Trinity Biotech plc

Annual Report 2021

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

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Corporate Information

DIRECTORS

Mr. Sun-Q Jeon	South Korea	Appointed May 3, 2022
Mr Ronan O'Caoimh		
Dr Jim Walsh		
Mr John Gillard		
Mr. Aris Kekedjian	US	Appointed May 3, 2022
Mr. Michael Sung Soo Kim	South Korea	Appointed May 3, 2022
Mr Kevin Tansley		Resigned May 3, 2022
Mr Clint Severson	US	Resigned May 3, 2022
Mr James Merselis	US	Resigned May 3, 2022

COMPANY SECRETARY

Mr John Gillard

REGISTERED OFFICE

IDA Business Park,
Bray,
Co. Wicklow,
Ireland.

LEGAL ADVISORS

Matheson,
70 Sir John Rogerson's Quay
Dublin 2,
Ireland

William Fry,
2 Grand Canal Square,
Dublin 2,
Ireland.

Carter, Ledyard & Milburn,
2 Wall Street,
New York,
United States of America.

AUDITOR

Grant Thornton
Chartered Accountants and Registered Auditors,
City Quay,
Dublin 2,
Ireland.

DEPOSITARY FOR AMERICAN SHARES

Bank of New York,
101 Barclay Street,
New York,
United States of America.

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 "Risk Factors" below.

Cautionary Statement Regarding Forward-Looking Statements

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

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

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

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 "Risk Factors" section of this Annual Report.

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.

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 with the understanding that our actual future results or performance may be materially different from what we expect.

Board of Directors and Executive Officers

Sun-Q Jeon, Chairman, joined the Board of Trinity Biotech as Chariman in May 2022. He is also Chairman of MiCo Ltd., Chief Executive Officer at KoMiCo Technology, Inc. (a subsidiary of MiCo Ltd.), Chairman for MiCo BioMed Co. Ltd. and Chairman for KoMiCo Ltd. He. He received an undergraduate degree from Seoul National University.

Ronan O'Caoimh, Chief Executive Officer, co-founded Trinity Biotech in June 1992 and acted as Chief Financial Officer until March 1994 when he became Chief Executive Officer. He was also elected Chairman in May 1995. In November 2007, it was decided to separate the role of Chief Executive Officer and Chairman and Mr O'Caoimh assumed the role of Executive Chairman. In October 2008, following the resignation of the Chief Executive Officer, Mr O'Caoimh resumed the role of Chief Executive Officer and Chairman. Prior to joining Trinity Biotech, Mr O'Caoimh was Managing Director of Noctech Limited, an Irish diagnostics company. Mr O'Caoimh was Finance Director of Noctech Limited from 1988 until January 1991 when he became Managing Director. Mr O'Caoimh holds a Bachelor of Commerce degree from University College Dublin. On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by a management agreement with Darnick Company. This arrangement ceased with effect from December 31, 2018 with Ronan O'Caoimh returning as an employee of the company.

Jim Walsh, PhD, Executive Director, initially joined Trinity Biotech in October 1995 as Chief Operations Officer. Dr Walsh resigned from the role of Chief Operations Officer in 2007 to become a Non- Executive Director of the Company. In October, 2010 Dr Walsh rejoined the company as Chief Scientific Officer. Dr Walsh transferred from this position in 2015 and focuses on Business Development activities. Prior to joining Trinity Biotech, Dr Walsh was Managing Director of Cambridge Diagnostics Ireland Limited ("CDIL"). He was employed with CDIL since 1987. Before joining CDIL he worked with Fleming GmbH as Research & Development Manager. Dr Walsh holds a PhD degree in Chemistry from University College Galway.

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

Aris Kekedjian, Non-executive Director, joined the Board of Trinity Biotech in May 2022. Mr. Kekedjian spent 30 years in GE in several senior roles, including as GE's Chief Investment Officer and Global Head of Business Development. Mr. Kekedjian previously held roles as President & Chief Executive Officer at Icahn Enterprises, Senior Advisor to ECN Capital, and Independent Director of various public companies including Xerox Corporation, Finserv Acquisition Corp. and XPO Logistics, Inc. He is currently Managing Partner at Webbs Hill Partners LLP. He received his undergraduate degree from Concordia University.

Michael Sung Soo Kim, Non-Executive Director, joined the Board of Trinity Biotech in May 2022**.** Mr. Kim has a wealth of financial experience having spent the last three decades within international finance across areas such as Asset Management, Real Estate Investments, Robo-Advisory and Wealth Management and has held several senior executive positions including CEO of Hyundai Securities Asia.

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

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

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 a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. This is a technology driven market with an emphasis on automation and emerging biomarkers. Trinity actively works on increasing automation for the clinical laboratory. Trinity seeks to bring novel biomarkers to market by licensing agreements with universities and innovative companies.

The Group's competition includes several large companies such as, but not limited to: Abbott Diagnostics, Arkray, Bio-Rad, Diasorin Inc., Johnson & Johnson, Roche Diagnostics, Siemens, Chembio, Thermo Fisher, Copan, Becton Dickenson and Tosoh.

Products and services

Our product and services portfolio is divided between Clinical Laboratory tests, Point-of-Care tests and Laboratory services. In 2021, our clinical laboratory division had revenue of US$74.7 million, the point-of-care division had revenue of US10.3 million and the revenue from laboratory services was US$7.9 million.

Clinical Laboratory

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

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

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

Infectious Diseases

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

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

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

Many of the products in our Infectious Diseases product line are FDA cleared for sale in the United States and CE marked in Europe. Products are sold in approximately 100 countries in total, with the focus on the Americas, Europe and Asia. The infectious disease products are sold through the sales and marketing organisation of Trinity Biotech to a variety of customers including public health authorities, clinical and reference laboratories directly in the U.S. and U.K. and through independent distributors and strategic partners in other countries.

Diabetes and Haemoglobinopathies

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

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

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

Trinity Biotech has launched the Premier Resolution, its next generation Haemoglobinapothy Analyzer in Europe and the Middle East after undergoing rigorous and successful field trials. The Company expects to obtain FDA approval of the Premier Resolution in 2022 or 2023. The submission has been significantly delayed due to the Covid-19 pandemic. The Premier Resolution uses an internally designed column as well as state of the art hardware and software.

Autoimmune Diseases

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

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

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

The Immco products are a seamless fit for the instrument platforms that Trinity Biotech markets for its infectious diseases portfolio. Additionally, Trinity sells a complete line of IFA processors. Many of Immco's products are FDA cleared for sale in the U.S. and CE marked in Europe.

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, 2021.

The Immco product line addresses the high growth, lower throughput, specialty autoimmune segment, where competition is limited. The principal autoimmune conditions in this segment are Rheumatoid Arthritis, Vasculitis, Lupus, Celiac and Crohn's Disease, Ulcerative Colitis, Neuropathy, Hashimoto's Disease and Grave's Disease.

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

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

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

Clinical Chemistry

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

Blood Bank Screening

Trinity Biotech manufactures enzyme-linked immunosorbent assays ("ELISA"), for the detection of Syphilis and Malaria. These products are sold through distributors and are manufactured under original equipment manufacturer agreements for other major third party diagnostic companies. The business is not currently operating in the United States.

In relation to products revenues are directly related to our ability to identify significant revenue-generating products while they are still in development and to bring them to market quickly produced at our facilities – these are as follows:

Bray, Ireland – Point-of-Care/HIV, Clinical Chemistry and Viral Transport Media products are manufactured at this site.

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

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

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.

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

Directors' Report
Year ended December 31, 2021

Principal activities

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

Business review

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

Clinical Laboratory goods revenues decreased by US$9.6 million in 2021, which represents a decrease of 11.4%. The decrease is mainly due to lower sales of our PCR VTM. In 2021, there was a partial return towards more normalised level of Haemoglobins testing. While COVID-19 public health restrictions remained in place in 2021 in many markets, these restrictions were not as severe as in 2020. As a result, diabetic related testing revenues increased by almost 20% in 2021 and we are continuing to see increasing demand for these instruments and consumables as diabetic testing programmes continue their return to normalisation. Offsetting this increase was lower sales in our haemoglobinopathies products due to the recall of the Ultra II instrument in U.S. in the early part of 2021.

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

Point-of-Care revenues increased from US$9.2 million in 2020 to US$10.3 million in 2021, an increase of US$1.1 million or 12.0%. This was driven by higher HIV sales in Africa.

The gross margin of 41.0% in 2021 compares to a gross margin of 47.6% in 2020. Gross margin remains susceptible to product mix changes, geographic spread, currency fluctuations and product level variation. The reduction in the gross margin in 2021 compared to 2020 is mainly due to comparatively higher sales prices for VTM in 2020 caused by exceptionally high demand with prices and consequently gross margin reducing progressively during 2021.

Other operating income increased from US$1.9 million in 2020 to US$4.7 million in 2021. In both years, this income almost entirely comprises income received under the U.S. government's Cares Act, principally its PPP and its Provider Relief Fund.

Research and development ("R&D") expenditures decreased from US$5.1 million in 2020 to US$4.5 million in 2021. The decrease in costs in 2021 is mainly due to the closure of an R&D centre located in Carlsbad, California in June 2020.

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

The Company recognized impairment charges of US$6.9 million in 2021. In 2020, the impairment charges were US$17.8 million. In accordance with the provisions of accounting standards under IFRS, a company is required to carry out impairment reviews in order to determine the appropriate carrying value of its net assets. A number of factors impacted this calculation including cash flow projections and net asset values across each of the Group's cash generating units, the Company's share price at the date on which the impairment test is performed (in 2021, two tests were performed, one at June 30 and one at December 31) and the cost of capital.

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

Financial income increased by US$1.2 million from US$0.04 million for the year-end December 31, 2020 to US$1.2 million in 2021. There was a decrease of US$33,000 in bank deposit interest mainly due to lower interest rates and an increase of US$1.2 million in the income arising from the revaluation of embedded derivatives at fair value. Financial expenses increased by US$0.3 million to US$7.1 million during 2021 due to loan origination costs of US$1.7 million incurred in 2021 relating to the new senior secured loan credit facility ("Term loan") from Perceptive Advisors which was drawn down in 2022. Offsetting this an expense of US$1.2 million which arose in 2020 from revaluation of embedded derivatives at fair value. The equivalent revaluation in 2021 is a gain which is recorded in financial income.

The Group recorded a tax credit on continuing operations of US$0.2 million for the year ended December 31, 2021 compared to a tax credit of US$0.6 million for the year ended December 31, 2020. The 2021 tax credit consists of US$0.2 million of current tax credit and US$0.04 million of a deferred tax charge. In 2020, the tax credit comprised US$0.4 million of current tax credit and US$0.2 million of a deferred tax credit.

The profit for the year from continuing operations was US$0.9 million, compared to a loss of US$6.0 million in 2020. The loss on discontinued operations is US$0.05 million in year ended December 31, 2021, which is mainly due to administrative expenses.

Dividends

In 2011 the Company announced that it intended to commence a dividend policy, to be paid once a year. As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars. Following on from this announcement, a dividend was paid in respect of the 2010 financial year. Dividends were paid in each of the four subsequent years, 2011 to 2014. In 2016, the Company announced that it was suspending dividend payments in order to commence a share repurchase programme. No dividend has been proposed in respect of the financial years 2015 to 2021.

Going Concern

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the closing of the financing with Perceptive Advisers and the Covid-19 pandemic. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At the date of this report the Group's financial position has substantially improved following the successful re-financing of the Group's debt in early 2022. This has significantly improved the Group's capital structure by reducing gross debt by approximately US$19 million and there are no material debt maturities in the next four years. Furthermore, the investment by MiCo IVD Holdings LLC, a subsidiary of the MiCo Group, will facilitate our exploring lower cost debt funding options, with the aim of further reducing our interest expense through refinancing the balance of the Group's Term Loan at lower interest rates. In May 2022, the Company announced the successful closing of a US$45 million strategic investment and partnership with the MiCo Group, a KOSDAQ-listed company. The investment consists of an equity investment of approximately US$25.2 million and a seven-year, unsecured junior convertible note issued by Trinity Biotech of US$20 million, with a fixed interest rate of 1.5% and an ADS conversion price of US$3.24 per ADS.

Developments during the year

In December 2021, the Company announced that it and its subsidiaries entered into a $81,250,000 senior secured term loan credit facility with Perceptive Advisors ("Perceptive"), an investment manager with an expertise in healthcare. Proceeds from the Term Loan, along with existing cash and the issuance of new American Depository Shares ("ADS") in the Company, were used to retire the 30-year Exchangeable Notes in early 2022. The Term Loan will mature on the fourth anniversary of the drawdown date and accrues interest at an annual rate equal to 11.25% plus the greater of (a) one-month LIBOR and (b) one percent per annum, and interest will be payable monthly in arrears in cash. The Term Loan does not require any amortization, and the entire unpaid balance will be payable upon maturity. The

Term Loan can be repaid, in part or in full, at a premium before the end of the four-year term. In connection with the Term Loan the Company has agreed, subject to drawdown of the Term Loan, to issue warrants (the "Warrants") exercisable for 2,500,000 of the Company's ADSs to Perceptive. The per ADS exercise price of the Warrants is equal to the lower of i) the 10-day volume weighted average price ("VWAP") for the Company's ADSs for the 10 business days prior to the Closing Date of the Credit Agreement for the Term Loan and ii) the 10-day VWAP for the Company's ADSs for the 10 business days prior to the drawdown date of the funding under the Term Loan. The Warrants are exercisable, in whole or part, until the seventh anniversary of the date of drawdown of the funding under the Term Loan.

In addition to the Term Loan, the Company has entered into exchange agreements (the "Exchange Agreements") with five institutional investors that hold approximately $99,700,000 of the outstanding Notes, which were puttable by the holders to the Company, at par, in April 2022. Under the terms of this agreement each holder has agreed to exchange their Notes at a discount to par and each holder will receive $0.87 of cash and the equivalent of $0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 9, 2021, discounted by 13%) per $1 nominal value of the Notes. This results in an effective discount on the exchange of the Notes of approximately 4%. The re-financing benefits the Company's capital structure by reducing gross debt by approximately $19 million with the Company having no material debt maturities before 2026. In addition, the fact that the Term Loan can be repaid, in part or in full, before the end of the four-year term should allow the Company increased optionality regarding its future capital structure. In May 2022, the Group repaid approximately $35 million of the Term Loan.

Key Performance Indicators

The key financial indicators are set out below:

	2021	***2020***
	US$'000	US$'000
Revenue	92,965	101,980
Operating profit	6,625	82
Profit/(loss) for the year	875	(6,388)

Research and Development activity

Historically, Trinity Biotech had been primarily focused on infectious diseases diagnostics. The Group acquired a broad portfolio of microtitre plate ("EIA") and Western Blot products and has added to these over the last number of years through additional internally developed products. More recently, the Group has entered into several other diagnostic areas including Point-of-Care ("POC") and clinical chemistry. The Research and Development ("R&D") activities of the Group have mirrored this expansion by developing new products in these areas also.

Haemoglobin Development Group

Premier Hb9210 Instrument for Haemoglobin A1c Testing

This project entails the development of a new HPLC instrument for testing HbA1c. Development was initiated in late 2007 and was launched outside of the United States in 2011 and in the United States in early 2012.

As part of our continuous improvement a new monitor, keyboard and frit housing have been customised and validated. These improvements maintain the competitiveness of the instruments.

Premier Resolution Instrument for Haemoglobin Variant Testing

We have developed the Premier Resolution instrument which is utilised for haemoglobin variant testing and is currently being rolled out in certain international markets outside of the USA. We expect to obtain FDA 510(k) approval of the Premier Resolution in 2022 or 2023. Meanwhile, Premier Resolution continues to be enhanced with unique features such as lot specific gradients, an optimised internally designed column with extended column life, and a rapidly expanding on-board variant library.

Low to Medium throughput Haemoglobin instrument for A1c Testing

We are developing a low to medium throughput Haemoglobin A1c instrument with a view to targeting the market segment for testing volumes which lie between the Tri-stat 2.0 and Premier Hb9210. We are targeting a launch date in 2023.

Point-of-Care Development Group

We have developed a rapid Covid-19 antigen test, which received CE marking for professional use only in 2022.

A syphilis point-of-care rapid test is also being developed using our existing lateral flow format. In 2021, other projects were prioritized, but it is expected this project will resume within the next twelve months.

Autoimmunity Development Group

IFA Smart Reader Project

We are developing two devices which will enable cell based Immunofluorescence Assays (IFA) to be read in a more automated manner. The first device, ScopeSmart will be an automated IFA reader capable of performing image capture, pattern recognition and analysis on IFA slides. This will then be followed by SlideSmart which will fully automate this entire testing process by integrating the sample preparation.

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 several new diagnostic tests and instrumentation, while at the same time enhancing its existing products.

Important events since the year end

Debt refinancing

In January 2022, the Company successfully closed a US$81,250,000 senior secured term loan credit facility with Perceptive Advisors, an investment manager with an expertise in healthcare. Proceeds from the Term Loan, along with existing cash and the issuance of 5.3 million American Depository Shares in the Company, were used to retire approximately US$99.7 million of the Exchangeable Notes.

The financial effect of these transactions is:

- the Group paid a total amount of US$86,730,000 to retire Exchangeable Notes with a carrying value of US$83,312,000 at December 31, 2021. Each holder that was party to the agreement received US$0.87 of cash per $1 nominal value of the Notes, and
- the Company also issued 5,333,000 ADSs (21,332,000 'A' Ordinary shares) representing the equivalent of $0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 9, 2021, discounted by 13%) per $1 nominal value of the Notes, as partial consideration for the exchange of the notes.

Approval of TrinScreen test by World Health Organisation

In February 2022, the Company received approval from the World Health Organisation for its new HIV screening product, TrinScreen™ HIV.

Strategic Investment and Partnership with The MiCo Group

In April 2022, the Group announced a US$45 million strategic investment and partnership with MiCo, a KOSDAQ-listed and Korea-based company. The investment consists of an equity investment of approximately US$25,200,000 (11,200,000 ADSs at a price of US$2.25 per ADS) and a seven-year, unsecured junior convertible note issued by Trinity Biotech of US$20 million, with a fixed interest rate of 1.5% and an ADS conversion price of US$3.24 per ADS. The convertible note mandatorily converts into ADS if the volume weighted average price of the Group's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days. The Group used these funds primarily to repay a portion of the Group's US$81.25 million Term Loan in May 2022. The Group also expects that this investment will facilitate it exploring lower cost debt funding options with the aim of further reducing the company's interest expense through refinancing the balance of the Group's Term Loan at lower interest rates.

In May 2022, the founder and chair of MiCo, Sun-Q Jeon, became Chairperson of Trinity Biotech and Aris Kekedjian and Michael Sung Soo Kim joined the Board. Kevin Tansley, Clint Severson and James Merselis retired from the Board.

Repayment of Term Loan debt

In May 2022, the Company made an early partial settlement of the senior secured term loan of approximately US$35 million and in accordance with the Term Loan's credit agreement, there was a penalty for early repayment of US$3.5 million. A total cash payment of US$38 million was made to Perceptive Advisors during the second quarter of 2022. After this repayment, the nominal amount of the outstanding Term Loan is approximately US$47 million. The part repayment of the loan reduces the ongoing annual interest payments by approximately US$4 million.

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, 2021, December 31, 2020 or subsequent date of appointment, except as follows:

	Number of 'A' Ordinary Shares December 31, 2021	Number of 'A' Ordinary Shares December 31, 2020	Number of options* December 31, 2021	Number of options* December 31, 2020	Weighted average exercise price of options outstanding at December 31, 2021	Weighted average exercise price of options outstanding at December 31, 2020
Directors						
Sun-Q Jeon	-	-	-	-	-	-
Ronan O'Caoimh**	7,057,501	7,057,501	11,704,000	11,704,000	US$0.69	US$0.69
John Gillard	-	-	600,000	600,000	US$0.67	US$0.67
Jim Walsh	1,393,612	1,393,612	1,510,000	1,510,000	US$1.00	US$1.00
Kevin Tansley	150,000	150,000	1,664,000	1,664,000	US$0.79	US$0.79
Aris Kekedjian	-	-	-	-	-	-
Michael Sung Soo Kim	-	-	-	-	-	-
James Merselis	188,600	188,600	630,000	630,000	US$0.79	US$0.79
Clint Severson	288,000	288,000	630,000	630,000	US$0.79	US$0.79

* 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 options during the year is as follows;

	Number of options held at January 1, 2021	Options granted during the year	Options lapsed /exercised/forfeited during the year	Number of options held at December 31, 2021
Directors				
Sun-Q Jeon	-	-	-	-
Ronan O'Caoimh	11,704,000	-	-	11,704,000
John Gillard	600,000	-	-	600,000
Jim Walsh	1,510,000	-	-	1,510,000
Kevin Tansley	1,664,000	-	-	1,664,000
Aris Kekedjian	-	-	-	-
Michael Sung Soo Kim	-	-	-	-
James Merselis	630,000	-	-	630,000
Clint Severson	630,000	-	-	630,000

The options outstanding at December 31, 2021 are exercisable and expire at various dates between 2023 and 2027. The exercise of these options is not conditional upon meeting performance criteria.

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, 2022 to July 31, 2022, the only purchases of shares by the Directors of the Company or by the Company Secretary was Ronan O'Caoimh purchased 2,666,664 'A' ordinary shares by exercising share options.

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 2020 Plan. The purpose of these Plans is to provide Trinity Biotech's employees, consultants, officers and directors with additional incentives to improve Trinity Biotech's ability to attract, retain and motivate individuals upon whom Trinity Biotech's sustained growth and financial success depends. These Plans are administered by the Board of Directors. Options under the Plans may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

The exercise price of options is determined by the Board of Directors. The term of an option will be determined by the Board, provided that the term may not exceed ten years from the date of grant. Option grants up to 30,000 'A' ordinary shares (7,500 ADRs) are administered by the Compensation Committee and subsequently ratified by the Board. The Committee will also determine the exercise price and term of these options. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity Biotech (or one year after such termination because of death or disability) except where a longer period is approved by the board of directors.

Under certain circumstances involving a change in control of Trinity Biotech, the Board may accelerate the exercisability and termination of options.

Transactions with directors

There were no transactions with directors other than those outlined in Note 27 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 basis for the executive directors' remuneration and level of annual bonuses is recommended by the Remuneration Committee of the board. In 2021, the Remuneration Committee consisted of Mr. Clint Severson (Committee Chairman and Lead Director) and Mr. James Merselis. The Committee meets annually, or more often if required, to review and amend the packages of executive directors.

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.

Total directors and non-executive directors' remuneration for the year ended December 31, 2021 amounted to US$1,414,000. The split of directors' remuneration set out by director is detailed in the table below:

Director	*Title*	*Salary/ Benefits US$'000*	*Performance related bonus US$'000*	*Defined contribution pension US$'000*	*Total 2021 US$'000*
Sun-Q Jeon	Chairperson	—	—	—	—
Ronan O'Caoimh	CEO	643	—	—	643
Jim Walsh	Executive Director	20	—	—	20
John Gillard	Chief Financial Officer	346	227	20	593
Kevin Tansley	Executive Director	56	—	4	60
Aris Kekedjian	Non-Executive director	—	—	—	—
Michael Sung Soo Kim	Non-Executive director	—	—	—	—
James Merselis	Non-Executive director	49	—	—	49
Clint Severson	Non-Executive director	49	—	—	49
		1,163	227	24	1,414

Subsidiary and associate undertakings

A list of the principal subsidiary undertakings of Trinity Biotech is given in Note 33 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, Co. Wicklow.

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 medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes

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

Environment

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 products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. Trinity Biotech is a significant provider of raw materials to the life sciences and research industries globally. Trinity Biotech also operates a licenced reference laboratory that specializes in diagnostics for autoimmune diseases.

Trinity Biotech plans to continue to pursue product and technological developments through its research and development programmes. The Group is currently developing several new diagnostic tests and instrumentation, while at the same time enhancing its existing products. We believe that our products make a meaningfully positive contribution to our customers and patients.

Employees

The average number of persons employed by the group during 2021 was 477 employees. 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 - Our business is typically deemed "essential" and we have continued to operate, manufacture and distribute products to customers throughout all of 2021. We implemented health and safety policies to help safeguard our on-site employees and maintain business continuity throughout the Covid-19 pandemic. We have also enhanced cleaning procedures, provided additional personal hygiene supplies and protective equipment to employees, limited access to our facilities to visitors, trained employees on social distancing and mask wearing. Where practical, we have facilitated many employees to work remotely. While the above is what we did to ensure the pandemic was controlled in the workplace and our staff were safe we have health and safety at the centre of all we do. 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. For example, we donated food and equipment to a local homeless charity in Ireland in the summer of 2021 during the challenging COVID 19 Pandemic.

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.

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 2021 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 19-46.

Financial Instruments
An analysis of the financial instruments used by the Group is contained in Note 29 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 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. 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. 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

In 2021, the Committee was chaired by independent directors, James Merselis and includes Clint Severson. The audit committee meet as required and specifically to review the financial statements and to consider the suitability and monitor the effectiveness of internal control processes.

The Audit Committee also reviews the findings of the external auditor and reviews accounting policies and material accounting judgements. The Audit Committee normally meets at least three times in each financial year and has unrestricted access to the Group's external auditor.

Auditors

Grant Thornton, Chartered Accountants, have expressed their willingness to remain in office in accordance with Section 383 (2) of the Companies Act, 2014.

