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, 2019

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)

Kevin Tansley
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	Name of each exchange on which registered
American Depositary Shares (each representing 4 'A' Ordinary Shares, par value US$0.0109)	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, 2019)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 7(a)(2)(B) of the Securities Act. ☐

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 and 333-195232.

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General

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 financial statements are presented in US Dollars and 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 applied are those effective for accounting periods beginning January 1, 2019. 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. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "Euro" or "€" are to European Union Euro. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

Forward-Looking Statements

This Annual Report on Form 20-F contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbour from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors – please refer to the risk factors in Item 3 for a more comprehensive outline of these risks and the threats which they pose to the Company and its results.

EXPLANATORY NOTE

We have filed this annual report on Form 20-F in reliance on the 45-day extension provided by an order issued by SEC under Section 36 of the Exchange Act Modifying Exemptions From the Reporting and Proxy Delivery Requirements for Public Companies, dated March 25, 2020 (Release No. 34-88465) (the "Order").

On April 27, 2020, we filed a Report on Form 6-K to indicate our intention to rely on the Order for such extension. Consistent with our statements made in the Form 6-K, we were unable to file the Original Form 20-F by April 30, 2020 because Covid-19 has caused severe disruptions in travel and transportation and limited access to our facilities resulting in limited support from our staff. We have been following the recommendations of local government and health authorities to minimize exposure risk for our employees. The disruptions delayed our ability to complete our annual review and prepare the Annual Report by April 30, 2020.

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

Not applicable.

Item 2 ***Offer Statistics and Expected Timetable***

Not applicable.

Item 3 ***Key Information***

The following selected consolidated financial data of Trinity Biotech as at December 31, 2019 and 2018 and for each of the years ended December 31, 2019, 2018 and 2017 have been derived from, and should be read in conjunction with, the audited consolidated financial statements and notes thereto set forth in Item 18 of this Annual Report. The selected consolidated financial data as at December 31, 2017, 2016 and 2015 and for the years ended December 31, 2016 and December 31, 2015 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December 31,				
	2019 US$ '000	*2018 US$'000*	*2017 US$'000*	*2016 US$'000*	2015 US$'000
Revenues	**90,435**	**97,035**	**99,140**	**99,611**	**100,195**
Cost of sales	(52,315)	(55,586)	(57,250)	(56,127)	(53,683)
Gross profit	**38,120**	**41,449**	**41,890**	**43,484**	**46,512**
Other operating income	91	102	100	239	288
Research and development expenses	(5,325)	(5,369)	(5,657)	(5,040)	(5,069)
Selling, general and administrative expenses	(27,661)	(29,477)	(32,246)	(30,366)	(28,225)
Selling, general and administrative expenses - impairment charges and inventory write-off/provision	(24,295)	(26,932)	(41,755)	(48,165)	—
Selling, general and administrative expenses – tax audit settlement	(5,042)	—	—	—	—
Operating (loss)/profit	**(24,112)**	**(20,227)**	**(37,668)**	**(39,848)**	**13,506**
Financial income	697	2,144	3,198	3,147	13,491
Financial expenses	(6,582)	(5,080)	(5,405)	(5,439)	(4,054)
Net financing (expense)/income	**(5,885)**	**(2,956)**	**(2,207)**	**(2,292)**	**9,437**
(Loss)/Profit before tax	**(29,997)**	**(23,183)**	**(39,875)**	**(42,140)**	**22,943**
Income tax credit/(expense)	1,006	525	1,214	3,557	(756)
(Loss)/Profit for the year	**(28,991)**	**(22,658)**	**(38,661)**	**(38,583)**	**22,187**
(Loss)/Profit for the year on discontinued operations	77	568	(1,609)	(62,042)	(391)
(Loss)/Profit for the year (all attributable to owners of the parent)	**(28,914)**	**(22,090)**	**(40,270)**	**(100,625)**	**21,796**
Basic (loss)/earnings per ADS (US Dollars)	(1.38)	(1.06)	(1.86)	(4.38)	0.94
Diluted (loss)/earnings per ADS (US Dollars)	(1.38)	(1.06)	(1.86)	(4.38)	0.46
Basic (loss)/earnings per 'A' ordinary share (US Dollars)	(0.35)	(0.27)	(0.47)	(1.10)	0.24
Diluted (loss)/earnings per 'A' ordinary share (US Dollars)	(0.35)	(0.27)	(0.47)	(1.10)	0.12
Weighted average number of shares used in computing basic EPS per ADS	20,901,703	20,903,227	21,621,602	22,964,703	23,161,773
Weighted average number of shares used in computing diluted EPS per ADS	25,467,516	25,877,205	26,877,544	28,299,399	27,407,793
Weighted average number of shares used in computing basic EPS per 'A' ordinary share	83,606,810	83,612,908	86,486,409	91,858,813	92,647,091
Weighted average number of shares used in computing diluted EPS per 'A' ordinary share	101,870,064	103,508,820	107,510,179	113,197,598	109,631,172

Consolidated Balance Sheet Data

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*	*December 31, 2016 US$'000*	*December 31, 2015 US$'000*
Net current assets (current assets less current liabilities)	51,941	69,057	91,362	108,208	143,085
Non-current liabilities	(106,909)	(90,001)	(106,549)	(115,585)	(129,646)
Total assets	131,071	151,659	192,974	249,592	363,683
Capital stock	1,213	1,213	1,213	1,213	1,209
Shareholders' equity	4,713	44,054	65,196	108,727	213,892

There were no dividends declared or paid during 2019 in respect of the fiscal year 2018 (no dividends paid in 2018 in respect of the fiscal year 2017, no dividends paid in 2017 in respect of the fiscal year 2016, final dividend of 22 cents per ADS was paid in 2015 in respect of the fiscal year 2014.

Risk Factors

You should carefully consider all of the information set forth in this Form 20-F, including the following risk factors, when investing in our securities. The risks described below are not the only ones that we face. Additional risks not currently known to us or that we presently deem immaterial may also impair our business operations. We could be materially adversely affected by any of these risks.

Risks Related to our Business

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 other 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 or a product during its development phase in which we have invested substantial time and money. During the fiscal years ended December 31, 2019, 2018 and 2017, we incurred US$9.6 million, US$9.9 million and US$10.4 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 United States 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 USA is dependent on clearance of products by the relevant regulatory authorities in those countries.

Our ability to sell products could be adversely affected by competition from new and existing diagnostic 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. The main competitors of Trinity Biotech (and their principal products with which Trinity Biotech competes) include: Abbott Diagnostics (AxSYM™, IMx™, i-STAT®, Determine™, Wampole™, Athena™, Biosite Triag®), Arkray (HA-8180), Bio-Rad (Bio-Plex™, Variant II, Turbo and D10™), Diasorin Inc. (Liasion™, ETIMAX™), The Carlyle Group – Ortho Clinical Diagnostics (Vitros™), OraSure Technologies, Inc. (OraQuick®), Roche Diagnostics (COBAS AMPLICOR™, Ampliscreen™, Accutrend™, Tina Quant™), Siemens – Beckman Coulter (Uni-Cel), Siemens – Dade-Behring (BEP 2000, Enzygnost®), Siemens – Bayer (Centaur™), Siemens – DPC (Immulite™), Thermo Fisher (Konelab™) and Tosoh (G8™).

- 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.

- 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 may have a competitive advantage because of their 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 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.

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 Health Products Regulatory Authority ("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 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 labeling 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, the majority 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.

- FDA can delay, limit or deny clearance or approval of a device for many reasons, including:
    - our ability 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.
- Our continued success is dependent on our ability to develop and market new 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.

Clinical trials necessary to support future premarket submissions will be expensive and will require enrollment 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 enrollment of patients who may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, and the availability of appropriate clinical trial investigators. Patients may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.
- Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA 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 enrollment 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 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.

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

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

- Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, 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 labeling, 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.

Our products may in the future 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 labeling 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, design or labeling 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.

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 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 Trinity Biotech's 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.

Modifications to our products, if cleared or approved, 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 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 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 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 devise chosen did not meet their requirements. Additionally the FDA asked us to withdraw our product from the market. This has been done in order to stay compliant. A new filing is underway using the predicate device indicated by the FDA. The new application is expected to be filed in the second half of 2020.

- 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 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. However, the FDA could disagree and require us to stop promoting our products for those specific uses until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials constitutes promotion of an unapproved use, it could request 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 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 labeling 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 labeling claims the FDA allows us to make are limited, orders may decline.

- 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.

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 payors 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;

- 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 Centers for Medicare & Medicaid Services ("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.

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.

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.

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

As of December 31, 2019, we had total indebtedness with a carrying value of approximately US$102.2 million, which included US$82.0 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.

Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;

- limit our ability to use our cash flow or obtain additional financing for working capital, capital expenditures, acquisitions or other general business purposes;

- require us to use a substantial portion of our cash flow from operations to make debt service payments;

- 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 exchanges of the exchangeable notes are settled in our ordinary shares;

- 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.

