Trinity Biotech plc

Annual Report 2025

This report has been prepared in accordance with the Companies Act 2014

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Corporate Information

DIRECTORS

Mr Ronan O'Caoimh	(resigned September 4, 2026)
Dr Jim Walsh	(retired September 30, 2025)
Mr John Gillard	
Mr Tom Lindsay	UK (resigned September 30, 2025)
Dr Andrew Omidvar	US
Mr John Paul Tivnan	(appointed August 6, 2025)
Mr Paul Murphy	(appointed September 4, 2026)

COMPANY SECRETARY
Mr John Gillard

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New York,
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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 the section entitled "*Risk Factors*" of 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 the section entitled "*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.

Board of Directors and Executive Officers

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 of directors 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.

Andrew Omidvar, Director joined the board of directors 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.

John Paul Tivnan, Director joined the board of directors of Trinity Biotech in August 2025. Mr Tivnan has over 25 years of senior leadership experience in finance, capital markets, and corporate governance across the infrastructure, energy, shipping, and cleantech sectors. He currently serves as Chief Financial Officer of Deriva Energy LLC, one of the largest independent renewable power producers in the United States and a Brookfield portfolio company. His previous roles include CFO of Brookfield Renewable Ireland and CFO of Ardmore Shipping Corporation, where he led the company's successful IPO on the New York Stock Exchange in 2013. Mr Tivnan has also served as a Director of Element 1 Corp, a developer of advanced hydrogen technologies.

Paul Murphy, Director and Interim Chief Financial Officer, joined Trinity Biotech in December 2024 as Head of Group Reporting and was appointed to Interim Chief Financial Officer in December 2025. Mr. Murphy joined the board of directors of Trinity Biotech in September 2026. Mr. Murphy is a PwC-trained Chartered Accountant (FCA) with broad experience across finance leadership, external reporting, technical accounting and business transformation in both private and public company environments. Prior to joining Trinity Biotech, he served as Finance Director of The Happy Pear, where he led the Group's finance, reporting and commercial functions. Earlier in his career, Mr. Murphy was a Senior Manager with PricewaterhouseCoopers in Dublin, working with multinational and listed clients across audit and advisory engagements. Mr. Murphy holds a Bachelor of Business & Legal Studies from University College Dublin.

Business Overview

Trinity Biotech develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. Trinity Biotech also operates a licenced reference laboratory that specializes in diagnostics for autoimmune diseases.

In January 2024, Trinity Biotech entered the wearable biosensor industry through the acquisition of the biosensor assets of Waveform Technologies Inc ("Waveform"). The Company is developing a platform of biosensor-enabled products and services focused on metabolic health, starting with a continuous glucose monitoring ("CGM") product.

Through its new Trinovium subsidiary, the Company is extending its fluid manufacturing and analytical capabilities into advanced liquid cooling solutions and fluid intelligence systems for AI data centre infrastructure.

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.

Trinity Biotech was 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, the Company completed an initial public offering of its securities in the US. The principal offices of the Group are located at IDA Business Park, Bray, County Wicklow, Ireland. The Group has expanded its product base through internal development and acquisitions.

Industry Overview

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.

Products and services

Our product and services portfolio is divided between Clinical Laboratory tests, point-of-care tests and Laboratory services. In 2025, our clinical laboratory division had revenue of US$31.7 million, the point-of-care division had revenue of US$8.1 million and the revenue from laboratory services was US$4.0 million.

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. Our Uni-Gold™ HIV product is a leading confirmatory HIV test in the African market.

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 HIV screening test, TrinScreen, received World Health Organisation ("WHO") approval in February 2022. We began commercial shipments of TrinScreen in 2023 and this ramped up significantly in 2024 and 2025.

In June 2025, we transitioned the upstream manufacturing processes for Uni-Gold™ HIV to an outsourced offshore model. In September 2025, following WHO regulatory approval, we commenced offshored and outsourced manufacturing of our TrinScreen HIV rapid test. We commenced the final phase of the Uni-Gold™ HIV manufacturing transition during the first quarter of 2026, enabling the transition of upstream manufacturing processes to commence in March 2026.

As these outsourced manufacturing models were implemented and scaled up, the Company experienced quarter-to-quarter variability in revenue and profitability resulting from the ramp-up of production capacity and the transition of supply-chain processes. While progress has been made in scaling these outsourced manufacturing platforms, we expect that ongoing scale-up activities may continue to contribute to variability in quarterly revenues and profitability through the remainder of 2026 and into early 2027.

These manufacturing transitions are intended to enhance supply-chain resilience and scalability, alongside improving gross margins and better aligning our cost base with the inherent variability of global HIV testing demand.

Clinical Laboratory

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

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

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

Infectious Diseases

Trinity Biotech manufactures kits for the detection of specialty and esoteric biomarkers of infectious diseases and other associated laboratory products. The products are used in processing patient samples whose results aid physicians in the diagnosis and clinical assessment of a broad range of infectious diseases. The key clinical laboratory disease areas that 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-CoV-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 measurement of haemoglobin A1c ("HbA1c") used in the monitoring 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 monitoring 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 is both CE marked and FDA cleared. In the United States 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.

In early 2025, we introduced our next-generation boronate-affinity buffer column system for the Premier Hb9210, which delivers significantly increased testing capacity, improved column stability and reduced instrument downtime. In February 2026, the Premier Hb9210, incorporating this newly launched Buffer A Plus column system, became the only HbA1c analyser worldwide to receive the prestigious IFCC Gold Classification for 2026, representing the highest level of analytical precision and bias certification awarded by the International Federation of Clinical Chemistry. This recognition reflects the platform's strong clinical accuracy and further strengthens the competitive position of the Premier Hb9210 in the global HbA1c testing market.

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

Trinity Biotech manufactures 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.

During 2025 and 2026, our development work on the next-generation CGM+ platform resulted in further improvements to sensor accuracy, electronics architecture, and the device's proprietary needle-free insertion process. These advancements have supported progression toward planned pivotal clinical trials in late 2026 or early 2027 and reflect continued refinement of the underlying multimodal biosensor architecture.

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. During 2025, the site continued to perform certain manufacturing processes related to HIV products, while significant aspects of the manufacturing process for these HIV products were transferred to a contract manufacturing partner in Q2 2025 and Q3 2025 following receipt of regulatory clearances. 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 operates as the Group's reference laboratory. This site previously manufactured 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..

Extrema, Brazil - this site is responsible for the manufacture of certain haemoglobin products sold in Brazil. During 2025, the site also commenced certain haemoglobin manufacturing processes for the Group's global markets, as production previously undertaken in Kansas City was transitioned to other facilities.

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

American Depository Shares

The Company's American Depositary Shares ("ADSs") are listed on Nasdaq under the symbol ''TRIB''. Each ADS represents a fixed number of the Company's Class A ordinary shares referred to as the "ADS ratio".

Effective 24 July 2026, the ADS ratio was changed from 20 Class A ordinary shares per ADS to 600 Class A ordinary shares per ADS ("2026 ADS ratio change").

Throughout this Annual Report references to ADSs and per-ADS amounts reflect the ADS ratio in effect at the relevant time. As a result:
Information relating to periods before 24 July 2026 reflects the former ratio of 1 ADS : 20 Class A ordinary shares.
Information relating to periods on or after 24 July 2026 reflects the current ratio of 1 ADS : 600 Class A ordinary shares.

Readers should be aware of this change when comparing per-ADS figures across periods, as historical and current amounts are not directly comparable on a per-ADS basis without adjustment for ratio change.

Directors' Report
Year ended December 31, 2025

Introduction
The directors submit their Annual Report, together with the audited financial statements of the Company and its subsidiaries ("Trinity Biotech" and/or "the Group"), for the year ended December 31, 2025.

Principal activities
Trinity Biotech is a biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors. Trinity Biotech is a significant provider of raw materials to the life sciences and research industries globally. Following the acquisition of the biosensor assets of Waveform Technologies Inc. ("Waveform") in 2024, we have been developing a range of biosensor devices and related services, beginning with a continuous glucose monitoring ("CGM") product. Through our subsidiaries, we develop, acquire, manufacture and market medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. Our products are used to detect autoimmune, infectious and sexually transmitted diseases, disorders of the liver and intestine, and to monitor markers for diabetes. In addition, through its new Trinovium subsidiary, the Company is extending its fluid manufacturing and analytical capabilities into advanced liquid cooling solutions and fluid intelligence systems for AI data centre infrastructure. 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.

Business review
Trinity Biotech's revenues for the year ended December 31, 2025 were US$43.8 million compared to revenues of US$61.6 million for the year ended December 31, 2024, which represents a decrease of US$17.8 million or 28.9%. The decrease was primarily driven by US$8.0 million decrease in Rapid HIV revenue alongside a US$3.4 million decrease in haemoglobin revenue.

The gross margin of 38.6% in 2025 compares to a gross margin of 34.8% in 2024. The improvement reflecting benefits from the Group's Comprehensive Transformation Plan, including manufacturing consolidation and improved operating efficiency. Gross profit decreased from US$21.4 million in 2024 to US$16.9 million in 2025, while cost of sales reduced to US$26.9 million in 2025 from US$40.1 million in 2024.

Other operating income increased from an expense of US$1.8 million for the year ended December 31, 2024 to an income of US$1.9 million in 2025. The income in 2025 reflects a fair value gain of US$1.9 million recognised in respect of the remeasurement of contingent consideration associated with the Waveform CGM acquisition, following its incorporation into the amended Perceptive term loan facility. The other operating loss in 2024 related to the reversal of US$1.8 million income from loan forgiveness of second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries recognised in 2020.

Research and development expenses decreased from US$4.5 million for the year ended December 31, 2024 to US$3.6 million for the year ended December 31, 2025, mainly due to lower capitalisation of payroll costs into product development intangible assets..

The Company recognised impairment charges of US$2.2 million in 2025 compared to US$1.4 million in 2024. The 2025 charge includes impairments across various CGUs and development projects.

Operating loss for the year ended December 31, 2025 was US$15.8 million, compared to an operating loss of US$21.2 million in 2024. The improvement was mainly due to increased gross margins, lower indirect and once off items costs. Excluding impairment, restructuring and once-off costs, the operating loss was US$9.5 million in 2025, compared to US$13.7 million in 2024

Financial expenses for the year ended December 31, 2025 were US$21.3 million compared to US$9.6 million in 2024, an increase of US$11.7 million. The increase was driven primarily by the US$10.0 million loss on extinguishment of the old senior secured term loan, recognised in connection with the refinancing of the Group's debt during the year (see Note 23). The loss on extinguishment arose principally from the termination of a contingent feature under the prior loan agreement, pursuant to which the Group had exposure of up to US$15.0 million linked to a partnership trigger; this was settled as part of the refinancing through the incorporation of US$7.5 million, into the new senior secured term loan.

There was no financial income for the year ended December 31, 2025 (2024: US$nil).

The Company recorded an income tax expense of US$0.2 million in 2025 compared to a tax expense of US$0.5 million in 2024. The 2025 tax expense includes current tax of US$465,000 and a deferred tax credit of US$266,000.

Loss before tax from continuing operations for the year ended December 31, 2025 was US$37.2 million, compared to US$30.7 million in 2024.

Loss from discontinued operations was US$Nil in 2025 compared to a loss of US$0.6 million in 2024. In 2024, a settlement agreement was reached with Biosynth to resolve all post-completion claims, resulting in a payable of US$150,000. During 2025, the Company paid US$75,000 with the remaining US$75,000 included in accrued liabilities in the consolidated financial statements as at December 31, 2025. The settlement fully resolves all disputes related to the sale of Fitzgerald Industries, and no further liabilities are expected to arise.

Dividends
No dividend has been proposed in respect of the financial year 2025.

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, 2025 and 2024, the Group recorded losses of US$37.4 million and US$31.8 million, respectively. For the year ended December 31, 2025, the Group reported cash outflows of US$0.1 million compared with cash inflows of US$1.7 million for 2024. As of December 31, 2025, the Group had net current liabilities of US$105.3 million and an accumulated deficit in equity attributable to the equity holders of the Company of US$72.0 million.

A significant judgement in the Group's going concern assessment is the maturity of the Perceptive Term Loan on 15 January 2027, which falls within the assessment period. As at August 31, 2026, approximately US$115 million was outstanding under the facility and there are no scheduled principal repayments prior to maturity. While the Company has continued to benefit from support from Perceptive as it executes its comprehensive transformation plan and strategic growth initiatives, and the maturity date for the Perceptive Term Loan has been extended on a number of occasions, as at the date of approval of these financial statements, no agreement has yet been reached regarding an extension of maturity.

A deficiency relating to the Nasdaq minimum market value of publicly held shares ("MVPHS") requirement remains outstanding. On August 28, 2026, the Company received a staff determination letter (the "Determination Letter") from the Staff notifying the Company that it had not regained compliance with the MVPHS Requirement by August 18, 2026. Accordingly, and as described in the Determination Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension/delisting. On September 4, 2026, the Company formally requested a hearing before the Panel.

The Company has a number of initiatives and strategic transactions at advanced stages, which, if completed, would be expected to increase the Company's MVPHS above the $15 million minimum. The Company intends to continue to progress these transactions and as such management remains confident that the actions currently underway will enable the Company to reach a MVPHS of over $15 million. The hearing request will automatically stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. In that regard, pursuant to the Nasdaq Listing Rules, the Panel has the authority to grant an extension not to exceed February 24, 2027.Notwithstanding the foregoing, there can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Global Select Market. A delisting from Nasdaq would likely result in the Company's ADSs trading on an over-the-counter market, which could reduce liquidity in the Company's securities, limit visibility within the public markets and make future capital raising activities more challenging. The Company would be required to satisfy applicable initial listing requirements in order to seek subsequent re-admission to Nasdaq.

These conditions indicate the existence of a material uncertainty which may cast significant doubt over the Group and the Company's ability to continue as a going concern.

The Group has made significant progress on a multi-year transformation plan aimed at improving profitability and simplifying its operating model. During 2024 and 2025, the Group substantially executed this programme, including the consolidation and outsourcing of global manufacturing operations, the closure of underutilised facilities, the transition of production to third-party manufacturing partners, the relocation of selected business support functions to lower-cost jurisdictions and a reduction in overall headcount. These actions have materially reduced the Group's fixed cost base and simplified its operational footprint, and the majority of the related transformation activities were completed during 2025. As a result, the Group entered 2026 with a leaner operating model and a materially lower underlying cost structure. In addition, the Group retains further levers to manage liquidity if required, including the ability to defer, phase or reprioritise discretionary research and development expenditure.

Management has prepared updated detailed cash flow forecasts covering a period of at least 12 months from the expected date of approval of these consolidated financial statements. These forecasts have been refreshed to reflect actual performance to date during 2026, updated financing arrangements and management's latest expectations regarding operating performance, liquidity and funding activities. The forecasts incorporate committed cost reduction measures, known financing arrangements and assumptions regarding the availability of additional equity financing consistent with the Group's recent capital raising activities and public disclosures.

The Group continues to benefit from support from Perceptive, its principal lender. Under the current Credit Agreement, the contractual maturity of the Perceptive Term Loan is January 15, 2027, and there are no scheduled principal repayments prior to that date. The maturity of the Perceptive Term Loan represents the most significant judgement within the directors' going concern assessment.

The Group breached the minimum revenue covenant under the facility for the quarter ended December 31, 2025. The covenant breach primarily reflected timing-related variability in HIV revenues, including the timing of the scale-up of the Group's outsourced and offshored manufacturing model. These factors affected the timing of shipments and revenue recognition between reporting periods, rather than indicating a deterioration in underlying demand. As part of the third amendment, Perceptive provided a waiver in respect of this breach. In addition, the Group received specific waivers and deferrals in respect of compliance with certain financial covenants applicable to covenant measurement periods occurring after year-end. In forming its going concern assessment, management has considered the contractual terms of the facility as amended, including the agreed waivers and deferrals.

In February 2026, Perceptive agreed that 50% of the cash interest due would be settled as payment-in-kind interest, in March and April 2026 Perceptive agreed that 100% of the cash interest due would be settled as payment-in-kind interest. On April 30, 2026, the Group entered into an amendment to the Credit Agreement with Perceptive which provided for an additional US$2.5 million term loan borrowing and certain covenant waivers and modifications. In August 2026, the Group entered into a further amendment to the Credit Agreement under which Perceptive granted limited waivers in respect of non-compliance with the minimum liquidity covenant during June and August 2026. Perceptive also agreed to maintain the minimum liquidity covenant at US$1.0 million through September 30, 2026, with the covenant increasing to US$3.0 million from October 1, 2026. In addition, Perceptive agreed that interest obligations from May through August 2026 would be settled through payment-in-kind arrangements. These arrangements have been reflected in management's updated cash flow forecasts.

Management's cash flow forecasts, which incorporate the terms of the Credit Agreement as amended, demonstrate that the Group is able to meet its obligations under the Perceptive facility throughout the going concern review period, including compliance with the amended financial covenants.

In forming their going concern assessment, the directors have considered the contractual terms of the Credit Agreement as amended, including the agreed waivers and covenant modifications. Management's updated cash flow forecasts incorporate the terms of the facility as amended and forecast compliance with the amended financial covenants throughout the going concern review period. The forecasts reflect the additional liquidity provided by Perceptive, the payment-in-kind treatment of interest obligations and management's ability to defer, phase or reprioritise certain discretionary expenditure if required.

The Group continues to evaluate the available alternatives for addressing the Perceptive Term Loan at or before maturity. These alternatives include refinancing or extending the facility, further equity financing, additional debt equitisation and potential strategic transactions. Perceptive has continued to engage constructively with the Group, including by providing additional funding, agreeing payment-in-kind interest arrangements and granting covenant relief. However, the completion of any refinancing, extension, equity financing, debt conversion or strategic transaction remains subject to execution risk and, where applicable, market conditions and the agreement of third parties.

The Group's going concern forecasts also include the assumption of equity funding, primarily through the issuance of ordinary shares under existing capital raising arrangements. Such funding is expected to support ongoing operations and continued investment in the Group's CGM development program and the management of the Group's financing obligations. While equity funding is subject to market conditions, the Group has an established track record of raising capital and maintains active engagement with investors. During June 2026, the Company raised approximately US$1.2 million through its At-The-Market programme. The directors have considered the Group's continued access to public equity markets as part of their assessment of the availability of funding throughout the going concern review period.

On August 7, 2026, Nasdaq confirmed that the Company had regained compliance with the minimum bid price requirement following implementation of a 30:1 ADS ratio change, resulting in a revised ratio of 600 ordinary shares to one ADS.

In preparing these forecasts, management has taken into account the discretionary nature of certain expenditure, including investment in the Group's CGM development programme, and has assumed that the timing and phasing of such expenditure will be aligned with available funding. Management therefore retains the ability to preserve liquidity, if required, while continuing to execute its strategic priorities without compromising covenant compliance.

The directors have considered the Group's current financial position and updated cash flow projections, taking into account all known events and developments through the date of approval of these consolidated financial statements, including the ongoing support of its principal lender and the availability of equity funding. Based on this assessment, the directors believe that the Group has access to adequate resources to continue in operational existence for at least 12 months from the date of approval of these consolidated financial statements, and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

Key Performance Indicators

The key financial indicators are set out below:

	2025	***2024***
	US$'000	US$'000
Revenue	43,785	61,555
Operating loss	(15,789)	(21,165)
Loss for the year	(37,376)	(31,789)

Business Combinations

There were no business combination transactions during the year ended December 31, 2025. During the comparative year ended December 31, 2024, the Group completed three business combinations aligned with its strategic objective of strengthening its diagnostics pipeline and expanding its technological capabilities across oncology and chronic disease detection.

In January 2024, the Group acquired certain assets of a Continuous Glucose Monitoring (CGM) technology platform. This transaction enabled the Group to secure proprietary sensor and algorithmic IP in the metabolic health space. The CGM assets are expected to support future product development initiatives in diabetes management and real-time biomarker monitoring.

In September 2024, the Group completed the acquisition of Metabolomic Diagnostics Ltd, a metabolomics-focused business specialising in large-scale biomarker discovery and analysis. This acquisition strengthens the Group's capabilities in systems biology and precision diagnostics, particularly in the context of early disease detection and population screening.

In October 2024, the Group completed the acquisition of Epicapture Ltd, an early-stage diagnostics company focused on the development of a urine-based test for early detection of prostate cancer.

The acquisition complements the Group's oncology strategy and provides access to promising molecular diagnostic IP. While the business is currently in a pre-commercial phase, it is expected to contribute to future growth as the test progresses toward market readiness.

Further information on each of these business combinations is provided in Note 29 to the consolidated financial statements.

Research and Development activity

Trinity Biotech has research and development groups focusing separately on product development in haemoglobins, infectious diseases and since January 2024, CGM. These groups are located in Ireland and the U.S. and largely mirror the production capability at each production site. In addition to in-house activities, Trinity Biotech sub-contracts some research and development from time to time to independent researchers based in the U.S. and Europe.

Haemoglobin Development Group

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 late 2026 or 2027, dependent on availability of resources.

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.

During 2025 and 2026, further development activities incorporated enhancements to the system's electronics architecture, resulting in additional improvements in glucose-measurement accuracy across multi-day wear. Clinical testing conducted on updated sensor and electronics components contributed more than 650 device-days of performance data and supported continued refinement of the calibration-free design.

Development work also expanded the device's multimodal sensing capability, integrating glucose with selected physiological metrics within a single modular platform. The proprietary needle-free insertion process was further validated through successful trials performed during this period, supporting the technical viability of the next-generation device design.

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.

Pre-eclampsia Development

In September 2024, we completed the acquisition of Metabolomics Diagnostics Ltd., an Irish biomarker-development company focused on early-pregnancy risk stratification, including its proprietary PrePsia™ preeclampsia-risk assessment technology. Following acquisition, activities during 2025 were directed exclusively toward the continued development, validation and regulatory preparation of the PrePsia programme.

Our ongoing development work on PrePsia is focused on assay optimisation, refinement of analytical workflows, and preparation for future regulatory submissions. We continue to augment our internal capabilities with specialist scientific and regulatory partners to support these development activities.

Prostate Cancer Test Development

In October 2024, we acquired EpiCapture Limited, an early-stage molecular diagnostics company developing a non-invasive urine-based prognostic test for progression to aggressive prostate cancer. Since acquisition, our development work has focused on data reanalysis, assay streamlining and preparation for two planned clinical studies intended to strengthen the test's clinical claims. Engagements with several leading US clinical institutions have progressed planning for these studies,

Advanced Liquid Cooling Solutions Development

In 2026, we established Trinovium, a subsidiary focused on the development of advanced liquid cooling solutions and fluid intelligence systems for AI data centre infrastructure. Development activities are focussing on high-purity cooling fluid formulations, system reliability and fluid-performance monitoring technologies, leveraging the Group's expertise in precision fluid manufacturing and analytical technologies. We continue to advance these technologies through a combination of internal development activities and industry collaborations.

Future developments

Trinity Biotech will continue to pursue product and technological developments through its research and development programmes and the expansion of existing activities through its sales and marketing programmes. As outlined above, the Group is currently developing continuous glucose monitoring and broader biosensor-enabled metabolic health solutions, advancing proprietary diagnostic technologies in women's health and oncology, and developing advanced liquid cooling and fluid intelligence technologies through its Trinovium subsidiary, while at the same time enhancing its existing products and technologies.

Important events since the year end

Covenant Compliance and Waivers under the Credit Agreement

Subsequent to December 31, 2025, the Company received a waiver from Perceptive in respect of compliance with the minimum revenue covenant for the twelve-month period ended December 31, 2025. The covenant breach primarily reflected timing-related variability in HIV revenues, including the timing of the scale-up of the Group's outsourced and offshored manufacturing model. These factors affected the timing of shipments and revenue recognition between reporting periods, rather than indicating a deterioration in underlying demand. Although this waiver was granted subsequent to the reporting date, the Company was not in compliance with this covenant as at December 31, 2025.

In addition, subsequent to year-end the Company obtained waivers in respect of the minimum revenue covenant applicable to quarterly measurement periods through July 1, 2026. The Company also received waivers in respect of the minimum liquidity covenant for the measurement periods ended March 31, 2026, April 30, 2026, June 30, 2026 and August 31, 2026.

The scheduled increase in the minimum liquidity threshold was also deferred until October 1, 2026. Each of these waivers and the liquidity covenant deferral relates to covenant measurement periods occurring after December 31, 2025.

Notwithstanding the waivers obtained subsequent to the reporting period, the senior secured term loan is classified as a current liability in the consolidated statement of financial position as at December 31, 2025. In accordance with IAS 1.69(d) and IAS 1.74, when a covenant breach exists at the reporting date and a waiver is obtained only after that date, the entity does not have an unconditional right to defer settlement of the liability for at least twelve months as at the reporting date.

The waivers described above and subsequent amendments to the Credit Agreement do not amend the contractual maturity of the Company's senior secured term loan, which remains January 15, 2027.

Amendment to senior secured term loan and convertible note agreement

On April 30, 2026, the Group entered into a third amendment to its Credit Agreement with Perceptive and a related amendment and restatement of the Senior Convertible Note. The amendment to the Credit Agreement provided for, among other things, an additional US$2.5 million term loan borrowing, the payment of certain interest through April 2026 as PIK interest, and a limited waiver of certain financial covenants. In connection with these amendments, the aggregate principal amount of indebtedness subject to conversion was increased from US$60.0 million to US$72.5 million. Under the amended and restated Senior Convertible Note, up to US$72.5 million of the aggregate principal amount of the Convertible Note is convertible, at the holder's election, into ADSs, at a conversion price of 97% of the VWAP of the ADSs at the time of each such conversion, subject to the minimum conversion price of $0.5061 (equal to 75% of the 30 day VWAP of the Company's ADSs for the period ended April 22, 2026). Following the 30:1 ADS ratio change which became effective on July 24, 2026, the minimum conversion price was correspondingly updated to US$15.183 per ADS. This amended conversion price also applies to amounts convertible pursuant to the Conversion Rights Agreement. All conversions remain subject to the beneficial ownership limitations and other terms and conditions set out in the relevant agreements.

On August 12, 2026, the Group entered into a further amendment to the Credit Agreement with Perceptive. The amendment provided for an additional US$2.5 million term loan borrowing, permitted interest obligations from May through August 2026 to be settled as payment-in-kind interest, provided limited waivers in respect of certain liquidity covenant requirements and maintained the minimum liquidity covenant at US$1.0 million through September 30, 2026, increasing to US$3.0 million from October 1, 2026.

Progress on Comprehensive Transformation Plan

During Quarter 1, 2026 the Company completed the transition of upstream manufacturing processes for its UniGold HIV rapid test to its outsourced and offshore manufacturing model. Outsourced production commenced in April 2026, and the Company is currently progressing through the initial scale-up phase of manufacturing. This marked the completion of the UniGold manufacturing transition under the Comprehensive Transformation Plan and forms part of the broader programme to improve the underlying cost structure and profitability profile of the business. While the UniGold outsourced manufacturing has commenced, the Company continues to work with the outsourcing provider to successfully scale-up the commercial production.

The transition to outsourcing and progression of the commercial scale-up of outsourced manufacturing has introduced quarter-to-quarter variability in HIV revenues, profitability and cashflow. While progress has been made in scaling the outsourced manufacturing platform, the Company expects that ongoing scale-up activities may continue to contribute to variability in quarterly revenues, profitability and cashflow through the remainder of 2026 and into early 2027.

The Company continues to progress other elements of the Comprehensive Transformation Plan, with a particular focus on the optimisation of its commercial operations in order to capitalise on the significant operational changes delivered under the plan. As part of these ongoing activities, the Company continued to review its operational footprint and organisational structure to further enhance operational efficiency and align its cost base with its strategic priorities.

These actions included continued evaluation of the scale and composition of the Company's operations and workforce as the business is further reoriented toward biosensor and reference laboratory testing activities. While the Company may continue to implement targeted initiatives in these areas, any future actions are expected to be of a lower scale and reduced complexity relative to the transformation activities undertaken as part of the Comprehensive Transformation Plan.

Nasdaq Listing Compliance

On February 11, 2026 and February 19, 2026, the Company received deficiency notices from the Listing Qualifications Department of Nasdaq indicating that the Company was not in compliance with (i) the minimum market value of publicly held shares ("MVPHS") requirement applicable to companies listed on the Nasdaq Global Select Market and (ii) the minimum bid price requirement of US$1.00 per ADS.

Nasdaq Listing Compliance (continued)

In accordance with Nasdaq Listing Rules, the Company was provided with a 180-day compliance period to regain compliance with each of these requirements. During this period, the Company's ADSs continue to trade on the Nasdaq Global Select Market. On August 7, 2026, the Company received written confirmation from Nasdaq that it had regained compliance with the minimum bid price requirement and that the matter was closed. The Company remains focused on regaining compliance with the MVPHS requirement and continues to take actions intended to achieve compliance with the applicable listing requirements.

Directors' and Secretary's interests

Neither the directors, the Company Secretary, their spouses or minor children had interests in the company or its subsidiary undertakings as at December 31, 2025, December 31, 2024 or subsequent date of appointment, except as follows:

	Number of A Ordinary Shares	Number of A Ordinary Shares	Number of options*	Number of options*	Weighted average exercise price of options outstanding at	Weighted average exercise price of options outstanding at
	December 31, 2025	December 31, 2024	December 31, 2025	December 31, 2024	December 31, 2025	December 31, 2024
Directors						
John Gillard	200,000	200,000	20,000,000	20,000,000	US$0.18	US$0.18
Ronan O'Caoimh**	9,724,160	9,724,165	8,193,336	8,193,336	US$0.58	US$0.58
Jim Walsh	3,095,620	3,095,620	2,000,000	2,000,000	US$0.15	US$0.15
Tom Lindsay	-	-	1,020,833	1,400,000	US$0.14	US$0.14
Andrew Omidvar	-	-	1,400,000	1,400,000	US$0.14	US$0.14

* Represents the number of A Ordinary Shares which can be purchased under the Company's share option plan.
** Includes options issued to Darnick Company which in the past provided Trinity Biotech with the services of Mr O'Caoimh as Chief Executive Officer.

Movement in directors' and company secretary A Ordinary Share options during the year is as follows;

	Number of options held at January 1, 2025	Options granted during the year	Options exercised during the year	Options forfeited during the year	Number of options held at December 31, 2025
John Gillard	20,000,000	-	-	-	20,000,000
Ronan O'Caoimh	8,193,336	-	-	-	8,193,336
Jim Walsh	2,000,000	-	-	-	2,000,000
Tom Lindsay	1,400,000	-	-	(379,167)	1,020,833
Andrew Omidvar	1,400,000	-	-	-	1,400,000

The directors' options outstanding at December 31, 2025 are exercisable and expire at various dates between 2026 and 2031.