On behalf of the board
Ronan O'Caoimh
John Gillard
Directors

6 September 2022

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 Report 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 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 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 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

Investing in our shares involves a high degree of risk and uncertainty. You should carefully consider all of the information set forth in this Annual Report, including the following summary of risk factors, when investing in our securities. These risks and uncertainties reflect the international scope of our company's operations and the highly regulated industry in which it operates. The risks and uncertainties presented below, which are discussed in more detail in the Risk Factors are reviewed on an annual basis and represent the principal risks and uncertainties faced by us at the time of compilation of this annual report. During the course of 2022, new risks and uncertainties may materialise attributable to changes in markets, regulatory environments and other factors and existing risks and uncertainties may become less relevant, including the following:

Risks Related to our Business & Industry

- **Competition and trading conditions** - our ability to sell products could be adversely affected by competition from new and existing diagnostic products, changing conditions in the diagnostic market, including, inter alia, reductions in government funding and sector consolidation.
- **New product development** - our long-term success depends upon the successful development and commercialization of new products.
- **Capital structure** - we may require future additional capital.
- **Borrowings** - we have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position. To the extent we are unable to repay our debt as it becomes due with cash on hand or from other sources, we will need to refinance our debt, sell assets or repay the debt with the proceeds from equity offerings in order to continue in business. Our ability to obtain additional funding may determine our ability to continue as a going concern. Failure to comply with the terms of the credit agreement for our Term Loan could result in a default under its terms and, if uncured, could result in action against our pledged assets.
- **Product recalls and claims** - our products may in the future be subject to product recalls that could harm our reputation, business and financial results. If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or regulatory agency enforcement actions. We may be subject to liability resulting from our products or services.
- **Corporate strategy** - failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.
- **Global economic conditions** – changes in global economic conditions may have a material adverse impact on our results.
- **Pandemic impact** - the Covid-19 outbreak could significantly disrupt our operations and adversely affect our results of operations.
- **People** - we are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees or the inability to attract and retain qualified personnel as necessary could adversely affect our operations.
- **Supply chains** - significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results. We are dependent on third-party suppliers for certain critical components and the primary raw materials required for our test kits. Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.
- **Distributor network** - our revenues are highly dependent on a network of distributors worldwide. Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.
- **Cyber security** - our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.
- **Foreign exchange** - our sales and operations are subject to the risks of fluctuations in currency exchange rates.
- **Financial impairment** - the large amount of intangible assets and goodwill recorded on our balance sheet may lead to significant impairment charges in the future.
- **Taxation** - tax matters, including disagreements with taxing authorities, the changes in corporate tax rates and imposition of new taxes could impact our results of operations and financial condition.
- **Acquisitions** - future acquisitions may be less successful than expected, not generate the expected benefits, disrupt our ongoing business, distract our management, increase our expenses and adversely affect our business, and therefore, growth may be limited.

- **Brexit** - the United Kingdom's withdrawal from the European Union could potentially impact our supply chains and the market for our products in the United Kingdom.
- **Environmental, Social and Governance** - increasing scrutiny and changing expectations from investors, lenders, customers and other market participants with respect to our Environmental, Social and Governance, or ESG, policies may impose additional costs on us or expose us to additional risks.

Risks Related to Government Regulations

- **Clinical trials** - clinical trials necessary to support future premarket submissions will be expensive and will require enrolment of suitable patients who may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects. If the third parties on whom we rely to conduct our pre-clinical studies and clinical trials and to assist in pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval or commercialize our products. The results of our clinical trials may not support our product candidate claims.
- **Regulatory compliance** - we may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses. If the FDA were to modify its policy of enforcement discretion with respect to our laboratory developed tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or other approvals.
- **Product approvals** - if we fail to maintain regulatory approvals and clearances our ability to commercially distribute and market these products could suffer. Failure to comply with FDA or other regulatory requirements may require us to suspend production of our products or institute a recall which could result in higher costs and a loss of revenues. Modifications to our products may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained. Our laboratory business could be harmed from the loss or suspension of a licence or imposition of a fine or penalties under, or future changes in, the law or regulations of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), or those of other state or local agencies.
- **International regulations** - we face risks relating to our international sales and business operations, including regulatory risks, which could impact our current business operations and growth strategy.
- **Healthcare industry laws** - we are subject to various laws targeting fraud and abuse in the healthcare industry. Changes in healthcare regulation could affect our revenues, costs and financial condition.
- **Public company regulations** - compliance with regulations governing public company corporate governance and reporting is complex and expensive.

Risks Related to Our Intellectual Property

- **Proprietary rights** - we may be unable to protect or obtain proprietary rights that we utilise or intend to utilise.
- **Patent protection** – our patent protection may not be sufficiently broad to compete effectively, the existing patents could be challenged; and trade secrets and confidential know-how could be obtained by competitors. Our patent protection could be reduced or eliminated for non-compliance with various procedural requirements or due to changes in patent law. We may be involved in lawsuits to enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful. Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

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

- **Significant shareholder** – MiCo by virtue of its 29.4% shareholding has significant influence over our management and affairs and may deter a change in control or other transaction that may be favorable to our shareholders.
- **Information** - as a foreign private issuer we are exempt from a number of reporting requirements under the Exchange Act and are permitted to file less information with the SEC than a domestic U.S. reporting company.
- **Passive foreign investment company** - we may be classified as a passive foreign investment company, or PFIC, which would subject our U.S. investors to adverse tax rules.
- **Volatility** - the market price of our ADSs has been, and may continue to be, highly volatile. Future sales of our ADSs could reduce the market price of the ADSs.
- **Capital** - we expect we will need additional capital in the future.
- **Dilution** - the conversion of our outstanding employee share options, any new employee share options and existing warrants would dilute the ownership interest of existing shareholders.

- **Governed by Irish law** - it could be difficult for U.S. holders of ADSs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.
- **Dividends** - we have no plans to pay dividends on our ADSs, and you may not receive funds without selling the ADSs.
- **Voting rights of holders of ADSs** – the terms of the deposit agreement limit the voting rights of holders of ADSs.
- **NASDAQ listing standards** - our securities could be delisted from Nasdaq if we do not comply with Nasdaq's listing standards.

Risks Related to our Business & Industry

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

We have invested in research and development but there can be no guarantees that our R&D programmes will not be rendered technologically obsolete or financially non-viable by the technological advances of our competitors, which would also adversely affect our existing product lines and inventory. Our main competitors (and their principal products with which we compete) include: Premier (1st response™), Chembio (Stat-Pak™), Abbott (Determine™, SD BioLine™, Abon™, Acon™), SD Biosensor, Wondf, Bejing Wanta, Abbott Architec, Roche TinaQuant 3™, Bio_Rad (Variant 2 Turbo™, D 100™) Tosoh (G8™ & G11™) Arkray 8180™, Allere Affinion™, Siemens DCA ™, Sebia Capyllaris 2&3™, Bio-Rad Variant 2™,Sebia Capyllaris 2, Euroimmun™, Bio-Rad™, Aesku™, Inova™, Copan™, Becton Dickenson™.

The diagnostics industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues and adversely affect our results of operations, cash flow and business.

We may in certain instances also face competition from products that are sold at a lower price. Where this occurs, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products. We may also be required to increase our marketing efforts in order to compete effectively, which would increase our costs.

Our tests compete with products made by our competitors. Multiple competitors are making investments in competing technologies and products, and a number of our competitors have significantly greater financial, technical, research and other resources. Some competitors offer broader product lines and may have greater market presence or name recognition than we have. If we receive FDA or other regulatory clearance, and in order to achieve market acceptance, we and/or our distributors will likely be required to undertake substantial marketing efforts and spend significant funds to inform potential customers and the public of the existence and perceived benefits of our products. Our marketing efforts for these products may not be successful. As such, there can be no assurance that these products will obtain significant market acceptance and fill the market needs that are perceived to exist on a timely basis, or at all.

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

As of December 31, 2021, we had total indebtedness with a carrying value of approximately US$99.2 million, which included US$83.3 million of outstanding indebtedness under our 4% exchangeable notes due in 2045. The exchangeable notes have a nominal amount of US$99.9 million and include a number of put and call options. The earliest date on which holders could require Trinity Biotech to repurchase their notes at par is April 1, 2022. In January 2022, the Company repaid US$99.7 million of the exchangeable notes mainly using funds from a Term Loan from Perceptive Advisors of US$81.25 million which is repayable in 2026. The credit agreement with Perceptive Advisors (the "Credit Agreement") was signed in December 2021. In April 2022, the Company announced a US$45 million strategic investment and partnership with MiCo, a Korea-based company. The investment consisted of an equity investment of approximately US$25.2 million and a seven-year, unsecured junior convertible note of US$20 million. Using funds received from MiCo, the Group repaid approximately US$35 million of the Perceptive Term Loan in May 2022, after which the outstanding loan principal reduced to just under US$47 million. We may face further liquidity challenges if we are unable to meet obligations set forth in the Credit Agreement, including a financial covenant requiring that we achieve specified minimum total revenue amounts measured as of the end of each quarter. A breach of the minimum total revenue covenant or any other covenant in the Credit Agreement would result in a default under the Credit Agreement, which could enable the lender to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. We cannot assure you that, in such an event, we would have sufficient assets to pay amounts due under the Credit Agreement.

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

purchase orders or the development or commercialization of one or more of our products or one or more of our other research and development initiatives, sell assets and/or cease trading.

Our debt may:

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

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

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

On December 15, 2021, the Company and certain of our subsidiaries, entered into the Credit Agreement, under which we obtained a US$81,250,000 senior secured term loan credit facility. The facility was conditioned on obtaining shareholder approval. Following shareholder approval in January 2022, the loan was drawn in full on January 28, 2022. The Credit Agreement is secured by substantially all of our property and assets, including our equity interests in our subsidiaries. See Note 30 of the financial statements for further details.

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

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

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

needed for our operations, could have a material adverse effect on our business, prospects, results of operations, liquidity and financial condition.

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

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

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

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

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

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

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

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

Our long-term viability and growth will depend upon the successful discovery, development and commercialization of new and enhanced products from our research and development ("R&D") activities. In order to remain competitive, we are committed to significant expenditures on R&D and the commercialization of new or enhanced products. The R&D process generally takes a significant amount of time from product inception to commercial launch. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. We may have to abandon a new or enhanced product during its development phase after our investment of substantial time and money. During the fiscal years ended December 31, 2021, 2020 and 2019, we incurred US$6.8 million, US$6.9 million and US$9.6 million, respectively, in capitalised R&D expenses. We expect to continue to incur significant costs related to our research and development activities.

Successful products require significant development and investment, including testing to demonstrate their performance capabilities, cost-effectiveness or other benefits prior to commercialization. In addition, unless exempt, regulatory clearance or approval must be obtained before our medical device products may be sold. Additional development efforts on these products may be required before we are ready to submit applications for marketing authorisation to any regulatory authority. Regulatory authorities may not clear or approve

these products for commercial sale or may substantially delay or condition clearance or approval. In addition, even if a product is successfully developed and all applicable regulatory clearances or approvals are obtained, there may be little or no market for the product. Accordingly, if we fail to develop and gain commercial acceptance for our products, or if we have to abandon a new product during its development phase, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flow and business.

Our future growth in the U.S. is dependent in part on Food and Drug Administration ("FDA") clearance of products. If FDA clearance is delayed or not achieved for these products, it could have a material impact on the future growth of our business.

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

We may require future additional capital.

Our future liquidity and ability to meet our future capital requirements will depend on numerous factors, including, but not limited to, the following:

- The costs and timing of expansion of sales and marketing activities;
- The timing and size of any repayment requirements for existing debt obligations;
- The timing and success of the commercial launch of new products;
- The extent to which we gain or expand market acceptance for existing, new or enhanced products;
- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with distributors and other business partners;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licences;
- The costs and liability associated with patent infringement or other types of litigation;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

If additional financing is needed, we may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to us on satisfactory terms, or at all.

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

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

Were this to happen to us, the relevant competent authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues. This would be carried out either by the competent authority or it could require that our Notified Body, carry out the inspection or assessment.

We have reported MDRs in the past, and we anticipate that in the future it is likely that we may experience events that would require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, or agency actions, such as inspection, mandatory recall or other enforcement action.

Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

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

We may be subject to claims for personal injuries or other damages if any of our products, services, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. There is no assurance that we would be successful in defending any product liability lawsuits brought against us. Regardless of merit or eventual outcome, product liability claims could result in:

- Decreased demand for our products;
- Lost revenues;
- Damage to our image or reputation;
- Costs related to litigation; and
- Diversion of management time and attention;

We have global product liability insurance in place for our manufacturing subsidiaries up to a maximum of €6,500,000 (US$7,365,000) for any one accident, limited to a maximum of €6,500,000 (US$7,365,000) in any one-year period of insurance and is subject to a deductible. We also have professional indemnity insurance for its laboratory services business up to a maximum of US$5,000,000 for each claim and aggregate limit and is subject to a deductible. There can be no assurance that our product liability insurance is sufficient to protect us against liability that could have a material adverse effect on our business. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

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

Manufacturers may, on their own initiative, initiate actions, including a non-reportable market withdrawal or a reportable product recall, for the purpose of correcting a material deficiency, improving device performance, or for other reasons. Additionally, the FDA and similar foreign health or governmental authorities have the authority to require an involuntary recall of commercialized products in the event of material deficiencies or defects in design, manufacturing or labelling or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, modifications, design or labelling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated.

Companies are required to maintain certain records of post-market actions, even if they determine such actions are not reportable to the FDA. If we determine that certain actions do not require notification of the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted or failing to timely report or initiate a reportable product action. Further, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner.

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

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

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

Uncertainty in global economic conditions may continue for the foreseeable future and intensify. The invasion of Ukraine by Russia has destabilised markets, increased volatility and created uncertainty, particularly in energy supply and energy prices. This uncertainty poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. Volatile economic conditions have adversely

affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions, refinance existing debts, or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding may be reduced or deferred as a result of economic conditions.

If global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. Even with the improvement of economic conditions, it may take time for our customers and suppliers to establish new budgets and return to normal purchasing and shipping patterns. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery.

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

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

The global spread of Covid-19 and the public healthcare measures implemented by governments, such as quarantines and the temporary closure of businesses has led to and may continue to lead to fewer patients presenting themselves for medical check-ups resulting in a fall in demand for certain of our products which was offset by increased demand within our Covid-19 related portfolio of products. Furthermore, funding allocated to combatting Covid-19 may result in a reduction or a postponement in the funding available for other diseases, conditions and disorders that our products are used to diagnose.

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

The situation with the Covid-19 pandemic remains fluid and uncertain at this time. While it is not possible to predict the full extent and duration of any further impacts, there could be a period where demand for our Covid-19 related portfolio of products declines but the revenues for our other, non-Covid related products remain below historical levels due to the pandemic. There is no certainty that we will be successful in our efforts to mitigate against these risks posed by Covid-19.

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

Our success is dependent to a large extent upon the contributions of our key employees who in 2021 were Ronan O'Caoimh, our CEO and Chairman, and John Gillard, our CFO/Executive Director. The effectiveness of our senior leadership team generally could have a significant impact on our results of operations. Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions. We may not be able to attract or retain a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products and other life science businesses.

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support research, development and clinical programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

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

Products manufactured at our facilities in Bray, Ireland, Jamestown and Buffalo, New York and Kansas City, Missouri accounted for the majority of our revenues during the fiscal year ended December 31, 2021. Our global supply of these products and services is dependent on the uninterrupted and efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products and product components. 2021 saw significant interruptions to international supply chains which look set to continue for some time to come.

If we do not negotiate long-term contracts, our suppliers will likely not be required to provide us with any guaranteed minimum production levels. As a result, we cannot assure you that we will be able to obtain sufficient quantities of product in the future. In addition, our reliance on third-party suppliers involves a number of risks, including, among other things:

- contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we or our contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
- we or our contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- we may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our suppliers or those of our contract manufacturer may wish to discontinue supplying components or services to us for risk management reasons;
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

The operations of our facilities or these third-party manufacturing facilities could be adversely affected by fire, power failures, natural or other disasters, such as earthquakes, floods, 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. 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.

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

The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. If our third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials

meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work.

Some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third-party vendors could adversely and materially affect our reputation, our attempts to complete our clinical trials or commercialization of our products and adversely and materially affect our business, operating results and prospects. We may also need to obtain FDA or other regulatory authorisations for the use of an alternative component or for certain changes to our products or manufacturing process. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including, warning letters, product recalls, termination of distribution, product seizures, or civil penalties. Completing that development and obtaining such authorisations could require significant time and expense and we may not obtain such authorisations on a timely basis, or at all. The availability of critical components and products from other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and United States import and customs regulations, which complicate and could delay shipments of components to us. In 2021, we experienced significant disruption to our international supply chain which caused some disruption to operations. There can be no assurance that these disruptions will not continue or intensify in the future which may create significant challenges in fulfilling customer orders that we may not be able to overcome.

Although 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. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

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

The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements.

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

Any failure or delay in our ability to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our revenues and results of operations.

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

We currently distribute our product portfolio through distributors in approximately 100 countries worldwide. Our continuing economic success and financial security is dependent on our ability to secure effective channels of distribution on favourable trading terms with suitable distributors.

The loss or termination of our relationship with these key distributors could significantly disrupt our existing business unless suitable alternatives were quickly found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

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

To the extent that we or our strategic partners fail to maintain a high-quality level of service and support for diagnostic products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. These risks have increased as a result of the public health restrictions put in

place due to Covid-19. This could result in slower adoption rates and lower than anticipated utilisation of our products which could have a material adverse effect on our business, financial condition and results of operations.

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, can cause all or portions of our websites to be unavailable, create system disruptions, shutdowns, erasure of critical data and software or unauthorised disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks and we have implemented solutions, processes, and procedures to help mitigate these risks, such as encryption, virus protection, security firewalls and comprehensive information security and privacy policies. However, despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We have been the victim of cyber-attacks but these have had no material impact on our operations. The age of our information technology systems, as well as the level of our protection and business continuity or disaster recovery capability, varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of personal information, including but not limited to employee or consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent further security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data, which could have a material adverse impact on our business, financial condition and results of operations. While we currently expend resources to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

In addition, the interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. If so, this could result in government-imposed fines or orders requiring that we change our data practices, which could have an adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

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 two Canadian subsidiaries and to the Brazilian Real through our Brazilian subsidiary. We also have revenues and costs denominated in British Sterling.

The invasion of Ukraine by Russia and the resulting sanctions imposed on Russia 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.

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, 2021 was US$36 million (2020: US$34 million) (2019: US$44 million). In 2021, we recorded total impairment charges of intangible assets of US$4 million (2020: US$15 million) (2019: US$17 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.

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. For example, in December, 2017, the U.S. Government enacted comprehensive tax legislation known as the Tax Cuts and Jobs Act. This legislation made broad and complex changes to the U.S. tax code, including but not limited to reducing the corporate tax rate from 35% to 21%, requiring a one-time mandatory deemed repatriation of certain deferred foreign earnings tax on and accelerating first year expensing of certain capital expenditures. The legislation also introduced new tax laws affecting our taxable income, which included a new provision designed to tax global intangible low taxed income, limited deductibility of certain executive compensation, created a base erosion anti-abuse tax and modified many deductions and credits. Changes to the tax code could also affect our valuation of deferred tax assets and liabilities. Any such change in valuation would have a material impact on our income tax expense and deferred tax balances.

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

We have has historically grown organically and through the acquisition of, and investment in, other companies, product lines and technologies. We may enter into strategic acquisitions or investments as a way to expand our business. These activities, and their impact on our business, are subject to many risks, including the following:

- Suitable acquisitions or investments may not be found or consummated on terms or schedules that are satisfactory to us or consistent with our objectives;
- The benefits expected to be derived from an acquisition may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, general economic conditions and increased competition;
- We may be unable to successfully integrate an acquired company's personnel, assets, management systems, products and/or technology into our business;
- Worse than expected performance of an acquired business may result in the impairment of intangible assets;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- We may not be able to accurately forecast the performance or ultimate impact of an acquired business;
- An acquisition and subsequent integration activities may require greater capital and other resources than originally anticipated at the time of acquisition;
- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;
- An acquisition may result in the loss of our or the acquired company's key personnel, customers, distributors or suppliers;
- An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations, and our inability to successfully assimilate differences in foreign business practices or overcome language or cultural barriers; and
- Our ability to integrate future acquisitions may be adversely affected by inexperience in dealing with new technologies.

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

The United Kingdom's withdrawal from the European Union could potentially impact our supply chains and the market for our products in the United Kingdom.

The United Kingdom ("UK") formally left the European Union in January 2020 and entered a transition period, to December 31, 2020, during which time the UK remained bound to the rules and regulations of the EU. A Trade and Cooperation Agreement was ratified by the European Union in April 2021 and sets out the future trading relationship between the UK and the European Union covering areas such as trade in goods and services. Uncertainties, however, remain over the challenges which could be posed by the operation of the trading agreement with delays in the import and export of goods being experienced at UK ports as customs check and regulatory procedures are carried out. Such checks could impact the performance of supply chains extending timelines and delaying supplier and customer commitments, while imposing additional taxes and duties dependent on rules of origin. The uncertainty might continue to create volatility for the Pound Sterling.

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

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

Risks Related to Government Regulations

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

Initiating and completing clinical trials necessary to support approval of future products under development, is time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies will require the enrolment of patients who may be difficult to identify and recruit. Patient enrolment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, and the availability of appropriate clinical trial investigators. Patients may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. Continuing public health measures against Covid-19 may increase the difficulty of conducting clinical trials.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA and/or other regulatory authorities may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Any challenges to patient enrolment may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, FDA and/or other regulatory authorities may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Our facilities and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50, 56 and 812, and Good Clinical Practices. Although the majority of our in-vitro diagnostic ("IVD") clinical studies meet the definition of exempted investigations under 21 Part 812 and are exempt from the Investigational Device Exemption ("IDE") regulations in 21 CFR Part 812, we are still required to meet the requirements of 21 CFR Parts 50 and 56 for informed consent and Institutional Review Board ("IRB") approval. FDA may conduct Bioresearch Monitoring ("BiMo") inspections of us and/or our clinical sites to assess compliance with FDA regulations, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action as well as refusal to accept all or part of our data in support of a 510(k) or PMA and/or we may need to conduct additional studies.

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

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

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

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

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

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

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

Our promotional materials must comply with FDA and other applicable laws and regulations. We believe that the specific uses for which our products are marketed fall within the scope of the indications for use that have been cleared or approved by the FDA or other relevant regulatory authorities. However, the FDA and/or the other relevant regulatory authorities could disagree and require us to stop promoting our products for those specific uses until we obtain clearance or approval for them. In addition, if the FDA or other relevant regulatory authorities determines that our promotional materials constitute promotion of an unapproved use, it could demand that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

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

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests ("LDTs"), although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to FDA regulation. The FDA defines the term "laboratory developed test" as an IVD test that is intended for clinical use and designed, manufactured and used within a single laboratory. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act, or FDA Act, with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims and erroneous results, the FDA issued guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight

of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing Congress and manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for any of our LDTs, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our current LDTs or to develop and introduce new LDTs. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

If FDA premarket review, including clearance or approval, is required for our current or future LDTs (either alone or together with sample collection devices), products or services we may develop, or if we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our LDTs while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our LDTs, there can be no assurance that any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labelling claims will be consistent with our current claims or adequate to support continued adoption of for our LDTs. If our LDTs are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational and we cannot offer the LDTs for diagnostic purposes, or if labelling claims, the FDA allows us to make are limited, orders may decline and adversely affect our results of operations, cash flow and business.

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

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

Our medical device products and operations are subject to rigorous government regulation in the United States by the FDA, and numerous other federal, state and foreign governmental authorities, as well as and by comparable regulatory authorities in other jurisdictions such as the HPRA in Ireland. In particular, we are subject to strict governmental controls on the development, manufacture, labelling, storage, testing, advertising, promotion, marketing, distribution and import and export of our products. In addition, we or our distributors are often required to register with and/or obtain clearances or approvals from foreign governments or regulatory bodies before we can import and sell our products in foreign countries. The clearance and approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive.

The process of obtaining and maintaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), or is the subject of an approved premarket approval application ("PMA") unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA.

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

In the United States, many of our currently commercialized products have received pre-market clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing

products than we had expected, our product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we currently market only one device pursuant to an approved PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended users;
- insufficient data from our pre-clinical studies and clinical trials to support clearance or approval, where required; and
- the failure of the manufacturing process or facilities we use to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. FDA's review of its 510(k) clearance process could result in additional changes to regulatory requirements or guidance documents which could increase the costs of compliance, or restrict our ability to maintain current clearances. In addition, as part of the Food and Drug Administration Safety and Innovation Act ("FDASIA"), Congress reauthorised the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Furthermore, regulatory authorities, including the FDA, may not agree with our interpretation of its policies and regulations which may lead to enforced modifications, restrictions, discontinuation, etc. of some of our products, even if they were previously approved.

Our continued success is dependent on our ability to develop and market new or updated products, some of which are currently awaiting clearance or approval from the applicable regulatory authorities. There is no certainty that such clearance or approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process. Further, regulatory authorities, including the FDA, may not approve or clear our future products for the indications that are necessary or desirable for successful commercialization. A regulatory authority may impose requirements as a condition to granting a marketing authorisation, may include significant restrictions or limitations as part of a marketing authorisation it grants and may delay or refuse to authorise a product for marketing, even though a product has been authorised for marketing without restrictions or limitations in another country or by another agency. Failure to receive clearance or approval for our new products, or commercially undesirable limitations on our clearances or approvals, would have an adverse effect on our ability to expand our business. Modifications made to our products may invalidate previously granted regulatory approvals which may lead to revised regulatory clearances, enforced modifications, restrictions, discontinuation, etc. of some of our products.

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

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

Even after we obtain clearance or approval for our medical devices, we are still subject to ongoing and extensive post market regulatory requirements. Regulation by the FDA and other federal, state and foreign regulatory agencies, such as the HPRA in E.U., impacts many aspects of our operations, and the operations of our suppliers and distributors, including manufacturing, labelling, packaging, adverse event reporting, storage, advertising, promotion, marketing, record keeping, import and export. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation ("QSR"), which covers the methods and documentation of the design, testing, production, control, quality assurance, labelling, packaging, sterilization, storage and shipping of our products. Our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections by the FDA to assess compliance with the QSR and other regulations, and by other comparable foreign regulatory authorities with respect to similar requirements in other jurisdictions. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved products or place conditions on any product clearances or approvals that could restrict the commercial applications of those products. The failure by us or one of our suppliers to comply with applicable statutes and regulations

administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

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

Other regulatory authorities have similar sanctions in their respective jurisdictions.

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

For example, in August 2020, our subsidiary received a Warning Letter from FDA following an inspection of our subsidiary's Kansas City, Missouri manufacturing facility that took place in January and February 2020. We have taken voluntary remediation actions to correct the observations noted in the Warning Letter.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labelling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labelling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.

In addition to the FDA and other regulations described above, laws and regulations in some countries may restrict our ability to sell products in those countries. While we intend to comply with any applicable restrictions, there is no guarantee we will be successful in these efforts.

