SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from to

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 0-22320

Trinity Biotech plc

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

Ireland
(Jurisdiction of incorporation or organization)

IDA Business Park, Bray, Co. Wicklow, Ireland
(Address of principal executive offices)

John Gillard
Chief Financial Officer
Tel: +353 1276 9800
Fax: +353 1276 9888
IDA Business Park, Bray, Co. Wicklow, Ireland
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (each representing 4 'A' Ordinary Shares, par value US$0.0109)	**TRIB**	**NASDAQ Global Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

83,606,810 Class 'A' Ordinary Shares (excluding Treasury Shares)
(as of December 31, 2021)

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

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

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

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

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

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

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

Item 17 ☐ Item 18 ☐

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

Yes ☐ No ☒

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form S-8 File Nos. 333-182279,333-195232 and 333-253070 and our Registration Statement on Form F-3 File No.333-239701.

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PART II

PART III

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

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

Our consolidated financial statements appearing in this Annual Report are prepared in accordance with International Financial Reporting Standards ("IFRS") both as issued by the International Accounting Standards Board ("IASB") and as adopted by the European Union ("EU"). The IFRS standards applied are those effective for accounting periods beginning January 1, 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, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. We present our consolidated financial statements in U.S. Dollars and except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "Euro" or "€" are to European Union Euro. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

MARKET, INDUSTRY AND OTHER DATA

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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

PART I

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

Not applicable.

Item 2. *Offer Statistics and Expected Timetable*

Not applicable.

Item 3. *Key Information*

A. Selected Financial Data

The Company has adopted the amended rule that registrants are no longer required to provide five years of selected financial data.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary of Risk Factors

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

- **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 can require Trinity Biotech to repurchase their notes at par is April 1, 2022. In January 2022, the Company retired exchangeable notes with a nominal value of US$99.7 million 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.

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 27, 2022. The Credit Agreement is secured by substantially all of our property and assets, including our equity interests in our subsidiaries. See Item 18, Note 30 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 USA 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. The Company also has 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, and any further transition as a result of these changes, could have a significant impact on our results of operations. Management transition is often difficult and inherently causes some loss of institutional knowledge, which could negatively affect our results of operations and financial condition. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with these transitions. We may not be able to attract or retain a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products and other life science businesses.

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

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

Products manufactured at our facilities in Bray, Ireland, Jamestown and Buffalo, New York and Kansas City, Missouri accounted for the majority of our revenues during the fiscal year ended December 31, 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 submit a 510(k) application for this successor instrument in 2022 which, if approved, will allow us to market this instrument in the United States.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and wilfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the Physician Self-Referral Law, also known as the "Stark Law", which provides for strict liability for referrals by physicians to entities with which they or their immediate family members have a financial arrangement for certain designated health services, including clinical laboratory services provided by our CLIA-certified laboratory owned and operated by our subsidiary Immco Diagnostics Inc., that are reimbursable by federal healthcare programs, unless an exception applies. Penalties for violating the Stark Law include denial of payment, civil monetary penalties of up to fifteen thousand dollars per claim submitted, and exclusion from federal health care programs, as well as a penalty of up to one-hundred thousand dollars for attempts to circumvent the law;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payers that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Often, to avoid the threat of treble damages and penalties under the False Claims Act, which in 2020 were $11,665 to $23,331 per false claim, companies will resolve allegations in a settlement without admitting liability to avoid the potential treble damages. Any such settlement could materially affect our business, financial operations, and reputation;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. We cannot assure you that we have and will successfully report all transfers of value by us, and any failure to comply could result in significant fines and penalties. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;

- federal and state laws governing the certification and licensing of clinical laboratories, including operational, personnel and quality requirements designed to ensure that testing services are accurate and timely, and federal and state laws governing the health and safety of clinical laboratory employees;

- the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorising the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which makes the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), has recently increased its scrutiny of interactions between health care companies and health care providers, which has led to a number of investigations, prosecutions, convictions and settlements in the health care industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with the DOJ or other law enforcement agencies have forced healthcare providers to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

Trinity Biotech currently owns a number of active patents, some with protection across multiple countries. These patents have remaining patent lives 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

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 (as defined below under Item 10E. "Additional Information – Taxation") of our ADSs and would likely cause a reduction in the value of such shares. A foreign corporation will be treated as a PFIC for U.S. federal income tax purposes if either (1) at least 75% of its gross income for any taxable year consists of certain types of "passive income," or (2) at least 50% of the average value of the corporation's gross assets produce, or are held for the production of, such "passive income." For purposes of these tests, "passive income" includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties that are received from unrelated parties in connection with the active conduct of a trade or business. If we are treated as a PFIC, U.S. Holders of ADSs would be subject to a special adverse U.S. federal income tax regime with respect to the income derived by us, the distributions they receive from us, and the gain, if any, they derive from the sale or other disposition of their ADSs. U.S. Holders should carefully read Item 10E. "Additional Information – Taxation" for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of ADSs.

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

The stock market in general and the market prices of the ADSs on Nasdaq, in particular, are or will be subject to fluctuation, and changes in these prices may be unrelated to our operating performance. During the first quarter of 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 Item 18, 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.

Item 4. Information on the Company

A. History and Development of the Company

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

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

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

B. Business Overview

Overview

We and our subsidiaries (the "Group") develop, acquire, manufacture and market medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. We are also a significant provider of raw materials to the life sciences and research industries globally.

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

Organisational Structure

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

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

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

Principal Markets

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

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

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

We sell our products through our direct sales organisations in the United States, Brazil and to an extent in the United Kingdom, France and Germany and then through our network of principal distributors and non-governmental bodies into approximately 100 countries globally.

Point-of-Care ("POC")

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

Uni-Gold™ HIV

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

The Future of Point-Of Care at Trinity Biotech

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

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

We are developing a rapid Covid-19 antigen test with which we intend to leverage our existing infectious disease rapid test design to expedite the development and validation timeframe and also generate scale efficiencies in manufacture and distribution.

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

Clinical Laboratory

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

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

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

Infectious Diseases

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

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

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

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

Diabetes and Haemoglobinopathies

Trinity Biotech manufactures products for in-vitro diagnostic measurement of haemoglobin A1c ("HbA1c") used in the monitoring and diagnosis of diabetes, as well identifying those who are at a high risk of developing diabetes (pre-diabetic). The Premier Hb9210 uses patented 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 submit the Premier Resolution to the FDA for approval in 2022. 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.

The point-of-care segment of the HbA1c market is addressed by the Tri-stat system. The Tri-stat offers rapid, precise analysis in a simple and highly cost effective manner. Using boronate affinity technology and a two phase optical system, the instrument can process three samples simultaneously with the three results available in just 10 minutes. In 2018, a new, second generation Tri-stat analyser was launched in international markets outside of the USA. In 2020 an enhanced version of the Tri-stat analyser was launched which includes a dual detector for improved performance.

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.

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.

Sales and Marketing

Trinity Biotech sells its products through its own direct sales force in the United States. Our sales team in the United States is responsible for marketing and selling the Trinity Biotech range of Point-Of-Care, Infectious Diseases, Haemoglobins, Autoimmune and Clinical Chemistry products. Meanwhile the direct sales force in Brazil sells the company's haemogloblins product range.

Through its international sales and marketing organisation, which is located in Ireland, Trinity Biotech sells:

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

Competition

The diagnostic industry is very competitive. There are many companies, both public and private, engaged in the sale of medical diagnostic products and diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. This is a technology driven market with an emphasis on automation and emerging biomarkers. Trinity actively works on increasing automation for the clinical laboratory. Trinity seeks to bring novel biomarkers to market by licensing agreements with universities and innovative companies.

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

Research and Development

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

Certain R&D activities of the Group have been outsourced to third parties. These activities are carried out in the normal course of business with these companies. During 2021, a number of third party consultants and contractors were engaged to assist with development projects, working principally on the Autoimmune Smart Reader project and the Covid antigen projects. The total amount paid to these R&D consultants and contractors in 2021 was US$807,000 (2020: US$658,000).

Research and Products under Development

Trinity Biotech has research and development groups focusing separately on haemoglobin, infectious diseases and autoimmune products. During 2021, these groups were located in Ireland and the USA and largely mirror the production capability at each production site. In addition to in-house activities, Trinity Biotech sub-contracts some research and development from time to time to independent researchers based in the USA and Europe.

Principal Development Projects

The following table sets forth for each of Trinity Biotech's main development projects, the costs incurred during each period presented and the cumulative costs (before amortization and impairment) incurred as at 31 December 2021:

Product Name	***2021*** ***US$'000***	***2020*** ***US$'000***	***Total project costs to December 31, 2021***[1] ***US$'000***
Premier Instrument for Haemoglobin A1c testing	2,538	1,359	35,924
HIV screening rapid test	1,488	2,278	12,240
Covid tests	1,320	467	1,787
Autoimmune Smart Reader	550	666	3,287
Mid-tier haemoglobins instrument	303	243	609
Tri-stat Point-of-Care instrument	245	203	9,477
Uni-Gold antigen improvement	-	556	2,918
Syphilis point-of-care test	-	618	1,942

[1] Cumulative costs to December 31, 2021 are shown before deduction of amortization and impairment losses.
[2] Syphilis point-of-care test – there was no capital expenditure on this development project in 2021 as other projects were prioritized. It is expected this project will resume within the next twelve months.

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

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

Some aspects of the development of a new product are outside of the control of Trinity Biotech. Notwithstanding the uncertainty surrounding these external factors, Trinity Biotech believes the planned completion dates of these projects are realistic and achievable. As the manufacturing lead time for these new products is relatively short, it is anticipated that material cash inflows will commence shortly after each of the project's planned completion date.

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

Haemoglobin Development Group

Premier Hb9210 Instrument for Haemoglobin A1c Testing

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 intend to submit it to the FDA for clearance in 2022. 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.

Tri-stat 2.0

Tri-stat 2.0 represents a new HbA1c device that offers rapid, precise analysis in a simple and highly cost effective manner. Using boronate affinity technology and a two phase optical system, three samples can be analysed simultaneously. This instrument though often characterised as point-of-care is targeted at very low volume laboratories and governmental outreach programs. The ability to perform three samples simultaneously enables the instrument to address these segments. Taking advantage of the latest technology the instrument features a colour touchscreen, multiple language capability, modern connectivity, increased storage capacity as well as replaceable diodes for state-of-the-art performance. Whilst the product has been launched in international markets, the company continues to make enhancements to further improve its operational efficiency and accuracy. In 2020 an enhanced version of the Tri-stat analyser was launched which includes a dual detector for improved performance.

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 2022.

Point-of-Care Development Group

We are developing a rapid Covid-19 antigen test, which we expect to have CE marked for professional use only in the second quarter of 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.

Patents and Licences

Patents

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

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

Licences

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

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

In 2013, Trinity Biotech entered into a licence agreement with a leading market participant, giving the Group a non-exclusive, worldwide licence access to a significant HIV-2 patent portfolio for the purpose of making, using and selling a HIV test kit, subject to certain limitations.

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

Each of the licensing arrangements disclosed under this subheading terminates on the date expiration or adjudication of invalidity or unenforceability of the last of the particular licenced patents covered by the respective agreement. Each licensor has the right to terminate the arrangement in the event of non-performance by Trinity Biotech. The key licensing arrangements, with the exception of the agreement entered into in 2013 which provides for the payment of a lump sum licence fee, require the Group to pay a royalty to the licence holder which is based on sales of the products which utilise the relevant technology being licenced. The total amount paid by Trinity Biotech under key licensing arrangements in 2021 was US$540,000 (2020: US$470,000).

Government Regulation

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

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

The process in each country varies considerably depending on the nature of the test, the perceived risk to the user and patient, the facility at which the test is to be used and other factors. As 62% of Trinity Biotech's 2021 revenues were generated in the Americas (with a large concentration of this in the United States) and as the United States represents a substantial proportion of the worldwide diagnostics market, an overview of FDA regulation has been included below.