Note 1. 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. The aforementioned hurdle prices are on the basis of the ADS ratio in effect at December 31, 2025. Following the ADS ratio change implemented on 24 July 2026, the applicable hurdle prices were adjusted in accordance with the terms of the relevant awards.

The Company's register of directors' interests, which is open to inspection at the registered office, contains full details of directors' shareholdings and share options. From January 1, 2026 to the date of this report, there were no purchases of shares by the Directors of the Company or by the Company Secretary.

Share option plans

The board of directors have adopted the Employee Share Option Plans (the "Plans") with the most recently adopted Share Option Plan being the Company's 2023 Amended & Restated Plan. The purpose of these Plans is to provide Trinity Biotech's employees, consultants, officers and directors with additional incentives to improve Trinity Biotech's ability to attract, retain and motivate individuals upon whom Trinity Biotech's sustained growth and financial success depends. These Plans are administered by the board of directors. Options under the Plans may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

The exercise price of options is determined by the board of directors, through its remuneration and employee compensation committees as the case may be. The term of an option will be determined by the board of directors, 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 of directors may accelerate the exercisability and termination of options.

Transactions with directors

There were no transactions with directors other than those outlined in Note 26 to the financial statements.

Directors' remuneration

The Group's policy in respect of remuneration of executive directors is to provide remuneration packages which attract, retain, motivate and reward the executives concerned and encourage them to enhance the Group's performance. In considering such packages, cognisance is taken of the levels of remuneration for comparable positions, the responsibilities of the individuals concerned and the overall performance of the Group.

Directors' and executive officers' remuneration shown below comprises emoluments, pension contributions and bonuses in respect of executive directors. The Company typically has a Remuneration Committee which is responsible for approving executive directors' remuneration including bonuses and share option grants. The board of directors has appointed an internationally recognised independent consulting firm to advise the board of directors on recruitment and compensation matters for directors and senior management.

Non-executive directors are remunerated by fees and the granting of share options. Non-executive directors who perform additional services outside the normal duties of a director receive additional fees. The fees payable to non-executive directors are determined by the board of directors.

Total directors and independent directors' remuneration, excluding pension, share options and provisions for performance related bonus, for the year ended December 31, 2025 amounted to US$886,000. The pension charge for the year amounted to US$38,000. See 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	Performance related bonus	Transaction related bonus	Defined contribution pension	Total 2025	Total 2024
		US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
John Gillard	President and Chief Executive Officer	660	441 *	—	38	1,139	1,213
Ronan O'Caoimh	Director, Founder & Executive Advisor	60	—	—	—	60	84
Jim Walsh	Executive Director Business Development	48	—	—	—	48	83
Tom Lindsay	Independent Director	52	—	—	—	52	57
Andrew Omidvar	Independent Director	51	—	—	—	51	57
Paul Tivnan	Independent Director	15	—	—	—	15	—
		886	441	—	38	1,365	1,494

** Amount relates to a bonus provision for the year ended December 31, 2025. The final amount remains subject to confirmation.*

Subsidiary and associate undertakings
A list of the principal subsidiary undertakings of Trinity Biotech is given in Note 32 to the consolidated financial statements. The Group does not have any branches outside of Ireland.

Accounting records
The directors are responsible for ensuring adequate accounting records, as outlined in Sections 281 to 285 of the Companies Act, 2014, are kept by the Company. To achieve this, the directors have appointed suitably qualified accounting personnel in order to ensure that these requirements are complied with. The accounting records of the Company are maintained at the Company's registered office at IDA Business Park, Bray, County Wicklow, Ireland.

Statement on relevant audit information
In accordance with Section 330 of the Companies Act 2014, the Directors confirm that, in so far as the Directors are aware, there is no relevant audit information of which the Company's statutory auditors are unaware, and the Directors have taken all the steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that the Company's statutory auditors are aware of that information.

Non-financial reporting

Introduction
At Trinity Biotech, in addition to advancing our strategic objectives and addressing relevant risks, we also work to support our customers, our employees and the communities we serve, and promote a sustainable environment.

Trinity Biotech 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. Trinity Biotech also operates a licenced reference laboratory that specializes in diagnostics for autoimmune diseases. Our products are sold in approximately 100 countries worldwide by the Group's own sales force and by a network of international distributors and strategic partners.

Environmental Matters
It is our objective to conduct our business in an environmentally responsible way that minimizes environmental impacts. As a manufacturer of medical devices we face risks associated with the handling and disposal of hazardous materials. We are committed to reducing waste generation and disposing of all waste through safe and responsible methods; minimizing environmental risks by employing safe technologies and operating procedures including engaging specialist service providers; and being prepared to respond appropriately to accidents and emergencies.

Social and Employee Matters
At Trinity Biotech plc, we are proud to devote our time and resources to initiatives that benefit our customers, our employees and our community.

Customers
We are focused on developing, manufacturing and marketing medical 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. Trinity Biotech also operates a licenced reference laboratory that specializes in diagnostics for autoimmune diseases.

Employees
The average number of persons employed by the group during 2025 was 287. We employee staff across a number of countries which increases the risks associated with staff management. The challenge given to all colleagues who work in Trinity Biotech is to demonstrate shared ownership, accountability and responsibility for the business. Personal leadership, an ability within us all, helps to create a vibrant workplace where we are challenged to do our best and be high performing at all times.

In our work environment we are responsible for ourselves, responsible for each other and responsible for the business. We trust each other and we strive to bring out the best qualities of our people; we practice behaviours that foster change and ultimately, assist every colleague to become the best they can be.

At Trinity Biotech, we work as a team. In a rapidly changing world we require flexibility from all colleagues to do what it takes in order to deliver an excellent job. We recognise that we are part of a complex adaptive system and so we support each other to thrive, through our behaviours and the relationships we build with each other.

In order to continue our track record of success, we need demonstrated leadership from all colleagues. We are committed to continually learning in order to create a high performing work environment where we continuously improve on what we do and how we do it.

Employee Safety - we implemented health and safety policies to help safeguard our on-site employees. We hold health and safety meetings daily and have key performance indicators we track to ensure that all issues are dealt with in a timely manner ensuring that our staff are safe in the workplace

Community
We take corporate social responsibility seriously. We are committed to promoting a working environment where all decisions are based on socially responsible and ethical principles. As a company we endorse such values as Learning, Trust, Leadership, Support and Teamwork, and as individuals we endeavour to do all we can to breathe life into these very values.

We believe strongly in corporate community involvement. Our colleagues are encouraged to take up activities intended to promote such involvement and foster good relations between Trinity Biotech and the communities within which our various sites are located. By visiting schools, for example, and demonstrating to students how science is central to the practical and beneficial work we do, we can engage meaningfully with the wider community and help create advocacy among possible employees of the future.

Of course we don't simply focus on communities close to hand. As an organisation that spans continents we are fully aware that distance is no barrier when it comes to forging connections between people.

The way we work with all communities reflects the values we hold dear as a company. We see ourselves as a progressive and dynamic group of people – and our charitable work is governed equally by these principles. Making a difference on the ground is essential.

We will seek to increase charitable activities as the company grows. We see such work as a vital constituent in the development of a successful and ethically grounded corporate organisation – and one which is central to the betterment of not only the lives of our colleagues but in the lives of all those we engage with.

Respect for Human rights, Bribery and Corruption
All our employees are required to adhere to our Code of Business and Ethical Conduct which requires all employees to comply with all laws and regulations applicable to Trinity's business, including any anti-bribery, anti-corruption, and human rights laws. The Code of Business and Ethical Conduct requires all staff to act with integrity in all business matters. The fact that we sell products to a large number of countries globally is an inherent risk regarding these matters.

Our Code of Business and Ethical Conduct requires staff to report any potential violations of the code to a designated senior individual in the Group or to the Chairman of the Group's Audit Committee. In 2025 no such potential violations were reported

Principal risks and uncertainties
Under Section 327(b) of the Companies Act 2014, the Group is required to give a description of the principal risk and uncertainties which it faces. These risk factors are outlined on pages 18-48.

Financial Instruments
An analysis of the financial instruments used by the Group is contained in Note 27 to the consolidated financial statements.

Directors' Compliance Statement

It is the policy of the Company to comply with its relevant obligations (as defined in the Companies Act 2014). The Directors have drawn up a compliance policy statement (as defined in section 225(3)(a) of the Companies Act 2014) and appropriate arrangements and structures are in place that are, in the Directors' opinion, designed to secure material compliance with the Company's relevant obligations. The Directors confirm that these arrangements and structures were reviewed during the financial year to which this report relates. As required by Section 225(2) of the Companies Act 2014, the Directors acknowledge that they are responsible for the Company's compliance with the relevant obligations as defined in Section 225(1). In discharging their responsibilities under Section 225, the Directors relied on the advice both of persons employed by the Company and of persons retained by the Company under contract, who they believe have the requisite knowledge and experience to advise the Company on compliance with its relevant obligations.

Audit Committee

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, Paul Tivnan.

Auditors

Grant Thornton, Chartered Accountants, having served as the Company's statutory auditor since their re-appointment on 30 September 2025, have expressed their willingness to remain in office in accordance with Section 383 (2) of the Companies Act, 2014.

On behalf of the board *of directors*

John Gillard
Director

September 8, 2026

Statement of Directors' Responsibilities in respect of the Annual Report and the Financial Statements

The directors are responsible for preparing the Annual Report and the consolidated financial statements in accordance with Irish law and regulations.

Irish company law requires the directors to prepare the consolidated and company financial statements for each financial year. Under the law, the directors have elected to prepare the financial statements in accordance with Companies Act 2014 and International Financial Reporting Standards (IFRSs) as adopted by the EU. Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the company as at the financial year end date and of the profit or loss of the group and the company for the financial year and otherwise comply with the Companies Act 2014.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and accounting estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the group and the company, enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy, enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014 and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the group and the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the company's website. Legislation in Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

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 Annual Report. 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

- 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.
- 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 business acquisitions.
- Our long-term success depends upon the successful development and commercialization of new products, particularly in the biosensor area.
- Our ability to sell products could be adversely affected by competition from new and existing diagnostic and biosensor 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.
- 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 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.
- Although the FDA's 2024 effort to regulate laboratory developed tests was vacated by a federal court and subsequently rescinded in 2025, future legislative or regulatory actions could again impose premarket review or other compliance obligations on our laboratory developed tests, resulting in potential costs and delays.
- 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 challenged, 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 Advisors, our principal lender, and MiCo IVD Holdings, LLC ("MiCo") own, or are entitled to acquire, a significant percentage of our share capital, 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 will need additional capital in the future.
- The conversion or exercise of our outstanding convertible instruments, share options, and warrants, and sales of ADSs under our committed equity financing, could significantly 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

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$37.4 million and US$31.8 million in the years ended December 31, 2025 and 2024, respectively, and had negative cash flows from operating activities of US$5.9 million and US$4.2 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, or if we are unable to access additional financing on acceptable terms, or at all, 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 escalating wars in the Middle East involving the United States, Israel, Iran, and regional armed groups, alongside the ongoing uncertainty in respect of the 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. Any further escalation in the Middle East could also lead to additional sanctions, trade restrictions, or security-related delays affecting the movement of medical equipment, components, or raw materials. 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, and are further advanced in implementing, key elements of this plan, including consolidating manufacturing, moving certain manufacturing activities offshore to improve operating margins, and centralizing significant business support functions in a lower-cost shared services environment, there remains execution risk. We may encounter delays, cost overruns, operational disruption, or lower-than-expected efficiency gains, and we cannot assure you that these initiatives will ultimately deliver the anticipated financial benefits or that we will 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 our 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, 2025, we had total indebtedness of approximately US$141.3 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 and conversion options issued to Perceptive, lease liabilities and a residual amount owing for an exchangeable note which was almost completely retired in 2022. In addition, a deferred consideration payment of US$5.0 million related to the acquisition of the biosensor assets of Waveform was extended to November 2025.

As of December 31, 2025, the Term Loan had an outstanding balance of US$108.0 million. Over recent years, the Group has increased its term loan borrowings through multiple amendments and restatements to the Credit Agreement, including the capitalisation of paid-in-kind interest, which has materially increased the outstanding principal balance.

On December 22, 2025, we entered into a series of agreements, including a further amendment to the Credit Agreement, under which our existing term loan obligations to Perceptive were restructured into a new senior convertible note representing the principal balance owed under the Credit Agreement at the time of approximately USD$95.8 million (IFRS carrying value US$93.3 million). This restructuring modified the terms, maturity profile and settlement mechanics of our indebtedness to Perceptive. Under these agreements, Perceptive may elect, at its discretion, to convert up to US$60.0 million outstanding principal under the Credit Agreement and US$12.5 million of other amounts owed to Perceptive into ADSs. The timing, volume and frequency of any conversions are entirely at Perceptive's election, and the Company has no control over whether, when, or to what extent such conversions may occur. The Second Amendment also provided for an additional US$5.0 million in new term loan borrowing.

Following this restructuring, our total indebtedness as of December 31, 2025 was approximately US$141.3 million (carrying value under IFRS), including the Convertible Note, the MiCo convertible note, derivative liabilities relating to Perceptive warrants, lease liabilities, and remaining exchangeable note balances.

In connection with MiCo's investment in 2022, we issued MiCo 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$486.00 for any five consecutive NASDAQ trading days (equivalent to US$16.20 per ADS prior to the ADS ratio change in 2026). Based on public filings, we understand that on December 2, 2025, MiCo was acquired by AI N M NET LTD as a result of a share purchase agreement with Dayli Trinity 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 will 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 a financial covenant requiring that we 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. 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 amended the Credit Agreement to reduce 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. Over recent years, we have repeatedly increased our term loan borrowings and paid interest in kind through multiple amendments and restatements to the Credit Agreement, which have materially increased the outstanding principal balance.

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, 2025, the total outstanding amount of our variable rate debt was US$108.0 million.

Our anticipated annual cash interest expense on US$108.0 million variable rate debt at the current rate of approximately 12.75 percent would be approximately US$13.8 million. Every one percent increase in the interest rate results in additional annual interest payable of approximately US$1.1 million, based on the current amount of indebtedness.

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.

Our long-term success depends upon the successful development and commercialization of new products, particularly in the biosensor area.

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 research and development ("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, 2025, 2024 and 2023, additions to intangible assets totalled US$9.0 million, US$10.9 million and US$1.8 million, respectively. The 2025 additions comprised US$6.1 million of capitalised development expenditure and US$2.9 million of borrowing costs capitalised in accordance 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.

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

We have invested in research and development but there can be no guarantees that our R&D programmes will succeed and 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), Beijing 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 terminations 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, and subsequently completed 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. Following the review period, certain foreign assistance programs have experienced pauses, reductions, or cancellations, and procurement and implementation timelines have been subject to change. In some cases, procurement for HIV rapid tests has continued under program-specific exemptions or alternative funding; however, there can be no assurance that such procurement will continue or that any reductions will be offset. We continue to monitor these developments. These U.S. policy shifts, appropriations changes, and procurement actions could reduce or delay funding available to our customers and, in turn, materially and adversely affect demand for our products, our sales, cash flows, and results of operations.

Changes in funding for the U.S. Food and Drug Administration (the "FDA") and other government agencies, 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 otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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 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. The current U.S. Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies.

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 by necessary government agencies, 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. There is also substantial uncertainty as to how regulatory reform measures being implemented by the current U.S. administration, and other political developments, such as government shutdowns or work stoppages, would impact U.S. regulatory agencies on which our operations rely. For example, in March 2025, the Department of Health and Human Services announced a broad-scale restructuring effort designed to significantly reduce FDA headcount. In April 2025, FDA employees began to receive reduction in force notices.

In addition, the U.S. government has shut down several times, including in October 2025, and certain regulatory agencies, such as the FDA, have previously had to furlough critical employees and stop critical activities. 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 conduct their regular inspections, reviews, or other regulatory activities, including the timely review and processing of our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Government funding of other agencies on which our operations may rely, including those that fund research and development activities and clinical trials, or which purchase our products, is subject to the political process, which is inherently fluid and unpredictable and disruptions to such agencies' funding or changes to their budgets, may negatively impact our operations and sales. For example, in 2025, the U.S. administration temporarily paused, and then further reduced funding for, HIV testing programs that utilize our rapid HIV tests, causing disruptions to ordering patterns and demand for our rapid HIV tests, with consequent disruptions to our payments and cashflow. 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.

There continues to be substantial uncertainty as to whether and how the current U.S. administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies that fund the purchase of our products, or with jurisdiction over the regulatory approval of our products. Additionally, the current U.S. 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 2025 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.

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, have already impacted and could further impact our business and operations, 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 recent years, the United States has imposed, and may continue to impose, tariffs, including so-called reciprocal tariffs, on a range of imported goods. Certain tariff actions have been subject to legal challenge, modification or reversal, while new or expanded tariffs have also been announced or implemented, creating ongoing uncertainty and volatility in U.S. trade policy. In February 2026, the United States Supreme Court ruled that the use of the International Emergency Economic Powers Act (IEEPA) to impose tariffs was not permitted, invalidating a significant portion of tariffs that had been in effect since April 2025. While the ruling struck down the IEEPA-based tariffs, it does not address the Administration's ability to impose tariffs using other mechanisms. The Administration responded by invoking alternative mechanisms to impose additional tariffs and has subsequently announced and implemented further tariff increases and country-specific trade measures. More recently, the United States has announced and implemented additional country-specific tariff measures, including increased tariffs on certain Canadian imports following the breakdown of trade negotiations between the two countries, and Canada has announced corresponding retaliatory tariffs on certain U.S. goods. These developments illustrate the continuing volatility and unpredictability of the international trade environment and the potential for further tariff escalation. Other governments have imposed, and may continue to impose, retaliatory or reciprocal 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, and we conduct business globally, including in markets that have been affected by reciprocal trade measures. Our operations and third-party suppliers span numerous countries outside the United States, and we sell instruments and other products into jurisdictions, such as China, where reciprocal tariffs and trade restrictions have adversely impacted demand and pricing. As a result, current or future U.S. tariffs, retaliatory or reciprocal measures, or further changes in trade policy could adversely affect our supply chain, increase the cost of components and raw materials, reduce sales of our products in certain international markets, and negatively impact our results of operations.

The enactment of tariffs and the uncertainty surrounding their scope, duration, and applicable rates, as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements and the continued threats of sanctions and other trade restrictions and barriers, 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, and are further advanced in implementing, key elements of this plan, including consolidating manufacturing, moving certain manufacturing activities offshore to improve operating margins, and centralizing significant business support functions in a lower-cost shared services environment, there remains execution risk. We may encounter delays, cost overruns, operational disruption, or lower-than-expected efficiency gains, and we cannot assure you that these initiatives will ultimately deliver the anticipated financial benefits or that we will 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.

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 HbA1c 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 recent years, including in 2022, we experienced disruptions to our international supply chain that adversely affected certain aspects of our operations. More recently, geopolitical instability and military conflicts in certain regions have contributed to ongoing logistical challenges, including increased transportation costs, extended delivery times and reduced shipping capacity. There can be no assurance that such disruptions will not continue or recur in the future, which could create significant challenges in fulfilling customer orders and may adversely affect our operating results.

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 serious injury, or malfunction in certain ways, we are subject to medical device reporting requirements, which may result in voluntary corrective actions or regulatory enforcement.

We are required to comply with the U.S. Food and Drug Administration ("FDA") Medical Device Reporting ("MDR") regulations, as well as comparable vigilance and reporting obligations in other jurisdictions, such as those enforced by the Health Products Regulatory Authority ("HPRA") in Ireland. Under the FDA's MDR regulations, we must report any event in which one of our products may have caused or contributed to a death or serious injury, or in which a malfunction would likely cause or contribute to a death or serious injury if it were to recur.

In the European Union, manufacturers of in vitro diagnostic medical devices are subject to the In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746) ("IVDR"). Several categories of devices require assessment and certification by an independent Notified Body before the manufacturer may affix a CE mark. Under the IVDR, we must notify the competent authority of any serious incidents or potential serious incidents involving our devices within defined timelines.

If a serious incident or malfunction were to occur, the relevant competent authority may initiate an investigation and may require additional inspection or assessment, either directly or through our Notified Body.

We have submitted MDRs in the past, and we anticipate that we may experience reportable events in the future. Any adverse event involving our products could result in voluntary corrective actions, such as field safety notices or product corrections, or regulatory enforcement actions, including inspections, safety communications, mandatory recalls, or other sanctions.

Any corrective action - whether voluntary or required - as well as any related litigation, could divert management's attention, require significant financial and operational resources, damage our reputation, and negatively affect our business, results of operations, and financial condition.

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$7,647,059) (December 31, 2025) for any one accident, limited to a maximum of €6,500,000 (US$7,647,059) (December 31, 2025) 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$3,000,000 for each claim and a US$4,000,000 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 voluntarily initiate market withdrawals, corrections, safety alerts, or reportable product recalls to address material deficiencies, improve device performance, or for other reasons. In addition, the FDA and comparable foreign regulatory authorities may require involuntary recalls when they identify material deficiencies or defects in a device's design, manufacturing, or labelling, or when a product poses an unacceptable risk to health. The FDA may mandate a recall upon determining that there is a reasonable probability that a device would cause serious adverse health consequences or death.

A government mandated or voluntary recall could occur due to component failures, manufacturing errors, design or labelling defects, or other deficiencies. Any recall of our products could divert managerial and financial resources and adversely affect our business, financial condition, and results of operations. Certain classifications of recalls must be reported to the FDA within ten working days of initiation.

We are required to maintain records of post-market actions, even when we determine that such actions are not reportable to the FDA. If we conclude that certain actions are not reportable, the FDA may disagree and require us to classify and report those actions as recalls. Any future recall announcement could harm our reputation with customers and negatively impact our sales.

The FDA may also take enforcement action if we fail to report recalls or other corrective actions, or if we fail to do so in a timely manner. Depending on the corrective actions needed to address a product deficiency, the FDA may require - or we may determine - that new clearances or approvals are necessary before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace recalled devices and resume commercial distribution 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, 2025, was US$57 million (December 31, 2024: US$51 million) (December 31, 2023: US$16 million). In the year ended December 31, 2025, we recorded total impairment charges on intangible assets of US$2.1 million (Year 2024: US$1.6 million) (Year 2023: US$5.8 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. International conflicts and related geopolitical tensions, including the Israel–Hamas war, the Russia–Ukraine war, and the escalating conflicts in the Middle East involving the United States, Israel, Iran, and regional armed groups 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 alongside our contract manufacturing facility in India accounted for the majority of our revenues during the fiscal year ended December 31, 2025. 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 additional third-party manufacturers to produce certain of our diagnostic products and product components. If we do not negotiate long-term contracts, our suppliers will likely not be required to provide us with any guaranteed minimum production levels. As a result, we cannot assure you that we will be able to obtain sufficient quantities of product in the future. In addition, our reliance on third-party suppliers involves a number of risks, including, among other things:

- contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we or our contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
- we or our contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;

- we may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our suppliers or those of our contract manufacturer may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to 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. In addition, as we continue to scale certain manufacturing activities through third-party manufacturing partners, we may experience challenges associated with the scale-up of production processes, optimisation of manufacturing yields, supply-chain coordination and capacity planning. Such challenges could result in production delays, increased costs, reduced product availability and variability in revenues and profitability. 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 that our products perform in accordance with their label claims, our customers' expectations, and applicable regulatory requirements.

Accordingly, our products and the materials used in their manufacture or assembly undergo routine inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human error, environmental conditions, or changes in materials or production methods by our vendors could cause our products or the materials used to produce or assemble them to fail inspections and testing or otherwise not perform as intended or not perform in accordance with our label claims or the expectations of our customers.

Any failure or delay in meeting 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, negatively impact our revenues, cashflows 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 senior leadership and key employees. We have recently experienced several transitions in senior leadership. The Company has experienced changes in certain senior leadership positions in recent years and may continue to experience management transitions from time to time. Such transitions may result in temporary disruption and could adversely affect our ability to execute our strategy and achieve our business objectives.

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 support our global operations, including product manufacturing, distribution, research and development, clinical activities, customer service, and financial reporting. Any significant disruption, failure, or unauthorised access to these systems could impair our ability to operate effectively.

Like many companies, we face an increasing number of cybersecurity threats, including system breaches, ransomware, malware, phishing attacks, and other forms of malicious activity. Such incidents may result in operational downtime, loss or corruption of data, unauthorised disclosure of confidential or personal information, reputational harm, and financial loss.

Although we maintain appropriate technical and organizational security measures designed to protect our systems and data, no cybersecurity framework can prevent all threats. Our systems may still be vulnerable to attack due to the sophistication of threat actors, human error, equipment failure, third-party vulnerabilities, or other unforeseen events.

We conduct cybersecurity assessments of our systems and technology, including penetration testing, vulnerability scanning, and risk-based remediation. These practices are designed to identify and address security vulnerabilities in our environment. As regulatory expectations for cybersecurity continue to evolve, we may need to make additional investments or implement further enhancements to maintain compliance and support the security of our systems and connected technologies.

We have experienced cyberattacks in the past; however, none have had a material impact on our operations to date. The age and configuration of our IT infrastructure varies across locations, and business continuity and disaster recovery capabilities may be less robust in certain sites, which could affect our response or recovery in the event of an incident.

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. Additionally, as a manufacturer of medical devices, we will also likely be subject to the EU's new cybersecurity legislative package, once fully transposed into Irish law. This would likely require us to implement a range of cybersecurity requirements including in respect of incident handling, business continuity, supply chain security, and governance.

We have conducted 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.

A significant cybersecurity incident could distract management or key personnel from core business operations and negatively affect our financial condition, results of operations, and 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 many industries face scrutiny relating to their ESG policies. While some investors, lenders and other market participants continue to focus on ESG practices and have placed greater importance on the implications and social cost of their investment, policy approaches vary across jurisdictions. This evolving landscape could affect our access to capital if investors or lenders adjust allocations based on 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 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 ADSs 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 requirements 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, those authorities may disagree and require us to stop promoting our products for certain uses until we obtain the necessary clearance or approval. If the FDA or other regulatory authorities determine that our promotional materials promote an unapproved use, they may require us to revise our materials or may take regulatory or enforcement action, including issuing an untitled letter, a warning letter, or imposing injunctions, seizures, civil fines, or criminal penalties.

Other federal, state, or foreign enforcement authorities may also take action if they view our promotional activities as promoting unapproved uses, potentially resulting in significant fines or penalties under other statutory regimes, including laws prohibiting the submission of false claims for reimbursement. Any such actions could damage our reputation and impair the adoption of our products.

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 any future requirement to obtain premarket clearance or other regulatory approvals.

Historically, the FDA has generally exercised enforcement discretion and has not actively enforced most medical device regulatory requirements with respect to laboratory developed tests ("LDTs"), although reagents, instruments, software, and other components supplied by third parties for use in LDTs may be subject to FDA oversight. The FDA defines an LDT as an in vitro diagnostic ("IVD") test that is intended for clinical use and designed, manufactured, and used within a single laboratory. In recent years, the FDA has also signaled that certain high risk or widely marketed LDTs may warrant increased regulatory oversight.

On September 29, 2023, the FDA proposed a rule clarifying that all IVDs are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer is a clinical laboratory. The final rule, adopted on April 29, 2024, would have significantly expanded FDA oversight of LDTs. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the final rule, holding that the FDA exceeded its statutory authority. As a result, the rule will not take effect unless reversed on appeal, and laboratories are not currently required to obtain FDA clearance or approval to market their LDTs. If the decision is upheld, the FDA's ability to regulate LDTs as medical devices may be substantially curtailed, and LDTs would continue to be regulated primarily under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Despite the court's ruling, the regulatory landscape for LDTs remains uncertain. The FDA may appeal the decision, pursue new rulemaking, or seek additional Congressional authority. Future legislative or regulatory changes could impose new premarket review requirements, quality system obligations, adverse event reporting requirements, or other compliance burdens on laboratories offering LDTs. Any such changes could require us to incur substantial costs, modify our operations, or delay the development, validation, and commercialization of our LDTs.

Congress has periodically considered legislation that would create a unified regulatory framework for all in vitro clinical tests, including those currently regulated solely as LDTs. If enacted, such legislation could impose new premarket review, quality system, adverse event reporting, and other operational requirements on laboratories, which could increase our regulatory burden and delay the commercialization of new tests.

Even in the absence of a binding FDA framework, individual states, commercial payors, and accrediting bodies may impose additional requirements on LDT providers. These parallel obligations could create inconsistent or overlapping compliance requirements, increase operational complexity, and raise the cost of maintaining and offering our LDTs.

Ongoing compliance obligations - including CLIA requirements, state licensure requirements, and any future FDA or legislative requirements - increase the cost and complexity of conducting our business. Failure to comply with applicable regulatory requirements may subject us to additional scrutiny, enforcement actions, or penalties, any of which could adversely affect our business, financial condition, or results of operations.

If we fail to maintain existing regulatory approval and clearances, or are unable to obtain, or experience significant delays in obtaining, regulatory clearances or approvals for our future products or product modifications, our ability to commercially distribute and market these products could be adversely affected.

Our medical device products and operations are subject to extensive regulation in the United States by the FDA and by numerous federal, state, and foreign authorities, including comparable regulatory bodies such as the Health Products Regulatory Authority ("HPRA") in Ireland. We are subject to strict governmental controls governing the development, manufacture, labelling, storage, testing, advertising, promotion, marketing, and distribution of our products, as well as the import and export of devices. In addition, we or our distributors, often must register with and/or obtain clearance or approval from foreign regulatory authorities before our products may be imported or sold in those markets. These clearance and approval processes vary across jurisdictions but are typically lengthy, detailed, and costly.

Obtaining and maintaining the regulatory clearances or approvals necessary to market a medical device can be expensive and time consuming, and we may not receive such clearances or approvals on a timely basis, or at all. In the United States, the FDA permits commercial distribution of a new medical device only after it has been cleared under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA") or has received premarket approval ("PMA"), unless it is exempt. The FDA will clear a device through the 510(k) process if the manufacturer demonstrates substantial equivalence to a previously cleared device. Higher risk devices - such as life sustaining, life supporting, or implantable devices - or devices that are not substantially equivalent to a legally marketed predicate require PMA approval.

The PMA process is significantly more costly, time consuming, and uncertain than the 510(k) pathway. A PMA must include extensive technical, preclinical, clinical, manufacturing, and labelling data demonstrating the safety and effectiveness of the device. While 510(k) clearance typically takes three to twelve months, the PMA process usually requires one to three years or more from submission to approval. There is no assurance that we will obtain clearance or approval for any future products or modifications.

Many of our currently marketed products in the United States have received 510(k) clearance. If the FDA requires us to undergo more rigorous premarket review for future products or for modifications to existing products, our product introductions could be delayed or cancelled. The FDA may also determine that certain future products require PMA approval rather than 510(k) clearance.