We must also comply with numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances and labour or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying

with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

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

Any modification to a 510(k)-cleared device in the United States that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

For example, we obtained 510(k) clearance for our Primus Variant System for the separation and quantification of normal and abnormal haemoglobin species as an aid in the diagnosis of haemoglobinopathies. The sample type used by this system was blood tubes. We subsequently introduced two systems based on the original Primus Variant System and they were named as ultra² GeneSys Variant System and ultra² Resolution Variant System. The primary focus of the GeneSys Variant System was on newborn screening using Dried Blood Spots as the sample type, while the Resolution was intended for confirmatory testing on the adult population using blood tubes as the sample type. We determined that these modifications to the indications for use to both systems were within our existing clearance and did not require the submission of a new 510(k) notification. The FDA stated that the use of Dried Blood Spots with the ultra² GeneSys Variant System was not part of the original submission and represented a new modified Intended Use. The FDA informed us that it disagreed with our decision not to seek new 510(k) clearances for these modifications, and we filed new 510(k) notifications to obtain clearance for these indications. The FDA rejected our filing on the basis that the predicate device chosen did not meet their requirements. Additionally, the FDA asked us to withdraw the ultra² GeneSys Variant System from the market. A recall was conducted and has since been closed.

Additionally, in August 2020, we received a Warning Letter from the FDA. In the Warning Letter, FDA stated that we had made additional changes to the ultra² Resolution Variant System not covered within our existing 510(k). Accordingly, we conducted a voluntary recall of the ultra² Resolution Variant System. We have developed the Premier Resolution as a successor instrument to the ultra² Resolution Variant System and this has already been launched in various jurisdictions outside the United States. We expect to obtain a 510(k) approval for this successor instrument in 2022 or 2023 which will allow us to market this instrument in the United States.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) notification for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) clearance will be required for modifications or changes to a previously cleared device. The FDA issued this report and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) clearance is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

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

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

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

Any failure by our distributors to comply with such laws, regulations or sanctions could have negative consequences, including reputational harm, government investigations and penalties.

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

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

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

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

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

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

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

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

Our laboratory operated by our subsidiary Immco Diagnostics Inc. is subject to CLIA, which is administered by CMS and extends federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA is designed to ensure the quality and reliability of clinical laboratories by, among other things, mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as the College of American Pathologists, among others. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties.

We are also subject to regulation of laboratory operations under state clinical laboratory laws of New York and of certain other states from where we accept specimens. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. For example, California requires that we maintain a licence to conduct testing in California, and California law establishes standards for our day-to-day laboratory operations, including the training and skill required of laboratory personnel and quality control.

In some respects, notably with respect to qualifications of testing personnel, California's clinical laboratory laws impose more rigorous standards than does CLIA. Certain other states, including Florida, Maryland, New York and Pennsylvania, require that we hold licences to test specimens from patients residing in those states, and additional states may require similar licences in the future. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licences, certificates and authorisations, which could adversely affect our business and results of operations.

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

If we fail to comply with federal and state health care laws, including fraud and abuse, false claims, physician payment transparency and privacy and security laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected. We are subject to anti-kickback laws, self-referral laws, false claims laws, and laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of our products. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and wilfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Physician Self-Referral Law, also known as the "Stark Law", which provides for strict liability for referrals by physicians to entities with which they or their immediate family members have a financial arrangement for certain designated health services, including clinical laboratory services provided by our CLIA-certified laboratory owned and operated by our subsidiary Immco Diagnostics Inc., that are reimbursable by federal healthcare programs, unless an exception applies. Penalties for violating the Stark Law include denial of payment, civil monetary penalties of up to fifteen thousand dollars per claim submitted, and exclusion from federal health care programs, as well as a penalty of up to one-hundred thousand dollars for attempts to circumvent the law;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payers that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Often, to avoid the threat of treble damages and penalties under the False Claims Act, which in 2020 were $11,665 to $23,331 per false claim, companies will resolve allegations in a settlement without admitting liability to avoid the potential treble damages. Any such settlement could materially affect our business, financial operations, and reputation;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. We cannot assure you that we have and will successfully report all transfers of value by us, and any failure to comply could result in significant fines and penalties. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;
- federal and state laws governing the certification and licensing of clinical laboratories, including operational, personnel and quality requirements designed to ensure that testing services are accurate and timely, and federal and state laws governing the health and safety of clinical laboratory employees;
- the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorising the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which makes the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbours available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or order our tests, our sales and marketing efforts and certain arrangements with customers, including those where we provide our instrumentation for free in exchange for minimum purchase requirements of our reagents, and our billing and claims processing practices, could be subject to challenge under one or more of such laws. By way of example, some of our consulting arrangements with physicians do not meet all of the criteria of the personal services safe harbour under the federal Anti-Kickback Statute. Accordingly, they do not qualify for safe harbour protection from government prosecution. A business arrangement that does not substantially comply with a safe harbour, however, is not necessarily illegal under the Anti-Kickback Statute, but may be subject to additional scrutiny by the government. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and distributors may engage in fraudulent or other illegal activity. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), has recently increased its scrutiny of interactions between health care companies and health care providers, which has led to a number of investigations, prosecutions, convictions and settlements in the health care industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with the DOJ or other law enforcement agencies have forced healthcare providers

to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

We have not yet developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are or may become subject. Although the development and implementation of such compliance programs can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, or any other laws that may apply to us, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of the laws described above or any other laws and regulations that apply to us, we could receive adverse publicity, face enforcement action and be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

Risks Related to Our Intellectual Property

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

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

Filing, prosecuting and defending patents covering our current and future products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licenced patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

Trinity Biotech currently owns a number of active patents with protection across multiple countries. As of April 2022, these patents have remaining patent lives varying from 6 year to 13 years.

We may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own, or in-licence, may fail to result in issued patents with claims that cover our current products or any future products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.

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

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We can provide no assurance that our patents will continue to be commercially valuable.

Trade secrets and confidential know-how are important to our scientific and commercial success. Although we seek to protect our proprietary information through confidentiality agreements and other contracts, we can provide no assurance that others will not independently develop the same or similar information or gain access to our proprietary information.

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

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

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

Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licenced or that we might obtain in the future. Similar changes could happen to patent laws outside of USA which would have the same consequences.

For example, the United States has enacted and implemented wide-ranging patent reform legislation, which could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have an adverse effect on our business and financial condition.

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

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

Litigation over intellectual property rights is prevalent in the diagnostic industry, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions.

As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third-party may claim infringement against us. For example, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may infringe. Defence of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of managerial and financial resources from our business. Parties making claims against us may obtain

injunctive or other equitable relief, which could effectively block our ability to further develop and commercialise one or more of our products. The pendency of any litigation may cause our distributors and customers to reduce or terminate purchases of our products. If found to infringe, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licences from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. Any substantial loss resulting from such a claim could cause our revenues to decrease and have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

If we need to obtain a licence as a result of litigation, we cannot predict whether any such licence would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licences from third parties to advance our research or allow commercialisation of our products. We may fail to obtain any of these licences at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialise one or more of our products, which could harm our business significantly.

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

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

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

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

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

Risks Related to Ownership of our ADSs

MiCo owns approximately 29.4% of the voting share capital of our Company, which gives MiCo significant influence over our management and affairs and may deter a change in control or other transaction that may be favorable to our shareholders.

MiCo owns approximately 11.2 million of our ADSs, which represents approximately 29.4% of the outstanding voting share capital of our Company and, under the terms of the Convertible Note and the Securities Purchase Agreement, MiCo is entitled to nominate a total of four individuals 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, three of which must be independent. Because of its ownership interest and right to nominate directors, MiCo will 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.

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

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

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

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

U.S. holders of our ADSs may face income tax risks. Based on the composition of our income, assets (including the value of our goodwill, going-concern value or any other unbooked intangibles, which may be determined based on the price of the ordinary shares), and operations, we believe we will not be classified as a "passive foreign investment company", or PFIC, for the 2020 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 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 the Company's Form 20-F, Item 10E. "Additional Information – Taxation" for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of ADSs.

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

The stock market in general and the market prices of the ADSs on Nasdaq, in particular, are or will be subject to fluctuation, and changes in these prices may be unrelated to our operating performance. During the first half of 2022, the market price of our ADSs fluctuated from a high of $1.44 per ADS to a low of $0.92 per ADS, and the price of our ADSs continues to fluctuate. We anticipate that the market prices of our securities will continue to be subject to wide fluctuations. The market price of our securities may be subject to a number of factors, including:

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

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

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

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

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

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

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

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

The total share options exercisable at December 31, 2021, as described in Note 21 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 "A" Ordinary Shares. The exercise of the outstanding share options will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders. For instance, if all of the vested options outstanding at April 15, 2022 were exercised, the Company would have to issue 13,121,338 additional "A" Ordinary Shares (3,280,335 ADSs). Similarly, at April 15, 2022, if all of the outstanding warrants to purchase "A" Ordinary Shares were exercised, the Company would have to issue 10,000,000 "A" Ordinary Shares (2,500,000 ADSs). On the basis of 107,670,894 "A" Ordinary Shares outstanding at April 15, 2022, the exercise of both the share options and the warrants would effectively dilute the ownership interest of the existing shareholders by approximately 18%.

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

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

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

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

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

Holders of ADSs do not have the same rights as our registered shareholders. As a holder of the ADSs, you will not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. You will only be able to exercise the voting rights which attach to the Class A ordinary shares underlying the ADSs indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement with the depositary, you may vote only by giving voting instructions to the depositary, as the registered holder of the Class A ordinary shares underlying the ADSs. If we ask for your instructions, then upon receipt of your voting instructions, the depositary will try to vote the underlying Class A ordinary shares in accordance with these instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with instructions you give, but it is not required to do so. You will not be able to directly exercise any right to vote with respect to the underlying Class A ordinary shares unless you withdraw the shares underlying your ADSs and become the registered holder of such shares prior to the record date for the general meeting. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to enable you to withdraw the shares underlying the ADSs and become the registered holder of such shares prior to the record date for such general meeting to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. Where any matter is to be put to a vote at a general meeting, upon our instruction, the depositary will notify you of the upcoming vote and deliver our voting materials to you. We cannot assure you that you will receive the voting materials in time to ensure you can direct the depositary to vote the Class A ordinary shares underlying

your ADSs in accordance with your instructions. In addition, the depositary and its agents are not responsible for failing to carry out your voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the shares underlying the ADSs are voted and you may have no legal remedy if the shares underlying the ADSs are not voted as you instructed.

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

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

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

Performance Review

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

Revenues

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

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

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

Clinical Laboratory Goods

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

There was a significant reduction in demand for new orders of VTM from early 2021 as COVID-19 testing volumes dropped and customers utilised stockpiled product. While the situation relating to COVID-19 products remains very fluid, with the evolving impact of the new variants the Company has retained the capability to flex manufacturing volumes should market conditions warrant it.

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

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

Clinical Laboratory Services

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

Point-of-Care

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

Revenues by Geographical Region

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

	Year ended December 31, 2021 US$'000	2020 US$'000	% Change
Revenues			
Americas	57,799	70,408	(17.9%)
Asia/Africa	25,504	22,567	13.0%
Europe	9,662	9,005	7.3%
Total	**92,965**	**101,980**	(8.8%)

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

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

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

Cost of sales, gross profit and gross margin

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

Other operating income

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

Research and development expenses

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

Selling, general and administrative expenses

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

The Group recorded a total share-based payments charge of US$1.1 million in 2021 compared to US$0.8 million in 2020. The increase of US$0.3 million in the total share-based payments expense is mainly due to a higher number of options being in their vesting period in 2021 compared to 2020 due to options granted in prior years. Share based payments included in selling, general and administrative expenses was US$1.1 million in 2021 and US$0.8 million in 2020. For further details, refer to Note 21 to the consolidated financial statements.

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

Recognition of contingent asset

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

Closure costs

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

Impairment charges

The Company recognized impairment charges of US$6.9 million in 2021. In 2020, the impairment charges were US$17.8 million. In accordance with the provisions of accounting standards under IFRS, a company is required to carry out impairment reviews in order to determine the appropriate carrying value of its net assets. A number of factors impacted this calculation including cash flow projections and net asset values across each of the Group's cash generating units, the Company's share price at the date on which the impairment test is performed (in 2021, two tests were performed, one at June 30 and one at December 31) and the cost of capital. The impairment loss of US$5.0 million for Immco Diagnostics Inc. mainly comprised a write down of intangible assets. Trinity Biotech Do Brasil incurred an impairment loss of almost US$1.0 million (mainly comprising property, plant and equipment assets) in 2021 as this CGU continues to be impacted by the weakness of the Brazilian Real. Trinity Biotech Manufacturing Limited recorded an impairment loss of US$0.8 million relating to one development project intangible asset. Biopool US Inc. incurred an impairment loss of US$0.1 million in 2021, with a downward trend in non-Covid-19 related infectious disease revenues in U.S. being a major factor. For further details, see Notes 13, 14 and 18 to the financial statements.

Operating profit

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

Net financing expenses

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

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

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

Income tax credit

The Group recorded a tax credit on continuing operations of US$0.2 million for the year ended December 31, 2021 compared to a tax credit of US$0.6 million for the year ended December 31, 2020. The 2021 tax credit consists of US$0.2 million of current tax credit and US$0.04 million of a deferred tax charge. In 2020, the tax credit comprised US$0.4 million of current tax credit and US$0.2 million of a deferred tax credit. For further details on the Group's tax charge please refer to Note 9 and Note 15 to the consolidated financial statements.

Profit from continuing operations

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

Loss from discontinued operations

The Cardiac Point-of-Care operation was discontinued during the year ended December 31, 2016. Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item in the Statement of Operations. The loss on discontinued operations is US$0.05 million in year ended December 31, 2021, which is mainly due to administrative expenses. The loss on discontinued operations is US$0.4 million in year ended December 31, 2020, which is mainly due to the unwinding of closure provisions and a change of estimate in relation to a tax receivable balance. For further details, see Note 10 to the financial statements.

Year Ended December 31, 2020 Compared with Year Ended December 31, 2019

Revenues

Revenues by Product Line

Trinity Biotech's revenues for the year ended December 31, 2020 were US$102.0 million compared to revenues of US$90.4 million for the year ended December 31, 2019, which represents an increase of US$11.6 million or 12.8%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31, 2020 US$'000	2019 US$'000	% Change
Revenues			
Clinical laboratory goods	84,280	68,127	23.7%
Clinical laboratory services	8,485	10,915	(22.3%)
Point-of-Care	9,215	11,393	(19.1%)
	101,980	**90,435**	**12.8%**

Clinical Laboratory Goods

Clinical Laboratory goods revenues increased by US$16.2 million in 2020, which represents an increase of 23.7%. The increase is mainly due to strong sales within our Covid-19 related portfolio of products, with our VTM products being the most significant contributor to revenue within that portfolio. Due mainly to the impact of Covid-19, revenues for Haemoglobins and Autoimmune products recorded decreases in 2020 compared to 2019. In our Haemoglobins business, revenues were affected by the deferral of Diabetes instrument purchases as healthcare resources were stretched by the pandemic. Autoimmune revenues were affected by fewer patients attending their doctors for consultations. Infectious Diseases revenues increased significantly due to the aforementioned Viral Transport Media sales, but this was partly offset by lower Lyme sales attributable to the continued migration away from Western Blot to other testing formats.

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 22.3% to US$8.5 million due to lower testing volumes mainly on account of the pandemic.

Point-of-Care

Point-of-Care revenues decreased from US$11.4 million in 2019 to US$9.2 million in 2020, which is a decrease of US$2.2 million (-19.1%). This was driven by lower HIV sales in both the U.S. and Rest of World. The decline in the U.S. was attributable to the decision to exit this market in 2019, which had been in decline for a number of years, whilst Rest of World sales were lower due to logistical and testing constraints arising from Covid-19 in the second and third quarters, with normal trading patterns only being restored in the fourth quarter of 2020.

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, 2020 US$'000	2019 US$'000	% Change
Revenues			
Americas	70,408	52,183	34.9%
Asia/Africa	22,567	27,686	(18.5%)
Europe	9,005	10,566	(14.8%)
Total	101,980	90,435	12.8%

In the Americas, revenues increased US$18.2 million or 34.9% mainly due to increased sales of our Viral Transport Media product which was used in the Covid-19 testing programs in USA and Canada. This increase was partly offset by (i) the decision to exit the HIV point-of-care testing market in USA during 2019, (ii) the continued migration of Lyme confirmatory testing away from Western Blot to alternative testing platforms and (iii) lower haemoglobins revenues due to the negative impact of Covid-19 in USA and Brazil and also due to a marked weakness in the Brazilian currency.

Asia/Africa revenues decreased by 18.5%, or US$5.1 million compared to 2019. The decrease is due i) to lower Point-of-Care revenues in Africa where logistical and testing constraints arose due to Covid-19 particularly in the second and third quarters and ii) a decrease in haemoglobins revenues as patients' scheduled diabetes tests in China and our other Asian markets were cancelled or postponed due to government quarantine enforcement in response to the pandemic. Our haemoglobins customers also deferred their instrument purchases as healthcare resources were stretched by the pandemic.

In Europe, revenues decreased by 14.8% or US$1.6 million, compared to 2019. The decrease was due to lower haemoglobin A1c and infectious diseases revenues in the territory, mainly due to the reduction in patients attending their doctors for heath checks on account of the public healthcare emergency. Similar to Asia/Africa, there was a drop in haemoglobins instrument sales in Europe as customers postponed their instrument purchases due to uncertainty created by the pandemic.

Cost of sales, gross profit and gross margin

Total cost of sales increased by US$1.1 million from US$52.3 million for the year ended December 31, 2019 to US$53.4 million, for the year ended December 31, 2020, an increase of 2.1%. This resulted in a gross profit of US$48.6 million for 2020 compared to a gross profit of US$38.1 million for 2019. The gross margin of 47.6% in 2020 compares to a gross margin of 42.2% in 2019. This increase was largely due to the impact of strong sales within our Covid-19 related portfolio of products, fewer instrument placements (which are lower than average margin), lower depreciation and a range of cost saving measures implemented during the year.

Other operating income

Other operating income increased from US$0.09 million in 2019 to US$1.9 million in 2020. In 2020, other operating income mainly relates to funding received under the U.S. government's Cares Act, principally its PPP. Two out of six PPP loans received by the Company were forgiven during the year. The four loans which remained unforgiven at year end, totaling US$2,905,000, are treated as short term liabilities at December 31, 2020. In 2019, other operating income mainly comprised the provision of canteen services to third parties in Ireland. Due to Covid-19 restrictions, these services were suspended in the second quarter of 2020.

Research and development expenses

R&D expenditure recorded in the Statement of Operations decreased from US$5.3 million in 2019 to US$5.1 million in 2020. The decrease in 2020 is due to cost saving measures implemented during the year including the furloughing of employees. For details of the Company's various R&D projects see the Research and Development activities section of the Directors' Report.

Selling, General & Administrative expenses

Total selling, general and administrative expenses decreased by US$1.3 million from US$27.7 million for the year ended December 31, 2019 to US$26.4 million for the year ended December 31, 2020.

Selling, general and administrative expenses excluding share-based payments and amortisation decreased from US$24.6 million for the year ended December 31, 2019 to US$24.2 million for the year ended December 31, 2020, which represents a decrease of 1.4%. The decrease of US$0.4 million is mainly attributable to:

- A range of cost saving measures implemented in response to the Covid-19 pandemic including the furloughing of employees in the second quarter of 2020, the receipt of government payroll subsidies, significantly reduced travel costs and the cancellation of trade shows and other marketing activities.
- Partially offsetting these savings were increased foreign currency losses mainly due to the re-translation of Euro-denominated lease liabilities for right-of-use assets and increased performance-related pay due to higher revenues and profits.

The share-based payments expense represents the fair value of share options granted to directors, employees and contractors, which is charged to the statement of operations over the vesting period of the underlying options. The Group has used a trinomial valuation model for the purposes of valuing these share options with the key inputs to the model being the expected volatility over the life of the options, the expected life of the option, the option price, the dividend yield and the risk-free rate. The Group recorded a total share-based payments charge of US$0.79 million (2019: US$0.76 million). The increase of US$0.03 million in the total share-based payments expense is mainly due to a higher number of options being in their vesting period in 2020 compared to 2019 due to options granted in 2020. The total charge is shown in the following expense headings in the statement of operations: US$0.01 million (2019: US$0.02 million) was charged against cost of sales and US$0.8 million (2019: US$0.7 million) was charged against selling, general & administrative expenses.

Amortisation decreased from US$2.4 million for the year ended December 31, 2019 to US$1.4 million for the year ended December 31, 2020. The decrease of US$1.0 million is due to the impairment recorded at December 31, 2019 which resulted in a lower carrying value for development projects and other intangible assets such as acquired technology, customer and supplier lists.

Selling, general and administrative expenses – recognition of contingent asset

In our financial statements for the year ended December 31, 2019, we disclosed a contingent asset of USD$1.2 million which had not been recognised. It was in connection with the 2019 tax audit settlement and was payable by Darnick Company. This balance was settled in the year ended December 31, 2020 and has been credited to the Statement of Operations within Selling, General and Administrative Expenses - recognition of contingent asset. The underlying amount was denominated in Euro. Due to a depreciation in the US Dollar since 2019, the US Dollar equivalent amount increased from US$1.2 million to US$1.3 million.

Selling, general and administrative expenses – tax audit settlement

In the year end December 31, 2019, a tax audit settlement of US$6.4 million arising in one of the jurisdictions in which the company operates was reached. The settlement consisted of US$3.9 million in relation to a patent dividend scheme, which had operated via Rayville Limited from 1995 to 2010, US$1.2 million in relation to payments for CEO Services made to Darnick Company (a company controlled by the family of Ronan O'Caoimh), and US$0.08 million in relation to R&D tax credits. Penalties were US$0.3 million. Interest charges were US$1.0 million and this is shown as a financial expense. The total settlement excluding interest of US$1.0 million was US$5.4 million and this was partially offset by an existing provision of US$0.4 million, resulting in an expense of US$5.0 million. There was no tax audit settlement charge recorded in the year end December 31, 2020.

Selling, general and administrative expenses – closure costs

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

Selling, general and administrative expenses - impairment charges

Impairment charges of US$17.8 million for the year ended December 31, 2020 are included in selling, general and administrative expenses. In 2019, the impairment charges were US$24.3 million. In accordance with the provisions of accounting standards under IFRS, a company is required to carry out annual impairment reviews in order to determine the appropriate carrying value of its net assets. A number of factors impacted this calculation including cash flow projections and net asset values across each of the Company's cash generating units, the Company's share price at December 31, 2020 and the cost of capital. Primus Corporation, which recorded an impairment loss of US$16.7 million in 2020, has been particularly impacted by the pandemic and changes to its product offering. Trinity Biotech Do Brasil also incurred a significant impairment loss in 2020 as this CGU continues to be impacted by the weakness of the Brazilian Real.

Net Financing Expense

Net financing expense was US$6.7 million for the year-end December 31, 2020 compared to US$5.9 million in 2019. Financial income decreased by US$0.7 million from US$0.7 million for the year-end December 31, 2019 to US$0.04 million in 2020. There was a decrease of US$0.4 million in bank deposit interest due to the lower cash deposits and lower interest rates and a decrease of US$0.2 million in the income arising from the revaluation of embedded derivatives at fair value.

Financial expenses increased by US$0.2 million to US$6.8 million during 2020 mainly due to an expense of US$1.2 million arising from revaluation of embedded derivatives at fair value, partly offset by non-recurring interest of US$1.0 million arising on a tax audit settlement in 2019.

Taxation

The Group recorded a tax credit on continuing operations of US$0.6 million for the year ended December 31, 2020 compared to a tax credit of US$1.0 million for the year ended December 31, 2019. The 2020 tax credit comprises US$0.5 million of current tax credit and US$0.2 million of a deferred tax credit. For further details on the Group's tax charge please refer to Note 9 and Note 15 to the consolidated financial statements.

Loss for the year from continuing operations

The loss for the year amounted to US$6.0 million, compared to a loss of US$29.0 million in 2019.

Discontinued operations

The Cardiac Point-of-Care operation was discontinued during the year ended December 31, 2016. Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item on the face of the Consolidated Statement of Operations.

The loss on discontinued operations was US$0.4 million in year ended December 31, 2020, which is mainly due to the unwinding of closure provisions and a change of estimate in relation to a tax receivable balance. The profit on discontinued operations was US$0.1 million in year ended December 31, 2019, which was mainly due to the release of Fiomi Diagnostic's accumulated foreign currency translation reserve.

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, which comprise the consolidated company statement of operations, the consolidated and parent company statements of comprehensive income, the consolidated and parent company balance sheets, 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, 2021, and the related notes to the financial statements, including the summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is Irish law and International Financial Reporting Standards (IFRS) as adopted by the European Union.

In our opinion:

- the consolidated financial statements give a true and fair view in accordance with IFRS as adopted by the European Union of the assets, liabilities and financial position of the group as at December 31, 2021 and of its loss and cash flows for the financial year then ended;
- the parent company financial statements give a true and fair view, in accordance with IFRS as adopted by the European Union, of the assets, liabilities and financial position of the parent company as at December 31, 2021 and cash flows for the financial year then ended; 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 'Responsibilities of the auditor 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.

Conclusions relating to 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:

- Examining management assessment on going concern and performed an independent assessment of the inputs and assumptions used by management in preparing their assessment on going concern by comparing the assumptions and estimates used elsewhere in the preparation of the financial statements;
- Reviewing the new financing agreement in January 2022, the new investment received in April 2022 and the subsequent repayment of the Exchangeable notes;
- Evaluating management's assessment of any liquidity issues with the company by reviewing if the company has enough liquidity sources from operating activities;
- Making inquiries with the Directors and reviewing board minutes available up to and including the date of authorisation of the financial statements in order to understand the future plans of the company;
- Assessing the adequacy of the disclosures with respect to the going concern assertion; and
- Obtaining a signed letter of representation from the Directors that it is appropriate to prepare the financial statements on a going concern basis and the Directors have considered various financing options to meet its repayment obligations under the exchangeable notes over the next 12 months.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group and parent company's ability to continue as a going concern for a period of at least twelve months from the date when the financial statements are authorised for issue.

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.

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, valuation of goodwill, capitalisation of development costs, impairment considerations, and revenue recognition. 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.

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. The company is also a significant provider of raw materials to the life sciences and research industries. 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 nine components covering entities across Europe and the Americas, which represent the principal business units within the group.

Of the nine components selected, we performed an audit of the complete financial information of six components ("full scope components") which were selected based on their size and risk characteristics. For the remaining three components ("specific scope components"), we performed audit procedures on specific accounts within that component 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 96% of the group's revenue and 96% 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 company 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 1% of revenues earned from third-party sources at December 31, 2021. 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 in a showing fluctuating profit and losses (as is the case for the group), revenues are the generally accepted auditing benchmark.

Key audit matters
We have set performance materiality at $0.6 million, having considered our prior year experience of the risk of misstatements, business risks and fraud risks associated with the entity and its the 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.

