note: table above contains rounded numbers*

The decrease of US$13.6 million in 2023 compared to 2022 is mainly due to two material expenses incurred in the year ended December 31, 2022, which were a loss of US$9.7 million on the disposal of the Exchangeable Notes and an early repayment penalty of just under US$3.5 million.

Interest on the senior secured term loan, comprising cash and non-cash interest, decreased from US$9.8 million in 2022 to US$8.4 million for 2023 mainly due to a lower term loan balance, although this was partly offset by the impact of higher prevailing interest rates during 2023. Interest on the convertible note, comprising cash and non-cash interest, increased from US$0.7 million in 2022 to US$1.1 million in 2023 due to the full year effect (the convertible note was issued in Q2 2022). An early repayment penalty of US$0.9 million was incurred in Q2, 2023 because of an early partial settlement of the term loan of US$10.1 million. Interest on the exchangeable notes decreased from US$0.4 million in 2022 to US$8,000 in 2023 because 99.7% of the exchangeable notes were retired during Q1, 2022.

***Financial income***

Financial income for the year ended December 31, 2023 was US$1.2 million compared to US$0.3 million for the year ended December 31, 2022. In both years, the financial income related to a fair value adjustment for the derivative liability related to warrants granted to the Group's principal lender.

***Income tax credit***

The Company recorded a tax credit on continuing operations of US$59,000 for the year ended December 31, 2023 compared to a tax credit of US$0.2 million for the year ended December 31, 2022. The 2023 tax credit consists of approximately US$264,000 of current tax charge and US$323,000 of a deferred tax credit. The 2022 tax credit consists of US$280,000 of current tax credit and US$86,000 of a deferred tax charge. For further details on the Group's tax charge please refer to Item 18, Note 7 and Note 14 to the consolidated financial statements.

***Loss before tax from continuing operations***

The loss before tax for continuing operations for the year ended December 31, 2023 was US$36.9 million, in comparison to US$43.8 million for the year ended December 31, 2022.

***Profit from discontinued operations***

The discontinued operations comprise Fitzgerald Industries which was divested in April 2023 and the discontinued cardiac point-of-care business on the Meritas platform. Profit for the period from discontinued operations totalled US$12.9 million, largely attributable to the gain of US$12.7 million on the divesture of Fitzgerald Industries. The gain comprises proceeds of approximately US$30 million offset by transaction costs of US$1.3 million with net assets eliminated on disposal of US$16.3 million. 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 February 2023, we announced that we 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. In April 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. We used approximately US$11 million of the proceeds of this sale to repay approximately US$10.1 million of the senior secured debt held by Perceptive plus we incurred an approximately US$0.9 million early repayment penalty.

In January 2024, we entered into a further amendment to the Perceptive credit facility, providing additional capital to fund the acquisition of the Waveform continuous glucose monitoring (CGM) assets. Subsequent amendments to the facility during 2024 provided incremental funding flexibility to support the ongoing development of our CGM platform. In connection with these amendments, Perceptive received new warrants to purchase 1.5 million ADSs and the exercise price of its existing warrants was repriced to US$0.80 per ADS. These steps reflect our ongoing strategy to secure funding for strategic growth initiatives while actively managing our capital structure.

*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 9.422 ADSs per US$1,000 principal amount of notes, equivalent to an exchange price of approximately US$109.40 per ADS. In February 2024, the Company adjusted its ADS ratio from 1 ADS: 4 ordinary shares to 1 ADS: 20 ordinary shares. The ADS amounts in this paragraph reflect this change. The notes include a number of non-financial covenants, all of which were complied with on December 31, 2024.

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 our own cash resources. We also issued a total of 1.06 million ADSs to the five note holders as partial consideration for the exchange of the notes. The remaining outstanding amount owing for exchangeable notes on December 31, 2024, was US$210,000.

*Term loan with Perceptive*

In December 2021, we entered into a US$81.3 million senior secured term loan credit facility with Perceptive. The term loan was drawn down in January 2022. The loan was originally due to January 2026, however this has since been amended to a maturity date of July 2026. The loan initially accrued 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 500,000 of our ADSs. The per ADS exercise price of the Warrants was US$6.50 (subsequently amended in 2023 and again in 2024). The warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the term loan.

The Company made an early partial settlement of the term loan of US$34.5 million in May 2022 and in accordance with the term loan's credit agreement, there was an early repayment penalty of US$3.45 million. In February 2023, we announced that we 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. On April 27, 2023, we used approximately US$11 million of the proceeds of the sale of Fitzgerald Industries to repay approximately US$10.1 million of the senior secured debt held by Perceptive plus an approximately US$0.9 million early repayment penalty.

In January 2024, we closed the acquisition of the Waveform CGM assets and liabilities and in connection with that acquisition, we drew down additional funding from Perceptive of US$22 million under an amended Credit Agreement. The amended Credit Agreement also provided for a further US$6.5 million facility that may be drawn down by the Company between April and December 2024. In April 2024 the Company drew down the additional funding of US$6.5 million as prescribed in the Amended Term Loan agreement. This funding will be used for general corporate purposes, including the further development of our CGM offering.

The amended agreement also immediately reduced the annual rate of interest on the loan by 2.5% to 8.75% (the "Base Rate") plus the greater of (a) Term Secured Overnight Financing Rate (SOFR) or (b) 4.0% per annum, and allows for a further 2.5% reduction in the Base Rate to 6.25% once the outstanding principal under the Amended Term Loan falls below $35 million. Additionally, the early repayment penalty was reduced from a range of 8% to 7% to 4.0% to 3.5%, dependent on timing of early repayment, and reduces the revenue covenants.

On December 23, 2024 we entered into the third amendment and restatement of the credit agreement governing the Term Loan. As part of this agreement, an additional US$2.0 million of funding was made available to us. We also agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. Additional warrants were also provided that allow an additional 1,500,000 ADSs to be purchased (2.5 million ADSs in total) at $0.80 per ADS. This amendment to the term loan also saw the repricing of the existing warrants to an exercise price of US$0.80 per ADS.

The outstanding amount owing for the term loan at December 31, 2024 is US$72.4 million.

Under the Amended Term loan, we are subject to a number of covenants and obligations. Perceptive temporarily reduced the aggregate unrestricted cash covenant to US$2.0 million for the period up to and including April 30, 2024.

On February 27, 2025, we entered into the fourth amended and restated credit agreement, which provided for an additional US$4.0 million increase to our outstanding Term Loan. On May 14th, 2025, we entered into a fifth amendment to the credit agreement, which provided for an additional US$2.0 million in term loan funding, extended the maturity date of the Term Loan to July 27, 2026, and provided that interest payments for the months of April, May, and June 2025 will be paid-in-kind.

*Investment from MiCo IVD Holdings, LLC*

In May 2022, the Company announced a US$45.2 million investment from MiCo IVD Holdings, LLC. 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 our ADSs is at or above US$12.96 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. During 2023, the lease term on the Wells Fargo agreement came to an end and the lease was not renewed. The Group also has lease liabilities relating to right-of-use assets with lease maturities between 1 and 10 years.

*Cash and cash equivalents*

At December 31, 2024, the cash and cash equivalents balance was US$5.2 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 our directors' opinion, we 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.

We have incurred net losses and negative cash flows from operating activities in the past two years and we may not be able to achieve or maintain profitability or positive cash flow in the future. We have incurred losses of US$31.8 million and US$24.0 million in the years ended December 31, 2024 and 2023, respectively and had negative cash flows from operating activities of US$4.2 million and US$11.6 million, respectively.

We expect to continue as a going concern. Our ability to continue as a going concern depends on our ability to generate cash flows from operations and to conduct adequate financing activities. We believe that we have access to sufficient cash reserves for our operating needs for at least the next twelve months from the date of this Annual Report. However, if negative cash flow from operating activities persists in the long run, cash resources may become insufficient to satisfy our on-going cash requirements.

Additional funding may not be available on acceptable terms, or at all. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. Further, as a result of geopolitical and macroeconomic events, including the Israel-Hamas and Russia-Ukraine wars, the global credit and financial markets have experienced volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

Expansion into new businesses may present operating and marketing challenges different from those we currently encounter, and we cannot assure that new business initiatives will be successful enough to justify the time, effort, and resources that we devote to them or ultimately achieve profitability.

***Cash Flows***

As at December 31, 2024, our consolidated cash and cash equivalents were US$5.2 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, | |
|---|---|---|
| | **2024 US$'000** | **2023 US$'000** |
| Net cash used in operating activities | (4,191) | (11,557) |
| **Net cash (used in)/generated by investing activities** | (22,968) | 24,756 |
| **Net cash generated by/(used in)from financing activities** | 28,810 | (16,042) |
| Net increase/(decrease) in cash and cash equivalents and short-term investments | 1,651 | (2,843) |

*Operating Activities*

Net cash used in operating activities for the year ended December 31, 2024 amounted to US$4.2 million (2023: US$11.6 million), a decrease in cash used of US$7.4 million. The decrease in net cash generated from operating activities of US$7.4 million is attributable to an increase in working capital outflows of US$6.7 million, and a decrease in operating cash flows before changes in working capital of US$0.2 million, partially offset by an increase in taxes received of US$0.7 million. The decrease in operating cash flows before changes in working capital is primarily driven by an increase in trade and other payables compared to the prior year.

*Investing Activities*

Net cash used in investing activities for the year ended December 31, 2024 amounted to US$23.0 million (2023: net cash generated of US$24.8 million) which were principally made up as follows:

- Payments to acquire intangible assets of US$9.7 million (2023: US$1.9 million), which principally related to development expenditure capitalised as part of the Group's on-going product development activities;
- Payments to acquire financial assets of US$nil million (2023: US$0.7 million);
- Acquisition of property, plant and equipment of US$0.4 million (2023: US$0.8 million) incurred as part of the Group's investment programme for its manufacturing and distributing activities; and,
- Payments to acquire trades or businesses of US$12.9 million (2023: US$nil) which relates primarily to the acquisition of the CGM assets of Waveform Technologies Inc.
- Proceeds from the sale of a business of US$nil (2023: US$28.2 million).

*Financing Activities*

Net cash generated from financing activities for the year ended December 31, 2024 amounted to US$28.8 million (2023: outflow of US$16.0 million). This inflow is due to additional draw down of the senior secured loan of US$30.2 million, additional share issuances of $7.4 million, payments for lease liabilities of US$2.5 million and interest payments of US$5.9 million. In 2023 the net outflow related to the partial early repayment of the term loan US$10.1 million, plus early payment penalty of US$0.9 million, payments for lease liabilities of US$2.3 million, interest payments of US$7.6 million, partly offset by the draw down of the term loan of US$5.0 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*

For a discussion of trends, see Item 4.B—Business Overview, Item 5.A—Operating Results and Item 5.B—Liquidity and Capital Resources.

### *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 U.S. which provides testing services to institutional customers and insurance companies. In the U.S., 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. 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 Note 22 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, 2024 the carrying value of capitalised development costs was US$20.9 million (2023: US$15.1 million) (see Note 12 to the consolidated financial statements). The increase in 2024 was mainly due to additions of US$8.6 million partly offset by impairment charges of US$1.6 million and amortization of US$1.2 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 our nine cash-generating units ("CGUs") is determined based on a value-in-use computation. The value-in-use calculations use cash flow projections based on the 2025 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 17% to 28% (2023 15% to 22%). 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.

Impairment charges decreased from US$11.1 million for the year ended December 31, 2023 to US$1.4 million for the year ended December 31, 2024. In year ended December 31, 2024, impairment loss was identified for four CGUs and specific development projects. Biopool US Inc's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.2 million). Immco Diagnostics's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.1 million). Clark Laboratories Inc's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.1 million) and as at December 31, 2024 (US$0.1 million). Trinity Biotech do Brasil's value in use was below the value of its relevant assets, and an impairment was provided for as at June 30, 2024 (US$0.2 million) and as at December 31, 2024 (US$0.2 million). During the year the Company reassessed the carrying value of its current development projects. Specific impairments were recognized in respect of two projects totaling US$1.2 million.

During 2023, the Company fully impaired its investment in imaware which constituted an amount paid of $0.7 million of the committed US$1.5 million investment with the remaining US $0.8 million, which had not yet been funded, recognized as an accrued liability. In 2024, the Company reversed US$0.8 million of the previously recognised impairment through profit or loss, corresponding to the accrued balance that was no longer payable under the terms of the investment agreement.

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, 2024.
- 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, 2024.

*Allowance for slow-moving and obsolete inventory*

We evaluate the realisability of our inventory on a case-by-case basis and adjust 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 2024, 2023 or 2022 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2024 our allowance for slow moving and obsolete inventory was US$7.6 million which represents approximately 28.3% of gross inventory value. At December 31, 2023 our allowance for slow moving and obsolete inventory was US$11.3 million, which represented approximately 36.3% of gross inventory value and at December 31, 2022 the provision was US$16.3 million, or approximately 42.0% of gross inventory value (see Note 16 to the consolidated financial statements).

The allowance for slow moving and obsolete inventory has decreased by US$3.7 million between 2023 and 2024 primarily due to the utilisation of the provision through scrappage during the year.

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$0.5 million at December 31, 2024 (2023: US$0.6 million) (2022: 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, we 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 totaling US$1.7 million. This balance was reduced by an early partial payment of the loan of US$34.5 million in early 2022. In early 2023, we completed a drawdown of US$5 million of additional funding on the term loan, and subsequently, in quarter two of 2023, repaid US$10 million against the loan on the back of the sale of Fitzgerald Industries. 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$0.2 million at December 31, 2024 (2023: US$0.2 million 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$1.7 million at December 31, 2024 (2023: US$0.5 million) 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 500,000 of the Company's ADSs. The initial per ADS exercise price of the warrants was US$6.50. 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 connection with the acquisition of the Waveform assets, the Company entered an amended credit agreement in January 2024 with Perceptive. Under the revised agreement, an additional US$22 million of funding drawn down, with US$12.5 million being used to acquire the Waveform assets. The remaining US$9.5 million is intended to be used for general corporate purposes including for the further development of the CGM and biosensor technologies. In addition, the amended agreement provides for additional liquidity of up to US$6.5 million, that may be drawn down between April and December 2024, and can be used for general corporate purposes, thereby providing further liquidity to fund the development of the CGM and biosensor technologies. In April 2024 the Company drew down the additional funding of US$6.5 million as prescribed in the Amended Term Loan agreement. This funding will be used for general corporate purposes, including the further development of our CGM offering.

The amended agreement also immediately reduced the annual rate of interest on the loan by 2.5% to 8.75% (the "Base Rate") plus the greater of (a) Term Secured Overnight Financing Rate (SOFR) or (b) 4.0% per annum, and allows for a further 2.5% reduction in the Base Rate to 6.25% once the outstanding principal under the Amended Term Loan falls below $35 million. Additionally, the early repayment penalty was reduced from a range of 8% to 7% to 4.0% to 3.5%, dependent on timing of early repayment, and reduces the revenue covenants.

On December 23, 2024, we entered into the third amendment and restatement of the credit agreement governing the Term Loan. As part of this agreement, an additional $2.0 million of funding was made available to us. We also agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. Additional warrants were also provided that allow an additional 1,500,000 ADS's to be purchased (2.5 million ADS's in total) at US$0.80 per ADS. This amendment to the term loan also saw the repricing of the existing warrants to an exercise price of US$0.80 per ADS. On February 27, 2025, we entered into the fourth amended and restated credit agreement, which provided for an additional US$4.0 million increase to our outstanding Term Loan. In addition, a deferred consideration payment of $5.0 million related to the acquisition of the biosensor assets of Waveform was extended to November 2025. On May 14th, 2025, we entered into a fifth amendment to the credit agreement, which provided for an additional US$2.0 million in term loan funding, extended the maturity date of the Term Loan to July 27, 2026, and provided that interest payments for the months of April, May, and June 2025 will be paid-in-kind.

*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 executive senior management. The following table presents information about our current executive officers and members of our board of directors. 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* | *Title* |
|---|---|
| *Directors* | |
| John Gillard | Director, President and Chief Executive Officer |
| Ronan O'Caoimh | Director, Founder & Executive Advisor |
| Jim Walsh, PhD | Executive Director of Business Development |
| Tom Lindsay | Independent Director |
| Andrew Omidvar PhD,MBA | Independent Director |
| | |
| *Executive Officers* | |
| Matthew Wictome | Vice President of Quality and Regulatory Affairs |
| Susan O'Connor | Interim Chief Financial Officer |
| Gary Keating, PhD | Chief Technology Officer |
| Eibhlín Kelly | Chief Information Officer |
| Colm Molloy | Group Director of Human Resources and Culture |

*Changes in Executive Officers and Board composition*

Des Fitzgerald, who has acted as interim CFO since December 2023 was replaced by Louise Tallon who joined as Chief Financial Officer and Company Secretary in August 2024. Susan O'Connor was appointed as Interim CFO in April 2025 succeeding Louise Tallon, who stepped down as CFO effective April 11, 2025. In addition, Matthew Wictome succeeded Ian Wells as Vice President of Quality and Regulatory Affairs in April 2025

**Directors**

**John Gillard, Director, President and Chief Executive Officer,** 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 assumed the role of CEO and President of Trinity Biotech in December 2023. 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. From June 2020 until November 2020, Mr. Gillard also acted as a business consultant. Mr. Gillard holds a Bachelor of Commerce degree from the National University of Ireland Galway and a Masters degree in Accounting from University College Dublin.

**Ronan O'Caoimh, Director, Founder & Executive Advisor,** 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.

**Tom Lindsay, Independent 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.

**Andrew Omidvar, Independent Director** joined the Board of Trinity Biotech in December 2023. With over twenty-five years of experience leading cross-functional teams to deliver cutting edge technology solutions in a variety of industries. He brings experience in development and product support for data and AI based systems in the medical device industry. Most recently Dr. Omidvar served as Vice President of Government R&D and Enterprise for Philips.

**Executive Officers**

**Dr. Matthew Wictome, Vice President of Quality and Regulatory Affairs**, was appointed to this role in January 2025. He is also the Founder and Managing Director of Datod Consulting, specialising in building world-class Quality organisations. With over 30 years of experience in the healthcare sector, Dr. Wictome has held leadership roles in R&D and Quality at Johnson & Johnson, Ortho Clinical Diagnostics, and the UK's Health Protection Agency. He holds a BSc in Biochemistry from the University of Bath, a PhD in Biochemistry from the University of Southampton, and an MSc in Strategy, Change and Leadership from the University of Bristol's Executive Development Program. Dr. Wictome is also the co-author of Transforming Quality Organizations: A Practical Guide (Business Expert Press, New York, April 2023).

**Susan O'Connor, Interim Chief Financial Officer**, joined the company in April 2025 as our CFO on an interim basis. She is a PwC-trained Chartered Accountant with over 20 years of diverse international experience in Technology, High-tech manufacturing, Health and Life Sciences, Professional Services and Financial Services sectors in Ireland, UK, Canada and Australia. Prior to joining Trinity Biotech, Ms. O'Connor was CFO of Glantus Holdings plc, where, having worked previously on its successful IPO, she led its transition through a trade sale and post-acquisition integration. She has held CFO and consulting roles in both public and private companies, supporting IPOs, M&A transactions, and operational restructurings and scale-ups. Ms. O'Connor holds a Master of Science in the Management of IT in Accounting from Dublin City University and a Diploma in Strategic Finance and Analytics from Chartered Accountants Ireland.

**Gary Keating, Chief Technology Officer**, joined us in October 2022. Dr Keating graduated from the University of Ulster at Jordanstown with a BSc in Applied Biochemical Sciences and pursued his interest in biosensors in Prof Richard O'Kennedy's Applied Biochemistry group at DCU, where he worked on the development of antibody-based optical biosensors for the detection of small drug molecules. Dr Keating earned his PhD in 1998; the external examiner for his doctorate was Prof George Guilbault, who described the first amperometric glucose electrode. Prior to joining Trinity Biotech, Dr Keating held the position of CTO with Hibergene Diagnostics Ltd. from October 2014 to August 2022. Previous to Hibergene, Dr Keating held a range of technical leadership roles in start-up and multinational diagnostics companies, including Transfer Manager at Abbott Diagnostics and R&D Manager at Diasorin Ireland.

**Eibhlín Kelly, Chief Information Officer,** has served as our Chief Information Officer 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 June 2019 to July 2020. His previous roles included HR Director at Storm Technology from March 2015 to June 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.

**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 solely by a resolution of our board of directors.

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 us 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 2024 remuneration scheme was approved by the Board of Directors.

Total directors and independent directors' remuneration, excluding pension and share options, for the year ended December 31, 2024 amounted to US$957,000. The pension charge for the year amounted to US$39,000. 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 2024 US$'000* | *Total 2023 US$'000* |
|---|---|---|---|---|---|---|---|
| John Gillard | President and Chief Executive Officer | 676 | 260* | 0 | 39 | 1,213 | 710 |
| Ronan O'Caoimh | Director, Founder & Executive Advisor | 84 | — | — | — | 84 | 80 |
| Jim Walsh | Executive Director Business Development | 83 | — | — | — | 83 | 50 |
| Tom Lindsay | Independent Director | 57 | — | — | — | 57 | 63 |
| Andrew Omidvar | Independent Director | 57 | — | — | — | 57 | 10 |
| | | 957 | 260 | 0 | 39 | 1,494 | 913 |

** Amount relates to a bonus provision for the year ended December 31, 2024. The final amount remains subject to confirmation.*

As at December 31, 2024 there was US$260,000 (2023 US$753,000) accrued to provide pay, pension, retirement or similar benefits for the directors.

In 2024, net options granted by the directors to subscribe for 'A' ordinary shares was 2,606,000 (equivalent to 130,300 ADSs), comprising options granted to subscribe for up to 5,600,000 'A' ordinary shares (equivalent to 280,000 ADSs) offset by options forfeited or expired to subscribe for 2,994,000 'A' ordinary shares (equivalent to 149,700 ADSs) (2023: 2,160,000).

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

**Compensation of Executive 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.

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 to increase the number of ordinary shares issuable under such plan by 30 million Class "A" ordinary shares (the equivalent to 1.5 million ADS). 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. Gillard'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 (US$5.00, US$7.50, US$10.00, US$15.00, US$20.00 and U$25.00 per ADS) during the term of the option.

For the financial year ended December 31, 2024, our executive officers as a group, received aggregate compensation of US$1,356,000 for services they rendered in all capacities during 2024, which amount includes base salary, commissions, bonuses, ex gratia payments and benefits in kind, excluding share options.

This does not include any of the directors listed above. Compensation paid to Mr. Fitzgerald, Ms. Tallon and Dr. Wells for their service during 2024 is included in the aggregate compensation disclosed for executive officers.

**C. Board Practices**

Our Articles provide that one third of the directors for the time being other than a director holding an executive office with us 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 of Directors has typically established audit, remuneration and employee compensation committees. The Company typically has a Remuneration Committee which is responsible for approving executive directors' remuneration including bonuses and share option grants. The Board has from time to time appointed independent consulting firms to advise the Board on recruitment and 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. As a transitional arrangement, the Audit Committee now comprises solely the independent director, Tom Lindsay.

The Board of Directors formed an employee compensation committee consisting of the CEO and CFO. This committee has delegated authority from the Board to approve share-based compensation grants to employees of the Group, other than executive directors, pursuant to the terms of the Employee Share Option Plan.

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

Because we are 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 and Limitations of Liability**

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.

**D. Employees**

The following table details certain data on the average number of employees of Trinity Biotech and its consolidated subsidiaries, including full-time, part-time, and temporary personnel who work under the direction and control of the Company:

| | Year Ended December 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **2022** |
| *Numbers of employees by geographic location* | | | |
| United States | 174 | 203 | 203 |
| Ireland | 185 | 143 | 146 |
| United Kingdom | 1 | - | 1 |
| Brazil | 41 | 34 | 34 |
| ***Total workforce*** | **401** | **380** | **384** |
| *Numbers of employees by category of activity* | | | |
| Research scientists & technicians | 33 | 23 | 26 |
| Manufacturing/Operations | 246 | 207 | 197 |
| Quality Assurance | 40 | 51 | 56 |
| Finance/Administration | 49 | 73 | 73 |
| Sales & Marketing | 33 | 26 | 32 |
| ***Total workforce*** | **401** | **380** | **384** |

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.

**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 2020 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. 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 March 31, 2025, our directors and executive officers as a group, then consisting of 11 persons, held options to purchase an aggregate of 32,993,336'A' Ordinary shares (1,649,667 ADS equivalent), having exercise prices ranging from US$0.12 per 'A' ordinary share (US$2.40 per ADS) to US$0.73 per 'A' ordinary share (US$14.60 per ADS) and expiration dates ranging from 2024 to 2031. Any options granted prior to the fourth quarter of 2022 vest over a two to four year period and have no performance conditions. The options granted in and since the fourth quarter of 2022 are performance share options.

The following table sets forth certain information as of March 31, 2025, 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) | 17,246,663 | 4.5% |
| Jim Walsh (4) | 2,722,779 | * |
| John Gillard (5) | 14,950,000 | 3.9% |
| Tom Lindsay (6) | 729,167 | * |
| Andrew Omidvar (7) | 729,167 | * |
| Ian Wells | - | - |
| Eibhlín Kelly | - | - |
| Gary Keating | - | - |
| Colm Molloy | - | - |
| Jacqueline O'Neill | - | - |
| Mícheál Roche | - | - |
| Executive officers and directors as a group (11 persons) | 36,377,776 | 9.1% |

* 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 372,640,384 'A' Ordinary Shares issued and outstanding as of March 31, 2025.

(3) Represents (a) 9,724,160 'A' ordinary shares and (b) 7,522,503 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of March 31, 2025. 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 (a) 1,393,612 'A' ordinary shares and (b) 1,329,167 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of March 31, 2025. 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.

(5) Represents (a) 200,000 'A' ordinary shares and (b) 14,750,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of March 31, 2025.

(6) Represents 729,167 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of March 31, 2025.

(7) Represents 729,167 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of March 31, 2025.