In addition, the holders of the exchangeable notes have the ability to require us to repurchase their notes for cash if we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution, or the delisting of our ordinary shares from the Nasdaq Global Market. Moreover, upon exchange of the exchangeable notes, unless we elect to deliver only our ordinary shares to settle such exchange, we will be required to make cash payments in respect of the exchangeable notes. It is our intent and policy to settle the principal amount of the exchangeable notes in cash upon exchange. However, we may not have enough available cash or be able to obtain financing at the time we are required to make any required repurchases of surrendered exchangeable notes or to pay cash upon exchanges of the exchangeable notes. Our failure to repurchase the exchangeable notes at a time when the repurchase is required by the indentures governing the exchangeable notes or to pay any cash payable on future exchanges of the exchangeable notes as required by the indentures governing the exchangeable notes would constitute a default under that indenture. A default under those indentures could also lead to a default under other debt agreements or obligations, including the amended credit agreement. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repay the related indebtedness, which could have a material adverse effect on our financial condition and our business. In this regard, if we are unable to repay amounts under the amended credit agreement, the lenders under the amended credit agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

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. 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.

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.

- Trinity Biotech 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.

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

- Trinity Biotech currently distributes its 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.

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 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.

Trinity Biotech may be subject to liability resulting from its products or services.

- Trinity Biotech may be subject to claims for personal injuries or other damages if any of our products, 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;

    - Diversion of management time and attention; and

    - Incurrence of damages payable to plaintiffs.

- Trinity Biotech has global product liability insurance in place for its manufacturing subsidiaries up to a maximum of €6,500,000 (US$7,291,000) for any one accident, limited to a maximum of €6,500,000 (US$7,291,000) in any one year period of insurance. A deductible of €5,000 ($5,600) for each claim and every claim increasing to US$25,000 in respect of USA/Canada is applicable to each insurance event that may arise. 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.

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, Kansas City, Missouri and Carlsbad, California comprised approximately 85% of revenues during the fiscal year ended December 31, 2019. 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.

- 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, 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 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 the Group's or third-party manufacturing capabilities could materially and adversely affect our operating results.

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

- Trinity Biotech's success is dependent to a large extent upon the contributions of certain key management personnel. Our key employees at December 31, 2019 were Ronan O'Caoimh, our CEO and Chairman, Jim Walsh, Executive Director, and Kevin Tansley, our CFO/Executive Director. 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.

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.

- Although Trinity Biotech does not expect to be dependent upon any one source for these critical components or raw materials, alternative sources of antibodies with the characteristics and quality desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

The Covid-19 outbreak could significantly disrupt our operations and adversely affect our results of operations.

- In December 2019, Covid-19 began to impact the population of Wuhan, China, a disease caused by a novel and highly contagious form of coronavirus. While initially the outbreak was largely concentrated in China and caused significant disruptions to its economy, it has now spread to several other countries and infections have been reported globally. The severity of the outbreak resulted in travel restrictions, quarantine and social distancing measures imposed by governments in virtually all of the countries in which we market our products. The Covid-19 outbreak made it difficult to carry out our marketing activities to promote our products to potential customers and gave rise to sudden significant changes in regional and global economic conditions that could interfere with purchases of products or services. We currently are unable to predict the duration and severity of the spread of the Covid-19, and responses thereto, and the impact on our business, results of operations, financial condition, cash flows and liquidity, as these depend on rapidly evolving developments, which are highly uncertain. Many factors are beyond our control, such as the continued spread or recurrence of contagion, the implementation of effective preventative and containment measures, the development of effective medical solutions, financial and other market reactions to the foregoing, and reactions and responses of communities and societies. However, we know the Covid-19 outbreak will result in lower revenues in 2020 and potentially beyond.

- Any similar future outbreak of a contagious disease, other adverse public health developments around the world, or the measures taken by the governments around the world in response to a future outbreak of a contagious disease may restrict economic activities in affected regions, resulting in reduced business volume, temporary closure of our facilities and offices or otherwise disrupt our business operations and adversely affect our results of operations.

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

- We currently generate significant operating cash flows, which combined with access to the credit markets provides us with discretionary funding capacity for research and development and other strategic activities. Uncertainty in global economic conditions may continue for the foreseeable future and intensify. 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 or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions.

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

We face risks relating to our international sales and business operations, including regulatory risks, which could impact our current business operations and growth strategy.

- Our international sales and operations are subject to various United States and foreign laws and regulations relating to export controls (including, without limitation, the U.S. Commerce Department's Export Administration Regulations), economic sanctions (including, without limitation, various sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control), and anti-corruption (including, without limitation, the United States Foreign Corrupt Practice Act). Failure to comply with such applicable laws and regulations could subject us to civil or criminal penalties, government investigations, debarment from export privileges, and reputational harm, which could have a material adverse effect on our business.

The U.K.'s withdrawal from membership of the E.U. could adversely affect us.

- The United Kingdom ("U.K.") exited the E.U. on January 31, 2020. There is now a transition period until the end of 2020 while the U.K. and E.U. negotiate additional arrangements. The existing rules on trade, travel, and business for the U.K. and E.U. continue to apply during the transition period. Our business in the U.K., the E.U. and world-wide could be affected by the impact of U.K.'s withdrawal from membership of the E.U. The U.K.'s exit from the E.U. could cause volatility in global financial markets, including in global currency exchange rates, resulting in a slow-down in economic activity in the U.K., Europe or globally, negatively impact new trade agreements between the U.K and other countries, and result in significant regulatory changes and uncertainty. One or more of these events could make it more difficult or costly to sell our products, particularly in the U.K. and Europe, and negatively affect our revenues and results of operations. The U.K.'s exit may also influence other countries and result in additional countries deciding to leave the E.U. This in turn could result in additional changes and uncertainty, any or all of which could negatively impact our business.

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

- A substantial portion of our operations is 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 competiveness. The Group has an exposure to the Canadian Dollar through its two Canadian entities (Nova Century Scientific and Phoenix Biotech) and to the Brazilian Real through its Brazilian entity. The Group also has revenues and costs denominated in British Sterling. The discontinued operation in Sweden, Fiomi Diagnostics, also gives us a Swedish Krona exposure.

- 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 conversion of our outstanding employee share options would dilute the ownership interest of existing shareholders.

- The total share options exercisable at December 31, 2019, as described in Item 18, Note 20 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 "A" Ordinary Shares. The exercise of the share options exercisable 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, should the options of the 6,622,667 "A" Ordinary Shares (1,655,667ADSs) exercisable at December 31, 2019 be exercised, Trinity Biotech would have to issue 6,622,667 additional "A" Ordinary Shares (1,655,667 ADSs). On the basis of 96,162,410 "A" Ordinary Shares outstanding at December 31, 2019, this would effectively dilute the ownership interest of the existing shareholders by approximately 7%.

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.

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.

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.

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 primarily from our business operations. If our business slows and we have less money available to fund research and development and clinical programs, we will have to decide at that time which programs to cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our business. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product, clinical and market development efforts are unsuccessful or delayed.

- Furthermore, our failure to successfully introduce new or enhanced products and develop new markets could have a material adverse effect on our business and prospects.

We 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 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 licenses;
- 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.

Investor confidence and share value may be adversely impacted if we and/or our independent registered public accounting firm conclude that our internal control over financial reporting is not effective.

- We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal control over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the overall quality of our internal controls may be affected by the internal control over financial reporting implemented by any business we acquire and our ability to assess and successfully integrate the internal controls of any such business.

- We could conclude that our internal control over financial reporting is not effective. These events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our common stock.

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 an annual 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 is US$44 million (2018: US$53 million). In 2019, we recorded total impairment charges of US$24 million (2018: US$27 million). 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 non-cash 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.

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

- To the extent that we or our strategic partners fail to maintain a high quality level of service and support for diagnostic products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could result in slower adoption rates and lower than anticipated utilisation of our products which could have a material adverse effect on our business, financial condition and results of operations.

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.

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

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

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

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

- Trinity Biotech currently owns 6 U.S. patents with remaining patent lives varying from 1 year to 14 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-license may fail to result in issued patents with claims that cover our current products or any future products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.

- We can provide no assurance that third parties will not challenge the validity, enforceability or scope of the patents 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 licensed 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 licensed or that we might obtain in the future.

- 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 recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have an adverse effect on our business and financial condition.

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

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

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

- As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third-party may claim infringement against us. For example, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may infringe. Defence of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of managerial and financial resources from our business. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialise one or more of our products. The pendency of any litigation may cause our distributors and customers to reduce or terminate purchases of our products. If found to infringe, we may have to pay substantial damages, including treble damages and attorneys' fees for wilful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. Any substantial loss resulting from such a claim could cause our revenues to decrease and have a material adverse affect on our profitability, and the damage to our reputation in the industry could have a material adverse affect on our business.

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

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

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

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

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

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

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. 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 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.