The FDA may delay, limit, or deny clearance or approval for a variety of reasons, including:

- our inability to demonstrate that our products are safe and effective for their intended uses;
- insufficient data from preclinical studies or clinical trials; and
- failure of our manufacturing processes or facilities to meet applicable requirements.

Additionally, the FDA may revise its clearance and approval policies, adopt new regulations, or modify existing regulations in ways that affect our ability to obtain or maintain clearances or approvals. Regulatory authorities may also disagree with our interpretation of existing policies, potentially resulting in required modifications, restrictions, or discontinuation of products - even if those products have previously been cleared or approved.

In the European Union, manufacturers of in vitro diagnostic medical devices are subject to the In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746) ("IVDR"). Several categories of devices require assessment and certification by an independent Notified Body before the manufacturer may affix a CE mark.

The ongoing phased transition to the IVDR has significantly increased regulatory scrutiny, documentation requirements, and vigilance obligations for manufacturers, including us. As additional device classifications transition into full IVDR oversight, we expect more frequent updates to technical documentation, expanded post-market performance follow-up requirements, and heightened expectations for trend reporting and risk management. These evolving obligations may increase our regulatory workload and the likelihood that authorities or our Notified Body will request supplemental information or corrective actions.

Our continued success depends on our ability to commercialize new or enhanced products, some of which are currently awaiting clearance or approval. Such clearances or approvals may not be granted, may be delayed, or may be limited by significant restrictions. Regulatory authorities may impose conditions or limitations as part of the marketing authorization or may refuse authorization altogether - even if the product has been authorized without restrictions in another jurisdiction. Modifications to our products may invalidate previously granted approvals or clearances, requiring new submissions or leading to enforced restrictions or discontinuation.

On September 29, 2023, the FDA proposed a rule - adopted on April 29, 2024 - clarifying that in vitro diagnostic products ("IVDs") are medical devices under the FDCA, including when manufactured by clinical laboratories. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the rule, holding that the FDA exceeded its statutory authority. As a result, the rule will not take effect unless reversed on appeal, and laboratories are not currently required to obtain FDA clearance to market laboratory developed tests ("LDTs"). If the ruling stands, FDA's authority to regulate LDTs as devices may be substantially limited, and these tests may continue to be regulated primarily under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Failure to comply with FDA or other regulatory requirements may require us to suspend production of our products or conduct recalls, and could result in significant costs, reputational harm, and loss of revenue.

Even after receiving regulatory clearance or approval for our medical devices, we remain subject to extensive, ongoing post-market regulatory requirements. Regulation by the FDA and by numerous federal, state, and foreign authorities - including the Health Products Regulatory Authority ("HPRA") in Ireland - affects nearly every aspect of our operations and those of our suppliers and distributors. These requirements govern manufacturing, labelling, packaging, adverse event reporting, storage, promotion, marketing, distribution, and import and export activities.

Our manufacturing operations, and those of our suppliers and distributors, must comply with the FDA's medical device regulations and comparable foreign quality system requirements. These regulations govern the methods and documentation used in the design, testing, production, control, quality assurance, labelling, sterilization, storage, and shipping of medical devices. Our facilities, and the facilities of our suppliers and distributors, are subject to periodic inspections - announced and unannounced - by the FDA and foreign regulatory authorities to assess compliance with these regulations.

As the legal manufacturer, Trinity Biotech is responsible for managing product and regulatory risks across the end-to-end supply chain. While certain activities may be carried out by outsourced partners or distributors, Trinity Biotech maintains oversight of these services through its Quality Management System. Nevertheless, any failure by external parties to meet contractual obligations or to properly execute assigned activities could negatively impact Trinity Biotech's regulatory standing and overall compliance status.

Regulatory agencies may also require post-marketing testing or surveillance to monitor the performance or safety of cleared or approved products and may impose restrictions or conditions on clearances or approvals that limit the commercial use of a product. Failure by us, or by any of our suppliers or distributors, to comply with applicable statutes or regulations - or failure to adequately address inspectional observations, deficiencies, or safety concerns - could result in enforcement actions, including:

- untitled letters, warning letters, fines, injunctions, consent decrees, or civil penalties;
- unanticipated expenditures in responding to or defending such actions;
- customer notifications, product corrections, repairs, replacements, or refunds;
- product recalls, detentions, or seizures;
- operating restrictions or suspension or shutdown of manufacturing;
- delays or refusals in granting 510(k) clearances or PMA approvals for new or modified products;
- withdrawal or suspension of existing clearances or approvals;
- restrictions on export or import activities; or
- criminal prosecution.

Foreign regulatory authorities may impose similar sanctions within their respective jurisdictions.

Any of these actions could damage our reputation, reduce customer confidence, limit our ability to sell products, and negatively affect our financial performance. Additionally, if suppliers or contract manufacturers fail to comply with applicable requirements, we may be unable to obtain critical components or manufacture products in required quantities or on the timelines needed to support commercial demand.

Even when regulatory clearance or approval is granted, it may include limitations on the intended uses for which a product may be marketed. Such limitations can reduce the commercial potential of a product. If the FDA determines that our promotional materials, labelling, training, or other marketing activities promote an unapproved use, the agency may require us to cease or modify such activities or may take enforcement action. Other federal, state, or foreign enforcement authorities may also impose significant fines or penalties under fraud and abuse or reimbursement related statutes, including laws prohibiting false claims for payment.

We may also be required to conduct additional post-market testing or surveillance to assess ongoing safety or effectiveness, and we must comply with medical device reporting requirements for adverse events and malfunctions. Newly identified safety issues - such as unexpected adverse events, increases in event frequency or severity, or manufacturing defects - or failures to comply with regulations or other post-market obligations may result in labelling changes, product restrictions, product withdrawals from the market, voluntary or mandatory recalls, repair or replacement obligations, fines, import or export restrictions, suspension of approvals, injunctions, seizures, or civil or criminal penalties. Any of these consequences could adversely affect our business, operations, and prospects.

In our ordinary course of business, we are frequently required to make interpretive or judgment-based decisions regarding compliance with complex and evolving regulatory requirements. If regulators disagree with our interpretations or determine that we have not complied fully with applicable laws, we could be subject to substantial civil or criminal penalties, as well as product seizures, recalls, or injunctions preventing sale of our products. Such penalties or restrictions could significantly damage our reputation and materially impair our ability to manufacture and market our products.

In addition to FDA and other device specific requirements, some foreign jurisdictions impose additional restrictions on the sale or distribution of medical devices. While we strive to comply with all applicable requirements, there can be no assurance that we will always be successful in obtaining or maintaining the clearances, approvals, or authorizations required to sell our products in particular markets.

We must also comply with numerous non-device-specific laws relating to environmental protection, safe working conditions, fire and hazard controls, handling and disposal of hazardous substances, and labour and employment practices. Compliance with these requirements, or with new or revised laws, could increase our operational costs. Because so many regulatory bodies and governmental agencies influence our operations, the full impact of these requirements is difficult to predict. If compliance costs become substantial, or if we are found not to be in compliance with any of these laws or requirements, our business and results of operations could be adversely affected.

Modifications to our products may require new 510(k) clearances or pre-market approvals, and in some cases may require us to cease marketing or recall the modified products until necessary clearances or approvals are obtained.

Any modification to a device cleared under Section 510(k) in the United States that could significantly affect its safety or effectiveness, or that results in a major change to its intended use, design, or manufacturing process, may require a new 510(k) submission or, in some cases, approval of a premarket approval application ("PMA"). Manufacturers are responsible for initially determining whether a modification triggers a new submission requirement; however, the FDA can review, question, or overrule these decisions at any time.

The FDA may not agree with our determination that certain product modifications do not require a new 510(k) notification or PMA. If the FDA disagrees and requires us to submit a new 510(k) or PMA for a modification to one of our previously cleared products, we could be required to cease marketing or recall the affected product until we obtain the necessary clearance or approval. We may also be subject to regulatory fines, penalties, or other enforcement actions.

In addition, our products may be subject to recall if the FDA determines that they are not safe or effective for their intended uses, regardless of whether a modification was involved. Any recall or requirement that we seek new clearances or approvals could result in significant delays, increased costs associated with redesign or validation, loss of revenue, adverse publicity, 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 U.S. PATRIOT Act, the U.K. Bribery Act 2010, the Criminal Justice (Corruption Offences) Act 2018 and other anti-corruption, anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption and anti-bribery laws may be enforced aggressively 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 provided to Medicare fee-for-service beneficiaries is determined by the Medicare Clinical Laboratory Fee Schedule (CLFS), which is established and periodically updated by the Centers for Medicare & 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 by the loss or suspension of a license, accreditation, or certification, or by the imposition of fines or penalties under CLIA or applicable state laws, as well as by future changes in regulatory requirements, reimbursement rates, or testing methodologies.

Our clinical laboratory, operated by our Immco Diagnostics Inc. subsidiary ("Immco"), is subject to the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), which are administered by CMS. CLIA extends federal oversight to virtually all clinical laboratories by requiring certification either directly from CMS or through a CMS approved accreditation organization. CLIA is intended to ensure the quality and reliability of clinical testing by establishing standards related to personnel qualifications, administration, proficiency testing, patient test management, quality control, quality assurance, documentation, and routine inspections. Laboratories must undergo onsite surveys at least every two years, which may be conducted by CMS or by a CMS approved accrediting body such as the College of American Pathologists ("CAP"). Failure to comply with CLIA requirements may result in suspension, limitation, or revocation of a laboratory's CLIA certificate - as well as civil monetary penalties or, in severe cases, criminal sanctions.

In addition to CLIA, our laboratory services are subject to state clinical laboratory laws of New York and certain other states and may be subject to additional state requirements as our testing footprint expands. These laws may impose personnel qualification requirements, mandate specific quality control procedures, establish facility standards, or require ongoing inspections. For example, California requires laboratories performing tests on California residents to maintain a state laboratory license and comply with state specific standards governing personnel, operations, and quality control. Some states impose requirements that are more stringent than CLIA, particularly with respect to personnel qualifications and documentation.

If we fail to comply with CLIA or applicable state laws, we could face significant civil or administrative penalties, experience suspension or loss of one or more laboratory licenses or certifications, or be barred from accepting specimens from patients in certain states. The loss, suspension, or denial of any required license, certification, accreditation, or permit could materially harm our business, limit our testing volume, impair our ability to serve patients and providers, and negatively impact our financial results.

In addition to federal and state regulators, commercial payors and accreditation bodies may impose their own operational requirements - sometimes more stringent than regulatory requirements - which may affect test methodologies, validation practices, or quality management systems. Failure to meet such third-party standards can result in loss of accreditation or pay or network status, restricting reimbursement or access to certain patient populations.

Our laboratory business is also subject to risk from changes in reimbursement policies, reimbursement rates, and coverage determinations by government programs and commercial payors, as well as shifts in preferred or reimbursable testing methodologies. CMS, state Medicaid programs, and private payors may modify payment rates, billing rules, or coverage criteria for particular assays, disease states, or testing approaches, including changes that favor alternative technologies or methodologies over those currently used by our laboratory. In addition, payors may reassess clinical utility, cost-effectiveness, or coding and payment treatment for certain tests, which could result in reduced reimbursement, denial of coverage, increased documentation or prior authorization requirements, or delays in payment. If reimbursement rates decline, coverage policies change, or testing methodologies evolve in a manner that disadvantages our assays or platforms, we may be required to modify or replace existing tests, invest in new technologies, or discontinue certain offerings, any of which could adversely affect our margins, test volumes, and financial performance.

The regulatory landscape for clinical laboratories continues to evolve. Even following the 2025 federal court decision vacating the FDA's attempt to regulate laboratory developed tests ("LDTs") as medical devices, future legislative or regulatory activity could lead to new requirements for test validation, quality system controls, premarket submissions, or adverse event reporting applicable to LDT providers. Individual states may also adopt new or more stringent requirements, creating inconsistent or overlapping compliance obligations. Any such changes could increase compliance costs, delay the introduction of new tests, impose additional administrative burdens, or require changes to our laboratory workflows or operations.

Any failure to comply with CLIA, state laboratory laws, accreditation standards, or future regulatory requirements could cause significant business disruption, reduce revenue, impair our reputation with physicians and patients, or limit our ability to operate our laboratory.

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 willfully 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, and exclusion from federal health care programs;

- 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.

- 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, teaching hospitals and others, 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. 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;

- 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. 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 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, because of the potential for large monetary exposure under the federal False Claims Act, which provides for treble damages and substantial mandatory minimum penalties per false claim or statement, healthcare providers often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages that may be awarded in litigation proceedings. Such settlements often contain 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.

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 been, and may in the future be, a party to various lawsuits, demands, claims, qui tam suits, governmental investigations and audits (including investigations or other actions resulting from our obligation to self-report suspected violations of law) and other legal matters, any of which could result in, among other things, substantial financial penalties or awards against us, mandated refunds, substantial payments made by us, required changes to our business practices, exclusion from participation in federal and state healthcare programs and possible criminal penalties, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and materially harm our reputation.

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 licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide any assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide any assurances that we will be successful in obtaining licenses or proprietary or patented technologies in the future, or that licenses granted to us by third parties will not be granted to other third parties who could potentially compete with us.

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 license to use the protected technology. There can be no assurance that we would be able to obtain license to use such technology or, obtain such licenses on satisfactory commercial terms. If we or our suppliers are unable to obtain or maintain a license 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 our 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 licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

We currently own a number of active patents, some with protection across multiple countries. Patents have a life of up to 20 years, and we generally file 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-license, may fail to result in issued patents with claims that cover our current products or any future products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.

We can provide no assurance that third parties will not challenge the validity, enforceability or scope of the patents we may apply for, or obtain, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products covered by those patents.

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.

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.

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 legalize 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.

As is the case with other biotechnology companies, our success is heavily dependent in intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industries involve both technological and legal complexity. Therefore, obtaining and enforcing related patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have ruled on several patent cases in recent years, and could do so again in the future, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, the USPTO has implemented patentability guidelines that may render the subject matter of a patent as non-patentable based on a lack of utility. 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. Depending on decisions by applicable courts and legislatures in the countries in which we may pursue patent protection, including those of the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents and the interpretations of such laws could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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 willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. Any substantial loss resulting from such a claim could cause our revenues to decrease and have a material adverse 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 license as a result of litigation, we cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialisation of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialise one or more of our products, which could harm our business significantly.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorised use, we may be required to file legal claims, which can be expensive and time-consuming. In certain cases, we may be actively evaluating or preparing potential enforcement actions relating to our diagnostic technologies, and there can be no assurance that any such actions, if pursued, would be successful. In addition, in an infringement proceeding, a Court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defence proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

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

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if, in litigation, the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ADSs.

Risks Related to Ownership of our ADSs

Perceptive and MiCo own, or are entitled to acquire, a significant percentage of the voting share capital of our Company, which may give each of them 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 75,000 of our ADSs (equivalent to 2.2 million ADS prior to the 2026 ADS ratio change), which represents approximately 8.6% of the outstanding voting share capital of our Company (12.8% 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 2, 2025, MiCo was acquired by AI N M NET Limited as a result of a share purchase agreement with Dayli Trinity 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, beneficially owns, on a fully diluted basis, approximately 9.9% of the outstanding voting share capital of our Company based on a Schedule 13D/A filed with the SEC on January 26, 2026. Perceptive does not currently own any ADSs of the Company. Its reported beneficial ownership includes ADSs issuable upon conversion of its senior convertible note, the exercise of outstanding warrants and the settlement of milestone and contingent payment obligations, all of which are subject to a 9.9% beneficial ownership cap limiting the number of ADSs Perceptive may acquire at any one time. 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 are currently not in compliance with and may not be able to fulfill in the future, thereby leading to a possible delisting of our ADSs.

Our ADSs are listed on the Nasdaq Global Select Market, which requires us to meet certain ongoing listing standards. We cannot guarantee that we will continue to meet these requirements.

A deficiency relating to the Nasdaq minimum market value of publicly held shares ("MVPHS") requirement remains outstanding. On August 28, 2026, the Company received a staff determination letter (the "Determination Letter") from the Staff notifying the Company that it had not regained compliance with the MVPHS Requirement by August 18, 2026. Accordingly, and as described in the Determination Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension/delisting. On September 4, 2026, the Company formally requested a hearing before the Panel.

The Company has a number of initiatives and strategic transactions at advanced stages, which, if completed, would be expected to increase the Company's MVPHS above the $15 million minimum. The Company intends to continue to progress these transactions and as such management remains confident that the actions currently underway will enable the Company to reach a MVPHS of over $15 million. The hearing request will automatically stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. In that regard, pursuant to the Nasdaq Listing Rules, the Panel has the authority to grant an extension not to exceed February 24, 2027. Notwithstanding the foregoing, there can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Global Select Market.

On August 7, 2026, Nasdaq confirmed that the Company had regained compliance with the minimum bid price requirement following implementation of a 30:1 ADS ratio change, resulting in a revised ratio of 600 ordinary shares to one ADS.

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. 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. For example, we are not required to file quarterly reviewed financial statements with the SEC and we are permitted to disclose limited compensation information for our executive officers on an individual basis.

As of March 18, 2026, our officers and directors are no longer exempt from the reporting provisions of Section 16 of the Exchange Act. Our principal shareholders continue to remain exempt from the reporting requirements contained in Section 16(a) of the Exchange Act and our officers, directors and principal shareholders continue to remain exempt from the short-swing profit recovery provisions contained in Section 16(b) of the Exchange Act as a foreign private issuer whose ADSs are listed on NASDAQ, we are permitted to follow certain home country practices instead of certain requirements of the NASDAQ listing rules. Among other, as a foreign private issuer we follow home country practice with regard to, the composition of the board of directors, director nomination procedure, compensation disclosure of officers and quorum at shareholders' meetings. In addition, we 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 our 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.

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. Historically, the market price of our ADSs has fluctuated and during the period from January 2026 through August 2026, the market price of our ADSs fluctuated from a high of US$28.87 per ADS to a low of US$7.94 per ADS (ADS prices presented post 2026 ADS ratio change). We anticipate that the market prices of our ADSs will continue to be subject to wide fluctuations. The market price of our ADSs 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 termination 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;
- 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 will need additional capital in the future to meet our working capital and business development expenditures. 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 will require additional capital in the future to fund our operations, product development and business development initiatives. 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 financing, asset sales, or other means. We have updated the registration in respect of our at-the-market equity offering programme (the "ATM Programme") with Lucid Capital Markets LLC pursuant to which we may, from time to time, offer and sell ADSs, subject to market conditions, applicable regulatory requirements and the availability of sufficient capacity under our registration statements, and we have entered into the Perceptive Conversion Documents, which, while they reduce our outstanding indebtedness upon conversion, do not generate new cash proceeds for the Company. Neither of these arrangements ensures that we will have sufficient capital to fund our operations and strategic initiatives. The extent to which we rely on the SEPA as a source of funding will depend on a number of factors, including the prevailing market price of our ADSs and the extent to which we are able to secure working capital from other sources.

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. Our outstanding convertible instruments with Perceptive and the ATM already provide for substantial potential dilution, any additional equity or equity-linked financing could compound such dilution. Our ability to raise additional capital may also be impaired by the large number of ADSs that may be issued under those existing arrangements and our outstanding warrants and options. These factors, individually and in combination, could make it more difficult to raise capital on acceptable terms and may put additional strain on our ability to satisfy the continued listing requirements of Nasdaq.

In recent years, we have relied on debt financing from Perceptive and have received additional term loans from Perceptive from time to time, in some cases in exchange for the issuance of additional warrants or the repricing of existing warrants to reflect lower prevailing share prices. Any further debt financing, whether from Perceptive or otherwise, 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 licenses on terms that are not favorable to us.

Future sales of our ADSs, including upon conversion of our outstanding convertible instruments, exercise of warrants, and sales under our committed equity financing, could reduce the market price of our ADSs and impair our ability to raise capital.

Substantial sales of our ADSs, or the perception that such sales may occur, could cause the market price of our ADSs to decline. There are a number of sources from which a significant volume of ADSs may enter the public market in the near term:

- Under the Perceptive Conversion Documents, Perceptive may convert up to US$72,500,000 in outstanding principal under the Credit Agreement and US$12,500,000 of other amounts owed to Perceptive into ADSs at its sole discretion. We do not control the timing of conversions, and Perceptive may resell any ADSs it receives upon conversion in the public market at any time.
- Pursuant to our At-the-Market ("ATM") offering programme with Lucid Capital Markets, we may sell up to US$4,352,314 of ADSs from time to time into the public market. Any such issuances, or the perception that additional issuances may occur, could adversely affect the market price of our ADSs and may make it more difficult for investors to sell their ADSs at times and prices that they deem appropriate

- We have outstanding warrants for up to 66,200,000 ordinary shares (110,333 ADSs) and outstanding share options for up to 40,017,505 ordinary shares (66,696 ADSs).
- 24,691,358 ordinary shares (represented by 41,152 ADSs) are issuable upon conversion of the MiCo Convertible Note.

The cumulative effect of potential conversions under the Perceptive Conversion Documents and Mico Convertible Note, sales pursuant to the ATM, and the exercise of warrants and options means that a very large number of additional ADSs could be issued and sold in the public market, which may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate, and may adversely affect the market price of our ADSs regardless of whether conversions, exercises, or sales have actually occurred. The potential for the issuance and resale of a substantial number of additional ADSs may contribute to continued downward pressure on the trading price and impair our ability to maintain compliance with the listing requirements of Nasdaq.

The conversion or exercise of our outstanding convertible instruments, share options, and warrants, and sales of ADSs under our committed equity financing, could significantly dilute the ownership interest of existing shareholders.

We have issued a number of convertible instruments, warrants, and share options that, if converted or exercised, would result in substantial dilution to existing shareholders. In particular, in December 2025, we entered into a series of agreements with funds managed by Perceptive Advisors (collectively, "Perceptive") pursuant to which Perceptive may elect to convert up to US$72,500,000 in outstanding principal under the Credit Agreement and US$12,500,000 of other amounts owed to Perceptive into ADSs (the "Perceptive Conversion Documents"). Conversions under the Perceptive Conversion Documents are at Perceptive's election - the Company does not control the timing, volume, or frequency of conversions. The conversion price under the Perceptive Conversion Documents is 97% of the volume weighted average price ("VWAP") of our ADSs, subject to a minimum conversion price of US$0.5061 per ADS (equal to 75% of the 30 day VWAP of the Company's ADSs for the period ended April 22, 2026). Following the ADS ratio change effected on July 24, 2026, the minimum conversion price was adjusted to US$15.183 per ADS to reflect the revised ADS ratio. Based on this minimum conversion price, full conversion could result in the issuance of approximately 5,600,000 ADSs, representing an aggregate of approximately 3,360,000,000 ordinary shares (each ADS representing 600 ordinary shares).

As of April 30, 2026, there were 405,017,380 ordinary shares outstanding. Accordingly, the ordinary shares issuable upon full conversion of the Perceptive Conversion Documents at the Floor Price would represent approximately 829% of our currently outstanding ordinary shares. Although conversions under the Perceptive Conversion Documents are subject to a 9.9% beneficial ownership cap, this cap limits only the number of ordinary shares and ADSs Perceptive may beneficially own at any given time and does not restrict the total number of ADSs that may ultimately be issued over time.

In addition, on June 11, 2026, we entered into an At-the-Market Offering Agreement (the "ATM Agreement") with Lucid Capital Markets, LLC ("Lucid"), pursuant to which we may offer and sell from time to time up to US$4.35 million of ADSs through Lucid acting as sales agent. Sales under the ATM Agreement may be made at prevailing market prices, and the number of ADSs that may be issued to raise a particular amount of capital will vary depending on the trading price of our ADSs at the time of sale. Accordingly, if our ADS trading price declines, we would be required to issue a greater number of ADSs to raise a given amount of capital

We also have outstanding warrants exercisable for up to 66,200,000 ordinary shares (110,333 ADSs) with exercise prices ranging from US$24.0 to US$25.80, share options exercisable for up to 40,017,505 ordinary shares (66,696 ADSs) with exercise prices ranging from US$3.60 to US$33.00 and a convertible note held by Mico IVD Holdings, LLC (the "MiCo Convertible Note"), convertible into 24,691,358 ordinary shares (41,152 ADSs) at conversion price of US$486.00 per ADS. The exercise of these warrants or options or conversion of the MiCo Convertible Note would further dilute the ownership interests of existing shareholders.

In the aggregate, if all of our outstanding convertible instruments, warrants, and share options were fully converted or exercised, and assuming the SEPA were fully utilized, the resulting issuances could, on the one hand, substantially reduce our debt and interest costs, it could also dilute the ownership interest of existing shareholders by a very significant amount.

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 2025 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.

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 judgment is for a debt or a definite sum of money;
- 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 refuse to enforce a judgment of the U.S. courts which meets the above requirements in certain circumstances, including:

- if the judgment was impeached 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; or
- 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.

An application to the Irish courts for the enforcement in Ireland of a judgment of the U.S. courts which meets the above requirements may also be successfully opposed if it can be demonstrated that:

- 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
- 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 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 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 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 A Ordinary Shares in accordance with those 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 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 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.

Performance Review

Year ended December 31, 2025 compared to the year ended December 31, 2024

Management's Discussion and Analysis of Financial Condition and Results of Operations

Strategic Repositioning and Transformation

Overview

During 2025, Trinity Biotech undertook a significant strategic repositioning of the Company, reflecting both structural changes in global healthcare markets and the Board and management's assessment of the long-term opportunities created by advances in sensor technology, artificial intelligence ("AI") and digitally delivered healthcare.

This repositioning was executed alongside a multi-initiative comprehensive transformation of the Company's existing diagnostics business, designed to materially improve financial performance, operational efficiency and capital discipline.

These actions were taken during a period of considerable external disruption, most notably a contraction and reprioritization of international funding for global health programs, including HIV-focused initiatives, which materially impacted demand for certain of the Company's legacy product lines during 2025. While this disruption affected near-term revenues and operating performance, the Company believes these funding dynamics have since begun to stabilize, with demand showing clear signs of recovery entering 2026.

In addition, changes in international trade and tariff practices caused further disruption and uncertainty across supply chains with an increase in operating costs. Management expects that given the current geopolitical environment, continued changes in this area should be expected. As such management continues to actively monitor the environment and has sought to restructure its supply chain and manufacturing locations so as to provide additional optionality with a view to mitigating the current and potential future impact of such changes, where commercially feasible.

Strategic Pivot Toward Digitally Delivered, AI-Driven Healthcare

A central element of the Company's 2025 repositioning was the continued development of its CGM+ program, which represents a strategic pivot beyond traditional in-vitro diagnostics toward digitally enabled, AI-driven healthcare solutions. CGM+ is being developed as an integrated continuous glucose monitoring and multimodal biosensing platform intended to support a broader metabolic intelligence offering, rather than a standalone hardware product.

Management believes that long-term value creation in metabolic health will increasingly be driven by the ability to generate longitudinal, real-world physiological data and translate that data into clinically actionable insights using AI and advanced analytics. The CGM+ program is designed to serve as a foundational layer within this ecosystem.

While CGM+ remains under development and has not yet been commercialized, the Company believes this strategy positions it to address emerging opportunities at the intersection of diabetes care, cardiometabolic disease and personalized medicine.

Transformation of the Existing Diagnostics Business

In parallel with the CGM+ development effort, Trinity Biotech significantly progressed its comprehensive transformation program for its existing diagnostics operations during 2025. This program is designed to address historical operating inefficiencies, improve cost structure and cash flow generation and reposition the legacy business to sustainably support investment in future growth initiatives.

Management views this transformation not as a short-term cost-reduction exercise, but as a structural reset aimed at delivering a step change in financial performance, including improved margins, reduced earnings volatility, and enhanced capital efficiency. In conjunction with this comprehensive transformation plan, the company continues to work with Barclay's on its previously announced strategic review to examine the most appropriate opportunities for its existing business lines in terms of the company's medium to long term strategic plan, product life-cycle stages, demand profile and capital structure optimization.

External Disruption and Market Environment

The strategic and operational changes undertaken in 2025 occurred against a backdrop of significant upheaval in the international funding landscape for global health programs. Funding disruptions and delays affecting major multilateral and government-supported HIV initiatives led to reduced and deferred purchasing activity across parts of the diagnostics sector, including certain markets served by us, most notably rapid HIV products.

These conditions negatively impacted revenue and operating results in specific product categories during 2025, with resultant management decisions around cash-flow optimization having further implications for other parts of the business. However, management believes these effects were primarily driven by funding timing and reprioritization rather than underlying demand fundamentals. In the latter part of 2025 and entering 2026, the Company has observed improving ordering patterns and engagement from customers and partners, suggesting that funding flows and demand are beginning to normalize, albeit with increased levels of order timing and payment variability.

Management Perspective

Management believes that the actions taken in 2025 represent a deliberate and necessary repositioning of Trinity Biotech for the next phase of its evolution. While these initiatives involved near-term disruption and execution risk, they were undertaken with the objective of aligning the Company with long-term trends in digital health, AI-enabled care, and value-based healthcare delivery, while simultaneously strengthening the financial foundation of the core diagnostics business and providing strengthened opportunities for capital structure optimization to support further company evolution and position the company for long-term growth in a healthcare environment that is set to be further dominated by digital solutions underpinned by an increased need for data.

The Company will continue to evaluate its capital allocation, capital structure, investment pace and operational priorities as CGM+ advances through development.

Revenues – continuing operations

Our revenues from continuing operations for the year ended December 31, 2025 were US$43.8 million compared to revenues of US$61.6 million for the year ended December 31, 2024, which represents a decrease of US$17.8 million or 28.9%.

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

	Year ended December 31,		
	2025 US$'000	**2024 US$'000**	**% Change**
Revenues – continuing operations			
Clinical laboratory goods	31,678	39,372	(19.5%)
Clinical laboratory services	4,006	4,750	(15.7%)
Point-of-Care	8,101	17,433	(53.5%)
	43,785	**61,555**	**(28.9%)**

Clinical Laboratory Goods

Clinical Laboratory goods revenues decreased by US$7.7 million in 2025, which represents a decrease of 19.5%, primarily due to lower haemoglobin and infectious diseases product revenues.

Haemoglobin revenues fell from US$20.1 million in 2024 to US$16.9 million in 2025, partly due to deferred manufacturing during the transition of certain production processes out of our Kansas City facility as part of our comprehensive transformation plan. While production normalised under a new operating model and sales improved later in the year, full-year revenues remained below the prior year. In addition, the Company is moving away from its relationship with one of its larger distributors with sales to that distributor falling during 2025, with expected further reductions in 2026. The Company has increased its sales and marketing resources in this area and is actively pursuing new distributor relationships that are more aligned with the Company's strategic plans for its haemoglobin business.