Food and Drug Administration

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

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

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

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

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

FDA premarket clearance and approval requirements

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

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

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

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

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

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

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

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

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

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

Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application", although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. In February 2020, FDA published proposed regulation to update the Quality System Regulation to incorporate the international standard specific for medical device quality management systems (ISO 13485). If finalized, the quality management system requirements for FDA-regulated devices would be harmonized with the ISO 13485 standards.

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

Clinical Studies

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

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

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

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

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

Post-market Regulation

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

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

We have registered our facilities with the FDA as medical device manufacturers. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers. In 2017, the FDA closed its pilot program for MDSAP (Medical Device Single Audit Program) and began accepting third party inspection reports from approved Auditing Organizations in lieu of conducting its own routine surveillance inspections. MDSAP audits are paid by the manufacturer and conducted annually. The FDA receives and reviews the MDSAP report and may respond to the manufacturer with its own inspection if it deems the facility is not in control. If the FDA finds any failure to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunctions, and civil penalties; recall or seizure of products; the issuance of public notices or warnings; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

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

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

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

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

Clinical Laboratory Improvement Amendments of 1988, ("CLIA")

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

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

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

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

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

Federal Oversight of Laboratory Developed Tests and Research Use Only Products

Trinity Biotech supplies clinical laboratories with raw materials, such as reagent products, that may be used by clinical laboratories in clinical laboratory tests, which are regulated under CLIA, as well as by applicable state laws. Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests, or LDTs. The FDA defines the term "laboratory developed test" as an in vitro diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic Act with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing, and concerns with several high-risk LDTs related to lack of evidentiary support for claims and erroneous results, the FDA issued guidance that, when finalized, would adopt a risk based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing Congress and manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate. FDA issued a discussion paper on LDTs in January 2017 discussing possible approaches to oversight of LDTs.

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

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

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

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

Product Imports/Exports

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

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

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

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

Foreign Corrupt Practices Act and Other Anti-Corruption Laws

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

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

Healthcare Reform

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

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

- includes a reduction in the annual update factor used to adjust payments under the CLFS for inflation. This update factor reflects the consumer price index for all urban consumers, or CPI-U, and the ACA reduces the CPI-U by 1.75% for the years 2011 through 2015. The Affordable Care Act also imposes a multifactor productivity adjustment in addition to the CPI-U, which may further reduce payment rates;

- requires certain medical device manufacturers to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA; and

- requires the coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and clinicians and initiatives to promote quality indicators in payment methodologies.

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

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

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

State and Federal Privacy and Security Laws

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

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

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

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

Federal and State Anti-Kickback Laws

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

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

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

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

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

Physician Self-Referral Prohibitions

In addition to the Anti-Kickback Statute, a federal law directed at physician "self-referral," commonly known as the Stark Law, prohibits, among other things, physicians who personally or through an immediate family member, have a financial relationship, including an investment, ownership or compensation relationship with an entity, including clinical laboratories, from referring Medicare patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. In addition, the clinical laboratory is prohibited from billing for any tests performed pursuant to a prohibited referral. Recent court cases have extended the Stark law's prohibition to referral of Medicaid patients as well. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to US$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to US$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states also have anti- "self-referral" and other laws that are not limited to Medicare and Medicaid referrals.

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

Civil Monetary Penalties Law

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

Federal Physician Payment Sunshine Act

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

Other Federal and State Fraud and Abuse Laws

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

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

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

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

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

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

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

New York Laboratory Licensing

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

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

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

Other States' Laboratory Licensing

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

Regulation outside the United States

Distribution of Trinity Biotech's products outside of the United States is also subject to foreign regulation. Each country's regulatory requirements for product approval and distribution are unique and may require the expenditure of substantial time, money, and effort. We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval (or pre-qualification or endorsement) from local regulators in such countries or international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. We generally pursue approval only in those countries that we believe have a significant market opportunity.

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

In the European Union (EU), diagnostic products are also categorized into different categories and the regulatory process, which has been governed by the European In Vitro Diagnostic Medical Device Directive, depends upon the category, with certain product categories requiring review and approval by an independent company, known as a Notified Body, before the manufacturer can affix a CE mark to the product to declare conformity to the Directive. Other products only require a self-certification process. In the second quarter of 2017, the EU adopted the new In Vitro Diagnostic Regulation (IVDR) which replaces the existing directive in the EU for in vitro diagnostic products. The IVDR will apply after a five-year transition period and imposes additional premarket and post market regulatory requirements on manufacturers of such products. The EU has recently announced updated transition periods for certain classes of in vitro medical devices.

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

In the EU, medical devices are also categorized into different classes and the regulatory process, which has been governed by the European Medical Device Directive and the Active Implantable Medical Device Directive, varies by class. Each product must bear a CE mark to show compliance with the Directive. In the second quarter of 2017, the EU adopted the new Medical Devices Regulation (MDR) which replaces the existing directives in the EU for medical devices and imposes additional premarket and post market regulatory requirements on manufacturers of such products. While the MDR was previously adopted to apply after a three year transition period, in 2020 the European Parliament postponed the date of application by one year. The MDR is officially effective as of May 26, 2021.

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

There can be no assurance that new laws or regulations will not have a material adverse effect on Trinity Biotech's business, financial condition, and results of operation. The time required to obtain needed product approval by particular foreign governments may be longer or shorter than that required for FDA clearance or approval. There can be no assurance that Trinity Biotech will receive on a timely basis, if at all, any foreign government approval necessary for marketing its products.

C. Organizational Structure

Please refer to Note 32 to our audited consolidated financial statements ("Group Undertakings") included elsewhere in this Annual Report for a listing of our significant subsidiaries, including name, country of incorporation, and proportion of ownership interest.

D. Property, Plants and Equipment

Our headquarters, manufacturing and research and development facilities as well as our sales offices are located in Bray Ireland. We have entered into a number of related party transactions with JRJ Investments ("JRJ"), a partnership currently owned by Mr Ronan O'Caoimh and Dr Walsh, directors of the Company, and directly with Mr O'Caoimh, to provide current and potential future needs for the Group's manufacturing and research and development facilities in Bray, Ireland. We have entered into an agreement for a 25 year lease with JRJ, for 15,780 square feet of offices at an annual rent of €381,000 (US$432,000), which expires in 2027 and have entered into lease agreements with Mr. 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 €787,605 (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. Towards the end of 2020, the Group occupied some additional space adjoining the warehouse. This is a short-term arrangement, and no payments were made for the additional space during 2020 and 2021. A sum of US$90,000 was accrued for rent payable to Mr O'Caoimh in relation to this additional space. See Item 7 – Major Shareholders and Related Party Transactions.

We have six main manufacturing sites worldwide, five in the Americas (Amherst, Williamsville and Jamestown, NY, Kansas City, MO, and Extrema, Brazil), and one in Bray, Ireland. An additional facility is owned in Burlington, Canada which serves as a distribution centre and also carries out some research and development activities.

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

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

Trinity Biotech USA operates from a 25,610 square foot FDA registered facility in Jamestown, New York. The facility was purchased in 1994. Additional warehousing space is also leased in Jamestown, New York at an annual rental charge of US$183,000.

Primus Corp. operates from a 39,000 square foot facility in Kansas City, Missouri and an adjacent 13,500 square foot facility mainly used for warehousing. The leases on these properties run until 2022 and 2025 respectively and annual rents are US$108,000 and US$44,000 respectively.

Immco Diagnostics Inc. operates from a 20,520 square foot facility in Amherst, New York and a 31,731 square foot facility in Williamsville, New York, subject to leases expiring in 2022 and 2033 respectively. The annual rent for the Amherst facility is US$259,000. The Williamsville facility's annual rent is currently US$416,000, rising to US$452,000 by 2029. An additional 5,120 square foot facility is owned by Trinity Biotech in Burlington, Canada.

Additional office and factory space is leased by the Group in Acton, Massachusetts, Sao Paulo, Brazil and Extrema, Brazil at an annual cost of US$96,000, US$8,000 and US$41,000 respectively.

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

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.

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.

Carlsbad, California – this facility specialises in the development and manufacture of products utilising Western Blot and lateral flow technology. Our suite of Lyme products were manufactured at this facility and our new Infectious Diseases Point-of-Care range were manufactured at this site. In 2020, management made the decision to close this facility permanently (see above).

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.

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

Principal Capital Expenditure and Divestitures

Our principal capital expenditure in the last three financial years has been on developing new products internally. The amount capitalized for development projects has been US$6,771,000, US$6,896,000, US$9,569,000 for years ended December 31, 2021, 2020 and 2019 respectively. In 2022, we expect the capital expenditure on development projects will be in the range US$6,500,000 to US$7,500,000.

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

Not applicable.

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

A. Operating Results

Overview

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

Our consolidated financial statements include the attributable results of Trinity Biotech plc and all its subsidiaries. This discussion covers the years ended December 31, 2021 and December 31, 2020 and should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this Form 20-F. The financial statements have been prepared in accordance with IFRS both as issued by the International Accounting Standards Board ("IASB") and as subsequently adopted by the European Union ("EU") (together "IFRS"). Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU.

We have relied on an exemption under the SEC's rules to prepare consolidated financial statements without a reconciliation to U.S. generally accepted accounting principles ("U.S. GAAP") as at and for the three year period ended December 31, 2021 as Trinity Biotech is a foreign private issuer and the financial statements have been prepared in accordance with IFRS as issued by the IASB.

Factors affecting our results

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

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

The comparability of our financial results for the years ended December 31, 2021 and 2020 were impacted by impairment losses as a result of impairment reviews during the years ended December 31, 2020 and 2021 (See Item 18, Note 14).

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

Going Concern

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

As reflected in the accompanying consolidated financial statements, for the years ended December 31, 2021 and 2020, we recorded a profit of US$0.9 million and a loss of US$6.4 million, respectively. In addition, we reported cash outflow of US$1.5 million for the year ended December 31, 2021 and a cash inflow of US$10.9 million for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit in equity attributable to the equity holders of the Company of US$0.3 million.

The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the 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 until 2026. Furthermore, the pending investment by MiCo IVD Holdings LLC, a subsidiary of the MiCo Group, will facilitate our exploring lower cost debt funding options, in the short-term, with the aim of further reducing our interest expense through refinancing the balance of the Group's term loan at substantially lower interest rates. In April 2022, the Company announced a US$45 million strategic investment and partnership with the MiCo Group, a KOSDAQ-listed company. The investment is subject to customary Korean central bank approvals. 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.

Impact of Currency Fluctuation

Trinity Biotech's revenue and expenses are affected by fluctuations in currency exchange rates especially the exchange rate between the US Dollar and the Euro, the Brazilian Real and Canadian Dollar. Trinity Biotech's revenues are primarily denominated in US Dollars and its expenses are incurred principally in US Dollars, Euro and Brazilian Real. The weakening of the US Dollar could have an adverse impact on future profitability.

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

Impact of Covid-19 Pandemic

Our revenues decreased by 8.8% in 2021 compared to 2020. This was mainly due to lower demand and selling prices for PCR Viral Transport Media ("VTM") products compared to 2020 when there was exceptional demand due to 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.

In 2020, most of our product lines were negatively impacted by the Covid-19 pandemic. Our business relies on people attending hospitals and clinics with ailments that need to be diagnosed through testing. Due to quarantine restrictions and peoples' fear of catching Covid-19, there was a marked decrease in 2020 in people attending hospitals and clinics. Haemoglobins revenues reduced for both instruments and consumables with the impact being greater on diabetes (A1c) rather than on haemoglobin variant revenues. In autoimmunity, testing volumes were particularly impacted at our reference laboratory in Buffalo, New York but there were also lower product sales in all major markets. HIV revenues in Africa were negatively impacted by logistical and testing constraints arising from COVID-19.

In 2021, there was an easing of quarantine restrictions and vaccination programs gave patients the confidence to visit their doctors again. For this reason, on a product-for-product basis, revenues outside of our Covid-19 product portfolio returned to near pre-pandemic levels in 2021.