Reductions in government funding and research budgets 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 organisations, service organisations and similar entities. Many of these customers depend to a significant degree on grants or funding provided by governmental agencies to run their operations including programs that use our 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 may be affected by various factors including future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding could cause our customers to delay, reduce or forego purchases of our products.

Risks Related to Government Regulation

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.

- 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.

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. 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 includes, but is not limited to, a new provision designed to tax global intangible low taxed income, limitations on the deductibility of certain executive compensation, creating a base erosion anti-abuse tax and modifying or repealing many deductions and credits. The ultimate impacts of the Tax Act may differ from the Company's estimates due to changes in the interpretations and assumptions made, as well as any forthcoming regulatory guidance. The 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.

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

Item 4 ***Information on the Company***

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

Trinity Biotech markets its portfolio of almost 850 products to customers in approximately 100 countries around the world through its own sales force and a network of international distributors and strategic partners.

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

The following represents the most recent acquisition made by Trinity Biotech:

Acquisition of Immco Diagnostics Inc

In 2013, the Group acquired 100% of the common stock of Immco Diagnostics Inc ("Immco") for US$32.88m.

Immco, which is headquartered in Buffalo, New York, specialises in the development, manufacture and sale of autoimmune test kits on a worldwide basis. This product line is complemented by specialised reference laboratory services in diagnostic immunology, pathology and immunogenetics, marketed to U.S. based hospitals and reference laboratories.

Principal Markets

The primary market for Trinity Biotech's diagnostic products is the Americas (which consists principally of North America and South America). During fiscal year 2019, 58% (US$52.2 million) (2018: US$57.6 million or 59%) (2017: 60% or US$59.5 million) of the Group's total revenues were derived from products sold in the Americas. Sales in the non-Americas (principally European, Asian and African countries) represented 42% (US$38.2 million) of total sales for fiscal year 2019 (2018: 41% or US$39.5 million) (2017: 40% or US$39.6 million)

For a more comprehensive segment analysis please refer to Item 5, "Results of Operations" and Item 18, Note 2 to the consolidated financial statements.

Principal Products

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

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

Trinity Biotech also sells raw materials to the life sciences industry and research institutes globally through its wholly owned subsidiary, Benen Trading Ltd., trading as Fitzgerald Industries.

Trinity Biotech sells its products through its direct sales organisations in the United States, Brazil and to an extent in the United Kingdom, France and Germany and then through its 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 centres 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 the dominant confirmatory HIV test in the African market and has been the gold standard for over 15 years. It is the confirmatory test of choice in the vast majority of significant African countries.

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 we are in the process of developing. Trinity Biotech has not previously competed in the larger screening market, which is valued at approximately US$150 million p.a. The screening market is addressed by few companies. TrinScreen will 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 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 product also exist in other territories, in particular in emerging countries.

The company also sells the only FDA approved and CLIA waived syphilis point-of-care test in the USA.

The Trinity Biotech Uni-Gold™ S. pneumonia, Uni-Gold™ Legionella, Uni-Gold™ C. difficile and Uni-Gold™ Syphilis are all Conformité Européenne ("CE") marked and we will concentrate selling these products on international markets outside of the USA.

These point-of-care products will be sold through Trinity Biotech's sales and marketing organisation to 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 specialty and esoteric biomarkers of infectious diseases. 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:

- Lyme disease,
- Sexually transmitted diseases, including Syphilis and Herpes.
- Markers for Epstein Barr, measles, mumps, toxoplasmosis, cytomegalovirus, rubella, varicella and other viral pathogens.

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

The vast majority of the Infectious Diseases product line of Trinity Biotech is 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 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 testing for 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 test for HbA1c which is a measure 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 A1c 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, primarily through the Ultra^2 instrument. This is used for the detection of haemoglobinapothies, which are genetic defects that result in abnormal structure of the haemoglobin molecule. Haemoglobinapathies include sickle-cell diseases, alpha and beta thalassemia which are amongst the most common genetic disorders in the world.

Trinity Biotech has launched the Premier Resolution, its next generation Haemoglobinapothy Analyzer in Europe and the Middle East after undergoing rigorous and successful field trials. In 2020, the Premier Resolution will be submitted to the FDA for approval. The Premier Resolution uses an internally developed column as well as state of the art hardware and software innovations in order to provide unparalleled variant detection. It is a best in class analyser that will enable Trinity to expand upon its leading position as a key supplier to this highly specialised segment.

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.

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 its infectious diseases products. Additionally, Trinity sells a complete line of IFA processors. The majority 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 is the only company able to market a panel of proprietary early markers for Sjogrens 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. Menarini Diagnostics, a European market leader in autoimmune testing, distributes Immco products in the key European markets.

The diagnostic product line is complemented by Immco’s New York state licensed 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, lactate, 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, OraSure Technologies Inc., Roche Diagnostics, Siemens (from the combined acquisitions of Bayer, Dade-Behring and DPC), Thermo Fisher and Tosoh.

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 key licensing arrangements including the following:

Immco entered into a license agreement on January 19, 2012, and subsequently an amended license agreement on June 14, 2018. The license 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.

In 2012, Trinity Biotech entered into a licence agreement with the CDC in Atlanta, Georgia, United States for the rights to use Cardiolipin and other immunoassays and mechanisms in developing and producing a Syphilis rapid test.

In 2006, Trinity Biotech entered into a new licence agreement with Inverness Medical Innovations ("IMI") to IMI's updated broad portfolio of lateral flow patents, which expanded the field of use to include over the counter ("OTC") for HIV products, thus ensuring Trinity Biotech's freedom to operate in the lateral flow market with its UniGold™ technology. As a platform technology, the lateral flow licences obtained from Inverness Medical Innovations also apply to Point-of-Care tests developed at our Carlsbad facility.

In 2005, Trinity Biotech obtained a licence from the University of Texas for the use of certain Lyme disease antigens, thus enabling the inclusion of these antigens in the Group's Lyme diagnostic products.

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 key licensing arrangements disclosed under this subheading terminates on the date expiration or adjudication of invalidity or unenforceability of the last of the particular licensed 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 licensed. The royalty rates vary from 1.6% to 12.5% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2019 was US$338,000 (2018: US$442,000).

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 Product Regulatory Authority (as the authority over Trinity Biotech in Europe) 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 58% of Trinity Biotech's 2019 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

All 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, labeling 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 labeling, 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.

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 labeling 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;
- labeling 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 Centers for Medicare & Medicaid Services, or 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 our CLIA certificate, 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.

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, labeling 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 Exports

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.

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 willfully 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.

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 licensed 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 licensed 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 license, censure the holder of the license 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.

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.

Organisational Structure

Trinity Biotech plc and its subsidiaries ("the Group") is a manufacturer of diagnostic test kits and instrumentation for sale and distribution worldwide.

Trinity Biotech's executive offices are located at Bray, Ireland while its 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;
- MarDx Diagnostics Inc, based in Carlsbad, California;
- 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, USA.

For a more comprehensive schedule of the subsidiary undertakings of the Group please refer to Item 18, Note 33 to the consolidated financial statements.

Property, Plant and Equipment

Trinity Biotech has seven manufacturing sites worldwide, five in the Americas. (Amherst, Williamsville and Jamestown, NY, Kansas City, MO, Carlsbad, CA 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 its 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 Trinity Biotech 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 Carlsbad, CA 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, 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 has entered into a number of related party transactions with JRJ Investments ("JRJ"), a partnership currently owned by Mr 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, located in Bray, Ireland. Trinity Biotech has 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$427,000), which expires in 2027. Trinity Biotech has 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$883,000) and the annual rent for the warehouse is €144,000 (US$162,000). These two leases expire in 2028 and 2026 respectively. See Item 7 – Major Shareholders and Related Party Transactions.

Trinity Biotech USA operates from a 25,610 square foot FDA and ISO 9001 approved facility in Jamestown, New York. The facility was purchased by Trinity Biotech USA in 1994. Additional warehousing space is also leased in Jamestown, New York at an annual rental charge of US$183,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,436 square feet and the second adjacent facility comprises 14,500 square feet. The last number of years have seen a steady migration of customers away from using Western Blot for diagnosing Lyme in favour of alternative testing platforms. Production volumes at our Carlsbad, California facility (which specialises in Western Blot manufacturing) have declined steadily to the extent that it no longer makes economic sense to continue. Consequently, in the early part of 2020 management decided to close this facility from June 30, 2020. Both facilities operated by Mardx are leased and in 2020, we have given notice to the landlords that we will terminate our leases on June 30, 2020. During the period until closure, final batches of Lyme Western Blot for our remaining customers will be produced, whilst simultaneously transferring non-Lyme product manufacturing to other Group facilities.

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$119,000 and US$47,000 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$257,000. The Williamsville facility's annual rent is currently US$405,000, rising to US$452,000 by 2029. An additional 5,120 square foot facility is owned by Trinity Biotech in Burlington, Canada.