As of March 31, 2025, 32,993,336 (1,649,667 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 |
|---|---|---|---|---|---|---|
| John Gillard | 600,000 | 30,000 | 0.67 | 13.40 | None | 23/10/2027 |
| | 1,400,000 | 70,000 | 0.27 | 5.40 | None | 25/03/2029 |
| | 2,000,000 | 100,000 | 0.29 | 5.80 | None | 19/12/2029 |
| | 666,667 | 33,333 | 0.29 | 5.80 | $15.00 | 19/12/2029 |
| | 666,667 | 33,333 | 0.29 | 5.80 | $20.00 | 19/12/2029 |
| | 666,667 | 33,333 | 0.29 | 5.80 | $25.00 | 19/12/2029 |
| | 7,000,000 | 350,000 | 0.12 | 2.40 | None | 18/12/2030 |
| | 2,333,333 | 116,667 | 0.12 | 2.40 | $5.00 | 18/12/2030 |
| | 2,333,333 | 116,667 | 0.12 | 2.40 | $7.50 | 18/12/2030 |
| | 2,333,334 | 116,667 | 0.12 | 2.40 | $10.00 | 18/12/2030 |
| Ronan O'Caoimh [1] | 4,060,000 | 203,000 | 0.69 | 13.80 | None | 14/06/2026 |
| | 333,336 | 16,667 | 0.19 | 3.80 | None | 20/03/2027 |
| | 2,400,000 | 120,000 | 0.73 | 14.60 | None | 17/11/2027 |
| | 700,000 | 35,000 | 0.14 | 2.80 | None | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $5.00 | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $7.50 | 28/01/2031 |
| | 233,334 | 11,667 | 0.14 | 2.80 | $10.00 | 28/01/2031 |
| Jim Walsh | 600,000 | 30,000 | 0.19 | 3.80 | None | 20/03/2027 |
| | 700,000 | 35,000 | 0.14 | 2.80 | None | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $5.00 | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $7.50 | 28/01/2031 |
| | 233,334 | 11,667 | 0.14 | 2.80 | $10.00 | 28/01/2031 |
| Thomas Lindsay | 700,000 | 35,000 | 0.14 | 2.80 | None | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $5.00 | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $7.50 | 28/01/2031 |
| | 233,334 | 11,667 | 0.14 | 2.80 | $10.00 | 28/01/2031 |
| Andrew Omidvar | 700,000 | 35,000 | 0.14 | 2.80 | None | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $5.00 | 28/01/2031 |
| | 233,333 | 11,667 | 0.14 | 2.80 | $7.50 | 28/01/2031 |
| | 233,334 | 11,667 | 0.14 | 2.80 | $10.00 | 28/01/2031 |

[1] Includes options issued to Darnick Company which in the past provided us 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 our ADSs, for ten trading days out of the thirty previous trading days, is equal to or greater than the relevant hurdle price of US$5.00, US$7.50, US$10.00, $15.00, $20.00 and $25.00 per ADS (adjusted for any stock splits, reverse splits or equivalent reorganisations) during the life of the option. At 31 March, 2025, none of the directors' share options with a hurdle price were exercisable as the hurdle price condition has not been achieved.

As of March 31, 2025 the following total options were outstanding:

| | Number of 'A' Ordinary Shares Subject to Options | Range of Exercise Price per Ordinary Share | Range of Exercise Price per ADS |
|---|---|---|---|
| Total options outstanding | 40,476,672 | $ US0.12-US$1.10 | $ US2.40-US$25.80 |

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

**A. Major Shareholders**

As of March 31, 2025, there were 372,640,384'A' Ordinary shares (excluding treasury shares) outstanding. Such total excludes 40,476,672 Ordinary shares issuable upon the exercise of outstanding options and 51,200,000 Ordinary 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 March 31, 2025, 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 | Percentage ownership (2) |
|---|---|---|---|
| MiCo IVD Holdings, LLC | 44,759,388(3) | 2,237,969(3) | 17.5%(3) |
| Perceptive Credit Holdings III, LP | 85,800,000(4) | 4,290,000(4) | 20.9%(4) |
| All directors and officers as a group | 36,377,775(1) | 1,818,889(1) | 9.1% |

(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 372,640,384 'A' Ordinary Shares outstanding (excluding treasury shares).

(3) Based upon a Schedule 13D filed on December 17, 2024, by MiCo IVD Holdings, LLC with the SEC. The percentage ownership in the table above includes the conversion of the maximum number of 'A' Ordinary Shares as permitted by the conversion terns of the Convertible Note. The principal business address of MiCo IVD Holdings, LLC is 85 Orchard Road. Skillman, New Jersey 08558 United States.

(4) Based upon Schedule 13D filed on February 14, 2025, by Perceptive Credit Holdings III, LP. The principal business address of Perceptive Credit Holdings III, LP is 51 Astor Place 10th Floor, New York, NY 10003.

**Significant Changes in the Ownership of Major Shareholders**

To our knowledge, other than as disclosed in the tables below there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2021.

The following shareholders have disclosed ownership above 5% since January 1, 2021 but their ownership is below 5% as at March 31, 2025 according to their Schedule 13G filings, except as indicated otherwise.

| | Number of 'A' Ordinary Shares Beneficially Owned | Number of ADSs Beneficially Owned (1) | Percentage 'A' Ordinary Shares | Percentage Total Voting Power | Date of Filing |
|---|---|---|---|---|---|
| Highbridge Capital Management, LLC | 675,064 | 33,753 | 0.2% | 0.2% | April 14, 2022 (1) |
| Renaissance Technologies LLC | 5,573,752 | 278,688 | 1.5% | 1.5% | February 13, 2023 |
| Stonehill Capital Management LLC | 6,690,592 | 334,530 | 1.8% | 1.8% | February 13, 2023 |

(1) Based on information provided by Highbridge Capital Management, LLC to the Company in a letter dated April 14, 2022

The ownership for the following shareholders rose above 5% since January 1, 2021:

| | Number of 'A' Ordinary Shares Beneficially Owned | Number of ADSs Beneficially Owned (1) | Percentage 'A' Ordinary Shares | Percentage Total Voting Power | Date of Filing |
|---|---|---|---|---|---|
| MiCo IVD Holdings, LLC | 44,759,388 | 2,237,969 | 15.8%(1) | 17.5%(1) | December 17, 2024 |
| Perceptive Credit Holdings III, LP | 85,800,000 | 4,290,000 | 20.9% | 20.9% | February 14, 2025 |

(1) The percentage ownership in the table above for MiCo IVD Holdings, LLC includes the conversion of the maximum number of 'A' Ordinary Shares as permitted by the conversion terms of the Convertible Note.

**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$421,000). 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$869,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. A rent review became effective on 1 July 2022 and, following an independent valuation and arbitration process, the annual rent increased to €1,050,000 (US$1,094,000), with backdated rent accruing from that date. Included within overhead costs in cost of sales in 2024 is an amount of US$659,000 in respect of this backdated rent.

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$159,000). A rent review became effective on 1 July 2021 and, following an independent valuation, the annual rent increased to €170,560 (US$162,000), with backdated rent accruing from that date. Included within overhead costs in cost of sales in 2024 is an amount of US$93,000 in respect of this backdated rent.

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

At the time that the arrangements were entered into, Trinity Biotech and its directors (excepting Mr O'Caoimh and Dr Walsh who expressed no opinion on this point) believed they 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 September 2024, the Company completed the acquisition of Metabolomics Diagnostics Ltd ("Metabolomics") for consideration of approximately $0.9 million, satisfied through the issuance of approximately 0.27 million ADSs and the extinguishment of amounts owed to the Company totalling $0.4 million. At the time of the acquisition, Dr. Jim Walsh, a director of the Company, held a 6% minority shareholding in Metabolomics. Based on the net assets acquired and goodwill recognised, the value attributable to Mr. Walsh's interest was estimated at approximately $55,000. Dr. Walsh fully disclosed his interest, and the acquisition was approved unanimously by the board, with appropriate procedures followed to manage the potential conflict of interest, including the passing of a resolution under the Company's Constitution to authorise Mr. Walsh's involvement in the decision-making process. The transaction was conducted at arm's length, and the board determined that it was in the best interests of the Company.

***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, 2024, the amount of our export sales (i.e., sales outside of Ireland) was approximately US$61,447,000 which represents 99.83% of our total sales. In the year ended December 31, 2023, export sales were approximately US$56,714,000, or 99.8% of total sales, while in the year ended December 31, 2022, export sales totalled approximately US$74,675,000, representing 99.9% of 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, other than as disclosed herein.

**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, 2024.

**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 twenty 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 31) 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 members. This register is open to inspection by members free of charge and to any individual on the payment of a small fee. The books containing the minutes of proceedings of the general meetings 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 also obliged to keep proper accounting records. Shareholders have no statutory right to inspect the accounting records of the Company. The only financial records, which are open to the members, are the statutory financial statements, which are sent to members together 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 Companies Act 2014 permits members 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 members 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 members 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 Irish 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 member 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 them or any of the members (including themselves), or in disregard of their interests as members, 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 their duties shall be liable to Trinity Biotech for any profit made by them 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 their 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$34.5 million. In February 2023, the Company entered into an amended and restated senior secured term loan credit agreement which allowed for an immediate US$5 million increase to its outstanding Term Loan and provided for a US$20 million 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.

In connection with the acquisition of the CGM assets of Waveform in January 2024, the Company entered into another amended and restated term loan. Under the Amended Term Loan, an additional US$22 million of funding has been made available to the Company, with US$12.5 million being used to acquire the CGM assets of Waveform. The remaining US$9.5 million is available for general corporate purposes including for the further development of the CGM and biosensor technologies. In addition, the Amended Term Loan provides for additional liquidity of up to US$6.5 million, that may be drawn down by the Company between April and December 2024, and can be used for general corporate purposes. In April 2024 the Company drew down the additional funding of US$6.5 million as prescribed in the Amended Term Loan agreement.

The Amended Term Loan also immediately reduced the annual rate of interest on the loan by 2.5% to 8.75% (the "Base Rate") plus the greater of (a) Term Secured Overnight Financing Rate (SOFR) or (b) 4.0% per annum, and allows for a further 2.5% reduction in the Base Rate to 6.25% once the outstanding principal under the Amended Term Loan falls below US$35 million. Additionally, the Amended Term Loan reduces the early repayment penalty from a range of 8% to 7% to 4.0% to 3.5%, dependent on timing of early repayment, and also reduces the revenue covenants.

In December 2024 the Company entered into another amended agreement with Perceptive. Under the terms of the agreement, a deferred consideration payment of US$5 million related to the acquisition of the biosensor assets of Waveform Technologies has been extended to November 2025. In addition, further additional liquidity in the amount of approximately US$5.5 million has been provided to Trinity Biotech through a combination of cash and payment-in-kind interest. This funding will be used for general corporate purposes, including the further development of our CGM offering.

On February 27, 2025, we entered into the fourth amended and restated credit agreement, which provided for an additional US$4.0 million increase to our outstanding Term Loan. On May 14th, 2025, we entered into a fifth amendment to the credit agreement, which provided for an additional US$2.0 million in term loan funding, extended the maturity date of the Term Loan to July 27, 2026, and provided that interest payments for the months of April, May, and June 2025 will be paid-in-kind.

*Warrant agreement with Perceptive Advisors*

On December 15, 2021, the Company agreed, subject to drawdown of the Term Loan, to issue warrants exercisable for 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$6.50, 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 500,000 warrants, originally issued to Perceptive, to a price of US$5.36 per ADS.

On January 30, 2024, the Company entered into a further amendment to its senior secured term loan credit facility with Perceptive. In connection with the Amended Term Loan, Perceptive received new warrants to purchase an additional 500,000 ADSs.

Additionally, on December 23, 2024, the Company entered into a further amendment to its senior secured term loan credit facility with Perceptive. In connection with the Amended Term Loan, Perceptive received new warrants to purchase an additional 1,500,000 ADSs, and reprice its existing ADS warrants at an exercise price of US$0.80 per ADS.

*Securities Purchase Agreement and Convertible Note related to MiCo Investment*

In April 2022, the Company announced a US$45 million investment from MiCo IVD Holdings LLP. The investment consisted of an equity investment of approximately US$25.2 million (2.24 million ADSs at a price of US$11.25 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$16.20 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$16.20 for any five consecutive NASDAQ trading days.

*Transition Agreement with Bayer Healthcare LLC*

The transition agreement with Bayer Healthcare LLC ("Bayer") derives from the acquisition of the CGM assets of Waveform Technologies, Inc in January 2024. As a portion of acquired intellectual property was developed originally by Bayer, the transition agreement provides that the Company will pay Bayer a royalty on net sales of the CGM products.

*Share Purchase Agreement in respect of Benen Trading Limited and Fitzgerald Industries International Inc.*

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 to repay intercompany loans owed to Trinity Biotech.

*Asset and share Purchase Agreement for CGM assets of Waveform Technologies, Inc.*

On January 30, 2024, the Company acquired the biosensor technology, including the CGM assets, of Waveform for an initial consideration of US$12.5 million in cash and 1.8 million ADSs of the Company plus contingent consideration. The Company intends to initially design an updated CGM sensor using the acquired Waveform assets together with a related data driven health and wellness insights platform and to further evolve the platform technology acquired through the acquisition of the Waveform assets to measure and analyse other valuable biomarkers and related datapoints.

*Share Purchase Agreement for Metabolomics Diagnostics Ltd*

On September 24, 2024, the Company completed the acquisition of 100% of Metabolomics Diagnostics Limited, for consideration of approximately US$0.9 million paid through the issuance of approximately 0.27 million American Depository Shares (ADS) of the Company alongside the extinguishment of monies owed to the company totalling US$0.4 million. The Company intends to develop and commercialise a screening test for preeclampsia risk using Metabolomics's Prepsia test.

*Share Purchase Agreement for EpiCapture Limited*

On October 22, 2024, the Group completed the acquisition of 100% of EpiCapture Limited, for initial consideration of approximately US$3.3 million paid through the issuance of approximately 1.7 million American Depository Shares (ADS) of the Company, with an additional consideration of US$0.5 million contingent on the achievement of future milestones. The Company intends to develop a non-invasive test for monitoring the risk of aggressive prostate cancer.

*Share Purchase Agreement in respect of Novus Diagnostics Limited*

On September 27, 2024, the Group completed a strategic investment in Novus Diagnostics Limited, acquiring a 12.5% equity stake at that time. The consideration comprised approximately 1.4 million American Depository Shares (ADS) of the Company, valued at approximately US$2.6 million. Novus Diagnostics is developing a rapid, point-of-care test for bloodstream infections, and the investment is expected to support the advancement and commercialization of its sepsis detection platform. A subsequent follow-on investment by another shareholder in 2025 resulted in a minor dilution of the Group's interest, which remains strategic in nature.

**D. Exchange Controls**

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish securities (including shares or depositary receipts of Irish companies such as the Company). Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities.

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 is a U.S. Holder (as defined below) and who holds the ADSs as capital assets. This summary is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. For the purposes of this summary, a U.S. Holder is: an individual who is a citizen or 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 2024, 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 are effectively 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. 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 and USC 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 4.1% 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 in Ireland or a country with which Ireland has a double taxation treaty; 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 person tax resident in a treaty jurisdiction receiving dividends, under which a non-resident person must 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 Irish Revenue 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

- the recipient is the direct beneficial owner of the ADSs, 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 shareholder beneficially entitled to the dividend and the depository bank receives confirmation from the intermediary that such 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 Irish Revenue claiming a full refund of DWT paid by filing a declaration / claim in the form prescribed by Irish Revenue. 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 (unless the ordinary shares or ADSs were acquired within four weeks prior to the deposition). 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 dispositions exceed the indexed base cost of the ordinary shares or ADSs disposed of and any incidental expenses. The current rate of CGT is 33% and this applies to disposals made on or after 6 December 2012. Indexation of the base cost of the ordinary shares or ADSs is available up to 31 December 2002, and only in respect of ordinary shares or ADSs held for more than 12 months prior to their disposal.

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

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

Where disposal proceeds are received in a currency other than Euro, they must be translated into Euro amounts to calculate the amount of any chargeable gain or loss. Similarly, acquisition costs denominated in a currency other than Euro must be translated at the date of acquisition 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 the 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% applies 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 provided the transfer is not made in contemplation of sale.

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. Finance Act 2023 introduced an exemption for any electronic transfers of interests in Irish shares within central securities depositories in either the USA or Canada, where the aforementioned shares are dealt in on a recognised stock exchange in either of those countries and the trade is settled through a securities settlement system located in the US or Canada. Prior to Finance Act 2023, this exemption was available by way of an administrative practice and taxpayers were required to seek Irish Revenue confirmation on a case-by-case basis as to whether this exemption applied.

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 if there is a transfer of beneficial ownership or the transfer is made in contemplation of sale. Such transfers will be exempt from Irish stamp duty if the transfer does not involve any change in the beneficial ownership in the underlying ordinary shares and the transfer is not made in contemplation of a sale. 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 44 days after the date of execution of the transfer. 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 2024 by approximately 2.0%.

**Exchange rate sensitivity**

At year-end 2024, 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$11.6 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 2024 year-end net worth by approximately US$1.2 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, 2024 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 8.75% 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%. At December 31, 2024 the carrying value of the Group's indebtedness totalled US$102,532,000 (2023: US$67,954,000) (2022: US$73,769,000) at interest rates of 1.5% to 14.1% (2023: 1.5% to 16.3%).

In broad terms, a one-percentage point increase in interest rates would increase interest expense by US$755,000 (2023: increase in interest expense of US$417,000).

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 2024.

The Group had foreign currency denominated cash balances equivalent to US$851,000 at December 31, 2024 (2023: US$1,283,000).

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

**A. Debt Securities**

Not applicable.

**B. Warrants and Rights**

In February 2024, the Company adjusted its ADS ratio from 1 ADS: 4 ordinary shares to 1 ADS: 20 ordinary shares. The ADS numbers shown hereunder reflect the revised ADS ratio.

On December 15, 2021, the Company agreed to issue warrants exercisable for 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$6.50. 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 500,000 warrants originally issued to Perceptive to an exercise price of US$5.36 per ADS.

On January 30, 2024, the Company entered into a further amendment to its senior secured term loan credit facility with Perceptive. In connection with the Amended Term Loan, Perceptive received new warrants to purchase an additional 500,000 ADSs.

Additionally, on December 23, 2024, the Company entered into a further amendment to its senior secured term loan credit facility with Perceptive. In connection with the Amended Term Loan, Perceptive received new warrants to purchase an additional 1,500,000 ADSs at an exercise price of US$0.80 per ADS, and the exercise price of its existing ADS warrants was also reset to US$0.80 per ADS.

Also on January 30, 2024, the Company issued warrants to a consultant assisting with our CGM business to purchase 60,000 ADSs with an exercise price of US$2.20 per ADS. The warrants are exercisable, in whole or part, until the fifth anniversary of the issue date.

**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.

On February 15, 2024, Trinity Biotech Plc finalized a ratio change of our American depositary shares ("ADSs") from one (1) ADS representing four (4) Class A ordinary shares to one (1) ADS representing twenty (20) Class A ordinary shares. The change in ADS ratio will have the same effect as a one-for-five reverse ADS split.

## 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, 2024.

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, 2024.

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, 2024.

***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 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 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, 2024* | | *Year ended December 31, 2023* | |
|---|---|---|---|---|
| | *US$'000* | *%* | *US$'000* | *%* |
| Audit | 1,244 | 90% | 909 | 66% |
| Tax | 141 | 10% | 463 | 34% |
| Total | 1,385 | | 1,372 | |

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 2024 or 2023.

**16F. Change in Registrant's Certifying Accountant**

Not applicable.

**16G. 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.

**16H. Mine Safety Disclosure**

Not applicable.

**16I. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections**

Not applicable.

**Item 16J. Insider Trading Policies**

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our ordinary shares by directors, officers and employees, that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq listing standards.

**Item 16K. Cybersecurity**

*Risk management and strategy*

We have not experienced any material cybersecurity incidents that have impacted our operations to date. However, like most companies, we are subject to frequent and evolving cybersecurity threats and attempted attacks from a range of sources, including opportunistic hackers, organised threat actors, and internal vulnerabilities.

To identify, assess, and mitigate cybersecurity risks, we have implemented a cybersecurity program covering the full scope of our information systems and data assets. This includes internally managed systems, cloud environments, third party-hosted infrastructure, and sensitive data such as intellectual property, clinical research information, strategic documents, personal data of employees and trial participants, and confidential commercial information, collectively referred to as our "Information Systems and Data."

Our cybersecurity program is led by our Chief Information Officer (CIO), who has over 20 years of IT leadership experience, and is supported by an internal security function that collaborates with our broader risk management team. The CIO works across the organisation to ensure that cybersecurity is embedded within our operations and treated as a core business risk.

We use a variety of tools and practices to assess the cybersecurity threat landscape and evaluate our posture. These include internal and external vulnerability scans, threat intelligence feeds, cyber risk assessments, penetration testing conducted by third-party firms, and tabletop simulations to evaluate and improve our incident response readiness. We also monitor emerging regulatory developments and industry standards to ensure our practices remain aligned with evolving expectations.

To mitigate risks identified through these processes, we implement a combination of technical, administrative, and physical controls. These include next-generation firewalls, endpoint protection and antivirus software, multi-factor authentication, access control protocols, encryption of sensitive data, network segmentation, continuous system monitoring, secure configuration standards, data backup and recovery protocols, and security awareness training for all staff, including phishing simulations. Our cybersecurity practices are regularly reviewed and enhanced in response to changing threat dynamics.

Cybersecurity risk management is also extended to our third-party service providers, who perform a wide range of business-critical services including data hosting, software delivery, clinical research, supply chain management, distribution, and contract manufacturing. We assess the cybersecurity posture of key vendors through a combination of tools, such as security questionnaires, audits, analysis of certifications (e.g., ISO 27001, SOC 2), reviews of written security policies, and assessment of penetration test results. Where necessary, we engage in direct discussions with vendors' security teams to evaluate controls. We also impose contractual obligations related to cybersecurity and data protection, including confidentiality and breach notification requirements. These measures are designed to reduce the risk of vulnerabilities introduced through our supply chain or external partners.

Cybersecurity risks are addressed through our overall approach to operational and strategic risk management. Key risks are discussed at senior management level and prioritised based on their potential to affect our systems, data, or business continuity.

*Governance*

Oversight of cybersecurity risk forms part of the Board of Directors' general risk oversight responsibilities. Our Chief Information Officer (CIO), who has over 20 years of experience in IT and security, is responsible for the day-to-day implementation and ongoing development of our cybersecurity program.

The CIO is involved in reviewing security assessments, monitoring threat activity, approving key cybersecurity controls, and helping coordinate incident preparedness across the organisation. In the event of a cybersecurity incident, our escalation procedures provide for involvement of senior management, including the CIO and, where appropriate, other members of the executive team and relevant support functions.

Cybersecurity matters are reported to senior management as needed, particularly in cases where a threat or incident may have a broader business impact. Our governance structure is designed to support informed decision-making around risk prioritisation, incident response, and investment in cybersecurity measures. As of the date of this filing, we are not aware of any cybersecurity threats, including past incidents, that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition.

## 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 101 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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

**Going concern**

As discussed in Note 1(iii) to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency. Management's evaluation of the events and conditions and managements' plans to mitigate these matters are also described in Note 1(iii).

**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 a critical audit matter 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 non-current assets*

Refer to Note 12 to the financial statements. As at December 31, 2024 prior to impairment analysis, the intangible assets of the Company totalled $52.9 million, property, plant and equipment of the Company totalled $5.6 million and prepayments of the Company totalled $2.0 million. The Company recognised $1.4 million impairment during the year ended December 31, 2024. In addition, the company acquired intangible assets and goodwill amounting to $37.9 million and property plant and equipment amounting to $4.5 million in 2024.

The Company's evaluation of the carrying value of long-lived assets for impairment involves the comparison of the recoverable amount 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.

The principal consideration for our determination that impairment of long-lived assets as a critical audit matter was 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 which have significant non-current assets 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 identified relevant CGUs with significant non-current assets for review.
- We agreed the underlying cash flow forecasts against budgets of the selected CGUs and we evaluated management's ability to accurately forecast future revenue, margins and expenses by:
    - performing a look-back analysis and comparing actual results to management's historical forecasts; and
    - assessing the reasonableness of cashflows of new and in-progress products.
- 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 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
- We performed sensitivity analyses around significant management assumptions, such as discount rate and growth rate, to account for uncertainties around assumptions in the valuation model.

*Business combination and valuation of goodwill*

Refer to Note 29 to the financial statements. The Company completed the acquisition of various businesses during the year ended December 31, 2024, which were accounted for under IFRS 3 "Business Combination". The transactions resulted in the recognition of goodwill and intangible assets with carrying value totalling $13.8 million and $13.2 million, respectively, as at December 31, 2024. The determination of the fair value of the identifiable assets acquired, liabilities assumed, and the resulting goodwill required management to make significant estimates and assumptions, particularly related to the projected future cash flows, discount rates, and the allocation of the purchase price to the net assets acquired.

The principal considerations for our determination that performing procedures relating to the business combination and valuation of goodwill is a critical audit matter are the significant judgment and estimation required by management in determining the fair values, especially those related to projected revenue growth rates, profit margins, terminal values, and discount rates used in the discounted cash flow models. These elements involved a high degree of complexity and subjectivity due to the sensitivity of the valuation to changes in assumptions, as well as the magnitude of the amounts involved.

*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 value of acquired assets and liabilities and the determination of goodwill included the following, among others:

- We evaluated the design effectiveness of certain internal controls related to the Company's business combination process, including controls over the development and selection of significant assumptions used in the valuation of acquired intangible assets.
- We reviewed the purchase price allocation and the identification and measurement of the fair value of acquired assets and assumed liabilities, including intangible assets, to evaluate compliance with relevant accounting standards.
- We evaluated the reasonableness of the significant assumptions used by management by comparing the information underlying the significant assumptions to recent industry and/or market data.
- We involved our valuation specialists to review the appropriateness of the discount rate and methodology used by the management's specialist in their report to value the intangible assets.
- We evaluated the competence, capabilities, and objectivity of the external valuer involved in the valuation process, including review of their qualifications, independence, and terms of engagement.
- We assessed the valuation of goodwill and other acquired assets for impairment at the acquisition date ("Day 1" review) and inspected subsequent adjustments recognized within the measurement period for appropriateness and adequacy of disclosure.
- We performed sensitivity analyses around significant assumptions used within each model, specifically on revenue and expense drivers, to account for uncertainties around assumptions in the valuation model.
- We assessed the adequacy of the Company's disclosure related to business combination, including the description of key assumptions and sensitivities as required under relevant accounting standards.