Covid-19 products

When the pandemic started, we were was well-positioned to respond with our established expertise in infectious disease products including our existing Viral Transport Media product which could be used to transport testing samples for Covid-19 PCR tests. Since the start of the pandemic to the end of 2021, VTM revenues have been in excess of US$50 million.

Beginning in 2020, we undertook development of three different Covid-19 diagnostic tests. A Covid-19 antibody test using an ELISA platform, a Covid-19 rapid antibody test and a rapid Covid-19 antigen test, with which we intend will leverage our existing rapid infectious disease test design.

Operations and Employee Safety

Many governments have implemented restrictive lockdowns requiring non-essential businesses to shut down operations. Our business is typically deemed "essential" and we continued to operate, manufacture and distribute products to customers throughout most of 2020 with no closures in 2021. We furloughed many of our work forces in the USA, Ireland and Canada in April 2020 but the majority of employees returned the following month.

We have implemented health and safety policies to help safeguard our on-site employees and maintain business continuity. 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. These measures have created additional challenges from our work methods and on our infrastructure and I.T. systems which may have resulted in decreased productivity and some increased operating costs. However, the various responses we have put in place have to date resulted in limited disruption to our normal business operations. To date, we have been able to maintain our operations without significant interruption and have been able to develop and quickly scale manufacturing capacity for new products related to the Covid-19 pandemic.

We have availed of governmental supports. This included the receipt of forgivable loans under the U.S. government's Paycheck Protection Program ("PPP"). In Ireland, the company also availed of economic support mechanisms in 2020 being provided by the Irish Government mainly in the form of wage subsidies.

Supply Chains

The pandemic has caused delays in deliveries of certain raw materials and components for our products, particularly those related to our Viral Transport Media product. Such delays can result in disruption to our business operations. We are continuously evaluating our supply chain to identify potential gaps and take steps intended to ensure continuity. Our inventory levels continue to fluctuate due to the change in our sales mix and the increased size of customer orders for Covid-19 related products. We successfully increased our production capacity for our viral transport media product, with the workforce mainly comprising of temporary staff.

Outlook

Management continues to monitor the pandemic situation closely and seeks to minimise the negative impacts on the business, while at the same time, optimising the opportunities presented to us as a medical diagnostic company. We sell our products in approximately 100 countries and there can be a large variance globally in the impact of the virus, the virus infection rates and public healthcare measures from country to country. It is therefore difficult to generalise about the recovery of demand for our products given the number of variables.

While the outlook is subject to significant uncertainty, we expect demand for our non-Covid related products to further increase in 2022 compared to 2021 as vaccination rollout allows for more patients to return to their doctors, which is what mainly drives our business. The extent to which demand for our Covid-19 portfolio of products is sustained into 2022 and beyond is highly uncertain and very difficult to predict. The launch of our rapid Covid-19 antigen test during 2022 is expected to drive growth as the market for that type of product is exceptionally large. Generally, demand for the Covid-19 tests depends on new information that may emerge concerning the severity of the coronavirus, the incidence of Covid-19 variants and the vaccination programmes plus competition from competing products.

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

Revenues

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

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

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

Clinical Laboratory Goods

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

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

In 2021, there was a partial return towards more normalised level of Haemoglobins testing. While COVID-19 public health restrictions remained in place in 2021 in many markets, these restrictions were not as severe as in 2020. As a result, diabetic related testing revenues increased by approximately 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 a FDA warning letter in the prior year.

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

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

Cost of sales, gross profit and gross margin

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

Other operating income

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

Research and development expenses

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

Selling, general and administrative expenses

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

The Group recorded a total share-based payments charge of US$1.1 million in 2021 compared to US$0.8 million in 2020. The increase of US$0.3 million in the total share-based payments expense is mainly due to a higher number of options being in their vesting period in 2021 compared to 2020 due to options granted in prior years. Share based payments included in selling, general and administrative expenses was US$1.1 million in 2021 and US$0.8 million in 2020. For further details, refer to Item 18, Note 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 Item 18, Notes 13, 14 and 18.

Operating profit

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

Net financing expenses

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

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

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

Income tax credit

The Group recorded a tax credit on continuing operations of US$0.2 million for the year ended December 31, 2021 compared to a tax credit of US$0.6 million for the year ended December 31, 2020. The 2021 tax credit consists of US$0.2 million of current tax credit and US$0.04 million of a deferred tax charge. In 2020, the tax credit comprised US$0.4 million of current tax credit and US$0.2 million of a deferred tax credit. For further details on the Group's tax charge please refer to Item 18, Note 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 Item 18, Note 10.

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 "Research and Products under Development" below.

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 Item 18, Note 9 and Note 15 to the consolidated financial statements.

Loss for the year from continuing operations

The loss for the year ended December 31, 2020 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.

B. Liquidity and Capital Resources

In 2021, the Group financed its operations mainly from internal sources in the form of existing cash resources and cash generated from operations. The only new external financing received in 2021 came from government-backed Covid-19 loans received by our U.S. subsidiaries.

The Group's capital structure is a mixture of debt and equity. The Group maintains a relationship with a number of lending banks. In 2021, the outstanding debt consisted of exchangeable notes, finance leases and government-backed Covid-19 loans.

Exchangeable Notes

The Group originally issued US$115.0 million of 30-year exchangeable senior notes in 2015. The notes are senior unsecured obligations and accrue interest at an annual rate of 4%, payable semi-annually in arrears. In August 2018, the Group purchased US$15.1 million of the exchangeable notes. The nominal amount of the debt since this purchase has been US$99.9 million. The notes are convertible into ordinary shares of the parent entity at the applicable exchange rate, at any time prior to the close of business on the second business day immediately preceding the maturity date, at the option of the holder, or repayable on April 1, 2045. The conversion rate is 47.112 ADSs per $1,000 principal amount of notes, equivalent to an exchange price of approximately $21.88 per ADS. The notes include a number of non-financial covenants, all of which were complied with at December 31, 2021.

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

Term loan with Perceptive Advisors

In December 2021, the Company and its subsidiaries entered into a US$81.3 million senior secured term loan credit facility (the "Term Loan") with Perceptive Advisors ("Perceptive"), an investment manager with an expertise in healthcare. The Term Loan was drawn down in January 2022, when the necessary shareholder approvals were obtained.

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

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

The re-financing of the exchangeable notes in early 2022 improved the Group's capital structure by reducing gross debt by approximately US$19 million with the Group having no material debt maturities until 2026. 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 Group increased optionality regarding its future capital structure.

Government-backed Covid-19 loans

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 under the program have been forgiven by the U.S. government before December 31, 2021 and therefore no liability for these loans exists at December 31, 2021.

In 2020, the Company received an interest-free loan of CAD$0.04 million (US$0.03 million) 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.

Leases

The Group entered into sale and leaseback arrangements in 2018 with Allied Irish Bank and Wells Fargo. At December 31, 2021, the amount owed under sale and leaseback arrangements was US$0.2 million. The Group also has lease liabilities relating to right-of-use assets with lease maturities between 1 and 12 years.

Cash and cash equivalents

At December 31, 2021, the cash and cash equivalents balance was US$25.9 million. In the future, the amount of cash generated from operations will depend on a number of factors which include the following:

- The ability of the Group to continue to generate revenue growth from its existing product lines and from new products following the successful completion of its development projects;
- The ability of the Group to mitigate the negative impacts of the Covid-19 pandemic and maximize the opportunities to sell our Covid-19 related portfolio of products;
- The extent to which capital expenditure is incurred on additional property plant and equipment;
- The level of investment required to undertake both new and existing development projects; and
- Successful working capital management in the context of a growing business.

Liquidity

In the Directors' opinion, the Group will have access to sufficient funds to support its existing operations for at least the next 12 months by utilising existing cash resources and cash generated from operations and external financing. The directors have considered the Group's current financial position and cash flow projections, taking into account all known events and developments including the Covid-19 pandemic and the pending financing from the MiCo Group.

In April 2022, the Company announced a US$45.0 million strategic investment and partnership with the MiCo Group, a KOSDAQ-listed company. The investment is subject to customary Korean central bank approvals. The investment consists of an equity investment of approximately US$25.2 million (11.2 million ADSs at a price of US$2.25 per ADS) and a seven-year, unsecured 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 Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days.

It is intended that the Company will use these funds primarily to repay a portion of the Group's US$81.25 million term loan. The Company also expects that this investment will facilitate it exploring lower cost debt funding options, in the short-term, with the aim of further reducing the company's interest expense through refinancing the balance of the Company's term loan at substantially lower interest rates.

Cash Flows

As at December 31, 2021, our consolidated cash and cash equivalents were US$25.9 million. Our cash and cash equivalents consist primarily of cash in bank accounts and short-term deposits.

The following table presents the major components of net cash flows used in and provided by operating, investing and financing activities.

	Year ended December 31,	
	2021 US$'000	**2020 US$'000**
Net cash inflow from operating activities	13,238	23,755
Net cash outflow from investing activities	(8,691)	(10,198)
Net cash outflow from financing activities	(6,019)	(2,716)
Net (decrease)/increase in cash and cash equivalents and short-term investments	(1,472)	10,841

Operating Activities

Net cash generated from operating activities for the year ended December 31, 2021 amounted to US$13.2 million (2020: US$23.8 million), a decrease of US$10.5 million. The decrease in net cash generated from operating activities of US$10.5 million is attributable to an increase in working capital outflows of US$4.8 million and a decrease in operating cash flows before changes in working capital of US$8.2 million partially offset by a decrease in interest and taxes paid of US$2.5 million. The decrease in operating cash flows before changes in working capital is primarily driven by a lower operating profit before impairment losses during the current financial year compared with an operating loss before impairment losses during the prior year. The working capital outflow increase, when compared to the prior year, is due to an increase outflow in trade and other payables of US$12.5 million partially offset by an increase in cash inflows for trade and other receivables of US$8.7 million and increase in cash outflows for inventories of US$1.0 million.

Investing Activities

Net cash outflows from investing activities for the year ended December 31, 2021 amounted to US$8.7 million (2020: US$10.2 million) which were principally made up as follows:

- Payments to acquire intangible assets of US$6.9 million (2020: US$7.0 million), which principally related to development expenditure capitalised as part of the Group's on-going product development activities; and
- Acquisition of property, plant and equipment of US$1.8 million (2020: US$3.2 million) incurred as part of the Group's investment programme for its manufacturing and distributing activities, and placement of instruments.

Financing Activities

Net cash outflows from financing activities for the year ended December 31, 2021 amounted to US$6.0 million (2020: outflows of US$2.7 million). This outflow is due to the payment of lease liabilities (US$3.0 million) and an interest payment on the exchangeable notes (US$4.0 million), refinancing costs (US$0.8m) partially offset by the receipt of loans in 2021 under the U.S. government's PPP (US$1.8 million). In 2020, the outflow was due to the payment of lease liabilities (US$3.2 million), an interest payment on the exchangeable notes (US$4.0 million) and partially offset by the receipt of loans in 2020 under the U.S. government's PPP (US$4.5 million).

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

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

D. Trend Information

The Group's revenues decreased in 2021 mainly due to lower demand and selling prices for PCR VTM products compared to 2020 when there was exceptional demand due to 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.

In 2020, most of our product lines were negatively impacted by the Covid-19 pandemic. Our business relies on people attending hospitals and clinics with ailments that need to be diagnosed through testing. Due to quarantine restrictions and peoples' fear of catching Covid-19, there was a marked decrease in 2020 in people attending hospitals and clinics. Haemoglobins revenues reduced for both instruments and consumables with the impact being greater on diabetes (A1c) rather than on haemoglobin variant revenues. In autoimmunity, testing volumes were particularly impacted at our reference laboratory in Buffalo, New York but there were also lower product sales in all major markets. HIV revenues in Africa were negatively impacted by logistical and testing constraints arising from COVID-19.