Additional office and factory space is leased by the Group in Acton, Massachusetts, Sao Paulo, Brazil and Extrema, Brazil at an annual cost of US$95,000, US$11,000 and US$33,000 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 produced at our facilities – these are as follows:

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

Jamestown, New York – this site specializes in the production of Microtitre Plate EIA products for infectious diseases and auto-immunity.

Carlsbad, California – this facility specialises in the development and manufacture of products utilising Western Blot and lateral flow technology. Our suite of Lyme products is manufactured at this facility and our new Infectious Diseases Point-of-Care range are 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 range of products.

Buffalo, New York – these sites are responsible for the manufacture of autoimmune test kits 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.

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

Not applicable.

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

Operating Results

Trinity Biotech's consolidated financial statements include the attributable results of Trinity Biotech plc and all its subsidiary undertakings collectively. This discussion covers the years ended December 31, 2019, December 31, 2018 and December 31, 2017, 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.

Trinity Biotech has availed of the exemption under SEC 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, 2019 as Trinity Biotech is a foreign private issuer and the financial statements have been prepared in accordance with IFRS as issued by the International Accounting Standards Board ("IASB").

Overview

Trinity Biotech develops, manufactures and markets 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 almost 850 different diagnostic products in approximately 100 countries. In addition, the Group manufactures its own and distributes third party infectious disease diagnostic instrumentation. Trinity Biotech, through its Fitzgerald subsidiary, is a provider of raw materials to the life sciences industry.

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 while they are still in development 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, 2019, 2018, 2017, 2016 and 2015 have been impacted by the decision to discontinue operations in Fiomi Diagnostics AB in 2016 following the withdrawal of the Troponin premarket submission to the U.S. Food and Drug Administration (see Item 18, Note 10). The Group also realised impairment losses in 2016, 2017, 2018 and in 2019 as a result of annual impairment reviews as at December 31, 2016, December 31, 2017, December 31, 2018 and December 31, 2019 (see Item 18, Note 13). There were no acquisitions made in 2019, 2018, 2017, 2016 or 2015.

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

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

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 or the possible return of goods. Revenue, including any amounts invoiced for shipping and handling costs, represents the transaction price the value of goods and services supplied to external customers, net of discounts and rebates and excluding sales taxes. The transaction price is determined by reference to the contract and arrangements with the customer.

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 apply.

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.

We operate a licenced reference laboratory 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. The laboratory is based in USA, where 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 laboratory 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.

In some countries, the Group leases instruments to customers 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. As a practical expedient, no allocation of the transaction price is done for instrument contracts which are less than one year's duration. 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).

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 24 for details.

Research and development expenditure

We write-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 the product is launched.

In-process research and development ("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, 2019 the carrying value of capitalised development costs was US$22,778,000 (2018 US$26,265,000) (see Item 18, Note 14 to the consolidated financial statements). The decrease in 2019 was mainly as a result of an impairment loss charge of US$11,904,000. This charge was partially offset by additions of US$9,569,000 and amortisation of US$1,182,000.

Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment annually, 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 an annual basis. The recoverable amount of each of the cash-generating units ("CGU") is determined based on a value-in-use computation, which is the only methodology applied by the Group and which has been selected due to the impracticality of obtaining fair value less costs to sell measurements for each reporting period. For the purpose of the annual impairment tests, goodwill is allocated to the relevant CGU. The impairment test performed as at December 31, 2019 identified a total impairment loss of US$76,740,000 in seven cash generating units ("CGUs"), of which US$24,295,000 has been recorded in the 2019 financial statements. Refer to Item 18, Note 14 for further information.

The value-in-use calculations use cash flow projections based on the 2020 budget and projections for a further four years using projected revenue and cost growth rates of between 0% and 7%.

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 key assumptions employed in arriving at the estimates of future cash flows are subjective and include projected EBITDA, net cash flows, discount rates and the duration of the discounted cash flow model. The assumptions and estimates used were derived from a combination of internal and external factors based on historical experience. The pre-tax discount rates used range from 20% to 27% (2018: 20% to 35%). Post tax discount rates have been calculated using external inputs such as prevailing short and long term interest rates, a small stock premium, a stock beta and the corporate tax rates applicable to each CGU. The discount rates reflect the risk profile of each CGU. See Item 18, Note 14 to the consolidated financial statements for further information.

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas;

- In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, there would be an additional impairment loss of US$743,000 at December 31, 2019
- In the event there was a 10% variation 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 an additional impairment loss of US$5,420,000 at December 31, 2019.

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 2019, 2018 or 2017 which would have an impact on the carrying values of inventory during those periods, except as discussed below. At December 31, 2019 our allowance for slow moving and obsolete inventory was US$6,716,000 which represents approximately 17.33% of gross inventory value. This compares with US$6,299,000, or approximately 17.18% of gross inventory value, at December 31, 2018 and US$7,543,000, or approximately 18.70% of gross inventory value, at December 31, 2017 (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 2019 and 2018 due our decision to cull some old and declining product lines. 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$774,000 at December 31, 2019 (2018: US$733,000) (2017: US$807,000) 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. 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 2019, 2018 or 2017 which would have an impact on the carrying values of receivables in these periods. At December 31, 2019, the allowance was US$5,443,000 which represents approximately 6.0% of Group revenues. This compares with US$4,202,000 at December 31, 2018 which represented approximately 4.3% of Group revenues and to US$3,590,000 at December 31, 2017 which represented approximately 3.6% of Group revenues. The increase in the allowance for impairment of receivables in the year ended December 31, 2019 was due to a general deterioration in the age of receivables. 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$452,000 at December 31, 2019 (2018: US$485,000) (2017: US$496,000) 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 25 to the consolidated financial statements for further information.

Impact of Recently Issued Accounting Pronouncements

The consolidated financial statements have been prepared in accordance with IFRS both as issued by the IASB and as subsequently adopted by the EU. The IFRS applied are those effective for accounting periods beginning 1 January 2019. 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. During 2019, the IASB and the International Financial Reporting Interpretations Committee ("IFRIC") issued additional standards, interpretations and amendments to existing standards which are effective for periods starting after the date of these financial statements. A list of these additional standards, interpretations and amendments, and the potential impact on the financial statements of the Group, is outlined in Item 18, Note 1(xxx).

Subsequent Events

Decision to close Carlsbad manufacturing plant in 2020

The last number of years have 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 at our Carlsbad, California facility (which specialises in Western Blot manufacturing) have declined steadily to the extent that it no longer makes economic sense to continue. Consequently, in the early part of 2020, management decided to close this facility from June 30, 2020.

During the period until closure, final batches of Lyme Western Blot for remaining customers will be produced, whilst simultaneously transferring non-Lyme product manufacturing to other Group facilities. No provision has been reflected in the 2019 financial statements relating to the costs associated with closing this facility, terminating employment contracts, transferring assets to new locations in the Group. The Company recorded a provision of US$2.4 million in its income statement for Q1, 2020 to cover the related closure costs. This primarily includes the write-off of inventory and redundancy costs and is mainly non-cash in nature.

Covid-19 pandemic

Impact on Revenues

Subsequent to the balance sheet date, the Company's revenues have been significantly impacted by the Covid-19 Pandemic with the greater impact being seen from April 2020 onwards. In particular, this resulted in significant reduction in:

- Haemoglobins revenues – including both instrument and consumables revenues with the impact being greater on diabetes (A1c) rather than on haemoglobin variant revenues.
- Autoimmune revenues – 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, Infectious Diseases and Clinical chemistry product sales.

However, there were increases in sales of our transport medium product (used to transport Covid-19 patient samples in a stable environment), respiratory tests for Legionnaire's Disease and Strep Pneumoniae and of coronavirus-related antibodies sold by our life sciences supply business, Fitzgerald.

Covid-19 Expenditure Reduction Measures

All of the company's operations have remained open during the pandemic though at reduced levels of output in line with expected demand. However, in response to the expected reduction in revenues, the company undertook a number cost cutting measures which included the following:

- The company furloughed a large percentage of its work forces in the USA, Ireland and Canada in April, 2020. Meanwhile, in Brazil and other locations, staff costs were also significantly reduced by means of pay cuts.
- The elimination of virtually all travel costs and significant reductions in discretionary sales and marketing expenditure.
- Availing of governmental supports. This included the receipt of US$4.5 million of loans under the U.S. government's Paycheck Protection Program ("PPP"). Under the provisions of the PPP, these loans will be partially or totally forgiven, based on the extent to which a borrower's workforce returns to normal levels in the eight-week period immediately following the loans being granted. Upon receipt of these loans, the Company ended the furloughing of all staff in the USA and therefore expects that a large percentage of these loans will be forgiven later in 2020, once the necessary verification has taken place. In Ireland, the company also availed of economic support mechanisms being provided by the Irish Government though a significant level of furloughing continued into June, 2020, mainly due to the expected lower demand for HIV products for the African market.

Impact on Working Capital

Due to the measures implemented by the company in response to falling demand for products the Company's cash position at May 31, 2020 was similar to that reported in the financial statements as at 31 December, 2019. Furthermore, the Company has not seen any significant deterioration in the recoverability of its inventory and accounts receivables balances as at 31 December, 2019. Meanwhile, the company is continuing to pay its creditors.