We agreed with the audit committee that we would report to them misstatements identified during our audit above 5% of materiality.

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.

a. Assessment of impairment of goodwill, other long-lived assets - valuation (Note 14)

Description of significant matter
As at December 31, 2021 prior to impairment analysis, the goodwill and intangible assets of the group totalled $39.8 million, property, plant and equipment of the group totalled $8.4 million and prepayments of the group totalled $2.5million. The company recognised $6.9 million impairment during the year ended December 31, 2021.

The company's impairment evaluation or calculation involves the comparison of the recoverable amount of goodwill, intangible assets of each cash generating unit (CGU) to their carrying value. The company used the value-in-use approach, which deploys a discounted cash flow model to estimate the recoverable amount. This requires management to make significant estimates and assumptions related to discount rates, short-term forecasts of future revenues and margins, and long-term growth rates which drive net cash flows. Changes in these assumptions could have a significant impact on the recoverable amount, the amount of any impairment charge, or both.

We identified the impairment of goodwill and intangible assets for certain CGUs as a key audit matter because of the significant judgements and assumptions made by management to estimate the recoverable value of certain CGUs. We focused on CGUs where impairments were recognised in the current year, CGUs identified as sensitive by management and CGUs with a significant change in cash flow forecasts in the current year (collectively the "selected CGUs").

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

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 included the following, among others:

- We evaluated the design effectiveness of controls over management's selection of the discount rates, short-term forecasts of future revenues and margins, and long-term growth rates used to determine the recoverable amount of each selected CGU.
- We agreed the underlying cash flow forecasts to the Board approved projections and we evaluated management's ability to accurately forecast future revenues and margins by:
    - performing a look-back analysis and comparing actual results to management's historical forecasts; and
    - assessing the reasonableness of the impact of COVID-19 and other macroeconomic activity on short-term cash flows;
- We assessed the reasonableness of the valuation model used by the company compared to generally accepted valuation practices and accounting standards.

Key audit matters (continued)

- 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 comparing those to the discount rates selected by management.
- We compared the long-term growth rates, used by management to grow cash flows in order to calculate a terminal value at that point, to independent external sources to assess the reasonableness of these rates.

b. Accounting for capitalised development costs (Note 14):

Description of significant matter
As discussed in Note 14 to the consolidated financial statements, the company capitalises certain internal development costs related to the design, development and enhancement of the company's products. The company capitalized $6.8 million of internal development costs during the year ended December 31, 2021.
The principal consideration for our determination that capitalized development cost is a key audit matter due to the degree of subjectivity involved in assessing which projects meet the capitalization criteria, based on the development stage of the project, and in determining the costs to be capitalized.

Audit response to significant matter
Our audit procedures related to the capitalization of internal development costs included the following, among others:

- We examined the supporting documents of internally generated intangible asset additions in the financial year to determine if they constituted development phase costs allowable for capitalisation as stipulated by accounting standards.
- We tested the key assumptions used by management in concluding that intangible projects capitalised at year-end demonstrate the required characteristics to permit capitalisation, particularly the commercial and technical feasibility of on-going development projects.
- We conducted detailed discussions with senior intangible project personnel to understand their rationale for concluding on the appropriateness of capitalisation of the development phase costs and, where necessary, challenged the underlying reasoning.
- We obtained a detailed understanding of the role of the employees in the development of the intangibles whose salaries are capitalized.

c. Revenue recognition – occurrence (Note 2):

Description of significant matter
Revenue recognition requires judgement by qualified personnel and often varies from contract to contract. The nature of such judgements result in them being susceptible to fraud. The recognition of revenue earlier than permitted by accounting standards was a deemed key audit risk.
The core principle is that an entity will recognise revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services, which requires the use of management judgement and gives rise to the risk of management override. The core principle is delivered in a five-step model framework: 1) identify the contract(s) with a customer, 2) identify the performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations in the contract and 5) recognise revenue when (or as) the entity satisfies a performance obligation.
We determined this as a key audit matter due to the high subjectivity and significant management judgement on certain revenue contracts.

Audit response to significant matter
Our audit procedures related to revenue included the following, among others:

- We tested the design and effectiveness of management review controls (including specific controls for review of revenue recognition and year end cut-off analyses).
- We selected a statistical sample of revenue transactions from each revenue stream and vouched to underlying documents.
- We examined contracts specific to the company's Covid-19 related portfolio of products for unusual terms. The company made significant revenue from these contracts during the year and some contracts have rights of return included in the agreement; and
- We examined post year-end sales activity, the assumptions made and the inputs used in the calculation of the return deferral.

Other information
Other information comprises information included in the annual report, other than the financial statements and the auditor's report thereon. 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.

Matters on which we are required to report by the Companies Act 2014

- We have obtained all the information and explanations which we consider 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 financial statements are in agreement with the accounting records.
- In our opinion the information given in the Directors' report is consistent with the financial statements. Based solely on the work undertaken in the course of our audit, in our opinion, the Directors' report has been prepared in accordance with the requirements of the Companies Act 2014.

Matters on which we are required to report by exception
Based on our knowledge and understanding of the group and the parent company and its environment obtained in the course of the audit, we have not identified material misstatements in the Directors' report.
Under the Companies Act 2014 we are required to report to you if, in our opinion, the disclosures of Directors' remuneration and transactions specified by sections 305 to 312 of the Act have not been made. We have no exceptions to report arising from this responsibility.

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 as adopted by the European Union, 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.

Responsibilities of the auditor for the audit of the financial statements
The auditor's objectives 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 their 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.

Responsibilities of the auditor for the audit of the financial statements (continued)

As part of an audit in accordance with ISAs (Ireland), the auditor will exercise professional judgement and maintain professional scepticism throughout the audit. The auditor will also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for their opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the group and parent company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the group and parent company's ability to continue as a going concern. If they conclude that a material uncertainty exists, they are required to draw attention in the auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify their opinion. Their conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the group or parent company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves a true and fair view.

The auditor communicates with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that may be identified during the audit.

Where the auditor is reporting on consolidated financial statements, the auditor's responsibilities are to obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. The auditor is responsible for the direction, supervision and performance of the audit, and the auditor remains solely responsible for the auditor's opinion.

The auditor also provides those charged with governance with a statement that they have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on their independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. These matters are described in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

The purpose of our audit work and to whom we owe our responsibilities

This report is made solely to the 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 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 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

6 September 2022

CONSOLIDATED STATEMENT OF OPERATIONS

	Notes	Year ended December 31 2021 Total US$'000	2020 Total US$'000	2019 Total US$'000
Revenues	2	**92,965**	**101,980**	**90,435**
Cost of sales		**(54,888)**	**(53,400)**	**(52,315)**
Gross profit		**38,077**	**48,580**	**38,120**
Other operating income	4	**4,672**	**1,860**	**91**
Research and development expenses		**(4,497)**	**(5,080)**	**(5,325)**
Selling, general and administrative expenses		**(24,683)**	**(26,390)**	**(27,661)**
Selling, general and administrative expenses – recognition of contingent asset	26	**-**	**1,316**	**-**
Selling, general and administrative expenses – closure costs	5	**-**	**(2,425)**	**-**
Selling, general and administrative expenses – tax audit settlement	6	**-**	**-**	**(5,042)**
Impairment charges	7	**(6,944)**	**(17,779)**	**(24,295)**
Operating profit/(loss)		**6,625**	**82**	**(24,112)**
Financial income	2, 8	**1,223**	**36**	**697**
Financial expenses	2, 8	**(7,097)**	**(6,751)**	**(6,582)**
Net financing expense		**(5,874)**	**(6,715)**	**(5,885)**
Profit/(Loss) before tax	11	**751**	**(6,633)**	**(29,997)**
Total income tax credit	2, 9	**178**	**620**	**1,006**
Profit/(Loss) for the year on continuing operations	2	**929**	**(6,013)**	**(28,991)**
(Loss)/Profit for the year on discontinued operations	10	**(54)**	**(375)**	**77**
Profit(Loss) for the year (all attributable to owners of the parent)	2	**875**	**(6,388)**	**(28,914)**
Basic profit/(loss) per ADS (US Dollars) – continuing operations	12	0.04	(0.29)	(1.39)
Diluted profit/(loss) per ADS (US Dollars) – continuing operations	12	0.04	(0.29)	(1.39)
Basic profit/(loss) per 'A' ordinary share (US Dollars) –continuing operations	12	0.01	(0.07)	(0.35)
Diluted profit/(loss) per 'A' ordinary share (US Dollars) – continuing operations	12	0.01	(0.07)	(0.35)
Basic profit/(loss) per ADS (US Dollars) – group	12	0.04	(0.31)	(1.38)
Diluted profit/(loss) per ADS (US Dollars) – group	12	0.04	(0.31)	(1.38)
Basic profit/(loss) per 'A' ordinary share (US Dollars) – group	12	0.01	(0.08)	(0.35)
Diluted profit/(loss) per 'A' ordinary share (US Dollars) – group	12	0.01	(0.08)	(0.35)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Year ended December 31		
	Notes	*2021 US$'000*	*2020 US$'000*	*2019 US$'000*
Profit/(Loss) for the year	2	875	(6,388)	(28,914)
Other comprehensive loss				
Items that will be reclassified subsequently to profit or loss				
Foreign exchange translation differences		(86)	(1,360)	(167)
Other comprehensive loss		(86)	(1,360)	(167)
Total Comprehensive Profit/(Loss) (all attributable to owners of the parent)		**789**	**(7,748)**	**(29,081)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	At December 31 2021 US$'000	2020 US$'000
ASSETS			
Non-current assets			
Property, plant and equipment	13	5,918	8,547
Goodwill and intangible assets	14	35,981	33,860
Deferred tax assets	15	4,101	4,185
Derivative financial instruments	24	-	150
Other assets	16	207	355
Total non-current assets		**46,207**	**47,097**
Current assets			
Inventories	17	29,123	30,219
Trade and other receivables	18	16,116	22,668
Income tax receivable		1,539	3,086
Cash and cash equivalents	19	25,910	27,327
Total current assets		**72,688**	**83,300**
TOTAL ASSETS	2	**118,895**	**130,397**
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	20	1,213	1,213
Share premium	20	16,187	16,187
Treasury shares	20	(24,922)	(24,922)
Accumulated surplus	20	12,559	10,573
Translation reserve	20	(5,379)	(5,293)
Other reserves	20	23	23
Total deficit		**(319)**	**(2,219)**
Current liabilities			
Income tax payable		22	154
Trade and other payables	22	15,127	24,335
Provisions	23	50	416
Exchangeable notes and other borrowings	24	83,312	-
Lease liabilities	25	1,980	2,153
Total current liabilities		**100,491**	**27,058**
Non-current liabilities			
Exchangeable notes and other borrowings	24	-	82,695
Derivative financial instruments	24	-	1,370
Lease liabilities	25	13,865	16,588
Deferred tax liabilities	15	4,858	4,905
Total non-current liabilities		**18,723**	**105,558**
TOTAL LIABILITIES	2	**119,214**	**132,616**
TOTAL EQUITY AND LIABILITIES		**118,895**	**130,397**

The financial statements were approved and authorised for issue by the Board on 6 September 2022 and signed on its behalf by:

Ronan O'Caoimh
Director

John Gillard
Director

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*	*Hedging reserves US$'000*	*Accumulated surplus US$'000*	*Total US$'000*
Balance at January 1, 2019	1,213	16,187	(24,922)	(3,766)	23	55,319	44,054
Loss for the period	-	-	-	-	-	(28,914)	(28,914)
Other comprehensive income	-	-	-	(167)	-	-	(167)
Total comprehensive loss	-	-	-	(167)	-	(28,914)	(29,081)
Share-based payments	-	-	-	-	-	839	839
Adjustment on transition to IFRS 16 (Note 13)	-	-	-	-	-	(11,099)	(11,099)
Balance at December 31, 2019	**1,213**	**16,187**	**(24,922)**	**(3,933)**	**23**	**16,145**	**4,713**
Balance at January 1, 2020	1,213	16,187	(24,922)	(3,933)	23	16,145	4,713
Loss for the period	-	-	-	-	-	(6,388)	(6,388)
Other comprehensive income	-	-	-	(1,360)	-	-	(1,360)
Total comprehensive loss	-	-	-	(1,360)	-	(6,388)	(7,748)
Share-based payments (Note 21)	-	-	-	-	-	816	816
Balance at December 31, 2020	**1,213**	**16,187**	**(24,922)**	**(5,293)**	**23**	**10,573**	**(2,219)**
Balance at January 1, 2021	1,213	16,187	(24,922)	(5,293)	23	10,573	(2,219)
Profit for the period	-	-	-	-	-	875	875
Other comprehensive income	-	-	-	(86)	-	-	(86)
Total comprehensive profit/(loss)	-	-	-	(86)	-	875	789
Share-based payments (Note 21)	-	-	-	-	-	1,111	1,111
Balance at December 31, 2021	**1,213**	**16,187**	**(24,922)**	**(5,379)**	**23**	**12,559**	**(319)**

CONSOLIDATED STATEMENT OF CASH FLOWS

	Notes	Year ended December 31, 2021 US$'000	2020 US$'000	2019 US$'000
Cash flows from operating activities				
Profit/(Loss) for the year		875	(6,388)	(28,914)
Adjustments to reconcile net profit/(loss) to cash provided by operating activities:				
Depreciation	11	1,827	1,674	2,526
Amortisation	11, 14	917	1,403	2,368
Income tax credit	9	(167)	(182)	(1,006)
Financial income	8	(1,223)	(36)	(697)
Financial expense	8	7,097	6,751	6,582
Share-based payments (net of capitalized amounts)	21	1,100	792	758
Foreign exchange gains on operating cash flows		(251)	(663)	(93)
(Gain)/Loss on disposal or retirement of property, plant and equipment	11	(1)	30	17
Movement in inventory provision	17	5,589	5,059	1,567
Impairment of prepayments	7, 18	583	562	1,376
Impairment of property, plant and equipment	7, 13	2,508	1,795	6,349
Impairment of intangible assets	7, 14	3,853	15,422	16,570
Other non-cash items		(5,317)	(634)	835
Operating cash flows before changes in working capital		**17,390**	**25,585**	**8,238**
Decrease / (Increase) in trade and other receivables		6,236	(2,489)	445
(Increase) in inventories		(4,406)	(3,419)	(2,959)
(Decrease) / Increase in trade and other payables		(7,591)	4,994	151
Cash generated from operations		**11,629**	**24,671**	**5,875**
Interest paid		(11)	(48)	(1,000)
Interest received		1	104	560
Income taxes received / (paid)		1,619	(972)	(18)
Net cash generated by operating activities		**13,238**	**23,755**	**5,417**
Cash flows from investing activities				
Payments to acquire intangible assets		(6,879)	(6,990)	(9,718)
Acquisition of property, plant and equipment		(1,812)	(3,178)	(2,118)
Disposal of property, plant and equipment		-	(30)	(17)
Net cash used in investing activities		**(8,691)**	**(10,198)**	**(11,853)**
Cash flows from financing activities				
Proceeds from Paycheck Protection loans		1,764	4,520	-
Interest payment on exchangeable notes	29	(3,996)	(3,996)	(3,996)
Refinancing Costs		(848)	-	-
Payment of lease liabilities	29	(2,939)	(3,240)	(3,533)
Net cash used in financing activities		**(6,019)**	**(2,716)**	**(7,529)**
(Decrease) / Increase in cash and cash equivalents and short term investments		(1,472)	10,841	(13,965)
Effects of exchange rate movements on cash held		55	86	88
Cash and cash equivalents and short-term investments at beginning of year		27,327	16,400	30,277
Cash and cash equivalents and short-term investments at end of year	19	**25,910**	**27,327**	**16,400**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2021

1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES

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

i) General information

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

ii) Statement of compliance

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") both as issued by the International Accounting Standards Board ("IASB") and as subsequently adopted by the European Union ("EU") (together "IFRS"). The IFRS applied are those effective for accounting periods beginning January 1, 2021. 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 2021 consolidated financial statements there are no differences regarding the effective date of new IFRS relevant to Trinity Biotech as issued by the IASB and as adopted by the EU. In relation to prior periods presented, none of the differences are relevant in the context of Trinity Biotech and the consolidated financial statements comply with IFRS both as issued by the IASB and as adopted by the EU.

iii) Basis of preparation

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

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

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

Judgements made by management that have a significant effect on the financial statements and estimates with a significant risk of material adjustment in the next year are discussed in Note 31.

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the Covid-19 pandemic. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At December 31, 2021, the Group had net currently liabilities. However, at the date of this report the Group's financial position has substantially improved following the successful re-financing of the Group's debt in early 2022. This has significantly improved the Group's capital structure by reducing gross debt by approximately US$19 million and there are no material debt maturities in the next four years. Furthermore, the investment by MiCo Group facilitated an early repayment of a substantial portion of the debt due to Perceptive Advisors and will also facilitate the Group exploring lower cost debt funding options with the aim of further reducing the Group's interest expense through refinancing the balance of the Group's term loan at substantially lower interest rates.

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

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

iv) Basis of consolidation

Subsidiaries

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

Transactions eliminated on consolidation

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

v) Property, plant and equipment

Owned assets

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

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

- Leasehold improvements 5-15 years
- Buildings 50 years
- Office equipment and fittings 10 years
- Computer equipment 3-5 years
- Plant and equipment 2-15 years

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

Leased assets - as lessee

The Group has applied IFRS 16, Leases, using the modified retrospective approach and therefore comparative information has not been restated.

Accounting policy applicable from 1 January 2019

For any new contracts entered into on or after 1 January 2019, 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:

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

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

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

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

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

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

Leased assets - as lessor

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

vi) Goodwill

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Amortisation

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

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

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

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

(a) once a diagnostic test becomes established, customers are reluctant to change to new technology until it is fully proven, thus resulting in relatively long product life cycles. There is also reluctance in customers to change to a new product as it can be costly both in terms of the initial changeover cost and as new technology is typically more expensive.

(b) demand for the diagnostic tests is enduring and robust within a wide geographic base. The diseases that the products diagnose are widely prevalent (HIV, Diabetes and Chlamydia being just three examples) in many countries. There is a general consensus that these diseases will continue to be widely prevalent in the future.

(c) there are significant barriers to new entrants in this industry. Patents and/or licences are in place for several of our products, though this is not the only barrier to entry. There is a significant cost and time to develop new products, it is necessary to obtain regulatory approval and tests are protected by proprietary know-how, manufacturing techniques and trade secrets.

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

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

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

viii) Impairment

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

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

For goodwill, assets that have an indefinite useful life and intangible assets that are not yet available for use, the recoverable amount is estimated at each balance sheet date at the cash generating unit level. The goodwill and indefinite-lived assets were reviewed for impairment at December 31, 2020 and December 31, 2021. See Note 14.

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

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

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

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

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

An impairment loss in respect of goodwill is not reversed.

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

ix) Inventories

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

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

x) Trade and other receivables

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

xi) Trade and other payables

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

xii) Cash and cash equivalents

Cash and cash equivalents comprise cash balances and short-term deposits which are readily available at year-end. Deposits with maturities less than six months as at the year-end date are recognised as cash and cash equivalents and are carried at fair value when there is no expected loss in value on early termination. The Group has no short-term bank overdraft facilities. Where restrictions are imposed by third parties, such as lending institutions, on cash balances held by the Group these are treated as financial assets in the financial statements.

xiii) Short-term investments

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

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

xiv) Share-based payments

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

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

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

xv) Government grants and financial support

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

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

xvi) Revenue recognition

Goods sold and services rendered

The Group recognises revenue when it transfers control over a good or service to a customer. Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group and the revenue can be measured. No revenue is recognised if there is uncertainty regarding recovery of the consideration due at the outset of the transaction. Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods and services supplied to external customers, net of discounts and rebates and excluding sales taxes.

Revenue from products is generally recorded as of the date of shipment, consistent with typical ex-works shipment terms. Where the shipment terms do not permit revenue to be recognised as of the date of shipment, revenue is recognised when the Group has satisfied all of its performance obligations to the customer in accordance with the shipping terms.

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

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

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

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

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

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

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

The Group's obligation to provide a refund for faulty products under the standard warranty terms is recognised as a provision, see Note 23 for details.

Other operating income

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

xvii) Employee benefits

Defined contribution plans

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

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

Other long-term benefits

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

Termination benefits

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

xviii) Foreign currency

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

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

Where Euro, Brazilian Real, Canadian Dollar or Swedish Kroner amounts have been referenced in this document, their corresponding US Dollar equivalent has also been included and these equivalents have been calculated with reference to the foreign exchange rates prevailing at December 31, 2021.

xix) Hedging

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

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

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

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

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

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

xx) Exchangeable notes and derivative financial instruments

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

The embedded derivatives are initially recognised at fair value and are restated at their fair value at each reporting date. The fair value changes of the embedded derivatives are recognised in the 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) 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.

xxii) Tax (current and deferred)

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

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.

xxiii) Provisions

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

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

xxiv) 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.

xxv) Finance income and costs

Financing expenses comprise interest costs payable on leases and 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 statement of operations as it accrues, using the effective interest method. Finance income also includes fair value adjustments to embedded derivatives associated with exchangeable notes.

xxvi) 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 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.

xxvii) 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.

xxviii) 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.

xxix) 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

xxx) New IFRS Standards and Interpretations not applied

The following new standards, interpretations and standard amendments became effective for the Group as of January 1, 2021 and did not result in a material impact on the Group's results:

- Amendments IFRS 9 *Financial Instruments*, IAS 39 *Financial Instruments: Recognition and measurement*
- IFRS 7 *Financial Instruments*: Disclosures
- IFRS 4 *Insurance Contracts*
- IFRS 16 *Leases* – Interest Rate Benchmark Reform – Phase 2

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

The following standard amendment was issued in March 2021 effective for annual reporting periods beginning on or after 1 April 2021 with earlier application permitted:

- Amendments to IFRS 16 – COVID-19-Related Rent Concessions beyond 30 June 2021. The amendment was adopted effective 1 January 2021 and did not result in a material impact on the Group's results.

2. SEGMENT INFORMATION

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing the performance of the operating segments, has been identified as the Board of Directors. Management has determined the operating segments based on the reports reviewed by the Board of Directors, which are used to make strategic decisions. The Board considers the business from a geographic perspective based on the Group's management and internal reporting structure. Sales of product between companies in the Group are made on commercial terms which reflect the nature of the relationship between the relevant companies. Segment results, assets and liabilities include items directly attributable to a segment as well as those that can be allocated on a reasonable basis. Unallocated items comprise interest-bearing loans, borrowings and expenses and corporate expenses. Segment capital expenditure is the total cost during the year to acquire segment plant, property and equipment and intangible assets that are expected to be used for more than one period, whether acquired on acquisition of a business combination or through acquisitions as part of the current operations.

The Group comprises two main geographical segments (i) the Americas and (ii) Rest of World - Ireland. The Group's geographical segments are determined by the location of the Group's assets and operations. The Group has also presented a geographical analysis of the segmental data for Ireland as is consistent with the information used by the Board of Directors.

The reportable operating segments derive their revenue primarily from one source (i.e. the market for diagnostic tests for a range of diseases and other medical conditions). In determining the nature of its segmentation, the Group has considered the nature of the products, their risks and rewards, the nature of the production base, the customer base and the nature of the regulatory environment. The Group acquires, manufactures and markets a range of diagnostic products. The Group's products are sold to a similar customer base and the main body whose regulation the Group's products must comply with is the Food and Drug Administration ("FDA") in the US.

The following presents revenue and profit information and certain asset and liability information regarding the Group's geographical segments.

i) The distribution of revenue by geographical area based on location of assets was as follows:

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

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

2. SEGMENT INFORMATION (CONTINUED)

Year ended December 31, 2019	*Americas* *US$'000*	*Rest of World* *Ireland* *US$'000*	*Rest of World* *Other* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Revenue from external customers	64,045	26,390	-	-	90,435
Inter-segment revenue	39,563	1,629	-	(41,192)	-
Total revenue	103,608	28,019	-	(41192)	90,435

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

Revenue	*December 31, 2021* *US$'000*	*December 31, 2020* *US$'000*	*December 31, 2019* *US$'000*
Americas	57,799	70,408	52,183
Asia / Africa	25,504	22,567	27,686
Europe (including Ireland) *	9,662	9,005	10,566
	92,965	101,980	90,435

* 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, 2021* *US$'000*	*December 31, 2020* *US$'000*	*December 31, 2019* *US$'000*
Clinical laboratory goods	74,700	84,280	68,127
Clinical laboratory services	7,928	8,485	10,915
Point-of-Care	10,337	9,215	11,393
	92,965	101,980	90,435

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

Revenue	*December 31, 2021* *US$'000*	*December 31, 2020* *US$'000*	*December 31, 2019* *US$'000*
Revenue from contracts with customers (a)	92,965	101,980	90,435
Revenue from other sources	-	-	-
	92,965	101,980	90,435

2. SEGMENT INFORMATION (CONTINUED)

(a) 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, 2021*	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
At a point in time	66,806	25,716	—	92,522
Over time	443	—	—	443
Total	67,249	25,716	—	92,965

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

Timing of revenue recognition *Year ended December 31, 2019*	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
At a point in time	63,300	26,390	—	89,690
Over time	745	—	—	745
Total	64,045	26,390	—	90,435

(b) 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, 2021*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	57,356	25,504	9,662	92,522
Over time	443	—	—	443
Total	57,799	25,504	9,662	92,965

2. SEGMENT INFORMATION (CONTINUED)

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

Timing of revenue recognition *Year ended December 31, 2019*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	51,438	27,686	10,566	89,690
Over time	745	—	—	745
Total	52,183	27,686	10,566	90,435

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

		Rest of World		
Year ended December 31, 2021	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
Result before impairment and unallocated expenses	9,276	5,084	(12)	14,348
Impairment	(6,088)	(856)	—	(6,944)
Result after impairment	3,188	4,228	(12)	7,404
Unallocated expenses *				(779)
Operating profit				6,625
Net financing expense (Note 8)				(5,874)
Profit before tax				751
Income tax credit (Note 9)				178
Profit for the year on continuing operations				929
Loss for the year on discontinued operations (Note 10)				(54)
Profit for the year				875

		Rest of World		
Year ended December 31, 2020	*Americas* *US$'000*	*Ireland* *US$'000*	*Other* *US$'000*	*Total* *US$'000*
Result before impairment and unallocated expenses	14,495	4,264	(71)	18,688
Impairment	(17,779)		—	(17,779)
Result after impairment	(3,284)	4,264	(71)	909
Unallocated expenses *				(827)
Operating profit				82
Net financing expense (Note 8)				(6,715)
Loss before tax				(6,633)
Income tax credit (Note 9)				620
Loss for the year on continuing operations				(6,013)
Loss for the year on discontinued operations (Note 10)				(375)
Loss for the year				(6,388)

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World		
Year ended December 31, 2019	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Result before impairment and unallocated expenses	5,239	(4,334)	(108)	797
Impairment	(14,562)	(9,733)	—	(24,295)
Result after impairment	(9,323)	(14,067)	(108)	(23,498)
Unallocated expenses *				(614)
Operating loss				(24,112)
Net financing expense (Note 8)				(5,885)
Loss before tax				(29,997)
Income tax credit (Note 9)				1,006
Loss for the year on continuing operations				(28,991)
Profit for the year on discontinued operations (Note 10)				77
Loss for the year				(28,914)

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

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

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

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
As at December 31, 2020	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Assets and liabilities				
Segment assets	58,164	37,632	3	95,799
Unallocated assets:				
Income tax assets (current and deferred)				7,271
Cash and cash equivalents and short-term investments				27,327
Total assets as reported in the Group balance sheet				130,397
Segment liabilities	20,431	107,080	46	127,557
Unallocated liabilities:				
Income tax liabilities (current and deferred)				5,059
Total liabilities as reported in the Group balance sheet				132,616

vii) 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, 2021 US$'000	*December 31, 2020 US$'000*
Rest of World – Ireland	22,617	19,927
Americas	19,489	22,835
	42,106	42,762

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Depreciation:			
Rest of World – Ireland	204	127	322
Americas	1,662	1,587	2,208
	1,866	1,714	2,530
Amortisation:			
Rest of World – Ireland	69	32	642
Americas	848	1,371	1,726
	917	1,403	2,368

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Rest of World – Ireland	1,072	722	659
Americas	28	70	99
	1,100	792	758

See Note 21 for further information on share-based payments.