We are now well positioned to capitalise on a more efficient, higher-capacity manufacturing base for future growth, particularly in the diabetes care HbA1c testing sector. With rising global diabetes prevalence, we plan to continue investing in working capital to support the expansion of our haemoglobin laboratory systems business, including HbA1c systems. In parallel, we have introduced a new high-capacity HbA1c column system in the U.S. and select international markets, designed to improve testing throughput and operational efficiency. We have also implemented strategic modifications to our instrumentation supply chain focused on cost reduction, improved reliability and lower service expenses, which we expect will support margin improvement and sustainable long-term growth.

Infectious disease product revenues decreased from US$5.6 million in 2024 to US$3.8 million in 2025, primarily reflecting lower sales volumes in certain international markets. The largest fall in revenue was from a legacy international customer from which the company derived particularly low margins. The Company is focused on reducing complexity and focusing on higher margin business.

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 15.7% to US$4.0 million. The decrease was mainly attributable to reduced testing volumes for Sjögren's syndrome. As part of our comprehensive transformation plan we have made changes to the operating structure supporting this service with a view to improving efficiency and increasing testing capacity over time. We believe these actions position this business to grow profitably as volumes recover.

Point-of-Care

Point-of-Care revenues decreased by 53.5% from US$17.4 million in 2024 to US$8.1 million in 2025. The first half of 2025 was impacted by considerable uncertainty regarding demand for our rapid HIV point-of-care products stemming from the U.S. President's Executive Order on Reevaluating and Realigning United States Foreign Aid, issued in January 2025, which instituted a pause, subject to certain exemptions, on new funding obligations for foreign assistance programmes. As U.S. Government funding supports certain HIV testing programmes that utilise our rapid HIV tests, this development affected both the timing and volume of product sales in the period. In response to this uncertainty, management minimised production of rapid HIV tests during the first half of 2025 to mitigate the risk of obsolete inventory and excess working capital, resulting in a decline in point-of-care revenues compared to the prior year. Point-of-care revenues in 2024 benefited from higher rapid HIV sales volumes throughout the year.

Production of our Uni-Gold HIV products recommenced in late Q2 2025, and we experienced a strengthening in sales during the second half of the year as manufacturing under the revised operating model ramped up and demand for rapid HIV tests began to normalise. In addition, manufacturing and commercial supply of our TrinScreen HIV product resumed in the second half of 2025 following the transition of production to an outsourced and offshored manufacturing model. While there was clear evidence of renewed market demand and improved operating performance in the second half of 2025, full-year point-of-care revenues remained below the prior year, reflecting the significant impact of the first-half disruption. In addition, the Company experienced a temporary revenue impact in Q4 2025 resulting from fine-tuning of manufacturing and supply-chain processes to accommodate the rise in demand for TrinScreen HIV. These processes have been successfully scaled up in early 2026.

During 2026, the Company also progressed the transition and commercial scale-up of outsourced upstream manufacturing for Uni-Gold HIV. While this transition is expected to support improved long-term profitability and scalability, the ongoing scale-up of the outsourced manufacturing model for Uni-Gold HIV has contributed to variability in HIV revenues and profitability between reporting periods and may continue to do so through the remainder of 2026 and into early 2027.

The business continues to experience some uncertainty regarding the timing of orders and comparatively longer payment cycles as a result of changes in market and funder processes.

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,		
	2025 US$'000	2024 US$'000	% Change
Revenues for continuing operations			
Americas	24,624	29,917	(17.7%)
Asia/Africa	15,383	24,775	(37.9%)
Europe	3,778	6,863	(45.0%)
Total	**43,785**	**61,555**	**(28.9%)**

In the Americas, revenues decreased US$5.3 million or 17.7%. The decrease was primarily driven by lower sales in our haemoglobin business, reflecting deferred manufacturing during the transition of certain production processes out of our Kansas City facility. In addition, revenues from our clinical laboratory services declined, reflecting lower autoimmune testing volumes.

In Asia/Africa, revenues decreased by 37.9%, or US$9.4 million compared to 2024. The decline was mainly attributable to lower sales of our rapid HIV point-of-care products, reflecting the impact of funding-related demand uncertainty in key African markets during the first half of the year and modest reductions in revenues from our haemoglobin and infectious disease product lines within the Asia region.

In Europe, revenues decreased by US$3.1 million, or 45.0% compared to 2024. The reduction was primarily driven by lower haemoglobin product revenues.

Cost of sales, gross profit and gross margin

Total cost of sales decreased by US$13.2 million from US$40.1 million for the year ended December 31, 2024 to US$26.9 million, for the year ended December 31, 2025, a decrease of 32.9%. This resulted in a gross profit for 2025 of US$16.9 million compared to a gross profit for December 31, 2024 of US$21.4 million. The gross margin of 38.6% in 2025 compares to a gross margin of 34.8% in 2024. The increase in gross margin in 2025 reflects the continued execution of the Group's Comprehensive Business Transformation Plan, with benefits from manufacturing consolidation, offshore production and improved operating efficiency under the new cost base. In addition, certain stranded costs incurred during the transition period were reclassified from cost of sales to selling, general and administrative expenses, contributing to the year-on-year improvement in gross margin.

Stranded costs represent costs that are no longer directly attributable to ongoing operations or revenue-generating activities following organisational changes, restructuring, site closures, or product rationalisation. Such costs typically include overheads, personnel costs and facility-related expenses that cannot be avoided or redeployed in the short term. Stranded costs are assessed each reporting period and are recognised in profit or loss as incurred, unless they relate directly to a qualifying asset or meet the criteria for capitalisation under relevant accounting standards.

Other operating (expense)/income

Other operating income was US$1.9 million for the year ended December 31, 2025, compared to other operating expense of US$1.8 million for the year ended December 31, 2024. The movement primarily reflects a fair value gain of US$1.9 million recognised in 2025 in respect of the remeasurement of contingent consideration associated with the Waveform CGM acquisition, following its incorporation into the amended Perceptive term loan facility. There was no comparable gain in the prior year.

The expense of US$1.8 million in 2024 related primarily to the reversal of US$1.8 million income from loan forgiveness of second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries recognised in 2020. The settlement of second-round Paycheck Protection Program ("PPP") loans during 2025 did not give rise to additional other operating income, with the agreed settlement amounts reflected within finance costs and once-off costs. For further details, see Notes 4, 5 and 6.

Research and development expenses

Research and development expenses decreased from US$4.5 million for the year ended December 31, 2024 to US$3.6 million for the year ended December 31, 2025, a decrease of 20.1%.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased for the year ended December 31, 2025 by US$4.1 million to US$24.7 million when compared to the year ended December 31, 2024, representing a decrease of 14.4%. A significant element of the US$4.1 million decrease relates to:

i) a US$3.1 million decrease in salaries and related personnel costs, reflecting the impact of organisational realignment measures undertaken as part of the transformation program.

ii) lower non-cash share-based payments expense of US$324,000 (US$1,316,000 in 2024) mainly due to forfeitures and expirations.

Impairment charges

Impairment charges increased from US$1.4 million for the year ended December 31, 2024 to US$2.2 million for the year ended December 31, 2025. 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.

Premier Resolution is a capitalised intangible asset held within Primus Corporation and relates to the Resolution platform for haemoglobinopathy and variant testing in the US market. While the platform has achieved technical feasibility and obtained FDA clearance in late 2023, the commercialisation pathway is dependent on securing adoption within a highly concentrated US reference laboratory market.

While the Group continues to pursue commercial opportunities for the platform and believes that it retains underlying potential, these factors have resulted in the recoverable amount of the asset being lower than its carrying value. Accordingly, the Group recognised a partial impairment charge of US$2.1 million during the year.

Immco Diagnostics's value in use was below the value of its relevant assets, and an impairment was provided for as at December 31, 2025 (US$20,000).

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, 2025 (US$28,000) and as at December 31, 2025 (US$2,000).

The impairment charges for the year ended December 31, 2024 related to impairment losses identified for four cash generating units, namely Biopool US Inc. (US$0.2 million), Immco Diagnostics Inc (US$0.1 million) Clark Laboratories Inc (US$0.1 million) and Trinity Biotech Do Brasil (US$0.2 million). For further details, see Notes 11, 12, and 13.

Transformation Costs

As part of a strategic initiative to enhance operational efficiency and align the Group's cost base with its long-term objectives, the Group has been executing a comprehensive business transformation programme, which was substantially progressed during the year ended December 31, 2025. The programme comprises targeted actions to improve operational profitability, streamline the organisational structure and consolidate manufacturing and support functions under a more efficient operating model.

As a result, we incurred transformation costs of US$4.3 million during 2025 (2024: US$4.2 million), which were primarily related to personnel-related expenses, outsourcing of selected functions, site transfers, stock-related adjustments and transition-related manufacturing inefficiencies. These costs are presented separately within Selling, General and Administrative expenses.

The largest component comprised costs of approximately US$3.3 million representing fixed manufacturing overheads that were not absorbed into cost of sales due to lower throughput at certain manufacturing sites during and following the consolidation and outsourcing of elements of the Group's manufacturing operations under the Comprehensive Transformation Plan. These costs arose as the Group transitioned away from legacy manufacturing locations and reconfigured its manufacturing footprint, resulting in a temporary mismatch between fixed cost capacity and production volumes. As manufacturing consolidation and outsourcing activities progress towards completion, and production volumes are stabilised under the new operating model, the Group expects a significant reduction in such stranded costs, although residual transformation-related costs may continue into 2026 as the programme reaches its final phases.

While the majority of the transformation activities were undertaken during 2025, the Group expects to incur further limited, residual transformation-related costs during 2026 as the final phases of the programme are executed. The overall level of transformation costs is expected to reduce as the programme enters its final stages. The transformation is intended to deliver a lower and more flexible cost base, supporting improved profitability and long-term financial performance. For further details, see Item 18, Note 5 "Impairment, transformation and once-off costs".

Once-Off Costs

During the year ended December 31, 2025, the Group recognised a gain of US$0.2 million (2024: loss of US$1.9 million) within operating expenses relating to a legacy, non-trading matter. The gain recognised in 2025 arose from the reversal of a provision previously recorded following settlement of the matter during the year. The loss recognised in 2024 related primarily to the initial recognition of the provision associated with this matter. These amounts do not relate to the Group's ongoing operations and are not expected to recur.

Operating Loss

Operating loss for the year ended December 31, 2025 was US$15.8 million, compared to an operating loss of US$21.2 million in the year ended December 31, 2024. The reduced loss was mainly attributable to increased gross margins and lower indirect costs.

Operating Loss excluding Impairment, Transformation & Once-off costs

Operating loss excluding Impairment, Transformation & Once-off costs for the year ended December 31, 2025 was US$9.5 million, compared to US$13.7 million for the year ended December 31, 2024, reflecting the improvement in gross margins, savings in indirect costs and increased impairment costs.

Financial expenses

Financial expenses in the year ended December 31, 2025 were US$21.3 million compared to US$9.6 million in the year ended December 31, 2024, an increase of US$11.7 million, broken down as follows:

	Year ended December 31, 2025	*Year ended December 31, 2024*
	US$m	*US$m*
Interest on senior secured term loan	12.3	8.6
Interest on convertible note	1.2	1.2
Lease interest	0.6	0.6
Interest payable on repayment of PPP loans	(0.2)	0.3
Capitalised borrowing costs	(2.9)	(2.1)
Loss on extinguishment of old loan balance	10.0	-
Other non-cash financial expense	0.3	1.0
Total	**21.3**	**9.6**

Note: table above contains rounded numbers

The increase of US$11.7 million in financial expenses in 2025 compared to 2024 was driven primarily by the US$10.0 million loss on extinguishment of the old senior secured term loan, recognised in connection with the refinancing of the Group's debt during the year (see Note 23). The loss on extinguishment arose principally from the termination of a contingent feature under the prior loan agreement, pursuant to which the Group had exposure of up to US$15.0 million linked to a partnership trigger; this was settled as part of the refinancing through the incorporation of US$7.5 million, into the new senior secured term loan.

In addition, interest expense on the senior secured term loan increased due to a higher average outstanding loan balance during 2025. These increases were partially offset by gains arising from the fair value remeasurement of embedded derivatives.

Interest on the senior secured term loan, comprising both cash and non-cash interest, increased from US$8.6 million in 2024 to US$12.3 million in 2025, mainly reflecting the higher term loan balance during the year. Interest on the convertible note, comprising cash and non-cash interest, remained unchanged at US$1.2 million in both 2024 and 2025.

During 2025, the Group capitalised borrowing costs of US$2.9 million into development assets, compared to US$2.1 million in 2024, in accordance with its accounting policy.

In October 2024, the Company became aware of a U.S. governmental review relating to second-round Paycheck Protection Program ("PPP") loans received by certain U.S. subsidiaries. As at December 31, 2024, estimated interest of US$0.3 million was accrued in respect of the related payable (see Note 4 for further details).

A settlement was reached during 2025 with respect to the PPP loans, a reversal of previously accrued interest of approximately US$0.2 million was recognised within financial expenses.

Income tax (expense)/credit

The Company recorded a tax expense on continuing operations of US$199,288 for the year ended December 31, 2025 compared to a tax expense of US$486,000 for the year ended December 31, 2024. The 2025 tax expense consists of approximately US$465,000 of current tax charge and US$266,000 of a deferred tax credit. The 2024 tax expense consists of approximately US$285,000 of current tax charge and US$201,000 of a deferred tax charge. For further details on the Group's tax charge please refer to 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, 2025 was US$37.2 million, in comparison to US$30.7 million for the year ended December 31, 2024.

Profit/(Loss) from discontinued operations

In 2023, discontinued operations comprised 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 a gain of US$12.7 million on the divestiture of Fitzgerald Industries. The gain comprised gross proceeds of approximately US$30.0 million, offset by transaction costs of US$1.3 million and the derecognition of net assets disposed of amounting to US$16.3 million.

Following negotiations, a settlement agreement relating to post-completion claims arising from the sale of Fitzgerald Industries 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 claims. During 2025, the Company paid US$75,000 with the remaining US$75,000 included in accrued liabilities in the consolidated financial statements as at December 31, 2025. The settlement fully resolves all disputes related to the sale of Fitzgerald Industries, and no further liabilities are expected to arise.

There were no discontinued operations in 2025.

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TRINITY BIOTECH PLC

Opinion
We have audited the group and parent company financial statements of Trinity Biotech plc (the "Company") and its subsidiaries (the "Group"), which comprise the consolidated statement of operations, the consolidated statement of comprehensive income, the consolidated and parent company statements of financial position, the consolidated and parent company statements of changes in equity and the consolidated and parent company statements of cash flows for the financial year ended December 31, 2025, and the related notes to the financial statements, including the material accounting policy information.

The financial reporting framework that has been applied in the preparation of the financial statements is Irish law and IFRS Accounting Standards as adopted by the European Union ('IFRS') (the "relevant accounting framework").

In our opinion:

- the consolidated financial statements give a true and fair view of the assets, liabilities and financial position of the Group as at December 31, 2025 and of its financial performance and cash flows for the financial year then ended;
- the parent company financial statements give a true and fair view, of the assets, liabilities and financial position of the parent company as at December 31, 2025 and of its cash flows for the financial year then ended;
- the financial statements have been properly prepared in accordance with relevant accounting framework; and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

Basis for opinion
We conducted our audit in accordance with International Standards on Auditing (Ireland) ('ISAs (Ireland)') and applicable law. Our responsibilities under those standards are further described in the 'Auditor's responsibilities for the audit of the financial statements' section of our report. We are independent of the Group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard for Auditors (Ireland) issued by the Irish Auditing and Accounting Supervisory Authority (IAASA), and the ethical pronouncements established by Chartered Accountants Ireland, applied as determined to be appropriate in the circumstances for the entity. We have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Material uncertainty related to going concern
In forming our opinion, which is not modified, we draw attention to the disclosures made in the Directors' Report, Note 1(iii), and Note 31 of the financial statements concerning the Group and the Company's ability to continue as a going concern. The Group incurred a loss of $37.4 million during the financial year ended December 31, 2025 and, as at that date, had net current liabilities of $105.3 million and an accumulated deficit attributable to the equity holders of the Company of $72.0 million. The Group's borrowings under the Perceptive Term Loan, under which $115 million was contractually payable, are due for repayment on January 15, 2027, which falls within the going concern assessment period. As at the date of approval of the financial statements, no agreement to refinance or extend the facility had been concluded.

The Group breached the minimum revenue covenant under the facility for the quarter ended December 31, 2025. As part of the third amendment, the lender provided a waiver in respect of this breach. The Directors' assessment is dependent on the continued support of the lender, on the Group's ability to refinance, repay or extend the facility on or before maturity, and on continued access to equity funding and to the reduction of indebtedness through debt equitisation.

On August 28, 2026, the Company received notification from Nasdaq that its American Depositary Shares are subject to delisting, the Company having failed to regain compliance with the minimum market value of publicly held shares requirement within the applicable compliance period. The Company has requested a hearing before a Nasdaq Hearings Panel, which is expected to take place at the end of September or during October 2026. The hearing request stays any suspension or delisting action pending completion of the appeals process. The outcome of the hearing is not within the Company's control and depends in part on the completion of initiatives and strategic transactions that had not been concluded at the date of approval of the financial statements. Were the American Depositary Shares to be delisted, the Group's ability to raise equity funding and to effect debt equitisation on the basis assumed in the Directors' forecasts would be adversely affected.

These conditions, along with the other matters set out in Note 1(iii), indicate the existence of a material uncertainty which may cast significant doubt over the Group and the Company's ability to continue as a going concern.

Material uncertainty related to going concern (continued)
The financial statements have been prepared on a going concern basis which assumes the Group and Company will continue in operational existence for the foreseeable future. The validity of this assumption depends on the continued support of the Group's principal lender, Perceptive, the ability to refinance, repay or extend the Perceptive Term Loan on or before its maturity on January 15, 2027, and the Group's continued ability to raise equity funding and to reduce indebtedness through debt equitisation.

The Directors believe that the continued support of Perceptive, ongoing progress within the Group's transformation and CGM development programmes, the resolution of the Nasdaq minimum bid price deficiency in August 2026 (which is separate from the aforementioned minimum market value of publicly held shares deficiency), and the range of funding, refinancing and deleveraging alternatives available to it will contribute to future revenue growth and ultimately lead to recurring profitability. They have reviewed detailed budgets, projected cash flows, and other relevant information and have a reasonable expectation that the Group has sufficient financial resources to continue operating for the foreseeable future.

The financial statements do not include the adjustments relating to the recoverability and classification of recorded asset amounts and classifications of liabilities that might be necessary should the Group and the Company be unable to continue as a going concern.

In auditing the financial statements, we have concluded that the Directors' use of going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the Directors' assessment of the entity's ability to continue as a going concern basis of accounting included the following:

- We obtained an understanding, evaluated the design and implementation of controls over management's going concern assessment process.
- We examined management's assessment on going concern covering at least twelve months from the date of approval of the financial statements 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 agreed the underlying cash flow forecasts against budgets of the trading CGUs and individual assets and we evaluated management's ability to accurately forecast future revenues, margins and expenses by performing a look-back analysis and comparing actual results to management's historical forecasts.
- We assessed management's sensitivity over the cash flow forecasts, including consideration of the level of deterioration required to result in covenant breaches, and evaluated whether sufficient headroom remained under reasonably possible downside scenarios.
- We reviewed management's communications with the lender and inspected the revised lending agreements, including executed waivers and amended covenants. We assessed the terms and conditions of the revised agreements against the cash flow forecast. In addition, we also discussed with management the options being considered in relation to repayment plan of the senior secured term loan.
- We discussed with management the alternatives available in respect of the Term Loan at or before maturity and evaluating the status of each.
- We inspected agreements in relation to the equity funding and debt equitisation. We evaluated the status of each through the cash raised in recent equity issuances and the debt equitised to date.
- We evaluated the effect of the Nasdaq delisting determination on the equity funding and debt equitisation assumed in the forecasts, inspecting the Company's submission to the Nasdaq Hearings Panel and the evidence supporting the initiatives on which it relies, and assessing the extent to which the forecasts remain achievable in the absence of that funding.
- We considered subsequent events up to the date of the auditor's report that may affect the going concern conclusion; and
- We evaluated the adequacy of the disclosures in the financial statements, including the description of uncertainties and management plans as required by relevant accounting standards.

Our responsibilities and the responsibilities of the Directors with respect to going concern are described in the relevant sections of this report.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current financial period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit, and the directing of efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and therefore we do not provide a separate opinion on these matters.

In addition to the matter described in "Material uncertainty related to going concern'', we have determined the matters described below to be the key audit matters to be communicated in our report.

Overall audit strategy
We designed our audit by determining materiality and assessing the risks of material misstatement in the financial statements. In particular, we looked at where the Directors made subjective judgements, for example, impairment considerations regarding goodwill and long-lived assets, recognition of revenue under bill-and-hold arrangements, and assessment of going concern. We also addressed the risk of management override of internal controls, including evaluating whether there was any evidence of potential bias that could result in a risk of material misstatement due to fraud.

Based on our considerations as set out below, our areas of focus included:
- Impairment of goodwill and long-lived assets; and
- Revenue recognised under bill-and-hold arrangements

How we tailored the audit scope
Trinity Biotech plc develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. Revenues are mainly generated from the clinical laboratory segment and from customers residing outside of the Republic of Ireland.

In establishing the overall approach to our audit we assessed the risk of material misstatement at a Group level, taking into account the nature, likelihood and potential magnitude of any misstatement. As part of our risk assessment, we considered the control environment in place at the Company and the Group.

In assessing the risk of material misstatement to the Group financial statements and to ensure we had adequate quantitative coverage of significant accounts in the financial statements, we selected ten components covering entities across Europe and the Americas, which represent the principal business units within the Group.

Of the ten components selected, we performed an audit of the complete financial information of four components ("Audit of financial information - assume responsibility") which were selected based on their size and risk characteristics. For the remaining six components ("Specified audit procedures (designed by group auditor)"), we performed audit procedures on specific accounts within those components that we considered had the potential for the greatest impact on the significant accounts in the financial statements either because of size of these accounts of their risk profile.

The reporting components within which audit procedures were conducted accounted for 100% of the Group's revenue and 90% of the Group's total assets.

Materiality and audit approach
The scope of our audit is influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, such as our understanding of the entity and its environment, the history of misstatements, the complexity of the Group and the reliability of the control environment, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the group to be $696,000, representing 1.5% of revenues earned from third-party sources for the year ended December 31, 2025. We have applied this benchmark because revenues are the primary measure used by shareholders in assessing performance of the entity. In situations where entities are generating fluctuating profit and losses (as is the case for the Group), revenues are the generally accepted auditing benchmark. For the parent company only financial statements, we used $511,000, representing 2% of total assets, as a basis of materiality. The parent company holds the Group's investments and is not in itself profit-oriented. The strength of the Company statement of financial position is the key measure of financial health that is important to shareholders.

Key audit matters (continued)

Materiality and audit approach (continued)

We have set performance materiality at $418,000, representing 60% of materiality, having considered our prior year experience of the risk of misstatements, business risks and fraud risks associated with the entity and its control environment. This is to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements in the financial statements exceeds materiality for the financial statements as a whole. For the parent company only financial statements, we applied $209,000, which is 50% of the Group performance materiality, as the basis for our procedures.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above $34,800, representing 5% of materiality, as well as differences below that threshold, which in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

Significant matters identified
The risks of material misstatement that had the greatest effect on our audit, including the allocation of our resources and effort, are set out below as significant matters together with an explanation of how we tailored our audit to address these specific areas in order to provide an opinion on the financial statements as a whole. This is not a complete list of all risks identified by our audit.

Impairment of goodwill and long-lived assets

Description of significant matter:
Refer to Note 1(viii), Note 5, Note 11, Note 12, Note 17, and Note 31 to the financial statements. As at December 31, 2025 prior to impairment analysis, the intangible assets of the Group totalled $59.1 million, property, plant and equipment of the Group totalled $5.5 million, and prepayments of the Group totalled $1.7 million. During the year, the Group recognised additions to intangible assets and goodwill of $9.0 million and to property, plant, and equipment of $2.2 million. The Group also recognised $2.2 million impairment charge during the year ended December 31, 2025.

The Group'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 Group used the value-in-use approach, which deploys a discounted cash flow model to estimate the recoverable amount.

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

We determined this to be a key audit matter because of the materiality of the carrying values concerned, the significant judgement exercised by the Directors in estimating recoverable amounts, and the extent and nature of the audit effort required to challenge those estimates. In particular:

- A significant proportion of the Group's non-current assets is held within CGUs that had not generated revenue by the reporting date, principally the continuous glucose monitoring ("CGM"), EpiCapture, and Metabolomics CGUs. For these CGUs there is no trading history against which to evaluate forecasts, and the value-in-use models depend on assumptions regarding the timing of regulatory clearance and commercial launch, achievable market penetration and market share, and pricing assumptions that are inherently uncertain and to which the models are sensitive.
- For the Group's trading CGUs, forecast cash flows reflect the outcome of the Group's transformation programme, including the transfer of point-of-care manufacturing to an outsourced and offshored model and the wind-down of the Kansas City facility, with associated assumptions as to revenue recovery and margin improvement that had not been fully realised at the reporting date.

We focused on CGUs which have significant non-current assets in the current year (collectively the "selected CGUs") and certain individual assets which exhibited indicators of impairment.

Key audit matters (continued)

The combination of material carrying values, forecasts extending beyond the Group's demonstrated trading history, and the sensitivity of the models to a small number of key assumptions required a high degree of auditor judgement, the involvement of our valuation specialists, and an increased extent of audit effort.

Audit response to significant matter:
Our audit procedures related to the assumptions, as described above, used by management to estimate the recoverable amounts of the selected CGUs and certain individual assets included the following, among others:

- We identified the selected CGUs with significant non-current assets and individual assets exhibiting impairment indicators, and evaluated the design effectiveness of controls over management's selection of key assumptions used to determine their recoverable amounts.
- We agreed the underlying cash flow forecasts against budgets of the trading CGUs and individual assets and we evaluated management's ability to accurately forecast future revenues, 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.
- For the pre-revenue CGUs, we challenged the commercial assumptions by reference to the Group's detailed commercial plans, held discussions with the CGM Programme Director, the Chief Technology Officer and external commercial advisers engaged by the Group, and benchmarked assumed market penetration, market share and pricing against independent external market data and comparable companies operating in the same markets.
- We assessed the reasonableness of the valuation model used by the Group compared to generally accepted valuation practices and accounting standards.
- We tested the mathematical accuracy of the discounted cash flow models, including the calculation of present values, terminal values, and internal consistency of assumptions applied across periods.
- 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 estimate 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.
- We evaluated the adequacy of the related disclosures, including the key assumptions applied and the sensitivity of recoverable amounts to reasonably possible changes in those assumptions, against the requirements of IAS 36.

Based on the procedures performed, we have determined management's assumptions used in their assessment of impairment of goodwill and long-lived assets and associated with selected CGUs and certain individual assets to be reasonable. We concluded that the related disclosures provided in the consolidated financial statements are appropriate.

Revenue recognised under bill-and-hold arrangements

Description of significant matter:
Refer to Note 1(xvi) and Note 31 to the financial statements. The Group recognised revenue under bill-and-hold arrangements amounting to $2.2 million for the year ended December 31, 2025, which were accounted for under the criteria set by IFRS 15 "Revenue from Contracts with Customers".

The determination of whether the criteria for recognising revenue before delivery of the goods had been met require significant judgement.

The principal considerations for our determination that revenue recognised under bill-and-hold arrangements as a key audit matter were the significant judgments involved in evaluating whether the criteria for bill-and-hold revenue recognition had been met. These included assessing whether the customer's request was substantive, whether the product was complete and ready for transfer, whether the goods were segregated and not available for alternative use, and whether control had effectively transferred to the customer. The complexity and judgment involved in evaluating these conditions increased the risk of premature or inappropriate revenue recognition, which required significant auditor attention.

Key audit matters (continued)

Audit response to significant matter:
Our audit procedures related to the assumptions, as described above, used by management to recognise revenue under bill-and-hold arrangements included the following, among others:

- We evaluated the design effectiveness of certain internal controls related to the Group's revenue recognition and cut-off process, including controls over assessment of whether the bill-and-hold criteria are met.
- We inspected customer requests, contracts, letters of ownership, supporting documentation and correspondence to assess whether the arrangements met the criteria for bill-and-hold revenue recognition under the applicable accounting framework.
- We sent confirmation letters to sampled customers under bill-and-hold arrangements to confirm the arrangement.
- We observed or inspected evidence that the arrangement is substantive and the goods were segregated, and not available for alternative use, including physical verification where appropriate.
- We tested the timing and accuracy of revenue recognised for bill-and-hold transactions and evaluated whether disclosures in the financial statements were complete and appropriate.

Based on the procedures performed, we have determined management's assumptions used in the revenue recognised under bill-and-hold arrangements to be reasonable. We concluded that the related disclosures provided in the consolidated financial statements are appropriate.

Other information
Other information comprises information included in the annual report, other than the financial statements and the auditor's report thereon, including the Directors' report, Market, Industry and Other Data, Cautionary Statement Regarding Forward-Looking Statements, Business overview, Risk Factors and Performance Review. The Directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify such material inconsistencies in the financial statements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinion on the matters prescribed by the Companies Act 2014
We have obtained all the information and explanations which to the best of our knowledge and belief, we considered necessary for the purposes of our audit.

In our opinion the accounting records of the Company were sufficient to permit the financial statements to be readily and properly audited.

The Company statement of financial position is in agreement with the accounting records and returns.

In our opinion, based on the work undertaken in the course of our audit:
- the information given in the Directors' report for the financial year is consistent with the financial statements.
- the Directors' report has been prepared in accordance with applicable legal requirements, excluding the requirements on sustainability reporting in Part 28.

Based on our knowledge and understanding of the Group and parent company and its environment obtained in the course of the audit, we have not identified any material misstatements in the Directors' report.

Matters on which we are required to report by exception
The Companies Act 2014 requires us to report to you if, in our opinion, the requirements of sections 305 to 312 of the Act, which relate to disclosure of Directors' remuneration and transactions with Directors, have not been complied with by the Company. We have nothing to report in this regard.

Responsibilities of management and those charged with governance for the financial statements
As explained more fully in the Directors' responsibilities statement, management is responsible for the preparation of the financial statements which give a true and fair view in accordance with IFRS, and for such internal control as they determine necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Group and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Group or parent company or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Group and parent company's financial reporting process.

Auditor's responsibilities for the audit of the financial statements
The objectives of an auditor are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Irish Auditing and Accounting Supervisory Authority's website at: http://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf. This description forms part of our auditor's report.

Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud
Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. Owing to the inherent limitations of an audit, there is an unavoidable risk that material misstatement in the financial statements may not be detected, even though the audit is properly planned and performed in accordance with the ISAs (Ireland). The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below.

The Company is subject to laws and regulations that directly affect the financial statements, including companies and financial reporting legislation such as Companies Act 2014, Irish and foreign tax legislation, US Securities Exchange Act 1934, and Stock Exchange Listing Rules. We assessed the extent of compliance with these laws and regulations as part of our procedures on the related financial statement items, including assessing the financial statement disclosures and agreeing them to supporting documentation when necessary.