Asset Impairment

The annual impairment test on the carrying value of goodwill and other assets was carried out as at December 31, 2019 – see note 14. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. However, the impairment test only takes into account conditions existing at the end of the reporting period. Covid-19 began to impact the population of Wuhan, China in December 2019 and initially the outbreak was largely concentrated in China. It was declared to be a pandemic by the World Health Organization in March 2020. The Company's impairment test as at December 31, 2019 therefore does not reflect the downturn in economic activity or the aforementioned impacts on the Company's revenues and expenditure caused by the Covid-19 pandemic.

If the impairment test was reperformed using projections which take into account the aforementioned impacts on revenues and expenditure, the impairment loss as at December 31, 2019 for Primus Corp. and Immco Diagnostics would be higher by US$1.8 million and US$1.7 million respectively. The reason these two Cash Generating Units are the only units affected is that the other Cash Generating Units' assets were already fully impaired, except Fitzgerald, as at December 31, 2019.

Results of Operations

Year ended December 31, 2019 compared to the year ended December 31, 2018

The following compares our results in the year ended December 31, 2019 to those of the year ended December 31, 2018 under IFRS. Our analysis is divided as follows:

1. *Overview*
2. *Revenues*
3. *Operating Loss*
4. *Loss for the year*
5. *Discontinued operations*

1. Overview

In 2019, revenues decreased by 6.8% from US$97.0 million in 2018 to US$90.4 million. The three main factors behind the decrease in revenues are:

i. Lyme disease revenues decreased following the loss of certain large customers that migrated their Lyme testing away from Western Blot assays to alternative testing platforms,
ii. HIV point-of-care sales decreased following our decision to discontinue sales of the Unigold HIV test in the USA and
iii. Revenues for our Fitzgerald business, which sells antibodies to the life sciences and research industries, reduced following higher than average revenues in 2018.

These declines were partially offset by Haemoglobins and Autoimmunity revenues which continued to grow in 2019.

Geographically, 58% of our sales were generated in the Americas, 30% in Africa/Asia and 12% in Europe.

There was a slight decrease in gross margin in 2019 (42.2% versus 42.7%) and this is mainly due to the impact of lower revenues, particularly in the context of our relatively high fixed cost base and the adverse currency movements. Selling General & Administrative Expenditure (excluding impairment charges and tax settlement) decreased from US$29.5 million in 2018 to US$27.7 million in 2019, which represents a decrease of 6.2%. The decrease is mainly attributable to a cost reduction programme, lower amortization charges and the impact of foreign currency fluctuations.

The Company recognized an impairment charge of US$24.3 million in 2019 (2018: US$26.9 million). A number of factors contributed to the impairment charges including the Company's market capitalisation at the end of the year which was lower when compared to the end of 2018, the inclusion of the latest cash flow projections and net asset values for each cash generating unit and increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

The settlement of a tax audit, mainly relating to payroll taxes, resulted in a charge of US$5.0m, excluding interest.

The operating loss for continuing operations was US$24.1 million for the year, which compares to US$20.2 million for 2018. Excluding the impairment charge and the once-off tax settlement, the operating profit for continuing operations for 2019 is US$5.2 million, compared to US$6.7 million in 2018. This decrease in operating profit before impairment charges and tax audit settlement in 2019 is mainly attributable to lower revenues and to a lesser extent the lower gross margin.

In 2019, net financing expense was US$5.9 million compared to US$3.0 million in 2018. The increase of US$2.9 million was due to the inclusion of notional interest expense on facility leases of US$0.9m due to the adoption of IFRS 16, Leases, interest on a tax audit settlement of US$1.0 million and lower deposit interest, offset by a reduction in interest payable on our Exchangeable Notes of $0.4m following the buyback of a portion of the notes in 2018.

The loss for the year from continuing operations amounted to US$29.0 million, compared to US$22.7 million in 2018. Before the impact of impairment charges and the tax audit settlement, the loss for 2019 from continuing operations would have been US$0.3 million, compared to a US$4.3 million profit for 2018.

2. Revenues

Trinity Biotech's revenues consist of sales of diagnostic kits and related instrumentation, laboratory testing services sales and sales of raw materials to the life sciences industry. 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. 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. 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.

In some countries, the Group leases instruments to customers 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 based on standalone selling prices. 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.

Revenues by Product Line

Trinity Biotech's revenues for the year ended December 31, 2019 were US$90,435,000 compared to revenues of US$97,035,000 for the year ended December 31, 2018, which represents a decrease of US$6,600,000 or 6.8%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2019 US$ '000	2018 US$'000	% Change
Revenues			
Clinical Laboratory	68,127	71,618	(4.9)%
Point-of-Care	11,393	14,836	(23.2)%
Laboratory Services	10,915	10,581	3.2%
Total	**90,435**	**97,035**	**6.8%**

Clinical Laboratory

Clinical Laboratory revenues decrease by US$3,491,000 in 2019, which represents a decrease of 4.9%. This decrease was mainly attributable to a 16% decrease in Infectious Diseases revenues. Lower sales of Western Blot tests for Lyme disease in USA mainly accounted for this decrease caused by the on-going migration of Lyme confirmatory testing to alternative testing platforms. Similarly, revenues for our other infectious diseases tests on ELISA platforms have also been declining for several years, particularly in USA but we have succeeded in partially making up for these declines by selling more to emerging markets, with China being the largest market. Our Fitzgerald business, which sells antibodies to the life sciences and research industries, had a decrease in revenues of 14% following a higher than average level of sales in 2018 driven by high sales in Asia. Partially offsetting these decreases was higher revenues for haemoglobin A1c testing.

Point-of-Care

Point-of-Care revenues decreased from US$14,836,000 in 2018 to US$11,393,000 in 2019, which is a decrease of US$3,443,000 (-23.2%). This decrease was mainly due to lower HIV revenues in USA following the decision during 2019 to discontinue sales of the Unigold HIV test in that market. The reduction in funding for public health HIV testing programs in addition to the CDC's recommendations in favour of fourth generation antigen testing led to the decline of HIV Point-of-Care sales in the USA for the last number of years. Volumes had declined to the extent that when manufacturing and marketing costs were taken into account it was no longer an economically viable product. The remaining decrease is due to lower Syphilis Point-of-Care tests revenues.

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. The laboratory had another good year in 2019, growing revenue by 3.2% to US$10,915,000. Revenues for Sjögrens Syndrome accounts for 23% of the total revenues in 2019.

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,		
	2019 US$'000	2018 US$'000	% Change
Revenues			
Americas	52,183	57,559	(9.3)%
Asia/Africa	27,686	29,466	(6.0)%
Europe	10,566	10,010	5.6%
Total	**90,435**	**97,035**	**(6.8)%**

In the Americas, revenues decreased US$5,376,000 or 9.3% mainly due to three factors: (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 in Brazil due to a marked weakness in the Brazilian currency. These declines were partially offset by growth in laboratory testing revenues from our autoimmune reference laboratory and higher revenues from our diabetes testing business in USA.

Asia/Africa revenues decreased by 6.0%, or US$1,780,000 compared to 2018. The main reason for this was lower revenues in Asia for our Fitzgerald business, which sells antibodies to the life sciences and research industries. In 2018, Fitzgerald achieved higher than average revenues in Asia and 2019 saw a return to a more normal level of sales in that territory. Higher haemoglobin A1c revenues partially offset the reduction in Fitzgerald sales in the territory.

In Europe, revenues increased by 5.6% or US$556,000, compared to 2018. The increase was due to higher haemoglobin A1c revenues due to the continued success of the Premier instrument. This was partly offset by lower sales of infectious diseases revenues in the territory.

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

3. Operating Loss – continuing operations

The following table sets forth the Group's operating loss from continuing operations:

	Year ended December 31,		
	2019 US$'000	2018 US$'000	% Change
Revenues	90,435	97,035	(6.8)%
Cost of sales	(52,315)	(55,586)	(5.9)%
Gross profit	**38,120**	**41,449**	**(8.0)%**
Other operating income	91	102	(10.8)%
Research & development	(5,325)	(5,369)	(0.8)%
SG&A expenses	(27,661)	(29,477)	(6.2)%
Selling, general and administrative expenses – tax audit settlement	(5,042)	—	—
Selling, general and administrative expenses - impairment charges	(24,295)	(26,932)	(9.8)%
Operating loss on continuing operations	**(24,112)**	**(20,227)**	**19.2%**

Cost of sales and gross margin

Total cost of sales decreased by US$3,271,000 from US$55,586,000 for the year ended December 31, 2018 to US$52,315,000, for the year ended December 31, 2019, a decrease of 5.9%. The gross margin of 42.2% in 2019 compares to a gross margin of 42.7% in 2018. This decrease was mainly due to the impact of lower revenues, particularly in the context of our relatively high fixed cost base and the adverse currency movements mentioned above. This was partly offset by cost savings that were implemented during the year and the changes resulting from the adoption of IFRS 16, Leases.