In 2021, there was an easing of quarantine restrictions and vaccination programs gave patients the confidence to visit their doctors again. For this reason, on a product-for-product basis, revenues outside of our Covid-19 product portfolio returned to near pre-pandemic levels in 2021.

The outlook for our Covid-19 related portfolio of products is unpredictable and will depend on numerous factors, including but not limited to, the future duration and extent of the pandemic and public health policies regarding Covid-19 testing protocols. Outside of our Covid-19 related portfolio of products, there has been a partial recovery since the second half of 2020 and this continued into 2021. We have seen some growth in other products beyond pre-pandemic levels, in particular our Sjögrens laboratory test and we expect this to continue. Overall, our business remains susceptible to the impact of COVID-19 and associated public health measures which makes it difficult to predict the future trends at this point.

E. Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

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

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

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

Some contracts oblige the Group to ship product to the customer ahead of the agreed payment schedule. For these shipments, a contract asset is recognised when control over the goods has transferred to the customer. The financing component is insignificant as invoicing for these shipments occurs within a short period of time after shipment has occurred and typically standard 30 day credit terms apply. Some contracts could be regarded as offering the customer a right of return. Due to the uncertainty of the magnitude and likelihood of product returns, there is a level of estimation involved in assessing the amount of revenue to be recognized for these 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.

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.

Research and development expenditures -capitalized development costs

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

Acquired in-process research and development (IPR&D) is valued at its fair value at acquisition date in accordance with IFRS 3. The Company determines this fair value by adopting the income approach valuation technique. Once the fair value has been determined, the Company will recognise the IPR&D as an intangible asset when it: (a) meets the definition of an asset and (b) is identifiable (i.e. is separable or arises from contractual or other legal rights). IPR&D is tested for impairment on an annual basis, in the fourth quarter, or more frequently if impairment indicators are present, using projected discounted cash flow models. If IPR&D becomes impaired or is abandoned, the carrying value of the IPR&D is written down to its revised fair value with the related impairment charge recognised in the period in which the impairment occurs. If the fair value of the asset becomes impaired as the result of unfavourable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercialising our programs, we could incur significant charges in the period in which the impairment occurs. The valuation techniques utilised in performing impairment tests incorporate significant assumptions and judgments to estimate the fair value, as described above. The use of different valuation techniques or different assumptions could result in materially different fair value estimates.

Factors which impact our judgement to capitalise certain research and development expenditure include the degree of regulatory approval for products and the results of any market research to determine the likely future commercial success of products being developed. We review these factors each year to determine whether our previous estimates as to feasibility, viability and recovery should be changed. At December 31, 2021 the carrying value of capitalised development costs was US$17.7 million (2020: US$13.4 million) (see Item 18, Note 14 to the consolidated financial statements). The increase in 2021 was mainly due to additions of US$6.8 million.

Impairment of intangible assets and goodwill

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

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

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

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

The value-in-use calculations use cash flow projections based on the 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%). Refer to Item 18, Note 14 for further information.

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

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

The impairment loss of US$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, and as in 2020 a downward trend in non-Covid-19 related infectious disease revenues in U.S. was a major factor in this impairment. For further details, see Item 18, Notes 13, 14 and 18.

In 2020, Primus Corporation, which recorded an impairment loss of US$16.7 million in 2020, was significantly impacted by the pandemic and changes to its product offering. The impairment loss for Primus mainly comprised a write down of intangible product developments assets. Trinity Biotech Do Brasil incurred an impairment loss of US$0.9 million (mainly comprising property, plant and equipment assets) in 2020 as this CGU continues to be impacted by the weakness of the Brazilian Real. Biopool US Inc. incurred an impairment loss of US$0.2 million in 2020, with a downward trend in non Covid-19 related infectious disease revenues in U.S. being a major factor.

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.

Allowance for slow-moving and obsolete inventory

We evaluate the realisability of our inventory on a case-by-case basis and make adjustments to our inventory provision based on our estimates of expected losses. We write off inventory that is approaching its "use-by" date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value. Given the allowance is calculated on the basis of the actual inventory on hand at the particular balance sheet date, there were no material changes in estimates made during 2021, 2020 or 2019 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2021 our allowance for slow moving and obsolete inventory was US$12.1 million which represents approximately 29.29% of gross inventory value. This compares with US$9.8 million, or approximately 24.45% of gross inventory value, at December 31, 2020 and US$6.7 million, or approximately 17.33% of gross inventory value, at December 31, 2019 (see Item 18, Note 17 to the consolidated financial statements). The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has increased between 2021 and 2020 due to declining demand for old and discontinued products and some Covid-19 specific products, and an increase in the obsolescence rate for product inventory due to a reduction in demand for certain products which has been partly impacted by Covid-19. In the case of raw materials and work in progress, the size of the provision has been based on expected future production of these products. Management is satisfied that the assumptions made with respect to future sales and production levels of these products are reasonable to ensure the adequacy of this provision. In the event that the estimate of the provision required for slow moving and obsolete inventory was to increase or decrease by 2% of gross inventory, which would represent a reasonably likely range of outcomes, then a change in allowance of US$0.8 million at December 31, 2021 (2020: US$0.8 million) (2019: US$0.8 million) would result.

Allowance for impairment of receivables

We make judgements as to our ability to collect outstanding receivables and where necessary make allowances for impairment. Such impairments are made based upon a specific review of all significant outstanding receivables. In determining the allowance, we analyse our historical collection experience and current economic trends in assessing the expected credit loss. If the historical data we use to calculate the allowance for impairment of receivables does not reflect the future ability to collect outstanding receivables, additional allowances for impairment of receivables may be needed and the future results of operations could be materially affected. Given the specific manner in which the allowance is calculated, there were no material changes in estimates made during 2021, 2020 or 2019 which would have an impact on the carrying values of receivables in these periods. At December 31, 2021, the allowance was US$3.0 million which represents approximately 3.2% of Group revenues. This compares with US$3.9 million at December 31, 2020 which represented approximately 3.8% of Group revenues and to US$5.4 million at December 31, 2019 which represented approximately 6.0% of Group revenues. The decrease in the allowance for impairment of receivables in the year ended December 31, 2021 was due to the write off of old receivable balances for which we had previously fully provided. 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$0.5 million at December 31, 2021 (2020: US$0.5 million) (2019: US$0.5 million) would result.

Accounting for income taxes

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

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

While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable. The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. In management's opinion, adequate provisions for income taxes have been made.

Item 18, Note 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 does not recognise deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilised before they expire.

Share-based payments

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

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

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

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

Exchangeable notes and derivative financial instruments

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 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. See Item 18, Note 24 to the consolidated financial statements for further information.

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

A. Directors and Senior Management

Executive Officers and Directors

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

Directors and Senior Management

Name	***Age***	***Title***
Directors		
Ronan O'Caoimh	66	Chairman and Chief Executive Officer
Jim Walsh, PhD	63	Executive Director
John Gillard	41	Chief Financial Officer, Company Secretary and Executive Director
Kevin Tansley	51	Executive Director
Clint Severson	73	Non-Executive Director/Lead Director
James D. Merselis	68	Non-Executive Director
Senior Management		
Simon Dunne	48	Chief Accounting Officer
Fernando Devia	59	Executive Vice President Sales
Sanjiv Suri	63	Senior Vice President Global Sales and General Manager North America
Terence Dunne, PhD	41	Business Development Director
Eibhlín Kelly	38	Chief Information Officer
Dan Goldsand	66	Vice President of Autoimmunity

On April 8, 2022 each of James Merselis, Clint Severson and Kevin Tansley tendered their resignations as directors of the Company subject to, but with effect from, closing of the MiCo transaction. For more information on the MiCo transaction, refer to Item 10 – Material Contracts.

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

Kevin Tansley, Executive Director, joined Trinity Biotech in March 2003 and was appointed Chief Financial Officer and Secretary to the Board of Directors in November 2007. Mr. Tansley was appointed to the board in September 2016 as Executive Director. In November 2020 it was announced that Mr. Tansley was stepping down as Chief Financial Officer and Company Secretary but remains a Director of the Company. Mr. Tansley trained as a chartered accountant in the Corporate Financial Services practice of Arthur Andersen & Co. Prior to joining Trinity Biotech in 2003, Mr. Tansley held a number of financial positions in the Irish electricity utility ESB. Mr. Tansley holds a Masters of Accounting degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

Clint Severson, Non-Executive director, joined the board of Trinity Biotech in November 2008 as a non-executive director. Mr. Severson served as Chairman and CEO of Abaxis Inc. from June, 1996 to August, 2018, a NASDAQ traded diagnostics company based in Union City, California. From February 1989 to May 1996, Mr. Severson served as President and Chief Executive Officer of MAST Immunosystems, Inc., a privately-held medical diagnostic company and to date he has accumulated over 40 years of experience in the medical diagnostics industry. Mr Severson is also on the board of Cutera, a provider of laser, light and other energy-based aesthetic systems for medical practitioners worldwide.

James D. Merselis, Non-Executive director, joined the board of Trinity Biotech in February 2009. He is currently a Co-Founder and Managing Director of Synchrony Bio LLC, a healthcare-focused venture investment fund based in St. Louis, MO. He is also a non-executive director for the following companies: Kypha Inc., a St. Louis, Missouri based diagnostic company focused on Complement assays in the diagnosis and management of patients with inflammatory diseases; Geneoscopy, a St. Louis, Missouri based company developing next generation diagnostics that leverage the power of RNA to better prevent, detect, and treat gastrointestinal disease. Mr. Merselis has more than forty years' experience in healthcare, including twenty-two years at Boehringer Mannheim Diagnostics (now Roche Diagnostics). Mr. Merselis has led a number of healthcare diagnostic start-ups. From 2002 to 2007, he served as President and CEO of HemoSense, Inc., a point-of-care diagnostics company providing patients and physicians with rapid test results to help manage the risk of stroke with the use of Warfarin or Coumadin. During this time he successfully took the company public (AMEX:HEM) followed two years later by its acquisition by Alere (now Abbott) (NYSE:ABT). His leadership at other start-ups has included: Nexus Dx (now Samsung), Alverix, Inc. (now Becton Dickenson), and Micronics, Inc. (now SONY).

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

Fernando Devia, Executive Vice President Sales, Mr. Fernando Devia, has been executive vice president at Trinity Biotech since October 2014. Mr. Devia started with Trinity April 2011 and received several promotions prior to his current position. Before joining Trinity Mr. Devia held various positions of increasing responsibility at Bio-Rad Laboratories & Hemagen diagnostics. Mr. Devia received an MBA degree in international management and a BS degree in biochemistry both from the University of Dallas.

Sanjiv Suri, Senior Vice President Global Sales and General Manager North America, has served as our Senior Vice President Global Sales and General Manager North America since 2019. Prior to joining us in March 2018, Mr. Suri was an independent consultant between June 2017 and February 2018. Mr. Suri held various management leadership positions with Pharm-Olam; Erba Mannheim and Bio-Rad, companies doing business in the CRO and IVD Segments from 2004 to 2017. He was the Chief Executive Officer of Pharm-Olam USA from 2014 to 2017, President, Erba Mannheim, Germany from 2011 to 2014 and General Manager Emerging Markets, Bio-Rad (USA) from 2004 to 2010. Mr Suri graduated from the University of Texas at Austin with a Master's degree in Business Administration and also has a Master's degree in Economics from the University of Bombay.

Terence Dunne, Business Development Director, has been employed by Trinity Biotech since 2016. Prior to joining Trinity Biotech, Mr. Dunne held various technical and management roles at EKF Diagnostics and a number of biotech start-ups. Mr. Dunne graduated from NUI Maynooth with a BSc. degree in Biotechnology in 2002, from University College Dublin with a PhD degree in Molecular Biology in 2008 and an MBA degree from UCD Smurfit Business School in 2017.