The Company is subject to other laws and regulations, for example, US Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations, data privacy & cybersecurity laws, employment, environmental & safety, anti-bribery, anti-corruption & trade laws, and US healthcare fraud and abuse laws, where the consequences of non-compliance could have a material impact on amounts or disclosures in the financial statements, such as through the imposition of fines or litigation.

The primary responsibility for the prevention and detection of irregularities, including fraud, rests with those charged with governance and management. There is an inherent risk that an audit may not detect all material misstatements in the financial statements, despite properly planning and performing our audit in accordance with auditing standards. In addition, as with any audit, there remains a higher risk of non-detection of irregularities, as these may involve collusion, forgery, intentional misrepresentations and omissions, or the override of internal controls. We are not responsible for preventing non-compliance and cannot be expected to detect non-compliance with all laws and regulations.

Auditor's responsibilities of the auditor for the audit of the financial statements (continued)
Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud (continued)
In response to these principal risks, our audit procedures included but were not limited to:

- application of professional sceptism throughout the audit;
- consideration by the audit engagement partner of the experience and expertise of the engagement team including IT specialists, tax specialists, and valuation specialists to ensure that the team had appropriate competence and capabilities to identify or recognise non-compliance with the laws and regulations;
- discussion amongst the engagement team in relation to the identified laws and regulations and regarding the risk of fraud, and remaining alert to any indications of non-compliance or opportunities for fraudulent manipulation of financial statements throughout the audit;
- evaluating management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls);
- enquiries of management, board and Audit Committee on the policies and procedures in place regarding compliance with laws and regulations, including consideration of known or suspected instances of non-compliance and whether they have knowledge of any actual, suspected or alleged fraud;
- inspection of the Group and parent company regulatory and legal correspondence and review of minutes of board meetings during the year to corroborate inquiries made;
- identifying and testing journal entries to address the risk of inappropriate journals and management override of controls;
- designing audit procedures to incorporate unpredictability around the nature, timing or extent of our testing;
- challenging assumptions and judgements made by management in their significant accounting estimates, including impairment assessment of goodwill and non-current assets, revenue recognised under bill-and-hold arrangements, and assessment of going concern; and
- review of the financial statement disclosures to underlying supporting documentation and inquiries of management.

The purpose of our audit work and to whom we owe our responsibilities
This report is made solely to the parent company's members, as a body, in accordance with section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the parent company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the parent company's members as a body, for our audit work, for this report, or for the opinions we have formed.

STEPHEN MURRAY

For and on behalf of
Grant Thornton
Chartered Accountants & Statutory Audit Firm
Dublin

September 8, 2026

CONSOLIDATED STATEMENT OF OPERATIONS

		Year ended December 31		
	Notes	*2025 Total US$'000*	*2024 Total US$'000*	*2023 Total US$'000*
Revenues	2	**43,785**	**61,555**	**56,832**
Cost of sales		(26,898)	(40,114)	(37,382)
Gross profit		**16,887**	**21,441**	**19,450**
Other operating income/(expense)	4	1,870	(1,787)	141
Research and development expenses		(3,629)	(4,543)	(4,379)
Selling, general and administrative expenses		(24,674)	(28,815)	(31,152)
Selling, general and administrative expenses – Transformation costs	5	(4,252)	(4,181)	-
Once off items	5	186	(1,872)	-
Impairment charges	5	(2,177)	(1,408)	(11,105)
Operating loss		**(15,789)**	**(21,165)**	**(27,045)**
Financial income	6	-	-	1,171
Financial expenses	6	(21,388)	(9,565)	(11,053)
Net financing expense		**(21,388)**	**(9,565)**	**(9,882)**
Loss before tax	7, 9	**(37,177)**	**(30,730)**	**(36,927)**
Total income tax (expense)/credit	2, 7	**(199)**	**(486)**	**59**
Loss for the year on continuing operations	2, 10	**(37,376)**	**(31,216)**	**(36,868)**
(Loss)/profit for the year on discontinued operations	8	**-**	**(573)**	**12,850**
Loss for the year (all attributable to owners of the parent)	2, 10	**(37,376)**	**(31,789)**	**(24,018)**
Basic loss per ADS (US Dollars) – continuing operations	10	(2.0)	(1.7)	(4.8)
Diluted loss per ADS (US Dollars) – continuing operations	10	(2.0)	(1.7)	(4.8)
Basic loss per 'A' ordinary share (US Dollars) – continuing operations	10	(0.1)	(0.1)	(0.2)
Diluted loss per 'A' ordinary share (US Dollars) – continuing operations	10	(0.1)	(0.1)	(0.2)
Basic loss per ADS (US Dollars) – group	10	(2.0)	(1.8)	(3.1)
Diluted loss per ADS (US Dollars) – group	10	(2.0)	(1.8)	(3.1)
Basic loss per 'A' ordinary share (US Dollars) – group	10	(0.1)	(0.1)	(0.2)
Diluted loss per 'A' ordinary share (US Dollars) – group	10	(0.1)	(0.1)	(0.2)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Year Ended December 31		
	Notes	*2025 US$'000*	*2024 US$'000*	*2023 US$'000*
Loss for the year	2	(37,376)	(31,789)	(24,018)
Other comprehensive (loss)/profit				
Items that will be reclassified subsequently to profit or loss				
Foreign exchange translation differences		(316)	245	69
Other comprehensive (loss)/profit		(316)	245	69
Total Comprehensive Loss (all attributable to owners of the parent)		**(37,692)**	**(31,544)**	**(23,949)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	At December 31 2025 US$'000	At December 31 2024 US$'000
ASSETS			
Non-current assets			
Property, plant and equipment	11	5,302	4,621
Goodwill and intangible assets	12	56,987	51,343
Financial assets	13	2,773	2,455
Deferred tax assets	14	3,924	3,553
Derivative financial instruments	23	249	166
Other assets	15	28	28
Total non-current assets		**69,263**	**62,166**
Current assets			
Inventories	16	18,828	19,374
Trade and other receivables	17	11,480	16,065
Income tax receivable		456	518
Cash and cash equivalents	18	5,138	5,167
Total current assets		**35,902**	**41,124**
TOTAL ASSETS	2	**105,165**	**103,290**
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	19	40	4,190
Share premium		63,800	63,397
Treasury shares	19	(24,922)	(24,922)
Accumulated deficit		(116,169)	(79,117)
Translation reserve	19	(5,777)	(5,461)
Equity component of convertible note	19, 23	6,709	6,709
Other reserves	19	4,337	23
Total deficit		**(71,982)**	**(35,181)**
Current liabilities			
Senior secured term loan	23	108,015	-
Income tax payable		348	364
Trade and other payables	21	29,703	26,782
Provisions	22	345	2,454
Exchangeable notes and other borrowings	23	210	210
Lease liabilities	24	2,588	2,285
Total current liabilities		**141,209**	**32,095**
Non-current liabilities			
Senior secured term loan	23	-	72,391
Derivative financial liability	23	3,320	1,658
Convertible note	23	16,330	15,401
Contingent consideration	23	-	1,813
Provisions	22	781	75
Lease liabilities	24	10,840	10,477
Deferred tax liabilities	14	4,667	4,561
Total non-current liabilities		**35,938**	**106,376**
TOTAL LIABILITIES	2	**177,147**	**138,471**
TOTAL EQUITY AND LIABILITIES		**105,165**	**103,290**

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, 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)**
Balance at January 1, 2025	4,190	63,397	(24,922)	(5,461)	6,709	23	(79,117)	(35,181)
Loss for the period	-	-	-	-	-	-	(37,376)	(37,376)
Other comprehensive income	-	-	-	(316)	-	-	-	(316)
Total comprehensive loss	-	-	-	(316)	-	-	(37,376)	(37,692)
Shares issued in the year (Note 19)	164	449	-	-	-	-	-	613
Reclass on reduction of nominal value of shares (Note 19)	(4,314)	-	-	-	-	4,314	-	-
Share-based payments (Note 20)	-	-	-	-	-	-	324	324
Share issue expenses	-	(46)	-	-	-	-	-	(46)
Balance at December 31, 2025	**40**	**63,800**	**(24,922)**	**(5,777)**	**6,709**	**4,337**	**(116,169)**	**(71,982)**

CONSOLIDATED STATEMENT OF CASH FLOWS

		Year Ended December 31,		
	Notes	*2025 US$'000*	*2024 US$'000*	*2023 US$'000*
Cash flows from operating activities				
Loss for the year		(37,376)	(31,789)	(24,018)
Adjustments to reconcile net loss to cash provided by operating activities:				
Depreciation	9, 11	1,299	675	831
Amortisation	9,12	1,385	1,190	946
Income tax expense/(credit)	7	199	486	(59)
Financial income	6	-	-	(1,171)
Financial expense	6	21,388	9,565	11,053
Share-based payments (net of capitalized amounts)	20	324	1,316	2,069
Foreign exchange gains/(losses) on operating cash flows		(1,102)	1,010	238
Movement in inventory provision	16	629	2,113	2,291
Inventory write off		-	1,884	-
Impairment of property, plant and equipment	5, 11	33	612	3,772
Impairment of intangible assets	5, 12	2,144	1,596	5,833
Once off items		(186)	-	-
Liabilities related to financial assets (reversal)/written off	5, 13	-	(800)	1,500
Gain on sale of business	8	-	-	(12,718)
Transformation provision		187	361	-
Other non-cash items		(908)	2,505	257
Operating cash flows before changes in working capital		**(11,984)**	**(9,276)**	**(9,176)**
Decrease/ (increase) in trade and other receivables		4,920	(2,368)	1,047
Decrease/ (increase) in inventories		90	(1,742)	(971)
Increase/ (decrease) in trade and other payables		1,391	8,185	(2,769)
Cash used in operations		**(5,583)**	**(5,201)**	**(11,869)**
Interest received		-	-	-
Income taxes (paid)/ received		(346)	1,010	312
Net cash used in operating activities		**(5,929)**	**(4,191)**	**(11,557)**
Cash flows from investing activities				
Payments to acquire intangible assets	12	(6,135)	(9,659)	(1,901)
Acquisition of property, plant and equipment	11	(88)	(405)	(803)
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		**(6,223)**	**(22,968)**	**24,756**
Cash flows from financing activities				
Issue of ordinary share capital including share premium (net of issuance costs)	19	547	7,391	-
Proceeds from shares to be issued		-	-	-
Net proceeds from senior secured term loan	23	15,000	30,176	5,000
Expenses paid in connection with debt financing	23	-	-	(147)
Repayment of senior secured term loan	23	-	-	(10,050)
Penalty for early settlement of term loan	23	-	-	(905)
Interest paid on senior secured term loan		-	(5,946)	(7,314)
Interest paid on convertible note	28	(300)	(300)	(300)
Interest paid on exchangeable notes	28	(8)	(8)	(8)
Payment of lease liabilities	28	(3,187)	(2,503)	(2,318)
Net cash generated by/(used in) financing activities		**12,052**	**28,810**	**(16,042)**
(Decrease)/ increase in cash and cash equivalents and short-term investments		(100)	1,651	(2,843)
Effects of exchange rate movements on cash held		71	(175)	(44)
Cash and cash equivalents and short-term investments at beginning of year		5,167	3,691	6,578
Cash and cash equivalents and short-term investments at end of year	18	**5,138**	**5,167**	**3,691**

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, 2025. 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 2025 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, 2025 and 2024, the Group recorded a loss of US$37.4 million and a loss of US$31.8 million, respectively. For the year ended December 31, 2025 we reported cash outflows of US0.1 million compared to cash inflows of US$1.7 million for 2024. As of December 31, 2025, we had net current liabilities of US$105.3 million and also an accumulated deficit in equity attributable to the equity holders of the Company of US$72.0 million.

A significant judgement in the Group's going concern assessment is the maturity of the Perceptive Term Loan on 15 January 2027, which falls within the assessment period. As at August 31, 2026, approximately US$115 million was outstanding under the facility and there are no scheduled principal repayments prior to maturity. While the Company has continued to benefit from support from Perceptive as it executes it comprehensive transformation plan and strategic growth initiatives, and the maturity date for the Perceptive Term Loan has been extended on a number of occasions, as at the date of approval of these financial statements, no agreement has yet been reached regrading an extension of maturity.

A deficiency relating to the Nasdaq minimum market value of publicly held shares ("MVPHS") requirement remains outstanding. On August 28, 2026, the Company received a staff determination letter (the "Determination Letter") from the Staff notifying the Company that it had not regained compliance with the MVPHS Requirement by August 18, 2026. Accordingly, and as described in the Determination Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension/delisting. On September 4, 2026, the Company formally requested a hearing before the Panel.

The Company has a number of initiatives and strategic transactions at advanced stages, which, if completed, would be expected to increase the Company's MVPHS above the $15 million minimum. The Company intends to continue to progress these transactions and as such management remains confident that the actions currently underway will enable the Company to reach a MVPHS of over $15 million. The hearing request will automatically stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing.

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

iii) Basis of preparation (continued)

In that regard, pursuant to the Nasdaq Listing Rules, the Panel has the authority to grant an extension not to exceed February 24, 2027.Notwithstanding the foregoing, there can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Global Select Market. A delisting from Nasdaq would likely result in the Company's ADSs trading on an over-the-counter market, which could reduce liquidity in the Company's securities, limit visibility within the public markets and make future capital raising activities more challenging. The Company would be required to satisfy applicable initial listing requirements in order to seek subsequent re-admission to Nasdaq.

These conditions indicate the existence of a material uncertainty which may cast significant doubt over the Group and the Company's ability to continue as a going concern.

The Group has made significant progress on a multi-year transformation plan aimed at improving profitability and simplifying its operating model. During 2024 and 2025, the Group substantially executed this programme, including the consolidation and outsourcing of global manufacturing operations, the closure of underutilised facilities, the transition of production to third-party manufacturing partners, the relocation of selected business support functions to lower-cost jurisdictions and a reduction in overall headcount. These actions have materially reduced the Group's fixed cost base and simplified its operational footprint, and the majority of the related transformation activities were completed during 2025. As a result, the Group entered 2026 with a leaner operating model and a materially lower underlying cost structure. In addition, the Group retains further levers to manage liquidity if required, including the ability to defer, phase or reprioritise discretionary research and development expenditure.

Management has prepared updated detailed cash flow forecasts covering a period of at least 12 months from the expected date of approval of these consolidated financial statements. These forecasts have been refreshed to reflect actual performance to date during 2026, updated financing arrangements and management's latest expectations regarding operating performance, liquidity and funding activities. The forecasts incorporate committed cost reduction measures, known financing arrangements and assumptions regarding the availability of additional equity financing consistent with the Group's recent capital raising activities and public disclosures.

The Group continues to benefit from support from Perceptive, its principal lender. Under the current Credit Agreement, the contractual maturity of the Perceptive Term Loan is January 15, 2027, and there are no scheduled principal repayments prior to that date. The maturity of the Perceptive Term Loan represents the most significant judgement within the directors' going concern assessment.

On April 30, 2026, the Group entered into an amendment to the Credit Agreement with Perceptive which provided for an additional US$2.5 million term loan borrowing and certain covenant waivers and modifications. In February 2026, Perceptive agreed that 50% of the cash interest due would be settled as payment-in-kind interest, and in March and April 2026 Perceptive agreed that 100% of the cash interest due would be settled as payment-in-kind interest. In August 2026, the Group entered into a further amendment to the Credit Agreement under which Perceptive granted limited waivers in respect of non-compliance with the minimum liquidity covenant during June and August 2026. Perceptive also agreed to maintain the minimum liquidity covenant at US$1.0 million through September 30, 2026, with the covenant increasing to US$3.0 million from October 1, 2026. In addition, Perceptive agreed that interest obligations from May through August 2026 would be settled through payment-in-kind arrangements. These arrangements have been reflected in management's updated cash flow forecasts.

The Group breached the minimum revenue covenant under the facility for the quarter ended December 31, 2025. The covenant breach primarily reflected timing-related variability in HIV revenues, including the timing of the scale-up of the Group's outsourced and offshored manufacturing model. These factors affected the timing of shipments and revenue recognition between reporting periods, rather than indicating a deterioration in underlying demand. As part of the third amendment, Perceptive provided a waiver in respect of this breach. In addition, the Group received specific waivers and deferrals in respect of compliance with certain financial covenants applicable to covenant measurement periods occurring after year-end. In forming its going concern assessment, management has considered the contractual terms of the facility as amended, including the agreed waivers and deferrals. Management's cash flow forecasts, which incorporate the terms of the Credit Agreement as amended, demonstrate that the Group is able to meet its obligations under the Perceptive facility throughout the going concern review period, including compliance with the amended financial covenants.

In forming their going concern assessment, the directors have considered the contractual terms of the Credit Agreement as amended, including the agreed waivers and covenant modifications. Management's updated cash flow forecasts incorporate the terms of the facility as amended and forecast compliance with the amended financial covenants throughout the going concern review period. The forecasts reflect the additional liquidity provided by Perceptive, the payment-in-kind treatment of interest obligations and management's ability to defer, phase or reprioritise certain discretionary expenditure if required.

The Group continues to evaluate the available alternatives for addressing the Perceptive Term Loan at or before maturity. These alternatives include refinancing or extending the facility, further equity financing, additional debt equitisation and potential strategic transactions. Perceptive has continued to engage constructively with the Group, including by providing additional funding, agreeing payment-in-kind interest arrangements and granting covenant relief. However, the completion of any refinancing, extension, equity financing, debt conversion or strategic transaction remains subject to execution risk and, where applicable, market conditions and the agreement of third parties.

The Group's going concern forecasts also include the assumption of equity funding, primarily through the issuance of ordinary shares under existing capital raising arrangements. Such funding is expected to support ongoing operations and continued investment in the Group's CGM development program and the management of the Group's financing obligations.

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

iii) Basis of preparation (continued)

While equity funding is subject to market conditions, the Group has an established track record of raising capital and maintains active engagement with investors. During June 2026, the Company raised approximately US$1.2 million through its At-The-Market programme. The directors have considered the Group's continued access to public equity markets as part of their assessment of the availability of funding throughout the going concern review period.

On August 7, 2026, Nasdaq confirmed that the Company had regained compliance with the minimum bid price requirement following implementation of a 30:1 ADS ratio change, resulting in a revised ratio of 600 ordinary shares to one ADS.

In preparing these forecasts, management has taken into account the discretionary nature of certain expenditure, including investment in the Group's CGM development programme, and has assumed that the timing and phasing of such expenditure will be aligned with available funding. Management therefore retains the ability to preserve liquidity, if required, while continuing to execute its strategic priorities without compromising covenant compliance.

The directors have considered the Group's current financial position and updated cash flow projections, taking into account all known events and developments through the date of approval of these consolidated financial statements, including the ongoing support of its principal lender and the availability of equity funding. Based on this assessment, the directors believe that the Group will have access to adequate resources to continue in operational existence for at least 12 months from the date of approval of these consolidated financial statements, and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

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

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

v) Property, plant and equipment (continued)

Leased assets

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

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

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

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

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

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

Leased assets - as lessor

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.

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

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.

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.

There were no acquisitions in the year ended December 31, 2025. Refer to Note 29 for details of acquisitions made during the year ended December 31, 2024.

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.

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

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

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

Borrowing costs that are directly attributable to the development of qualifying intangible assets are capitalised in accordance with IAS 23 and IAS 38. Where development expenditure is funded through general borrowings, borrowing costs are capitalised using a weighted average capitalisation rate based on borrowings outstanding during the period. Capitalisation commences when expenditure and borrowing costs are incurred and development activities are in progress, and ceases when the asset is substantially ready for its intended use. All other borrowing costs are expensed 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

The Group uses a useful economic life of 15 years for capitalised development costs. This represents management's best estimate of the useful economic life of the related products, based on expected product life cycles and relevant industry characteristics. 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.

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

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

(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, 2025, the Group capitalised US$6.1 million in development costs and US$2.9 million in borrowing costs related to intangible assets acquired in 2024. 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, 2024, December 31, 2024, June 30, 2025 and December 31, 2025. 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.

Stranded costs represent costs that are no longer directly attributable to ongoing operations or revenue-generating activities following organisational changes, restructuring, site closures, or product rationalisation. Such costs typically include overheads, personnel costs and facility-related expenses that cannot be avoided or redeployed in the short term. Stranded costs are assessed each reporting period and are recognised in profit or loss as incurred, unless they relate directly to a qualifying asset or meet the criteria for capitalisation under relevant accounting standards.

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

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.

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 recognised 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 recognised 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.

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

xvi) Revenue recognition (continued)

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 diagnostic and analytical 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 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, 2025, other operating income also included gains arising from the remeasurement of contingent consideration liabilities to fair value. Such gains may arise where contingent obligations recognised on business combinations are reassessed and extinguished or lapse, and are recognised in profit or loss when the associated liability is derecognised or remeasured.

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.

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

xviii) Foreign currency

A majority of the revenue of the Group is generated in US Dollars. The Group's management has determined that the US Dollar is the primary currency of the economic environment in which the Company and its subsidiaries (with the exception of the Group's subsidiaries in Brazil, Canada and Sweden) principally operate. Thus, the functional currency of the Company and its subsidiaries (other than the Brazilian, Canadian and Swedish subsidiaries) is the US Dollar. The functional currency of the Brazilian entity is the Brazilian Real, the functional currency of the Swedish entity is the Swedish Krona 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.

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, Swedish Krona 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, 2025.

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. The Group 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.

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

xx) Exchangeable notes and derivative financial instruments (continued)

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.

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. In 2025, further changes to the Group's debt arrangements resulted in the extinguishment of the existing liability and recognition of a new financial liability. 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. The prepayment premium is not solely compensation for time value of money or credit risk and, as a result, the prepayment option is not closely related to the debt host. 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.

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

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 conversion feature is settled 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.

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.

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

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.

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.

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

xxxii) Fair values

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

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

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

Level 3: valuation techniques for which the lowest level of inputs that have a significant effect on the recorded fair value are not based on observable market data

xxxiii) New IFRS Standards

The following new accounting standards and interpretations became effective for annual periods beginning on or after 1 January 2025. The adoption of these standards did not have a material impact on the Group's consolidated financial statements:

- IAS 21 (Amendments) – Lack of Exchangeability; new guidance on assessing exchangeability, estimating spot rates, and enhanced disclosures.

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:

- 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
- Contracts Referencing Nature-dependent Electricity (IFRS 9/IFRS 7)
- 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
- Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (Amendments to IFRS 10 and IAS 28)

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 *Year ended December 31, 2025*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Revenue from external customers	32,390	11,395	-	43,785
Inter-segment revenue	19,586	3,606	(23,192)	-
Total revenue	51,976	15,001	(23,192)	43,785

Revenue *Year ended December 31, 2024*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'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

2. SEGMENT INFORMATION (CONTINUED)

Revenue	*Americas*	*Rest of World Ireland*	*Eliminations*	*Total*
Year ended December 31, 2023	*US$'000*	*US$'000*	*US$'000*	*US$'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

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

Revenue	*December 31, 2025 US$'000*	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Americas	24,624	29,917	32,282
Asia / Africa	15,383	24,775	18,909
Europe (including Ireland) *	3,778	6,863	5,641
	43,785	61,555	56,832

* 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, 2025 US$'000*	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Clinical laboratory goods	31,678	39,372	42,288
Clinical laboratory services	4,006	4,750	5,453
Point-of-care	8,101	17,433	9,091
	43,785	61,555	56,832

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

Revenue	*December 31, 2025 US$'000*	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Revenue from contracts with customers	43,785	61,555	56,832
	43,785	61,555	56,832

2. SEGMENT INFORMATION (CONTINUED)

(v) Disaggregation of revenue from contracts with customers:

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

Timing of revenue recognition *Year ended December 31, 2025*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Total* *US$'000*
At a point in time	31,949	11,395	43,344
Over time	441	-	441
Total	32,390	11,395	43,785

Timing of revenue recognition *Year ended December 31, 2024*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Total* *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 *Year ended December 31, 2023*	*Americas* *US$'000*	*Rest of World Ireland* *US$'000*	*Total* *US$'000*
At a point in time	44,692	11,848	56,540
Over time	292	-	292
Total	44,984	11,848	56,832

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

Timing of revenue recognition *Year ended December 31, 2025*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	24,182	15,383	3,778	43,343
Over time	442	-	-	442
Total	24,624	15,383	3,778	43,785

Timing of revenue recognition *Year ended December 31, 2024*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'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

2. SEGMENT INFORMATION (CONTINUED)

Timing of revenue recognition *Year ended December 31, 2023*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'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

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

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
Year ended December 31, 2025	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Result before transformation costs, impairment and unallocated expenses	(1,291)	(5,639)	(327)	(7,257)
Transformation costs	(1,241)	(3,011)	-	(4,252)
Impairment charges	(2,177)	-	-	(2,177)
Result after impairment	(4,709)	(8,650)	(327)	(13,686)
Unallocated expenses *				(2,103)
Operating loss				(15,789)
Net financing expense (Note 6)				(21,388)
Loss before tax				(37,177)
Income tax charge (Note 7)				(199)
Loss for the year on continuing operations				(37,376)
Loss for the year on discontinued operations (Note 8)				-
Loss for the year				(37,376)

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
Year ended December 31, 2024	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Result before transformation costs, impairment and unallocated expenses	(2,503)	(9,386)	(315)	(12,204)
Transformation 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 charge (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)

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
Year ended December 31, 2023	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Result before transformation 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 credit (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)

* 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		
	Americas	*Ireland*	*Other*	*Total*
As at December 31, 2025	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Assets and liabilities				
Segment assets	35,219	60,404	24	95,647
Unallocated assets:				
Income tax assets (current and deferred)				4,380
Cash and cash equivalents and short-term investments				5,138
Total assets as reported in the Group balance sheet				105,165
Segment liabilities	129,073	43,033	26	172,132
Unallocated liabilities:				
Income tax liabilities (current and deferred)				5,015
Total liabilities as reported in the Group balance sheet				177,147

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
As at December 31, 2024	*US$'000*	*US$'000*	*US$'000*	*US$'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

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, 2025 US$'000	*December 31, 2024 US$'000*
Rest of World – Ireland	44,110	43,504
Americas	20,980	14,943
	65,090	58,447

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Depreciation:			
Rest of World – Ireland	153	160	162
Americas	1,146	515	668
	1,299	675	830
Amortisation:			
Rest of World – Ireland	796	770	458
Americas	589	420	487
	1,385	1,190	945

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Rest of World – Ireland	215	843	1,650
Americas	109	473	419
	324	1,316	2,069

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, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Rest of World – Ireland	171	(5)	(385)
Rest of World – Other	(6)	9	(235)
Americas	(364)	(490)	679
	(199)	(486)	59

xiii) During 2025, 2024 and 2023 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, 2025 US$'000	*December 31, 2024 US$'000*
Rest of World – Ireland	8,848	37,929
Americas	2,389	2,753
	11,237	40,682

Capital expenditure for the year ended December 31, 2025 includes additions arising from CGM and Metabolomics Diagnostic Limited (see Note 29). In addition, capitalised development costs decreased from US$8.6 million in 2024 to US$6.1 million in 2025.

3. EMPLOYMENT

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

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
Research and development	26	33	23
Administration and sales	71	82	99
Manufacturing and quality	190	286	258
	287	401	380

The average number of employees, including discontinued operations, was 287 (2024: 401; 2023: 383).

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Wages and salaries	18,804	25,570	23,718
Social welfare costs	1,916	2,219	2,061
Pension costs	355	451	508
Share-based payments	324	1,316	2,069
Transformation cost	153	596	485
	21,552	30,152	28,841

3. EMPLOYMENT (CONTINUED)

Total employment costs, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2025, amounted to US$24,046,000 (2024: US$33,584,000) (2023: US$29,975,000). Total share-based payments amounted to US$324,000 for the year ended December 31, 2025 (2024: US$1,316,000) (2023: US$2,069,000). See Note 20 for further details.

Employment costs including discontinued operations, are analysed as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Wages and salaries	18,804	25,570	24,343
Social welfare costs	1,916	2,219	2,097
Pension costs	355	451	510
Share-based payments	324	1,316	2,069
Transformation cost	153	596	485
	21,552	30,152	29,504

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$355,000 (2024: US$451,000) (2023: US$508,000). The pension accrual for the Group at December 31, 2025 was US$147,000 (2024: US$nil) (2023: US$56,000).

4. OTHER OPERATING INCOME / (EXPENSE)

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Other income	-	40	138
Rental income from premises	-	-	3
Government supports	-	(1,827)	-
Fair value gain on contingent consideration	1,870	-	-
	1,870	(1,787)	141

Fair value gain on contingent consideration

As part of the acquisition for the continuous glucose monitoring ("CGM") assets, the Group recognised a contingent consideration liability to Perceptive in respect of commercial partnering agreements with certain glucose pump manufacturers (see Note 29). The fair value assigned to this contingent consideration at acquisition was US$1.9 million, with this item disclosed as a contingent liability as at December 31, 2024.

In December 2025, as part of a broader restructuring and amendment of the Perceptive term loan facility, which also addressed contingent consideration obligations arising in connection with the Waveform acquisition and included the introduction of a conversion feature (refer to Note 23 for further details), the Group reassessed the contingent consideration. At the amendment date, the contractual trigger period for the partnering milestone had less than six weeks remaining, and no commercial discussions or actions were underway that could reasonably be expected to result in the milestone being achieved within the remaining period. Management therefore concluded that the probability-weighted expected payoff was insignificant and, as a result, the fair value of the contingent consideration was assessed as being materially close to nil and the liability was remeasured to US$nil. The remeasurement of the contingent consideration liability to US$nil resulted in the recognition of a US$1.9 million gain in other operating income.

4. OTHER OPERATING INCOME / (EXPENSE)

Government Support

In October 2024, the Company received an inquiry from a U.S. governmental authority concerning second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries. At December 31, 2024, 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.

A settlement was reached during 2025 with respect to the PPP loans. No additional amounts were recognised within other operating (expense)/income during the year. As a result of the settlement, a partial reversal of the previously recognised provision was recorded, giving rise to a credit of US$0.2 million within once-off costs (Note 5). In addition, a reversal of previously accrued interest of approximately US$0.2 million was recognised within financial expenses (Note 6).

5. IMPAIRMENT, TRANSFORMATION AND ONCE OFF COSTS

Transformation costs

During the year ended December 31, 2025, the Group continued with its comprehensive business transformation program (the program has been in effect since FY 2024) 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 transformation costs of US$4.3 million (2024: US$4.2 million) (2023: US$nil) which are presented separately in the consolidated statement of operations within 'Selling, general and administrative expenses – Transformation costs'.