2. SEGMENT INFORMATION (CONTINUED)

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Rest of World – Ireland	540	293	831
Rest of World – Other	(2)	(8)	—
Americas	(360)	335	175
	178	620	1,006

xi) During 2020 and 2019 there were no customers generating 10% or more of total revenues. In 2021, one customer accounted for more than 10% of total revenues.

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Rest of World – Ireland	3,826	5,609
Rest of World – Other	-	-
Americas	4,776	4,317
	8,602	9,926

3. EMPLOYMENT

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

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
Research and development	41	52	57
Administration and sales	134	148	159
Manufacturing and quality	302	343	363
	477	543	579

Employment costs charged in the Consolidated Income Statement for continuing operations are analysed as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Wages and salaries	26,561	26,187	25,885
Social welfare costs	2,403	2,195	2,538
Pension costs	352	447	503
Tax settlement (Note 6)	-	-	5,094
Share-based payments	1,100	792	758
Restructuring Cost	270	388	-
Recognition of contingent asset (Note 26)	-	(1,316)	-
	30,686	28,693	34,778

3. EMPLOYMENT (CONTINUED)

Employment costs are shown net of capitalisations and Irish government wage subsidies. Total employment costs, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2021 amounted to US$33,366,000 (2020: US$33,347,000) (2019: US$36,288,000). Total Irish government wage subsidies received in 2021 US$NIL (2020: US$1,752,000). Total share based payments, inclusive of amounts capitalised in the balance sheet, amounted to US$1,111,000 for the year ended December 31, 2021 (2020: US$816,000) (2019: US$838,000). See Note 21 for further details.

The Group operates defined contribution pension schemes for certain of its full time employees. The benefits under these schemes are financed by both Group and employee contributions. Total contributions made by the Group in the financial year and charged against income amounted to US$352,000 (2020: US$447,000) (2019: US$503,000). The pension accrual for the Group at December 31, 2021 was US$47,000 (2019: US$47,000), (2019: US$43,000).

4. OTHER OPERATING INCOME

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Government supports - COVID-19	4,668	1,840	-
Other income	-	17	88
Rental income from premises	4	3	3
	4,672	1,860	91

Government supports - COVID-19 comprises funding received under the U.S. government's Cares Act, specifically its Paycheck Protection Program and its Provider Relief Fund. Six Paycheck Protection Program ("PPP") loans received by the Company, amounting to US$4,668,000 were forgiven during 2021. Four out of six loans were treated as short term liabilities at December 31, 2020 (refer to Note 22). In addition, the company received US$225,000 under the Provider Relief Fund in 2020. No funding was received under the Provider Relief Fund in 2021. As of December 31, 2021, all these loans were forgiven.

Other income comprises US$NIL (2020: US$17,000) for provision of canteen services to third parties in Ireland. Due to COVID-19 restrictions, these services were suspended in the second quarter of 2020.

5. SELLING, GENERAL AND ADMINISTRATIVE EXPENSES – CLOSURE COSTS

In early 2020, management decided to close a production facility in Carlsbad, California facility which specialized in Western Blot manufacturing. The last number of years had seen a steady migration of customers away from using the Western Blot testing format for diagnosing Lyme in favour of alternative testing platforms. Production volumes declined steadily at the plant to the extent that it no longer made economic sense to continue. The plant was closed on June 30, 2020. Production of remaining products was transferred to other locations in the Group.

The charge for closing the facility was US$2.4 million which comprised redundancy costs, the write-off of inventory, the cost of exiting lease obligations and other costs associated with the closure of the facility.

6. SELLING, GENERAL AND ADMINISTRATIVE EXPENSES – TAX AUDIT SETTLEMENT

In the year ended December 31, 2019, the Company reached a tax settlement of US$6,442,000 arising out of a tax audit in one of the jurisdictions in which the company operates. The settlement consisted of US$3,863,000 in relation to a patent dividend scheme, which had operated via Rayville Limited from 1995 to 2010, US$1,231,000 in relation to payments for CEO Services made to Darnick Company (a company controlled by the family of Ronan O'Caoimh) and US$75,000 in relation to R&D tax credits. Penalties were US$273,000. Interest was US$1,000,000 and this is shown as a financial expense. The total settlement excluding interest of US$5,442,000 was partially offset by a provision of US$400,000, resulting in an expense of US$5,042,000 in the year ended December 31, 2019, which is shown as Selling, general and administrative expenses – tax audit settlement.

6. SELLING, GENERAL AND ADMINISTRATIVE EXPENSES – TAX AUDIT SETTLEMENT (CONTINUED)

Darnick Company agreed to contribute US$1,231,000 to the above settlement and this amount was outstanding at December 31, 2019 and was treated as a contingent asset and not recognized in the 2019 financial statements. This balance was settled in the year ended December 31, 2020 and has been credited to the Statement of Operations within Selling, General and Administrative Expenses. The underlying amount was denominated in Euro. Due to a depreciation in the US Dollar since 2019, the US Dollar equivalent amount increased from US$1,231,000 to US$1,316,000. The settlement amount received by the Company was US$177,000 more than the balance owed and this overpayment is recorded as a related party current liability for the benefit of Ronan O'Caoimh as at December 31, 2020. The amount was settled by the Group in January 2021.

7. IMPAIRMENT CHARGES

In accordance with IAS 36, *Impairment of Assets*, the Group carries out periodic impairment reviews of the asset valuations. A number of factors impacted this calculation including the Company's market capitalization during the year ended 31 December 2021, 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 statement of operations for the year ended December 31, 2021, December 31, 2020, December 31, 2019 was as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Selling, general & administration expenses			
Impairment of PP&E (Note 13)	2,508	1,795	6,349
Impairment of goodwill and other intangible assets (Note 14)	3,853	15,422	16,570
Impairment of prepayments (Note 18)	583	562	1,376
Total impairment loss	**6,944**	**17,779**	**24,295**
Income tax impact of impairment loss	**-**	**-**	148
Total impairment loss after tax	**6,944**	**17,779**	**24,443**

8. FINANCIAL INCOME AND EXPENSES

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Financial income:			
Non-cash financial income	1,220	-	233
Interest income	3	36	464
	1,223	36	697
Financial expense:			
Interest on leases	(815)	(896)	(947)
Interest on tax audit settlement (Note 6)	-	-	(1,000)
Cash interest on exchangeable notes	(3,996)	(3,996)	(3,996)
Loan origination costs	(1,638)	-	-
Non-cash interest on exchangeable notes (Note 24)	(648)	(643)	(639)
Non-cash financial expense	-	(1,216)	-
	(7,097)	(6,751)	(6,582)
Net Financing Expense	(5,874)	(6,715)	(5,885)

8. FINANCIAL INCOME AND EXPENSES (CONTINUED)

The Company and its subsidiaries entered into a US$81,250,000 senior secured term loan credit facility with Perceptive Advisors in December 2021. Loan origination costs of US$1,638,000 were incurred, comprising loan commitment and professional fees. These costs have been expensed in the Statement of Operations, as the term loan was subject to shareholder approval and that approval was not received until post year end. For more information on this term loan, refer to Note 30, Post Balance Sheet events.

Exchangeable note interest expense and non-cash financial income and expense relate to the exchangeable senior notes issued in 2015. For further information, refer to Note 24.

9. INCOME TAX CREDIT

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Current tax (credit)/expense			
Irish Corporation tax	(511)	(480)	(312)
Foreign taxes (a)	296	179	197
Adjustment in respect of prior years	-	(152)	(50)
Total current tax credit	(215)	(453)	(165)
Deferred tax credit (b)			
Origination and reversal of temporary differences (see Note 15)	620	48	(625)
Origination and reversal of net operating losses (see Note 15)	(583)	(215)	(216)
Total deferred tax credit	37	(167)	(841)
Total income tax credit on continuing operations in statement of operations	(178)	(620)	(1,006)
Tax charge on discontinued operations (see Note 10)	11	438	-
Total tax credit	(167)	(182)	(1,006)

(a) In 2021, the foreign taxes relate primarily to USA and Canada.

(b) In 2021, there was a deferred tax charge of US$118,000 (2020: charge of US$53,000; 2019: credit of US$444,000) recognised in respect of Ireland and a deferred tax credit of US$81,000 (2020: credit of US$220,000;2019: credit of US$397,000) recognised in respect of overseas tax jurisdictions.

Effective tax rate	*December 31, 2021*	*December 31, 2020*	*December 31, 2019*
Profit/(Loss) before taxation – continuing operations (US$'000)	751	(6,633)	(29,997)
As a percentage of loss before tax:			
Current tax %	28.63%	(6.83%)	(0.55%)
Total (current and deferred) %	23.70%	(9.35%)	(3.36%)

9. INCOME TAX CREDIT (CONTINUED)

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

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
Irish corporation tax	12.5%	(12.5%)	(12.5%)
Effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised (a)	49.63%	24.13%	13.21%
Effect of tax rates on overseas earnings	(0.22%)	(9.92%)	(3.05%)
Effect of Irish income taxable at higher tax rate	98.68%	5.92%	0.04%
Adjustments in respect of prior years	(0.01%)	(10.66%)	(0.17%)
R&D tax credits	(79.22%)	(11.00%)	(2.69%)
Other items (b)	(105.06%)	4.68%	1.80%
Effective tax rate	(23.70%)	(9.35%)	(3.36%)

(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/expenses not deductible for tax purposes. In 2021, this mainly comprises the income from the Paycheck Protection Program loans which is not chargeable for tax purposes.

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Rest of World – Ireland	1,862	296	(20,318)
Rest of World – Other	3,939	3,304	4,760
Americas	(5,050)	(10,233)	(14,439)
	751	(6,633)	(29,997)

At December 31, 2021, the Group had unutilised net operating losses for continuing operations as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Rest of World – Ireland	68,132	78,700	73,754
Rest of World – Other	1,000	2,185	-
Americas	4,761	4,313	6,823
	73,893	85,198	80,577

9. INCOME TAX CREDIT (CONTINUED)

At December 31, 2021, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Rest of World – Ireland – unused tax losses	9,272	12,514	12,062
Rest of World – Other – unused tax losses	279	546	-
Americas – unused tax losses	5,891	1,466	5,259
Americas – unused tax credits	3,368	2,862	493
Unrecognised deferred tax asset	18,810	17,388	17,814

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.

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

In 2016, management decided to cease the development of Cardiac point-of-care tests on the Meritas platform. These products were being developed by the Group's subsidiary Fiomi Diagnostics ("Fiomi") located in Sweden. The decision to cease the development work and to close the Swedish operation came after the company held a meeting with the U.S. Food and Drug Administration ("FDA") in order to obtain an update on the Meritas Troponin premarket submission. At that meeting the FDA suggested that the submission should be withdrawn. The FDA made it known that any new point-of-care Troponin product would be required to demonstrate performance equivalent to the most recently cleared laboratory-based device. As there was no certainty that this level of performance could ever be achieved by the point-of-care Meritas product, even with the benefit of further development efforts, management decided to cease the development work on Troponin I and the analyzer and its sister products, BNP and D-dimer.

Expenses, gains and losses relating to the discontinuation of the Cardiac point-of-care tests operation have been eliminated from profit or loss from the Group's continuing operations and are shown as a single line item (net of related taxes) on the face of the Consolidated Statement of Operations. The discontinued operation had no revenues since commencement as the products were still in their development phase. In 2016, the loss on discontinued operations included the write off of the carrying value of all capitalised development costs, goodwill, property, plant and equipment, inventories and other assets associated with the Meritas project. It also included a provision for the cost of closing the Swedish facility, mainly consisting of contractual obligations associated with terminating premises and supplier contracts, as well as redundancy costs for 41 employees.

In 2018, taxes paid to the Swedish tax authorities were recovered and there was a resulting tax credit of US$590,000. In 2021, closure costs of US$42,000 were incurred and a tax charge of US12,000 was expensed due to a change of estimate.

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

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
(Loss)/Profit on re-measurement of assets and liabilities:			
Closure provision	(42)	127	(8)
Foreign currency translation reserve	—	(64)	85
Tax (expense)/credit	(12)	(438)	—
Total (loss)/profit	(54)	(375)	77
(Loss)/Profit for the year from discontinued operations	**(54)**	**(375)**	**77**

Basic earnings per ordinary share – discontinued operations

Basic (loss)/earnings per ordinary share for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$54,000 (2020: loss US$375,000) (2019: profit US$77,000) for the financial year by the weighted average number of 'A' ordinary shares in issue. As at December 31, 2021, this amounted to 83,606,810 shares (2020: 83,606,810 shares) (2019: 83,606,810 shares), see note 12 for further details.

Diluted earnings per ordinary share – discontinued operations

Diluted (loss)/earnings per ordinary share for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$54,000 (2020: loss US$375,000) (2019: profit US$77,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 106,518,650 (2020: 105,024,732) (2019: 101,870,064), see note 12 for further details. Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. Therefore, diluted loss per ADS in accordance with IFRS is equal to basic earnings per ADS.

Earnings per ADS

In June 2005, Trinity Biotech adjusted its ADS ratio from 1 ADS: 1 ordinary share to 1 ADS: 4 ordinary shares. Earnings per ADS for all periods presented have been restated to reflect this exchange ratio.

Basic (loss)/earnings per ADS for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$54,000 (2020: loss US$375,000) (2019: profit US$77,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2020: 20,901,703) (2019: 20,901,703), see note 12 for further details.

Diluted (loss)/earnings per ADS for discontinued operations is computed by dividing the loss after taxation on discontinued operations of US$54,000 (2020: loss US$375,000) (2019: profit US$77,000) for the financial year, by the diluted weighted average number of ADS in issue of 26,629,663 (2020: 25,256,183) (2019: 25,256,183), see note 12 for further details.

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
Basic earnings/(loss) per ADS (US Dollars) – discontinued operations	0.00	(0.02)	0.00
Diluted earnings/(loss) per ADS (US Dollars) – discontinued operations	0.00	(0.02)	0.00
Basic earnings/(loss) per 'A' share (US Dollars) – discontinued operations	0.00	0.00	0.00
Diluted earnings/(loss) per 'A' share (US Dollars) – discontinued operations	0.00	0.00	0.00

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

Cash flows

The cash flows attributable to discontinued operations are as follows:

	December 31, 2021 *US$000*	*December 31, 2020* *US$000*	*December 31, 2019* *US$000*
Cash flows from operating activities	(40)	(22)	(5)

There were no cash flows from investing or financing activities attributable to discontinued operations for the years ended December 31, 2021, 2020 or 2019.

11. PROFIT/LOSS BEFORE TAX

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

	December 31, 2021 *US$'000*	*December 31, 2020* *US$'000*	*December 31, 2019* *US$'000*
Directors' emoluments (including non-executive directors):			
Remuneration	1,391	2,020	1,238
Pension	24	41	42
Share based payments	986	678	624
Auditor's remuneration			
Audit fees	549	533	523
Tax fees	77	146	172
Other non-audit fees	31	25	-
Depreciation*	1,827	1,674	2,526
Amortisation (Note 14)	917	1,403	2,368
(Profit)/Loss on the disposal of property, plant and equipment	(1)	30	17
Net foreign exchange differences	(789)	583	(179)

* Note that US$38,000 (2020: US$40,000) (2019: US$4,000) of depreciation was capitalised to research and development projects during 2021 in line with the Group's capitalisation policy for Intangible projects.

12. PROFIT/(LOSS) PER SHARE

Basic earnings per ordinary share

Basic earnings/(loss) per ordinary share for the group is computed by dividing the profit after taxation of US$875,000 (2020: loss of US$6,388,000) (2019: loss of US$28,914,000) for the financial year by the weighted average number of 'A' ordinary shares in issue. Basic earnings/(loss) per ordinary share for continuing operations is computed by dividing the profit after taxation for continued operations of US$929,000 (2020: loss of US$6,013,000) (2019: loss of US$28,991,000) for the financial year by the weighted average number of 'A' ordinary shares in issue.

As at December 31, 2021, this amounted to 83,606,810 shares (2020: 83,606,810 shares) (2019: 83,606,810 shares).

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
'A' ordinary shares	83,606,810	83,606,810	83,606,810
Basic earnings per share denominator	83,606,810	83,606,810	83,606,810
Reconciliation to weighted average earnings per share denominator:			
Number of 'A' ordinary shares at January 1 (Note 20)	96,162,410	96,162,410	96,162,410
Weighted average number of shares issued during the year*	-	-	-
Weighted average number of treasury shares	(12,555,600)	(12,555,600)	(12,555,600)
Basic earnings per share denominator	83,606,810	83,606,810	83,606,810

*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 earnings per ordinary share

Diluted earnings/(loss) per ordinary share for the group is computed by dividing the adjusted profit after tax of US$4,299,000 (2020: loss of US$533,000) (2019: loss of US$24,512,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 106,518,650 (2020: 105,024,732) (2019: 101,870,064). Diluted earnings/(loss) per ordinary share for continuing operations is computed by dividing the adjusted profit on continuing operations of US$4,353,000 (2020: loss of US$158,000) (2019: loss of US$24,590,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 106,518,650 (2020: 105,024,732) (2019: 101,870,064). The adjusted profit after tax on continuing operations is computed by adding back the interest expense, accretion interest and movements in the fair value of the derivatives on the exchangeable notes to the loss after taxation for continuing operations.

Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. Therefore, diluted loss per ordinary share in accordance with IFRS would be equal to basic loss per ordinary share when a loss occurs.

The basic weighted average number of ordinary shares for the Group may be reconciled to the number used in the diluted earnings per ordinary share calculation as follows:

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
Basic earnings per share denominator (see above)	83,606,810	83,606,810	83,606,810
Issuable on exercise of options and warrants	4,648,586	3,154,668	-
Issuable on conversion of exchangeable notes	18,263,254	18,263,254	18,263,254
Diluted earnings per share denominator	106,518,650	105,024,732	101,870,064

12. PROFIT/(LOSS) PER SHARE (CONTINUED)

The profit/(loss) after tax for the year may be reconciled to the amount used in the diluted earnings per ordinary share calculation as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Profit/(Loss) after tax for the year	875	(6,388)	(28,914)
Non-cash financial (income)/expense (Note 8)	(1,220)	1,216	(233)
Cash interest expense (Note 8)	3,996	3,996	3,996
Non-cash interest on exchangeable notes (Note 8)	648	643	639
Adjusted profit/(loss) after tax	4,299	(533)	(24,512)

Earnings per ADS

In June 2005, Trinity Biotech adjusted its ADS ratio from 1 ADS: 1 ordinary share to 1 ADS: 4 ordinary shares. Earnings per ADS for all periods presented have been restated to reflect this exchange ratio.

Basic earnings per ADS for the Group is computed by dividing the profit after taxation of US$875,000 (2020: loss of US$6,388,000) (2019: loss of US$28,914,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2020: 20,901,703) (2019: 20,901,703). Basic earnings per ADS for continuing operations is computed by dividing the profit after taxation of US$929,000 (2020: loss of US$6,013,000) (2019: loss of US$28,991,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2020: 20,901,703) (2019: 20,901,703).

	December 31, 2020	*December 31, 2020*	*December 31, 2019*
ADS	20,901,703	20,901,703	20,901,703
Basic earnings per share denominator	20,901,703	20,901,703	20,901,703
Reconciliation to weighted average earnings per share denominator:			
Number of ADS at January 1 (Note 20)	24,040,602	24,040,602	24,040,602
Weighted average number of shares issued during the year*	-	-	-
Weighted average number of treasury shares	(3,138,899)	(3,138,899)	(3,138,899)
Basic earnings per share denominator	20,901,703	20,901,703	20,901,703

Diluted earnings per ADS for the Group is computed by dividing the adjusted profit after taxation of US$4,299,000 (2020: loss of US$533,000) (2019: loss of US$24,512,000) for the financial year, by the diluted weighted average number of ADS in issue of 26,629,663 (2020: 26,256,183) (2019:25,467,516).

Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. Therefore, diluted earnings/(loss) per ADS in accordance with IFRS would be equal to basic earnings per ADS when a loss occurs.

*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.

The basic weighted average number of ADS shares for the Group may be reconciled to the number used in the diluted earnings per ADS share calculation as follows:

	December 31, 2021	*December 31, 2020*	*December 31, 2019*
Basic earnings per share denominator (see above)	20,901,703	20,901,703	20,901,703
Issuable on exercise of options and warrants	1,162,146	788,666	-
Issuable on conversion of exchangeable notes	4,565,814	4,565,814	4,565,814
Diluted earnings per share denominator	26,629,663	26,256,183	25,467,517

13. PROPERTY, PLANT AND EQUIPMENT

	Land & Buildings US$'000	*Leasehold Improvements US$'000*	*Computer & Offic Equipment US$'000*	*Plant & Equipment US$'000*	*Total US$'000*
Cost					
At January 1, 2020	24,269	3,005	4,292	38,676	70,242
Additions	8	41	96	2,766	2,911
Disposals or retirements	—	(299)	(66)	(5,758)	(6,123)
Exchange adjustments	10	(77)	(13)	(1,845)	(1,925)
At December 31, 2020	24,287	2,670	4,309	33,839	65,105
At January 1, 2021	24,287	2,670	4,309	33,839	65,105
Additions	46	126	144	1,392	1,708
Disposals or retirements	—	(186)	(255)	(2,410)	(2,851)
Reallocations/ reclassifications	—	—	—	—	—
Exchange adjustments	1	(18)	2	(484)	(499)
At December 31, 2021	24,334	2,592	4,200	32,337	63,463
Accumulated amortisation and Impairment losses					
At January 1, 2020	(18,493)	(2,037)	(3,682)	(36,740)	(60,952)
Charge for the year	(783)	(146)	(181)	(604)	(1,714)
Impairment losses as at December 31, 2020	(347)	(78)	(180)	(1,190)	(1,795)
Disposals or retirements	—	299	84	5,590	5,973
Exchange adjustments	(6)	78	13	1,845	1,930
At December 31, 2020	(19,629)	(1,884)	(3,946)	(31,099)	(56,558)
At January 1, 2021	(19,629)	(1,884)	(3,946)	(31,099)	(56,558)
Charge for the year	(628)	(149)	(115)	(974)	(1,866)
Disposals or retirements	—	186	255	2,410	2,851
Impairment losses	(1,196)	(279)	(98)	(935)	(2,508)
Reallocations/ reclassifications	—	—	—	—	—
Exchange adjustments	21	(5)	(46)	566	536
At December 31, 2021	(21,432)	(2,131)	(3,950)	(30,032)	(57,545)
Carrying amounts					
At December 31, 2021	2,902	461	250	2,305	5,918
At December 31, 2020	4,658	786	363	2,740	8,547

13. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

Right-of-use assets

The right-of-use assets are included in the same line item as the corresponding underlying assets would be presented if they were owned. The Group has used the modified retrospective application method for its first time application of IFRS 16, *Leases* in 2019. Right-of-use assets were assessed for impairment on transition by applying IAS 36, *Impairment* as at January 1, 2019. Right of Use assets leased by three Cash Generating Units, in which there was an unallocated impairment loss as at December 31, 2018, were impaired by a total of US$11,099,000. This amount is shown in the Consolidated Statement of Changes in Equity as a movement in Accumulated Surplus.

	US$000
Right-of-use assets cost at transition before impairment	21,185
Impairment adjustment on transition	(11,099)
Right-of-use assets value at transition after impairment	10,086

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

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

	Carrying amount At December 31, 2020	*Depreciation Charge Year ended December 31, 2020*	*Impairment Charge Year ended December 31, 2020*
	US$000	*US$000*	*US$000*
Buildings	4,200	(673)	(347)
Computer equipment	3	(4)	-
Plant and Equipment	-	(70)	(154)
	4,203	(747)	(501)

Income from sub-letting right-of-use buildings amounted to US$3,000 in the year ended December 31, 2021 (2020: US$3,000).

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

13. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

Right-of-Use assets at 31 December 2020	*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	12	1 to 13	4	1	-	2	4
Vehicle	16	1 to 3	2	-	16	-	16
I.T. and office equipment	10	1 to 2	1	-	-	-	1

The details of the impairment review are described in Note 14. 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$2,508,000 was allocated to property, plant and equipment as at December 31, 2021 (2020: US$1,795,000). The recoverable amount of property, plant and equipment was determined to be the value in use of each cash generating unit.

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

The Company has a number of assets included in plant and equipment which generate operating lease revenue for the Group. The net book value of these assets as at December 31, 2021 and 2020 is US$Nil following full write down of the assets due to group impairment (refer to Note 14). Depreciation charged on these assets in 2021 amounted to US$27,000 (2020: US$21,000).

Property, plant and equipment under construction

There were no assets under construction included in property, plant and equipment at December 31, 2021 (2020: US$Nil).