*Going Concern*

Refer to Note 1(iii) to the financial statements. Management assessed that it is appropriate to prepare the consolidated financial statements on a going concern basis. In making this assessment, in particular the directors have considered the significant progress on their multi-year transformation plan which will be largely completed by mid-2025 and which is expected to deliver significant annualized cost savings. The directors also considered the launching of their strategic realignment review of the Company's businesses which would generate material capital proceeds to reduce maturing obligations and support current projects. Lastly, the directors considered the continuing support obtained from the Company's principal lender and largest investor. The amended agreement with the lender deferred the date of the maturity of the senior secured term loan amounting to $72.4 million from January 2026 to July 2026 which provides the Company flexibility to preserve liquidity to continue to execute its updated strategy, including the Company's comprehensive transition plan. The Company has suffered recurring losses from operations, net cash outflows from operating activities, and has a significant accumulated deficit.

The principal considerations for our determination that the going concern is a critical audit matter are the uncertainties surrounding the achievability of management's forecast, the success of the Company's multi-year transformation plan and strategic realignment review of the Company's businesses, and the support obtained from the Company's principal lender. These considerations require significant auditor judgment in assessing the uncertainties surrounding the management's assumptions on their ability to continue as going concern.

*How the critical audit matter was addressed in the audit*

Our audit procedures related to going concern included the following, among others:

- We obtained an understanding, evaluated the design effectiveness of controls over management's going concern assessment process.
- We evaluated management's assessment on going concern and performed an independent assessment of the inputs and assumptions used by management in preparing their cash flow forecast by comparing the assumptions and estimates used elsewhere in the preparation of the financial statements.
- We assessed management communication and revised agreements with the lender to extend the maturity of the senior secured term loan to July 2026. We also discussed with management the options being considered in relation to repayment plan of the senior secured term loan.
- We evaluated the credit agreement and inspected management's assessment on the Company's compliance with debt covenants, including inspection of any related waivers obtained for breaches.
- We considered subsequent events up to the date of the auditor's report that may affect the going concern conclusion.
- We evaluated the adequacy of the Company's disclosure in the financial statements, including the description of substantial doubt and management plans as required by relevant accounting standards.

/s/ GRANT THORNTON

Dublin, Ireland

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

15 May 2025

**CONSOLIDATED STATEMENT OF OPERATIONS**

| | | *Year ended December 31* | | |
|---|---|---|---|---|
| | *Notes* | *2024 Total US$'000* | *2023 Total US$'000* | *2022 Total US$'000* |
| **Revenues** | 2 | **61,555** | **56,832** | **62,521** |
| Cost of sales | | (40,114) | (37,382) | (45,253) |
| **Gross profit** | | **21,441** | **19,450** | **17,268** |
| Other operating (expense)/income | 4 | **(1,787)** | **141** | **343** |
| Research and development expenses | | (4,543) | (4,379) | (4,138) |
| Selling, general and administrative expenses | | (28,815) | (31,152) | (26,983) |
| Selling, general and administrative expenses – Restructuring costs | 5 | (4,181) | - | - |
| Once off items | 5 | (1,872) | - | - |
| Impairment charges | 5 | (1,408) | (11,105) | (5,839) |
| **Operating loss** | | **(21,165)** | **(27,045)** | **(19,349)** |
| Financial income | 6 | - | 1,171 | 303 |
| Financial expenses | 6 | (9,565) | (11,053) | (24,734) |
| **Net financing expense** | | **(9,565)** | **(9,882)** | **(24,431)** |
| **Loss before tax** | 7, 9 | **(30,730)** | **(36,927)** | **(43,780)** |
| Total income tax (expense)/credit | 2, 7 | **(486)** | **59** | **194** |
| **Loss for the year on continuing operations** | 2, 10 | **(31,216)** | **(36,868)** | **(43,586)** |
| (Loss)/profit for the year on discontinued operations | 8 | **(573)** | **12,850** | **2,577** |
| **Loss for the year (all attributable to owners of the parent)** | 2, 10 | **(31,789)** | **(24,018)** | **(41,009)** |
| Basic loss per ADS (US Dollars) – continuing operations | 10 | (1.74) | (4.81) | (6.46) |
| Diluted loss per ADS (US Dollars) – continuing operations | 10 | (1.74) | (4.81) | (6.46) |
| Basic loss per 'A' ordinary share (US Dollars) – continuing operations | 10 | (0.09) | (0.24) | (0.32) |
| Diluted loss per 'A' ordinary share (US Dollars) – continuing operations | 10 | (0.09) | (0.24) | (0.32) |
| Basic loss per ADS (US Dollars) – group | 10 | (1.77) | (3.14) | (6.08) |
| Diluted loss per ADS (US Dollars) – group | 10 | (1.77) | (3.14) | (6.08) |
| Basic loss per 'A' ordinary share (US Dollars) – group | 10 | (0.09) | (0.16) | (0.30) |
| Diluted loss per 'A' ordinary share (US Dollars) – group | 10 | (0.09) | (0.16) | (0.30) |

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

| | | Year ended December 31 | | |
|---|---|---|---|---|
| | *Notes* | *2024 US$'000* | *2023 US$'000* | *2022 US$'000* |
| Loss for the year | 2 | (31,789) | (24,018) | (41,009) |
| **Other comprehensive profit/(loss)** | | | | |
| **Items that will be reclassified subsequently to profit or loss** | | | | |
| Foreign exchange translation differences | | 245 | 69 | (396) |
| | | | | |
| ***Other comprehensive profit/(loss)*** | | 245 | 69 | (396) |
| | | | | |
| ***Total Comprehensive Loss (all attributable to owners of the parent)*** | | **(31,544)** | **(23,949)** | **(41,405)** |

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

| | Notes | At December 31 2024 US$'000 | 2023 US$'000 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | 11 | 4,621 | 1,892 |
| Goodwill and intangible assets | 12 | 51,343 | 16,270 |
| Financial assets | 13 | 2,455 | - |
| Deferred tax assets | 14 | 3,553 | 1,975 |
| Derivative financial instruments | 23 | 166 | 178 |
| Other assets | 15 | 28 | 79 |
| **Total non-current assets** | | **62,166** | **20,394** |
| **Current assets** | | | |
| Inventories | 16 | 19,374 | 19,933 |
| Trade and other receivables | 17 | 16,065 | 13,901 |
| Income tax receivable | | 518 | 1,516 |
| Cash and cash equivalents | 18 | 5,167 | 3,691 |
| **Total current assets** | | **41,124** | **39,041** |
| **TOTAL ASSETS** | 2 | **103,290** | **59,435** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity attributable to the equity holders of the parent** | | | |
| Share capital | 19 | 4,190 | 1,972 |
| Share premium | | 63,397 | 46,619 |
| Treasury shares | 19 | (24,922) | (24,922) |
| Accumulated deficit | | (79,117) | (48,644) |
| Translation reserve | 19 | (5,461) | (5,706) |
| Equity component of convertible note | 19, 23 | 6,709 | 6,709 |
| Other reserves | 19 | 23 | 23 |
| **Total deficit** | | **(35,181)** | **(23,949)** |
| **Current liabilities** | | | |
| Income tax payable | | 364 | 279 |
| Trade and other payables | 21 | 26,782 | 12,802 |
| Provisions | 22 | 2,454 | 50 |
| Exchangeable notes and other borrowings | 23 | 210 | 210 |
| Lease liabilities | 24 | 2,285 | 1,694 |
| **Total current liabilities** | | **32,095** | **15,035** |
| **Non-current liabilities** | | | |
| Senior secured term loan | 23 | 72,391 | 40,109 |
| Derivative financial liability | 23 | 1,658 | 526 |
| Convertible note | 23 | 15,401 | 14,542 |
| Contingent consideration | 23 | 1,813 | - |
| Provisions | 22 | 75 | - |
| Lease liabilities | 24 | 10,477 | 10,872 |
| Deferred tax liabilities | 14 | 4,561 | 2,300 |
| **Total non-current liabilities** | | **106,376** | **68,349** |
| **TOTAL LIABILITIES** | 2 | **138,471** | **83,384** |
| **TOTAL EQUITY AND LIABILITIES** | | **103,290** | **59,435** |

**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, 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 19) | 750 | 30,271 | - | - | - | - | - | 31,021 |
| Shares to be issued | - | - | - | - | - | 63 | - | 63 |
| Equity component of convertible note (Note 19) | - | - | - | - | 6,709 | - | - | 6,709 |
| Share-based payments (Note 20) | - | - | - | - | - | - | 1,755 | 1,755 |
| | | - | - | | | | | |
| **Balance at December 31, 2022** | **1,963** | **46,458** | **(24,922)** | **(5,775)** | **6,709** | **86** | **(26,695)** | **(2,176)** |
| | | | | | | | | |
| Balance at January 1, 2023 | 1,963 | 46,458 | (24,922) | (5,775) | 6,709 | 86 | (26,695) | (2,176) |
| Loss for the period | - | - | - | - | - | - | (24,018) | (24,018) |
| Other comprehensive income | - | - | - | 69 | - | - | - | 69 |
| | | | | | | | | |
| Total comprehensive loss | - | - | - | 69 | - | - | (24,018) | (23,949) |
| Shares issued in the year (Note 19) | 9 | 161 | - | - | - | (63) | - | 107 |
| Share-based payments (Note 20) | - | - | - | - | - | - | 2,069 | 2,069 |
| | | - | - | | | | | |
| **Balance at December 31, 2023** | **1,972** | **46,619** | **(24,922)** | **(5,706)** | **6,709** | **23** | **(48,644)** | **(23,949)** |
| Balance at January 1, 2024 | 1,972 | 46,619 | (24,922) | (5,706) | 6,709 | 23 | (48,644) | (23,949) |
| Loss for the period | - | - | - | - | - | - | (31,789) | (31,789) |
| Other comprehensive income | - | - | - | 245 | - | - | - | 245 |
| | | | | | | | | |
| Total comprehensive loss | - | - | - | 245 | - | - | (31,789) | (31,544) |
| Shares issued in the year (Note 19) | 2,218 | 16,778 | - | - | - | - | - | 18,996 |
| Share-based payments (Note 20) | - | - | - | - | - | - | 1,316 | 1,316 |
| | | | | | | | | |
| **Balance at December 31, 2024** | **4,190** | **63,397** | **(24,922)** | **(5,461)** | **6,709** | **23** | **(79,117)** | **(35,181)** |

**CONSOLIDATED STATEMENT OF CASH FLOWS**

| | | Year ended December 31, | | |
|---|---|---|---|---|
| | Notes | 2024 US$'000 | 2023 US$'000 | 2022 US$'000 |
| **Cash flows from operating activities** | | | | |
| Loss for the year | | (31,789) | (24,018) | (41,009) |
| *Adjustments to reconcile net loss to cash provided by operating activities:* | | | | |
| Depreciation | 9, 11 | 675 | 831 | 1,410 |
| Amortisation | 9,12 | 1,190 | 946 | 923 |
| Income tax expense/(credit) | 7 | 486 | (59) | (192) |
| Financial income | 6 | - | (1,171) | (303) |
| Financial expense | 6 | 9,565 | 11,053 | 24,745 |
| Share-based payments (net of capitalized amounts) | 20 | 1,316 | 2,069 | 1,755 |
| Foreign exchange gains on operating cash flows | | 1,010 | 238 | (76) |
| Loss on disposal or retirement of property, plant and equipment | 9 | - | - | 2 |
| Movement in inventory provision | 16 | 2,113 | 2,291 | 7,391 |
| Inventory write off | | 1,884 | - | - |
| Impairment of prepayments | 5, 17 | - | - | 482 |
| Impairment of property, plant and equipment | 5, 11 | 612 | 3,772 | 733 |
| Impairment of intangible assets | 5, 12 | 1,596 | 5,833 | 4,624 |
| Liabilities related to financial assets (reversal)/written off | 5, 13 | (800) | 1,500 | - |
| Gain on sale of business | 8 | - | (12,718) | - |
| Restructuring provision | | 361 | - | - |
| Other non-cash items | | 2,505 | 257 | 269 |
| **Operating cash flows before changes in working capital** | | **(9,276)** | **(9,176)** | **754** |
| (Increase)/decrease in trade and other receivables | | (2,368) | 1,047 | (966) |
| Increase in inventories | | (1,742) | (971) | (877) |
| Increase/(decrease) in trade and other payables | | 8,185 | (2,769) | 181 |
| **Cash used in operations** | | **(5,201)** | **(11,869)** | **(908)** |
| Interest received | | - | - | 2 |
| Income taxes received/(paid) | | 1,010 | 312 | (15) |
| **Net cash used in operating activities** | | **(4,191)** | **(11,557)** | **(921)** |
| **Cash flows from investing activities** | | | | |
| Payments to acquire intangible assets | 12 | (9,659) | (1,901) | (4,876) |
| Acquisition of property, plant and equipment | 11 | (405) | (803) | (1,101) |
| Payments to acquire financial asset | 13 | - | (700) | - |
| Proceeds from sale of business (net of transaction costs) | 8 | - | 28,160 | - |
| Payments to acquire trades or businesses | 29 | (12,904) | - | - |
| **Net cash (used in)/generated by investing activities** | | **(22,968)** | **24,756** | **(5,977)** |
| **Cash flows from financing activities** | | | | |
| Issue of ordinary share capital including share premium (net of issuance costs) | 19 | 7,391 | - | 25,336 |
| Proceeds from shares to be issued | | - | - | 63 |
| Net proceeds from senior secured term loan | 23 | 30,176 | 5,000 | 80,015 |
| Proceeds from convertible note issued | 23 | - | - | 20,000 |
| Expenses paid in connection with debt financing | 23 | - | (147) | (2,356) |
| Purchase of exchangeable notes | 23 | - | - | (86,730) |
| Repayment of senior secured term loan | 23 | - | (10,050) | (34,500) |
| Penalty for early settlement of term loan | 23 | - | (905) | (3,450) |
| Repayment of other loan | | - | - | (23) |
| Interest paid on senior secured term loan | | (5,946) | (7,314) | (6,424) |
| Interest paid on convertible note | | (300) | (300) | (199) |
| Interest paid on exchangeable notes | 28 | (8) | (8) | (1,293) |
| Payment of lease liabilities | 28 | (2,503) | (2,318) | (2,761) |
| **Net cash generated by/(used in) financing activities** | | **28,810** | **(16,042)** | **(12,322)** |
| Increase/(decrease) in cash and cash equivalents and short-term investments | | 1,651 | (2,843) | (19,220) |
| Effects of exchange rate movements on cash held | | (175) | (44) | (112) |
| Cash and cash equivalents and short-term investments at beginning of year | | 3,691 | 6,578 | 25,910 |
| **Cash and cash equivalents and short-term investments at end of year** | 18 | **5,167** | **3,691** | **6,578** |

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2024**

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 is a commercial stage biotechnology company focused on diabetes management solutions and human diagnostics, including wearable biosensors. The Company develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood and the Company intends to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product.

*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, 2024. 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 2024 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 and going concern

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 31.

The accompanying consolidated financial statements have been prepared assuming that we 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, 2024 and 2023, the Group recorded a loss of US$31.8 million and a loss of US$24.0 million, respectively. For the year ended December 31, 2024 we reported cash inflows of US1.7 million compared to cash outflows of US$2.8 million for 2023. As of December 31, 2024, we had net current assets of US$9.0 million but had an accumulated deficit in equity attributable to the equity holders of the Company of US$79.1 million.

We have made significant progress on a multi-year transformation plan aimed at improving profitability and simplifying our operating model. Key actions implemented include the consolidation and outsourcing of global manufacturing, closure of underutilized facilities, relocation of certain business support functions to lower-cost jurisdictions, and a reduction in overall headcount. These restructuring measures, largely completed by mid-2025, are expected to deliver significant annualized cost savings. Additionally, the Group retains further levers to manage liquidity if required, including deferring projected research and development spend.

A temporary decline in revenue occurred during the first four months of 2025, primarily due to transitional impacts associated with the Group's restructuring initiatives, including the consolidation of manufacturing operations and the transfer of Point-of-Care/HIV products to a third-party contract manufacturing partner. These initiatives have since progressed materially. Sales were also affected by reduced HIV test volumes resulting from uncertainty surrounding potential changes to U.S. foreign aid policy following a presidential executive order. In light of these temporary factors, the Group sought and received a formal waiver from Perceptive in respect of the Q1 2025 minimum revenue covenant, to ensure that no breach occurred under the Perceptive credit facility. In May 2025, the Group signed a buy-sell agreement with a contract manufacturing partner. We also have obtained World Health Organisation ("WHO") approval to commence assembly at the new site. It is expected that WHO approval for full production of our Trinscreen product to be received in July 2025, with approval for full production of our UniGold product expected in August 2025. The directors have alternative options and have prepared financial forecasts to address a scenario whereby WHO approval for production with our contract manufacturing partner takes longer than expected to achieve and the facility takes longer than expected to get up to full operational capacity. In such a scenario, management remain confident that all revenue covenants will be met through to 31 December 2025. In addition, the minimum revenue covenant thresholds for Q2, Q3 and Q4 2025 have been renegotiated to align with the Group's updated forecasts. Accordingly, management is confident in the Group's ability to maintain compliance with its debt covenants for the remainder of the going concern review period. Furthermore, Perceptive have a track record of supporting the Company and, when required, have provided covenant waivers and amendment of terms which indicates an appreciation of the Company's circumstances in terms of our transformational plan for the business and temporary declines in revenue. If a similar need were to recur in the foreseeable future, management are confident of their continued support.

We have also launched a strategic realignment review of our businesses in partnership with Barclays Bank. This process, is expected to make significant progress by the end of 2025 and may generate material capital proceeds that can be potentially used to reduce debt and support investment, including CGM investment.

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

*iii) Basis of preparation (continued)*

In addition, the Group has continued to benefit from strong support from Perceptive, its principal lender and largest investor. On December 23, 2024, we entered into the third amendment and restatement of the credit agreement governing the Term Loan. As part of this agreement, an additional US$2.0 million of funding was made available to us. We also agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. In February 2025, we entered into a fourth amendment to the credit agreement, which provided for an additional US$4.0 million in term loan funding. On May 14, 2025, we entered into a fifth amendment to the credit agreement, which provided for a further US$2.0 million in funding, extended the maturity date of the Term Loan by six months from January 2026 to July 27, 2026, and confirmed that interest payments for the months of April, May, and June 2025 would be paid-in-kind. There are no material debt maturities until July 2026. These successive amendments demonstrate Perceptive's continued support and demonstrate their willingness to flex terms to preserve liquidity while the Company continues to execute its updated strategy, including its comprehensive transformation plan.

Under the fifth amendment to the credit agreement, the minimum liquidity covenant was reduced to US$1 million through to October 31, 2025, after which it reverts to US$3 million. While management is confident in the Group's ability to maintain compliance with this covenant, it is noted that the Group has planned significant R&D expenditure related to its CGM development program in the second half of 2025. However, the Group retains full discretion over the timing and phasing of these activities, which enables management to align expenditure with available funding and preserve liquidity if required.

In addition to lender support, our going concern forecasts include expected equity raises. These funds are expected to support ongoing CGM development activities. The Group has a strong track record of capital raising, including over US$7 million secured in 2024, and maintains active engagement with existing and potential investors. Management believes that the equity raise is achievable based on the Group's strategic focus and transformation progress to date.

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, The directors believe that, based on currently available information and reasonable assumptions, the Group will be able to continue its operations for at least the next 12 months from the year-end date, and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements. The accounting policies have been applied consistently by all Group entities. The comparative information agrees with the amounts and other disclosures presented in the prior period consolidated financial statements or, when appropriate, have been restated.

*iv) Basis of consolidation*

***Subsidiaries***

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases. A change in the ownership interest of a subsidiary without a change in control is accounted for as an equity transaction. The Group currently holds a majority of voting rights in all entities in the Group and as a result there are no non-controlling interests reflected in the consolidated financial statements.

***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.

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.

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

*v) Property, plant and equipment (continued)*

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) Business combinations & goodwill*

At the time of each transaction, the Group evaluates whether the acquisition constitutes a business combination in accordance with the definition in IFRS 3 Business Combinations. A business is defined as an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return. The assessment considers whether the acquired set includes inputs and substantive processes that together significantly contribute to the ability to create outputs. Where such criteria are not met, the transaction is accounted for as an asset acquisition. Transactions assessed as asset acquisitions do not give rise to 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 Irish GAAP.

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.

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

*vi) Business combinations & goodwill (continued)*

At the acquisition date, any goodwill is allocated to each of the Group's cash-generating units expected to benefit from the combination's synergies. Following initial recognition, goodwill is stated at cost less any accumulated impairment losses and is not amortised but is tested annually for impairment.

This policy has been applied to acquisitions completed during the year, including the acquisition of the CGM assets of Waveform Technologies, Inc. in January 2024, and the acquisitions of EpiCapture Limited and Metabolomics Diagnostics Limited, further details of which are disclosed in Note 29 to the consolidated financial statements losses.

*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. In the case of recent acquisitions, the Group has recognised technology-based intangible assets, comprising know-how, trade secrets and similar intellectual property. These assets are classified as finite-lived and are initially recognised at fair value as determined by independent valuation.

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.

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)

*vii) Intangibles, including research and development (other than goodwill) (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. Demand for biosensors is showing high growth in recent years due to the ease of use and the appeal of real time information.

(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.

During the year ended December 31, 2024, the Group capitalised US$7.0 million in development costs related to newly acquired intangible assets. As the underlying intellectual property remains at a pre-commercialisation stage and is not yet available for use, amortisation has not commenced. Amortisation will begin when the assets are brought into use, in accordance with the Group's stated policy.

Technology-based intangible assets acquired as part of business combinations are assigned finite useful lives in line with the Group's amortisation policies, based on independent valuation reports. Amortisation of these assets will commence when they are available for use, i.e., when they are in the location and condition necessary for them to be capable of operating in the manner intended by management. For technology-based intangible assets acquired in 2024, amortisation has not commenced as the technologies have not yet been commercialised.

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 June 30, 2023, December 31, 2023, June 30, 2024 and December 31, 2024. See Note 12.

In-process research and development (IPR&D) is tested for impairment on a bi-annual basis, 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)

*viii) Impairment (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) Financial Assets*

On initial recognition, a financial asset is classified as measured at amortised cost and subsequently measured using the effective interest rate (EIR) method and subject to impairment. Financial assets may also be initially measured at fair value with any movement being reflected through other comprehensive income or the Consolidated Statement of Operations.

On initial recognition of an equity investment that is not held for trading, the Group may irrevocably elect to present subsequent changes in the investment's fair value in other comprehensive income. This election is made on an investment-by investment basis.

Where such an election is not made, and the investment is not held for trading, the equity instrument is classified as measured at fair value through profit or loss (FVTPL). Subsequent changes in fair value are recognised in the Consolidated Statement of Operations. During 2024, the Group acquired a strategic equity interest in an unlisted entity accounted for under this classification. Refer to Note 13.

Financial assets are written off when there is no reasonable expectation of recovery, such as when the debtor has entered bankruptcy, when collection efforts have been exhausted, or when the asset has been significantly past due (typically over 365 days) without any recent payments or active correspondence. The Group considers both quantitative factors (such as aging) and qualitative indicators (e.g., legal or insolvency proceedings) in making this assessment. Where receivables are written off but remain subject to enforcement activity, such as legal action or engagement with collection agencies, these efforts are continued until formally closed.

*x) 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.

*xi) 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.

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

*xii) 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.

*xiii) 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.

*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.

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

*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.

If it is no longer reasonably assured that the terms of forgiveness will be met, any income previously recognised in respect of such a loan is reversed in the period in which the change in assessment occurs. 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 on a systematic basis over the useful life of the asset. R&D tax credits claimed from tax authorities are credited to the taxation line in the consolidated statement of operations.

*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.

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.

Revenue is recognised on bill-and-hold transactions when all of the criteria in IFRS 15 are met, including: (i) the arrangement is at the customer's request and has a substantive business reason; (ii) the products are separately identified as belonging to the customer; (iii) the products are ready for physical transfer to the customer; and (iv) the Group has no ability to use the products or redirect them to another customer. The Group assesses each bill-and-hold arrangement individually for compliance with these criteria. When all criteria are satisfied, control is deemed to have transferred and revenue is recognised.

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).

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

*xvi) Revenue recognition (continued)*

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 recognised them as expense as they are incurred.

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 22 for details.

*xvi) Other operating income*

Other operating income primarily includes items of income that arise outside the normal course of business, including government grant income from forgiven loans, insurance proceeds, sublease income, and other non-recurring items. Income is recognised when it is probable that the economic benefits associated with the transaction will flow to the Group and the amount can be measured reliably.

During the year ended December 31, 2024, other operating income included the reversal of $1.8 million previously recognised in relation to the forgiveness of Paycheck Protection Program (PPP) loans. This reversal was recognised following the commencement of a U.S. Department of Justice investigation regarding the eligibility of certain U.S. subsidiaries for loan forgiveness.

*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.

*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 and the functional currency of the Canadian subsidiary is the Canadian Dollar.

The presentation currency of the Company and Group is the US Dollar. Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the balance sheet date. The resulting gains and losses are included in the 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.

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

*xviii) Foreign currency (continued)*

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, or Canadian Dollar 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, 2024.

*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.

*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.

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

*xxi) Senior secured term loan (continued)*

In accordance with IFRS 9, the Group assesses any changes to the contractual terms of its borrowings to determine whether such changes result in a substantial modification. A modification is considered substantial if the revised cash flows differ significantly from those of the original arrangement, in which case the original liability is derecognised and a new financial liability is recognised. If a modification is not substantial, the loan is remeasured using the original EIR, with any resulting gain or loss recognised in profit or loss.

During 2024, the Group amended the terms of its senior secured term loan; however, this was assessed under IFRS 9 and determined not to constitute a substantial modification. Refer to Note 23 for further details.

*xxii) Warrants and loan prepayment option*

The Company has issued warrants to third parties. 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 and contingent liabilities*

A provision is recognised in the balance sheet when the Group has a present legal or constructive obligation because of a past event, and it is probable that an outflow of economic benefits will be required to settle the obligation. The status of any significant claim and legal proceeding in which the Group 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.