Other operating income

In 2019, other operating income mainly comprises income from the provision of canteen services recognised under a Transitional Services Agreement with Diagnostica Stago. Other operating income decreased by 10.8% to US$91,000 mainly due to currency movements.

Research and development expenses ("R&D")

Research and development expenditure recorded in the Statement of Operations decreased from US$5,369,000 in 2018 to US$5,325,000 in 2019. The decrease in 2019 is mainly due to lower salaries expenses resulting from a cost reduction programme. For details of the Company's various R&D projects see "Research and Products under Development" below.

Selling, General & Administrative expenses ("SG&A")

Total SG&A expenses decreased by US$1,816,000 from US$29,477,000 for the year ended December 31, 2018 to US$27,661,000 for the year ended December 31, 2019.

The following table outlines the breakdown of SG&A expenses in 2019 compared to 2018.

	Year ended December 31,		
	2018 US$'000	2018 US$'000	% Change
SG&A (excl. share-based payments and amortisation)	24,561	25,317	(3.0)%
Share-based payments	732	1,335	(45.2)%
Amortisation	2,368	2,825	(16.2)%
Total	**27,661**	**29,477**	**(6.2)%**

Selling General & Administrative Expenditure (excluding share-based payments and amortisation)

SG&A expenses excluding share-based payments and amortisation decreased from US$25,317,000 for the year ended December 31, 2018 to US$24,561,000 for the year ended December 31, 2019, which represents a decrease of 3.0%. The decrease of US$756,000 is mainly attributable to:

- full year effect of cost savings implemented in 2018 as part of a cost saving programme. This resulted in lower costs under a wide range of headings including salaries, I.T. costs and discretionary sales and marketing costs and commission payments,
- lower pay for employees as a consequence of lower revenues,
- the foreign currency impact which resulted in Euro-denominated and Brazilian-denominated costs being lower by 5% and 7% respectively,
- partly offset by a gain on the purchase of a portion of our exchangeable notes recorded in 2018 (US$463,000) and higher legal fees and tax professional fees mainly associated with the tax audit which was concluded in 2019 in one of the jurisdictions in which the Group operates.

Share-based payments

The expense represents the fair value of share options granted to directors and employees, 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$758,000 (2018: US$1,369,000). The decrease of US$611,000 in the total share-based payments expense is due to a lower number of share options still being in their vesting period in 2019 compared to 2018. The total charge is shown in the following expense headings in the statement of operations: US$26,000 (2018: US$34,000) was charged against cost of sales and US$732,000 (2018: US$1,335,000) was charged against selling, general & administrative expenses.

For further details, refer to Item 18, Note 22 to the consolidated financial statements.

Amortisation

Amortisation decreased from US$2,825,000 for the year ended December 31, 2018 to US$2,368,000 for the year ended December 31, 2019. The decrease of US$457,000 is due to lower amortisation on development projects. The decrease was partly as a consequence of the impairment recorded at December 31, 2018 which resulted in a lower carrying value for development projects.

Selling, general and administrative expenses – tax audit settlement

A tax audit settlement of US$6,442,000 arising in one of the jurisdictions in which the company operates was reached in the year end December 31, 2019. The tax audit concluded in December 2019. 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), US$75,000 in relation to R&D tax credits. Penalties were US$273,000. Interest charges were US$1,000,000 and this is shown as a financial expense. The total settlement excluding interest of US$1,000,000 was US$5,442,000 and this was partially offset by an existing provision of US$400,000, resulting in an expense of US$5,042,000.

Selling, general and administrative expenses - impairment charges

Impairment charges of US$24,295,000 for the year ended December 31, 2019 are included in selling, general and administrative expenses. In 2018, impairment charges of US$26,932,000 were included in selling, general and administrative expenses. The Group carries out an annual impairment review of asset valuations. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. A number of factors affected this calculation in 2019 including:

- the Company's market capitalisation at the end of the year which was lower when compared to the end of 2018.
- the inclusion of the latest cash flow projections and net asset values for each cash generating unit; and
- increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

For further details, see Item 18, Notes 13, 14 and 18.

4. Loss for the year

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

	Year ended December 31,		
	2019 US$'000	**2018 US$'000**	**% Change**
Operating loss	(24,112)	(20,227)	19.2%
Net financing expense	(5,885)	(2,956)	99.1%
Loss before tax	(29,997)	(23,183)	29.4%
Income tax credit	1,006	525	91.6%
Loss for the year from continuing operations	**(28,991)**	**(22,658)**	28.0%

Net Financing income

Net financing expense was US$5,885,000 for the year-end December 31, 2019 compared to US$2,956,000 in 2018. Financial income decreased by US$1,427,000 from US$2,124,000 for the year-end December 31, 2018 to US$697,000 in 2019. There was a decrease of US$1,155,000 in the income arising from the revaluation of embedded derivatives at fair value and a decrease of US$272,000 in bank deposit interest due to the lower cash deposits and lower interest rates.

Financial expenses increased by US$1,502,000 to US$6,582,000 during 2019 mainly due to interest arising on a tax audit settlement of US$1,000,000 and an increase of US$908,000 in lease interest mainly resulting from the adoption of IFRS 16, Leases on January 1, 2019. The new accounting treatment brings operating leases onto the Balance Sheet with a related interest expense. Offsetting this increase was lower cash and non-cash exchangeable notes interest (down by US$406,000) following the buyback of a portion of the exchangeable notes in the third quarter of 2018.

Taxation

The Group recorded a tax credit on continuing operations of US$1,006,000 for the year ended December 31, 2019 compared to a tax credit of US$525,000 for the year ended December 31, 2018. The 2019 tax credit comprises US$165,000 of current tax credit and US$841,000 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 amounted to US$28,991,000, compared to a loss of US$22,658,000 in 2018, representing an increase of 28.0%.

5. 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 following table sets forth selected statement of operations data for each of the periods indicated.

	Year ended December 31,	
	2019	**2018**
	US$'000	**US$'000**
Profit on discontinued operations	77	568

The profit on discontinued operations is US$77,000 in year ended December 31, 2019, which is mainly due to the unwinding of cardiac point-of-care business Fiomi Diagnostics accumulated foreign currency translation reserve. A profit of US$568,000 was recorded in the year ended December 31, 2018 mainly due to the recovery of taxes paid in Sweden by Fiomi. For further details, see Item 18, Note 10.

Results of Operations

Year ended December 31, 2018 compared to the year ended December 31, 2017

The following compares our results in the year ended December 31, 2018 to those of the year ended December 31, 2017 under IFRS. Our analysis is divided as follows:

1. *Overview*
2. *Revenues*
3. *Operating Loss*
4. *Loss for the year*
5. *Discontinued operations*

1. Overview

In 2018, revenues decreased by 2.1% from US$99.1 million in 2017 to US$97.0 million. This was mainly attributable to a 12% fall in point-of-care revenues primarily due to lower HIV sales in the African market where there was some overstocking in one of the larger countries in which we operate. Clinical Laboratory revenues decreased by 2% with a decline in US infectious diseases revenues being partially offset by higher revenues for haemoglobin A1c testing. These declines were partially offset by lab services revenues which performed strongly.

Geographically, 59% of our sales were generated in the Americas, 30% in Africa/Asia and 11% in Europe.

There was a slight increase in gross margin in 2018 (42.7% versus 42.3%) and this is mainly attributable to cost savings implemented during the year. Selling General & Administrative Expenditure (excluding impairment charges and inventory write-offs) decreased from US$32.2 million in 2017 to US$29.5 million for 2018, which represents a decrease of 9%. The decrease is mainly attributable to a cost reduction programme, lower amortization charges and certain non-recurring costs in the prior year.

The annual impairment test resulted in impairment charges of US$26.9 million in 2018 (2017: US$41.8 million). A number of factors contributed to the impairment charges including the Company's market capitalisation at the end of the year that was lower when compared to the end of 2017, the inclusion of the latest cash flow projections and net asset values for each cash generating unit and increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

The operating loss for continuing operations is US$20.2 million for the year, which compares to US$37.7 million for 2017. Excluding the impairment charge, the operating profit for continuing operations for 2018 is US$6.7 million, compared to US$4.1 million in 2017. The increase of US$2.6 million in operating profit before impairment charges in 2018 is mainly attributable to the higher gross profit and lower selling, general and administrative expenses.

In 2018, net financing expense was US$3.0 million compared to US$2.2 million in 2017. The increase of US$0.8 million is mainly attributable to the revaluation of embedded derivatives at fair value, which resulted in lower income of US$1.0 million in 2018 compared to 2017.

The loss for the year from continuing operations amounted to US$22.7 million, compared to US$38.7 million in 2017. Before the impact of impairment charges, the profit for 2018 from continuing operations would have been US$4.3 million, compared to US$3.1 million for 2017.