14. GOODWILL AND INTANGIBLE ASSETS

	Goodwill US$'000	*Development costs US$'000*	*Patents and licences US$'000*	*Other US$'000*	*Total US$'000*
Cost					
At January 1, 2020	81,689	156,377	9,951	34,266	282,283
Additions	—	6,896	30	89	7,015
Disposals or retirements	(2,507)	(34,318)	(1,034)	(1,044)	(38,903)
Exchange adjustments	—	22	—	—	22
At December 31, 2020	79,182	128,977	8,947	33,311	250,417
At January 1, 2021	79,182	128,977	8,947	33,311	250,417
Additions	—	6,771	102	21	6,894
Disposals or retirements	—	(14,576)	(342)	(134)	(15,052)
Exchange adjustments	—	1	—	—	1
At December 31, 2021	79,182	121,173	8,707	33,198	242,260
Accumulated amortisation and Impairment losses					
At January 1, 2020	(69,098)	(133,599)	(9,819)	(26,113)	(238,629)
Charge for the year	—	(959)	(5)	(439)	(1,403)
Disposals or retirements	2,507	34,318	1,034	1,044	38,903
Impairment losses	—	(15,287)	—	(135)	(15,422)
Exchange adjustments	—	(6)	—	—	(6)
At December 31, 2020	(66,591)	(115,533)	(8,790)	(25,643)	(216,557)
At January 1, 2021	(66,591)	(115,533)	(8,790)	(25,643)	(216,557)
Charge for the year	—	(482)	(7)	(428)	(917)
Disposals or retirements	—	14,573	342	132	15,047
Impairment losses	(54)	(2,053)	(106)	(1,640)	(3,853)
Exchange adjustments	—	1	—	—	1
At December 31, 2021	(66,645)	(103,494)	(8,561)	(27,579)	(206,279)
Carrying amounts					
At December 31, 2021	12,537	17,679	146	5,619	35,981
At December 31, 2020	12,591	13,444	157	7,668	33,860

Included within development costs are costs of US$7,994,000 which were not amortised in 2021 (2020: US$6,980,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at December 31, 2021 or at December 31, 2020. As at December 31, 2021 these projects are expected to be completed during the period from January 1, 2022 to December 31, 2024 at an expected further cost of approximately US$5,857,000.

14. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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

Product Name	2021 US$'000	2020 US$'000
Premier Instrument for Haemoglobin A1c testing	2,538	1,359
HIV screening rapid test	1,488	2,278
COVID tests	1,320	467
Autoimmune Smart Reader	550	666
Mid-tier haemoglobins instrument	303	243
Tri-stat point-of-care instrument	245	203
Uni-gold raw material stabilisation	144	-
Sjögrens tests	88	99
Uni-Gold antigen improvement	-	556
Syphilis point-of-care test	-	618
Column enhancement	-	151
Other projects	95	256
Total capitalised development costs	**6,771**	**6,896**

All of the development projects for which costs have been capitalised are judged to be technically feasible, commercially viable and likely to produce future economic benefits. In reaching this conclusion, many factors have been considered including the following:

(a) The Group only develops products within its field of expertise. The R&D team is experienced in developing new products in this field and this experience means that only products which have a high probability of technical success are put forward for consideration as potential new products.

(b) A technical feasibility study is undertaken in advance of every project. The feasibility study for each project is reviewed by the R&D team leader, and by other senior management depending on the size of the project. The feasibility study occurs in the initial research phase of the project and costs in this phase are not capitalised.

(c) Nearly all of our new product developments involve the transfer of our existing product know-how to a new application. The Group does not engage in pure research. Every development project is undertaken with the intention of bringing a particular new product to market for which there is an expected demand.

(d) The commercial feasibility of each new product is established prior to commencement of a project by ensuring it is projected to achieve an acceptable income after applying appropriate discount rates.

Other intangible assets

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

Amortisation

Amortisation is charged to the statement of operations through the selling, general and administrative expenses line.

14. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

Impairment testing for intangibles including goodwill and indefinite lived assets

Goodwill and other intangibles are subject to impairment testing on a periodic basis. The recoverable amount of seven CGUs is determined based on a value-in-use computation. Among other macroeconomic considerations, the impact of the COVID-19 pandemic has been factored into our impairment testing.

The value-in-use calculations use cash flow projections based on the 2022 projections for each CGU and a further four years projections using estimated revenue and cost average growth rates of between 0% and 5%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate of 2%, are used in the value-in-use calculations. The value-in-use represents the present value of the future cash flows, including the terminal value, discounted at a rate appropriate to each CGU. The pre-tax discount rates used range from 16% to 25% (2020: 16% to 44%).

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.

2021 impairment test

The impairment tests performed at June 30, 2021 and at December 31, 2021 identified an impairment loss in three CGUs, Immco Diagnostics Inc, Trinity Biotech Do Brasil and Biopool US Inc. A specific impairment loss on an intangible asset owned by Trinity Biotech Manufacturing Limited was also incurred in 2021.

The table below sets forth the impairment loss recorded for each of the CGU's:

	December 31, 2021 US$'000	***December 31, 2020 US$'000***
Immco Diagnostics Inc	4,979	-
Trinity Biotech Manufacturing Limited	856	-
Trinity Biotech Do Brasil	956	919
Biopool US Inc.	153	154
Primus Corp	-	16,706
Total impairment loss	**6,944**	**17,779**

The carrying value of the intangible assets for the COVID-19 antibody rapid test was written off in full in the year ended December 31, 2021 and is included in the total impairment charge in the table above. This product development was an asset of Trinity Biotech Manufacturing Limited and the impairment charge recorded for this asset was US$856,000.

14. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

The COVID-19 antibody rapid test was submitted to the FDA under an Emergency Use Authorisation ("EUA") application. The FDA informed the Company that given the volume of EUA requests it has received, it was not currently prioritising this type of serological test for review and thus would not review an EUA application for the test at this time. The Company has examined other potential pathways to regulatory approval to allow US sales of this test, but it is expected that these would require significant additional investment. Due to the advent and widespread adoption of COVID-19 vaccines since this antibody test was envisaged and the focus of public health authorities on using evidence of vaccination rather than the presence of antibodies as proof of immunity, the Company now expects that the use for such tests will be limited and thus the potential revenues from the sales of this product to be minimal. Given this current limited market demand for such antibody tests, the Company decided not to devote additional investment to this test and the full costs to date for the development of the rapid test was written off. Instead, the Company is focusing its resources on a COVID-19 antigen test for which we expect a much larger market.

Immco Diagnostics Inc., which recorded the largest impairment loss of any CGU in this financial year, has been particularly impacted by the pandemic and changes to its product offering.

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Goodwill and other intangible assets (see Note 14)	3,853	15,422
Property, plant and equipment (see Note 13)	2,508	1,795
Prepayments (see Note 18)	583	562
Total impairment loss	**6,944**	**17,779**

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

- In the event that there was a reduction of 10% in the assumed level of future growth in revenue growth rate, which would represent a reasonably likely range of outcomes, there would be no additional impairment loss recorded at December 31, 2021.
- 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, 2021.

Significant Goodwill and Intangible Assets with Indefinite Useful Lives

CGUs or combinations of CGUs for which the carrying amount of goodwill is significant for the purposes of impairment testing periodically, in comparison with the Group's total carrying amount of goodwill are those where the percentage is greater than 20% of the total.

14. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

The additional disclosures required for the CGU with significant goodwill are as follows:

Fitzgerald Industries	*December 31, 2021*	*December 31, 2020*
Carrying amount of goodwill (US$'000)	12,591	12,591
Discount rate applied (real pre-tax)	19.66%	19.98%
Excess value-in-use over carrying amount (US$'000)	3,496	7,915
% EBITDA would need to decrease for an impairment to arise	18.15%	31.98%
Long-term growth rate	2.0%	2.0%

The key assumptions and methodology used in respect of this CGU are consistent with those described above. The assumptions and estimates used are specific to the individual CGU and were derived from a combination of internal and external factors based on historical experience.

Intangible Assets with Indefinite Useful lives (included in other intangibles)	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
Fitzgerald Industries International CGU		
Fitzgerald trade name	970	970
RDI trade name	560	560
Primus Corporation CGU		
Primus trade name	365	365
Immco Diagnostic CGU		
Immco Diagnostic trade name	2,069	2,938
Total	**3,964**	**4,833**

The trade name assets purchased as part of the acquisition of Fitzgerald in 2004, Primus and RDI in 2005 and Immco Diagnostics in 2013 were valued using the relief from royalty method and based on factors such as (1) the market and competitive trends and (2) the expected usage of the name. It was considered that these trade names will generate net cash inflows for the Group for an indefinite period.

In 2020, an impairment loss of US$135,000 was allocated against the Primus trade name as the carrying value of the CGU's net assets exceeded its discounted future cashflows. In 2021, an impairment loss of US$869,000 was allocated against the Immco Diagnostic trade name as the carrying value of the CGU's net assets exceeded its discounted future cashflows.

15. 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*	
	2021	*2020*	*2021*	*2020*	*2021*	*2020*
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Property, plant and equipment	477	733	(11)	(9)	466	724
Intangible assets	—	—	(3,969)	(4,072)	(3,969)	(4,072)
Inventories	620	750	—	—	620	750
Provisions	1,871	2,159	—	—	1,871	2,159
Tax value of loss carry-forwards	1,016	433	—	—	1,016	433
Other items	117	110	(878)	(824)	(761)	(714)
Deferred tax assets/(liabilities)	4,101	4,185	(4,858)	(4,905)	(757)	(720)

The deferred tax asset in 2021 is mainly due to deductible temporary differences relating to provisions, loss carry-forwards, property, plant and equipment and the elimination of unrealised intercompany inventory profit. In 2021, the deferred tax asset decreased by US$84,000 mainly due to a reduction in deductible temporary differences principally attributable to property, plant and equipment, provisions and inventories.

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 decreased by US$47,000 in 2021, principally because of the impairment of intangible assets on which the deferred tax liabilities were recognised.

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, 2021 and at December 31, 2020 no deferred tax assets and liabilities are offset as it is not certain as to whether there is a legally enforceable right to set off current tax assets against current tax liabilities and it is also uncertain as to what current tax assets may be set off against current tax liabilities and in what periods.

Most temporary differences are expected to reverse after 2023.

Movement in temporary differences during the year

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

15. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

	Balance January, 1 2020 *US$'000*	*Recognised in income* *US$'000*	*Balance December 31, 2020* *US$'000*
Property, plant and equipment	1,018	(294)	724
Intangible assets	(6,099)	2,027	(4,072)
Inventories	642	108	750
Provisions	3,622	(1,463)	2,159
Tax value of loss carry-forwards	216	217	433
Other items	(286)	(428)	(714)
	(887)	167	(720)

Unrecognised deferred tax assets

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

	December 31, 2021 *US$'000*	*December 31, 2020* *US$'000*
Capital losses	8,293	8,293
Net operating losses	73,893	85,198
US alternative minimum tax credits	1,704	1,848
Other temporary timing differences	21,301	21,878
US state credit carry-forwards	1,664	802
	106,855	118,019

There was a decrease of US$11,164,000 in the unrecognised deferred tax assets during the year ended December 31, 2021. The above amounts are the gross values and have not been tax effected.

16. OTHER NON-CURRENT ASSETS

	December 31, 2021 *US$'000*	*December 31, 2020* *US$'000*
Finance lease receivables (see Note 18)	151	291
Other assets	56	64
	207	355

The Group leases instruments as part of its business. For details of future minimum finance lease receivables with non-cancellable terms, please refer to Note 18.

17. INVENTORIES

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Raw materials and consumables	13,650	12,168
Work-in-progress	5,546	5,169
Finished goods	9,927	12,882
	29,123	30,219

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$12,063,000 (2020: US$9,781,000) (2019: US$6,716,000). Cost of sales in 2021 includes inventories expensed of US$49,299,000 (2020: US$48,342,000), (2019: US$50,748,000).

The movement on the inventory provision for the three year period to December 31, 2021 is as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Opening provision at January 1	9,781	6,716	6,299
Charged during the year	5,589	5,179	1,567
Utilised during the year	(3,307)	(1,994)	(1,150)
Released during the year	-	(120)	-
Closing provision at December 31	12,063	9,781	6,716

During 2021, US$Nil (2020: US$120,000), (2019: US$Nil) of inventory provision relating to net realisable value was released to the statement of operations following a current year review of inventory usage.

After January 27, 2022, the assets of the Group are pledged as security for the term loan from Perceptive Advisors. Refer to Note 30, Post Balance Sheet events.

18. TRADE AND OTHER RECEIVABLES

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Trade receivables, net of impairment losses	13,290	20,025
Prepayments	1,945	1,159
Contract assets	739	1,177
Value added tax	-	92
Finance lease receivables	142	215
	16,116	22,668

Trade receivables are shown net of an impairment losses provision of US$2,986,000 (2020: US$3,922,000) (see Note 28). Prepayments are shown net of impairment of US$583,000 (2020: US$562,000) (see Note 7).

Contract assets have decreased compared to the prior year as the Group shipped less product to customers with cost per test contracts in the last part of the year.

18. TRADE AND OTHER RECEIVABLES (CONTINUED)

Long-term contract receivable

(i) Finance lease commitments – Group as lessor

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

	December 31, 2021 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	292	150	142
Between one and five years (Note 16)	310	159	151
	602	309	293

	December 31, 2020 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	415	200	215
Between one and five years (Note 16)	591	300	291
	1,006	500	506

The Group classified future minimum lease receivables between one and five years of US$151,000 (2020: US$291,000) as Other Assets, see Note 16. Under the terms of the lease arrangements, no contingent rents are receivable.

(ii) Operating lease commitments – Group as lessor

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

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

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

	December 31, 2020 US$'000	
	Instruments	Total
Less than one year	2,767	2,767
Between one and five years	171	171
	2,938	2,938

19. CASH AND CASH EQUIVALENTS

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Cash at bank and in hand	22,790	24,209
Short-term deposits	3,120	3,118
Cash and cash equivalents	25,910	27,327

20. CAPITAL AND RESERVES

Share capital

In thousands of shares	*Class 'A' Ordinary shares 2021*	*Class 'A' Ordinary shares 2020*
In issue at January 1	96,162	96,162
Issued for cash	-	-
In issue at December 31	96,162	96,162

In thousands of ADSs	*ADS 2021*	*ADS 2020*
Balance at January 1	24,041	24,041
Issued for cash	-	-
Balance at December 31	24,041	24,041

In thousands of shares	*Class 'A' Treasury shares 2021*	*Class 'A' Treasury shares 2020*
Balance at January 1	12,556	12,556
Purchased during the year	-	-
Balance at December 31	12,556	12,556

In thousands of ADSs	*ADS Treasury shares 2021*	*ADS Treasury shares 2020*
Balance at January 1	3,139	3,139
Purchased during the year	-	-
Balance at December 31	3,139	3,139

The Group had authorised share capital of 200,700,000 'A' ordinary shares of US$0.0109 each (2020: 200,700,000 'A' ordinary shares of US$0.0109 each) as at December 31, 2021. The Group did not issue any shares from the exercise of employee options and did not repurchase any 'A' ordinary shares under its share buyback program in either 2020 or 2021. No dividends have been paid in the last five years. The last dividend paid was in respect of the 2014 financial year.

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.

20. CAPITAL AND RESERVES (CONTINUED)

Hedging reserve

The hedging reserve comprises the effective portion of the cumulative net change in the fair value of cash flow hedging instruments related to hedged transactions entered into but not yet crystallised. The hedging reserve is shown within Other Reserves in the Consolidated Statement of Financial Position.

Treasury shares

During 2021, the Group did not purchase any (2020: nil) (2019: nil) 'A' Ordinary shares (2019: nil ADS's) (2019: nil ADS's) 'Treasury shares'.

21. SHARE OPTIONS

Options

Under the terms of the Company's Employee Share Option Plans, options to purchase 18,727,990 'A' Ordinary Shares (4,681,998 ADS's) were outstanding at December 31, 2021. Under these Plans, options are granted to officers, employees and consultants of the Group at the discretion of the Compensation Committee (designated by the Board of Directors), under the terms outlined below.

Certain options have been granted to consultants of the Group and, where this is the case, the Group has measured the fair value of the services provided by these consultants by reference to the fair value of the equity instruments granted. This approach has been adopted in these cases as it is impractical for the Group to reliably estimate the fair value of such services.

The terms and conditions of the grants are as follows, whereby all options are settled by physical delivery of shares:

Vesting conditions

The options vest following a period of service by the officer or employee. The required period of service is determined by the Board and Remuneration Committee at the date of grant of the options (usually the date of approval by the Compensation Committee) and it is generally over a three to four-year period. There are no market conditions associated with the share option vesting periods.

Contractual life

The term of an option is determined by the Board, Compensation Committee and Remuneration Committee provided that the term may not exceed a period of between seven to ten years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with the Group (or one year after such termination because of death or disability) except where a longer period is approved by the Board of Directors. Under certain circumstances involving a change in control of the Group, the Compensation Committee may accelerate the exercisability and termination of options

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21. SHARE OPTIONS (CONTINUED)

The number and weighted average exercise price of share options and warrants per ordinary share is as follows (as required by IFRS 2, this information relates to all grants of share options and warrants by the Group):

	Options and warrants 'A' Ordinary Shares	*Weighted-average exercise price US$* Per 'A' Ordinary Share	*Range US$* Per 'A' Ordinary Share
Outstanding January 1, 2019	10,908,200	1.83	0.67 – 4.36
Granted	4,370,000	0.68	0.46 – 0.78
Exercised	-	-	-
Expired / Forfeited	(2,974,210)	2.25	0.66 – 4.23
Outstanding at end of year	12,303,990	1.31	0.46 – 4.36
Exercisable at end of year	6,622,667	1.73	1.24 – 4.36
Outstanding January 1, 2020	12,303,990	1.31	0.46 – 4.36
Granted	9,100,000	0.38	0.19 – 1.10
Exercised	-	-	-
Expired / Forfeited	(1,918,000)	2.14	0.19-4.21
Outstanding at end of year	19,485,990	0.79	0.19-4.36
Exercisable at end of year	7,959,323	1.27	0.66-4.36
Outstanding January 1, 2021	19,485,990	0.79	0.19-4.36
Granted	-	-	-
Exercised	-	-	-
Expired / Forfeited	(758,000)	1.07	0.19-4.21
Outstanding at end of year	18,727,990	0.78	0.19-4.36
Exercisable at end of year	13,401,322	0.93	0.19-4.36

21. SHARE OPTIONS (CONTINUED)

	Options and warrants 'ADS' Equivalent	Weighted-average exercise price US$ Per 'ADS'	Range US$ Per 'ADS'
Outstanding January 1, 2019	2,727,050	7.32	2.68– 17.44
Granted	1,092,500	2.72	1.83 - 3.10
Exercised	-	-	-
Expired / Forfeited	(743,552)	8.99	2.64 – 16.92
Outstanding at end of year	3,075,998	5.24	1.83 – 17.45
Exercisable at end of year	1,655,667	6.92	4.95 – 17.45
Outstanding January 1, 2020	3,075,998	5.24	1.83 – 17.45
Granted	2,275,000	1.52	0.77-4.41
Exercised	-	-	-
Expired / Forfeited	(479,500)	8.56	0.77-16.84
Outstanding at end of year	4,871,498	3.15	0.77-17.45
Exercisable at end of year	1,989,831	5.08	2.64-17.45
Outstanding January 1, 2021	4,871,498	3.15	0.77-17.45
Granted	-	-	-
Exercised	-	-	-
Expired / Forfeited	(189,500)	4.28	0.76-16.84
Outstanding at end of year	4,681,998	3.12	0.76-17.44
Exercisable at end of year	3,350,331	3.72	0.76-17.44

There were no share options exercised during 2021, 2020 or 2019.

The opening share price per 'A' Ordinary share at the start of the financial year was US$0.95 or US$3.81 per ADS (2020: US$0.27 or US$1.07 per ADS) (2019: US$0.57 or US$2.29 per ADS) and the closing share price at December 31, 2021 was US$0.36 or US$1.43 per ADS (2020: US$0.95 or US$3.81 per ADS) (2019: US$0.26 or US$1.03 per ADS). The average share price for the year ended December 31, 2021 was US$0.77 per 'A' Ordinary share or US$3.07 per ADS.

A summary of the range of prices for the Company's stock options for the year ended December 31, 2021 follows:

	Outstanding			**Exercisable**		
Exercise price range	No. of options 'A' ordinary shares	Weighted – average exercise price	Weighted-average contractual life remaining (years)	No. of options 'A' ordinary shares	Weighted– average exercise price	Weighted-average contractual life remaining (years)
US$0.19-US$0.99	13,000,006	0.48	3.54	7,960,004	0.55	2.92
US$1.00-US$2.05	5,228,000	1.34	0.79	4,941,334	1.35	0.99
US$2.06- US$2.99	439,984	2.53	0.03	439,984	2.53	0.04
US$3.00 -US$4.36	60,000	4.17	0.00	60,000	4.17	0.00
	18,727,990			13,401,322		

21. SHARE OPTIONS (CONTINUED)

	Outstanding			Exercisable		
Exercise price range	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.77-US$3.96	3,250,002	1.94	3.54	1,990,001	2.19	2.92
US$4.00-US$8.20	1,307,000	5.36	0.79	1,235,334	5.40	0.99
US$8.24- US$11.96	109,996	10.13	0.03	109,996	10.13	0.04
US$12.00 -US$17.45	15,000	16.67	0.00	15,000	16.67	0.00
	4,681,998			3,350,331		

A summary of the range of prices for the Company's stock options for the year ended December 31, 2020 follows:

	Outstanding			Exercisable		
Exercise price range	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'A' ordinary shares	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.19-US$0.99	13,260,006	0.48	4.14	2,106,673	0.69	1.44
US$1.00-US$2.05	5,664,000	1.34	1.11	5,290,667	1.35	2.44
US$2.06- US$2.99	499,984	2.52	0.05	499,984	2.52	0.13
US$3.00 -US$4.36	62,000	4.17	0.00	62,000	4.17	0.01
	19,485,990			7,959,324		

	Outstanding			Exercisable		
Exercise price range	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$0.77-US$3.96	3,315,002	1.92	4.17	526,668	2.76	1.44
US$4.00-US$8.20	1,416,000	5.36	1.10	1,322,667	5.40	2.44
US$8.24- US$11.96	124,996	10.08	0.05	124,996	10.08	0.13
US$12.00 -US$17.45	15,500	16.68	0.00	15,500	16.68	0.01
	4,871,498			1,989,831		

The weighted-average remaining contractual life of options outstanding at December 31, 2021 was 4.35 years (2020: 5.32 years).

21. SHARE OPTIONS (CONTINUED)

Charge for the year under IFRS 2

The charge for the year is calculated based on the fair value of the options granted which have not yet vested.

The fair value of the options is expensed over the vesting period of the option. US$1,100,000 was charged to the statement of operations in 2021, (2020: US$792,000), (2019: US$758,000) split as follows :

	December 31, 2021 US$'000	*December 31, 2020 US$'000*	*December 31, 2019 US$'000*
Share-based payments – cost of sales	5	12	26
Share-based payments – selling, general and administrative	1,095	780	732
Total – continuing operations	1,100	792	758
Share-based payments – discontinued operations	-	-	-
Total	1,100	792	758

The total share based payments charge for the year was US$1,111,000 (2020: US$816,000) (2019: US$839,000). However, a total of US$11,000 (2020: US$24,000) (2019: US$80,000) of share based payments was capitalised in intangible development project assets during the year.

The fair value of services received in return for share options granted are measured by reference to the fair value of share options granted. The estimate of the fair value of services received is measured based on a trinomial model. There were no share options issued during 2021. The following are the input assumptions used in determining the fair value of share options granted in 2021, 2020 and 2019:

	Key management personnel	**Other employees**	**Key management personnel**	**Other employees**	**Key management personnel**	**Other employees**
	2021	**2021**	**2020**	**2020**	**2019**	**2019**
Weighted average fair value at measurement date per 'A' share / (per ADS)	- / -	- / -	US$0.20 / (US$0.80)	US$0.27 / (US$1.08)	US$0.14 / (US$0.56)	US$0.25 / (US$1.02)
Total 'A' share options granted / (ADS's equivalent)	- / -	- / -	8,480,000 / (2,120,000)	620,000 / (155,000)	4,060,000 / (1,015,000)	310,000 / (77,500)
Weighted average share price per 'A' share / (per ADS)	- / -	- / -	US$0.38 / (US$1.52)	US$0.48 / (US$1.96)	US$0.46 / (US$1.84)	US$0.64 / (US$2.53)
Weighted average exercise price per 'A' share / (per ADS)	- / -	- / -	US$0.38 / (US$1.52)	US$0.48 / (US$1.96)	US$0.69 / (US$2.74)	US$0.64 / (US$2.53)
Weighted average expected volatility	-%	-%	66.98%	65.89%	51.18%	47.31%
Weighted average expected life	-	-	4.34	4.35	4.15	4.42
Weighted average risk free interest rate	-%	-%	0.44%	0.42%	1.84%	2.23%

21. SHARE OPTIONS (CONTINUED)

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility is based on the historic volatility (calculated based on the expected life of the options). The Group has considered how future experience may affect historical volatility.

The profile and activities of the Group are not expected to change in the immediate future and therefore Trinity Biotech would expect estimated volatility to be consistent with historical volatility.

22. TRADE AND OTHER PAYABLES

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Trade payables	6,763	7,103
Payroll taxes	398	688
Employee related social insurance	130	344
Accruals and other liabilities	7,595	8,850
Deferred income	141	4,445
Deferred government grants	69	-
Other payables	31	-
Government COVID-19 loans (Note 4)	-	2,905
	15,127	24,335

Deferred income has reduced in 2021 as there was a lower amount of sales under customer contracts which could be regarded as offering the customer a right of return (for more information on the deferral of revenue, refer to Note 31, Revenue Recognition).

Government COVID-19 loans comprises funding received under the U.S. government's Cares Act, specifically its Paycheck Protection Program. All loans received under the Paycheck Protection Program ("PPP") have been forgiven during the year.

Included in Accruals and other liabilities at December 31, 2020 was US$194,000 relating to contracted licence payments and at December 31, 2021 this number is US$Nil. A related party current liability for the benefit of Ronan O'Caoimh, at December 31 2020 was US$177,000 and at December 31, 2021 is US$Nil (refer to Note 26 (e) for more information).