Due to the uncertainties inherent in such matters, the related provisions are based on the best information available at the time. As additional information becomes available on pending claims, the potential liability is reassessed and revisions are made to the amounts accrued as appropriate. Such revisions in the judgments and estimates of the potential liabilities could have an impact on the results of operations and financial position of the Group in future accounting periods.

Provisions for restructuring costs are recognised only when the Group has approved a detailed formal plan and has either commenced implementation or raised a valid expectation among those affected that the restructuring will be carried out. Under IAS 37, restructuring provisions must only include direct expenditures that are necessarily incurred by the restructuring and not associated with the ongoing activities of the business.

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

*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.

*xxix) 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 and any gain or loss on disposal.

*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

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

*xxxiii) New IFRS Standards*

The following new accounting standards and interpretations became effective for annual periods beginning on or after 1 January 2024. The adoption of these standards did not have a material impact on the Group's consolidated financial statements:

- Classification of Liabilities as Current or Non-current (Amendments to IAS 1)
- Lease Liability in a Sale and Leaseback (Amendments to IFRS 16)
- Supplier Finance Arrangements (Amendments to IAS 7 and IFRS 7)

The Company is currently assessing the impact of the new standards and amendments on the Company's accounting policy disclosure.

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

The standards and amendments that have been issued but are not yet effective as at the date of issuance of the financial statements, and which may have an impact on the Group's financial statements in future periods, are listed below. The Group intends to adopt these standards, if applicable, when they become effective:

- Lack of Exchangeability (Amendments to IAS 21), effective from 1 January 2025
- Amendments to the Classification and Measurement of Financial Instruments (Amendments to IFRS 9 and 7), effective from 1 January 2026
- Annual Improvements to IFRS Accounting Standards, effective from 1 January 2026
- IFRS 18 'Presentation and Disclosure in Financial Statements', effective from 1 January 2027
- IFRS 19 'Subsidiaries without Public Accountability: Disclosures', effective from 1 January 2027

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 Group's products must comply with various regulators worldwide in the markets that we serve.

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**<br>*Year ended December 31, 2024* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Eliminations*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| Revenue from external customers | 41,792 | 19,763 | - | 61,555 |
| Inter-segment revenue | 19,815 | 702 | (20,517) | - |
| Total revenue | 61,607 | 20,465 | (20,517) | 61,555 |

| **Revenue**<br>*Year ended December 31, 2023* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Eliminations*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| Revenue from external customers | 44,984 | 11,848 | - | 56,832 |
| Inter-segment revenue | 21,867 | 872 | (22,739) | - |
| Total revenue | 66,851 | 12,720 | (22,739) | 56,832 |

2. SEGMENT INFORMATION (CONTINUED)

| **Revenue**<br>*Year ended December 31, 2022* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Eliminations*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| Revenue from external customers | 50,508 | 12,013 | - | 62,521 |
| Inter-segment revenue | 26,110 | 828 | (26,938) | - |
| Total revenue | 76,618 | 12,841 | (26,938) | 62,521 |

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

| **Revenue** | *December 31, 2024*<br>*US$'000* | *December 31, 2023*<br>*US$'000* | *December 31, 2022*<br>*US$'000* |
|---|---|---|---|
| Americas | 29,917 | 32,282 | 35,557 |
| Asia / Africa | 24,775 | 18,909 | 20,401 |
| Europe (including Ireland) * | 6,863 | 5,641 | 6,563 |
| | 61,555 | 56,832 | 62,521 |

* 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, 2024*<br>*US$'000* | *December 31, 2023*<br>*US$'000* | *December 31, 2022*<br>*US$'000* |
|---|---|---|---|
| Clinical laboratory goods | 39,372 | 42,288 | 46,036 |
| Clinical laboratory services | 4,750 | 5,453 | 7,272 |
| Point-of-care | 17,433 | 9,091 | 9,213 |
| | 61,555 | 56,832 | 62,521 |

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

| **Revenue** | *December 31, 2024*<br>*US$'000* | *December 31, 2023*<br>*US$'000* | *December 31, 2022*<br>*US$'000* |
|---|---|---|---|
| Revenue from contracts with customers | 61,555 | 56,832 | 62,521 |
| | 61,555 | 56,832 | 62,521 |

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**<br>*Year ended December 31, 2024* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|
| At a point in time | 41,536 | 19,763 | 61,299 |
| Over time | 256 | - | 256 |
| Total | 41,792 | 19,763 | 61,555 |

| **Timing of revenue recognition**<br>*Year ended December 31, 2023* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|
| At a point in time | 44,692 | 11,848 | 56,540 |
| Over time | 292 | - | 292 |
| Total | 44,984 | 11,848 | 56,832 |

| **Timing of revenue recognition**<br>*Year ended December 31, 2022* | *Americas*<br>*US$'000* | *Rest of World Ireland*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|
| At a point in time | 50,174 | 12,013 | 62,187 |
| Over time | 334 | - | 334 |
| Total | 50,508 | 12,013 | 62,521 |

(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**<br>*Year ended December 31, 2024* | *Americas*<br>*US$'000* | *Asia / Africa*<br>*US$'000* | *Europe*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| At a point in time | 29,661 | 24,775 | 6,863 | 61,299 |
| Over time | 256 | - | - | 256 |
| Total | 29,917 | 24,775 | 6,863 | 61,555 |

| **Timing of revenue recognition**<br>*Year ended December 31, 2023* | *Americas*<br>*US$'000* | *Asia / Africa*<br>*US$'000* | *Europe*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| At a point in time | 31,990 | 18,909 | 5,641 | 56,540 |
| Over time | 292 | - | - | 292 |
| Total | 32,282 | 18,909 | 5,641 | 56,832 |

2. SEGMENT INFORMATION (CONTINUED)

| **Timing of revenue recognition**<br>*Year ended December 31, 2022* | *Americas*<br>*US$'000* | *Asia / Africa*<br>*US$'000* | *Europe*<br>*US$'000* | *Total*<br>*US$'000* |
|---|---|---|---|---|
| At a point in time | 35,223 | 20,401 | 6,563 | 62,187 |
| Over time | 334 | - | - | 334 |
| Total | 35,557 | 20,401 | 6,563 | 62,521 |

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

| | | *Rest of World* | | |
|---|---|---|---|---|
| *Year ended December 31, 2024* | *Americas*<br>*US$'000* | *Ireland*<br>*US$'000* | *Other*<br>*US$'000* | *Total*<br>*US$'000* |
| **Result before restructuring costs, impairment and unallocated expenses** | (2,503) | (9,386) | (315) | (12,204) |
| Restructuring costs | (2,025) | (2,156) | | (4,181) |
| Impairment charges | (612) | (796) | - | (1,408) |
| **Result after impairment** | (5,140) | (12,338) | (315) | (17,793) |
| Unallocated expenses * | | | | (3,372) |
| Operating loss | | | | (21,165) |
| Net financing expense (Note 6) | | | | (9,565) |
| Loss before tax | | | | (30,730) |
| Income tax credit (Note 7) | | | | (486) |
| Loss for the year on continuing operations | | | | (31,216) |
| Loss for the year on discontinued operations (Note 8) | | | | (573) |
| Loss for the year | | | | (31,789) |

| | | *Rest of World* | | |
|---|---|---|---|---|
| *Year ended December 31, 2023* | *Americas*<br>*US$'000* | *Ireland*<br>*US$'000* | *Other*<br>*US$'000* | *Total*<br>*US$'000* |
| **Result before restructuring costs, impairment and unallocated expenses** | (4,365) | (7,886) | (104) | (12,355) |
| Impairment charges | (11,105) | - | - | (11,105) |
| **Result after impairment** | (15,470) | (7,886) | (104) | (23,460) |
| Unallocated expenses * | | | | (3,585) |
| Operating loss | | | | (27,045) |
| Net financing expense (Note 6) | | | | (9,882) |
| Loss before tax | | | | (36,927) |
| Income tax charge (Note 7) | | | | 59 |
| Loss for the year on continuing operations | | | | (36,868) |
| Profit for the year on discontinued operations (Note 8) | | | | 12,850 |
| Loss for the year | | | | (24,018) |

2. SEGMENT INFORMATION (CONTINUED)

| | | Rest of World | | |
|---|---|---|---|---|
| *Year ended December 31, 2022* | *Americas US$'000* | *Ireland US$'000* | *Other US$'000* | *Total US$'000* |
| **Result before restructuring costs, impairment and unallocated expenses** | (5,892) | (5,112) | (33) | (11,037) |
| Impairment | (2,331) | (3,508) | - | (5,839) |
| **Result after impairment** | (8,223) | (8,620) | (33) | (16,876) |
| Unallocated expenses * | | | | (2,473) |
| Operating loss | | | | (19,349) |
| Net financing expense (Note 6) | | | | (24,431) |
| Loss before tax | | | | (43,780) |
| Income tax credit (Note 7) | | | | 194 |
| Loss for the year on continuing operations | | | | (43,586) |
| Profit for the year on discontinued operations (Note 8) | | | | 2,577 |
| Loss for the year | | | | (41,009) |

* 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, 2024* | *Americas US$'000* | *Ireland US$'000* | *Other US$'000* | *Total US$'000* |
| **Assets and liabilities** | | | | |
| Segment assets | 32,798 | 61,254 | - | 94,052 |
| *Unallocated assets:* | | | | |
| Income tax assets (current and deferred) | | | | 4,071 |
| Cash and cash equivalents and short-term investments | | | | 5,167 |
| Total assets as reported in the Group balance sheet | | | | 103,290 |
| Segment liabilities | 84,863 | 48,621 | 62 | 133,546 |
| *Unallocated liabilities:* | | | | |
| Income tax liabilities (current and deferred) | | | | 4,925 |
| Total liabilities as reported in the Group balance sheet | | | | 138,471 |

2. SEGMENT INFORMATION (CONTINUED)

| | | Rest of World | | |
|---|---|---|---|---|
| *As at December 31, 2023* | *Americas US$'000* | *Ireland US$'000* | *Other US$'000* | *Total US$'000* |
| **Assets and liabilities** | | | | |
| Segment assets | 26,230 | 26,023 | - | 52,253 |
| *Unallocated assets:* | | | | |
| Income tax assets (current and deferred) | | | | 3,491 |
| Cash and cash equivalents and short-term investments | | | | 3,691 |
| Total assets as reported in the Group balance sheet | | | | 59,435 |
| Segment liabilities | 49,398 | 31,387 | 20 | 80,805 |
| *Unallocated liabilities:* | | | | |
| Income tax liabilities (current and deferred) | | | | 2,579 |
| Total liabilities as reported in the Group balance sheet | | | | 83,384 |

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, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Rest of World – Ireland | 43,504 | 12,448 |
| Americas | 14,943 | 5,793 |
| | 58,447 | 18,241 |

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

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| ***Depreciation:*** | | | |
| Rest of World – Ireland | 160 | 162 | 123 |
| Americas | 515 | 668 | 1,282 |
| | 675 | 830 | 1,405 |
| ***Amortisation:*** | | | |
| Rest of World – Ireland | 770 | 458 | 89 |
| Americas | 420 | 487 | 800 |
| | 1,190 | 945 | 889 |

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

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | 843 | 1,650 | 632 |
| Americas | 473 | 419 | 1,123 |
| | 1,316 | 2,069 | 1,755 |

See Note 20 for further information on share-based payments.

2. SEGMENT INFORMATION (CONTINUED)

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

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | (5) | (385) | 286 |
| Rest of World – Other | 9 | (235) | (4) |
| Americas | (490) | 679 | (88) |
| | (486) | 59 | 194 |

xiii) During 2024, 2023 and 2022 there were no customers generating 10% or more of total revenues.

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

| | *December 31 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Rest of World – Ireland | 37,929 | 251 |
| Americas | 2,753 | 2,547 |
| | 40,682 | 2,798 |

Capital expenditure for the year ended December 31, 2024 includes significant additions arising from the acquisitions of Waveform assets, EpiCapture Limited, and Metabolomics Diagnostic Limited (see Note 29). In addition, capitalised development costs increased from US$1.8 million in 2023 to US$8.6 million in 2024, reflecting investment in development of newly acquired intangible assets.

3. EMPLOYMENT

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

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Research and development | 33 | 23 | 26 |
| Administration and sales | 82 | 99 | 105 |
| Manufacturing and quality | 286 | 258 | 253 |
| | 401 | 380 | 384 |

The average number of employees, including discontinued operations, was 401 (2023: 383; 2022: 398).

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

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Wages and salaries | 25,570 | 23,718 | 22,364 |
| Social welfare costs | 2,219 | 2,061 | 1,965 |
| Pension costs | 451 | 508 | 347 |
| Share-based payments | 1,316 | 2,069 | 1,755 |
| Restructuring cost | 596 | 485 | 274 |
| | 30,152 | 28,841 | 26,705 |

3. EMPLOYMENT (CONTINUED)

Employment costs are shown net of capitalisations and Irish government wage subsidies. There were no Irish government wage subsidies netted against employment costs in the year ended December 31, 2024. Total employment costs, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2024, amounted to US$33,584,000 (2023: US$29,975,000) (2022: US$27,528,000). Total share-based payments in the balance sheet amounted to US$1,316,000 for the year ended December 31, 2024 (2023: US$2,069,000) (2022: US$1,755,000). See Note 20 for further details.

Employment costs including discontinued operations, are analysed as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Wages and salaries | 25,570 | 24,343 | 23,608 |
| Social welfare costs | 2,219 | 2,097 | 2,036 |
| Pension costs | 451 | 510 | 352 |
| Share-based payments | 1,316 | 2,069 | 1,755 |
| Restructuring cost | 596 | 485 | 274 |
| | 30,152 | 29,504 | 28,025 |

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 in respect of continuing operations amounted to US$451,000 (2023: US$508,000) (2022: US$347,000). The pension accrual for the Group at December 31, 2024 was US$nil (2023: US$56,000) (2022: US$44,000).

4. OTHER OPERATING (EXPENSE) / INCOME

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Other income | 40 | 138 | - |
| Rental income from premises | - | 3 | 3 |
| Government supports | (1,827) | - | 7 |
| Government grants | - | - | 333 |
| | (1,787) | 141 | 343 |

The other income for year ended December 31, 2024 relates to income from a transition services agreement with the acquirers of Fitzgerald Industries for the provision of bookkeeping and I.T. services.

In October 2024, the Company was notified that it is the subject of a U.S. Department of Justice (DOJ) investigation relating to second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries. At year-end, a payable of US$2,165,000 was recognised, covering the US$1,827,000 in loans and estimated interest of US$338,000. As the original loan income was recognised in other operating income, the reversal to the extent of the loan to be repaid has been recorded as a corresponding charge to other operating (expense)/income, noted as “Government supports”. The interest costs incidental to the loan repayment has been charged to finance costs.

5. IMPAIRMENT, RESTRUCTURING AND ONCE OFF COSTS

Impairment charges

In accordance with IAS 36, *Impairment of Assets*, the Company 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 December 31 2024, 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, 2024, 2023, and 2022 are as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| *Selling, general & administration expenses* | | | |
| Impairment of PP&E (Note 11) | 612 | 3,772 | 733 |
| Impairment of goodwill and other intangible assets (Note 12) | 1,596 | 5,833 | 4,624 |
| Impairment of prepayments (Note 17) | - | - | 482 |
| (Reversal)/Impairment of financial assets (Note 13) | (800) | 1,500 | - |
| **Total impairment loss** | **1,408** | **11,105** | **5,839** |

Restructuring costs

During the year ended December 31, 2024, the Group undertook a comprehensive business transformation program aimed at improving long-term operational efficiency and aligning the organization with its strategic priorities. These changes were previously communicated to the market and include operationally profitability measures, organizational realignment, and changes to business unit structures.

As a result, the Group recognized restructuring costs of US$4.2 million (2023: US$nil) (2022: US$nil) which are presented separately in the consolidated statement of operations within 'Selling, general and administrative expenses – Restructuring costs'.

The restructuring costs incurred during the year comprised the following:

| | *December 31, 2024 US$'000* |
|---|---|
| *Nature of cost* | |
| Personnel related costs | 1,216 |
| Outsourcing costs | 754 |
| Site transfer costs | 1,281 |
| Inventory related costs | 772 |
| Other restructuring costs | 158 |
| **Total restructuring costs** | **4,181** |

Included within Site transfer costs above is US$356,000 related to the impairment of plant & equipment arising as part of the restructuring program. Refer to Note 11. We have provided for additional restructuring costs of US$1.6 million as at December 31, 2024 (see Note 22).

5. IMPAIRMENT, RESTRUCTURING AND ONCE OFF COSTS (CONTINUED)

Once off costs

During the year ended 31 December 2024, the Company incurred exceptional, non-trading costs totaling US$1.9 million, which is made up as follows:

In October 2024, the Company issued 650,000 American Depositary Shares ("ADSs") to a corporate finance advisor as a non-refundable retainer fee in respect of advisory services provided in connection with a planned future equity raise. The fair value of the ADSs issued, amounting to US$1.1 million, was recognized directly in equity, with a corresponding charge recorded within the consolidated statement of operations as an exceptional cost.

During the year, the Company recognized a provision of US$0.7 million in respect of a legacy matter currently subject to resolution. Owing to the sensitive nature of ongoing discussions, further disclosure has been withheld in accordance with IAS 37.92, as the Directors believe such disclosure could seriously prejudice the Company's position.

6. FINANCIAL INCOME AND EXPENSES

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Financial income: | | | |
| Non-cash financial income | - | 1,171 | 303 |
| | | | |
| Financial expense: | | | |
| Interest on leases (Note 24) | (592) | (624) | (647) |
| Loss on disposal of exchangeable notes (Note 23) | - | - | (9,678) |
| Penalty for early partial settlement of senior secured term loan (Note 23,28) | - | (905) | (3,450) |
| Cash interest payable on senior secured term loan | (6,293) | (7,289) | (7,039) |
| Cash interest payable on convertible note | (300) | (300) | (199) |
| Cash interest on exchangeable notes | (8) | (8) | (296) |
| Cash interest payable on PPP loans (Note 4) | (338) | - | - |
| Non-cash interest on exchangeable notes | - | - | (84) |
| Non-cash interest on senior secured term loan (Note 23) | (2,355) | (1,131) | (2,772) |
| Non-cash interest on convertible note | (859) | (796) | (495) |
| Non-cash financial expense | (1,172) | - | (74) |
| Unwinding of discount on deferred contingent consideration | (53) | - | - |
| Capitalisation of borrowing costs | 2,085 | - | - |
| Non-cash loan modification gain (Note 23,28) | 3,567 | - | - |
| Capitalisation of unpaid interest on term loan | (3,247) | - | - |
| | (9,565) | (11,053) | (24,734) |
| Net financing expense | (9,565) | (9,882) | (24,431) |

For more information on the senior secured term loan, convertible note and exchangeable notes, refer to Note 23 Interest-Bearing Loans and Borrowings.

Non-cash financial expense relates to the fair value loss on warrant liabilities during the year. Refer to Note 23 for further details.

7. INCOME TAX (EXPENSE)/CREDIT

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| *Current tax expense/(credit)* | | | |
| Irish Corporation tax | 21 | - | (336) |
| Foreign taxes (a) | 254 | 462 | (5) |
| Adjustment in respect of prior years | 10 | (198) | 61 |
| Total current tax expense/(credit) | 285 | 264 | (280) |
| *Deferred tax credit* (b) | | | |
| Origination and reversal of temporary differences (see Note 14) | (41) | (547) | 324 |
| Origination and reversal of net operating losses (see Note 14) | 242 | 224 | (238) |
| Total deferred tax charge/(credit) | 201 | (323) | 86 |
| Total income tax charge/(credit) on continuing operations in statement of operations | 486 | (59) | (194) |
| Tax charge on discontinued operations (see Note 8) | - | - | 2 |
| Total tax charge/(credit) | 486 | (59) | (192) |

(a) In 2024, the foreign taxes relate primarily to Luxembourg and Canada.

(b) In 2024, there was a deferred tax credit of US$43,000 (2023: charge of US$174,000) (2022: charge of US$109,000) recognised in respect of Ireland and a deferred tax charge of US$244,000 (2023: credit of US$497,000) (2022: credit of US$26,000) recognised in respect of overseas tax jurisdictions.

| *Effective tax rate* | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Loss before taxation – continuing operations (US$'000) | (30,730) | (36,927) | (43,780) |
| As a percentage of loss before tax: | | | |
| Current tax % | (0.93)% | (0.72)% | (0.64)% |
| Total (current and deferred) % | (1.58)% | (0.16)% | (0.44)% |

7. INCOME TAX (EXPENSE)/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, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| 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) | 15.89% | 17.19% | 10.97% |
| Effect of tax rates on overseas earnings | 6.63% | (7.82)% | (7.30)% |
| Effect of Irish income taxable at higher tax rate | (4.09)% | 2.62% | 3.93% |
| Adjustments in respect of prior years | 0.04% | (0.53)% | 0.14% |
| R&D tax credits | - | - | (0.75)% |
| Other items (b) | (7.55)% | 0.88% | 5.07% |
| Effective tax rate | (1.58)% | (0.16)% | (0.44)% |

(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. In 2022, other items mainly related to the loss on disposal of the exchangeable notes which was non-recurring.

The distribution of loss before taxes by geographical area was as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | (17,296) | (12,922) | (22,354) |
| Rest of World – Other | (315) | (104) | (33) |
| Americas | (13,119) | (23,901) | (21,393) |
| | (30,730) | (36,927) | (43,780) |

At December 31, 2024, the Group had unutilised net operating losses for continuing operations as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | 107,093 | 69,851 | 62,731 |
| Rest of World – Other | 52,852 | 52,511 | 448 |
| Americas | 22,866 | 13,840 | 12,778 |
| | 182,811 | 136,202 | 75,957 |

7. INCOME TAX (EXPENSE)/CREDIT (CONTINUED)

At December 31, 2024, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Rest of World – Ireland – unused tax losses | 13,275 | 8,464 | 7,489 |
| Rest of World – Other – unused tax losses | 14,777 | 14,701 | 124 |
| Americas – unused tax losses | 2,149 | 3,395 | 3,163 |
| Americas – unused tax credits | 5,702 | 5,806 | 4,658 |
| | | | |
| Unrecognised deferred tax asset | 35,903 | 32,366 | 15,434 |

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)/PROFIT FOR THE YEAR ON DISCONTINUED OPERATIONS

In April 2023, the Company announced 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 results of Fitzgerald Industries were presented as discontinued operations in the 2023 financial statements.

During 2024, the Company recognised additional costs related to the 2023 disposal of Fitzgerald Industries, following a settlement agreement with Biosynth that was finalised prior to year-end and formally signed in January 2025. A provision of US$150,000 was recorded in respect of the full and final settlement of all post-completion claims. In addition, outstanding receivables of US$423,000 from Biosynth relating to completion account adjustments were written off as unrecoverable under the terms of the settlement.

The operating profit for the discontinued operations are summarised as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Revenue | - | 2,784 | 12,258 |
| Operating expenses | - | (2,652) | (9,679) |
| Tax expense (Note 7) | - | - | (2) |
| | | | |
| Profit from operating activities | - | 132 | 2,577 |
| | | | |
| (Loss)/Gain on sale of discontinued operations | (573) | 12,718 | - |
| | | | |
| **(Loss)/Profit for the year from discontinued operations** | **(573)** | **12,850** | **2,577** |

8. (LOSS)/PROFIT FOR THE YEAR ON DISCONTINUED OPERATIONS (CONTINUED)

The net cashflows generated from discontinued operations are as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Cash received from sale of the discontinued operations net of transaction costs | - | 28,935 |
| Cash sold as a part of discontinued operations | - | (775) |
| **Net cash inflow on date of disposal** | **-** | **28,160** |

The following amounts relating to the Biosynth transaction were recognised in 2024 as post-disposal adjustments, reflecting the write-off of receivables and provision for settlement costs:

| | *Net assets disposed in 2023 US$'000* | *Post disposal adjustment US$'000* | *Net assets disposed/ adjusted US$'000* |
|---|---|---|---|
| Property plant & equipment | 103 | - | 103 |
| Goodwill and intangible assets | 14,123 | - | 14,123 |
| Inventory | 1,160 | - | 1,160 |
| Cash | 775 | - | 775 |
| Trade and other receivables | 1,309 | (423) | 886 |
| Trade and other payables | (864) | (150) | (1,014) |
| Lease liabilities | (106) | - | (106) |
| Current corporation tax | (2) | - | (2) |
| Deferred tax liability | (195) | - | (195) |
| Total net assets disposed | 16,303 | (573) | 15,730 |

The consideration from the sale of Fitzgerald Industries which was receivable as at December 31, 2024 was US$Nil (2023: US$373,000) (refer to Note 17).

*Basic (loss)/earnings per ordinary share – discontinued operations*

Basic (loss)/earnings per ordinary share for discontinued operations is computed by dividing the profit/ (loss) after taxation on discontinued operations of US$(573,000), (2023: US$12,850,000) (2022: US$2,577,000) for the financial year by the weighted average number of 'A' ordinary shares in issue as at December 31, 2024, this amounted to 359,193,482 shares (2023: 153,099,405 shares) (2022: 134,939,327 shares), see Note 10 for further details.

*Diluted (loss)/earnings/ per ordinary share – discontinued operations*

Diluted (loss)/earnings per ordinary share for discontinued operations is computed by dividing the profit/ (loss) after taxation on discontinued operations of US$(573,000), (2023: US$12,850,000) (2022: US$2,577,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 404,096,277 shares (2023: 178,016,062 shares) (2022: 155,498,651 shares), see Note 10 for further details.

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

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Basic (loss)/earnings per 'A' share (US Dollars) – discontinued operations | (0.00) | 0.08 | 0.02 |
| Diluted (loss)/earnings per 'A' share (US Dollars) – discontinued operations | (0.00) | 0.07 | 0.02 |

*Basic (loss)/earnings per ADS – discontinued operations*

In February 2024, the Company changed the ratio of the ADSs representing its 'A' ordinary shares from one (1) ADS representing four (4) 'A' ordinary shares to one (1) ADS representing twenty (20) 'A' ordinary shares.

Basic earnings per ADS for discontinued operations is computed by dividing the profit/(loss) after taxation on discontinued operations of US$(573,000), (2023: US$12,850,000) (2022: US$2,577,000) for the financial year by the weighted average number of ADS in issue of 17,959,674 (2023: 7,654,970) (2022: 6,746,966), see Note 10 for further details.