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

Dan Goldsand, Vice President of Autoimmunity, joined Trinity Biotech in February 2022 as Vice President of Autoimmunity. Prior to joining Trinity Biotech, Mr. Goldsand held a number of positions in the autoimmune industry. Mr Goldsand served as US Associate Director – Automation and US National Sales Manager, with EUROIMMUN US. Instrument Account Manager, with INOVA Diagnostics Inc, Regional Manager with Euro-Diagnostica Inc, Senior Account Executive, with Bio-Rad Laboratories, and District Sales Manager, with Fisher Healthcare.

Additional Information

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

Our articles of association provide for a Board of Directors of not less than four and not more than ten members. Our Board of Directors is currently composed of six directors. Officers serve at the pleasure of the Board of Directors, subject to the terms of any agreement between the officer and us.

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

B. Compensation

The 2021 remuneration scheme was approved by the Board of Directors.

Total directors and non-executive directors' remuneration, excluding pension and share options, for the year ended December 31, 2021 amounted to US$1,390,000. The pension charge for the year amounted to US$24,000. See Item 18, Note 11 to the consolidated financial statements. 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*	*Total 2020 US$'000*
Ronan O'Caoimh	Chairman and CEO	643	—	—	643	1,052
Jim Walsh	Executive Director	20	—	—	20	38
John Gillard	Chief Financial Officer	346	227	20	593	52
Kevin Tansley	Executive Director	56	—	4	60	757
Denis R. Burger	Non-Executive director	—	—	—	—	48
James Merselis	Non-Executive director	49	—	—	49	57
Clint Severson	Non-Executive director	49	—	—	49	57
		1,163	227	24	1,414	2,061

As at December 31, 2021 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2020: NIL).

In 2021, no 'A' share options were granted to the directors (2020: 8,480,000).

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

Compensation of Senior Management

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

For the financial year ended December 31, 2021, our executive officers and directors, as a group (11 persons for 2021), received aggregate compensation of US$2,675,000 for services they rendered in all capacities during 2021, which amount includes base salary, bonuses and benefits in kind, excluding share options.

C. Board Practices

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

The Board of Directors has established Audit, Remuneration and Compensation Committees. The Remuneration Committee consists of Mr Clint Severson (committee chairman and lead director) and Mr James Merselis. This Committee is responsible for approving executive directors' remuneration including bonuses and share option grants. The Audit Committee reviews the Group's annual and interim financial statements and reviews reports on the effectiveness of the Group's internal controls. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The Audit Committee comprises the two non-executive directors of the Group, Mr James Merselis (Committee Chairman) and Mr Clint Severson. The Compensation Committee currently comprises Mr Ronan O'Caoimh (Committee Chairman), Dr Jim Walsh and Mr Kevin Tansley. The Board of Directors administers the Employee Share Option Plan. The Board determines the exercise price and the term of the options. Individual option grants of less than 30,000 'A' ordinary shares (7,500 ADRs) are approved by the Compensation Committee and subsequently ratified by the Board. Options granted to the members of the Compensation Committee are approved by the Remuneration Committee and share options granted to non-executive directors are decided by the other members of the board.

Because Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 5600 as they apply to U.S. domestic companies.

As part of the exchange agreements entered into with the five bondholders in December 2021, the Company agreed to update some of its corporate governance processes - for further details on the exchange agreements refer to Item 18, Note. 30

Indemnification of Directors and Officers

Our currently effective memorandum and articles of association permit, subject to the Securities Act, indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from dishonesty or fraud which may attach to such directors or officers.

Under our Constitution no director or other officer shall be liable for (i) any acts, receipts, neglect or defaults of any other director or officer for joining in any receipt or other act for conformity; (ii) any loss or expense that may happen to us through the inefficiency or deficiency of title to any property acquired by order of the directors or on our behalf; (iii) the inefficiency or deficiency of any security in or upon which any of our monies shall be invested; (iv) any loss or damage arising from bankruptcy, insolvency or tortuous act of any person with whom any monies, securities or effects shall be deposited; (v) any loss occasioned by any error of judgment, omission, default or oversight on the persons part; or (vi) any other loss damage or misfortune whatsoever which shall happen in relation to those things unless the same shall happen through the persons own negligence, default, breach of duty, breach of trust or dishonesty.

In addition, our Constitution provides that to the extent permitted by law, we may pay, or agree to pay, a premium in respect of a contract insuring a person who is or has been an officer of our company or one of our subsidiaries against a liability:

- incurred by the person in his or her capacity as an officer of our company or a subsidiary of our company provided that the liability does not arise out of a conduct involving a wilful breach of duty in relation to our company or a subsidiary of our company; or
- for costs and expenses incurred by that person defending proceedings, whatever their outcome.

D. Employees

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Numbers of employees by geographic location			
United States	237	310	334
Ireland	211	199	215
United Kingdom	2	3	2
Brazil	27	31	28
Total workforce	**477**	**543**	**579**
Numbers of employees by category of activity			
Research scientists & technicians	41	52	57
Manufacturing/Operations	239	280	303
Quality Assurance	63	63	60
Finance/Administration	68	65	66
Sales & Marketing	66	83	93
Total workforce	**477**	**543**	**579**

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

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

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

E. Share Ownership

Beneficial Ownership of Executive Officers and Directors

Stock Option Plans

The Board of Directors have adopted the Employee Share Option Plans (the “Plans”); with the most recently adopted Share Option Plan being the 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.

As of April 15, 2022, our directors and executive officers as a group, then consisting of 12 persons, held options to purchase an aggregate of 15,431,000 'A' shares (3,858,000 ADS equivalent), having exercise prices ranging from US$0.19 per 'A' ordinary share (US$0.77 per ADS) to US$4.36 per 'A' ordinary share (US$17.45 per ADS) and expiration dates ranging from 2022 to 2027. Generally, the options vest over a three year period.

The following table sets forth certain information as of April 15, 2022, regarding the beneficial ownership by each of our directors and executive officers:

Name	Number of 'A' Ordinary Shares Beneficially Owned [1]	Percentage of Ownership [2]
Ronan O'Caoimh (3)	17,228,160	15.0%
Jim Walsh (4)	2,863,612	2.6%
John Gillard (5)	150,000	*
Kevin Tansley (6)	1,547,336	1.4%
Clint Severson (7)	878,000	*
James Merselis (8)	778,600	*
Simon Dunne (9)	210,000	*
Fernando Devia (10)	330,000	*
Sanjiv Suri (11)	280,000	*
Terence Dunne (12)	283,336	*
Dan Goldsand	-	*
Eibhlín Kelly	-	*
Executive officers and directors as a group (12 persons)	24,549,044	20.4%

* Less than 1%

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

(2) The percentages shown are based on 'A' Ordinary Shares issued and outstanding as of April 15, 2022.

(3) Represents (a) 9,724,160 'A' ordinary shares and (b) 7,504,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022. Includes options issued to Darnick Company which in the past provided Trinity Biotech with the services of Mr. O'Caoimh as Chief Executive Officer.

(4) Represents (a) 1,393,612 'A' ordinary shares and (b) 1,470,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022. Note that 1,393,612 'A' ordinary shares of Dr Walsh's shares are held in trust for the benefit of Dr Walsh's immediate family.

(5) Represents 150,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(6 Represents (a) 150,000 'A' ordinary shares and (b) 1,397,336 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(7) Represents (a) 288,000 'A' ordinary shares and (b) 590,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(8) Represents (a) 188,600 'A' ordinary shares and (b) 590,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(9) Represents 210,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(10) Represents 330,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(11) Represents 280,000 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

(12) Represents 283,336 'A' ordinary shares underlying options that are currently vested and exercisable or that vest within sixty days of April 15, 2022.

As of April 15, 2022, 14,071,336 (3,517,834 ADS equivalent) of the options outstanding were held by the directors of Trinity Biotech as follows:

Director/Company Secretary	Number of Options 'A' Shares	Number of Options ADS Equivalent	Exercise Price (Per 'A' Share)	Exercise Price (Per ADS)	Expiration Date of Options
Ronan O'Caoimh*	1,000,000	250,000	1.34	5.35	07/09/2024
	1,000,000	250,000	1.34	5.35	07/09/2024
	244,000	61,000	1.34	5.35	07/09/2024
	2,030,000	507,500	0.69	2.74	14/06/2026
	2,030,000	507,500	0.69	2.74	14/06/2026
	333,336	83,334	0.19	0.77	20/03/2027
	1,200,000	300,000	0.73	2.90	17/11/2027
	1,200,000	300,000	0.73	2.90	17/11/2027
Jim Walsh	53,333	13,333	2.43	9.73	24/02/2023
	53,333	13,333	2.43	9.73	24/02/2023
	53,334	13,334	2.43	9.73	24/02/2023
	360,000	90,000	1.34	5.35	07/09/2024
	360,000	90,000	1.34	5.35	07/09/2024
	30,000	7,500	1.34	5.35	07/09/2024
	280,000	70,000	0.19	0.77	20/03/2027
	280,000	70,000	0.19	0.77	20/03/2027
	40,000	10,000	0.19	0.77	20/03/2027
Kevin Tansley	340,000	85,000	1.34	5.35	07/09/2024
	340,000	85,000	1.34	5.35	07/09/2024
	184,000	46,000	1.34	5.35	07/09/2024
	266,668	66,667	0.19	0.77	20/03/2027
	266,668	66,667	0.19	0.77	20/03/2027
	266,664	66,666	0.19	0.77	20/03/2027

Director/Company Secretary	Number of Options 'A' Shares	Number of Options ADS Equivalent	Exercise Price (Per 'A' Share)	Exercise Price (Per ADS)	Expiration Date of Options
Jim Merselis	20,000	5,000	2.43	9.73	24/02/2023
	20,000	5,000	2.43	9.73	24/02/2023
	20,000	5,000	2.43	9.73	24/02/2023
	95,000	23,750	1.34	5.35	07/09/2024
	95,000	23,750	1.34	5.35	07/09/2024
	20,000	5,000	1.34	5.35	07/09/2024
	160,000	40,000	0.19	0.77	20/03/2027
	160,000	40,000	0.19	0.77	20/03/2027
	40,000	10,000	0.19	0.77	20/03/2027
Clint Severson	20,000	5,000	2.43	9.73	24/02/2023
	20,000	5,000	2.43	9.73	24/02/2023
	20,000	5,000	2.43	9.73	24/02/2023
	95,000	23,750	1.34	5.35	07/09/2024
	95,000	23,750	1.34	5.35	07/09/2024
	20,000	5,000	1.34	5.35	07/09/2024
	160,000	40,000	0.19	0.77	20/03/2027
	160,000	40,000	0.19	0.77	20/03/2027
	40,000	10,000	0.19	0.77	20/03/2027
John Gillard	150,000	37,500	0.67	2.69	23/10/2027
	150,000	37,500	0.67	2.69	23/10/2027
	150,000	37,500	0.67	2.69	23/10/2027
	150,000	37,500	0.67	2.69	23/10/2027

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

As of April 15, 2022 the following total options were outstanding:

	Number of 'A' Ordinary Shares Subject to Option	Range of Exercise Price per Ordinary Share	Range of Exercise Price per ADS
Total options outstanding	15,964,662	US$0.19-US$4.36	US$0.76-US$17.44

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

A. Major Shareholders

As of April 15, 2022, Trinity Biotech has outstanding 107,670,894 'A' Ordinary shares (excluding treasury shares). Such totals exclude 15,964,662 shares issuable upon the exercise of outstanding options and 10,000,000 shares issuable upon the exercise of outstanding warrants.

The following table sets forth, as of April 15, 2022, the Trinity Biotech 'A' Ordinary Shares beneficially held by each person believed by Trinity Biotech to beneficially hold 5% or more of such shares.

Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated.