Other payable

Other payables relates to an interest-free loan received under the Canada Emergency Business Account ("CEBA"). The CEBA loans were provided by the Canadian Government to mitigate the financial impact of the Covid-19 outbreak. This interest-free loan is repayable by December 31, 2022.

23. PROVISIONS

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Product warranty provision	50	50
Other provisions	-	366
	50	416

During 2021 and 2020 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, 2021 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, 2021.

Other provisions relates to claims and contingencies for which there is no liability existing at December 31, 2021.

24. EXCHANGEABLE NOTES AND OTHER BORROWINGS

The carrying value of exchangeable senior notes and other borrowings is as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Current liabilities		
Exchangeable senior notes	83,312	-
Total non-current liabilities	83,312	-

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Non-Current liabilities		
Exchangeable senior notes	-	82,664
Other borrowings	-	31
Total value of embedded derivatives – liability	-	1,370
Total non-current liabilities	-	84,065

Exchangeable senior notes

The exchangeable senior notes have been presented within current liabilities at December 31, 2021 as the Company does not have an unconditional right to defer settlement of the exchangeable notes for at least 12 months after the reporting period due to the existence of a put option which allows the holders to put the exchangeable notes to the issuer at par on April 1, 2022. This accounting treatment of the exchangeable notes is required by IAS 1.

On December 15, 2021, Trinity Biotech agreed terms with 5 holders of the exchangeable notes for the repurchase of approximately 99.7% of the outstanding notes. The agreement was conditional on certain lending conditions being met and required shareholder approval, which was obtained in January 2022. In respect of the company's financial position as at

24. EXCHANGEABLE NOTES AND OTHER BORROWINGS (CONTINUED)

December 31, 2021, the agreement to repurchase the exchangeable notes is a non-adjusting event under IAS 10. For more information on the retiring of the exchangeable notes, refer to Note 30, Post Balance Sheet events.

The Group originally issued US$115,000,000 of exchangeable senior notes in 2015, which will mature on April 1, 2045, subject to earlier repurchase, redemption or exchange. The notes are senior unsecured obligations and accrue interest at an annual rate of 4%, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on October 1, 2015.

The notes are convertible into ordinary shares of the parent entity at the applicable exchange rate, at any time prior to the close of business on the second business day immediately preceding the maturity date, at the option of the holder, or repayable on April 1, 2045. The conversion rate is 47.112 ADSs per $1,000 principal amount of notes, equivalent to an exchange price of approximately $21.88 per ADS. The exchange rate is subject to adjustment upon the occurrence of certain events but will not be adjusted for any accrued and unpaid interest. The notes include a number of non-financial covenants, all of which were complied with at December 31, 2021.

In August 2018, the Group purchased US$15,100,000 of the exchangeable notes, at a rate of 79.75 cents in the Dollar. The amount paid was US$12,042,000 plus accrued interest of US$205,000. The gain on the purchase was US$468,000 and this was shown within selling, general and administrative expenses in the statement of operations for the year ended December 31, 2018. The nominal amount of the debt after the purchase is US$99,900,000.

The movement in the Exchangeable senior notes is as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Balance at 1 January	82,664	82,021
Accretion interest (Note 8)	648	643
	83,312	82,664

Embedded derivatives

The notes include a number of put and call options, and these embedded derivatives are measured at fair value through the Consolidated Statement of Operations. The first date on which holders can exercise their put option is April 1, 2022. If the put option is exercised, the issuer has to repurchase the notes at par. The exchangeable notes are treated as a host debt instrument with embedded derivatives attached. On initial recognition, the host debt instrument is recognised at the residual value of the total net proceeds of the bond issue less fair value of the embedded derivatives. Subsequently, the host debt instrument is measured at amortised cost using the effective interest rate method.

The embedded derivatives are summarised as follows:

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Non-current assets		
Exchangeable note bond call option	-	150
Non-current liabilities		
Exchangeable note equity conversion option	-	1,370
Exchangeable note bond put option	-	-
	-	1,370
Total value of embedded derivatives – net liability	-	1,220

24. EXCHANGEABLE NOTES AND OTHER BORROWINGS (CONTINUED)

Financial income in the consolidated statement of operations for the year includes US$1,220,000 (2020 financial expense: US$1,216,000) arising from the revaluation of embedded derivatives at fair value at December 31, 2021.

This liability will accrete back to its nominal value of US$99,900,000 at the end of the full term of the debt maturity in 2045 using an effective interest rate methodology. Financial expense in the consolidated statement of operations for the year includes US$648,000 (2020: US$643,000) of accretion interest.

Other borrowings

Other borrowings relates to an interest-free loan received under the Canada Emergency Business Account ("CEBA"). The CEBA loans were provided by the Canadian Government to mitigate the financial impact of the Covid-19 outbreak. This interest-free loan is repayable by December 31, 2022.

25. 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 13).

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, 2021 US$'000	*December 31, 2020 US$'000*
Current liabilities		
Lease liabilities related to Right of Use assets	1,878	2,054
Sale and leaseback liabilities	102	99
	1,980	2,153
Non-Current liabilities		
Lease liabilities related to Right of Use assets	13,790	16,407
Sale and leaseback liabilities	75	181
	13,865	16,588

25. LEASE LIABILITIES (CONTINUED)

	December 31, 2021 US$'000 Lease liabilities related to Right of Use assets			*December 31, 2021 US$'000 Sale and leaseback Liabilities*		
	Minimum lease payments	Interest	Principal	Minimum lease payments	Interest	Principal
Less than one year	2,575	697	1,878	109	7	102
In more than one year, but not more than two	2,175	621	1,554	77	2	75
In more than two years but not more than five	5,985	1,469	4,516	-	-	-
more than five years	8,992	1,272	7,720	-	-	-
	19,727	4,059	15,668	186	9	177

	December 31, 2020 US$'000 Lease liabilities related to Right of Use assets			*December 31, 2020 US$'000 Sale and leaseback liabilities*		
	Minimum lease payments	Interest	Principal	Minimum lease payments	Interest	Principal
Less than one year	2,877	823	2,054	111	12	99
In more than one year, but not more than two	2,644	730	1,914	111	7	104
In more than two years but not more than five	6,621	1,765	4,856	79	2	77
more than five years	11,389	1,752	9,637	-	-	-
	23,531	5,070	18,461	301	21	280

Lease payments not recognised as a liability

No short term lease expenses were incurred for the year ended December 31, 2021. In 2020 the Group elected not to recognise a lease liability for short term leases (leases with an expected term of 12 months or less) or for leases of low value assets. Payments made under such leases are expensed on a straight-line basis. In addition, certain variable lease payments are not permitted to be recognised as lease liabilities and are expensed as incurred.

Terms and debt repayment schedule

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2021 are as follows:

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	Euro	4.53%	2023	65	65
Sale and leaseback liabilities	USD	5.51%	2023	111	111
Total interest-bearing loans and borrowings				176	176

25. LEASE LIABILITIES (CONTINUED)

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2020 are as follows:

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	Euro	4.53%	2023	106	106
Sale and leaseback liabilities	USD	5.51%	2023	174	174
Total interest-bearing loans and borrowings				280	280

The total paid in respect of lease liabilities in the year ended December 31, 2021 was US$2,938,000 (2020: US$3,240,000).

26. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has capital commitments authorised and contracted for of US$440,000 as at December 31, 2021 (2020: US$156,000).

(b) ***Leasing Commitments***

The Group's leasing commitments are shown in Note 25.

(c) ***Bank Security***

At December 31, 2021, the Group's sale and leaseback borrowings were at fixed rates of interest and consisted Euro and USD denominated borrowings, refer to Note 28. The banks providing the financing have a charge over the equipment for which the borrowing pertains.

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

Pursuant to the provisions of Section 357, Irish Companies Act, 2014, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, Trinity Research Limited, Benen Trading Limited and Trinity Biotech Financial Services Limited subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2021 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 357, Irish Companies Act, 2014. Where the Company enters into these guarantees of the indebtedness of other companies within its Group, the Company considers these to be insurance arrangements and accounts for them as such. The Company treats the guarantee contract as a contingent liability until such time as it becomes probable that the company will be required to make a payment under the guarantee. The Company does not enter into financial guarantees with third parties.

(e) ***Contingent Asset***

In the 2019 financial statements, a contingent asset of US$1,231,000 was disclosed in connection with the 2019 tax audit settlement payable by Darnick Company. This balance was settled in the year ended December 31, 2020 and has been credited to the Statement of Operations within Selling, General and Administrative Expenses. The underlying amount was denominated in Euro. Due to a depreciation in the US Dollar since 2019, the US Dollar equivalent amount increased from US$1,231,000 to US$1,316,000. The settlement amount received by the Company was US$177,000 more than the balance owed and this overpayment is recorded as a related party current liability for the benefit of Ronan O'Caoimh as at December 31, 2020. The amount was settled by the Group in January 2021. There are no contingent assets as of December 31, 2021 (2020: US$Nil).

26. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(f) ***Government Grant Contingencies***

The Group has received training and employment grant income from Irish development agencies. Subject to existence of certain conditions specified in the grant agreements, this income may become repayable. No such conditions existed as at December 31, 2021. However, if the income were to become repayable, the maximum amounts repayable as at December 31, 2021 would amount to US$3,095,000 (2020: US$3,130,000).

To mitigate the financial impact of the Covid-19 outbreak, the Company has availed of governmental supports. In 2020, the Company received US$4.5 million of Paycheck Protection Program ("PPP") loans and in 2021, a further US$1.8 million of PPP loans were received. All of the loans received to date under the program have been forgiven by the US government before December 31, 2021 and therefore no liability for these loans exists at December 31, 2021.

(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.

27. RELATED PARTY TRANSACTIONS

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

Leasing arrangements with related parties

The following is a description of our related party transactions since January 1, 2021.

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

The Group has entered into an agreement for a 25-year lease with JRJ for offices that adjacent to its then premises at IDA Business Park, Bray, Co. Wicklow, Ireland. The annual rent of €381,000 (US$432,000) is payable from January 1, 2004. Upward-only rent reviews are carried out every five years and there have been no increases arising from these rent reviews.

The Group has also entered into lease agreements with Ronan O'Caoimh for a 43,860 square foot manufacturing facility in Bray, Ireland and an adjacent warehouse of 16,000 square feet. The annual rent for the manufacturing facility is €787,000 (US$891,000) and the annual rent for the warehouse is €144,000 (US$163,000). These two leases expire in 2028 and 2026 respectively. At the time, independent valuers advised the Group that the rent in respect of each of the leases represents a fair market rent. Upward-only rent reviews are carried out every five years and there have been no increases arising from these rent reviews.

27. RELATED PARTY TRANSACTIONS (CONTINUED)

Beginning in Q4 2020, the Group occupied some additional space adjoining the warehouse. A sum of €90,000 (US$102,000) was accrued for rent payable to Mr O'Caoimh in relation to this additional space as at 31 December 2021.

Trinity Biotech and its directors (excepting Mr O'Caoimh and Dr Walsh who express no opinion on this point) believe at the time that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises. Dr Walsh has no ownership interest in the additional space adjoining the warehouse owned by Mr O'Caoimh and was therefore entitled to express an opinion on this arrangement.

Compensation of key management personnel of the Group

At December 31, 2021 the key management personnel of the Group were made up of the four executive directors; Mr. Ronan O'Caoimh, Dr Jim Walsh, Mr. John Gillard and Mr. Kevin Tansley. Compensation for the year ended December 31, 2021 of these personnel is detailed below:

	December 31, 2021 *US$'000*	December 31, 20120 *US$'000*
Short-term employee benefits	1,054	1,274
Performance related bonus	227	584
Post-employment benefits	24	41
Share-based compensation benefits	965	626
	2,270	2,525

The amounts disclosed in respect of directors' emoluments in Note 11 includes non-executive directors' fees of US$98,000 (2020: US$162,000) and share-based compensation benefits of US$61,000 (2020: US$51,000). Total directors' remuneration is also included in "personnel expenses" (Note 3) and "Profit before tax" (Note 11). In 2021, share-based compensation benefits included in Note 11 exclude capitalised amounts of US$Nil (2020: US$Nil). The performance bonuses for Mr. Gillard in respect of fiscal year 2021 have been accrued as at December 31, 2021.

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

	'A' Ordinary Shares	*Share options*
At January 1, 2021	9,077,706	17,394,004
Shares of retired director	—	—
Options of retired director	—	(656,000)
Shares purchased during the year	—	—
Shares sold during the year	—	—
Granted	—	—
Expired / forfeited	—	—
At December 31, 2021	9,077,706	16,738,004

27. RELATED PARTY TRANSACTIONS (CONTINUED)

	'A' Ordinary Shares	*Share options*
At January 1, 2020	9,077,709	10,414,004
Shares of retired director	—	—
Options of retired director	—	—
Shares purchased during the year	—	—
Shares sold during the year	—	—
Granted	—	8,480,000
Expired / forfeited	—	(1,500,000)
At December 31, 2020	9,077,706	17,394,004

Rayville Limited, an Irish registered company, which was wholly owned by three executive directors and certain other former executives of the Group, owned all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries, and these 'B' shares were surrendered through Trinity Research Limited in 2021.

28. 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 earnings per share as a measure of performance, which the Group defines as profit after tax divided by the weighted average number of shares in issue.

At December 31, 2021 the Group has no bank loans, it maintains a relationship with a number of lending banks and Trinity Biotech is listed on the NASDAQ, which allows the Group to potentially raise funds through equity financing. In 2015, the Group raised US$115 million through the issuance of 30-year exchangeable senior notes. In 2018 the Group repurchased US$15.1 million of the exchangeable senior notes, leaving US$99.9 million outstanding. In January 2022, the Group successfully closed a US$81,250,000 senior secured term loan credit facility (the "Term Loan") with Perceptive Advisors. Proceeds from the Term Loan, along with existing cash and the issuance of 5.3 million American Depository Shares in the Company, were used to retire approximately US$99.7 million of the Exchangeable Notes. For more information, refer to Note 30, Post Balance Sheet Events.

In April 2022, the Company announced a US$45 million strategic investment and partnership with MiCo, a KOSDAQ-listed and Korea-based company. The investment consists of an equity investment of approximately US$25.2 million and a seven-year, unsecured junior convertible note of US$20 million. For more information, refer to Note 30, Post Balance Sheet Events.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Fair Values

The table below sets out the Group's classification of each class of financial assets/liabilities, their fair values and under which valuation method they are valued:

	Note	*Level 1 US$'000*	*Level 2 US$'000*	*Total carrying amount US$'000*	*Fair Value US$'000*
December 31, 2021					
Loans and receivables at amortised cost					
Trade receivables	*18*	13,290	—	13,290	13,290
Cash and cash equivalents	*19*	25,910	—	25,910	25,910
Finance lease receivable	*16, 18*	293	—	293	293
		39,493	—	39,493	39,493
Liabilities at amortised cost					
Exchangeable note[1]	*24*	—	(83,312)	(83,312)	(83,312)
Lease liabilities	*25*	(15,845)	—	(15,845)	(15,845)
Trade and other payables (excluding deferred income)	*22*	(14,986)	—	(14,986)	(14,986)
Provisions	*23*	(50)	—	(50)	(50)
		(30,881)	(83,312)	(114,193)	(114,193)
Fair value through profit and loss (FVPL)					
Exchangeable note bond call option	*24*	—	—	—	—
Exchangeable note equity conversion option	*24*	—	—	—	—
		—	—	—	—
		8,612	(83,312)	(74,700)	(74,700)

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years or the exchange agreements entered into with five exchangeable note holders in December 2021.

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.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

	Note	*Level 1 US$'000*	*Level 2 US$'000*	*Total carrying amount US$'000*	*Fair Value US$'000*
December 31, 2020					
Loans and receivables at amortised cost					
Trade receivables	*18*	20,025	—	20,025	20,025
Cash and cash equivalents	*19*	27,327	—	27,327	27,327
Finance lease receivable	*16, 18*	506	—	506	506
		47,858	—	47,858	47,858
Liabilities at amortised cost					
Exchangeable note	*24*	—	(82,664)	(82,664)	(82,664)
Lease liabilities	*25*	(18,741)	—	(18,741)	(18,741)
Trade and other payables (excluding deferred income)	*22*	(19,890)	—	(19,890)	(19,890)
Provisions	*23*	(416)	—	(416)	(416)
		(39,047)	(82,664)	(121,711)	(121,711)
Fair value through profit and loss (FVPL)					
Exchangeable note bond call option	*24*	—	150	150	150
Exchangeable note equity conversion option	*24*	—	(1,370)	(1,370)	(1,370)
		—	(1,220)	(1,220)	(1,220)
		8,811	(83,884)	(75,073)	(75,073)

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years or the exchange agreements entered into with five exchangeable note holders in December 2021.

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.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

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.

Interest rate risk

Effective and repricing analysis

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

As at December 31, 2021	*Note*	*Effective interest rate*	*Total US$'000*	*6 mths or less US$'000*	*6 –12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*> 5 years US$'000*
Cash and cash equivalents	*19*	0.01%	25,910	25,910	—	—	—	—
Lease receivable	*16,18*	4.0%	293	81	61	89	62	—
Exchangeable note[1]	*24*	4.8%	(83,312)	—	—	—	—	(83,312)
Other borrowings	*22*	0%	(31)	—	(31)	—	—	—
Lease payable on Right of Use assets	*25*	5.0%	(15,668)	(973)	(905)	(1,554)	(4,516)	(7,720)
Lease payable on sale & leaseback transactions	*25*	5.0%	(177)	(51)	(51)	(75)	—	—
Total			(72,985)	24,967	(926)	(1,540)	(4,454)	(91,032)

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years or the exchange agreements entered into with five exchangeable note holders in December 2021.

As at December 31, 2020	*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	*19*	0.1%	27,327	27,327	—	—	—	—
Lease receivable	*16,18*	4.0%	506	120	95	142	149	—
Licence payments	*23*	8.1%	(194)	(194)	—	—	—	—
Exchangeable note[1]	*24*	4.8%	(82,664)	—	—	—	—	(82,664)
Other borrowings	*22*	0%	(31)	—	—	(31)	—	—
Lease payable on Right of Use assets	*25*	5.0%	(18,461)	(1,022)	(1,032)	(1,914)	(4,856)	(9,637)
Lease payable on sale & leaseback transactions	*25*	5.0%	(280)	(49)	(50)	(104)	(77)	—
Total			(73,797)	26,182	(987)	(1,907)	(4,784)	(92,301)

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years or the exchange agreements entered into with five exchangeable note holders in December 2021.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$31,000 (2020: US$31,000) and would not affect the interest expense (2020: nil) resulting in an increase in net interest income of US$31,000 (2020: increase in net interest income of US$31,000).

28. 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, 2021 US$'000	*December 31, 2020 US$'000*
Fixed rate instruments		
Fixed rate financial liabilities (licence fees)	-	(194)
Fixed rate financial liabilities (exchangeable note)	(83,312)	(82,664)
Fixed rate financial liabilities (borrowings)	(31)	(31)
Fixed rate financial liabilities (lease payables)	(15,844)	(18,741)
Financial assets (short-term deposits and short-term investments)	3,121	3,118
Financial assets (lease receivables)	298	506
	(95,768)	(98,006)

Financial assets comprise cash and cash equivalents and short-term investments as at December 31, 2021 and December 31, 2020 (see Note 19 and 20).

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, 2021 would not affect profit or loss. There was no significant difference between the fair value and carrying value of the Group's trade receivables and trade and other payables at December 31, 2021 and December 31, 2020 as all fell due within 6 months.

Liquidity risk

The Group's operations were cash generating in the year to December 31, 2021. Short-term flexibility is achieved through the management of the Group's short-term deposits.

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

As at December 31, 2021 US$'000	*Carrying amount US$'000*	*Contractual cash flows US$'000*	*6 mths or less US$'000*	*6 mths – 12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*>5 years US$'000*
Financial liabilities							
Trade & other payables	15,127	15,127	15,127	—	—	—	—
Lease payable on Right of Use assets	15,668	15,668	973	905	1,554	4,516	7,720
Lease payable on sale & leaseback transactions	177	177	51	51	75	—	—
Other borrowings	31	31	—	31	—	—	—
Exchangeable notes [1]	83,312	99,900	—	—	—	—	99,900
Exchangeable note interest	999	93,906	1,998	1,998	3,996	11,988	73,926
	115,314	224,809	18,149	2,985	5,625	16,504	181,546

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years or the exchange agreements entered into with five exchangeable note holders in December 2021.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

As at December 31, 2020 US$'000	*Carrying amount US$'000*	*Contractual cash flows US$'000*	*6 mths or less US$'000*	*6 mths – 12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*>5 years US$'000*
Financial liabilities							
Trade & other payables	24,335	24,335	24,335	—	—	—	—
Lease payable on Right of Use assets	18,461	18,461	1,022	1,032	1,914	4,856	9,637
Lease payable on sale & leaseback transactions	280	280	49	50	104	77	—
Other borrowings	31	31	—	—	31	—	—
Exchangeable notes [1]	82,664	99,900	—	—	—	—	99,900
Exchangeable note interest	999	97,902	1,998	1,998	3,996	11,988	77,922
	126,770	240,909	27,404	3,080	6,045	16,921	187,459

[1] The maturity of the Exchangeable Notes is based on the contractual maturity date of April 1, 2045 and does not take into account the potential exercise of put and call options in the next five years.

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. Arising from this, where considered necessary, the Group pursues a treasury policy which periodically aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions. Forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at December 31, 2021.

Foreign currency short term financial assets and liabilities which expose the Group to currency risk are disclosed below. The amounts shown are those reported to key management translated into US Dollars at the closing rate:

As at December 31, 2021	*EUR US$'000*	*GBP US$'000*	*SEK US$'000*	*CAD US$'000*	*BRL US$'000*	*Other US$'000*
Cash	327	115	5	4,617	1,370	—
Trade and other receivable	464	58	—	488	1,538	—
Trade and other payables	(2,456)	(28)	(11)	(166)	(629)	—
Total exposure	(1,665)	145	(6)	4,939	2,279	—

As at December 31, 2020	*EUR US$'000*	*GBP US$'000*	*SEK US$'000*	*CAD US$'000*	*BRL US$'000*	*Other US$'000*
Cash	1,229	152	9	2,859	776	—
Trade and other receivable	1,105	63	—	3,191	1,357	—
Trade and other payables	(2,821)	(57)	(1)	(449)	(529)	—
Total exposure	(487)	158	8	5,601	1,604	—

The Group states its forward exchange contracts at fair value in the balance sheet. The Group classifies its forward exchange contracts as hedging forecasted transactions and thus accounts for them as cash flow hedges. There were no forward exchange contracts in place at December 31, 2021 or December 31, 2020.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Sensitivity analysis

A 10% strengthening of the US Dollar against the Euro at December 31, 2021 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, 2021	
Euro	780
December 31, 2020	
Euro	541

A 10% weakening of the US Dollar against the Euro at December 31, 2021 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, 2021	
Euro	(953)
December 31, 2020	
Euro	(661)

Credit Risk

The Group has no significant concentrations of credit risk. Exposure to credit risk is monitored on an ongoing basis. The Group maintains specific provisions for potential credit losses. To date such losses have been within management's expectations. Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

With respect to credit risk arising from the other financial assets of the Group, which comprise cash and cash equivalents and deferred consideration, the Group's exposure to credit risk arises from default of the counter-party, with a maximum exposure equal to the carrying amount of these instruments. The Group'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 and enters into forward contracts, when necessary, with various financial institutions. The Group performs regular and detailed evaluations of these financial institutions to assess their relative credit standing. The carrying amount reported in the balance sheet for cash and cash equivalents and forward contracts approximate their fair value.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Exposure to credit risk

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk is as follows:

	Carrying Value December 31, 2021 US$'000	*Carrying Value December 31, 2020 US$'000*
Third party trade receivables (Note 18)	13,290	20,025
Finance lease income receivable (Note 18)	293	506
Cash and cash equivalents (Note 19)	25,910	27,327
	39,493	47,858

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

	Carrying Value December 31, 2021 US$'000	*Carrying Value December 31, 2020 US$'000*
United States	5,822	10,730
Euro-zone countries	1,072	1,360
United Kingdom	118	98
Other European countries	-	13
Other regions	6,571	8,330
	13,583	20,531

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, 2021 US$'000	*Carrying Value December 31, 2020 US$'000*
End-user customers	6,923	11,812
Distributors	6,220	8,186
Non-governmental organisations	440	533
	13,583	20,531

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

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

Impairment Losses

The ageing of trade receivables at December 31, 2021 is as follows:

	Gross 2021 US$'000	*Impairment 2021 US$'000*	*Expected Credit Loss Rate 2021 %*	*Gross 2020 US$'000*	*Impairment 2020 US$'000*	*Expected Credit Loss Rate 2020 %*
Not past due	8,461	-	-%	16,754	112	0.7%
Past due 0-30 days	2,423	1	0.1%	1,829	222	12.1%
Past due 31-120 days	1,981	97	4.9%	1,755	60	3.4%
Greater than 120 days	3,011	2,888	73.0%	3,609	3,528	97.8%
	15,876	2,986	—	23,947	3,922	—

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

	2021 US$'000	*2020 US$'000*	*2019 US$'000*
Balance at January 1	3,922	5,443	4,202
Charged to costs and expenses	76	166	1,276
Amounts written off during the year	(1,012)	(1,687)	(35)
Balance at December 31	2,986	3,922	5,443

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.

29. 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, 2021	*22,24, 25*	84,065	18,741
Cash-flows:			
Interest paid		(3,996)	(11)
Repayment		—	(2,939)
Non-cash:			—
Interest charged		3,996	—
Additions (related to Right of Use assets)		—	71
Exchange adjustment		—	(820)
Accretion interest		648	803
Fair value	*8*	(1,370)	—
Balance at December 31, 2021	*24,25*	83,343	15,845

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

	Note	*Borrowings & derivative financial instruments US$'000*	*Lease liabilities US$'000*
Balance at 1 January 2020	*22,24, 25*	82,025	20,149
Cash-flows:			
Interest paid		(3,996)	—
Proceeds from government Covid-19 loan (Note 24)		31	—
Repayment		—	(3,240)
Non-cash:			
Interest charged		3,996	—
Additions (related to Right of Use assets)		—	224
Disposals[1]		—	(216)
Exchange adjustment		—	928
Accretion interest	*8*	643	896
Fair value		1,366	—
Balance at 31 December 2020	*24,25*	84,065	18,741

[1] Disposal of Lease liabilities relates to the early termination of a lease for a right-of-use building asset in Carlsbad, California. This facility was closed in June 2020.