*Diluted (loss)/earnings per ADS – discontinued operations*

Diluted earnings per ADS for discontinued operations is computed by dividing the profit/ (loss) after taxation on discontinued operations of US$(573,000), (2023: US$12,850,000) (2022: US$2,577,000) for the financial year, by the diluted weighted average number of ADS in issue of 20,204,814 (2023: 8,900,803) (2022: 7,774,933), see Note 10 for further details.

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Basic (loss)/earnings per ADS (US Dollars) – discontinued operations | (0.03) | 1.68 | 0.38 |
| Diluted (loss)/earnings per ADS (US Dollars) – discontinued operations | (0.03) | 1.44 | 0.33 |

*Cash flows*

The cash flows attributable to discontinued operations are as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* | *December 31, 2022 US$000* |
|---|---|---|---|
| Cash (outflow)/inflow from operating activities | - | (177) | 3,798 |
| Cash inflow from investing activities | - | 28,160 | - |
| Cash outflow from financing activities | - | - | (10,800) |

There were no cash inflows from discontinued operations during the year ended December 31, 2024.

9. LOSS BEFORE TAX

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

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Directors' emoluments (including non- executive directors): | | | |
| Remuneration | 1,454 | 2,058 | 1,639 |
| Pension | 39 | 26 | 24 |
| Share based payments (Note 26) | 931 | 1,601 | 1,707 |
| Auditor's remuneration | | | |
| Audit fees | 1,082 | 861 | 888 |
| Tax fees | 175 | 407 | 89 |
| Depreciation (Note 11) [1] | 675 | 830 | 1,405 |
| Amortisation (Note 12) | 1,190 | 945 | 889 |
| Loss on the disposal of property, plant and equipment | - | - | 2 |
| Net foreign exchange differences | 376 | 336 | (1,210) |

[1] In 2024, US$204,000 was capitalised to research and development projects (2023: US$Nil) (2022: US$Nil).

Depreciation for discontinued operations for the year ended December 31, 2024 is US$Nil (2023: US$1,000) (2022:US$5,000)

Amortisation for discontinued operations for the year ended December 31, 2024 is US$Nil (2023: US$1,000) (2022:US$34,000).

10. LOSS PER SHARE

*Basic loss per ordinary share*

Basic loss per ordinary share is calculated by dividing the net loss attributable to owners of the parent of US$31,789,000 (2023: loss of US$24,018,000) (2022: loss of US$41,009,000) by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year. Basic loss per ordinary share from continuing operations is calculated by dividing the loss from continuing operations attributable to owners of the parent of US$31,216,000 (2023: loss of US$36,868,000) (2022: loss of US$43,586,000) by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year.

As at December 31, 2024, the number of 'A' ordinary shares for the purposes of the calculation of basic loss per share are 359,193,482 shares (2023: 153,099,405 shares) (2022: 134,939,327 shares).

10. LOSS PER SHARE (CONTINUED)

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| 'A' ordinary shares | 359,193,482 | 153,099,405 | 134,939,327 |
| Basic loss per share denominator | 359,193,482 | 153,099,405 | 134,939,327 |
| *Reconciliation to weighted average loss per share denominator:* | | | |
| Number of 'A' ordinary shares at January 1 (Note 19) | 165,865,882 | 164,985,882 | 96,162,410 |
| Weighted average number of 'A' ordinary shares issued during the year* | 205,883,200 | 669,123 | 51,332,517 |
| Weighted average number of treasury shares | (12,555,600) | (12,555,600) | (12,555,600) |
| Basic loss per share denominator | 359,193,482 | 153,099,405 | 134,939,327 |

*The weighted average number of shares issued during the year is calculated by taking the number of shares issued multiplied by the number of days in the year each share is in issue, divided by 365 days.

*Diluted loss per ordinary share*

Diluted loss per ordinary share is calculated by dividing the net loss 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 per 'A' ordinary share and diluted loss 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 per 'A' ordinary share.

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Potentially Dilutive Instruments: | | | |
| Issuable on exercise of options (Note 20) | - | 186,908 | 2,752,153 |
| Issuable on exercise of warrants to Perceptive (Note 23) | 20,173,151 | - | - |
| Issuable on conversion of Exchangeable notes (Note 23) | 38,391 | 38,391 | 1,436,463 |
| Issuable on conversion of Convertible notes (Note 23) | 24,691,358 | 24,691,358 | 16,370,709 |
| Total number of potentially dilutive instruments excluded from the weighted average number of 'A' ordinary shares in calculating dilutive loss per 'A' ordinary share | 44,902,900 | 24,916,657 | 20,559,325 |

Of the 'A' ordinary shares issuable on exercise of options, NIL 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.

10. LOSS PER SHARE (CONTINUED)

*Loss per ADS*

In February 2024, the Company changed the ratio of the ADSs representing its 'A' ordinary shares from one (1) ADS representing four (4) 'A' ordinary shares to one (1) ADS representing twenty (20) 'A' ordinary shares.

Basic loss per ADS is calculated by dividing the loss attributable to owners of the parent of US$31,789,000 (2023: loss of US$24,018,000) (2022: loss of US$41,009,000) by the weighted average number of ADS in issue, net of any Treasury Shares, during the year. Basic loss per ADS from continuing operations is calculated by dividing the loss of US$31,216,000 (2023: loss of US$36,868,000) (2022: loss of US$43,586,000) by the weighted average number of ADS in issue, net of any Treasury Shares, during the year.

As at December 31, 2024, the number of ADS for the purposes of the calculation of basic loss per ADS were 17,959,674 ADS (2023: 7,654,970 ADS) (2022: 6,746,966 ADS).

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| ADS | 17,959,674 | 7,654,970 | 6,746,966 |
| Basic loss per ADS denominator | 17,959,674 | 7,654,970 | 6,746,966 |
| *Reconciliation to weighted average loss per ADS denominator:* | | | |
| Number of ADS at January 1 (Note 19) | 8,293,294 | 8,249,294 | 4,808,120 |
| Weighted average number of shares issued during the year* | 10,294,160 | 33,456 | 2,566,626 |
| Weighted average number of treasury shares | (627,780) | (627,780) | (627,780) |
| Basic loss per ADS denominator | 17,959,674 | 7,654,970 | 6,746,966 |

*The weighted average number of ADSs issued during the year is calculated by taking the number of ADSs issued multiplied by the number of days in the year each share is in issue, divided by 365 days.

*Diluted loss per ADS*

Diluted loss per ADS is calculated by dividing the net loss 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 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.

10. LOSS PER SHARE (CONTINUED)

| | *December 31, 2024* | *December 31, 2023* | *December 31, 2022* |
|---|---|---|---|
| Potentially Dilutive Instruments: | | | |
| Issuable on exercise of options (Note 20) | - | 9,345 | 137,608 |
| Issuable on exercise of warrants to Perceptive (Note 23) | 1,008,658 | - | - |
| Issuable on conversion of Exchangeable notes (Note 23) | 1,920 | 1,920 | 71,823 |
| Issuable on conversion of Convertible notes (Note 23) | 1,234,568 | 1,234,568 | 818,535 |
| Total number of potentially dilutive instruments excluded from the weighted average number of ADS in calculating dilutive loss per ADS | 2,245,146 | 1,245,833 | 1,027,966 |

Of the ADS issuable on exercise of options, NIL 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.

11. PROPERTY, PLANT AND EQUIPMENT

| | *Land & Buildings US$'000* | *Leasehold Improvements US$'000* | *Computer & Office Equipment US$'000* | *Plant & Equipment, Vehicles US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| *Cost* | | | | | |
| At January 1, 2023 | 24,682 | 2,701 | 4,540 | 33,683 | 65,606 |
| Additions | 55 | 87 | 173 | 596 | 911 |
| Disposals or retirements | (480) | (40) | (115) | (220) | (855) |
| Reallocations/ reclassifications | - | (8) | 8 | - | - |
| Exchange adjustments | 11 | 20 | 6 | 370 | 407 |
| At December 31, 2023 | 24,268 | 2,760 | 4,612 | 34,429 | 66,069 |
| At January 1, 2024 | 24,268 | 2,760 | 4,612 | 34,429 | 66,069 |
| Additions# | 752 | - | 150 | 478 | 1,380 |
| Additions through acquisition (Note 29) | - | 51 | 582 | 740 | 1,373 |
| Disposals or retirements | - | - | - | (14) | (14) |
| Remeasurement of ROU assets | 1,764 | - | - | - | 1,764 |
| Reallocations/ reclassifications | - | - | - | 53 | 53 |
| At December 31, 2024 | 26,784 | 2,811 | 5,344 | 35,686 | 70,625 |
| *Accumulated depreciation and Impairment losses* | | | | | |
| At January 1, 2023 | (21,885) | (2,284) | (4,178) | (31,577) | (59,924) |
| Charge for the year (Note 9) | (272) | (64) | (178) | (317) | (831) |
| Disposals or retirements | 385 | 38 | 115 | 213 | 751 |
| Impairment losses | (2,246) | (339) | (101) | (1,086) | (3,772) |
| Exchange adjustments | (4) | (20) | (7) | (370) | (401) |
| At December 31, 2023 | (24,022) | (2,669) | (4,349) | (33,137) | (64,177) |
| At January 1, 2024 | (24,022) | (2,669) | (4,349) | (33,137) | (64,177) |
| Charge for the year (Note 9) | (325) | (58) | (283) | (9) | (675) |
| Disposals or retirements | - | - | (5) | - | (5) |
| Impairment losses* | (410) | (1) | (80) | (477) | (968) |
| Reallocations/ reclassifications | - | - | - | (179) | (179) |
| At December 31, 2024 | (24,757) | (2,728) | (4,717) | (33,802) | (66,004) |
| *Carrying amounts* | | | | | |
| At December 31, 2024 | 2,027 | 83 | 627 | 1,884 | 4,621 |
| At December 31, 2023 | 246 | 91 | 263 | 1,292 | 1,892 |

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

# Additions include US$0.9 million additions in ROU assets.

* The total impairment charge recognised against Property, Plant & Equipment during the year was US$1.0 million. Of this, US$0.6 million, corresponding to the impairment loss allocated to property, plant and equipment as described above, is presented within 'Impairment Charges' in the Consolidated Statement of Operations. The remaining US$0.4 million is included within 'Restructuring Costs' (see Note 5).

Remeasurement of ROU assets during the year includes adjustments arising from rent reviews on leased properties in Bray, Ireland. These relate to leases with a related party, Mr. O'Caoimh, and reflect revised future lease payments following independent valuations. Further details are provided in Note 26 – Related Party Transactions

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, 2024 US$000* | *Depreciation Charge Year ended December 31, 2024 US$000* | *Impairment Charge Year ended December 31, 2024 US$000* |
|---|---|---|---|
| Buildings | 2,126 | (325) | (356) |
| Computer equipment | 72 | (56) | (43) |
| | 2,198 | (381) | (399) |

| | *Carrying amount At December 31, 2023 US$000* | *Depreciation Charge Year ended December 31, 2023 US$000* | *Impairment Charge Year ended December 31, 2023 US$000* |
|---|---|---|---|
| Buildings | 229 | (196) | (1,930) |
| Computer equipment | 166 | (51) | - |
| Plant and Equipment, vehicles | - | (26) | (86) |
| | 395 | (273) | (2,016) |

Income from sub-letting right-of-use buildings amounted to US$nil in the year ended December 31, 2024 (2023: US$3,000).

| ***Right-of-Use assets at 31 December 2024*** | ***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 | 10 | 0 to 9 | 3 | 1 | - | - | - |
| Vehicle | 22 | 0 to 2 | 1 | - | 22 | - | 22 |
| I.T. and office equipment | 6 | 2 to 5 | 3 | - | - | - | - |

| ***Right-of-Use assets at 31 December 2023*** | ***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 | 7 | 1 to 10 | 5 | 1 | - | - | - |
| Vehicle | 22 | 1 to 3 | 2 | - | 22 | - | 22 |
| I.T. and office equipment | 5 | 3 | 3 | - | - | - | - |

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$0.6 million was allocated to property, plant and equipment as at December 31, 2024 (2023: US$3.8 million). The recoverable amount of property, plant and equipment was determined to be the value in use of each cash-generating unit.

12. GOODWILL AND INTANGIBLE ASSETS

| | *Goodwill* *US$'000* | *Development costs* *US$'000* | *Patents and licenses* *US$'000* | *Technology based intangibles* *US$'000* | *Other* *US$'000* | *Total* *US$'000* |
|---|---|---|---|---|---|---|
| *Cost* | | | | | | |
| At January 1, 2023 | 79,182 | 125,584 | 8,729 | - | 33,580 | 247,075 |
| Additions | - | 1,758 | 19 | - | 110 | 1,887 |
| Disposals or retirements | (12,591) | - | - | - | (14,488) | (27,079) |
| Reclassifications | 54 | - | (54) | - | - | - |
| Exchange adjustments | - | 23 | - | - | - | 23 |
| At December 31, 2023 | 66,645 | 127,365 | 8,694 | - | 19,202 | 221,906 |
| At January 1, 2024 | 66,645 | 127,365 | 8,694 | - | 19,202 | 221,906 |
| Additions | - | 8,582 | 1 | - | 2,280 | 10,863 |
| Additions through acquisition | 13,839 | 122 | - | 13,105 | - | 27,066 |
| Disposals or retirements | - | (70) | - | - | - | (70) |
| At December 31, 2024 | 80,484 | 135,999 | 8,695 | 13,105 | 21,482 | 259,765 |
| *Accumulated amortisation and Impairment losses* | | | | | | |
| At January 1, 2023 | (66,645) | (108,576) | (8,570) | - | (28,015) | (211,806) |
| Charge for the year (Note 9) | - | (753) | 30 | - | (223) | (946) |
| Disposals or retirements | - | - | - | - | 12,956 | 12,956 |
| Impairment losses (Note 5) | - | (2,926) | (9) | - | (2,898) | (5,833) |
| Exchange adjustments | - | (7) | - | - | - | (7) |
| At December 31, 2023 | (66,645) | (112,262) | (8,549) | - | (18,180) | (205,636) |
| At January 1, 2024 | (66,645) | (112,262) | (8,549) | - | (18,180) | (205,636) |
| Charge for the year (Note 9) | - | (1,190) | - | - | - | (1,190) |
| Impairment losses (Note 5) | - | (1,596) | - | - | - | (1,596) |
| At December 31, 2024 | (66,645) | (115,048) | (8,549) | - | (18,180) | (208,422) |
| *Carrying amounts* | | | | | | |
| At December 31, 2024 | 13,839 | 20,951 | 146 | 13,105 | 3,302 | 51,343 |
| At December 31, 2023 | - | 15,103 | 145 | - | 1,022 | 16,270 |

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

Included within development costs are projects with a carrying value of US$7,040,000 which were not amortised in 2024 (2023: US$1,596,000) (2022: US$6,982,000). 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, 2024 these projects are expected to be completed during the period from January 1, 2025 to December 31, 2026 at an expected further cost of approximately US$20 million to US$25 million.

Included within technology-based intangibles in 2024 is an amount of US$13.1 million related to the recognition of acquired technology-based intangible assets from the Waveform, Metabolomics, and Epicapture acquisitions. These assets were recognised at fair value in accordance with IFRS 3. Further details of these acquisitions are provided in Note 29. As the acquired technologies were not yet available for use at year-end, no amortisation has been recorded in 2024. Amortisation will commence when the technologies are brought into commercial use.

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 | *2024 US$'000* | *2023 US$'000* |
|---|---|---|
| Continuous glucose monitoring testing | 7,040 | - |
| Premier Instruments for A1c and haemoglobinopathies testing | 1,542 | 1,669 |
| Mid-tier haemoglobins instrument | - | 51 |
| HIV screening rapid test | - | 6 |
| Other projects | - | 32 |
| **Total capitalised development costs** | **8,582** | **1,758** |

**Other intangible assets**

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

During the year ended December 31, 2024, additions of US$13.2 million were recorded in respect of intangible assets acquired through business combinations. These relate to the fair value of identifiable intangible assets recognised as part of the acquisitions of Waveform, EpiCapture and Metabolomics. The acquired intangible assets comprise the following:

- Customer relationships
- Trade names and brand assets
- Proprietary technology and software
- Supplier agreements
- Website and digital assets

The fair values of these assets were determined as part of the purchase price allocation process in accordance with IFRS 3 Business Combinations. Refer to Note 29 for further detail on the business combinations.

**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. The value-in-use calculations use cash flow projections based on the 2025 and 2026 projections for each CGU and a further three years projections using estimated revenue and cost average growth rates of between 2% and 3%. 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 17% to 28% (2023: 15% to 22%).

*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)

*Impairment tests of cash-generating units*

The impairment tests performed at June 30, 2024 and at December 31, 2024 resulted in an impairment loss being recorded in four CGUs, Immco Diagnostics Inc, Trinity Biotech Do Brasil, Clark Laboratories and Biopool Inc

The table below sets forth the impairment loss recorded for each of the CGU's, comprising both the specific asset impairment charges recorded in year ended December 31, 2024 as per the below table and the impairments arising from the CGU impairment tests:

| | ***December 31, 2024 US$'000*** | ***December 31, 2023 US$'000*** |
|---|---|---|
| Immco Diagnostics Inc. | 101 | 9,331 |
| Trinity Biotech Manufacturing Limited | (120) | 1,500 |
| Trinity Biotech Do Brasil | 162 | 274 |
| Primus Corp | 916 | - |
| Clark Laboratories Inc. | 130 | - |
| Biopool US Inc. | 219 | - |
| Total impairment loss | **1,408** | **11,105** |

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

| | ***December 31, 2024 US$'000*** | ***December 31, 2023 US$'000*** |
|---|---|---|
| Goodwill and other intangible assets | 1,596 | 5,833 |
| Property, plant and equipment (see Note 11) | 612 | 3,772 |
| Financial assets (see Note 13) | (800) | 1,500 |
| Total impairment loss | **1,408** | **11,105** |

The impairment tests performed at June 30, 2024 and at December 31, 2024 resulted in an impairment loss being recorded in four CGUs, Immco Diagnostics Inc, Trinity Biotech Do Brasil, Clark Laboratories Inc, and Biopool Inc.

Management is seeking to implement profit improvement initiatives across these entities, however the values in use of these CGUs at June 30, 2024 and December 31, 2024, defined as the present value of the future projected cash flows, were below the value of the carrying amount of their assets, other than inventories, accounts receivable, cash and cash equivalents and deferred tax assets.

Included within the impairment for Trinity Biotech Manufacturing Limited was the reversal of a previously recognised financial asset impairment of US$0.8 million, refer to Note 13 for further details.

*Specific asset impairment charges in year ended December 31, 2024*

In the year ended December 31, 2024, two internally developed intangible assets were fully impaired, and certain plant items in our Bray production facility and the right-of-use asset associated with the Kansas production facility were both fully impaired as a result of restructuring activities. These impairments are shown in the table below. There were no specific asset impairment charges in the year ended December 31, 2023.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

| *Asset name* | *Entity* | *2024 US$'000* |
|---|---|---|
| T10 HPLC Analyzer | Trinity Biotech Manufacturing Ltd | 916 |
| Syphilis Point-of-Care | Trinity Biotech Manufacturing Ltd | 680 |
| Trinscreen plant & equipment | Trinity Biotech Manufacturing Ltd | 223 |
| Kansas right-of-use asset | Primus Corp. | 133 |
| Total | | 1,952 |

The T10 HPLC Analyzer project was an internally developed HPLC analyser designed for mid-volume haemoglobin testing laboratories, with the Chinese market identified as a key commercial opportunity. Although the project achieved technical feasibility and early market validation, recent developments in global trade relations, particularly increasing tensions between the United States and China, have created significant uncertainty around market access and the ability to generate sufficient future sales. While the Company continues to pursue a licensing arrangement with a local Chinese partner, this is not expected to generate adequate economic returns to support the carrying value of the asset. As a result, the Company has fully impaired the related intangible asset and recognised an impairment charge of US$916,000. This was recorded in the Primus Corp. entity.

The Syphilis Point of Care project is an internally developed lateral flow assay intended for the global syphilis and HIV/syphilis dual testing markets. Although the project demonstrated technical feasibility prior to 2020, the suspension of development activities during the COVID-19 pandemic and subsequent changes in manufacturing strategy have introduced additional uncertainty around technical completion, regulatory approval timelines, and cost to completion. As a result of this reassessment, and in light of the need for further development work before the product can be commercialised, the Group have fully impaired the project and recorded an impairment charge of US$680,000.

Trinscreen, one of the Group's HIV screening products, was manufactured at Trinity Biotech Manufacturing Ltd in 2024. In line with the planned transfer of Point-of-Care/HIV product manufacturing to a contract manufacturing partner by Q2 2025, certain plant and equipment at Trinity Biotech Manufacturing Limited were assessed as having limited future utility. An impairment charge of US$223,000 was recognised to reflect the revised recoverable amount. This has been included within 'Selling, general and administrative expenses – Restructuring costs'. See also Note 11.

The Kansas City facility, operated by Primus Corporation, previously supported the manufacture and R&D of the Group's haemoglobin product range. At year-end, the Group assessed that the associated right-of-use asset no longer has future economic benefit, and a full impairment charge of US$133,000 was recognized within 'Selling, general and administrative expenses – Restructuring costs'. See also Note 11.

The value-in-use calculations for CGUs are 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, 2024.
- 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, 2024.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

**Significant Goodwill and Intangible Assets with Indefinite Useful Lives**

Following the disposal of Fitzgerald Industries during 2023, the carrying value of goodwill was US$nil as at December 31, 2023. During 2024, goodwill was recognised in connection with the acquisitions of Waveform Technologies' CGM assets, EpiCapture, and Metabolomics. The carrying value of goodwill as at December 31, 2024 was US$13,829,000. The CGUs for which goodwill is considered significant from a Group perspective, and the additional disclosures required for these CGUs, are set out below.

Goodwill arising from the purchase of CGM assets from Waveform Technologies

| | *December 31, 2024* |
|---|---|
| Carrying amount of goodwill (US$'000) | 12,403 |
| Discount rate applied (real pre-tax) | 18.6% |
| % EBITDA would need to decrease for an impairment to arise | 56.51% |
| Long-term growth rate | 2.0% |

The Waveform CGM CGU includes proprietary continuous glucose monitoring (CGM) technology and related assets acquired from Waveform Technologies in January 2024. The value-in-use was determined using a discounted cash flow model based on seven years of forecast cash flows, reflecting the expected development and commercialisation trajectory of the technology, followed by a terminal value using a 2% long-term growth rate. The pre-tax discount rate of 26% reflects the high-risk, early-stage nature of the opportunity and incorporates market-based risk adjustments.

The assumptions and estimates used are specific to this CGU and were derived from a combination of internal forecasts, external market data, and management's expectations regarding development timelines, regulatory approvals, and commercial potential.

No impairment loss was recognised for this CGU in 2024. Management concluded that no reasonably possible change in key assumptions would lead to the carrying amount exceeding the recoverable amount.

Goodwill arising from the acquisition of EpiCapture Limited

| | *December 31, 2024* |
|---|---|
| Carrying amount of goodwill (US$'000) | 1,420 |
| Discount rate applied (real pre-tax) | 21.9% |
| % EBITDA would need to decrease for an impairment to arise | 84.35% |
| Long-term growth rate | 2.0% |

The EpiCapture CGU includes oncology diagnostics technology and associated intellectual property acquired in 2024. The value-in-use was determined using a discounted cash flow model incorporating probability-weighted scenarios reflecting the early-stage nature of the development pipeline, projected regulatory milestones, and anticipated commercialisation timelines. The model included ten years of forecast cash flows followed by a terminal value using a 2.0% long-term growth rate. The pre-tax discount rate of 29.4% reflects the significant risk and uncertainty associated with product development, clinical validation, and future market access.

The assumptions and estimates used are specific to this CGU and were developed based on internal forecasts, external market data, and management's expectations regarding product viability and commercial uptake.

No impairment loss was recognised for this CGU in 2024. Management concluded that no reasonably possible change in key assumptions would lead to the carrying amount exceeding the recoverable amount.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Goodwill arising from the acquisition of Metabolomic Diagnostics Limited

Goodwill of US$6,000 was also recognised in connection with the acquisition of Metabolomics. This amount is not considered individually material to the Group, and therefore no further disclosures have been provided in accordance with IAS 36.

| **Intangible Assets with Indefinite Useful lives (included in other intangibles)** | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| **Primus Corporation CGU** | | |
| Primus trade name | 365 | 365 |
| **Total** | **365** | **365** |

In 2023, an impairment loss of US$2,069,000 was allocated against the Immco Diagnostic trade name as the carrying value of the CGU's net assets exceeded its discounted future cashflows. In 2023, the Group sold the Fitzgerald Industries business and the Fitzgerald trade name and RDI trade name were disposed of as part of that divestment.

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.

13. FINANCIAL ASSETS

| | *December 31, 2024 US$'000* |
|---|---|
| *Cost* | |
| At January 1, 2023 | - |
| Additions in year | 1,500 |
| At December 31, 2023 | 1,500 |
| At January 1, 2024 | 1,500 |
| Additions in year | 2,562 |
| Write off in the year | (800) |
| Fair value remeasured through profit & loss | (107) |
| At December 31, 2024 | 3,155 |
| *Provision for impairment* | |
| At January 1, 2023 | - |
| Impairment in the current year | (1,500) |
| At December 31, 2023 | (1,500) |
| At January 1, 2024 | (1,500) |
| Reversal of impairment in the current year (Note 5) | 800 |
| At December 31, 2024 | (700) |
| *Carrying amounts* | |
| At December 31, 2024 | 2,455 |
| At December 31, 2023 | - |

In January 2023, the Company entered into a strategic partnership with imaware Inc. ("imaware"), combining imaware's digital health platform with the Company's reference laboratory capabilities to support the delivery of at-home and remote testing programs. As part of the partnership, the Company agreed to invest US$1.5 million in imaware through a convertible note arrangement. In addition, a five-year agreement was signed appointing the Company as imaware's laboratory testing partner. As at December 31, 2023, the Company had paid US$0.7 million of the committed US$1.5 million investment. The remaining US$0.8 million, which had not yet been funded, was recognised as an accrued liability. The partnership did not generate any income in 2023. Due to continued uncertainty over imaware's financial performance and the recoverability of the investment, the Company recognised a full impairment loss of US$1.5 million in the year ended December 31, 2023. In 2024, following the acquisition of Imaware by SuperTruth, and subsequent engagement with the acquirer, it was confirmed that the Company is not liable to settle the outstanding US$0.8 million and it was written off against the corresponding impairment previously recognised. No further amounts are expected to be paid under the original convertible note agreement.