The transformation costs incurred during the year comprised the following:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Nature of cost		
Personnel related costs	261	1,216
Outsourcing costs	-	754
Site transfer costs	714	1,281
Inventory related costs	-	772
Other transformation costs	-	158
Total transformation costs	975	4,181
Stranded costs	3,277	-
Total transformation costs	**4,252**	**4,181**

Transformation costs recognised during the year ended December 31, 2025 include US$3.3 million of fixed overheads associated with certain manufacturing facilities that were not absorbed within cost of sales as a result of reduced production volumes during the period. These costs arose in connection with the consolidation and outsourcing of manufacturing activities undertaken as part of the Group's Comprehensive Transformation Plan. Such costs primarily reflect under-absorbed fixed overheads during the transition phase as manufacturing volumes were reallocated between sites and outsourced partners. The Group expects these stranded costs to reduce as manufacturing transitions are completed and production volumes stabilise under the revised operating model, although residual costs may continue to be incurred during 2026.

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

Included within Site transfer costs above is US$0.2 million (2024: US$0.4 million) related to the impairment of plant & equipment arising as part of the transformation program. Refer to Note 11. We have provided for additional transformation costs of US$1.1 million as at December 31, 2025 (see Note 22).

Once off costs

During the year ended 31 December 2025, the Company recorded a gain in exceptional, non-trading costs totaling US$0.2 million (2024: charge of $1.9 million).

During 2024, the Company recognized a provision of US$0.7 million in respect of the investigation relating to Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries. Following the settlement of this matter during 2025, a portion of the previously recognised provision was reversed, resulting in a gain of US$0.2 million recognised within once-off items. Further details of the settlement are disclosed in Note 4.

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.

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, 2025, 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, 2025, 2024, and 2023 are as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Selling, general & administration expenses			
Impairment of PP&E (Note 11)	33	612	3,772
Impairment of goodwill and other intangible assets (Note 12)	2,144	1,596	5,833
(Reversal)/Impairment of financial assets (Note 13)	-	(800)	1,500
Total impairment loss	**2,177**	**1,408**	**11,105**

Premier Resolution

Premier Resolution is a capitalized intangible asset held within Primus Corporation and relates to the Resolution platform for haemoglobinopathy and variant testing in the US market. While the platform has achieved technical feasibility and obtained FDA clearance in late 2023, the commercialization pathway is dependent on securing adoption within a highly concentrated US reference laboratory market.

While the Group continues to pursue commercial opportunities for the platform and believes that it retains underlying potential, these factors have resulted in the recoverable amount of the asset being lower than its carrying value. Accordingly, the Group recognized a partial impairment charge of US$2.1 million during the year.

6. FINANCIAL INCOME AND EXPENSES

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Financial income:			
Non-cash financial income	-	-	1,171
Financial expense:			
Interest on leases (Note 24)	(644)	(592)	(624)
Loss on extinguishment on old loan (Note 23)	(9,999)	-	-
Penalty for early partial settlement of senior secured term loan (Note 23)	-	-	(905)
Cash interest payable on senior secured term loan	-	(6,293)	(7,289)
Cash interest payable on convertible note	(300)	(300)	(300)
Cash interest on exchangeable notes	(8)	(8)	(8)
Cash interest payable on PPP loans (Note 4)	221	(338)	-
Non-cash interest on senior secured term loan (Note 23)	(2,646)	(2,355)	(1,131)
Non-cash interest on convertible note (Note 23)	(929)	(859)	(796)
Non-cash financial expense	(202)	(1,172)	-
Unwinding of discount on deferred contingent consideration	(87)	(53)	-
Capitalisation of borrowing costs (Note 12)	2,899	2,085	-
Non-cash loan modification gain (Note 23,28)	1,706	3,567	-
Payment-in-kind (PIK) Interest (Note 23)	(11,399)	(3,247)	-
	(21,388)	(9,565)	(11,053)
Net financing expense	(21,388)	(9,565)	(9,882)

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, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Current tax expense/ (credit)			
Irish corporation tax	(154)	21	-
Foreign taxes (a)	290	254	462
Adjustment in respect of prior years	329	10	(198)
Total current tax expense/(credit)	465	285	264
Deferred tax credit (b)			
Origination and reversal of temporary differences (see Note 14)	(266)	(41)	(547)
Origination and reversal of net operating losses (see Note 14)	-	242	224
Total deferred tax (credit)/ charge	(266)	201	(323)
Total income tax charge/(credit) on continuing operations in statement of operations	199	486	(59)
Tax charge on discontinued operations (see Note 8)	-	-	-
Total tax charge/(credit)	199	486	(59)

(a) In 2025, the foreign taxes relate primarily to USA and Canada.

(b) In 2025, there was a deferred tax credit of US$28,000 (2024: credit of US$43,000) (2023: charge of US$174,000) recognised in respect of Ireland and a deferred tax credit of US$238,000 (2024: charge of US$244,000) (2023: credit of US$497,000) recognised in respect of overseas tax jurisdictions.

Effective tax rates	*December 31, 2025*	*December 31, 2024*	*December 31,2023*
Loss before taxation – continuing operations (US$'000)	(37,177)	(30,730)	(36,927)
As a percentage of loss before tax:			
Current tax %	(1.25%)	(0.93%)	(0.72%)
Total (current and deferred tax)	(0.54%)	(1.58%)	(0.16%)

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, 2025	*December 31, 2024*	*December 31, 2023*
Irish corporation tax	(12.50)%	(12.50)%	(12.50)%
Effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised (a)	20.86%	15.89%	17.19%
Effect of tax rates on overseas earnings	(10.97)%	6.63%	(7.82)%
Effect of Irish income taxable at higher tax rate	3.84%	(4.09)%	2.62%
Adjustments in respect of prior years	0.89%	0.04%	(0.53)%
R&D tax credits	(0.46)	-	-
Other items (b)	(2.20)%	(7.55)%	0.88%
Effective tax rate	(0.54)%	(1.58)%	(0.16)%

(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.

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Rest of World – Ireland	(12,490)	(17,296)	(12,922)
Rest of World – Other	(327)	(315)	(104)
Americas	(24,360)	(13,119)	(23,901)
	(37,177)	(30,730)	(36,927)

At December 31, 2025, the Group had unutilised net operating losses for continuing operations as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Rest of World – Ireland	102,751	107,093	69,851
Rest of World – Other	51,678	52,852	52,511
Americas	26,707	22,866	13,840
	181,136	182,811	136,202

At December 31, 2025, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Rest of World – Ireland – unused tax losses	13,725	13,275	8,464
Rest of World – Other – unused tax losses	14,465	14,777	14,701
Americas – unused tax losses	2,149	2,149	3,395
Americas – unused tax credits	6,813	5,702	5,806
Unrecognised deferred tax asset	37,152	35,903	32,366

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 (loss)/profit for the discontinued operations are summarised as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Revenue	-	-	2,784
Operating expenses	-	-	(2,652)
Tax expense (Note 7)	-	-	-
Profit from operating activities	-	-	132
(Loss)/Gain on sale of discontinued operations	-	(573)	12,718
(Loss)/Profit for the year from discontinued operations	**-**	**(573)**	**12,850**

There were no discontinued operations in the year ended December 31, 2025 (2024: US$0.6 million). Accordingly, there are no earnings per share from discontinued operations for the year ended December 31, 2025.

The net cashflows generated from discontinued operations are as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'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**

During 2024, the Biosynth transactions were recognised as post-disposal adjustments, reflecting the write-off of receivables and provision for settlement costs.

	Net assets disposed in 2023 US$'000	*Post disposal adjustment in 2024 US$'000*	*Net assets disposed/adjusted as on 31 December 2024 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

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

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$Nil, (2024: Loss of US$573,000) (2023: Profit of US$12,850,000) for the financial year by the weighted average number of 'A' ordinary shares in issue as at December 31, 2025, this amounted to 371,513,458 shares (2024: 359,193,482 shares) (2023: 153,099,405 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$Nil, (2024: Loss of US$573,000) (2023: Profit of US$12,850,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 488,155,270 shares (2024: 404,096,277 shares) (2023: 178,016,062 shares), see Note 10 for further details.

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
Basic (loss)/earnings per 'A' share (US Dollars) – discontinued operations	-	(0.00)	0.08
Diluted (loss)/earnings per 'A' share (US Dollars) – discontinued operations	-	(0.00)	0.07

Basic (loss)/earnings per ADS – discontinued operations

Basic earnings per ADS for discontinued operations is computed by dividing the profit/(loss) after taxation on discontinued operations of US$Nil, (2024: Loss of US$573,000) (2023: Profit of US$12,850,000) for the financial year by the weighted average number of ADS in issue of 18,575,673 (2024: 17,959,674) (2023: 7,654,970), 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$Nil, (2024: Loss of US$573,000) (2023: Profit of US$12,850,000) for the financial year, by the diluted weighted average number of ADS in issue of 24,407,764 (2024: 20,204,814) (2023: 8,900,803), see Note 10 for further details.

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
Basic (loss)/earnings per ADS (US Dollars) – discontinued operations	-	(0.03)	1.68
Diluted (loss)/earnings per ADS (US Dollars) – discontinued operations	-	(0.03)	1.44

Cash flows

The cash flows attributable to discontinued operations are as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Cash (outflow) from operating activities	-	-	(177)
Cash inflow from investing activities	-	-	28,160
Cash outflow from financing activities	-	-	-

9. LOSS BEFORE TAX

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Directors' emoluments (including non- executive directors):			
Remuneration	1,327	1,454	2,058
Pension	38	39	26
Share based payments (Note 26)	149	931	1,601
Auditor's remuneration			
Audit fees	1,161	1,082	861
Tax fees	76	175	407
Depreciation (Note 11) [1]	1,299	675	830
Amortisation (Note 12)	1,385	1,190	945
Net foreign exchange differences	494	376	336

[1] In 2025, US$249,000 was capitalised to research and development projects (2024: US$204,000) (2023: US$Nil).

Depreciation for discontinued operations for the year ended December 31, 2025 is US$Nil (2024: US$Nil) (2023:US$1,000)

Amortisation for discontinued operations for the year ended December 31, 2025 is US$Nil (2024: US$Nil) (2023:US$1,000).

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$37,376,000 (2024: loss of US$31,789,000) (2023: loss of US$24,018,000) 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$37,376,000 (2024: loss of US$31,216,000) (2023: loss of US$36,868,000) by the weighted average number of 'A' ordinary shares in issue, net of any Treasury Shares, during the year.

As at December 31, 2025, the number of 'A' ordinary shares for the purposes of the calculation of basic loss per share are 371,513,458 shares (2024: 359,193,482 shares) (2023: 153,099,405 shares).

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
'A' ordinary shares	371,513,458	359,193,482	153,099,405
Basic loss per share denominator	371,513,458	359,193,482	153,099,405
Reconciliation to weighted average loss per share denominator:			
Number of 'A' ordinary shares at January 1 (Note 19)	371,749,080	165,865,882	164,985,882
Weighted average number of 'A' ordinary shares issued during the year*	12,319,978	205,883,200	669,123
Weighted average number of treasury shares	(12,555,600)	(12,555,600)	(12,555,600)
Basic loss per share denominator	371,513,458	359,193,482	153,099,405

*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.

10. LOSS PER SHARE (CONTINUED)

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
Potentially Dilutive Instruments:			
Issuable on exercise of options (Note 20)	-	-	186,908
Issuable on exercise of warrants to Perceptive (Note 23)	57,200,000	20,173,151	-
Issuable on exercise of conversion options to Perceptive (Note 23)	34,712,063	-	-
Issuable on conversion of Exchangeable notes (Note 23)	38,391	38,391	38,391
Issuable on conversion of Convertible notes (Note 23)	24,691,358	24,691,358	24,691,358
Total number of potentially dilutive instruments excluded from the weighted average number of 'A' ordinary shares in calculating dilutive loss per 'A' ordinary share	116,641,812	44,902,900	24,916,657

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.

Potential ordinary shares arising from the Perceptive financing arrangements, including conversion options subject to share price conditions, are contingently issuable under IAS 33. These instruments have been excluded from diluted earnings per share as the Group incurred losses in all periods presented and their inclusion would be anti-dilutive.

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$37,376,000 (2024: loss of US$31,789,000) (2023: loss of US$24,018,000) 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$37,376,000 (2024: loss of US$31,216,000) (2023: loss of US$36,868,000) by the weighted average number of ADS in issue, net of any Treasury Shares, during the year.

As at December 31, 2025, the number of ADS for the purposes of the calculation of basic loss per ADS were 18,575,673 ADS (2024: 17,959,674 ADS) (2023: 7,654,970 ADS).

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
ADS	18,575,673	17,959,674	7,654,970
Basic loss per ADS denominator	18,575,673	17,959,674	7,654,970
Reconciliation to weighted average loss per ADS denominator:			
Number of ADS at January 1 (Note 19)	18,587,454	8,293,294	8,249,294
Weighted average number of shares issued during the year*	615,999	10,294,160	33,456
Weighted average number of treasury shares	(627,780)	(627,780)	(627,780)
Basic loss per ADS denominator	18,575,673	17,959,674	7,654,970

*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.

10. LOSS PER SHARE (CONTINUED)

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

	December 31, 2025	*December 31, 2024*	*December 31, 2023*
Potentially Dilutive Instruments:			
Issuable on exercise of options (Note 20)	-	-	9,345
Issuable on exercise of warrants to Perceptive (Note 23)	2,860,000	1,008,658	-
Issuable on exercise of conversion options to Perceptive (Note 23)	1,735,603	-	-
Issuable on conversion of Exchangeable notes (Note 23)	1,920	1,920	1,920
Issuable on conversion of Convertible notes (Note 23)	1,234,568	1,234,568	1,234,568
Total number of potentially dilutive instruments excluded from the weighted average number of ADS in calculating dilutive loss per ADS	5,832,091	2,245,146	1,245,833

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.

Potential ordinary ADS arising from the Perceptive financing arrangements, including conversion options subject to share price conditions, are contingently issuable under IAS 33. These instruments have been excluded from diluted earnings per share as the Group incurred losses in all periods presented and their inclusion would be anti-dilutive.

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, 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
At January 1, 2025	26,784	2,811	5,344	35,686	70,625
Additions #	1,777	15	2	408	2,202
Reallocations/ reclassifications	-	-	-	(2)	(2)
At December 31, 2025	28,561	2,826	5,346	36,092	72,825
Accumulated depreciation and Impairment losses					
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)
Exchange adjustments	-	-	-	(179)	(179)
At December 31, 2024	(24,757)	(2,728)	(4,717)	(33,802)	(66,004)
At January 1, 2025	(24,757)	(2,728)	(4,717)	(33,802)	(66,004)
Charge for the year (Note 9)	(720)	(14)	(66)	(499)	(1,299)
Impairment losses*	-	(2)	(1)	(217)	(220)
Exchange adjustments	-	-	-	-	-
At December 31, 2025	(25,477)	(2,744)	(4,784)	(34,518)	(67,523)
Carrying amounts					
At December 31, 2025	3,084	82	562	1,574	5,302
At December 31, 2024	2,027	83	627	1,884	4,621

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

Additions include US$2.1 million in additions to ROU assets (2024: US$0.9 million).

* The total impairment charge recognised against Property, Plant & Equipment during the year was US$ 220,000 (2024: US$ 968,000). which pertains to plant and equipment, vehicles as described above, of which is US$33,000 is presented within 'Impairment Charges' in the Consolidated Statement of Operations. The remaining US$187,000 is included within 'Transformation Costs' (see Note 5).

In 2024, remeasurement of ROU assets during the year included 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, 2025 US$000	*Depreciation Charge Year ended December 31, 2025 US$000*	*Impairment Charge Year ended December 31, 2025 US$000*
Buildings	3,215	(720)	-
Computer and office equipment	20	(52)	-
Plant and equipments	312	(25)	-
	3,547	(797)	-

	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 and office equipment	72	(56)	(43)
	2,198	(381)	(399)

Right-of-Use assets at 31 December 2025	***No. of Right-of-Use leased assets***	***Range of remaining term in years***	***Average remaining lease term (years)***	***No. of Leases with extension options***	***No. of Leases with options to purchase***	***No. of leases with variable payments linked to index***	***No. of leases with termination options***
Building	11	0 to 8	3	1	-	3	1
Vehicle	11	1 to 3	1	-	6	-	-
I.T. and office equipment	8	1 to 4	2	-	-	-	-

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	-	-	-	-

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$0.2 million was allocated to property, plant and equipment as at December 31, 2025 (2024: US$0.6 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, 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
At January 1, 2025	80,484	135,999	8,695	13,105	21,482	259,765
Additions	-	6,115	-	-	2,920	9,035
Disposals or retirements	-	(9,339)	-	-	-	(9,339)
Exchange differences	127	19	-	-	-	146
At December 31, 2025	80,611	132,794	8,695	13,105	24,402	259,607
Accumulated amortisation and Impairment losses						
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)
At January 1, 2025	(66,645)	(115,048)	(8,549)	-	(18,180)	(208,422)
Charge for the year (Note 9)	-	(1,381)	-	-	(4)	(1,385)
Impairment losses (Note 5)	-	(2,128)	-	-	(16)	(2,144)
Disposals or retirements	-	9,339	-	-	-	9,339
Exchange differences	-	(8)	-	-	-	(8)
At December 31, 2025	(66,645)	(109,226)	(8,549)	-	(18,200)	(202,620)
Carrying amounts						
At December 31, 2025	13,966	23,568	146	13,105	6,202	56,987
At December 31, 2024	13,839	20,951	146	13,105	3,302	51,343

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$12.8 million which were not amortised in 2025 (2024: US$7.0 million) (2023: US$1.6 million). 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, 2025 these projects are expected to be completed during the period from January 1, 2026 to December 31 2027, at an expected further cost of approximately US$15 million to US$25 million.

During the year ended December 31, 2025, the Group derecognised development costs that were fully amortised as of December 31, 2024. As these assets were fully amortised, the derecognition resulted in an equal reduction of the gross carrying amount and accumulated amortisation of US$9.3 million, with no impact on the Group's net assets or profit for the year.

Borrowing costs of US$2.9 million were capitalised during the year in respect of qualifying intangible assets (2024: US$2.1 million) (see Note 6 – Financial income and expenses)

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 during 2025 and 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	*2025* *US$'000*	*2024* *US$'000*
Continuous glucose monitoring testing	4,370	7,040
Premier Instruments for A1c and haemoglobinopathies testing	383	1,542
Metabolomic - PrePsia	1,340	-
Other projects	22	-
Total capitalised development costs	**6,115**	**8,582**

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.

During the year ended December 31, 2025, no additions were recorded in respect of intangible assets acquired through 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 nine 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 2026 and 2027 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 15% to 21% (2024: 17% to 28%).

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, 2025 and at December 31, 2025 resulted in an impairment loss being recorded in four CGUs, Trinity Biotech Manufacturing Limited, Immco Diagnostics Inc, Primus Corp and Clark Laboratories.

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, 2025 as per the below table and the impairments arising from the CGU impairment tests:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Immco Diagnostics Inc.	18	101
Trinity Biotech Manufacturing Limited	187	(120)
Trinity Biotech Do Brasil	-	162
Primus Corp	2,129	916
Clark Laboratories Inc.	30	130
Biopool US Inc.	-	219
Total impairment loss	**2,364**	**1,408**

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Goodwill and other intangible assets (see Note 12)	2,144	1,596
Property, plant and equipment (see Note 11)	220	612
Financial assets (see Note 13)	-	(800)
Total impairment loss	**2,364**	**1,408**

Management is seeking to implement profit improvement initiatives across these entities, however the values in use of these CGUs at June 30, 2025 and December 31, 2025, 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.

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, 2025.
- 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, 2025.

Specific asset impairment charges

In the year ended December 31, 2025, certain plant items in our Bray production facility related to the production of UniGold HIV were fully impaired because of transformation activities. In line with the transfer of upstream manufacturing processes to a contract manufacturing partner by Q2 2026, certain plant and equipment related to UniGold HIV production were assessed as having limited future utility. An impairment charge of US$187,000 was recognised to reflect the revised recoverable amount. This has been included within 'Selling, general and administrative expenses – Transformation costs. See also Note 5 and 11.

12 GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Premier Resolution is a capitalized intangible asset held within Primus Corporation and relates to the Resolution platform for haemoglobinopathy and variant testing in the US market. While the platform has achieved technical feasibility and obtained FDA clearance in late 2023, the commercialization pathway is dependent on securing adoption within a highly concentrated US reference laboratory market. While the Group continues to pursue commercial opportunities for the platform and believes that it retains underlying potential, these factors have resulted in the recoverable amount of the asset being lower than its carrying value. Accordingly, the Group recognized a partial impairment charge of US$2.1 million during the year.

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:

The T10 HPLC Analyzer project was an internally developed HPLC analyser intended for mid-volume haemoglobin testing laboratories, with the Chinese market identified as the primary commercial opportunity. While the project achieved technical feasibility and initial market validation, developments in global trade relations, including increased uncertainty regarding market access between the United States and China, significantly reduced the expected commercial viability of the asset. The related intangible asset was fully impaired and an impairment charge of US$916,000 was recognised in the Primus Corp. entity in the year ended December 31, 2024.

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 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 fully impaired the project and recorded an impairment charge of US$680,000 in the year ended December 31, 2024.

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 and was included in within 'Selling, general and administrative expenses – transformation costs' (see Note 11) in the year ended December 31, 2024.

The Kansas City facility, operated by Primus Corporation, supports 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 – transformation costs' in the year ended December 31, 2024.

Significant Goodwill and Intangible Assets with Indefinite Useful Lives

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, 2025 was US$14.0 million. The CGUs for which goodwill is considered significant from a Group perspective, and the additional disclosures required for these CGUs, are set out below.

12 GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Goodwill arising from the purchase of CGM assets from Waveform Technologies

	December 31, 2025
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. As at December 31, 2025, goodwill allocated to the CGM cash-generating unit ("CGU") amounted to US$12.4 million.

The Group performed an impairment assessment of goodwill as at December 31, 2025. The recoverable amount of the CGU was determined based on a value-in-use model, using forecast cash flows and a terminal value. The key assumptions applied in the impairment assessment were consistent with the prior year and included a pre-tax discount rate of 16.2% and a long-term growth rate of 2.0%.

No impairment loss was recognised in respect of the Waveform CGM CGU during the years ended December 31, 2025 and December 31, 2024. Management concluded that there were no indicators of impairment, that the recoverable amount of the CGU exceeded its carrying amount, and 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, 2025
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. As at December 31, 2025, goodwill allocated to the EpiCapture CGU amounted to US$1.4 million.

The Group performed an impairment assessment of goodwill as at December 31, 2025. The recoverable amount of the CGU was determined based on a value-in-use model, using forecast cash flows and a terminal value. The key assumptions applied in the impairment assessment were consistent with the prior year and included a pre-tax discount rate of 20.0% and a long-term growth rate of 2.0%.

No impairment loss was recognised in respect of the EpiCapture CGM CGU during the years ended December 31, 2025 and December 31, 2024. Management concluded that there were no indicators of impairment, that the recoverable amount of the CGU exceeded its carrying amount, and that no reasonably possible change in key assumptions would lead to the carrying amount exceeding the recoverable amount.

Goodwill arising from the acquisition of Metabolomic Diagnostics Limited

Goodwill of US$6,000 was 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)

The trade name assets purchased as part of the acquisition of Primus in 2005 was 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. At December 31, 2025, the carrying value of this trade name asset was US$365,000 (December 31, 2024: US$365,000). Management has determined that this trade name is expected to generate net cash inflows for the Group for an indefinite period and, accordingly, they are classified as intangible assets with indefinite useful lives.

13. FINANCIAL ASSETS

	December 31, 2025 US$'000
Cost	
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
At January 1, 2025	3,155
Additions in year	-
Write off in the year	-
Fair value remeasured through profit & loss	318
At December 31, 2025	3,473
Provision for impairment	
At January 1, 2024	(1,500)
Reversal of impairment in the current year (Note 5)	800
At December 31, 2024	(700)
At January 1, 2025	(700)
At December 31, 2025	(700)
Carrying amounts	
At December 31, 2025	2,773
At December 31, 2024	2,455

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. Also, the Company did not make 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, 2025 and 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 gain of US$0.3 million was recognised in profit or loss for the year ended December 31, 2025 (2024: loss of US$0.1 million). The remeasurement gain reflects the translation of the euro-denominated investment into US dollars.

The fair value of the investment is determined by reference to observable third-party investment information for the underlying investee, including the pricing and terms of recent arm's length transactions with external investors, adjusted as necessary to reflect the rights and attributes of the Group's investment. As the investment is denominated in euro, the fair value is translated into US dollars at the period-end exchange rate.

Carrying amounts at December 31, 2025 of US$2.8 million relates solely to the Novus investment.

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*	
	2025 US$'000	*2024 US$'000*	*2025 US$'000*	*2024 US$'000*	*2025 US$'000*	*2024 US$'000*
Property, plant and equipment	601	224	-	-	601	224
Intangible assets	-	-	(4,140)	(3,001)	(4,140)	(3,001)
Inventories	679	776	-	-	679	776
Provisions	1,424	1,414	-	-	1,424	1,414
Tax value of loss carry-forwards	1,025	1,026	-	-	1,025	1,026
Other items	195	113	(527)	(1,560)	(332)	(1,447)
Deferred tax assets/(liabilities)	3,924	3,553	(4,667)	(4,561)	(743)	(1,008)

The deferred tax asset at December 31, 2025 is mainly due to deductible temporary differences relating to provisions and loss carry-forwards in 2025, the deferred tax asset increased by US$0.4 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$0.1 million in 2025, 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, 2025 and at December 31, 2024 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, 2025 US$'000	*Recognised in income US$'000*	*Recognised in discontinued operations US$'000*	*Balance December 31, 2025 US$'000*
Property, plant and equipment	224	377	-	601
Intangible assets	(3,001)	(1,139)	-	(4,140)
Inventories	776	(97)	-	679
Provisions	1,414	10	-	1,424
Tax value of loss carry-forwards	1,026	(1)	-	1,025
Other items	(1,447)	1,115	-	(332)
	(1,008)	265	-	(743)

	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)

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, 2025 US$'000	*December 31, 2024 US$'000*
Capital losses	8,293	8,293
Net operating losses	181,136	180,810
US alternative minimum tax credits	1,791	1,791
Other temporary timing differences	19,246	19,246
	210,466	210,140

15. OTHER NON-CURRENT ASSETS

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Other assets	28	28
	28	28

16. INVENTORIES

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Raw materials and consumables	11,485	10,032
Work-in-progress	3,738	4,989
Finished goods	3,605	4,353
	18,828	19,374

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$7,101,000 (2024: US$7,648,000) (2023: US$11,344,000). Cost of sales in 2025 includes inventories expensed of US$29,546,000 (2024: US$38,001,000) (2023: US$35,091,000).

The movement on the inventory provision for the three-year period to December 31, 2025 is as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*	*December 31, 2023 US$'000*
Opening provision at January 1	7,648	11,344	16,274
Charged during the year	629	2,113	2,291
Utilised during the year	(1,176)	(5,809)	(5,456)
Eliminated on disposal of business	-	-	(1,765)
Closing provision at December 31	7,101	7,648	11,344

17. TRADE AND OTHER RECEIVABLES

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Trade receivables, net of impairment losses	9,362	13,416
Prepayments	1,654	1,979
Contract assets	326	460
Value added tax	122	42
Other receivables	16	168
	11,480	16,065

Trade receivables are shown net of an impairment losses provision of US$1.1 million (2024: US$2.3 million) (see Note 27).

Long-term contract receivable

(i) Finance lease commitments – Group as lessor

As at December 31, 2025, the Group had no finance lease arrangements as lessor (2024: Nil)

(ii) Operating lease commitments – Group as lessor

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

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

	Instruments	
	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Less than one year	1,762	1,461
	1,762	1,461

18. CASH AND CASH EQUIVALENTS

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Cash at bank and in hand	5,138	5,167
Cash and cash equivalents	5,138	5,167

19. CAPITAL AND RESERVES

Share capital

During the year 2025 and 2024, the Company maintained the ADS ratio of 20:1 meaning, *twenty (20) 'A' ordinary shares of the Company representing one (1) American Depository Share (ADS)* .

	December 31, 2025 Class 'A' Ordinary shares '000s	*December 31, 2024 Class 'A' Ordinary shares '000s*
In thousands of shares		
In issue at January 1	371,749	165,866
Issued for a cash consideration (a)	13,447	81,628
Issued for non-cash consideration (b)	1,566	124,255
At period end	386,762	371,749

	December 31, 2025 ADS	*December 31, 2024 ADS*
In thousands of ADSs		
Balance at January 1	18,587	8,293
Issued for a cash consideration	672	4,081
Issued for non-cash consideration	78	6,213
At period end	19,337	18,587

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

	December 31, 2025 Class 'A' Treasury shares '000s	*December 31, 2024 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

19. CAPITAL AND RESERVES (CONTINUED)

	December 31, 2025 Class 'A' Treasury shares '000s	*December 31, 2024 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, 2025, the Company issued 13,447,000 'A' Ordinary shares for consideration of US$0.55 million settled in cash. The Company incurred expenses of US$0.04 million in connection with the issuances. No employee share options were exercised during the year.

(b) During the year ended December 31, 2025, the Company issued 1,566,000 'A' Ordinary shares (78,000 ADS) for a non-cash consideration to Chronomed, Inc. pursuant to a settlement agreement.

(c) 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.

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 of:

i) 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.

ii) During 2025, the shareholders of the Company approved a reduction in the nominal value of each 'A' Ordinary share from US$0.0109 to US$0.0001. The number of 'A' ordinary shares in issue remained unchanged. The reduction resulted in a transfer of US$4.3 million from equity share capital to other reserve (being non-distributable in nature). The transaction had no impact on profit or loss or cashflows.

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$486.00 per ADS (equivalent to US$16.20 per ADS prior to the ADS ratio change effected on July 24, 2026) 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 2025, the Group did not purchase any 'A' Ordinary shares (2024: nil) (2023: nil) 'Treasury shares'.

20. SHARE OPTIONS

Options

Under the terms of the Company's Employee Share Option Plans, options to purchase 40,017,505'A' Ordinary Shares (2,000,876 ADS's) were outstanding at December 31, 2025. 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, 2025.

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, 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
Outstanding January 1, 2025	40,506,672	0.26	0.12-1.29
Expired / Forfeited	(489,167)	0.35	0.14-1.29
Outstanding December 31, 2025	40,017,505	0.26	0.12-1.10
Exercisable December 31, 2025	24,123,755	0.32	0.12-1.10

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 2025 and 2024 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, 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
Outstanding January 1, 2025	2,025,334	5.20	2.40-25.80
Expired / Forfeited	(24,458)	6.99	2.80-25.80
Outstanding December 31, 2025	2,000,876	5.20	2.40-22.05
Exercisable December 31, 2025	1,206,188	6.39	2.40-22.05

The opening share price per 'A' Ordinary share at the start of the financial year was US$0.04 or US$0.89 per ADS (2024: US$0.10 per 'A' ordinary share or US$2.00 per ADS) (2023: US$0.24 per 'A' ordinary share or US$4.8 per ADS) and the closing share price at December 31, 2025 was US$0.04 per 'A' ordinary share or US$0.79 per ADS (2024: 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).