	Number of 'A' Ordinary Shares Beneficially Owned	Number of ADSs Beneficially Owned (1)	Percentage 'A' Ordinary Shares (2)	Percentage Total Voting Power
Renaissance Technologies LLC	6,274,220(3)	1,568,555	5.8%	5.8%
Paradice Investment Management, LLC	6,172,460(4)	1,543,115	5.7%	5.7%
Ronan O'Caoimh	17,228,160(5)	4,307,040	15.0%	15.0%
Stonehill Capital Management LLC	9,272,872(6)	2,318,218	8.6%	8.6%
Perceptive Credit Holdings III, LP	10,000,000(7)	2,500,000	8.5%	8.5%

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

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

(3) Based on a Schedule 13G/A filed on February 11, 2022, with the SEC by Renaissance Technologies LLC and Renaissance Technologies Holdings Corporation. The principal business address of each of these entities is 800 Third Avenue, New York, NY 10022 United States.

(4) Based on a Schedule 13G/A filed on February 7, 2020 by Paradice Investment Management, LLC with the SEC. The principal business address of Paradice Investment Management, LLC is 257 Fillmore Street, Suite 200, Denver, Colorado 80206 United States.

(5) Based on information provided to the Company, the above total includes 'A' Ordinary shares issuable upon exercise of options issued to Darnick Company. The address of Mr. O'Caoimh is c/o Trinity Biotech plc, Bray, Co. Wicklow, Ireland.

(6) Based on a Schedule 13G/A filed on February 4, 2022 by Stonehill Capital Management, LLC with the SEC. The principal business address of Stonehill Capital Management, LLC is 320 Park Ave., 26th Floor, New York, NY 10022 United States.

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

Significant Changes in the Ownership of Major Shareholders

To our knowledge, other than as disclosed in the table below there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2019.

The following shareholders have disclosed ownership above 5% since January 1, 2019 but their ownership is below 5% as at April 15, 2022 according to their Schedule 13G filings or Irish Companies Act notifications.

	Number of 'A' Ordinary Shares Beneficially Owned	Number of ADSs Beneficially Owned (1)	Percentage 'A' Ordinary Shares (2)	Percentage Total Voting Power	Date of Filing
Whitefort Capital Master Fund, LP	2,342,280	585,570	2.2%	2.2%	February 16, 2021
Highbridge Capital Management, LLC	675,064	168,766	0.6%	0.6%	April 14, 2022

Major Shareholders Voting Rights

Our major shareholders do not have different voting rights.

B. Related Party Transactions

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

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.

Darnick Company is wholly-owned by members of Mr. O'Caoimh's immediate family. In 2019, the relationship with Darnick was terminated and Mr O'Caoimh returned as an employee. All liabilities in relation to Darnick Company were extinguished as of December 31, 2021.

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.

Indemnity Agreements

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

Related Person Transaction Policy

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

C. Interests of Experts and Counsel

Not applicable.

Item 8. ***Financial Information***

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

See Item 18. "*Financial Statements*."

Export Sales

In the year ended December 31, 2021, the amount of our export sales (i.e., sales outside of Ireland) was approximately US$92,729,000 which represents 99.75% of our total sales.

Legal and Arbitration Proceedings

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

Dividend Policy

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

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2021.

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

A. Offer and Listing Details

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

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Shareholders

Not Applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. ***Additional Information***

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

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

Irish Law

Each of Trinity Biotech's principal subsidiary undertakings incorporated in Ireland (refer to Item 18, Note 32) is registered as a private company limited by shares under the Companies Act 2014. Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept in Ireland and are kept at the registered office of the Company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper accounting records. The shareholders have no statutory right to inspect the accounting records. The only financial records, which are open to the shareholders, are the statutory financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information regarding certain events relating to the Company (such as changes to share rights, changes to the Board of Directors etc). This information is filed with the Companies Registration Office in Ireland and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that the relevant resolution is signed by all the members for the time being entitled to vote and attend at general meeting. A general meeting can be convened by ordinary shareholders which hold not less than 50 per cent of the paid up share capital of the Company carrying the right of voting at general meetings of the Company. In addition, the directors of the Company are required to convene a general meeting forthwith upon the deposit of a requisition signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the Company carrying the right of voting at general meetings of the Company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the Company. Any shareholder who complains that the affairs of the Company are being conducted or that the powers of the directors of the Company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the Company.

Directors have extensive and wide–ranging duties under Irish law. These arise from both common law and statute (principally the Companies Act 2014, which codified a number of key fiduciary duties). Our directors owe their duties individually and primarily to Trinity Biotech and not its shareholders (although directors are required to have regard to the interests of shareholders and employees). Those duties include duties to act in good faith in the interests of Trinity Biotech, act honestly and responsibly in the conduct of the Company's affairs, act in accordance with the Company's Constitution and exercise their powers only for purposes allowed by law, not use the Company's property for their own or a third party's, benefit (unless duly authorised), not agree to restrict their power to exercise an independent judgment (subject to limited exceptions) and avoid conflicts of interests (unless they are properly released). A director must exercise the care, skill and diligence which would be exercised in the same circumstances by a reasonable person having the knowledge and experience that (a) may reasonably be expected of a person in the same position as the director and (b) which that particular director has. When directors, as agents in transactions, make contracts on behalf of the Company, they generally incur no personal liability under these contracts. It is Trinity Biotech, as principal, which will be liable under them, as long as the directors have acted within Trinity Biotech's objects and within their own authority. A director who commits a breach of his duties shall be liable to Trinity Biotech for any profit made by him or for any damage suffered by Trinity Biotech as a result of the breach. In addition to the above, a breach by a director of his duties may (where relevant) lead to the summary dismissal of the director, civil or criminal sanction from a Court, including penalties or imprisonment, and/or the imposition of orders restricting or disqualifying the director from acting as a director.

C. Material Contracts

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

Term loan agreement with Perceptive Advisors

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

The drawdown of the Term Loan by the Company was subject to a number of conditions precedent including the repayment of at least 99.7% of the Exchangeable Notes and approval by the Company's shareholders of the Term Loan, an increase in the authorized share capital of the Company and the issuance of the Warrants. At the Extraordinary General Meeting held on January 25, 2022, the Company's shareholders approved all of the four resolutions put to the meeting, with each resolution being approved by at least 97% of votes cast. The term loan was drawn down on January 27, 2022.

Warrant agreement with Perceptive Advisors

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

Exchange agreement with certain holders of the Exchangeable Notes

On December 15, 2021, the Company entered into exchange agreements (the "Exchange Agreements") with five institutional investors that held approximately US$99,700,000 of the outstanding Exchangeable Notes, which are puttable by the holders to the Group, at par, in April 2022. Under the terms of this agreement each holder agreed to exchange their Notes at a discount to par with each holder receiving $0.87 of cash and the equivalent of $0.08 of the Company's ADS (based upon the 5-day trailing VWAP of the ADSs on NASDAQ on December 9, 2021, discounted by 13%) per $1 nominal value of the Notes. The consummation of the Exchange Agreements was conditional upon (among other things) the approval by the Company's shareholders of the issuance of ADSs pursuant to the Exchange Agreements and certain matters related to the drawdown of the Term Loan. At the Extraordinary General Meeting held on January 25, 2022, the Company's shareholders approved all of the four resolutions put to the meeting, with each resolution being approved by at least 97% of votes cast. The Company retired the Notes owned by the five institutional investors on January 28, 2022.

Strategic Investment and Partnership with The MiCo Group

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 (11.2 million 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 Company's ADSs is at or above US$3.24 for any five consecutive NASDAQ trading days.

The investment is subject to customary Korean central bank approvals. It is intended that the Company will use these funds primarily to repay a portion of the Company's US$81.25 million term loan. The Company also expects that this investment will facilitate it exploring lower cost debt funding options, in the short term, with the aim of further reducing the company's interest expense through refinancing the balance of the Company's term loan at substantially lower interest rates.

The founder and chair of MiCo, Sun-Q Jeon, is set to become Chairperson of Trinity Biotech and Aris Kekedjian and Michael Sung Soo Kim are expected to join the Board once the investment has completed. Current directors Kevin Tansley, Clint Severson and James Merselis will retire from the Board on completion of the investment.

D. Exchange Controls

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

Under the Financial Transfers Act 1992 (the "1992 Act"), the Minister for Finance of Ireland may make provision for the restriction of financial transfers between Ireland and other countries. Financial transfers are broadly defined, and the acquisition or disposal of the ADRs, which represent shares issued by an Irish incorporated company, the acquisition or the disposal of Ordinary Shares and associated payments may fall within this definition. Dividends or payments on the redemption or purchase of shares and payments on the liquidation of an Irish-incorporated company would fall within this definition.

The 1992 Act and underlying EU regulations prohibit financial transfers involving a number of persons, entities and bodies, which are subject to amendment on an ongoing, regular basis and currently include, but are not limited to: certain persons and activities in Sudan, South Sudan, the Central African Republic, Libya, Iraq, the Democratic People's Republic of Korea, Myanmar/Burma, Tunisia, Zimbabwe, Egypt, Venezuela, certain persons, entities and bodies in Syrian Arab Republic, the Republic of Guinea-Bissau, Nicaragua, Democratic Republic of Congo, Iran, Ukraine, associated with the Taliban in Afghanistan; associated with ISIL (Da'esh) and Al-Qaeda; associated with Turkey's unauthorized drilling activities in the Eastern Mediterranean and certain known terrorists and terrorist groups and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland.

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

E. Taxation

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

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

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

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

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

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

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

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

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

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

Dividends and Other Distributions on ADSs

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

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

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

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

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

Dispositions of the ADSs

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

Passive Foreign Investment Company

For U.S. federal income tax purposes, a foreign corporation is treated as a "passive foreign investment company" (or "PFIC") in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable "look through" rules, either (1) at least 75% of the corporation's gross income is passive income or (2) at least 50% of the average value of the corporation's assets is attributable to assets that produce passive income or are held for the production of passive income. Based on the nature of its present business operations, assets and income, Trinity Biotech believes that for the year 2021, it was not a PFIC. However, no assurance can be given that changes will not occur in Trinity Biotech's business operations, assets and income that might cause it to be treated as a PFIC at some future time.

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

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

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

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

Information Reporting and Backup Withholding

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

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

Information with Respect to Foreign Financial Assets

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

Medicare Contribution Tax

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

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

Republic of Ireland Taxation

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

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

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

In 2011, the Board decided that it was an appropriate time to commence a dividend policy for the first time in the Company's history but the payment of dividends has subsequently been suspended (see section below on Dividend Policy). Up to 31 December 2019, the payment of a dividend was generally subject to dividend withholding tax ("DWT") at the standard rate of income tax in force at the time the dividend is paid (the applicable rate was 20% in 2019). However, the rate of DWT has increased to 25% in respect of dividends paid on or after 1 January 2020. Irish Revenue also plan to introduce a new "real time" collection system for DWT based on an individual's marginal income tax rate, however the introduction of this proposed system has been postponed at present. Under current legislation, where DWT applies, Trinity Biotech will be responsible for withholding it at source.

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

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

Individual Irish Holders will be subject to income tax on the gross amount of any dividend (that is the amount of the dividend received plus any DWT withheld), at their marginal rate of income tax, currently either 20% or 40% depending on the individual's circumstances, excluding Pay Related Social Insurance ("PRSI") and the Universal Social Charge ("USC"). Individual Irish Holders will be able to claim a credit against their resulting income tax liability in respect of DWT withheld. Individual Irish Holders may, depending on their circumstances, also be subject to the Irish USC of up to 8%, with a further 3% surcharge also arising on certain income in excess of €100,000 and a PRSI contribution of up to 4% in respect of their dividend income.