2. Revenues

Trinity Biotech's revenues consist of sales of diagnostic kits and related instrumentation, laboratory testing services sales and sales of raw materials to the life sciences industry. 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. 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. 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 based on 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.

Revenues by Product Line

Trinity Biotech's revenues for the year ended December 31, 2018 were US$97,035,000 compared to revenues of US$99,140,000 for the year ended December 31, 2017, which represents a decrease of US$2,105,000 or 2.1%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2018 US$'000	2017 US$'000	% Change
Revenues			
Clinical Laboratory	71,618	73,366	(2.4)%
Point-of-Care	14,836	16,774	(11.6)%
Laboratory Services	10,581	9,000	17.6%
Total	**97,035**	**99,140**	**(2.1)%**

Clinical Laboratory

Clinical Laboratory revenues decrease by US$1,748,000 in 2018, which represents a decrease of 2.4%. This decrease was mainly attributable to a 14% decrease in Infectious Diseases revenues. These tests are used to detect infectious and sexually transmitted diseases, and disorders of the liver and intestine. Revenues for these tests have been declining for several years, particularly in USA but we have succeeded in partially making up for these declines by selling more to emerging markets, with China being the largest market. Another factor was that a significant Lyme disease contract with one of the major clinical laboratory service providers in the US was lost. Partially offsetting these decreases was higher revenues for haemoglobin A1c testing, which increased by 4% compared to 2017.

Point-of-Care

Point-of-Care revenues decreased by US$1,938,000, which represents a reduction of 11.6%. Revenues for our Unigold HIV test in 2018 were down $1.9 million compared to 2017. Sales prices were relatively stable during 2018 and the reduction in point-of-care revenues arose in the African market, where sales are more erratic and variable in nature and was in a large part due to overstocking in one of the larger countries in which we operate. In the Americas, HIV revenues in USA declined slightly but this was offset by a strong performance in Latin America.

Laboratory Services

We offer laboratory-testing services for autoimmune disorders from our lab in Buffalo, New York. In recent years, there has been a growing demand for autoimmune diagnostic testing and this growth accelerated in 2018 with laboratory services revenues recording a 17.6% increase equating to US$1,581,000. Revenues for Sjögrens Syndrome accounts for 23% of the total revenues.

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,		
	2018 US$'000	2017 US$'000	% Change
Revenues			
Americas	57,559	59,539	(3.3)%
Asia/Africa	29,466	27,131	8.6%
Europe	10,010	12,470	(19.7)%
Total	**97,035**	**99,140**	(2.1)%

In the Americas, revenues decreased US$1,980,000 or 3.3% due to the multi-year trend of falling sales of infectious diseases tests in the USA. In addition, a significant Lyme disease contract with one of the major clinical laboratory service providers in the US was lost in 2018. These declines were partially offset by strong growth (17.6%) in laboratory testing revenues from our autoimmune reference laboratory, higher point-of-care revenues in Latin America and higher revenues from our diabetes testing business, although the increase was impacted negatively by a marked weakness in the Brazilian currency.

Asia/Africa revenues increased by 8.6%, or US$2,335,000 compared to 2017. The main reasons for this was increased revenues for haemoglobin A1c in Asia/Middle East and higher revenues in Asia for our Fitzgerald business, which sells antibodies to the life sciences and research industries. Haemoglobin A1c revenues in the territory were driven by continued strong demand for our diabetes analyser, the Premier. These increases were partially offset by lower HIV sales in Africa due to erratic ordering patterns and was contributed to by the impact of significant overstocking by one larger customer that occurred during 2017.

In Europe, revenues decreased by 19.7% or US$2,460,000, compared to 2017. The decrease was due to lower haemoglobin A1c revenues mainly caused by one major European customer purchasing significantly fewer instruments due to overstocking in the previous year. There was also lower sales of infectious diseases revenues in the territory.

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

3. Operating Loss – continuing operations

The following table sets forth the Group's operating loss from continuing operations:

	Year ended December 31,		
	2018 US$'000	2017 US$'000	% Change
Revenues	97,035	99,140	(2.1)%
Cost of sales	(55,586)	(57,250)	(2.9)%
Gross profit	41,449	41,890	(1.1)%
Other operating income	102	100	2.0%
Research & development	(5,369)	(5,657)	(5.1)%
SG&A expenses	(29,477)	(32,246)	(8.6)%
Selling, general and administrative expenses - impairment charges and inventory write-off/provision	(26,932)	(41,755)	(35.5)%
Operating loss on continuing operations	**(20,227)**	**(37,668)**	**(46.3)%**

Cost of sales and gross margin

Total cost of sales decreased by US$1,664,000 from US$57,250,000 for the year ended December 31, 2017 to US$55,586,000, for the year ended December 31, 2018, a decrease of 2.9%. The gross margin of 42.7% in 2018 compares to a gross margin of 42.3% in 2017. The increase in gross margin in 2018 is mainly attributable to cost savings implemented during the year and a lower depreciation charge. Both of these factors outweighed the negative impact of lower point-of-care and Lyme revenues.

Other operating income

In 2018, other operating income mainly comprises income from the provision of canteen services recognised under a Transitional Services Agreement with Diagnostica Stago. Other operating income increased by 2% to US$102,000 mainly due to currency movements.

Research and development expenses ("R&D")

Research and development expenditure recorded in the Statement of Operations decreased from US$5,657,000 in 2017 to US$5,369,000 in 2018. The decrease in 2018 is mainly due to some non-recurring regulatory costs in 2017. For details of the Company's various R&D projects see "Research and Products under Development" below.

Selling, General & Administrative expenses ("SG&A")

Total SG&A expenses decreased by US$2,769,000 from US$32,246,000 for the year ended December 31, 2017 to US$29,477,000 for the year ended December 31, 2018.

The following table outlines the breakdown of SG&A expenses in 2018 compared to 2017.

	Year ended December 31,		
	2018 US$'000	2017 US$'000	% Change
SG&A (excl. share-based payments and amortisation)	25,317	28,050	(9.7)%
Share-based payments	1,335	893	(49.5)%
Amortisation	2,825	3,303	(14.5)%
Total	**29,477**	**32,246**	**(8.6)%**

Selling General & Administrative Expenditure (excluding share-based payments and amortisation)

SG&A expenses excluding share-based payments and amortisation decreased from US$28,050,000 for the year ended December 31, 2017 to to US$25,317,000 for the year ended December 31, 2018, which represents a decrease of 9.7%. The decrease of US$2,733,000 is mainly attributable to:

- flood damage incident at one of our U.S. plants in 2017 (US$894,000),
- a settlement in relation to a licence royalty dispute in 2017 (US$497,000),
- a gain on the purchase of a portion of our exchangeable notes in 2018 (US$463,000),
- cost savings implemented in 2018 as part of a cost saving programme.

Share-based payments

The expense represents the fair value of share options granted to directors and employees, 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$1,369,000 (2017: US$928,000). The increase of US$441,000 in the total share-based payments expense is due to a larger number of share options being in their vesting period in 2018 compared to 2017. The total charge is shown in the following expense headings in the statement of operations: US$34,000 (2017: US$35,000) was charged against cost of sales and US$1,335,000 (2017: US$893,000) was charged against selling, general & administrative expenses.

For further details, refer to Item 18, Note 22 to the consolidated financial statements.

Amortisation

Amortisation decreased from US$3,303,000 for the year ended December 31, 2017 to US$2,825,000 for the year ended December 31, 2018. The decrease of US$478,000 is due to lower amortisation on development projects.

Selling, general and administrative expenses - impairment charges and inventory write-off/provision

Impairment charges of US$26,932,000 for the year ended December 31, 2018 are included in selling, general and administrative expenses. In 2017, impairment charges of US$41,755,000 were included in selling, general and administrative expenses. The Group carries out an annual impairment review of the asset valuations. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. A number of factors affected this calculation including:

- the Company's market capitalisation at the end of the year that was lower when compared to the end of 2017.
- the inclusion of the latest cash flow projections and net asset values for each cash generating unit; and
- increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

For further details, see Item 18, Notes 13, 14 and 18.

4. Loss for the year

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

	Year ended December 31,		
	2018 US$'000	**2017 US$'000**	**% Change**
Operating loss	(20,227)	(37,668)	(46.2)%
Net financing expense	(2,956)	(2,207)	33.9%
Loss before tax	(23,183)	(39,875)	(41.9)%
Income tax credit	525	1,214	(56.8)%
Loss for the year from continuing operations	**(22,658)**	**(38,661)**	**(41.4)%**

Net Financing income

Net financing expense was US$2,956,000 for the year-end December 31, 2018 compared to US$2,207,000 in 2017. Financial income decreased by US$1,074,000 from US$3,198,000 for the year-end December 31, 2017 to US$2,124,000 in 2018. There was a decrease of US$1,002,000 in the income arising from the revaluation of embedded derivatives at fair value and a decrease of US$72,000 in bank deposit interest due to the lower cash deposits.

Financial expenses decreased by US$325,000 to US$5,080,000 during 2018 mainly due to lower interest following the buyback of a portion of the exchangeable notes in the third quarter of 2018.