During 2024, the Company purchased a strategic investment in Novus Diagnostics Limited, a company pioneering a rapid sepsis testing platform, acquiring a 12.5% stake at that time. This investment will accelerate the development and commercialization of Novus' groundbreaking point-of-care diagnostic solutions, including its 15-minute bloodstream infection test. The investment was valued at approximately US$2,562,000 and was made through issuance of approximately 1,399,985 ADSs in the Company. The ADS issuance was recognised directly in equity. The investment does not meet the criteria for classification at amortised cost, as it is not held to collect contractual cash flows. Nor did the Company make the irrevocable election to measure it at fair value through other comprehensive income (FVOCI). Accordingly, the investment is measured at fair value through profit or loss (FVTPL) in accordance with IFRS 9. As at December 31, 2024, the investment is classified within Level 3 of the fair value hierarchy under IFRS 13, as it is not quoted in an active market and the fair value was determined using unobservable inputs. A remeasurement loss of US$0.1 million was recognised in profit or loss for the year ended December 31, 2024.

## 14. 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* | |
|---|---|---|---|---|---|---|
| | *2024 US$'000* | *2023 US$'000* | *2024 US$'000* | *2023 US$'000* | *2024 US$'000* | *2023 US$'000* |
| Property, plant and equipment | 224 | 168 | - | - | 224 | 168 |
| Intangible assets | - | - | (3,001) | (931) | (3,001) | (931) |
| Inventories | 776 | 105 | - | - | 776 | 105 |
| Provisions | 1,414 | 558 | - | - | 1,414 | 558 |
| Tax value of loss carry-forwards | 1,026 | 1,030 | - | - | 1,026 | 1,030 |
| Other items | 113 | 114 | (1,560) | (1,369) | (1,447) | (1,255) |
| Deferred tax assets/(liabilities) | 3,553 | 1,975 | (4,561) | (2,300) | (1,008) | (325) |

The deferred tax asset at December 31, 2024 is mainly due to deductible temporary differences relating to provisions and loss carry-forwards In 2024, the deferred tax asset increased by US$1.6 million mainly due to an increase in deductible temporary differences principally attributable to imputed interest provisions.

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$2.3 million in 2024, principally because of temporary differences in relation to acquired intangible assets.

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, 2024 and at December 31, 2023 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.

**Movement in temporary differences during the year**

| | *Balance January 1, 2024 US$'000* | *Recognised in income US$'000* | *Recognised in discontinued operations US$'000* | *Balance December 31, 2024 US$'000* |
|---|---|---|---|---|
| Property, plant and equipment | 168 | 56 | - | 224 |
| Intangible assets | (931) | (2,070) | - | (3,001) |
| Inventories | 105 | 671 | - | 776 |
| Provisions | 558 | 856 | - | 1,414 |
| Tax value of loss carry-forwards | 1,030 | (4) | - | 1,026 |
| Other items | (1,255) | (192) | - | (1,447) |
| | (325) | (683) | - | (1,008) |

14. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

| | *Balance January 1, 2023 US$'000* | *Recognised in income US$'000* | *Recognised in discontinued operations US$'000* | *Balance December 31, 2023 US$'000* |
|---|---|---|---|---|
| Property, plant and equipment | 224 | (56) | - | 168 |
| Intangible assets | (3,950) | 2,827 | 192 | (931) |
| Inventories | 423 | (318) | - | 105 |
| Provisions | 2,194 | (1,636) | - | 558 |
| Tax value of loss carry-forwards | 1,254 | (224) | - | 1,030 |
| Other items | (985) | (270) | - | (1,255) |
| | (840) | 323 | 192 | (325) |

**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, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Capital losses | 8,293 | 8,293 |
| Net operating losses | 180,810 | 136,202 |
| US alternative minimum tax credits | 1,791 | 1,790 |
| Other temporary timing differences | 19,246 | 57,986 |
| US state credit carry-forwards | - | 4,015 |
| | 210,140 | 208,286 |

15. OTHER NON-CURRENT ASSETS

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Finance lease receivables (see Note 17) | - | 36 |
| Other assets | 28 | 43 |
| | 28 | 79 |

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 17.

16. INVENTORIES

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Raw materials and consumables | 10,032 | 10,053 |
| Work-in-progress | 4,989 | 4,498 |
| Finished goods | 4,353 | 5,382 |
| | 19,374 | 19,933 |

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$7,648,000 (2023: US$11,344,000) (2022: US$16,274,000). Cost of sales in 2024 includes inventories expensed of US$38,001,000 (2023: US$35,091,000) (2022: US$45,340,000).

The movement on the inventory provision for the three-year period to December 31, 2024 is as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Opening provision at January 1 | 11,344 | 16,274 | 12,063 |
| Charged during the year | 2,113 | 2,291 | 7,391 |
| Utilised during the year | (5,809) | (5,456) | (3,180) |
| Eliminated on disposal of business | - | (1,765) | - |
| Closing provision at December 31 | 7,648 | 11,344 | 16,274 |

17. TRADE AND OTHER RECEIVABLES

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Trade receivables, net of impairment losses | 13,416 | 10,698 |
| Prepayments | 1,979 | 2,036 |
| Contract assets | 460 | 525 |
| Value added tax | 42 | 43 |
| Finance lease receivables | - | 119 |
| Consideration due from sale of business (Note 8) | - | 373 |
| Other receivables | 168 | 107 |
| | 16,065 | 13,901 |

Trade receivables are shown net of an impairment losses provision of US$2,286,000 (2023: US$2,324,000) (2022: US$2,691,000) (see Note 27). Prepayments are shown after impairment charges of US$Nil (2023: US$Nil) (2022: US$482,000) (see Note 5).

17. 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, 2024 US$'000* | | |
|---|---|---|---|
| | Gross investment | Unearned income | Minimum payments receivable |
| Less than one year | - | - | - |
| Between one and five years (Note 15) | - | - | - |
| | - | - | - |

| | *December 31, 2023 US$'000* | | |
|---|---|---|---|
| | Gross investment | Unearned income | Minimum payments receivable |
| Less than one year | 170 | 4 | 119 |
| Between one and five years (Note 15) | 54 | 3 | 36 |
| | 224 | 7 | 155 |

The Group classified future minimum lease receivables between one and five years of US$Nil (2023: US$36,000) as Other Assets, see Note 15. 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, 2024 US$'000* | |
|---|---|---|
| | Instruments | Total |
| Less than one year | 1,461 | 1,461 |
| | 1,461 | 1,461 |

17. TRADE AND OTHER RECEIVABLES (CONTINUED)

*(ii) Operating lease commitments – Group as lessor*

| | *December 31, 2024 US$'000* | |
|---|---|---|
| | Instruments | Total |
| Less than one year | 1,995 | 1,995 |
| | 1,995 | 1,995 |

18. CASH AND CASH EQUIVALENTS

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Cash at bank and in hand | 5,167 | 3,691 |
| Cash and cash equivalents | 5,167 | 3,691 |

19. CAPITAL AND RESERVES

***Share capital***

In February 2024, the Company adjusted its ADS ratio from 1 ADS: 4 ordinary share to 1 ADS: 20 ordinary shares. The 2024 and 2023 ADS amounts in the below tables reflect this change.

| | *December 31, 2024 Class 'A' Ordinary shares '000s* | *December 31, 2023 Class 'A' Ordinary shares '000s* |
|---|---|---|
| *In thousands of shares* | | |
| In issue at January 1 | 165,866 | 164,986 |
| Issued for a cash consideration (a) | 81,628 | 880 |
| Issued for non-cash consideration (b) | 124,255 | - |
| At period end | 371,749 | 165,866 |

| | *December 31, 2024 ADS* | *December 31, 2023 ADS* |
|---|---|---|
| *In thousands of ADSs* | | |
| Balance at January 1 | 8,293 | 8,249 |
| Issued for a cash consideration | 4,081 | 44 |
| Issued for non-cash consideration | 6,213 | - |
| At period end | 18,587 | 8,293 |

19. 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, 2024 Class 'A' Treasury shares '000s* | *December 31, 2023 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, 2024 Class 'A' Treasury shares '000s* | *December 31, 2023 Class 'A' Treasury shares '000s* |
|---|---|---|
| *In thousands of ADSs* | | |
| Balance at January 1 | 628 | 628 |
| Purchased during period | - | - |
| At period end | 628 | 628 |

(a) During the year ended December 31, 2024, the Company issued 81,628,000 'A' Ordinary shares for a consideration of US$7.4 million settled in cash. The Company incurred expenses of US$0.7 million in connection with the issuances. No employee share options were exercised during the year.

(b) During the year ended December 31, 2024, the Company issued following shares for a consideration other than cash:

i) On January 31, 2024, the Company issued 36,000,000 'A' Ordinary shares (1,800,000 ADS) as a part of the purchase consideration to acquire Waveform Technologies Inc., as a wholly owned subsidiary.

ii) On September 24, 2024, the Company issued 5,406,000 'A' Ordinary shares (270,000 ADS) as a part of the purchase consideration to acquire Metabolomic Diagnostics Limited, as a wholly owned subsidiary.

iii) On October 10, 2024, the Company issued 13,000,000 'A' Ordinary shares (650,000 ADS) to Craig-Hallum pursuant to the Advisory Agreement.

iv) On October 10, 2024, the Company issued 7,237,000 'A' Ordinary shares (362,000 ADS) to Native Design Limited pursuant to a design services agreement.

v) On October 25, 2024, the Company issued 34,612,000 'A' Ordinary shares (1,731,000 ADS) as a purchase consideration to acquire EpiCapture Limited, as a wholly owned subsidiary.

vi) On October 25, 2024, the Company issued 28,000,000 'A' Ordinary shares (1,400,000 ADS) as a purchase consideration to acquire 12.5% equity stake in Novus Diagnostics.

19. CAPITAL AND RESERVES (CONTINUED)

***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. 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.

***Equity component of Convertible Note***

In May 2022, the Company completed a US$45.2 million investment from MiCo IVD Holdings, LLC (“MiCo”). 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$16.20 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 2024, the Group did not purchase any ‘A’ Ordinary shares (2023: nil) (2022: nil) ‘Treasury shares’.

20. SHARE OPTIONS

***Options***

Under the terms of the Company's Employee Share Option Plans, options to purchase 40,506,672'A' Ordinary Shares (2,025,334 ADS's) were outstanding at December 31, 2024. 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.

Share options are sometimes granted to consultants of the Group and the fair value of the services provided by these consultants is measured by reference to the fair value of the equity instruments granted. This approach is adopted as it is impractical for the Group to reliably estimate the fair value of such services. There are 2,000,000 outstanding options for consultants at December 31, 2024.

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 or any other relevant delegated 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*

Since 2022, share options were granted to directors and certain employees 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 payments, 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 or employee 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 or employee does not receive the share-based payment due to a failure to meet the non-vesting condition.

*Contractual life*

The term of an option is determined by the Board of Directors, typically through its Remuneration Committee and Employee Compensation Committee, provided that the term may not exceed 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 Board may accelerate the exercisability and termination of options.

20. SHARE OPTIONS (CONTINUED)

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, 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 December 31, 2022 | 44,814,672 | 0.47 | 0.19-2.43 |
| Exercisable December 31, 2022 | 14,138,004 | 0.89 | 0.19-2.43 |
| Outstanding January 1, 2023 | 44,814,672 | 0.47 | 0.19-2.43 |
| Granted | 19,600,000 | 0.14 | 0.12-0.25 |
| Exercised | (880,000) | 0.19 | 0.19-0.19 |
| Expired / Forfeited | (16,620,000) | 0.33 | 0.27-2.43 |
| Outstanding December 31, 2023 | 46,914,672 | 0.39 | 0.12-1.34 |
| Exercisable December 31, 2023 | 19,764,672 | 0.67 | 0.19-1.34 |
| Outstanding January 1, 2024 | 46,914,672 | 0.39 | 0.12-1.34 |
| Granted | 12,100,000 | 0.14 | 0.14-0.14 |
| Expired / Forfeited | (18,508,000) | 0.50 | 0.12-1.34 |
| Outstanding December 31, 2024 | 40,506,672 | 0.26 | 0.12-1.29 |
| Exercisable December 31, 2024 | 17,275,422 | 0.41 | 0.12-1.29 |

20. SHARE OPTIONS (CONTINUED)

In February 2024, the Company adjusted its ADS ratio from 1 ADS: 4 ordinary shares to 1 ADS: 20 ordinary shares. The 2024 and 2023 ADS amounts in the below tables reflect this change.

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

| | Share Options 'ADS' Equivalent | Weighted-average exercise price US$ Per 'ADS' | Range US$ Per 'ADS' |
|---|---|---|---|
| Outstanding January 1, 2022 | 936,400 | 15.60 | 3.80-87.20 |
| Granted | 1,470,000 | 5.40 | 5.40-5.80 |
| Exercised | (136,666) | 3.80 | 3.80-3.80 |
| Expired / Forfeited | (29,000) | 37.40 | 13.80-87.20 |
| Outstanding December 31, 2022 | 2,240,734 | 9.40 | 3.80-48.60 |
| Exercisable December 31, 2022 | 706,900 | 17.80 | 3.80-48.60 |
| Outstanding January 1, 2023 | 2,240,734 | 9.40 | 3.80-48.60 |
| Granted | 980,000 | 2.80 | 2.40-5.00 |
| Exercised | (44,000) | 3.80 | 3.80-3.80 |
| Expired / Forfeited | (831,000) | 6.60 | 5.40-48.60 |
| Outstanding December 31, 2023 | 2,345,734 | 7.80 | 2.40-26.80 |
| Exercisable December 31, 2023 | 988,234 | 13.40 | 3.80-26.80 |
| Outstanding January 1, 2024 | 2,345,734 | 7.80 | 2.40-26.80 |
| Granted | 605,000 | 2.80 | 2.80-2.80 |
| Expired / Forfeited | (925,400) | 10.00 | 2.40-26.80 |
| Outstanding December 31, 2024 | 2,025,334 | 5.20 | 2.40-25.80 |
| Exercisable December 31, 2024 | 863,771 | 8.20 | 2.40-25.80 |

The opening share price per 'A' Ordinary share at the start of the financial year was US$0.10 or US$2.00 per ADS (2023: US$0.24 per 'A' ordinary share or US$4.8 per ADS) (2022: US$0.36 per 'A' ordinary share or US$7.35 per ADS) and the closing share price at December 31, 2024 was US$0.04 per 'A' ordinary share or US$0.88 per ADS (2023: US$0.11 per 'A' ordinary share or US$2.15 per ADS) (2022: US$0.25 per 'A' ordinary share or US$4.95 per ADS). The average share price for the year ended December 31, 2024 was US$0.10 per 'A' Ordinary share or US$1.96 per ADS.

20. SHARE OPTIONS (CONTINUED)

A summary of the range of prices for the Company's share options for the year ended December 31, 2024 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$0.12-US$0.99 | 40,356,672 | 0.25 | 5.00 | 17,125,422 | 0.40 | 4.78 |
| US$1.00-US$1.29 | 150,000 | 1.14 | 2.38 | 150,000 | 3.76 | 2.36 |
| | 40,506,672 | | | 17,275,422 | | |

| | 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$2.40-US$19.80 | 2,017,834 | 5.00 | 5.00 | 856,271 | 8.00 | 4.78 |
| US$20.00-US$25.80 | 7,500 | 22.80 | 2.38 | 7,500 | 22.80 | 3.38 |
| | 2,025,334 | | | 863,771 | | |

The weighted-average remaining contractual life of options outstanding at December 31, 2024 was 4.98 years (2023: 5.03 years).

A summary of the range of prices for the Company's share options for the year ended December 31, 2023 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$0.12-US$0.99 | 42,266,672 | 0.28 | 5.50 | 15,116,672 | 0.47 | 4.16 |
| US$1.00-US$1.74 | 4,648,000 | 1.33 | 0.79 | 4,648,000 | 1.33 | 0.79 |
| | 46,914,672 | | | 19,764,672 | | |

| | 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$2.40-US$19.80 | 2,113,334 | 5.64 | 5.50 | 755,834 | 9.32 | 4.16 |
| US$20.00-US$34.80 | 232,400 | 26.54 | 0.79 | 232,400 | 26.54 | 0.79 |
| | 2,345,734 | | | 988,234 | | |

20. 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. In 2024, US$1,316,000 (2023: US$2,069,000) (2022: US$1,755,000) was charged to the statement of operations split as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* | *December 31, 2022 US$'000* |
|---|---|---|---|
| Share-based payments – cost of sales | - | - | - |
| Share-based payments – selling, general and administrative | 1,316 | 2,069 | 1,755 |
| Total – continuing operations | 1,316 | 2,069 | 1,755 |
| Share-based payments – discontinued operations | - | - | - |
| Total | 1,316 | 2,069 | 1,755 |

No share-based payment expense was capitalised in intangible development project assets during the years ended December 31, 2022, 2023 or 2024.

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 2024, 2023 and 2022:

| | **Key management personnel 2024** | **Key management personnel 2023** | **Key management personnel 2022** |
|---|---|---|---|
| Weighted average fair value at measurement date per 'A' share / (per ADS) | $ US$0.10 / (US$2.08) | $ US0.50 / (US$10.04) | $ US0.19 / (US$3.80) |
| Total 'A' share options granted / (ADS's equivalent) | 12,100,000 / (605,000) | 19,600,000 / (980,000) | 29,400,000 / (1,470,000) |
| Weighted average share price per 'A' share / (per ADS) | $ US0.14/ (US$2.80) | $ US0.14 / (US$2.80) | $ US0.27 / (US$5.40) |
| Weighted average exercise price per 'A' share / (per ADS) | $ US0.14 / (US$2.80) | $ US0.14 / (US$2.80) | $ US0.27 / (US$5.40) |
| Weighted average expected volatility | 74.40% | 40.21% | 76.79% |
| Weighted average expected life | 7 | 7 | 6.82 |
| Weighted average risk-free interest rate | 4.06% | 4.13% | 3.59% |

20. 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.

The model assumed an expected dividend yield of 0%, consistent with the Group's current dividend policy.

21. TRADE AND OTHER PAYABLES

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Trade payables | 6,833 | 3,885 |
| Accruals and other liabilities | 13,597 | 7,552 |
| Amounts payable for financial assets (Note 13) | - | 800 |
| Payroll taxes | 659 | 405 |
| Employee related social insurance | 112 | 110 |
| Contingent consideration | 5,384 | - |
| Deferred income | 197 | 50 |
| | 26,782 | 12,802 |

Included in trade and other payables at December 31, 2024 was US$185,000 (2023: US$144,000) relating to contracted licence payments.

22. PROVISIONS

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| Product warranty provision | 50 | 50 |
| Legal & regulatory provision | 735 | - |
| Disposal-related warranty settlement provision | 150 | - |
| Restructuring provision | 1,594 | - |
| | 2,529 | 50 |
| Current | 2,454 | 50 |
| Non-current | 75 | - |

During 2024 and 2023 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, 2024 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, 2024.

During the year ended December 31, 2024, the Group recognised a provision of US$150,000 in respect of a post-completion settlement related to the sale of Fitzgerald Industries. The settlement agreement was finalised prior to year-end and signed in January 2025. The provision is payable in two instalments: US$75,000 within one year and US$75,000 after more than one year. Refer to note 25 for further details.

22. PROVISIONS (CONTINUED)

During the year, the Group recognised a provision of US$0.7 million in respect of a legacy matter currently subject to resolution. Owing to the sensitive nature of ongoing discussions, further disclosure has been withheld in accordance with *IAS 37.92: seriously prejudicial exemption for non-disclosure of certain information on provision*, as the Directors believe such disclosure could seriously prejudice the Group's position.

At 31 December 2024, the Company recognised a provision of US$2.9 million (2023: US$nil) in respect of restructuring activities undertaken as part of the Group's business transformation programme (refer to Note 5). The restructuring provision is expected to be fully utilised during the next 12 months. No further restructuring provisions are anticipated at the reporting date.

23. INTEREST-BEARING LOANS AND BORROWINGS

The carrying value of interest-bearing loans, borrowings and related balances is as follows:

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| *Current liabilities* | | |
| Exchangeable senior notes | 210 | 210 |
| Total | 210 | 210 |

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| *Non-Current liabilities* | | |
| Senior secured term loan | 72,391 | 40,109 |
| Derivative financial liability | 1,658 | 526 |
| Contingent liability (Note 29) | 1,813 | - |
| Convertible note | 15,401 | 14,542 |
| Total non-current liabilities | 91,263 | 55,177 |

| | *December 31, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| *Non-Current assets* | | |
| Derivative financial asset | 166 | 178 |
| Total non-current assets | 166 | 178 |

*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 1,066,600 ADSs (21,332,000 'A' Ordinary shares) representing the equivalent of US$0.40 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.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

*Exchangeable senior notes (continued)*

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$83.2 million. 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, 2024 is US$210,000 and this is shown within Current Liabilities.

The movement in the exchangeable notes balance was as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* |
|---|---|---|
| Balance at January 1 | (210) | (210) |
| Liability | (210) | (210) |

*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 with Perceptive, an investment manager with an expertise in healthcare. The Term Loan was drawn down in January 2022. The Term Loan is secured by a charge over the Group's assets. The 48-month Term Loan was originally due to expire in January 2026, however this has since been amended to a maturity date of July 2026. The loan 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. In connection with the initial draw down of the Term Loan the Company agreed to issue warrants to Perceptive for 500,000 of the Company's ADSs. The per ADS exercise price of the Warrants was US$6.50.

The Term Loan can be repaid, in part or in full, at a premium before the end of the four-year term at the discretion of the Company.

In accordance with IFRS accounting standards, the Term Loan is represented by three separate balances in the statement of financial position, US$72.4 million (2023: US$40.1 million) is shown as a non-current liability balance representing the carrying value of the loan, a derivative financial asset estimated at US$0.2 million (2023: US$0.2 million) representing the value to the Company of being able to repay the Term Loan early and potentially refinance at a lower interest rate and a derivative financial liability estimated at US$1.7 million (2023: US$0.5 million) representing the fair value of the warrants issued to Perceptive.

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 February 2023, the Company announced that it 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 loan facility, 500,000 warrants originally issued under the Term Loan were repriced, with the Warrants having a per ADS exercise price of US$5.36 compared to their initial per ADS exercise price of US$6.50.

On April 27, 2023, the Company announced that it had closed the sale of our Fitzgerald Industries life sciences supply business, 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, which has been recorded as a financial expense in the year ended December 31, 2023. In connection with this transaction, the Company entered an amendment to its senior secured Term Loan credit facility with Perceptive Advisors, which significantly reduced the Company's minimum revenue covenants under that loan.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

In January 2024, as part of the agreement to purchase the Waveform assets, we entered into an amended credit agreement with Perceptive. Under this agreement, an additional US$22 million of funding has been made available to us, with US$12.5 million being used to acquire the Waveform assets. The remaining US$9.5 million was made available for general corporate purposes including for the further development of the CGM and biosensor technologies. The Amended Term Loan also provides for additional liquidity of up to US$6.5 million, that may be drawn down between April and December 2024 and can be used for general corporate purposes. In April 2024, the Company drew down the additional funding of US$6.5 million as prescribed in the Amended Term Loan agreement. This funding will be used for general corporate purposes, including the further development of our CGM offering.

In December 2024, the Company entered into a further amendment to the credit agreement with Perceptive. As part of this amendment, the Company drew down an additional US$2 million for general corporate purposes. We also agreed that certain interest payments payable in 2024 and 2025 would be paid-in-kind on the applicable payment date by increasing the outstanding principal amount of the Term Loan. This included the interest payments due for the period from September through December 2024, which were settled through PIK. Additionally, as part of this amendment the Company granted Perceptive new warrants to purchase an additional 1,500,000 ADSs at an exercise price of US$0.80 per ADS, and the exercise price of its existing ADS warrants was also reset to US$0.80 per ADS.

The issuance of additional warrants and repricing of existing warrants was not considered a modification of the original financial liability under IFRS. All warrants are classified as financial liabilities and are measured at fair value through profit or loss. For the year ended December 31, 2024, a non-cash fair value loss of US$2.1 million was recognized in finance expense, reflecting the initial recognition of the newly issued warrants, the repricing of existing warrants, and subsequent remeasurement of all warrant liabilities.

During the year ended December 31, 2024 accretion interest of US$2.4 million (2023: US$1.1 million) was accrued to leave a closing carrying value of US$72.4 million at year end (2023: US$40.1 million).

*Senior secured term loan*
The movement in the Term Loan was as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* |
|---|---|---|
| Balance at January 1 | (40,109) | (44,301) |
| Principal amount loaned | (30,500) | (5,000) |
| Loan drawdown costs | 325 | 194 |
| Derivative financial liability at date of drawdown | - | 90 |
| Derivative financial asset at date of drawdown | (28) | (11) |
| Accretion interest (Note 6) | (2,355) | (1,131) |
| Cash repayment of principal | - | 10,050 |
| Payment-in-kind (PIK) Interest | (3,291) | - |
| Non-cash Loan Modification Gain | 3,567 | - |
| Balance at December 31 | (72,391) | (40,109) |

The fair value of the derivative financial asset is estimated at US$0.2 million at December 31, 2024 (2023: US$0.2 million). The fair value of the derivative financial liability is estimated at US$1.7 million at December 31, 2023 (2023: $0.5 million) The fair value remeasurement for these two derivative financial balances at December 31, 2024, resulted in the recognition of net financial income of US$26,000 (2023: US$1.2 million) in the consolidated statement of operations.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

In Q1 2024, the Company negotiated a 2.5% reduction in the base interest rate on its term loan facility, lowering the rate from 11.25% to 8.75%. In accordance with IFRS 9, this amendment was treated as a non-substantial modification of the financial liability. As a result, the carrying amount of the loan was remeasured using the original effective interest rate (EIR), and a non-cash gain of $3.6 million was recognised in finance income. This gain reflects the difference between the previous carrying amount of the loan and the present value of the modified cash flows, discounted at the original EIR, and is presented in the consolidated statement of operations as a "Non-cash loan modification gain.".