20. SHARE OPTIONS (CONTINUED)

A summary of the range of prices for the Company's share options for the year ended December 31, 2025 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	39,897,505	0.26	3.99	24,003,755	0.33	3.38
US$1.00-US$1.29	120,000	1.10	1.96	120,000	1.10	1.96
	40,017,505			24,123,755		

	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	1,994,876	5.20	3.99	1,200,188	6.56	3.38
US$20.00-US$25.80	6,000	22.05	1.96	6,000	22.05	1.96
	2,000,876			1,206,188		

The weighted-average remaining contractual life of options outstanding at December 31, 2025 was 3.99 years (2024: 4.98 years).

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		

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 2025, US$324,000 (2024: US$1,316,000) (2023: US$2,069,000) was charged to selling, general and administrative expenses in the statement of operations.

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. There were no share options granted in 2025. The following are the input assumptions used in determining the fair value of share options granted in 2024 and 2023.:

	Key management personnel 2025	**Key management personnel 2024**	**Key management personnel 2023**
Weighted average fair value at measurement date per 'A' share / (per ADS)	$ -	US$0.10 /(US$2.08)	US$0.50 /(US$10.04)
Total 'A' share options granted / (ADS's equivalent)	-	12,100,000 / (605,000)	19,600,000 / (980,000)
Weighted average share price per 'A' share / (per ADS)	$ -	US$0.14/(US$2.80)	US$0.14 /(US$2.80)
Weighted average exercise price per 'A' share / (per ADS)	$ -	US$0.14/(US$2.80)	US$0.14 /(US$2.80)
Weighted average expected volatility	-%	74.40%	40.21%
Weighted average expected life	-	7	7
Weighted average risk-free interest rate	-%	4.06%	4.13%

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, 2025 US$'000	*December 31, 2024 US$'000*
Trade payables	11,478	6,833
Accruals and other liabilities	16,932	13,597
Payroll taxes	310	659
Employee related social insurance	383	112
Contingent consideration	413	5,384
Deferred income	187	197
	29,703	26,782

Included in trade and other payables at December 31, 2025 was US$218,000 (2024: US$185,000) relating to contracted licence payments.

Contingent consideration of US$5.0 million included in this balance at 31 December 2024 has been reclassified to accruals and other liabilities during the year following the amendment to the Perceptive term loan facility in December 2025, as the amount is no longer contingent in nature. Further details on the modification of contingent consideration arrangements are disclosed in Note 29.

22. PROVISIONS

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Product warranty provision	50	50
Legal & regulatory provision	-	735
Disposal-related warranty settlement provision	-	150
Transformation provision	1,076	1,594
	1,126	2,529
Current	345	2,454
Non-current	781	75

During 2025 and 2024 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, 2025 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, 2025.

During the year, the Group recognised a provision of US$Nil (2024: US$0.7 million) in respect of a matter relating to second-round Paycheck Protection Program (PPP) loans received by certain U.S. subsidiaries. During 2025, this matter was settled. Of the provision recognised at 31 December 2024, approximately US$0.3 million was utilised as part of the settlement. The remaining balance was released, resulting in a credit of US$0.2 million recognised within once-off costs and a further credit of US$0.2 million recognised within finance costs, reflecting the reversal of previously accrued interest. As the matter has now been resolved, the Directors no longer consider that the disclosure of further information would be seriously prejudicial to the Group's position, and accordingly the exemption applied under IAS 37.92 in the prior year is no longer required.

22. PROVISIONS (CONTINUED)

At December 31, 2025, the Company recognised a provision of US$1.1 million (2024: US$2.5 million) in respect of transformation activities undertaken as part of the Group's business transformation programme (refer to Note 5). The transformation provision is expected to be fully utilised during the next 12 months. No further transformation provisions are anticipated at the reporting date.

The movement on provisions is as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Opening provision at January 1	2,529	50
Charged during the year	328	2,479
Utilised during the year	(1,316)	-
Released during the year	(415)	
Closing provision at December 31	1,126	2,529

23. INTEREST-BEARING LOANS AND BORROWINGS

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Current liabilities		
Exchangeable senior notes	210	210
Senior secured term loan	108,015	-
Total current liabilities	108,225	210

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Non-Current liabilities		
Senior secured term loan	-	72,391
Derivative financial liability	3,320	1,658
Contingent liability (Note 29)	-	1,813
Convertible note	16,330	15,401
Total non-current liabilities	19,650	91,263

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Non-Current assets		
Derivative financial asset	249	166
Total non-current assets	249	166

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.

The movement in the exchangeable notes balance was as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'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 January 2027. The loan 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. 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.

In February 2023, the Company 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 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.

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 provided for additional liquidity of up to US$6.5 million for general corporate purposes which the Company drew down in April 2024.

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$2.0 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.

On February 27, 2025, we entered into the 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.

On August 7, 2025, we entered into a sixth 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 a further three months to October 1, 2026, and confirmed that interest payments for the months of July and August 2025 would be paid-in-kind. Additional warrants were also provided that allow an additional 750,000 ADSs to be purchased at $0.86 per ADS.

On October 16, 2025, the Company entered into an amendment to the sixth amendment to the credit agreement, which provided for a further US$2.0 million in funding, and confirmed that interest payments for the months of September and October 2025 would be paid-in-kind.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

Senior secured term loan (continued)

On 22 December 2025, the Group entered a further amendment of its senior secured term loan facility with Perceptive. The terms of the amendment were assessed under IFRS 9 and determined to result in a substantial modification of the existing financial liability. Accordingly, the original term loan, with a carrying amount of US$93.3 million immediately prior to the amendment, was derecognised, together with the associated embedded derivative balances. The derecognition gave rise to a loss recognised in finance expense in the consolidated statement of operations for the year, including a loss on extinguishment of US$10.0 million representing the difference between the carrying amount of the extinguished facility and the fair value of the new facility recognised. Further, the amendment extended the maturity date of the Term Loan to January 15, 2027.

Following derecognition, the amended facility was recognised as a new financial liability at its fair value on the amendment date. The new term loan was recognised at an initial amortised cost of US$106.9 million representing the replacement of the existing facility of US$101.9 million, together with an additional US$5.0 million drawdown. In accordance with IFRS 9, embedded call option and conversion option features were separately recognised as derivative financial assets and liabilities on initial recognition. The movements in both the extinguished liability and the newly recognised loan are presented in the loan movement table below.

In connection with the December 22, 2025 amendment, we issued a senior convertible note evidencing the Term Loans outstanding under the Credit Agreement at the time. Up to US$60.0 million of the aggregate principal amount of the Convertible Note with Perceptive is convertible at the holder's election into ADSs, at a conversion price of 97% of the VWAP of the ADSs at the time of each such conversion, subject to a floor price of US$1.03 (the "Conversion Price") and a beneficial ownership cap. The Convertible Note restricts the conversion thereof to the extent that, upon such conversion, the number of the Company's ordinary shares then beneficially owned by the holder and its "Attribution Parties" (as defined in the Convertible Note), including its affiliates and any other person or entities with which such holder would constitute a Section 13(d) "group," would exceed 9.9% of the total number of ordinary shares then outstanding (the "Perceptive Beneficial Ownership Cap").

As part of the December 22, 2025 amendment, the parties also addressed two separate contingent consideration obligations arising in connection with the Waveform acquisition.

In connection with the December 22, 2025 amendment, TRIB Biosensors Inc. ("TRIB B") Perceptive Credit Holdings II, L.P entered into a conversion rights agreement with Perceptive Credit Holdings II, L.P. (the "Conversion Rights Agreement"), pursuant to which we and Perceptive agreed to permit a US$5.0 million payment obligation of TRIB B owed to Perceptive in connection with the Waveform acquisition (the "Milestone Payment Obligation") to be satisfied, at Perceptive's election, by converting that obligation (in whole or in part) into our ADSs at the Conversion Price, as defined above, at the time of each such conversion. This payment obligation of US$5.0 million is included within 'Accruals and other liabilities' as at December 31, 2025 (US$5.0 million included in 'Contingent consideration' as at December 31, 2024), see Note 21.

The Conversion Rights Agreement also provided for the termination of TRIB B's contingent payment obligation in connection with the Waveform acquisition of up to US$15.0 million in exchange for TRIB B's agreement to pay US$7.5 million to Perceptive, and the parties' agreement to permit that obligation to be satisfied (in whole or in part), at Perceptive's election, by converting such obligation into ADSs at the Conversion Price at the time of each conversion. Perceptive's ability to convert obligations under the Conversion Rights Agreement is also subject to the Perceptive Beneficial Ownership Cap. This obligation had a fair value of nil immediately prior to the amendment and was replaced with a fixed settlement amount of US$7.5 million. The US$7.5 million amount was incorporated into the revised term loan balance recognised upon derecognition of the old loan and recognition of a new loan under IFRS 9.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

Senior secured term loan (continued)

The movement in the Term Loan was as follows:

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Balance at January 1	(72,391)	(40,109)
Drawdowns under old loan (pre-extinguishment)	(10,000)	(30,500)
Loan drawdown costs (pre-extinguishment)	339	325
Payment-in-kind (PIK) Interest	(11,399)	(3,291)
Accretion interest (Note 6)	(2,646)	(2,355)
Non-cash loan modification gain	1,706	3,567
Extinguishment of old loan (IFRS 9 derecognition)	93,323	-
Initial recognition of new term loan	(101,947)	-
Loan drawdown under new term loan	(5,000)	
Derivative financial asset at date of drawdown	-	(28)
Balance at December 31	(108,015)	(72,391)

Drawdowns under old loan (pre-extinguishment) represent additional funding advanced under the existing credit agreement prior to the amendment on December 22, 2025, including incremental funding made available through amendments to the facility during the year. As these drawdowns occurred before the amendment date, they form part of the carrying amount of the original financial liability that was derecognised.

Loan drawdown costs (pre-extinguishment) comprise incremental transaction costs directly attributable to obtaining additional funding under the existing term loan facility. These costs were capitalised and amortised as part of the effective interest rate of the original facility until derecognition.

Payment-in-kind ("PIK") interest relates to interest amounts contractually permitted to be settled by capitalising the interest and increasing the outstanding principal balance of the term loan instead of being settled in cash. These amounts increased the carrying value of the loan in accordance with IFRS 9.

Accretion interest represents the non-cash unwinding of the discount on the term loan recognised through the effective interest rate method, reflecting the time value of money and the amortisation of transaction costs and fair value adjustments embedded in the loan.

In Q1 2024, the Company negotiated a 2.5% reduction in the 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 US$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 contractual cash flows, discounted at the original EIR, and is presented in the consolidated statement of operations as a "Non-cash loan modification gain." The reduced base interest rate of 8.75% remained in effect throughout 2025. During the year, further non-substantial amendments were executed, primarily relating to extensions of the loan maturity date. These amendments altered the timing of contractual cash flows and, when remeasured in accordance with IFRS 9 using the original EIR, resulted in an additional non-cash loan modification gain of US$1.7 million recognised in finance income.

Extinguishment of old loan (IFRS 9 derecognition) reflects the derecognition of the original term loan, with a carrying amount of US$93.3 million immediately prior to the amendment on December 22, 2025, following the conclusion that the amended terms represented a substantial modification under IFRS 9.

Covenant compliance and waivers under the senior secured term loan

Subsequent to December 31, 2025, the Company received a waiver from Perceptive in respect of a compliance breach of the minimum revenue covenant for the twelve-month period ended December 31, 2025. The covenant breach primarily reflected timing-related variability in HIV revenues, including the timing of the scale-up of the Group's outsourced and offshored manufacturing model. These factors affected the timing of shipments and revenue recognition between reporting periods, rather than indicating a deterioration in underlying demand. Although this waiver was granted subsequent to the reporting date, the Company was not in compliance with this covenant as at December 31, 2025.

In addition, subsequent to year-end the Company obtained waivers of the minimum revenue covenant applicable to quarterly measurement periods through July 1, 2026. The Company also received waivers in respect of the minimum liquidity covenant for the measurement periods ended March 31, 2026, April 30, 2026, June 30, 2026 and August 31, 2026. The scheduled increase in the minimum liquidity threshold was also deferred until October 1, 2026. Each of these waivers and the liquidity covenant deferral relates to covenant measurement periods occurring after December 31, 2025.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

Notwithstanding the waivers obtained subsequent to the reporting period, the senior secured term loan is classified as a current liability in the consolidated statement of financial position as at December 31, 2025. In accordance with IAS 1.69(d) and IAS 1.74, when a covenant breach exists at the reporting date and a waiver is obtained only after that date, the entity does not have an unconditional right to defer settlement of the liability for at least twelve months as at the reporting date.

The waivers described above do not amend the contractual maturity of the Company's senior secured term loan, which remains January 15, 2027.

Post - balance sheet amendment to senior secured term loan and Convertible Note agreement

On April 30, 2026, the Group entered into a third amendment to its Credit Agreement with Perceptive and a related amendment and restatement of the Senior Convertible Note. The amendment to the Credit Agreement provided for, among other things, an additional US$2.5 million term loan borrowing, the payment of certain interest through April 2026 as PIK interest, and a limited waiver of certain financial covenants. In connection with these amendments, the aggregate principal amount of indebtedness subject to conversion was increased from US$60.0 million to US$72.5 million. Under the amended and restated Senior Convertible Note, up to US$72.5 million of the aggregate principal amount of the Convertible Note is convertible, at the holder's election, into ADSs, at a conversion price of 97% of the VWAP of the ADSs at the time of each such conversion, subject to the minimum conversion price of $0.5061 (equal to 75% of the 30 day VWAP of the Company's ADSs for the period ended April 22, 2026). Following the ADS ratio change effected on July 24, 2026, the minimum conversion price was adjusted to US$15.183 per ADS to reflect the revised ADS ratio. This amended conversion price also applies to amounts convertible pursuant to the Conversion Rights Agreement. All conversions remain subject to the beneficial ownership limitations and other terms and conditions set out in the relevant agreements.

In August 2026, the Group entered into a further amendment to the Credit Agreement pursuant to which Perceptive provided an additional US$2.5 million term loan borrowing, granted limited waivers in respect of certain financial covenants and agreed that interest obligations from May through August 2026 would be settled through payment-in-kind arrangements.

Derivative financial asset and financial liability

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Balance at January 1	166	178
Derivative financial asset at date of drawdown	-	28
Fair value adjustments in the period (old derivative)	(166)	(40)
Initial recognition of new derivative asset (call option)	249	-
Non-current asset at December 31	249	166

As part of the amendment to the senior secured term loan on December 22, 2025, the Group identified a new embedded call option that meets the definition of a derivative under IFRS 9. In line with the derecognition of the original term loan on the amendment date, the embedded derivatives associated with the previous facility were also derecognised. A new call option embedded in the amended loan was recognised at fair value on initial recognition and is subsequently measured at fair value through profit or loss. The carrying value of this derivative financial asset at December 31, 2025 was US$0.25 million (2024: US$0.2 million).

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

	December 31, 2025 US$'000	*December 31, 2024 US$'000*
Balance at January 1	(1,658)	(526)
Derivative financial liability at date of drawdown	-	(1,066)
Fair value adjustments in the period	(179)	(66)
Recognition of new derivative liabilities (conversion options)	(1,483)	-
Non-current liability at December 31	(3,320)	(1,658)

Under the amended loan arrangements, the Group identified embedded conversion features that are not closely related to the economic characteristics and risks of the host instruments. Accordingly, these features were separated from their host contracts and recognised as derivative financial liabilities at fair value on initial recognition. During the year, new embedded conversion options with a fair value of US$1.5 million were recognised. The Group's total derivative financial liabilities, including previously recognised instruments and fair value movements, amounted to US$3.3 million at December 31, 2025 (2024: US$1.7 million).

All derivative financial instruments are remeasured at each reporting date, with gains or losses arising from changes in fair value recognised in finance income or finance expense in the consolidated statement of operations.

23. INTEREST-BEARING LOANS AND BORROWINGS (CONTINUED)

7-year convertible note

In connection with MiCo's investment in 2022, we issued MiCo 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$486.0 for any five consecutive NASDAQ trading days (equivalent to US$16.20 per ADS prior to the ADS ratio change in 2026). Based on public filings, we understand that on December 2, 2025, MiCo was acquired by AI n M net Limited because of a share purchase agreement with Dayli Trinity Holdings Limited.

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, 2025, the carrying value of the convertible note's debt component was US$16.3 million (2024: US$15.4 million) and accretion interest of US$0.9 million (2024: US$0.9 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, 2025 US$'000	*December 31, 2024 US$'000*
Balance at January 1	(15,401)	(14,542)
Accretion interest	(929)	(859)
Non-current liability at December 31	(16,330)	(15,401)

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, 2025 US$'000	*December 31, 2024 US$'000*
Current liabilities		
Lease liabilities related to Right of Use assets	2,588	2,285
	2,588	2,285
Non-Current liabilities		
Lease liabilities related to Right of Use assets	10,840	10,477

	December 31, 2025 US$'000		
	Lease liabilities related to Right of Use assets		
	Minimum lease payments	Interest	Principal
Less than one year	3,215	627	2,588
In more than one year, but not more than two	3,000	485	2,515
In more than two years but not more than five	6,110	845	5,265
More than five years	3,318	258	3,060
	15,643	2,215	13,428

24. LEASE LIABILITIES (CONTINUED)

	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

Lease payments not recognised as a liability

No short-term lease expenses were incurred for the year ended December 31, 2025. 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, 2025, was US$3,187,000 (2024: US$2,503,000).

25. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has capital commitments authorised and contracted for of US$ nil as at December 31, 2025 (2024: US$ nil).

(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.

(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, Konamite Limited, Metabolomic Diagnostics Limited, EpiCapture Limited and Trinity Biotech Financial Services Limited subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2025 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, 2025. However, if the income were to become repayable, the maximum amounts repayable as at December 31, 2025 would amount to US$3,557,000 (2024: US$3,313,000).

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

As part of the acquisition of the CGM assets of Waveform Technologies, Inc., the Company agreed to contingent consideration of up to US$20.0 million based on share price, trading volume and commercial milestones. In December 2025, as part of the amendment to the Perceptive term loan facility, this contingent consideration arrangement was contractually modified.

A US$5.0 million trading-based component became an unconditional obligation of the Group and is therefore no longer contingent in nature and is recognised within accruals and other liabilities as at December 31, 2025. The remaining US$15.0 million was extinguished as contingent consideration and incorporated into the amended Perceptive term loan facility as part of the amendment to the loan in December 2025.

Accordingly, there was no contingent consideration relating to the Waveform acquisition outstanding as at December 31, 2025. 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, 2025. Refer to Note 29 for further details.

(g) ***Other Contingencies***

The Company has other contingencies primarily relating to claims and legal proceedings, onerous contracts, product warranties and employee related provisions. The status of each significant claim and legal proceeding in which the Company is involved is reviewed by management on a periodic basis and the Group's potential financial exposure is assessed. If the potential loss from any claim or legal proceeding is considered probable, and the amount can be reliably estimated, a liability is recognised for the estimated loss. Because of the uncertainties inherent in such matters, the related provisions are based on the best information available at the time; the issues taken into account by management and factored into the assessment of legal contingencies include, as applicable, the status of settlement negotiations, interpretations of contractual obligations, prior experience with similar contingencies/claims, and advice obtained from legal counsel and other third parties. The Group expects the majority of these provisions will be utilised within one to three years of the balance sheet date; however due to the nature of the legal provisions there is a level of uncertainty in the timing of settlement as the Group generally cannot determine the extent and duration of the legal process.

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 Ronan O'Caoimh, a director of the Company, and a former director, Dr Jim Walsh who resigned in September 2025, as well as directly with Mr O'Caoimh, to provide premises in Bray, 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$429,000). 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$887,000). 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 (US$1,183,000), 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$162,000). 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 (a director of the Company at that time before his retirement in September 2025) 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, then 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 year ended December 31, 2025, the Group's key management personnel comprised directors Mr. Ronan O'Caoimh, and Mr. John Gillard and Dr. Jim Walsh. Dr Jim Walsh resigned in September 2025. (2024: Mr. Ronan O'Caoimh, and Mr. John Gillard and Dr. Jim Walsh) 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, 2025 US$'000	*December 31, 2024 US$'000*
Short-term employee benefits	768	843
Performance related bonus	441	440
Post-employment benefits	38	39
Share-based compensation benefits as calculated under IFRS 2	149	931
	1,396	2,253

The amounts disclosed in respect of directors' emoluments in Note 9 includes independent directors' fees and non-executive director fees of US$118,000 (2024: US$114,000) and share-based compensation benefits of US$58,000 (2024: US$213,000). Total directors' remuneration is also included in "employment" (Note 3) and "(Loss)/profit before tax" (Note 9).

At 31 December 2025, an amount accrued of US$984,000 (2024: US$658,000) in respect of bonus compensation related to the Chief Executive Officer remained unpaid. The balance reflects a voluntary deferral agreed by the Chief Executive Officer. The balance is unsecured and bears no interest.

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

	'A' Ordinary Shares	*Share options*
At January 1, 2025	11,317,777	32,993,336
Shares purchased during the year	-	-
Granted	-	-
Expired / forfeited	-	(379,167)
At December 31, 2025	11,317,777	32,614,169

	'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

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, 2025						
Loans and receivables at amortised cost						
Trade receivables	*17*	9,362	-	-	9,362	9,362
Cash and cash equivalents	*18*	5,138	-	-	5,138	5,138
		14,500	-	-	14,500	14,500
Liabilities at amortised cost						
Senior secured term loan	*23*	-	(108,015)	-	(108,015)	(108,015)
Convertible note	*23*	-	(16,330)	-	(16,330)	(16,330)
Exchangeable note	*23*	-	(210)	-	(210)	(210)
Lease liabilities	*24*	(13,428)	-	-	(13,428)	(13,428)
Trade and other payables (excluding deferred income)	*21*	(29,516)	-	-	(29,516)	(29,516)
Provisions	*22*	(1,126)	-	-	(1,126)	(1,126)
		(44,070)	(124,555)	-	(168,625)	(168,625)
Fair value through profit and loss (FVPL)						
Derivative liability - warrants	*23*	-	(3,320)	-	(3,320)	(3,320)
Derivative asset – prepayment option	*23*	249	-	-	249	249
Equity investments in Novus	*13*	-	-	2,773	2,773	2,773
		249	(3,320)	2,773	(298)	(298)
		(29,321)	(127,875)	2,773	(154,423)	(154,423)

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, 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)

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, 2025, 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, 2025 and 2024, indicating their effective interest rates and the period in which they re-price:

As at December 31, 2025	*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*	0.0%	5,138	5,138	-	-	-	-
Exchangeable note[1]	*23*	4.0%	(210)	-	-	-	-	(210)
Senior secured term loan[2]	*23*	12.8%	(108,015)	(108,015)	-	-	-	-
Convertible note[3]	*23*	1.5%	(16,330)	-	-	-	(16,330)	-
Lease payable on Right of Use assets	*24*	5 to 14.8%	(13,428)	(1,331)	(1,257)	(2,515)	(5,265)	(3,060)
Total			(132,845)	(104,208)	(1,257)	(2,515)	(21,595)	(3,270)

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*	0.0%	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)

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. On 22 December 2025, the Group entered a further amendment of its senior secured term loan facility with Perceptive. The terms of the amendment were assessed under IFRS 9 and determined to result in a substantial modification of the existing financial liability. The loan has a contractual maturity in January 2027 under the new modified loan terms.
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$Nil (2024: US$Nil) as at December 31, 2025 the Company holds no funds in interest-bearing accounts; while the annual impact on the interest expense would be an increase of US$1,080,000 (2024: US$724,000) 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, 2025 US$'000	*December 31, 2024 US$'000*
Variable rate instruments		
Cash at bank and in hand	5,138	5,167
Variable rate financial liabilities (senior secured term loan)	(108,015)	(72,391)
	(102,877)	(67,224)
Fixed rate instruments		
Fixed rate financial liabilities (exchangeable note)	(210)	(210)
Fixed rate financial liabilities (convertible note)	(16,330)	(15,401)
Fixed rate financial liabilities (lease payables)	(13,428)	(12,762)
	(29,968)	(28,373)

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, 2025 or December 31, 2024 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, 2025 and December 31, 2024 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, 2025 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)	29,516	29,516	29,516	-	-	-	-
Lease payable on Right of Use assets	13,428	15,643	1,661	1,554	3,000	6,110	3,318
Senior secured term loan[1]	108,015	117,854	4,725	113,129	-	-	-
Convertible note	16,330	21,025	150	150	300	20,425	-
Exchangeable notes	210	372	4	4	8	24	332
	167,499	184,410	36,056	114,837	3,308	26,559	3,650

[1] The contractual cash flows of interest on the senior secured term loan is estimated based on the prevailing interest rate at December 31, 2025

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

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)	26,585	26,585	26,585	-	-	-	-
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
	127,349	144,967	29,896	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.

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, 2025 or December 31, 2024.

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, 2025	*EUR* *US$'000*	*GBP* *US$'000*	*SEK* *US$'000*	*CAD* *US$'000*	*BRL* *US$'000*	*Other* *US$'000*
Cash	657	27	-	169	253	-
Trade and other receivable	490	17	16	127	901	-
Trade and other payables	(13,669)	(277)	(34)	(40)	(129)	(2)
Lease liabilities	(8,504)	-	-	-	(299)	-
Total exposure	(21,026)	(233)	(18)	256	726	(2)

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)

27. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Sensitivity analysis

A 10% strengthening of the US Dollar against the Euro at December 31, 2025 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, 2025	
Euro	1,911
December 31, 2024	
Euro	1,167

A 10% weakening of the US Dollar against the Euro at December 31, 2025 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, 2025	
Euro	(2,336)
December 31, 2024	
Euro	(1,427)

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, 2025 US$'000	*Carrying Value December 31, 2024 US$'000*
Third party trade receivables (Note 17)	9,362	13,416
Cash and cash equivalents (Note 18)	5,138	5,167
	14,500	18,583

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

	Carrying Value December 31, 2025 US$'000	*Carrying Value December 31, 2024 US$'000*
United States	2,667	4,185
Euro-zone countries	409	742
United Kingdom	211	741
Other regions	6,075	7,748
	9,362	13,416

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, 2025 US$'000	*Carrying Value December 31, 2024 US$'000*
End-user customers	2,598	3,828
Distributors	6,412	8,236
Non-governmental organisations	352	1,352
	9,362	13,416

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, 2025 is as follows:

	Gross 2025 US$'000	*Impairment 2025 US$'000*	*Expected Credit Loss Rate 2025 %*	*Gross 2024 US$'000*	*Impairment 2024 US$'000*	*Expected Credit Loss Rate 2024 %*
Not past due	7,718	22	0.3%	9,363	-	-
Past due 0-30 days	485	16	3.4%	1,455	-	-
Past due 31-120 days	504	17	3.3%	1,753	31	1.8%
Greater than 120 days	1,741	1,030	59.2%	3,131	2,255	72.0%
	10,448	1,085	-	15,702	2,286	-

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, 2025, 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:

	2025 US$'000	*2024 US$'000*
Balance at January 1	2,286	2,324
(Reversed)/charged to costs and expenses	(324)	225
Amounts written off during the year	(876)	(263)
Balance at December 31	1,086	2,286

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, 2025	23,24	91,474	12,762
Cash-flows:			
Loan drawdown under old term loan		10,000	-
Loan origination costs paid		(339)	-
Interest paid for convertible note		(300)	-
Interest paid for exchangeable notes		(8)	-
Repayment of leases		-	(3,187)
Loan drawdown under new term loan		5,000	-
Non-cash:			
Interest charged		308	-
Conversion options on the date of new loan		1,625	-
Additions (related to Right of Use assets)		-	2,110
Exchange adjustment		-	1,099
Accretion interest		3,575	644
Fair value of derivative liability - warrants		(285)	-
Fair value of additional derivative liability - warrants		464	-
Fair value of conversion - warrants		(142)	
Interest capitalised on outstanding loans and balances		11,456	-
Fair value movement on contingent liability		(1,871)	-
Non-cash loan modification gain		(1,706)	-
Extinguishment of old term loan		(93,323)	-
Recognition of new term loan		101,947	-
Balance at December 31, 2025		127,875	13,428

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

	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

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 up to a maximum of US$20 million formed part of the total consideration. 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 was accounted for as a business combination under IFRS 3 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 was contractually payable upon the occurrence of certain events, including;

- US$5.0 million payment if, within the next 12 months after acquisition date, (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
- An amount equal to 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 within 24 months of the acquisition date. At the acquisition date, the fair value assigned to this element of the contingent consideration was US$1.8 million which was 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 was classified as a current liability (Note 21), while US$1.8 million was recognised as a contingent consideration liability under IFRS 3 and subsequently remeasured at fair value. During 2025, the contingent consideration relating to potential partnering arrangements was incorporated into the amended Perceptive term loan facility as part of the modification and extinguishment of the prior debt instrument. At the date of modification, management assessed the fair value of this contingent consideration as being nil, and the liability was derecognised, resulting in the recognition of a fair value gain of $1.8 million in profit or loss (Note 4).

Acquisition-related costs amounting to US$1.5 million in respect of the Waveform transaction were 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' in the year ended December 31, 2024.

The initial assignment of fair values to identifiable net assets acquired was 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.

	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**

29. BUSINESS COMBINATIONS (CONTINUED)

In accordance with IFRS 3 Business Combinations, the Group finalised the fair value assessments relating to the acquisition of the Waveform CGM assets and 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 were 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.

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, 2025, 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$10 thousand, 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.

29. BUSINESS COMBINATIONS (CONTINUED)

	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**

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 were 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' in the year ended December 31, 2024.

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.

There were no measurement-period adjustments or other changes during the year ended December 31, 2025 in respect of the acquisition accounting for Metabolomics Diagnostics Limited.

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.

29. BUSINESS COMBINATIONS (CONTINUED)

	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	**-**

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, 2025, 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, were 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' in the year ended December 31, 2024.

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, 2025, 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$160,000 (before group recharges), mainly comprising legal 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, 2025, without undue cost or effort

There were no measurement-period adjustments or other changes during the year ended December 31, 2025 in respect of the acquisition accounting for EpiCapture Limited.

30. POST BALANCE SHEET EVENTS

Covenant Compliance and Waivers under the Credit Agreement

Subsequent to December 31, 2025, the Company received a waiver from Perceptive in respect of compliance with the minimum revenue covenant for the twelve-month period ended December 31, 2025. The covenant breach primarily reflected timing-related variability in HIV revenues, including the timing of the scale-up of the Group's outsourced and offshored manufacturing model. These factors affected the timing of shipments and revenue recognition between reporting periods, rather than indicating a deterioration in underlying demand. Although this waiver was granted subsequent to the reporting date, the Company was not in compliance with this covenant as at December 31, 2025.