30. POST BALANCE SHEET EVENTS

Debt refinancing

In January 2022, the Company successfully closed a US$81,250,000 senior secured term loan credit facility (the "Term Loan") with Perceptive Advisors, an investment manager with an expertise in healthcare. Proceeds from the Term Loan, along with existing cash and the issuance of 5.3 million American Depository Shares in the Company, were used to retire approximately US$99.7 million of the Exchangeable Notes.

The financial effect of these transactions is:

- the Group paid a total amount of US$86,730,000 to retire Exchangeable Notes with a carrying value of US$83,312,000 at December 31, 2021. Each holder that was party to the agreement received US$0.87 of cash per $1 nominal value of the Notes, and
- the Company also issued 5,333,000 ADSs (21,332,000 'A' Ordinary shares) representing the equivalent of $0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 9, 2021, discounted by 13%) per $1 nominal value of the Notes, as partial consideration for the exchange of the notes.

Approval of TrinScreen test by World Health Organisation

In February 2022, the Company received approval from the World Health Organisation for its new HIV screening product, TrinScreen™ HIV.

30. POST BALANCE SHEET EVENTS (CONTINUED)

Strategic Investment and Partnership with The MiCo Group

In April 2022, the Group announced a US$45 million strategic investment and partnership with MiCo, a KOSDAQ-listed and Korea-based company. The investment consists of an equity investment of approximately US$25,200,000 (11,200,000 ADSs at a price of US$2.25 per ADS) and a seven-year, unsecured junior convertible note issued by Trinity Biotech of US$20 million, with a fixed interest rate of 1.5% and an ADS conversion price of US$3.24 per ADS. The convertible note mandatorily converts into ADS if the volume weighted average price of the Group's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days. The investment was subject to customary Korean central bank approvals which was received in May 2022. The Group expects that this investment will facilitate it exploring lower cost debt funding options, with the aim of reducing the company's interest expense through refinancing the balance of the Group's Term Loan at lower interest rates.

The founder and chair of MiCo, Sun-Q Jeon, became Chairperson of Trinity Biotech and Aris Kekedjian and Michael Sung Soo Kim joined the Board once the investment completed. Existing directors Kevin Tansley, Clint Severson and James Merselis retired from the Board on completion of the investment

Early repayment of Term loan

In May 2022, the Company made an early partial settlement of the senior secured term loan of approximately US$35 million and in accordance with the Term Loan's credit agreement, there was a penalty for early repayment of US$3.5 million. A total cash payment of US$38 million was made to Perceptive Advisors during the second quarter of 2022. After this repayment, the nominal amount of the outstanding Term Loan is approximately US$47 million. The part repayment of the loan reduces the ongoing annual interest payments by approximately US$4 million.

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 14 contains information about the assumptions and the risk factors relating to goodwill impairment. Note 21 outlines information regarding the valuation of share options and warrants. Note 24 outlines the valuation techniques used by the Company in determining the fair value of exchangeable notes and the associated embedded derivatives. In Note 28, 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 type of contracts. In accordance with IFRS 15, when estimating the effect of an uncertainty on an amount of variable consideration to which the Group will be entitled, all information that is reasonably available, including historical, current and forecast, is considered.

We operate a licenced reference laboratory in New York, USA that specializes in diagnostics for autoimmune diseases. The laboratory provides testing services to two types of customers. Firstly, institutional customers, such as hospitals and

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

commercial diagnostic testing providers, and secondly insurance companies on behalf of their policyholders. The revenue recognition for services provided to insurance companies requires some judgement. In the US, there are rules requiring all insurance companies

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

At December 31, 2021 US$141,000 (2020: US$4,445,000) of revenue was deferred in accordance with IFRS15. For further information, refer to Note 22.

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 14.

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, 2021 the carrying value of capitalised development costs was US$17,679,000 (2020: US$13,444,000) (see Note 14 to the consolidated financial statements). The increase in 2021 was mainly as a result of additions of US$6,771,000. In 2021, an impairment charge of US$2,053,000 was incurred. This charge was partially offset by additions of US$6,771,000 and amortisation of US$482,000.

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.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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

The impairment testing performed as at December 31, 2021 identified an impairment loss in four CGUs, namely Trinity Biotech Manufacturing Limited, Biopool US Inc, Immco Diagnostics, and Trinity Biotech Do Brazil. For further information, refer to Note 14.

Allowance for slow-moving and obsolete inventory

We evaluate the realisability of our inventory on a case-by-case basis and make adjustments to our inventory provision based on our estimates of expected losses. We write-off any inventory that is approaching its "use-by" date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value. At December 31, 2021 our allowance for slow moving and obsolete inventory was US$12,063,000 which represents approximately 29.29% of gross inventory value. This compares with US$9,781,000, or approximately 24.45% of gross inventory value, at December 31, 2020 and US$6,716,000, or approximately 17.33% of gross inventory value, at December 31, 2019. 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$824,000 at December 31, 2021 (2020: US$800,000) (2019: US$774,000) would result. For further information, refer to Note 17.

Allowance for impairment of receivables

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 or the possible return of goods. We make judgements as to our ability to collect outstanding receivables and where necessary make allowances for impairment, otherwise known as a bad and doubtful debt provision. Such impairments or provisions are made based upon a specific review of all significant outstanding receivables. In determining the allowance, we analyse our historical collection experience and current economic trends. If the historical data we use to calculate the allowance for impairment of receivables does not reflect the future ability to collect outstanding receivables, additional allowances for impairment of receivables may be needed and the future results of operations could be materially affected. At December 31, 2021, the allowance was US$2,986,000 which represents approximately 3.2% of Group revenues. This compares with US$ US$3,922,000 at December 31, 2020 which represented approximately 3.8% of Group revenues and to US$5,443,000 at December 31, 2019 which represented approximately 6.0% of Group revenues. In the event that the estimate of impairment was to increase or decrease by 0.5% of Group revenues, which would represent a reasonably likely range of outcomes, then a change in the allowance of US$465,000 at December 31, 2021 (2020: US$510,000) (2019: US$452,000) would result. For further information, refer to Note 28.

Accounting for income taxes

Significant judgement is required in determining our worldwide income tax expense provision. In the ordinary course of a global business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Some of these uncertainties arise as a consequence of revenue sharing and cost reimbursement arrangements among related entities, the process of identifying items of revenue and expense that qualify for preferential tax treatment and segregation of foreign and domestic income and expense to avoid double taxation. In addition, we operate within multiple taxing jurisdictions and are subject to periodic audits in these jurisdictions.

Deferred tax assets and liabilities are determined for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities, using tax rates projected to be in effect for the year in which the differences are expected to reverse. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable. The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

Note 15 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and includes details of the unrecognised deferred tax assets at year end. The Group derecognised deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilized before they expire. The derecognition of these deferred tax assets was considered appropriate due to the uncertainty over the timing of the utilization of the tax losses. Except for the derecognition of deferred tax assets there were no material changes in estimates used to calculate the income tax expense provision during 2021, 2020 or 2019.

IFRS 16

IFRS 16, *Leases*, requires entities to make certain judgements and estimations. Critical judgements were required by the Company in the following areas:

- Determining whether or not a contract contains a lease. Company assessed if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.
- Significant judgement is also required in establishing whether or not it is reasonably certain that an extension option will be exercised, considering whether or not it is reasonably certain that a termination option will not be exercised. In making this decision, management considered the facts and circumstances that create a significant economic incentive. Factors specific to the asset, the entity and the wider market were also considered.
- Further, critical judgement is involved in determining whether or not variable lease payments are truly variable, or in-substance fixed. In-substance variable lease payments are treated as fixed lease payments.

Key source of estimation and uncertainty is calculation of the appropriate discount rate to use. When making the determination, the company considered the rate of interest that they would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment.

Going Concern

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the Covid-19 pandemic. The directors believe that the Group will be able to continue its operations for at least the next 12 months from the date of this report and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

At December 31, 2021, the Group had net currently liabilities. However, at the date of this report the Group's financial position has substantially improved following the successful re-financing of the Group's debt in early 2022. This has significantly improved the Group's capital structure by reducing gross debt by approximately US$19 million and there are no material debt maturities until 2026. Furthermore, the investment by MiCo Group did facilitate an early repayment of a substantial portion of the debt due to Perceptive Advisors and will also facilitate the Group exploring lower cost debt funding options with the aim of further reducing the Group's interest expense through refinancing the balance of the Group's Term Loan at lower interest rates.

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.

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 Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland	100%
Trinity Research Limited IDA Business Park, Bray Co. Wicklow, Ireland	Research and development	Ireland	100%
Benen Trading Limited IDA Business Park, Bray Co. Wicklow, Ireland	Trading	Ireland	100%
Trinity Biotech Manufacturing Services Limited IDA Business Park, Bray Co. 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	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Fitzgerald Industries International, Inc 2711 Centerville Road, Suite 400 Wilmington, New Castle Delaware, 19808, USA	Management services company	U.S.A.	100%
Biopool US Inc (trading as Trinity Biotech Distribution) Girts Road, Jamestown NY14702, USA	Sale of diagnostic test kits	U.S.A.	100%
Primus Corporation 4231 E 75th Terrace Kansas City, MO 64132, USA	Manufacture and sale of diagnostic test kits and instrumentation	U.S.A.	100%

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	Holding Company	Sweden	100%
Fiomi Diagnostics AB Dag Hammarskjöldsv 52A SE-752 37 Uppsala Sweden	Discontinued operation	Sweden	100%
Trinity Biotech Do Brasil Comercio e Importacao Ltda Rua Silva Bueno 1.660 – Cj. 101/102 Ipiranga Sao Paulo Brazil	Sale of diagnostic test kits	Brazil	100%
Trinity Biotech (UK) Ltd Mills and Reeve LLP Botanic House 100 Hills Road Cambridge, CB2 1PH United Kingdom	Sales & marketing activties	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%

COMPANY STATEMENT OF COMPREHENSIVE INCOME

	Year ended December 31,	
	2021	*2020*
	US$'000	*US$'000*
Profit/(loss) for the year	2,627	(2,255)
Total comprehensive income/(loss) (all attributable to equity holders)	2,627	(2,255)

COMPANY STATEMENT OF FINANCIAL POSITION

	Notes	*December 31, 2021 US$'000*	*December 31, 2020 US$'000*
ASSETS			
Non-current assets			
Investment in subsidiaries	36	21,812	19,939
Advances to subsidiaries	37	38,730	36,755
Total non-current assets		60,542	56,694
Current assets			
Receivables from group undertakings and other receivables		7,026	31
Cash and cash equivalents	39	3,798	11,452
Total current assets		10,824	11,483
TOTAL ASSETS		71,366	68,177
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital		1,213	1,213
Share premium		16,187	16,187
Treasury Shares	41	(24,922)	(24,922)
Retained earnings	40	10,062	6,324
Total (deficit)/equity		2,540	(1,198)
Current liabilities			
Other payables	42	68,767	69,316
Total current liabilities		68,767	69,316
Non-Current liabilities			
Deferred tax liability	38	59	59
TOTAL LIABILITIES		68,826	69,375
TOTAL EQUITY AND LIABILITIES		71,366	68,177

The Group is availing of the exemption in Section 304 of the Companies Act 2014 from filing its Company Statement of Comprehensive Income. The profit for the financial year generated by the Company is US$2,627,000 (loss 2020: US$2,255,000).

The financial statements were approved and authorised for issue by the Board on 6 September 2022 and signed on its behalf by:

Ronan O'Caoimh
Director

John Gillard
Director

COMPANY STATEMENT OF CHANGES IN EQUITY

	Share capital 'A' ordinary shares	*Share premium*	*Treasury Shares*	*Retained earnings*	*Total*
	US$'000	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Balance at January 1, 2020	**1,213**	**16,187**	**(24,922)**	**7,763**	**241**
Loss for the period	-	-	-	**(2,255)**	**(2,255)**
Total comprehensive loss	-	-	-	**(2,255)**	**(2,255)**
Share-based payments (Note 22)	-	-	-	816	816
Balance at December 31, 2020	**1,213**	**16,187**	**(24,922)**	**6,324**	**(1,198)**
Balance at January 1, 2021	**1,213**	**16,187**	**(24,922)**	**6,324**	**(1,198)**
Profit for the period	-	-	-	**2,627**	**2,627**
Total comprehensive profit	-	-	-	**2,627**	**2,627**
Share-based payments (Note 22)	-	-	-	1,111	1,111
Balance at December 31, 2021	**1,213**	**16,187**	**(24,922)**	**10,062**	**2,540**

COMPANY STATEMENT OF CASH FLOWS

	Notes	Year ended December 31, 2021 US$'000	2020 US$'000
Cash flows from operating activities			
Profit/(loss) for the year		2,627	(2,255)
Adjustments to reconcile net loss/profit to cash provided by operating activities:			
Income tax expense	38	-	2,915
Financial expense		2,688	4,622
Financial income		(1,231)	(1,513)
Share-based payments		21	51
Recovery of impairment on advance to a subsidiary	37	(583)	(6,320)
Reversal of impairment on advance to a subsidiary	37	-	(13,133)
Provision for impairment of investment in subsidiaries	36	83	83
Provision for impairment on advances to a subsidiary	37	2,257	14,272
Operating cash outflow before changes in working capital		**5,862**	**(1,278)**
(Increase)/decrease in receivables from group undertakings and other receivables		(6,996)	30
Increase in other payables		760	116
Net cash outflow from operating activities		**(374)**	**(1,132)**
Cash flows from investing activities			
Net cash (paid)/received from group undertakings		(7,280)	12,421
Net cash (outflow)/inflow from investing activities		**(7,280)**	12,421
(Decrease)/increase in cash and cash equivalents		(7,654)	11,289
Cash and cash equivalents at beginning of year		11,452	163
Cash and cash equivalents at end of year	39	**3,798**	**11,452**

34. 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 and advances to subsidiaries.

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

d) Advances to subsidiaries
Advances to subsidiaries are shown at fair value less any provisions for impairment in value. The fair value of these, where they relate to non-interest bearing advances, are calculated by discounting the expected repayments using a market rate of interest which is applicable to assets of a similar risk profile. The implied interest income is recognised in the income statement over the period for which the advance is outstanding.

35. PERSONNEL EXPENSES AND AUDITORS' REMUNERATION - COMPANY

	Company December 31, 2021 US$'000	*Company December 31, 2020 US$'000*
Wages and salaries	1,354	2,079
Social welfare costs	113	148
Pension costs	24	44
Share-based payments	986	678
	2,477	2,949
Less costs borne by subsidiary*	(2,281)	(2,668)
	196	281

* In 2021 and 2020, certain key management wages and salaries costs, social welfare costs, share based payments expense and pension costs were borne by Trinity Biotech Manufacturing Limited, a subsidiary of Trinity Biotech plc. Compensation paid to key management is set out in Note 27.

The average number of persons employed by the Company (excluding non-executive directors), all in administration, in the financial year was 1 (2020: 1).

Auditors' remuneration – Company
The Company incurred auditors' fees of US$107,000 in 2021 (2020: US$107,000) which were paid by a subsidiary of the Company. These were incurred in respect of the following categories:

Company	**2021 US$'000**	**2020 US$'000**
Audit of individual company accounts	97	97
Other assurance services	-	-
Tax advisory services	10	10
Other non-audit services	-	-

36. INVESTMENT IN SUBSIDIARIES – COMPANY

	Company December 31, 2021 US$'000	*Company December 31, 2020 US$'000*
Investment in subsidiaries	21,812	19,939

The movement on investments in subsidiaries is as follows:

	US$'000
Balance at January 1, 2020	18,732
Capital contribution – share based payments	765
Capital contribution – relating to advances to subsidiaries	700
Deferred tax arising on capital contributions – relating to advances to subsidiaries	(175)
Impairment of investments	(83)
Balance at December 31, 2020	19,939
Balance at January 1, 2021	19,939
Capital contribution – share based payments	1,090
Capital contribution – relating to advances to subsidiaries	866
Impairment of investments	(83)
Balance at December 31, 2021	21,812

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.

Capital contribution - advances to subsidiaries
Capital contributions during 2021 amounted to US$866,000 (2020: US$700,000) and relate to advances given to subsidiary undertakings, Immco Diagnostics, Benen Trading Limited, Biopool US Inc and Trinity Biotech Inc.

Impairment and deferred tax
The annual impairment review performed at December 31, 2021 showed that the carrying value of the Company's assets exceeded the amount that could be recovered through their use or sale and on that basis an impairment charge against the carrying value of investments amounting to US$83,000 has been recognised. For more information, refer to Note 14. In the Company financial statements, total impairment charges have been recognised in the Statement of Comprehensive Income of US$2,340,000, net of tax. This relates to the carrying value of the investment in Biopool US Inc. and the provisions for impairment of advances owed by Biopool US Inc.

In 2020, the total impairment charges recognised in the Statement of Comprehensive Income was US$14,355,000, net of tax.

37. ADVANCES TO SUBSIDIARIES - COMPANY

	Company December 31, 2021 US$'000	*Company December 31, 2020 US$'000*
Advances to subsidiaries	38,730	36,755

The movement on advances to subsidiaries is as follows:

	US$ '000
Balance at January 1, 2020	42,862
Advances to subsidiaries	15,131
Repayment of advances to subsidiaries	(27,932)
Reversal of prior year impairment	13,133
Provision for impairment	(14,272)
Recovery of impaired balances	6,320
Imputed Interest on advances to subsidiaries	1,513
Balance at December 31, 2021	36,755
Balance at January 1, 2021	36,755
Advances to subsidiaries	8,526
Repayment of advances to subsidiaries	(6,108)
Provision for impairment	(2,257)
Recovery of impaired balances	583
Imputed Interest on advances to subsidiaries	1,231
Balance at December 31, 2021	38,730

In addition to providing permanent investment capital, the Company also provides advances to certain of its subsidiary undertakings on a periodic basis with a view to them being repaid from future cash flows.

The provision for impairment of US$2,257,000 recorded in the financial year ended December 31, 2021 relates to advances owing by the subsidiary entity Biopool US Inc. The impairment provision has been recorded to reduce the balances to the expected recoverable amount from these subsidiaries. The recovery of impaired balances during the year of US$583,000 relates to Trinity Biotech Manufacturing Limited.

The provision for impairment of US$14,272,000 recorded in the financial year ended December 31, 2020 relates to loans owing by the subsidiary entity Trinity Biotech Inc and Trinity Biotech Luxembourg SARL. The impairment provision has been recorded to reduce the balances to the expected recoverable amount from these subsidiaries. A prior year impairment of an advance owing by Trinity Biotech Financial Services Limited has been partially reversed in the financial year ended December 31, 2020 based on the fair value of this balance. The balance is now stated at US$13,133,000. The recovery of impaired balances during the year of US$6,320,000 relates to Trinity Biotech Manufacturing Limited and Biopool US Inc.

38. DEFERRED TAX LIABILITIES - COMPANY

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

Deductible temporary differences	*2021 US$'000*	*2020 US$'000*
Investment in subsidiaries and interest-bearing loans to subsidiaries	(59)	(59)
Total	(59)	(59)

38. DEFERRED TAX ASSETS AND LIABILITIES - COMPANY (CONTINUED)

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

	December 31, 2021 US$'000	*December 31, 2020 US$'000*
Management expenses carried forward	359	398
Timing difference related to interest expenses	3,794	3,693
Total	4,153	4,091
Capital losses	8,293	8,293

The deferred tax assets relating to management expenses carried forward and timing differences for interest expenses have not been recognised due to uncertainty over recoverability.

No deferred tax asset is recognised in 2021 or 2020 in respect of a capital loss of US$8,293,000 (2020: 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.

Movement in temporary differences during the year

	Balance January 1, 2021 US$'000	*Recognised in income US$'000*	*Recognised in investment in subsidiaries US$'000*	*Balance December 31, 2021 US$'000*
Investment in subsidiaries and advances to subsidiaries	(59)	-	-	(59)

	Balance January 1, 2020 US$'000	*Recognised in income US$'000*	*Recognised in investment in subsidiaries US$'000*	*Balance December 31, 2020 US$'000*
Investment in subsidiaries and advances to subsidiaries	2,681	(2,915)	175	(59)

39. CASH AND CASH EQUIVALENTS - COMPANY

	Company December 31, 2021 US$ '000	*Company December 31, 2020 US$ '000*
Cash at bank and in hand	3,798	11,452

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

40. RETAINED EARNINGS - COMPANY

	Retained earnings US$'000
Balance at January 1, 2020	7,763
Total comprehensive loss	(2,255)
Share-based payments	816
Balance at December 31, 2020	6,324
Balance at January 1, 2021	6,324
Total comprehensive profit	2,627
Share-based payments	1,111
Balance at December 31, 2021	10,062

41. OTHER RESERVES - COMPANY

	December 31, 2021 US$ '000	*December 31, 2020 US$ '000*
Treasury shares	(24,922)	(24,922)

Treasury Shares

No shares were repurchased by the Group in 2021 or 2020.

42. OTHER PAYABLES - COMPANY

	December 31, 2021 US$ '000	*December 31, 2020 US$ '000*
Amounts owed to group undertakings	67,888	69,197
Accrued liabilities	879	119
	68,767	69,316

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.

43. DERIVATIVES AND FINANCIAL INSTRUMENTS - COMPANY

The Company uses a range of financial instruments (including cash, receivables 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 As at December 31, 2021 US$'000	*Note*	*Effective interest rate*	*Total Gross US$'000*	*6 mths or less US$'000*	*6 – 12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*5 years or more US$'000*	*Impairment US$'000*	*Net US$'000*
Cash and cash equivalen	*39*	*0%*	3,798	3,798	-	-	-	-	-	3,798
Advances to subsidiaries	*37*	*3%*	40,987	9,010	4,541	21,988	5,448	-	(2,257)	38,730
Total			44,785	12,808	4,541	21,988	5,448	-	(2,257)	42,528

Company As at December 31, 2020 US$'000	*Note*	*Effective interest rate*	*Total Gross US$'000*	*6 mths or less US$'000*	*6 – 12 mths US$'000*	*1-2 years US$'000*	*2-5 years US$'000*	*5 years or more US$'000*	*Impairment US$'000*	*Net US$'000*
Cash and cash equivalen	*39*	*0%*	11,452	11,452	-	-	-	-	-	11,452
Advances to subsidiaries	*37*	*3%*	51,027	8,216	8,213	27,863	6,735	-	(14,272)	36,755
Total			62,479	19,668	8,213	27,863	6,735		(14,272)	48,207

Interest rate risk

At December 31, 2021, the Company had no third party borrowings and had cash and cash equivalents of US$3,798,000 (2020: US$11,452,000.)

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, 2021 US$ '000	*December 31, 2020 US$ '000*
Variable rate instruments		
Financial assets	3,798	11,452
Amounts owed to group undertakings	(67,888)	(69,197)
	(64,090)	(57,745)

43. DERIVATIVES AND FINANCIAL INSTRUMENTS – COMPANY (CONTINUED)

Cash flow sensitivity analysis for variable rate instruments
An increase of 100 basis points in interest rates at the reporting date would have the effect of decreasing the profit for the period by US$222,000. This assumes that all other variables, in particular foreign currency rates, remain constant.

Fair Values
The Company shows its advances to subsidiaries at fair value less any provisions for impairment in value (see Note 36). The fair values of these advances are calculated by discounting the expected repayments using a market rate of interest which is applicable to assets of a similar risk profile. There is uncertainty over the timing of these repayments and hence management's best estimate of cash flows from the relevant subsidiary undertakings forms the basis for the fair value calculations. Notwithstanding this estimation, the balance sheet classification as non-current reflects management's expectation that the assets will not be realised within 12 months of the balance sheet date.

The fair value of the inter-company and other payable balances are calculated by discounting the expected repayments using a market rate of interest. There is uncertainty over the timing of these repayments and hence management's best estimate of cash flows to the relevant subsidiary undertakings and other creditors forms the basis for the fair value calculations.

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, 2021					
US$'000					
Advances to subsidiaries	*37*	38,730	-	38,730	38,730
Cash and cash equivalents	*39*	3,798	-	3,798	3,798
Inter-company and other payables	*42*	-	(68,767)	(68,767)	(68,767)
		42,528	(68,767)	(26,239)	(26,239)

	Note	*Loans and receivables*	*Liabilities at amortised cost*	*Total carrying amount*	*Fair value*
December 31, 2020					
US$'000					
Advances to subsidiaries	*37*	36,755	-	36,755	36,755
Cash and cash equivalents	*39*	11,452	-	11,452	11,452
Inter-company and other payables	*42*	-	(69,316)	(69,316)	(69,316)
		48,207	(69,316)	(21,109)	(21,109)

43. DERIVATIVES AND FINANCIAL INSTRUMENTS – COMPANY (CONTINUED)

Liquidity risk
The subsidiary undertakings owned by the Company are cash generating and remit cash on a periodic basis. Short-term flexibility is achieved through the management of the group's short-term deposits.

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

As at December 31, 2021 *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*
Financial liabilities							
Inter-company and other payables	*42*	68,767	68,767	68,767	-	-	-
		68,767	68,767	68,767	-	-	-

As at December 31, 2020 *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*
Financial liabilities							
Inter-company and other payables	*42*	69,316	70,699	70,699	-	-	-
		69,316	70,699	70,699	-	-	-

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 Company has no significant concentrations of credit risk. The carrying amount reported in the balance sheet for cash and cash equivalents and loans to subsidiaries approximates their fair value.

43. DERIVATIVES AND FINANCIAL INSTRUMENTS – COMPANY (CONTINUED)

Exposure to credit risk
The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk is as follows:

	Note	*Carrying value December 31, 2021 US$'000*	*Carrying value December 31, 2020 US$'000*
Advances to subsidiaries	*37*	38,730	36,755
Cash and cash equivalents	*39*	3,798	11,452
		42,528	48,207

Capital management
An analysis of the capital structure of the Group is contained in Note 29 and the same factors apply to the capital structure of the Company.

44. RELATED PARTY TRANSACTIONS - COMPANY

The Company has related party relationships with other subsidiaries within the Group. The Company provides permanent investment capital and advances to certain of its subsidiary undertakings on a periodic basis with a view to them being repaid from future cash flows (see Notes 36 and 37). The Company's principal subsidiaries are listed in Note 33 and the Company has balances outstanding with and, in certain cases, payable to, virtually all of these companies. The aggregate amounts outstanding are set out in Notes 36 and 37 and the payable amounts are set out in Note 42.

The related party relationships of the Group with its subsidiaries, and with its directors and executive officers are set out in Note 28.

45. BOARD APPROVAL

The Board of Directors approved and authorised for issue the financial statements in respect of the year ended December 31, 2021 on 6 September 2022.