*Contingent liability*
As part of the consideration for the acquisition of the CGM assets from Waveform Technologies, Inc., the Group recognised a contingent liability of US$1.8 million at the acquisition date. This relates to potential additional consideration payable upon entering into certain commercial partnering agreements with designated glucose pump manufacturers within 24 months of the acquisition. As the payment is subject to the occurrence of uncertain future events, it is disclosed as a contingent liability rather than a recognised financial liability. Refer to Note 29.

The movement in the derivative financial asset in the year was as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* |
|---|---|---|
| Balance at January 1 | 178 | 128 |
| Derivative financial asset at date of drawdown | 28 | 11 |
| Fair value adjustments in the period | (40) | 39 |
| Non-current asset at December 31 | 166 | 178 |

The movement in the derivative financial liability in the year was as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* |
|---|---|---|
| Balance at January 1 | (526) | (1,569) |
| Derivative financial liability at date of drawdown | (1,066) | (90) |
| Fair value adjustments in the period | (66) | 1,133 |
| Non-current liability at December 31 | (1,658) | (526) |

*7-year convertible note*

In May 2022, the Company completed a US$45.2 million investment from MiCo IVD Holdings, LLC. Based on public filings, we understand that on December 17, 2024, MiCo was acquired by Dayli Trinity Holdings Limited as a result of a share purchase agreement with Mainstream Holdings Limited. 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$16.20 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.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

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, 2024, the carrying value of the convertible note's debt component was US$15.4 million (2023: US$14.5 million) and accretion interest of US$0.9 million (2023: US$0.8 million) has been recognised as a financial expense in the year. 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 7-year convertible note in the year was as follows:

| | *December 31, 2024 US$000* | *December 31, 2023 US$000* |
|---|---|---|
| Balance at January 1 | (14,542) | (13,746) |
| Accretion interest | (859) | (796) |
| Non-current liability at December 31 | (15,401) | (14,542) |

## 24. 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, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| **Current liabilities** | | |
| Lease liabilities related to Right of Use assets | 2,285 | 1,694 |
| | 2,285 | 1,694 |
| **Non-Current liabilities** | | |
| Lease liabilities related to Right of Use assets | 10,477 | 10,872 |

| | *December 31, 2024 US$'000* | | |
|---|---|---|---|
| | *Lease liabilities related to Right of Use assets* | | |
| | Minimum lease payments | Interest | Principal |
| Less than one year | 2,862 | 577 | 2,285 |
| In more than one year, but not more than two | 2,214 | 472 | 1,742 |
| In more than two years but not more than five | 5,487 | 955 | 4,532 |
| More than five years | 4,652 | 449 | 4,203 |
| | 15,215 | 2,453 | 12,762 |

24. LEASE LIABILITIES (CONTINUED)

| | *December 31, 2023 US$'000* | | |
|---|---|---|---|
| | *Lease liabilities related to Right of Use assets* | | |
| | Minimum lease payments | Interest | Principal |
| Less than one year | 2,221 | 577 | 1,644 |
| In more than one year, but not more than two | 2,243 | 498 | 1,745 |
| In more than two years but not more than five | 5,442 | 1,017 | 4,425 |
| more than five years | 5,400 | 648 | 4,752 |
| | 15,306 | 2,740 | 12,566 |

**Lease payments not recognised as a liability**

No short-term lease expenses were incurred for the year ended December 31, 2024. 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.

The total paid in respect of lease liabilities in the year ended December 31, 2024, was US$2,503,000 (2023: US$2,318,000).

25. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has capital commitments authorised and contracted for of US$nil as at December 31, 2024 (2023: US$39,900).

(b) ***Leasing Commitments***

The Group's leasing commitments are shown in Note 24.

25. 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 23.

During 2023, the sale and leaseback liability matured as the lease came to an end and was not renewed, as a result, the bank charge against the equipment for which the borrowings pertained did not exist as at December 31, 2023.

(d) ***Group Company Guarantees***

Pursuant to the provisions of Section 357, 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, 2024 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 357, 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) ***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, 2024. However, if the income were to become repayable, the maximum amounts repayable as at December 31, 2024 would amount to US$3,313,000 (2023: US$3,410,000).

(f) ***Contingency relating to the sale of Fitzgerald Industries***

On April 27, 2023 the Company announced it had closed the sale of Fitzgerald Industries ("Fitzgerald") to Biosynth for cash proceeds of approximately US$30 million subject to customary adjustments. In a telephone call conducted in March 2024, a representative of Biosynth alleged a breach of certain of the warranties set out in the Share Purchase Agreement for the sale of Fitzgerald. Following negotiations, a settlement agreement was finalised prior to December 31, 2024 and subsequently signed in January 2025. Under the terms of the settlement, the Company agreed to pay Biosynth US$150,000 in full and final settlement of all post-completion claims. Accordingly, a provision of US$150,000 has been recorded in the consolidated financial statements as at December 31, 2024, see Note 22. In addition, outstanding receivables of US$423,000 from Biosynth relating to completion account adjustments were written off as unrecoverable under the terms of the settlement. The settlement fully resolves all disputes related to the sale of Fitzgerald Industries, and no further liabilities are expected to arise.

(g) ***Contingent considerations relating to business combinations***

As part of the acquisition of the CGM assets of Waveform Technologies, Inc., the Company may pay up to US$20 million in contingent consideration based on share price, trading volume, and commercial milestones. The fair value of this contingent consideration is US$6.8 million as of December 31, 2024. Refer to Note 29 for further details.

As part of the acquisition of EpiCapture Limited (see Note 29), contingent consideration of up to US$0.5 million may become payable based on cumulative revenue targets. The fair value of this contingent consideration is US$0.4 million as of December 31, 2024. Refer to Note 29 for further details.

(h) ***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.

26. RELATED PARTY TRANSACTIONS

The Group has related party relationships with its subsidiaries, and with its directors and executive officers.

***Leasing arrangements with related parties***

The Group has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of 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$421,000). Upward-only rent reviews are carried out every five years and there have been no increases arising from these rent reviews.

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 €787,000 (US$834,000). Subsequent to the signing of this lease, the ownership of the building transferred from JRJ to Mr O'Caoimh solely. A rent review for this property became effective 1 July 2022 and, following an independent valuation, the annual rent increased to €1,050,000, with backdated rent accruing from that date. Included within overhead costs in cost of sales is an amount of $686,000 in respect of backdated rent. 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$159,000). A rent review for this property became effective on 1 July 2021 and, following an independent valuation, the annual rent increased to €170,560, with backdated rent accruing from that date. Included within overhead costs in cost of sales is an amount of $97,000 in respect of backdated rent. Independent valuers advised the Group that the rent in respect of each of the leases represented a fair market rent.

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.

At the time that the arrangements were entered into, Trinity Biotech and its directors (excepting Mr O'Caoimh and Dr Walsh who expressed no opinion on this point) believed they 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 September 2024, the Company completed the acquisition of Metabolomics Diagnostics Ltd ("Metabolomics") for consideration of approximately US$0.9 million, satisfied through the issuance of approximately 0.27 million ADSs and the extinguishment of amounts owed to the Company totaling US$0.41 million. At the time of the acquisition, Dr. Jim Walsh, a director of the Company, held a 6% minority shareholding in Metabolomics. Based on the net assets acquired and goodwill recognised, the value attributable to Dr. Walsh's interest was estimated at approximately $55,000. Dr. Walsh fully disclosed his interest, and the acquisition was approved unanimously by the board, with appropriate procedures followed to manage the potential conflict of interest, including the passing of a resolution under the Company's Constitution to authorise Dr. Walsh's involvement in the decision-making process. The transaction was conducted at arm's length, and the board determined that it was in the best interests of the Company.

26. RELATED PARTY TRANSACTIONS (CONTINUED)

***Compensation of key management personnel of the Group***

During the years ended December 31, 2024 and 2023, the Group's key management personnel comprised directors Mr. Ronan O'Caoimh, Dr. Jim Walsh, and Mr. John Gillard. The Group does not engage a separate management entity, as all key management personnel are employed directly by the Group. Compensation for the year for these personnel is detailed below:

| | December 31, 2024 *US$'000* | December 31, 2023 *US$'000* |
|---|---|---|
| Short-term employee benefits | 843 | 1,774 |
| Performance related bonus | 260 | 211 |
| Post-employment benefits | 39 | 26 |
| Share-based compensation benefits as calculated under IFRS 2 | 931 | 1,601 |
| | 2,073 | 3,612 |

The amounts disclosed in respect of directors' emoluments in Note 9 includes independent directors' fees and non-executive director fees of US$114,000 (2023: US$73,000) and share-based compensation benefits of US$Nil (2023: US$Nil). Total directors' remuneration is also included in "employment" (Note 3) and "(Loss)/profit before tax" (Note 9).

*Directors' interests in the Company's shares and share option plan*

| | *'A' Ordinary Shares* | *Share options* |
|---|---|---|
| At January 1, 2024 | 11,117,777 | 30,387,336 |
| Shares purchased during the year | 200,000 | - |
| Granted | - | 5,600,000 |
| Expired / forfeited | - | (2,994,000) |
| At December 31, 2024 | 11,317,777 | 32,993,336 |

| | *'A' Ordinary Shares* | *Share options* |
|---|---|---|
| At January 1, 2023 | 11,117,777 | 40,547,336 |
| Options of retired director | - | (20,000,000) |
| Granted | - | 14,000,000 |
| Expired / forfeited | - | (4,160,000) |
| At December 31, 2023 | 11,117,777 | 30,387,336 |

27. 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.

**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* | *Level 3 US$'000* | *Total carrying amount US$'000* | *Fair Value US$'000* |
|---|---|---|---|---|---|---|
| **December 31, 2024** | | | | | | |
| *Loans and receivables at amortised cost* | | | | | | |
| Trade receivables | *17* | 13,416 | - | - | 13,416 | 13,416 |
| Cash and cash equivalents | *18* | 5,167 | - | - | 5,167 | 5,167 |
| | | 18,583 | - | - | 18,583 | 18,583 |
| *Liabilities at amortised cost* | | | | | | |
| Senior secured term loan | *23* | - | (72,391) | - | (72,391) | (72,391) |
| Convertible note | *23* | - | (15,401) | - | (15,401) | (15,401) |
| Exchangeable note | *23* | - | (210) | - | (210) | (210) |
| Lease liabilities | *24* | (12,762) | - | - | (12,762) | (12,762) |
| Trade and other payables (excluding deferred income) | *21* | (26,585) | - | - | (26,585) | (26,585) |
| Provisions | *22* | (2,529) | - | - | (2,529) | (2,529) |
| | | (41,876) | (88,002) | - | (129,878) | (129,878) |
| *Fair value through profit and loss (FVPL)* | | | | | | |
| Derivative liability - warrants | *23* | - | (1,658) | - | (1,658) | (1,658) |
| Derivative asset – prepayment option | *23* | - | 166 | - | 166 | 166 |
| Equity investments in Novus | *13* | - | - | 2,455 | 2,455 | 2,455 |
| | | - | (1,492) | 2,455 | 963 | 963 |
| | | (23,293) | (89,494) | 2,455 | (110,332) | (110,332) |

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.

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

| | *Note* | *Level 1 US$'000* | *Level 2 US$'000* | *Level 3 US$'000* | *Total carrying amount US$'000* | *Fair Value US$'000* |
|---|---|---|---|---|---|---|
| **December 31, 2023** | | | | | | |
| *Loans and receivables at amortised cost* | | | | | | |
| Trade receivables | *17* | 10,698 | - | - | 10,698 | 10,698 |
| Cash and cash equivalents | *18* | 3,691 | - | - | 3,691 | 3,691 |
| Finance lease receivable | *15, 17* | 155 | - | - | 155 | 155 |
| | | 14,544 | - | - | 14,544 | 14,544 |
| *Liabilities at amortised cost* | | | | | | |
| Senior secured term loan | *23* | - | (40,109) | - | (40,109) | (40,109) |
| Convertible note | *23* | - | (14,542) | - | (14,542) | (14,542) |
| Exchangeable note[1] | *23* | - | (210) | - | (210) | (210) |
| Lease liabilities | *24* | (12,566) | - | - | (12,566) | (12,566) |
| Trade and other payables (excluding deferred income) | *21* | (12,752) | - | - | (12,752) | (12,752) |
| Provisions | *22* | (50) | - | - | (50) | (50) |
| | | (25,368) | (54,861) | - | (80,229) | (80,229) |
| *Fair value through profit and loss (FVPL)* | | | | | | |
| Derivative liability - warrants | *23* | - | (526) | - | (526) | (526) |
| Derivative asset – prepayment option | *23* | - | 178 | - | 178 | 178 |
| | | - | (348) | - | (348) | (348) |
| | | (10,824) | (55,209) | - | (66,033) | (66,033) |

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.

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

***Interest rate risk***

As of December 31, 2024, all of the Group's financial instruments referencing interest rates are based on SOFR, a post-reform benchmark rate. The Group no longer has exposure to interest rate benchmarks subject to IBOR reform; therefore, the disclosure requirements related to benchmark interest rate reform are not applicable.

***Effective and repricing analysis***

The following tables sets out all interest-earning financial assets and interest-bearing financial liabilities held by the Group at December 31, 2024 and 2023, indicating their effective interest rates and the period in which they re-price:

| *As at December 31, 2024* | *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 | *18* | 0.00% | 5,167 | 5,167 | - | - | - | - |
| Exchangeable note[1] | *23* | 4.0% | (210) | - | - | - | - | (210) |
| Senior secured term loan[2] | *23* | 16.3% | (72,391) | - | - | (72,391) | - | - |
| Convertible note[3] | *23* | 1.5% | (15,401) | - | - | - | (15,401) | - |
| Lease payable on Right of Use assets | *24* | 5.0% | (12,762) | (1,150) | (1,135) | (1,742) | (4,532) | (4,203) |
| Total | | | (95,597) | 4,017 | (1,135) | (74,133) | (19,933) | (4,413) |

| *As at December 31, 2023* | *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 | *18* | 0.00% | 3,691 | 3,691 | - | - | - | - |
| Lease receivable | *15,17* | 4.0% | 155 | 62 | 39 | 49 | 5 | - |
| Exchangeable note[1] | *23* | 4.8% | (210) | - | - | - | - | (210) |
| Senior secured term loan[2] | *23* | 16.3% | (40,109) | - | - | - | (40,109) | - |
| Convertible note[3] | *23* | 1.5% | (14,542) | - | - | - | - | (14,542) |
| Lease payable on Right of Use assets | *24* | 5.0% | (12,566) | (812) | (832) | (1,745) | (4,425) | (4,752) |
| Total | | | (63,581) | 2,941 | (793) | (1,696) | (44,529) | (19,504) |

[1] The maturity of the exchangeable notes is based on the contractual maturity date of April 1, 2045.
[2] The senior secured term loan is a variable instrument. In January 2024, the amended term loan agreement reduced the annual rate of interest on the loan by 2.5% to 8.75% plus the greater of (a) Term Secured Overnight Financing Rate or (b) 4.0% per annum, and allows for a further 2.5% reduction in the base rate to 6.25% once the outstanding principal under the term loan falls below US$35 million. The loan matures in July 2026.
[3] The 7-year convertible note was issued in May 2022 and is a fixed rate instrument which bears a fixed rate of interest of 1.5% per annum.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$Nil (2023: US$Nil) as at December 31, 2024 the Company holds no funds in interest-bearing accounts; while the annual impact on the interest expense would be an increase of US$755,000 (2023: US$417,000) on the costs of servicing the senior secured term loan.

27. 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, 2024 US$'000* | *December 31, 2023 US$'000* |
|---|---|---|
| ***Variable rate instruments*** | | |
| Cash at bank and in hand | 5,167 | 3,691 |
| Variable rate financial liabilities (senior secured term loan) | (72,391) | (40,109) |
| | (67,224) | (36,418) |
| ***Fixed rate instruments*** | | |
| Fixed rate financial liabilities (exchangeable note) | (210) | (210) |
| Fixed rate financial liabilities (convertible note) | (15,401) | (14,542) |
| Fixed rate financial liabilities (lease payables) | (12,762) | (12,566) |
| Financial assets (lease receivables) | - | 155 |
| | (28,373) | (27,163) |

***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, 2024 or December 31, 2023 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, 2024 and December 31, 2023 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, 2024 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 and other payables (excluding deferred income) | 25,286 | 25,286 | 25,286 | - | - | - | - |
| Lease payable on Right of Use assets | 12,762 | 15,214 | 1,454 | 1,408 | 2,213 | 5,487 | 4,652 |
| Senior secured term loan[1] | 72,391 | 81,438 | 1,703 | 3,319 | 76,416 | - | - |
| Convertible note | 15,401 | 21,350 | 150 | 150 | 300 | 900 | 19,850 |
| Exchangeable notes | 210 | 380 | 4 | 4 | 8 | 24 | 340 |
| | 126,050 | 143,668 | 28,597 | 4,881 | 78,937 | 6,411 | 24,842 |

[1] The contractual cash flows of interest on the senior secured term loan is estimated based on the prevailing interest rate at December 31, 2024

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

| *As at December 31, 2023* *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 and other payables (excluding deferred income) | 12,752 | 12,752 | 12,752 | - | - | - | - |
| Lease payable on Right of Use assets | 12,566 | 15,306 | 1,107 | 1,114 | 2,243 | 5,442 | 5,400 |
| Senior secured term loan[1] | 40,109 | 56,121 | 3,461 | 3,461 | 6,922 | 42,277 | - |
| Convertible note | 14,542 | 21,650 | 150 | 150 | 300 | 900 | 20,150 |
| Exchangeable notes | 210 | 389 | 4 | 4 | 8 | 24 | 349 |
| | 80,179 | 106,218 | 17,474 | 4,729 | 9,473 | 48,643 | 25,899 |

[1] The contractual cash flows of interest on the senior secured term loan is estimated based on the prevailing interest rate at December 31, 2023.

***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, 2024 or December 31, 2023.

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, 2024* | *EUR US$'000* | *GBP US$'000* | *SEK US$'000* | *CAD US$'000* | *BRL US$'000* | *Other US$'000* |
|---|---|---|---|---|---|---|
| Cash | 116 | 50 | 20 | 293 | 373 | - |
| Trade and other receivable | 1,009 | 74 | - | 294 | 1,019 | - |
| Trade and other payables | (7,098) | (453) | (12) | (114) | (135) | (1) |
| Lease liabilities | (6,867) | - | - | - | (171) | - |
| Total exposure | (12,840) | (329) | 8 | 473 | 1,086 | (1) |

| *As at December 31, 2023* | *EUR US$'000* | *GBP US$'000* | *SEK US$'000* | *CAD US$'000* | *BRL US$'000* | *Other US$'000* |
|---|---|---|---|---|---|---|
| Cash | 219 | 15 | 5 | 191 | 854 | - |
| Trade and other receivable | 856 | 100 | - | 533 | 1,533 | - |
| Trade and other payables | (3,766) | (100) | (12) | (220) | (704) | (1) |
| Lease liabilities | (8,349) | - | - | - | (241) | - |
| Total exposure | (11,040) | 15 | (7) | 504 | 1,442 | (1) |

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Sensitivity analysis

A 10% strengthening of the US Dollar against the Euro at December 31, 2024 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, 2024** | |
| Euro | 1,167 |
| | |
| **December 31, 2023** | |
| Euro | 1,004 |

A 10% weakening of the US Dollar against the Euro at December 31, 2024 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, 2024** | |
| Euro | (1,427) |
| | |
| **December 31, 2023** | |
| Euro | (1,227) |

The sensitivity analysis is based on the Group's foreign currency exposures at the reporting date and assumes a 10% movement in the US Dollar against the Euro. The analysis includes monetary assets and liabilities denominated in Euro at the reporting date and assumes that exchange rate changes occur at the period-end and are applied to the net exposure. Non-monetary items and future forecast transactions are excluded. The analysis assumes that all other variables, including interest rates, remain constant. The analysis does not incorporate interdependencies between variables, such as interest rate effects on exchange rates, and is not based on a value-at-risk model.

The objective of this analysis is to assess the potential impact of reasonably possible changes in exchange rates on the Group's profit or loss and equity, based on exposures at the reporting date. The analysis reflects only monetary assets and liabilities denominated in foreign currencies and does not include future transactions or embedded derivatives. The analysis has inherent limitations, as it is based on a hypothetical movement in a single variable (foreign exchange rate) and assumes all other variables remain constant. It does not consider the potential interdependence between risk factors (such as changes in interest rates or inflation), nor does it reflect management's dynamic hedging activities or the potential impact on fair value from market volatility occurring after the reporting date.

***Credit Risk***

The Group has no significant concentrations of credit risk. Exposure to credit risk is monitored on an ongoing basis. For trade receivables, the Group applies the simplified approach to measuring expected credit losses and recognizes a lifetime expected credit loss allowance. A receivable is considered credit-impaired when it is more than 120 days past due or when there is evidence of significant financial difficulty. 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.

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

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.

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, 2024 US$'000* | *Carrying Value December 31, 2023 US$'000* |
|---|---|---|
| Third party trade receivables (Note 17) | 13,416 | 10,698 |
| Finance lease income receivable (Note 17) | - | 155 |
| Cash and cash equivalents (Note 18) | 5,167 | 3,691 |
| | 18,583 | 14,544 |

The maximum exposure to credit risk for trade receivables and finance lease income receivable by geographic location is as follows:

| | *Carrying Value December 31, 2024 US$'000* | *Carrying Value December 31, 2023 US$'000* |
|---|---|---|
| United States | 4,185 | 4,041 |
| Euro-zone countries | 742 | 851 |
| United Kingdom | 741 | 126 |
| Other regions | 7,748 | 5,835 |
| | 13,416 | 10,853 |

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, 2024 US$'000* | *Carrying Value December 31, 2023 US$'000* |
|---|---|---|
| End-user customers | 3,828 | 5,029 |
| Distributors | 8,236 | 5,399 |
| Non-governmental organisations | 1,352 | 425 |
| | 13,416 | 10,853 |

Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

**Impairment Losses**

The ageing of trade receivables at December 31, 2024 is as follows:

| | *Gross 2024 US$'000* | *Impairment 2024 US$'000* | *Expected Credit Loss Rate 2024 %* | *Gross 2023 US$'000* | *Impairment 2023 US$'000* | *Expected Credit Loss Rate 2023 %* |
|---|---|---|---|---|---|---|
| Not past due | 9,363 | - | - | 8,031 | - | - |
| Past due 0-30 days | 1,455 | - | - | 1,534 | - | - |
| Past due 31-120 days | 1,753 | 31 | 1.8% | 856 | 22 | 2.6% |
| Greater than 120 days | 3,131 | 2,255 | 72.0% | 2,601 | 2,302 | 88.5% |
| | 15,702 | 2,286 | - | 13,022 | 2,324 | - |

The Group considers that the credit risk of a financial asset may have increased since initial recognition when it is more than 30 days past due, unless there is evidence to the contrary. As at December 31, 2024, all trade receivables past due more than 30 days were assessed for changes in credit risk since initial recognition. Based on this assessment:

- Receivables past due between 31 and 120 days are not automatically considered to have an increased credit risk unless other qualitative indicators are present (e.g., known financial difficulty, adverse changes in circumstances, etc.).
- Receivables past due more than 120 days are generally considered to have a higher credit risk and are assessed for lifetime expected credit losses.

The Group applies a simplified approach in measuring expected credit losses which uses a provision matrix based on historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The movement in the allowance for impairment in respect of trade receivables during the year was as follows:

| | *2024 US$'000* | *2023 US$'000* |
|---|---|---|
| Balance at January 1 | 2,324 | 2,691 |
| Charged to costs and expenses | 225 | 715 |
| Amounts written off during the year | (263) | (977) |
| Eliminated on disposal of business | - | (105) |
| Balance at December 31 | 2,286 | 2,324 |

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.

The Group does not provide financing to customers as a main business activity and therefore is not required to present credit risk exposure disclosures by credit risk grade.

28. 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, 2024 | *23,24* | 55,387 | 12,566 |
| Cash-flows: | | | |
| Principal amount loaned – term loan | | 30,500 | - |
| Loan origination costs paid | | (324) | - |
| Interest paid for senior secured term loan | | (6,253) | - |
| Interest paid for convertible note | | (300) | - |
| Interest paid for exchangeable notes | | (8) | - |
| Repayment of leases | | - | (2,503) |
| | | | |
| Non-cash: | | | - |
| Interest charged | | 6,561 | - |
| Derivative financial asset at date of issue | | 28 | - |
| Remeasurement of ROU assets | | - | 1,764 |
| Additions (related to Right of Use assets) | | - | 855 |
| Exchange adjustment | | - | (512) |
| Accretion interest | | 3,214 | 592 |
| Fair value of derivative liability - warrants | | 66 | - |
| Fair value of additional derivative liability - warrants | | 1,066 | - |
| Payment-in-kind (PIK) Interest | | 3,291 | - |
| Contingent liability | | 1,813 | - |
| Non-cash loan modification gain | | (3,567) | - |
| Balance at December 31, 2024 | *23,24* | 91,474 | 12,762 |

28. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES (CONTINUED)

| | *Note* | *Borrowings & derivative financial instruments US$'000* | *Lease liabilities US$'000* |
|---|---|---|---|
| Balance at January 1, 2023 | *23,24* | 59,826 | 13,943 |
| Cash-flows: | | | |
| Principal amount loaned – term loan | | 5,000 | - |
| Loan origination costs paid | | (194) | - |
| Interest paid for senior secured term loan | | (7,314) | - |
| Interest paid for convertible note | | (300) | - |
| Interest paid for exchangeable notes | | (8) | - |
| Repayment of term loan | | (10,050) | |
| Repayment of leases | | - | (2,318) |
| Penalty paid for early settlement of term loan | | (905) | - |
| | | | |
| Non-cash: | | | — |
| Interest charged | | 7,622 | - |
| Penalty for early settlement charged | | 905 | - |
| Derivative financial asset at date of issue | *23* | 11 | - |
| Disposals (related to Right of Use assets) | | - | (106) |
| Additions (related to Right of Use assets) | | - | 112 |
| Exchange adjustment | | - | 311 |
| Accretion interest | | 1,927 | 624 |
| Fair value of derivative liability - warrants | | (1,133) | - |
| | | | |
| Balance at December 31, 2023 | *23,24* | 55,387 | 12,566 |

29. BUSINESS COMBINATIONS

Acquisition of the CGM assets of Waveform Technologies, Inc.