In addition, subsequent to year-end the Company obtained waivers in respect of the minimum revenue covenant applicable to quarterly measurement periods through July 1, 2026. The Company also received waivers in respect of the minimum liquidity covenant for the measurement periods ended March 31, 2026, April 30, 2026, June 30, 2026 and August 31, 2026. The scheduled increase in the minimum liquidity threshold was also deferred until October 1, 2026. Each of these waivers and the liquidity covenant deferral relates to covenant measurement periods occurring after December 31, 2025.

Notwithstanding the waivers obtained subsequent to the reporting period, the senior secured term loan is classified as a current liability in the consolidated statement of financial position as at December 31, 2025. In accordance with IAS 1.69(d) and IAS 1.74, when a covenant breach exists at the reporting date and a waiver is obtained only after that date, the entity does not have an unconditional right to defer settlement of the liability for at least twelve months as at the reporting date.

The waivers described above do not amend the contractual maturity of the Company's senior secured term loan, which remains January 15, 2027.

Amendment to senior secured term loan and convertible note agreement

On April 30, 2026, the Group entered into a third amendment to its Credit Agreement with Perceptive and a related amendment and restatement of the Senior Convertible Note. The amendment to the Credit Agreement provided for, among other things, an additional US$2.5 million term loan borrowing, the payment of certain interest through April 2026 as PIK interest, and a limited waiver of certain financial covenants. In connection with these amendments, the aggregate principal amount of indebtedness subject to conversion was increased from US$60.0 million to US$72.5 million. Under the amended and restated Senior Convertible Note, up to US$72.5 million of the aggregate principal amount of the Convertible Note is convertible, at the holder's election, into ADSs, at a conversion price of 97% of the VWAP of the ADSs at the time of each such conversion, subject to the minimum conversion price of $0.5061 (equal to 75% of the 30 day VWAP of the Company's ADSs for the period ended April 22, 2026). Following the ADS ratio change effected on July 24, 2026, the minimum conversion price was adjusted to US$15.183 per ADS to reflect the revised ADS ratio. This amended conversion price also applies to amounts convertible pursuant to the Conversion Rights Agreement. All conversions remain subject to the beneficial ownership limitations and other terms and conditions set out in the relevant agreements.

In August 2026, the Group entered into a further amendment to the Credit Agreement pursuant to which Perceptive provided an additional US$2.5 million term loan borrowing, granted limited waivers in respect of certain financial covenants and agreed that interest obligations from May through August 2026 would be settled through payment-in-kind arrangements.

Progress on Comprehensive Transformation Plan

During Quarter 1, 2026 the Company completed the transition of upstream manufacturing processes for its UniGold HIV rapid test to its outsourced and offshore manufacturing model. Outsourced production commenced in April 2026 and the Company is currently progressing through the initial scale-up phase of manufacturing. This marked the completion of the UniGold manufacturing transition under the Comprehensive Transformation Plan and forms part of the broader programme to improve the underlying cost structure and profitability profile of the business.

This transition to outsourcing and progression of the commercial scale-up of outsourced manufacturing has introduced quarter-to-quarter variability in HIV revenues, profitability and cashflow. The ongoing scale-up of the outsourced manufacturing model has resulted in variability in HIV revenues and profitability between reporting periods. While progress has been made in scaling the outsourced manufacturing platform, the Company expects that ongoing scale-up activities may continue to contribute to variability in quarterly HIV revenues and profitability through the remainder of 2026 and into early 2027.

The Company continues to progress other elements of the Comprehensive Transformation Plan, with a particular focus on the optimisation of its commercial operations in order to capitalise on the significant operational changes delivered under the plan. As part of these ongoing activities, the Company continued to review its operational footprint and organisational structure to further enhance operational efficiency and align its cost base with its strategic priorities.

These actions included continued evaluation of the scale and composition of the Company's operations and workforce as the business is further reoriented toward biosensor and reference laboratory testing activities. While the Company may continue to implement targeted initiatives in these areas, any future actions are expected to be of a lower scale and reduced complexity relative to the transformation activities undertaken as part of the Comprehensive Transformation Plan.

30. POST BALANCE SHEET EVENTS

Nasdaq Listing Compliance

On February 11, 2026 and February 19, 2026, the Company received deficiency notices from the Listing Qualifications Department of Nasdaq indicating that the Company was not in compliance with (i) the minimum market value of publicly held shares ("MVPHS") requirement applicable to companies listed on the Nasdaq Global Select Market and (ii) the minimum bid price requirement of US$1.00 per ADS.

On August 7, 2026, Nasdaq confirmed that the Company had regained compliance with the minimum bid price requirement following implementation of a 30:1 ADS ratio change, resulting in a revised ratio of 600 ordinary shares to one ADS.

A deficiency relating to the Nasdaq minimum market value of publicly held shares ("MVPHS") requirement remains outstanding. On August 28, 2026, the Company received a staff determination letter (the "Determination Letter") from the staff notifying the Company that it had not regained compliance with MVPHS Requirements by August 18, 2026. Accordingly and as described in the Determination Letter, unless the Company timely requests a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension/delisting. On September 4, 2026, the Company formally requested a hearing before the Panel.

The Company has a number of initiatives and strategic transactions at advanced stages, which, if completed, would be expected to increase the Company's MVPHS above the $15 million minimum. The Company intends to continue to progress these transactions and as such management remains confident that the actions currently underway will enable the Company to reach a MVPHS of over $15 million. The hearing request will automatically stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. In that regard, pursuant to the Nasdaq Listing Rules, the Panel has the authority to grant an extension not to exceed February 24, 2027. Notwithstanding the foregoing, there can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Global Select Market.

Capital Structure and Funding

The Company continues to evaluate various financing and capital structure options expected to be available to assist in meeting its obligations, to the extent such obligations cannot be met from cash on hand. These considerations include the refinancing of existing debt, the repayment of debt using the proceeds from potential equity or debt offerings, and the sale of assets. The Company has continued to engage with corporate finance advisors, investment banks and potential investors to assess options to optimise its capital structure. This ongoing review also includes consideration of the effectiveness of the equitisation mechanisms within the Company's existing financing arrangements with Perceptive.

Standby Equity Purchase Agreement

On February 24, 2026, we entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, LTD. ("Yorkville"). During the period in which the facility was available, the Company raised approximately US$0.85 million in gross proceeds through the issuance of ADSs. Subsequent to year-end, the Standby Equity Purchase Agreement was terminated and is no longer available to the Company.

At-the-Market Offering Programme

On June 11, 2026, the Company entered into an At-the-Market Offering Agreement (the "ATM Agreement") with Lucid Capital Markets, LLC ("Lucid"), pursuant to which the Company may offer and sell from time to time up to US$4.35 million of its ADSs through Lucid acting as sales agent. The ADSs may be sold in transactions that are deemed to be "at the market offerings" under applicable U.S. securities laws. Under the terms of the ATM Agreement, Lucid is entitled to receive a commission of 3.0% of the gross proceeds from ADSs sold under the programme. The Company intends to use any proceeds raised under the ATM programme for general corporate purposes, including working capital. Since commencement of the ATM programme, the Company has raised approximately US$1.7 million in gross proceeds through the issuance of ADSs under the arrangement.

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.

In certain limited circumstances, the Group enters into bill-and-hold arrangements with customers, whereby products are invoiced and control transfers to the customer prior to physical delivery. The recognition of revenue under such arrangements requires judgement, including the assessment of whether the criteria specified in IFRS 15 for bill-and-hold transactions are met, in particular that the product is separately identified, is ready for physical transfer, and cannot be redirected or used to fulfil other orders. We assesses that the arrangement is substantive and that control has transferred to the customer. Revenue is recognised only when all relevant criteria are satisfied.

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, billing practices and regulatory requirements generally require 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, 2025 US$nil (2024: US$nil) (2023: US$50,000) of revenue was deferred in accordance with IFRS15.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

Research and development expenditure – capitalized development costs

Under IFRS as issued by IASB, the Group writes off research and development expenditure as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalised at cost within intangible assets and amortised over its expected useful life of 15 years, which commences when commercial production starts. For further information, refer to Note 12.

Acquired in-process research and development (IPR&D) is valued at its fair value at acquisition date in accordance with IFRS 3. The Company determines this fair value by adopting the income approach valuation technique. Once the fair value has been determined, the Company will recognise the IPR&D as an intangible asset when it: (a) meets the definition of an asset and (b) is identifiable (i.e., is separable or arises from contractual or other legal rights).

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

At December 31, 2025 the carrying value of capitalised development costs was US$23,568,000 (2024: US$20,951,000) (see Note 12 to the consolidated financial statements). The increase in 2025 was mainly because of additions of US$6,115,000

Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment periodically while goodwill and indefinite lived assets are tested for impairment at least annually, individually or at the cash-generating unit level.

Factors considered important, as part of an impairment review, include the following:

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

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, 2025 resulted in impairment losses being recorded totalling US$2.1 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 2025, 2024 or 2023 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2025 our allowance for slow moving and obsolete inventory was US$7.1 million which represents approximately 27.4% of gross inventory value. At December 31, 2024 our allowance for slow moving and obsolete inventory was US$7.6 million which represented approximately 28.3% of gross inventory value and at December 31, 2023 the provision was US$11.3 million, or approximately 36.3% of gross inventory value. The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has decreased between 2024 and 2025 due to the physical scrapping of obsolete inventory.

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, 2025 (2024: US$0.5 million) (2023: US$0.6 million) would result. For further information, refer to Note 16.

Business Combinations

The Group did not complete any business combinations during the year. The Group completed three business combinations during 2024: 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 2024, 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 IDA Business Park, Bray County Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland	100%
Trinity Research Limited IDA Business Park, Bray County Wicklow, Ireland	Research and development	Ireland	100%
Trinity Biotech Manufacturing Services Limited IDA Business Park, Bray County Wicklow, Ireland	Dormant	Ireland	100%
Trinity Biotech Luxembourg Sarl 1, rue Bender, L-1229 Luxembourg	Investment and provision of financial services	Luxembourg	100%
Trinity Biotech Inc Girts Road, Jamestown, NY 14702, USA	Holding Company	U.S.A.	100%
Clark Laboratories Inc Trading as Trinity Biotech (USA) Girts Road, Jamestown NY14702, USA	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Mardx Diagnostics Inc 5919 Farnsworth Court Carlsbad CA 92008, USA	Dormant	U.S.A.	100%
Biopool US Inc (trading as Trinity Biotech Distribution) Girts Road, Jamestown NY14702, USA	Sale of diagnostic test kits	U.S.A.	100%
Primus Corporation 4231 E 75th Terrace Kansas City, MO 64132, USA	Manufacture and sale of diagnostic test kits and instrumentation	U.S.A.	100%

32. GROUP UNDERTAKINGS (CONTINUED)

Name and registered office	*Principal activity*	*Principal Country of incorporation and operation*	*Group % holding*
Phoenix Bio-tech Corp. 1166 South Service Road West Oakville, ON L6L 5T7 Canada.	Dormant	Canada	100%
Fiomi Diagnostics Holding AB Dag Hammarskjöldsv 52A SE-752 37 Uppsala Sweden	Discontinued operation (in liquidation)	Sweden	100%
Fiomi Diagnostics AB Dag Hammarskjöldsv 52A SE-752 37 Uppsala Sweden	Discontinued operation (in liquidation)	Sweden	100%
Trinity Biotech Do Brasil Comercio e Importacao Ltda Rua Silva Bueno 1.660 – Cj. 101/102 Ipiranga Sao Paulo Brazil	Sale of diagnostic test kits	Brazil	100%
Trinity Biotech (UK) Ltd Mills and Reeve LLP Botanic House 100 Hills Road Cambridge, CB2 1PH United Kingdom	Sales & marketing activities	UK	100%
Immco Diagnostics Inc 60 Pineview Drive Buffalo NY 14228, USA	Manufacture and sale of autoimmune products and laboratory services	U.S.A.	100%
Nova Century Scientific Inc 5022 South Service Road Burlington Ontario Canada	Manufacture and sale of autoimmune products and infectious diseases	Canada	100%
Trinity Biotech Investment Ltd PO Box 309 Ugland House Grand Cayman KY1-1104 Cayman Islands	Investment and provision of financial services	Cayman Islands	100%

32. GROUP UNDERTAKINGS (CONTINUED)

Name and registered office	*Principal activity*	*Principal Country of incorporation and operation*	*Group % holding*
Trib Biosensors Inc. 27700 S.W. 95th Avenue, Wilsonville, Oregon 97070, USA	Manufacturing, development, and sale of biosensors	USA	100%
Konamite Limited IDA Business Park, Bray County Wicklow, Ireland	Research and development	Ireland	100%
Trinity Biotech Joint Venture Limited IDA Business Park, Bray County Wicklow, Ireland	Holding Company	Ireland	100%
EpiCapture Limited 19 Mather Road, Mount Merrion, Dublin, Ireland	Research and development	Ireland	100%
Metabolomics Diagnostics Limited Hoffman Park, Inchera, Little Island, Co. Cork, Ireland	Research and development	Ireland	100%
Waveform Technologies Inc. Obrtna cesta 18, 8310 Sentjernej, Slovenia	Manufacturing, development, and sale of biosensors	Slovenia	100%

COMPANY STATEMENT OF COMPREHENSIVE INCOME

	Year ended December 31,	
	2025	*2024*
	US$'000	US$'000
Loss for the year	(9,699)	(10,166)
Total comprehensive loss (all attributable to equity holders)	(9,699)	(10,166)

COMPANY STATEMENT OF FINANCIAL POSITION

	Notes	*December 31, 2025* US$'000	December 31, 2024 US$'000
ASSETS			
Non-current assets			
Investment in subsidiaries	35	10,401	10,077
Total non-current assets		10,401	10,077
Current assets			
Receivables from Group undertakings and other receivables	36	15,100	23,768
Cash and cash equivalents	37	37	192
Total current assets		15,137	23,960
TOTAL ASSETS		25,538	34,037
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	19	40	4,190
Share premium	19	63,800	63,397
Equity component of convertible note	38	6,709	6,709
Treasury Shares	19	(24,922)	(24,922)
Other reserves	19	4,314	-
Accumulated deficit		(43,101)	(33,726)
Total equity		6,840	15,648
Current liabilities			
Other payables	39	2,369	2,988
Total current liabilities		2,369	2,988
Non-Current liabilities			
Convertible note	38	16,329	15,401
Total Non-Current liabilities		16,329	15,401
TOTAL LIABILITIES		18,698	18,389
TOTAL EQUITY AND LIABILITIES		25,538	34,037

The Group is availing of the exemption in Section 304 of the Companies Act 2014 from filing its Company Statement of Comprehensive Income. The loss for the financial year generated by the Company is US$9,699,000 (2024 loss: US$10,166,000).

The financial statements were approved and authorised for issue by the Board on September 8, 2026 and signed on its behalf by:

John Gillard
Director

Paul Murphy
Director

COMPANY STATEMENT OF CHANGES IN EQUITY

	Share capital 'A' ordinary shares	*Share premium*	*Treasury Shares*	*Equity component of convertible note*	*Other reserves*	*Accumulated (deficit)/surplus*	*Total*
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Balance at January 1, 2024	**1,972**	**46,619**	**(24,922)**	**6,709**	**-**	**(24,876)**	**5,502**
Loss for the period	**-**	**-**	**-**	-	-	**(10,166)**	**(10,166)**
Total comprehensive loss	-	-	-	**-**	**-**	**(10,166)**	**(10,166)**
Shares issued in the year (Note 19)	2,218	16,778	-	**-**	**-**	**-**	**18,996**
Shares to be issued (Note 19)	-	-	-	**-**	**-**	**-**	**-**
Share-based payments (Note 20)	-	-	-	-	-	1,316	**1,316**
Balance at December 31, 2024	**4,190**	**63,397**	**(24,922)**	**6,709**	**-**	**(33,726)**	**15,648**
Balance at January 1, 2025	**4,190**	**63,397**	**(24,922)**	**6,709**	**-**	**(33,726)**	**15,648**
Loss for the period	**-**	**-**	**-**	**-**	**-**	**(9,699)**	**(9,699)**
Total comprehensive loss	**-**	**-**	**-**	**-**	**-**	**(9,699)**	**(9,699)**
Reclass on reduction of nominal value of shares (Note 19)	(4,314)	-	-	-	4,314	-	**-**
Shares issued in the year (Note 19)	164	449	-	-	-	-	**613**
Share issue expenses (Note 19)		(46)					**(46)**
Share-based payments (Note 20)	-	-	-	-	-	324	**324**
Balance at December 31, 2025	**40**	**63,800**	**(24,922)**	**6,709**	**4,314**	**(43,101)**	**6,840**

COMPANY STATEMENT OF CASH FLOWS

US$'000	Notes	*Year ended December 31,* *2025* US$'000	*2024* US$'000
Cash flows from operating activities			
Loss for the year		(9,699)	(10,166)
Adjustments to reconcile net loss to cash provided by operating activities:			
Gain on sale of subsidiary undertaking		-	-
Write off		-	9
Income tax credit		-	-
Financial expense		1,258	1,189
Financial income		(3,907)	(3,512)
Share-based payments		-	-
Provision for impairment of investment in subsidiaries	35	-	427
Provision for impairment on amounts due from subsidiaries		9,721	7,204
Operating cash outflow before changes in working capital		**(2,627)**	**(4,849)**
Decrease in receivables from group undertakings and other receivables		-	223
(Increase)/decrease in other payables		(614)	(421)
Net cash outflow from operating activities		**(3,241)**	**(5,047)**
Cash flows from investing activities			
Proceeds from sale of investment		-	-
Interest paid on convertible note		(300)	(300)
Net cash received/(paid) from/to group undertakings		3,386	5,207
Net cash inflow from investing activities		**3,086**	**4,907**
(Decrease)/increase in cash and cash equivalents		(155)	(140)
Cash and cash equivalents at beginning of year		192	332
Cash and cash equivalents at end of year	37	**37**	**192**

During the year ended December 31, 2025, the Company issued 13,447,000 'A' Ordinary shares settled for cash. The associated cash consideration of $0.6 million was received by another Group entity on behalf of Trinity Biotech plc, the ultimate beneficiary. As a result, this transaction is presented within "Net cash received/(paid) from/to group undertakings" in the Company's Statement of Cash Flows.

33. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES – COMPANY

The principal accounting policies adopted by the Group in the consolidated financial statements are set out in Note 1. These accounting policies have also been applied by the Company in the preparation of its separate financial statements.

a) Statement of compliance

The separate financial statements of the Company ("Company financial statements") have been prepared in accordance with IFRSs as adopted by the EU and as applied in accordance with the Irish Companies Act 2014 which permit a company, that publishes its Company and Group financial statements together, to take advantage of the exemption in Section 304 of the Companies Act, 2014 from presenting to its members its Company Statement of Operations and related notes that form part of the approved Company financial statements.

b) Non-current assets

Non-current assets comprise investments in subsidiaries.

c) Investments in subsidiaries

Investments in subsidiaries are shown at cost less provisions for impairment in value.

d) Amounts due from Group undertakings

Amounts due from Group undertakings are repayable on demand and are shown in current assets net of any provisions for impairment in value.

34. PERSONNEL EXPENSES AND AUDITORS' REMUNERATION - COMPANY

	Company December 31, 2025 US$'000	*Company December 31, 2024 US$'000*
Wages and salaries	1,288	1,194
Social welfare costs	80	104
Pension costs	41	44
Share-based payments	324	931
	1,733	2,273
Less costs related to subsidiaries*	(1,466)	(2,130)
Total personnel expenses charge	267	143

* Certain key management wages and salaries costs, social welfare costs, share-based payments expense and pension costs were related to employees of Trinity Biotech Manufacturing Limited and Trinity Biotech Inc., subsidiaries of Trinity Biotech plc.

The average number of persons employed by the Company (excluding non-executive directors), all in administration, in the financial year was 0.5 (2024: 1).

Auditors' remuneration – Company
The Company incurred auditors' fees of US$114,000 in 2025 (2024: US$107,000) which were paid by a subsidiary of the Company. These were incurred in respect of the following categories:

Company	**2025 US$'000**	**2024 US$'000**
Audit of individual company accounts	97	97
Other assurance services	-	-
Tax advisory services	17	10
Other non-audit services	-	-

35. INVESTMENT IN SUBSIDIARIES – COMPANY

The movement on investments in subsidiaries is as follows:

	Company December 31, 2025 US$'000	*Company December 31, 2024* US$'000
Balance at January 1	10,077	4,894
Subscription for shares in new subsidiary undertaking	-	4,294
Capital contribution – share-based payments	324	1,316
Impairment of investments	-	(427)
Balance at December 31	10,401	10,077

Subscription for shares in new subsidiary undertaking
In 2024, the Company acquired two wholly owned direct subsidiaries, EpiCapture Limited and Metabolomic Diagnostics Limited, through equity investments of US$3,384,000 and US$910,000, respectively.

Capital contribution – share-based payments
The share-based payments represent additional capital contributions made to the Company's subsidiaries to reflect the value of employee services received by these subsidiaries borne by the parent Company.

Impairment of investments in subsidiaries
The annual impairment review performed at December 31, 2025 concluded that no impairment charge was required in respect of the Company's investments in subsidiaries and, accordingly, no impairment charge was recognised in 2025 (2024: US$427,000). The impairment charge in 2024 related to the investments in the parent of our US subsidiaries, Trinity Biotech Inc.

36. AMOUNTS DUE FROM GROUP UNDERTAKINGS AND OTHER RECEIVABLES - COMPANY

	Company December 31, 2025 US$'000	*Company December 31, 2024 US$'000*
Amounts due from Group undertakings falling due in less than one year	15,100	23,768
Consideration owing on sale of subsidiary undertaking	-	-
Prepayments	-	-
	15,100	23,768

Amounts due from Group undertakings falling due in less than one year are shown net of provisions for impairment in value. Amounts due from Group undertakings are deemed to be repayable on demand and are therefore recorded in Current Assets.

37. CASH AND CASH EQUIVALENTS - COMPANY

	Company December 31, 2025 US$ '000	*Company December 31, 2024 US$ '000*
Cash at bank	37	192

Cash relates to all cash balances which are readily available for use at year end.

38. CONVERTIBLE NOTE - COMPANY

The movement in the 7-year convertible notes in the year ended December 31, 2025 is summarised as follows:

	December 31, 2025 US$000	*December 31, 2024 US$000*
Balance at January 1	(15,401)	(14,542)
Principal amount loaned	-	-
Loan origination costs	-	-
Equity component at date of issue	-	-
Accretion interest	(928)	(859)
Non-current liability at December 31	(16,329)	(15,401)

In May 2022, the Company announced a US$45.2 million investment from MiCo IVD Holdings, LLC. 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 US486.00 for any five consecutive NASDAQ trading days (equivalent to US$16.20 per ADS prior to the ADS ratio change in 2026). For further details on the convertible note, refer to the Company's Form 6-K filings with the SEC on April 11, 2022.

The convertible loan note is accounted for as a compound financial instrument containing both an equity and liability element. The debt component is accounted for at amortised cost in accordance with IFRS 9. At December 31, 2025, the carrying value of the convertible note's debt component was US$16.3 million (2024: US$15.4 million) and accretion interest of US$0.9 million (2024: US$0.9 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.

39. OTHER PAYABLES – COMPANY

	December 31, 2025 US$ '000	*December 31, 2024 US$ '000*
Amounts owed to Group undertakings	1,443	1,448
Accrued liabilities	926	1,540
	2,369	2,988

Amounts owed to group undertakings are unsecured and are repayable on demand. Accrued liabilities are payable at various dates over the coming months in accordance with the suppliers' usual and customary credit terms.

40. DEFERRED TAX LIABILITIES - COMPANY

Deferred tax liabilities of the Company are attributable to the following:

Deductible temporary differences	*2025 US$'000*	*2024 US$'000*
Investment in subsidiaries and interest-bearing loans to subsidiaries	-	-
Total	-	-

Unrecognised deferred tax assets

Deferred tax assets have not been recognised by the Company in respect of the following items:

	December 31, 2025 *US$'000*	*December 31, 2024 US$'000*
Management expenses carried forward	-	-
Timing difference related to interest expenses	-	-
Total	-	-

The deferred tax assets at December 31, 2025 relating to management expenses carried forward have not been recognised due to uncertainty over recoverability. In addition, there is a temporary difference between the carrying amount of investments in subsidiaries and the base cost for tax purposes of US$8.9 million, no deferred tax asset is recognised in respect of this difference.

No deferred tax asset is recognised in 2025 or 2024 in respect of a capital loss of US$8,293,000 (2024: US$8,293,000) in Trinity Biotech plc as it was not probable that there will be future capital gains against which to offset these capital losses.

41. CAPITAL AND FINANCIAL RISK MANAGEMENT – COMPANY

The Company uses a range of financial instruments (including cash, convertible note and payables) to fund its operations. These instruments are used to manage the liquidity of the Company and Group in a cost effective, low-risk manner. Working capital management is a key additional element in the effective management of overall liquidity. The Company 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 credit risk.

Effective interest rate and repricing analysis
The following table sets out all interest-earning financial assets held by the Company at December 31, indicating their effective interest rates and the period in which they re-price:

Company

December 31, 2025	*Note*	*Effective interest rate*	Total Gross	6 mths or less	6 – 12 mths	Impairment	Net
US$'000			US$'000	US$'000	US$'000	US$'000	US$'000
Cash and cash equivalents	*37*	*0%*	37	37	-	-	37
Amounts due from Group undertakings falling due within one year	*36*	*0%-8.75%*	212,090	212,090	-	(196,990)	15,100
Total			212,127	212,127	-	(196,990)	15,137

Company

December 31, 2024	*Note*	*Effective interest rate*	Total Gross	6 mths or less	6 – 12 mths	Impairment	Net
US$'000			US$'000	US$'000	US$'000	US$'000	US$'000
Cash and cash equivalents	*37*	*0%*	192	192	-	-	192
Amounts due from Group undertakings falling due within one year	*36*	*0%-8.75%*	211,041	211,041	-	(187,273)	23,768
Total			211,233	211,233	-	(187,273)	23,960

41. CAPITAL AND FINANCIAL RISK MANAGEMENT – COMPANY continued

Interest rate risk
At December 31, 2025, the Company had a convertible note of with a nominal value of US$20.0 million with a fixed interest rate of 1.5% and had cash and cash equivalents of US$37,000 (2024: US$192,000). Amounts owed by and to subsidiaries carry a variable rate of interest.

Interest rate profile of financial assets and liabilities
The interest rate profile of the financial assets and liabilities of the Company was as follows:

	December 31, 2025 US$ '000	*December 31, 2024 US$ '000*
Variable rate instruments		
Amounts owed by Group undertakings	15,100	23,768
Amounts owed to Group undertakings	(1,443)	(1,448)
	13,657	22,320

Cash flow sensitivity analysis for variable rate instruments
An increase of 1% in interest rates at the reporting date would have the effect of decreasing the loss for the period by US$537,000. This assumes that all other variables remain constant.

The table below sets out the Company's classification of each class of financial assets and liabilities and their fair values:

	Note	*Loans and receivables*	*Liabilities at amortised cost*	*Total carrying amount*	*Fair value*
December 31, 2025					
US$'000					
Amounts due from Group undertakings	*36*	15,100	-	15,100	15,100
Cash and cash equivalents	*37*	37	-	37	37
Convertible note	*38*	-	(16,329)	(16,329)	(16,329)
Inter-company and other payables	*39*	-	(2,369)	(2,369)	**(2,369)**
		15,137	(18,698)	(3,561)	(3,561)

	Note	*Loans and receivables*	*Liabilities at amortised cost*	*Total carrying amount*	*Fair value*
December 31, 2024					
US$'000					
Amounts due from Group undertakings	*36*	23,768	-	23,768	23,768
Cash and cash equivalents	*37*	192	-	192	192
Convertible note	*38*	-	(15,401)	(15,401)	(15,401)
Inter-company and other payables	39	-	(2,988)	(2,988)	(2,988)
		23,960	(18,389)	5,571	5,571

41. CAPITAL AND FINANCIAL RISK MANAGEMENT – COMPANY continued

Liquidity risk

The following are the contractual maturities of financial liabilities, including estimated interest payments:

As at December 31, 2025 US$'000	*Note*	*Carrying amount* US$'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								
Convertible note	*38*	16,329	21,025	150	150	300	20,425	-
Inter-company and other payables	*39*	2,369	2,369	2,369	-	-	-	-
		18,698	23,394	2,519	150	300	20,425	-

As at December 31, 2024 US$'000	*Note*	*Carrying amount* US$'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								
Convertible note	*38*	15,401	21,350	150	150	300	900	19,850
Inter-company and other payables	*39*	2,988	2,988	2,988	-	-	-	-
		18,389	24,338	3,138	150	300	900	19,850

Foreign exchange risk
The majority of the Company's activities are transacted in US Dollars. As only a small proportion of the activities of the Company are in other currencies the level of foreign exchange risk is negligible.

Credit risk
The Company has investments in and made advances to subsidiary undertakings. The carrying amount of these investments and advances 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 and a provision made for any impairment.

The carrying amount reported in the balance sheet for cash and cash equivalents and loans to subsidiaries approximates 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:

	Note	*Carrying value* December 31, 2025 US$'000	*Carrying value* December 31, 2024 US$'000
Amounts due from Group undertakings	*36*	15,100	23,768
Cash and cash equivalents	37	37	192
		15,137	23,960

The Company is a co-guarantor of the senior secured term loan with Perceptive Advisors. The outstanding term loan balance was US$101.9 million at December 31, 2025. As per the amendments, up to US$72.5 million of the aggregate principal amount of the term loan with Perceptive is convertible at the holder's election into ADSs and the outstanding balance not so converted will be payable upon maturity. The term loan matures in January 2027. (See note 23).

Capital management
An analysis of the capital structure of the Group is contained in Note 27 and the same factors apply to the capital structure of the Company.

42. RELATED PARTY TRANSACTIONS - COMPANY

The Company has related party relationships with other subsidiaries within the Group. The Company provides permanent investment capital (Note 35) and advances to certain of its subsidiary undertakings on a periodic basis with a view to them being repaid from future cash flows. The Company's principal subsidiaries are listed in Note 32 and the Company has balances outstanding with and, in certain cases, payable to, virtually all of these companies. The aggregate receivable amounts are set out in Note 36.

The related party relationships of the Group with its subsidiaries, and with its directors and executive officers are set out in Note 26.

43. BOARD APPROVAL

The Board of Directors approved and authorised for issue the financial statements in respect of the year ended December 31, 2025 on September 8, 2026.