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

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

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

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

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

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

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

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

Disposals of Ordinary Shares or ADSs

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

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

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

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

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

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

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

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

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

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

Irish stamp duty, which is a tax imposed on certain documents, is payable on all transfers of ordinary shares of an Irish registered company (other than transfers made between spouses, transfers made between 90% associated companies, or certain other exempt transfers) regardless of where the document of transfer is executed. Irish stamp duty is also payable on electronic transfers of ordinary shares. A transfer of ordinary shares made as part of a sale or gift will generally be stampable at the ad valorem rate of 1% of the value of the consideration received for the transfer, or, if higher, the market value of the shares transferred. With effect from 6 December 2017, stamp duty at a rate of 6% applied in certain circumstances to the sale or transfer of shares which derive their value, or the greater part of their value, from non-residential property in Ireland (this rate was increased to 7.5% in respect of instruments executed on or after 9 October 2019). Any instrument executed on or after 24 December 2008 which transfers stock or marketable securities on sale where the amount or value of the consideration is €1,000 or less may be exempt from stamp duty. Where the consideration for a sale is expressed in a currency other than Euro, the duty will be charged on the Euro equivalent calculated at the rate of exchange prevailing at the date of the transfer.

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

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

Transfers of ordinary shares from the Depositary or the Depositary's custodian upon surrender of ADSs for the purposes of withdrawing the underlying ordinary shares from the ADS system, and transfers of ordinary shares to the Depositary or the Depositary's custodian for the purposes of transferring ordinary shares onto the ADS system, will be stampable at the ad valorem rate of 1% of the value of the shares transferred if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of ordinary shares. Such transfers will be exempt from Irish stamp duty if the transfer does not relate to or involve any change in the beneficial ownership in the underlying ordinary shares and the transfer form contains the appropriate certification. The person accountable for the payment of stamp duty is the transferee or, in the case of a transfer by way of gift or for consideration less than the market value, both parties to the transfer. Stamp duty is normally payable within 30 days after the date of execution of the transfer (with a possible 14 day extension for online filings and payments). Late or inadequate payment of stamp duty may result in liability for interest, penalties, surcharge and fines.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

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

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

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

I. Subsidiary Information

Not applicable.

Item 11. ***Quantitative and Qualitative Disclosures about Market Risk***

Quantitative information about Market Risk

Interest rate sensitivity

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

Trinity Biotech estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Group is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be a decrease in the profit before tax for 2021 by approximately 2.2%. This does not include any impact from the refinancing of the majority of the fixed interest rate exchange notes with the Perceptive Term Loan as this took place post December 31, 2021.

Exchange rate sensitivity

At year-end 2021, the total net liability denominated in currencies other than the US Dollar, principally the Euro, Brazilian Real, Canadian Dollar, Swedish Krona and Great British Pound was US$6,434,000.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Group operates, would have the approximate effect of increasing or reducing the Group's 2021 year-end net worth by US$643,000.

Qualitative information about Market Risk

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

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

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

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

At December 31, 2021 Group borrowings were at fixed rates of interest and consisted of US Dollar denominated exchangeable notes and Euro and US Dollar denominated finance leases. At December 31, 2021 year-end borrowings totalled US$99,156,000 (2020: US$102,625,000) (2019: US$102,174,000) at interest rates of 4.00% to 5.51% (2020: 4.00% to 5.51%) (2019: 4.00% to 5.51%). The nominal amount of the Loan Note borrowings is US$99,900,000. The first date on which holders of the Loan Note can exercise their put option is April 1, 2022. If the put option is exercised, the issuer has to repurchase the notes at par.

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 in 2021 or 2020; resulting in an increase in interest income of US$31,000 (2020: US$31,000).

As set out further in Note 30, Post Balance Sheet Events, the group refinanced the majority of the exchangeable notes in January 2022 with the Term Loan with Perceptive Advisors. In addition, the company entered into agreements with the MiCo Group with regards to investment in equity and convertible bond investment, with a combined value of approximately US$45,000,000 - See Note 30, Post Balance Sheet Events.

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro and Brazilian Real denominated expenses as a result of the movement in the exchange rate between the US Dollar and those currencies. Arising from this, where considered necessary, the Group periodically pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro and Real expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cash flow hedging instruments whose objective is to cover a portion of these Euro or Real forecasted transactions. These forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at 31 December, 2021.

The Group had foreign currency denominated cash balances equivalent to US$6,434,000 at December 31, 2021 (2020: US$5,025,000).

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

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable

C. Other Securities

Not applicable.

D. American Depositary Shares

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

Fees and Charges Payable by ADS Holders

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

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

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

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

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

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

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

In the event of refusal to pay taxes or other governmental charges by the holder of an ADS, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of such tax or other governmental charge from any distribution to be made to the ADS holder, and the ADS holder would remain liable for any deficiency.
The disclosure under this heading "Fees and Charges Payable by ADS Holders" is subject to and qualified in its entirety by reference to the full text of the Deposit Agreement.

Part II

Item 13. ***Defaults, Dividend Arrearages and Delinquencies***

Not applicable.

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

Not applicable.

Item 15. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

The Group's disclosure and control procedures are designed so that information required to be disclosed in reports filed or submitted under the Securities Exchange Act 1934 is prepared and reported on a timely basis and communicated to management, to allow timely decisions regarding required disclosure**.** Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(d) of the Securities Exchange Act of 1934 as of the end of the period covered by this Form 20-F. The Chief Executive Officer and Chief Financial Officer have concluded that disclosure controls and procedures were effective as of December 31, 2021.

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

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Management has assessed the effectiveness of internal control over financial reporting based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management has concluded that the Group's internal control over financial reporting was effective as of December 31, 2021.

Since Trinity Biotech is a non-accelerated filer, our auditor, Grant Thornton, an independent registered public accounting firm, is not required to issue an attestation report on the Group's internal control over financial reporting as of December 31, 2021.

Changes in Internal Control over Financial Reporting

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

Item 16. Reserved

16 A. Audit Committee Financial Expert

Mr James Merselis is an independent director and a member of the Audit Committee. Our board of directors has determined that Mr James Merselis meets the definition of an audit committee financial expert, as defined in Item 401 of Regulation S-K.

16 B. Code of Ethics

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

16 C. Principal Accounting Fees and Services

Fees Billed by Independent Public Accountants

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

	Year ended December 31, 2021		*Year ended December 31, 2020*	
	US$'000	*%*	*US$'000*	*%*
Audit	477	72%	495	80%
Audit-related	94	14%	-	-
Tax	89	14%	124	20%
Total	660		619	

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

Pre-Approval Policies and Procedures

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

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

16 D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

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

None.

Share Buyback

Trinity Biotech did not purchase any of its own shares during 2021 or 2020.

16 F. Change in Registrant's Certifying Accountant

Not applicable.

16 G. Corporate Governance

NASDAQ Stock Market Rules and Home Country Practice

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

- The Rule requiring maintaining a majority of independent directors (Rule 5605(b)(1)). Instead, under Irish law and practice, we are not required to appoint a majority of independent directors.
- The Rule requiring that our independent directors have regularly scheduled meetings at which only independent directors are present (Rule 5605(b)(2)). Instead, we follow Irish law according to which independent directors are not required to hold executive sessions.
- The Rule regarding independent director oversight of director nominations process for directors (Rule 5605(e)). Instead, we follow Irish law and practice according to which our board of directors recommends directors for election/re-election by our shareholders.
- The requirement to obtain shareholder approval for the establishment or amendment of certain equity based compensation plans (Rule 5635(c)), an issuance that will result in a change of control of the company (Rule 5635(b)), certain transactions other than a public offering involving issuances of a 20% or more interest in the company (Rule 5635(d)) and certain acquisitions of the stock or assets of another company (Rule 5635(a)). Instead, we follow Irish law and practice in approving such procedures, according to which Board approval may suffice in certain circumstances, depending on the extent existing general authorities to issue shares are in place.
- The Rule requiring maintaining an audit committee consisting of at least three independent directors (Rule 5605(c)(2). Instead, we follow Irish law that requires that an audit committee have at least one independent director. Our audit committee consists of two independent directors.
- The Rule requiring a compensation committee consisting of at least two independent directors (Rule 5605(d)(2). We have a compensation committee, which we refer to as the remuneration committee, and although it consists of two independent directors, we may follow Irish law in the future, which does not require us to have an independent compensation committee.
- The Rule requiring a quorum of 33 1/3% at any meeting of shareholders (Rule 5620(c)). Instead, we follow the provisions of our Articles of Association which require a quorum of 40%> If a quorum is not present, unless the meeting has been convened by shareholders in which case the meeting shall be dissolved, the meeting will be adjourned to another date. If a quorum is not present within 15 minutes of the time set for the adjourned meeting, the meeting may commence so long as there are two shareholders present.

16 H. Mine Safety Disclosure

Not applicable.

16 I. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

Part III

Item 17 ***Financial Statements***

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

Item 18 ***Financial Statements***

The audited consolidated financial statements as required under Item 18 are attached hereto starting on page 94 of this Annual Report. The audit report of Grant Thornton (PCAOB ID 1402), independent registered public accounting firm, is included herein preceding the audited consolidated financial statements.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Trinity Biotech plc

Opinion on the financial statements
We have audited the accompanying consolidated statements of financial position of Trinity Biotech plc and its subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income, changes in equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

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

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

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

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

Impairment of goodwill and other long-lived assets valuation:

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

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

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

We identified goodwill and other long-lived assets for certain CGUs as a critical audit matter because of the significant judgements made by management to estimate the recoverable value of certain CGUs and the difference between their recoverable amounts and carrying values. We focused on CGUs 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.

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

- We evaluated the design effectiveness of controls over management's selection of the discount rates, short-term forecasts of future revenues and margins, and long-term growth rates used to determine the recoverable amount of each selected CGU.
- We 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 new products, the COVID-19 pandemic, and other macroeconomic activity on short-term cash flows.
- We assessed the reasonableness of the valuation model used by the Company compared to generally accepted valuation practices and accounting standards.
- We tested the source information underlying the determination of the discount rates through use of observable inputs from independent external sources.
- We developed independent estimates and compared those to the discount rates selected by management.
- We compared the long-term growth rates, used by management to grow cash flows in order to calculate a terminal value, to independent external sources to assess the reasonableness of these rates.

Accounting for capitalised development costs

As discussed in Note 14 to the financial statements, the Company capitalizes certain internal development costs related to the design, development and enhancement of the Company's products. The Company capitalized $6.8 million of internal development costs during the year ended December 31, 2021. We identified capitalization of development costs to be a critical audit matter.

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

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

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

Revenue recognition:

Revenue recognition requires judgment by qualified personnel and often varies from contract to contract. The nature of such judgments result in them being susceptible to fraud. The recognition of revenue earlier than permitted under 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 Company expects to be entitled in exchange for those goods or services, which requires the use of management judgment and gives rise to the risk of management override. Revenue is recognised in accordance with the core principle by applying 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 Company satisfies a performance obligation.

We determined this as a critical audit matter due to the high subjectivity and significant management judgement on certain revenue contracts with the level of revenue recognised.

How the critical audit matter was addressed in the audit
Our audit procedures related to specific revenue contracts with high subjectivity were as follows:

- We tested the design and operating effectiveness of operational controls (including specific controls for review of revenue recognition and year end cut-off analyses).
- We selected a statistical sample of revenue transactions to vouch to underlying documents.
- We examined contracts specific to samples selected and assessed revenue recognition in accordance with the accounting standards.
- We evaluated management assumptions in recognising revenue related to the performance obligation of certain contracts with high subjectivity.

/s/ GRANT THORNTON

Dublin, Ireland

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

May 2, 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

	Notes	Year ended December 31 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$'000	At December 31 2020 US$'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**

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)
Loan Origination 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**

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 until 2026. Furthermore, the investment by MiCo Group will 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, in the short term, 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.

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

vi) Goodwill

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

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

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

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

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

An intangible asset, which is an identifiable non-monetary asset without physical substance, is recognised to the extent that it is probable that the expected future economic benefits attributable to the asset will flow to the Group and that its cost can be measured reliably. The asset is deemed to be identifiable when it is separable (that is, capable of being divided from the entity and sold, transferred, 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.

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

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

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.

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

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

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.

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

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.

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.

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

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.

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.

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

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

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

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

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

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

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.

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

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

Where Euro, Brazilian Real, 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.