On January 30, 2024, the Company purchased the biosensor and continuous glucose monitoring ("CGM") assets of privately held Waveform Technologies, Inc. ("Waveform") for the initial consideration of US$12.5 million in cash and 36 million 'A' Ordinary shares (represented by 1.8 million ADSs) of the Company, which had a fair value of US$3,960,000 on the date of acquisition. In addition contingent consideration of a maximum of US$20 million. We intend to update the Waveform CGM device, which is not being marketed, and optimize it for broad adoption and then evolve this platform technology to measure and analyze other valuable biomarkers and related datapoints. Our vision is to develop a portfolio of technologies that can offer users and clinicians valuable actionable health and wellness insights. Control was obtained through the acquisition of substantially all of Waveform's operational assets and intellectual property, representing an integrated set of activities and assets capable of being conducted and managed to provide a return in the form of outputs. The integrated set of activities and assets purchased will significantly contribute to achieving our vision and its associated outputs.

This transaction has been accounted for as a business combination under IFRS 3. The determination was based on the acquisition of an integrated set of activities and assets, including intellectual property, technical processes, and a skilled workforce, that together constitute a business capable of being conducted and managed to provide returns

The fair value of non-cash consideration in the form of ADSs issued in connection with the acquisition was determined using the volume-weighted average price (VWAP) of the Company's ADSs on the acquisition date.

Contingent consideration of up to US$20 million may be payable upon the occurrence of certain events, including;

- US$5.0 million payment if, within the next 12 months after closing, (i) the closing price of the Company's ADSs does not exceed US$7.50 per ADS for at a least 20 consecutive trading days and (ii) the average daily trading volume of the Company's ADSs does not equal or exceed 20,000 ADSs for 20 consecutive trading days, and

- 50% of the proceeds received by the Company (up to a maximum payment of additional consideration of US$15.0 million) on our entering into certain commercial partnering agreements with certain glucose pump manufacturers in the 24 months from date of acquisition. The fair value assigned to this element of the contingent consideration was US$1.8 million at the acquisition date. This is disclosed as a contingent liability in Note 23.

The fair value of the contingent consideration at date of acquisition was US$6.8 million. Of this, US$5.0 million is classified as a current liability (Note 21), while the US$1.8 million is disclosed as a contingent liability (see Note 23). As of December 31, 2024, there have been no changes to the amount recognized or to the assumptions used in its initial measurement.

Acquisition-related costs amounting to US$1.5 million in respect of the Waveform transaction are not included as part of consideration transferred and have been recognised as an expense in the condensed consolidated statement of operations, within 'Selling, general and administrative expenses'.

The initial assignment of fair values to identifiable net assets acquired has been performed on a provisional basis in respect of the above acquisitions. Any amendments to these acquisition fair values within the 12-month timeframe from the date of acquisition will be disclosed in the relevant Annual Report as stipulated by IFRS 3 Business Combinations.

29. BUSINESS COMBINATIONS (CONTINUED)

| | *Provisional value US$'000* | *Measurement period adjustment US$'000* | *Adjusted values US$'000* |
|---|---|---|---|
| Property, plant and equipment | 1,569 | (206) | 1,363 |
| Intangible assets – arising on acquisition | 9,360 | - | 9,360 |
| Financial assets | 9 | - | 9 |
| Inventory | 1,296 | (1,296) | - |
| Trade and other receivables | 135 | - | 135 |
| Trade and other payables | (50) | - | (50) |
| Deferred tax liabilities | (1,170) | 1,170 | - |
| **Net assets acquired** | **11,149** | **(332)** | **10,817** |
| Goodwill | 12,071 | 332 | 12,403 |
| **Consideration** | **23,220** | **-** | **23,220** |
| | | | |
| *Satisfied by:* | | | |
| Cash consideration | 12,500 | - | 12,500 |
| Non-cash consideration | 3,960 | - | 3,960 |
| Deferred contingent consideration | 6,760 | - | 6,760 |
| **Total consideration** | **23,220** | **-** | **23,220** |
| | | | |
| Net cash outflow – arising on acquisition | | | |
| Cash consideration | 12,500 | - | 12,500 |
| **Net cash outflow** | **12,500** | **-** | **12,500** |

In accordance with IFRS 3 Business Combinations, the Group finalised the fair value assessments relating to the acquisition of the Waveform CGM assets during the year. As part of this process, the Group reassessed the fair value of several acquired balances based on new information obtained during the measurement period.

The fair value of intellectual property related to the acquired technology at the Closing Date was derived using the multi-period excess earnings method. Significant assumptions used in the valuation including CGM cash flow projections which were based on estimates used to price the Waveform acquisition, and the discount rate applied was benchmarked with reference to the implied rate of return to the Company's pricing model and the weighted-average cost of capital. The intangible asset for acquired technology will be amortized over the respective estimated periods for which the intangible assets will provide economic benefit to the Company, which is 15 years.

Following further evaluation, the deferred tax liability of US$1.2 million initially recognised on acquisition was reversed. This adjustment was based on a more detailed analysis of the tax base of the acquired intangible assets, which concluded that a deferred tax liability was not required.

In addition, the fair value of inventory was reduced by US$1.3 million. This reduction reflects a revised assessment of net realisable value. Although initial discussions with management and potential buyers such as Bayer India suggested a potential market in emerging economies, further exploration indicated that the additional expenditure required to bring the acquired raw materials, finished goods and work-in-progress to market would render the inventory commercially unviable. As a result, the inventory was deemed to have no recoverable value.

The value of property, plant and equipment was also reduced by US$0.2 million. These assets were found to be specific to the legacy CGM product and, following further technical review, were determined to have no future economic value. Accordingly, their fair value was adjusted to nil.

These adjustments have been accounted for retrospectively as measurement period adjustments in accordance with IFRS 3. These measurement period adjustments resulted in a corresponding increase in goodwill of US$0.3 million. Comparative figures have not been restated as the acquisition occurred during the current financial year.

29. BUSINESS COMBINATIONS (CONTINUED)

The goodwill recognised from the acquisition of the Waveform CGM assets primarily reflects expected synergies from integrating Waveform's European-approved CGM technology with Trinity Biotech's global manufacturing and diabetes expertise. The platform is expected to accelerate the development of a next-generation, affordable, and user-friendly CGM device, and supports the Group's strategy to expand into adjacent biosensor markets. None of the goodwill is expected to be deductible for tax purposes.

Waveform was acquired on January 30, 2024. As of December 31, 2024, the acquiree had not generated any revenue since the acquisition date, and therefore no revenue has been included in the Group's consolidated statement of comprehensive income for the reporting period. In addition, the acquired business incurred a net loss of US$1.3 million, which has been included in the Group's consolidated results. The reported loss excludes interest on intercompany funding arrangements in order to reflect the underlying performance of the acquired business. Waveform Technologies, Inc. was a privately held company in the late stages of product development and commercial readiness. Although the company was not generating revenue, it had developed a CE-marked CGM device. It did not maintain financial information in accordance with IFRS, and as such, the Group is unable to reliably reconstruct the required historical information for pro forma disclosure without incurring undue cost or effort.

Acquisition of Metabolomics Diagnostics Limited

In September 2024, the Company completed the acquisition of 100% of Metabolomics Diagnostics Ltd ("Metabolomics"), a privately-owned Irish deep-tech company, specializing in the development of novel biomarker-based diagnostic solutions for complex diseases, with the initial focus being screening for preeclampsia risk using the company's PrePsia test. Control was obtained through the execution of a share purchase agreement, resulting in the acquisition of 100% of the voting interests. The primary reason for the acquisition was to enter a new area of medical diagnostics with significant long-term growth potential. The acquisition aligns with the Group's strategy of combining its established capabilities with innovative technologies to unlock new revenue opportunities. The Group intends to leverage this platform to commercialise the PrePsia test in the U.S. through its Immco laboratory and to explore opportunities in international markets.

The Company acquired Metabolomics for consideration of approximately US$0.9 million paid through the issuance of approximately 0.27 million ADSs of the Company alongside the extinguishment of monies owed to the Company totalling US$0.4 million. The fair value of non-cash consideration in the form of ADSs issued in connection with the acquisition was determined using the volume-weighted average price (VWAP) of the Company's ADSs on the acquisition date.

| | *Metabolomics Provisional value US$'000* |
|---|---|
| Property, plant and equipment | 10 |
| Intangible assets – arising on acquisition | 1,200 |
| Inventory | 144 |
| Trade and other receivables | 181 |
| Trade and other payables | (494) |
| Deferred tax liabilities | (150) |
| Cash acquired | 9 |
| **Net assets acquired** | **900** |
| Goodwill | 6 |
| **Consideration** | **906** |
| | |
| *Satisfied by:* | |
| Cash consideration | 412 |
| Non-cash consideration | 494 |
| **Total consideration** | **906** |
| | |
| Net cash outflow – arising on acquisition | |
| Cash consideration | 412 |
| Less: Cash and cash equivalents | (8) |
| **Net cash outflow** | **404** |

29. BUSINESS COMBINATIONS (CONTINUED)

Transaction costs associated with the acquisition of Metabolomics amounted to US$0.3 million, relating to the disbursement of agreed fees and closing bonuses. These costs have been expensed as incurred in accordance with IFRS 3 and have been recognised in the condensed consolidated statement of operations, within 'Selling, general and administrative expenses'

The goodwill recognised in respect of the Metabolomics acquisition is attributable to expected synergies arising from the combination of operations, as well as the assembled workforce of the acquired business. None of the goodwill recognised is expected to be deductible for tax purposes.

Metabolomics was acquired in September 2024. As of December 31, 2024, the acquiree had not generated any revenue since the acquisition date, and therefore no revenue has been included in the Group's consolidated statement of comprehensive income for the reporting period. The acquired business incurred a net loss of US$0.3 million, primarily relating to ongoing development and administrative costs, which has been included in the Group's consolidated results. Metabolomics was a privately held, early-stage Irish entity focused on biomarker-based diagnostics. The company did not prepare its financial information in accordance with IFRS, and the Group is therefore unable to reliably reconstruct the necessary historical financial information to provide pro forma consolidated revenue and profit or loss data without incurring undue cost or effort.

Acquisition of EpiCapture Limited

In October 2024, the Company completed the acquisition of 100% of EpiCapture Limited ("EpiCapture"), a company developing a non-invasive test for monitoring the risk of aggressive prostate cancer. Control was obtained through the execution of a share purchase agreement, resulting in the acquisition of 100% of the voting interests. The primary reason for the acquisition was to strengthen the Group's oncology diagnostics pipeline by acquiring a novel, epigenetics-based prostate cancer test aligned with our strategy of combining Trinity's established capabilities with cutting-edge technologies to address large-scale, urgent, and important clinical issues.

The Company acquired EpiCapture for an initial consideration of approximately US$3.0 million, with an additional consideration of US$0.5 million contingent (Note 21) on the achievement of future milestones. The initial consideration was paid through the issuance of approximately 1.7 million ADS in Trinity Biotech. The fair value of non-cash consideration in the form of Company ADSs issued in connection with the acquisition was determined using the volume-weighted average price (VWAP) of the Company's ADSs on the acquisition date.

| | *EpiCapture Provisional value US$'000* |
|---|---|
| Intangible assets – arising on acquisition | 2,668 |
| Trade and other payables | (406) |
| Deferred tax liabilities | (333) |
| **Net assets acquired** | **1,929** |
| Goodwill | 1,420 |
| **Consideration** | **3,349** |
| | |
| *Satisfied by:* | |
| Non-cash consideration | 2,965 |
| Deferred contingent consideration | 384 |
| **Total consideration** | **3,349** |
| | |
| Net cash outflow – arising on acquisition | |
| **Net cash outflow** | **-** |

29. BUSINESS COMBINATIONS (CONTINUED)

The contingent consideration related to the acquisition of EpiCapture Limited comprises deferred consideration with a fair value of US$0.4 million. An amount of US$0.5 million will become payable if cumulative revenues from EpiCapture's operations reach US$1.0 million within a period of three years, commencing from the date on which the Company obtains validation of the EpiCapture prostate test under the New York State Department of Health's Clinical Laboratory Evaluation Programme. As of December 31, 2024, there have been no changes to the amount recognized or to the assumptions used in its initial measurement.

Transaction costs associated with the acquisition of EpiCapture amounted to US$26,000, have been expensed as incurred in accordance with IFRS 3 and have been recognised in the condensed consolidated statement of profit or loss, within 'Selling, general and administrative expenses'.

The goodwill recognised in respect of the EpiCapture acquisition is attributable to expected synergies arising from the combination of operations. None of the goodwill recognised is expected to be deductible for tax purposes.

EpiCapture was acquired in October 2024. As of December 31, 2024, the acquiree had not generated any revenue since the acquisition date, and therefore no revenue has been included in the Group's consolidated statement of comprehensive income for the reporting period. The acquired business incurred a net loss of US$20,000, mainly comprising transaction-related expenses, which has been included in the Group's consolidated results. EpiCapture Limited was a privately held, early-stage Irish company developing a novel epigenetics-based diagnostic test. As the entity did not prepare its financial information in accordance with IFRS, it is not practicable for the Group to reconstruct the required historical financial information to present pro forma consolidated results for the year ended December 31, 2024, without undue cost or effort

The initial assignment of fair values to the identifiable net assets acquired in respect of the Metabolomics and EpiCapture acquisitions has been performed on a provisional basis. Any amendments to these acquisition fair values within the 12-month timeframe from the respective dates of acquisition will be disclosed in future financial statements in accordance with IFRS 3 Business Combinations.

It is impracticable for the Group to disclose the pro forma consolidated revenue and profit or loss for the year ended December 31, 2024, as if the acquisitions of Waveform, Metabolomics, and EpiCapture had occurred on January 1, 2024. All three entities were privately held, early-stage businesses that did not maintain financial information in accordance with IFRS. As a result, the Group is unable to reliably reconstruct the required historical financial information without incurring undue cost or effort.

There were no individually immaterial business combinations that are collectively material during the year. All business combinations completed during the year have been assessed as individually material and have been disclosed separately in the notes to the consolidated financial statements.

30. POST BALANCE SHEET EVENTS

**Amendment and Restatement of Term Loan**

During 2025, the Company entered into further amendments to its senior secured term loan credit agreement with its principal lender, Perceptive, to access additional funding and enhance its financial position.

On February 27, 2025, the Company entered into a fourth amendment to the credit agreement, pursuant to which Perceptive provided an additional US$4.0 million in term loan funding. This funding will be used for general corporate purposes, including the further development of our CGM offering.

On May 14, 2025, the Company entered into a fifth amendment to the credit agreement, which provided for a further US$2.0 million in term loan funding, extended the maturity date of the Term Loan from January 2026 to July 27, 2026, and confirmed that interest payments for the months of April, May, and June 2025 would be paid-in-kind. This funding is also intended to support general corporate purposes and continued investment in the Company's CGM and biosensor development programs.

These 2025 amendments reflect the ongoing support of Perceptive and have further strengthened the Company's liquidity position, while providing greater operational and financial flexibility to support the execution of its strategic and commercial objectives.

31. 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 the impairment of goodwill, other intangible assets, property, plant and equipment and financial asset. Note 20 outlines information regarding the valuation of share options. Note 23 outlines the valuation techniques used by the Company in determining the fair value of the Group's interest-bearing loans and borrowings. In Note 27, 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.

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, 2024 US$nil (2023: US$50,000) (2022: US$114,000) of revenue was deferred in accordance with IFRS15.

*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.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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, 2024 the carrying value of capitalised development costs was US$20,951,000 (2023: US$15,103,000) (see Note 12 to the consolidated financial statements). The increase in 2024 was mainly as a result of additions of US$8,582,000, partially offset by impairment losses of US$1,596,000 recognised during the year.

*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.

When we determine that the carrying value of intangibles and non-current assets 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, 2024 resulted in impairment losses being recorded in four cash generating units, namely Immco Diagnostics Inc, Trinity Biotech Do Brasil, Biopool US Inc and Clark Laboratories Inc totalling US$1.4 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 2024, 2023 or 2022 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2024 our allowance for slow moving and obsolete inventory was US$7.6 million which represents approximately 28.3% of gross inventory value. At December 31, 2023 our allowance for slow moving and obsolete inventory was US$11.3 million which represented approximately 36.3% of gross inventory value and at December 31, 2022 the provision was US$16.3 million, or approximately 42.0% of gross inventory value. The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has decreased between 2023 and 2024 due to the physical scrapping of obsolete inventory and better inventory management.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

*Allowance for slow-moving and obsolete inventory (continued)*

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$0.5 million at December 31, 2024 (2023: US$0.6 million) (2022: US$0.8 million) would result. For further information, refer to Note 16.

*Business Combinations*

The Group completed three business combinations during the year: the acquisitions of Waveform Technologies, Metabolomics Health, and EpiCapture. Significant judgement was required in determining whether each transaction met the definition of a business under IFRS 3 Business Combinations, based on the acquisition of an integrated set of activities and assets capable of generating outputs.

In accounting for these transactions, management was required to make key estimates in the determination of the fair value of the identifiable assets acquired and liabilities assumed, including the recognition and measurement of separately identifiable intangible assets and contingent consideration. The valuations involved the use of discounted cash flow models and required management to estimate future cash flows, apply appropriate discount rates reflecting the Group's weighted average cost of capital, and assess the probability of meeting contingent consideration milestones. The Group engaged an independent third-party valuation specialist to assist with the purchase price allocation for all three acquisitions. These estimates had a material impact on the allocation of consideration between identifiable intangible assets and goodwill.

*Investment in Novus Diagnostics*

During the year, the Group acquired a minority equity interest in a privately held company that is not quoted in an active market. The investment is classified as a financial asset at fair value through profit or loss (FVTPL) in accordance with IFRS 9. The fair value of the investment was initially based on the transaction price. As the investment is classified within Level 3 of the fair value hierarchy under IFRS 13, subsequent remeasurement requires the use of unobservable inputs and significant management judgement. This includes consideration of investee-specific developments, commercial progress, and market conditions.

*Going Concern*

The accompanying consolidated financial statements have been prepared assuming that we 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.

Management's assessment of the Group's ability to continue as a going concern involves significant judgement. For details of the assumptions and considerations underpinning this assessment, refer to the "Going concern" section of Note 1, which outlines the basis of preparation..

32. 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<br>IDA Business Park, Bray<br>County Wicklow, Ireland | Manufacture and sale of diagnostic test kits | Ireland | 100% |
| Trinity Research Limited<br>IDA Business Park, Bray<br>County Wicklow, Ireland | Research and development | Ireland | 100% |
| Trinity Biotech Manufacturing Services Limited<br>IDA Business Park, Bray<br>County Wicklow, Ireland | Dormant | Ireland | 100% |
| Trinity Biotech Luxembourg Sarl<br>1, rue Bender,<br>L-1229 Luxembourg | Investment and provision of financial services | Luxembourg | 100% |
| Trinity Biotech Inc<br>Girts Road,<br>Jamestown,<br>NY 14702, USA | Holding Company | U.S.A. | 100% |
| Clark Laboratories Inc<br>Trading as Trinity Biotech (USA)<br>Girts Road, Jamestown<br>NY14702, USA | Manufacture and sale of diagnostic test kits | U.S.A. | 100% |
| Mardx Diagnostics Inc<br>5919 Farnsworth Court<br>Carlsbad<br>CA 92008, USA | Dormant | U.S.A. | 100% |
| Biopool US Inc (trading as Trinity Biotech Distribution)<br>Girts Road, Jamestown<br>NY14702, USA | Sale of diagnostic test kits | U.S.A. | 100% |
| Primus Corporation<br>4231 E 75th Terrace<br>Kansas City,<br>MO 64132, USA | Manufacture and sale of diagnostic test kits and instrumentation | U.S.A. | 100% |

32. GROUP UNDERTAKINGS (CONTINUED)

| *Name and registered office* | *Principal activity* | *Principal Country of incorporation and operation* | *Group % holding* |
|---|---|---|---|
| Phoenix Bio-tech Corp.<br>1166 South Service Road West<br>Oakville, ON L6L 5T7<br>Canada. | Dormant | Canada | 100% |
| Fiomi Diagnostics Holding AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden | Holding Company | Sweden | 100% |
| Fiomi Diagnostics AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden | Discontinued operation<br>(in liquidation) | Sweden | 100% |
| Trinity Biotech Do Brasil<br>Comercio e Importacao Ltda<br>Rua Silva Bueno<br>1.660 – Cj. 101/102<br>Ipiranga<br>Sao Paulo<br>Brazil | Sale of diagnostic test kits | Brazil | 100% |
| Trinity Biotech (UK) Ltd<br>Mills and Reeve LLP<br>Botanic House<br>100 Hills Road<br>Cambridge, CB2 1PH<br>United Kingdom | Sales & marketing activities | UK | 100% |
| Immco Diagnostics Inc<br>60 Pineview Drive<br>Buffalo<br>NY 14228, USA | Manufacture and sale of autoimmune products and laboratory services | U.S.A. | 100% |
| Nova Century Scientific Inc<br>5022 South Service Road<br>Burlington<br>Ontario<br>Canada | Manufacture and sale of autoimmune products and infectious diseases | Canada | 100% |
| Trinity Biotech Investment Ltd<br>PO Box 309<br>Ugland House<br>Grand Cayman<br>KY1-1104<br>Cayman Islands | Investment and provision of financial services | Cayman Islands | 100% |

32. GROUP UNDERTAKINGS (CONTINUED)

| *Name and registered office* | *Principal activity* | *Principal Country of incorporation and operation* | *Group % holding* |
|---|---|---|---|
| Trib Biosensors Inc.<br>27700 S.W. 95th Avenue,<br>Wilsonville,<br>Oregon 97070, USA | Manufacturing, development, and sale of biosensors | USA | 100% |
| Konamite Limited<br>IDA Business Park, Bray<br>County Wicklow, Ireland | Sales & marketing activities | Ireland | 100% |
| Trinity Biotech Joint Venture Limited<br>IDA Business Park, Bray<br>County Wicklow, Ireland | Holding Company | Ireland | 100% |
| EpiCapture Limited<br>19 Mather Road, Mount Merrion, Dublin, Ireland | Research and development | Ireland | 100% |
| Metabolomics Diagnostics Limited<br>Hoffman Park, Inchera, Little Island, Co. Cork, Ireland | Research and development | Ireland | 100% |
| Waveform Technologies Inc.<br>Obrtna cesta 18, 8310 Sentjernej, Slovenia | Manufacturing, development, and sale of biosensors | Slovenia | 100% |

33. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on May 15, 2025.

***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/ John Gillard
Mr John Gillard
Director/
Chief Executive Officer

Date: May 15, 2025

By: /s/ Susan O'Connor
Susan O'Connor
Interim Chief Financial Officer

Date: May 15, 2025

**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) (included as Exhibit 1.1 to our Annual Report on Form 20-F filed on May 16, 2023 and incorporated herein by reference). |
| 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 (included as Exhibit 2.1 to our Annual Report on Form 20-F filed on May 16, 2023 and incorporated herein by reference) |
| 4.1 | Trinity Biotech plc Share Option Plan 2020 (included as Exhibit 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 2017 (included as Exhibits 4.3 to our Registration Statement on Form S-8, filed on February 12, 2021 and incorporated herein by reference). |
| 4.3 | 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). |
| 4.4 | 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). |
| 4.5 | 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). |
| 4.6 | 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). |
| 4.7 | 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). |
| 4.8 | 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). |
| 4.9 | 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). |
| 4.10 | 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). |
| 4.11 | Warrant to purchase American Depositary Shares of Trinity Biotech plc, dated January 27, 2022 (included as Exhibit 4.11 to our Annual Report on Form 20-F filed on April 30, 2024 and incorporated herein by reference). |
| 4.12 | 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). |
| 4.13 | Second Amendment to Warrant to purchase American Depositary Shares of Trinity Biotech plc dated January 30, 2024. |
| 4.14 | Third Amendment to Warrant to purchase American Depositary Shares of Trinity Biotech plc dated December 23, 2024 |
| 4.15 | 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). |
| 4.16 | 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). |

| Exhibit No. | Description of Exhibit |
|---|---|
| 4.17 | Investor Subordination Agreement dated May 3, 2022 (included as Exhibit 4.15 to our Annual Report on Form 20-F filed on April 30, 2024 and incorporated herein by reference). |
| 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 † | Transition Agreement, dated as of December 20, 2023, among Bayer Healthcare LLC, Waveform Technologies, Inc. and TRIB Biosensors Inc. (included as Exhibit 4.17 to our Annual Report on Form 20-F filed on April 30, 2024 and incorporated herein by reference) |
| 4.20*† | Asset and Share Purchase Agreement dated as of January 30, 2024 (included as Exhibit 4.20 to our Report on Form 6-K filed on February 1, 2024 and incorporated herein by reference). |
| 4.21* | Fifth Amended and Restated Credit Agreement and Guaranty, dated as of May 14, 2025 (included as Exhibit 99.1 to our Report on Form 6-K filed on May 15, 2025 and incorporated herein by reference). |
| 4.22 | Warrant to purchase American Depositary Shares of Trinity Biotech plc, dated January 30, 2024 (included as Exhibit 4.20 to our Annual Report on Form 20-F filed on April 30, 2024 and incorporated herein by reference). |
| 4.23 | First Amendment to Warrant to purchase American Depositary Shares of Trinity Biotech plc dated December 23, 2024. |
| 4.24 | Warrant to purchase to purchase American Depositary Shares of Trinity Biotech plc, dated December 23, 2024 (of Perceptive Credit Holdings III, LP) |
| 4.25 | Warrant to purchase to purchase American Depositary Shares of Trinity Biotech plc, dated December 23, 2024 (of Perceptive Credit Holdings II, LP) |
| 8.1 | List of significant subsidiaries of Trinity Biotech plc (included as Item 18, note 32 to the consolidated financial statements in this Annual Report). |
| 11.1 | Insider trading policy (included as Exhibit 4.21 to our Annual Report on Form 20-F filed on April 30, 2024 and incorporated herein by reference). |
| 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 | Statement of Assets Acquired and Liabilities Assumed as of January 30, 2024 (on Form 6-K filed on April 30, 2024 and incorporated herein by reference). |
| 15.2 | Consent of Independent Registered Public Accounting Firm |
| 97.1 | Clawback Policy. |
| 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). |

* Certain schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby agrees to furnish a copy of any omitted schedules to the Commission upon request.

† Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.