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.

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

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.

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.

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

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

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)

		Rest of World			
Year ended December 31, 2019	*Americas US$'000*	*Ireland US$'000*	*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	-	(41,192)	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		
As at December 31, 2020	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'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

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 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.

3. EMPLOYMENT (CONTINUED)

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)

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)	12	438	-
Total tax credit	(166)	(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.

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

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.

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: profit 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: 25,467,517), see note 12 for further details.

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

	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

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	1,390	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
(Gain)/Loss on the disposal of property, plant and equipment	(1)	30	17
Net foreign exchange differences	(789)	583	(179)

* Note that US$39,000 (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, 2021	*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) (2019:25,467,517).

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

	Carrying amount	*Depreciation Charge*	*Impairment Charge*
	At December 31, 2020 US$000	*Year ended December 31, 2020 US$000*	*Year ended December 31, 2020 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 US$'000	*2020 US$'000*	*2021 US$'000*	*2020 US$'000*	*2021 US$'000*	*2020 US$'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

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 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 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.

24. EXCHANGEABLE NOTES AND OTHER BORROWINGS (CONTINUED)

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$'000			*December 31, 2021 US$'000*		
	Lease liabilities related to Right of Use assets			*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$'000			*December 31, 2020 US$'000*		
	Lease liabilities related to Right of Use assets			*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.

25. LEASE LIABILITIES (CONTINUED)

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

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.

26. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(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).

(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.

27. RELATED PARTY TRANSACTIONS (CONTINUED)

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.

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$'000*	December 31, 2020 *US$'000*
Short-term employee benefits	1,065	1,274
Performance related bonus	227	584
Post-employment benefits	24	41
Share-based compensation benefits	965	626
	2,281	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$21,000 (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.

27. RELATED PARTY TRANSACTIONS (CONTINUED)

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

	'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.

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.

28. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)

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.

	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	*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)	293	506
	(95,773)	(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	*22, 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	*22, 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$45,000,000 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 is subject to customary Korean central bank approvals. It is intended that the Group will use these funds primarily to repay a portion of the Group's US$81.25 million term loan. The Group also expects that this investment will facilitate it exploring lower cost debt funding options, in the short term, with the aim of further reducing the company's interest expense through refinancing the balance of the Group's term loan at substantially lower interest rates.

The founder and chair of MiCo, Sun-Q Jeon, is set to become Chairperson of Trinity Biotech and Aris Kekedjian and Michael Sung Soo Kim are expected to join the Board once the investment has completed. Current directors Kevin Tansley, Clint Severson and James Merselis are set to retire from the Board on completion of the investment

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.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

We operate a licenced reference laboratory in New York, USA that specializes in diagnostics for autoimmune diseases. The laboratory provides testing services to two types of customers. Firstly, institutional customers, such as hospitals and commercial diagnostic testing providers, and secondly insurance companies on behalf of their policyholders. The revenue recognition for services provided to insurance companies requires some judgement. In the US, there are rules requiring all insurance companies to be billed the same amount per test. However, the amount that each insurance company pays for a particular test varies according to their own internal policies and this can typically be considerably less than the amount invoiced. We recognise lab services revenue for insurance companies by taking the invoiced amount and reducing it by an estimated percentage based on historical payment data. We review the percentage reduction annually based on the latest data. As a practical expedient, and in accordance with IFRS, we apply a portfolio approach to the insurance companies as they have similar characteristics. We judge that the effect on the financial statements of using a portfolio approach for the insurance companies will not differ materially from applying IFRS 15 to the individual contracts within that portfolio.

At December 31, 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 Item 18, 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.

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.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

The impairment testing performed during year ended December 31, 2021 identified an impairment loss in four CGUs, namely Trinity Biotech Manufacturing Limited, Biopool US Inc, Immco Diagnostics, and Trinity Biotech Do 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.

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.

31. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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 will 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, in the short term, 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.

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%

33. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on May 2, 2022.

Signatures

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorised the undersigned to sign this Annual Report on its behalf.

TRINITY BIOTECH PLC

By /s/ Ronan O'Caoimh
Mr Ronan O'Caoimh
Director/
Chief Executive Officer

Date: May 2, 2022

By: /s/ John Gillard
Mr John Gillard
Company secretary/
Chief Financial Officer

Date: May 2, 2022

Item 19 ***Exhibits***

Exhibit No.	Description of Exhibit
1.1	Memorandum and Articles of Association of Trinity Biotech plc (included as Exhibit 1 to our Annual Report on Form 20-F filed on March 31, 2006 and incorporated herein by reference).
2.0	Form of Deposit Agreement dated as of October 21, 1992, as amended and restated, among Trinity Biotech plc, The Bank of New York as Depositary, and all Owners and holders from time to time of American Depositary Receipts issued thereunder (included as Exhibit 1 to our Form F-6 filed on January 15, 2004 and incorporated herein by reference).
2.1	Description of Rights of Securities Registered under Section 12 of the Securities and Exchange Act of 1934
4.1	Trinity Biotech plc Employee Share Option Plan 2017 and Trinity Biotech Share Option Plan 2020 (included as Exhibit 4.3 and 4.4 to our Registration Statement on Form S-8, filed on February 12, 2021 and incorporated herein by reference).
4.2	Trinity Biotech plc Employee Share Option Plan 2013 (included as Exhibit 4.1 to our Registration Statement on Form S-8 filed on April 11, 2014 and incorporated herein by reference).
4.3	Trinity Biotech plc Employee Share Option Plan 2011 (included as Exhibit 4 to our Registration Statement on Form S-8 filed on June 22, 2012 and incorporated herein by reference).
4.4	Lease agreement dated as of October 18, 2004 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of office premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.1 to our Annual Report on Form 20-F filed on March 31, 2006 and incorporated herein by reference).
4.5	Lease agreement dated as of November 26, 2004 between Ronan O'Caoimh, Jonathon O'Connell and Jim Walsh with Trinity Biotech plc in respect of warehouse premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.2 to our Annual Report on Form 20-F filed March 31 2006 and incorporated herein by reference).
4.6	Lease agreement dated as of December 20, 2007 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of warehouse premises in Bray, Co Wicklow, Ireland (included as Exhibit 4.13 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.7	CDC Non-Exclusive Patent Licence Agreement dated as of May 22, 2012 (included as Exhibit 4.19 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.8	Inverness Medical Innovations, Inc. Patent Licence Agreement renewal dated as of August 3, 2006 (included as Exhibit 4.21 to our Annual Report on Form 20-F filed on March 25, 2015 and incorporated herein by reference).
4.9	National Institute of Health Non-Exclusive Patent Licence Agreement dated as of December 17, 1999 (included as Exhibit 4.22 to our Report on Form 6-K filed on March 25, 2015 and incorporated herein by reference).
4.10	Credit Agreement and Guaranty Dated as of December 15, 2021 Among Trinity Biotech, Inc., Fitzgerald Industries International, Inc., Clark Laboratories, Inc. (D/B/A Trinity Biotech (USA)), Biopool U.S., Inc. (D/B/A Trinity Biotech Distribution), Primus Corporation, Mardx Diagnostics, Inc. and Immco Diagnostics, Inc. as the Borrowers, Trinity Biotech PLC and Certain of its Subsidiaries as Guarantors and Perceptive Credit Holdings III, LP, as Administrative Agent (included as Exhibit 99.2 to our Report on Form 6-K , filed on December 16, 2021 and incorporated herein by reference).
4.11	Form of Exchange Agreement with Holders of Exchangeable Senior Notes. (included as Exhibit 99.3 to our Report on Form 6-K, filed on December 23, 2021 and incorporated herein by reference.
4.12	Form of Warrant Certificate to purchase American Depositary Shares of Trinity Biotech plc (included as Exhibit 99.1 to our Report on Form 6-K filed on December 23, 2021 and incorporated herein by reference).
4.13	Securities Purchase Agreement between Trinity Biotech Plc and MiCo IVD Holdings, LLC dated April 11, 2022 (included as Exhibit 99.2 to our Report on Form 6-K filed on April 11, 2022 and incorporated herein by reference).
4.14	Convertible Loan Note (included as Exhibit 99.3 to our Report on Form 6-Kfiled on April 11, 2022 and incorporated herein by reference).
8.1	List of significant subsidiaries of Trinity Biotech plc (included as Item 18, note 32 to the consolidated financial statements in this Annual Report).
12.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
12.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
13.1	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm
101.INS	XBRL Instance Document (The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Exhibit 2.1

DESCRIPTION OF SHARE CAPITAL AND CONSTITUTION OF TRINITY BIOTECH PLC

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

Objects

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

Powers and Duties of Directors

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

A director may enter into a contract and be interested in any contract or proposed contract with the Company either as vendor, purchaser or otherwise and shall not be liable to account for any profit made by him resulting therefrom provided that he has first disclosed the nature of his interest in such a contract at a meeting of the board as required by Section 231 of the Irish Companies Act 2014. Generally, a director must not vote in respect of any contract or arrangement or any proposal in which he has a material interest (otherwise than by virtue of his holding of shares or debentures or other securities in or through the Company). In addition, a director shall not be counted in the quorum at a meeting in relation to any resolution from which he is barred from voting.

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

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

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

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

Rights, Preferences and Restrictions Attaching to Shares

The Company may, subject to the provisions of the Irish Companies Act 2014, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution.

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

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

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

The Company has only one class of shares in issue, "A" Ordinary Shares of US$0.0109 each. All such "A" Ordinary Shares rank equally with respect to voting, payment of dividends and on any winding-up of the Company.

In addition, if all cheques in respect of at least three dividends paid to a shareholder in a 12-year period remain uncashed, the Company is, subject to compliance with the procedure set out in the Articles of Association, entitled to sell the shares of that shareholder.

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

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

Action Necessary to Change the Rights of Shareholders

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

Calling of AGMs and EGMs of Shareholders

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in the Republic of Ireland unless all of the members entitled to attend and vote at such meeting consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Irish Companies Act 2014.

In the case of an annual general meeting or a meeting at which a special resolution is proposed, at least 21 clear days' notice of the meeting is required and in any other case at least seven clear days' notice is required. Notice must be given in writing to all members and to the auditors in accordance with the Articles of Association and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided for in the Irish Companies Act 2014, extended notice of a general meeting is required. These include a meeting at which a resolution for the removal of a director before the expiration of his term of office is proposed.

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

However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in Item 10 - D -"Exchange Controls". In addition, Irish competition law may restrict the acquisition by a party of shares in the Company but this does not apply on the basis of nationality or residence.

Other Provisions of the Memorandum and Articles of Association

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

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

Exhibit 12.1

CERTIFICATION PURSUANT TO
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Ronan O'Caoimh, certify that:

1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the company's auditors and the audit committee of the company's board of directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE: May 2, 2022

/s/ Ronan O'Caoimh*
Ronan O'Caoimh
Chief Executive Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

Exhibit 12.2

CERTIFICATION PURSUANT TO
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, John Gillard, certify that:

1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the company's auditors and the audit committee of the company's board of directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE: May 2, 2022

/s/ John Gillard*
John Gillard
Chief Financial Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronan O'Caoimh, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Ronan O'Caoimh*
Ronan O'Caoimh
Chief Executive Officer

DATE: May 2, 2022

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by Trinity Biotech plc for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Gillard, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ John Gillard*
John Gillard
Chief Financial Officer

Date May 2, 2022

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by Trinity Biotech plc for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated May 2, 2022, with respect to the consolidated financial statements included in the Annual Report of Trinity Biotech plc on Form 20-F for the year ended December 31, 2021. We consent to the incorporation by reference of said report in the following Registration Statements of Trinity Biotech plc:

Form Type	File Number	Effective Date
Form S-8	333-182279	6/22/2012
Form S-8	333-195232	4/11/2014
Form S-8	333-253070	2/12/2021

/s/ GRANT THORNTON
Dublin, Ireland

May 2, 2022