Taxation

The Group recorded a tax credit on continuing operations of US$525,000 for the year ended December 31, 2018 compared to a tax credit of US$1,214,000 for the year ended December 31, 2017. The 2018 tax credit comprises US$119,000 of current tax credit and US$406,000 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 amounted to US$22,658,000, compared to a loss of US$38,661,000 in 2017, representing a decrease of 41.4.%.

5. Discontinued operations

The Cardiac Point-of-Care operation was discontinued during 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 following table sets forth selected statement of operations data for each of the periods indicated.

	Year ended December 31,	
	2018	**2017**
	US$'000	**US$'000**
Profit/(Loss) on discontinued operations	568	(1,609)

The profit on discontinued operations is US$568,000 in year ended December 31, 2018, which mainly comprises recovery of taxes paid in Sweden by the cardiac point-of-care business Fiomi Diagnostics. A loss of US$1,609,000 was recorded in the year ended December 31, 2017 mainly due to the unwinding of Fiomi's accumulated foreign currency translation reserve. For further details, see Item 18, Note 10.

Liquidity and Capital Resources

Financing

The Group entered into finance lease arrangements with Allied Irish Bank in 2015 and 2018 and with Wells Fargo in 2018. The Group has no other bank borrowings. During 2015, the Group issued US$115,000,000 of exchangeable senior notes 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. In August 2018, the Group purchased US$15,100,000 of the exchangeable notes. The nominal amount of the debt after the purchase is US$99,900,000. The exchangeable note was issued in order to fund potential future acquisitions and for general corporate purposes, including continued product development and commercialization and share buyback.

To mitigate the financial impact of the Covid-19 outbreak, the Company has availed of governmental supports. This included the receipt of US$4.5 million of loans in 2020 under the U.S. government's Paycheck Protection Program ("PPP"). Under the provisions of the PPP, these loans will be partially or totally forgiven, based on the extent to which a borrower's workforce returns to normal levels in the eight-week period immediately following the loans being granted. Upon receipt of these loans, the Company ended the furloughing of all staff in the USA and therefore expects that a large percentage of these loans will be forgiven later in 2020, once the necessary verification has taken place.

Working capital

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. 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. While acknowledging that there will be a temporary decrease in revenues due to Covid-19, the company has taken measures to reduce expenditure, to obtain government pandemic supports in Ireland and USA and to exploit sales opportunities of products related to coronavirus. (For more information on the impact of Covid-19 – refer to Subsequent Events in Item 18, Note 31).

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;
- The ability of the Group to generate revenues from new products following the successful completion of its development projects;
- The extent to which capital expenditure is incurred on additional property plant and equipment;
- The level of investment required to undertake both new and existing development projects; and
- Successful working capital management in the context of a growing business.

Cash management

As at December 31, 2019, Trinity Biotech's consolidated cash and cash equivalents and short term investments were US$15,231,000 and US$1,169,000 respectively. This compares to cash and cash equivalents and short-term investments of US$30,277,000 and US$nil respectively at December 31, 2018.

Cash generated from operations for the year ended December 31, 2019 amounted to US$5,875,000 (2018: US$5,978,000), a decrease of US$103,000. The decrease in cash generated from operations of US$103,000 is attributable to a decrease in working capital outflows of US$5,028,000 and a decrease in operating cash flows before changes in working capital of US$5,131,000. The decrease in operating cash flows before changes in working capital of US$5,131,000 is primarily driven by the increase in operating loss before impairment losses during the current financial year. The working capital outflow decrease, when compared to the prior year, is due to an increase in trade and other payables of US$3,570,000 and an increase in cash outflows for inventories of US$4,947,000 offset by the decrease in cash outflows for trade and other receivables of US$6,405,000.

The cash generated from operations was mainly attributable to an operating loss of US$24,112,000 (2018: loss of US$20,227,000), as adjusted for non cash items of US$32,273,000 (2018: US$33,618,000) plus cash outflows due to changes in working capital of US$2,363,000 (2018: cash outflows of US$7,391,000).

Other non-cash charges decreased from US$33,618,000 for the year ended December 31, 2018 to US$32,273,000 for the year ended December 31, 2019. Once off charges in 2019 are mainly attributable to the impairment of intangible assets (US$16,570,000), property, plant and equipment (US$6,349,000) and prepayments (US$1,376,000).

The net cash outflows in 2019 due to changes in working capital of US$2,363,000 are due to the following:

- An decrease in trade and other receivables of US$445,000 partially due to the decrease, year on year, in the debtors days number;
- An increase in trade and other payables balance of US$151,000 due to timing of payments; and
- An increase in inventory of US$2,959,000 due to the strategic management of inventory levels during the course of the year.

Net interest received amounted to US$560,000 (2018: US$874,000). This included interest received of US$464,000 (2018: US$735,000) on the Group's cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2019 amounted to US$11,853,000 (2018: US$17,391,000) which were principally made up as follows:

- Payments to acquire intangible assets of US$9,718,000 (2018: US$9,863,000), 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$2,118,000 (2018: US$7,528,000) incurred as part of the Group's investment programme for its manufacturing and distribution activities, and placement of instruments.
- Disposal of property, plant and equipment of US$17,000 (2018: US$nil) incurred as part of the Group's investment programme for its manufacturing and distribution activities, and placement of instruments.

Net cash outflows from financing activities for the year ended December 31, 2019 amounted to US$7,529,000 (2018: outflows of US$16,872,000). This outflow is due to the payment of lease liabilities (US$3,533,000) and an Interest payment on exchangeable notes (US$3,996,000). In 2018 the outflow was primarily due to the purchase of exchangeable notes of $12,042,000 and interest payments related to exchangeable notes of $4,503,000. In 2018 payments of finance lease liabilities in the year were US$374,000, offset by the receipt of US$481,000 from sale and leaseback transactions.

The majority of the Group's transactions are conducted in US Dollars. The primary 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. The Group also faces foreign exchange risk from movement in the exchange rate between the US Dollar and British Sterling, Canadian Dollar and Brazilian Real. Trinity Biotech continuously monitors its exposure to foreign currency movements and expectations of future exchange rate exposure and, if deemed necessary, will cover a portion of this exposure through the use of forward contracts. When used, these forward contracts are cash flow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions.

For a more comprehensive discussion of the Group's use of financial instruments, its currency and interest rate structure and its funding and treasury policies please refer to Item 11 "Quantitative and Qualitative Disclosures about Market Risk".

Contractual obligations

The following table summarises our minimum contractual obligations and commercial commitments, including interest, as of December 31, 2019:

	Payments due by Period				
Contractual Obligations	Total US$'000	less than 1 year US$'000	1-2 Years US$'000	2-5 Years US$'000	more than 5 years US$'000
Exchangeable note*	99,900	—	—	—	99,900
Exchangeable note interest	101,898	3,996	3,996	11,988	81,918
Right of asset leases obligations	19,630	2,156	2,012	4,840	10,622
Sale and leaseback lease obligations	519	247	95	177	—
Total	221,947	6,399	6,103	17,005	192,440

* The exchangeable notes will mature in 2045, however, they can be called early on April 1, 2022 and other subsequent dates.

In the past, Trinity Biotech incurred debt and raised equity to pursue its policy of growth through acquisition. However, since the divestiture of the Coagulation product line in 2010, the Group has eliminated bank debt (with the exception of some equipment leasing) and has adequate cash resources. The Group raised US$110,529,000 (net of fees) during 2015 through the issuance of exchangeable loan notes (see Item 18, Note 25 for further information). The Group intends to grow organically for the foreseeable future and Trinity Biotech believes that it will have sufficient funds to meet its capital commitments and continue existing operations in to the future, in excess of 12 months. If the Group was to make a large and unanticipated cash outlay, the Group would have further funding requirements which could be met through access to equity and debt markets.

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.

Off-Balance Sheet Arrangements

After consideration of the following items the Group's management have determined that there are no off-balance sheet arrangements which need to be reflected in the financial statements.

Leases with Related Parties

The Group has entered into lease arrangements for premises in Ireland with JRJ Investments ("JRJ"), a partnership currently owned by Mr O'Caoimh and Dr Walsh, directors of Trinity Biotech plc, and directly with Mr O'Caoimh. When entering into the lease arrangements, independent valuers have advised Trinity Biotech that the rent fixed with respect to these leases represents a fair market rent. Details of these leases with related parties are set out in Item 4 "Information on the Company", Item 7 "Major Shareholders and Related Party Transactions" and Item 18, Note 28 to the consolidated financial statements.

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 2019, a number of third party consultants and contractors were engaged to assist with development projects, working principally on the Autoimmune Smart Reader project. The total amount paid to these R&D consultants and contractors in 2019 was US$1,285,000 (2018: US$363,000).

Research and Products under Development

Trinity Biotech has research and development groups focusing separately on haemoglobin products, infectious diseases and autoimmune products. During 2019, 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 2019:

Product Name	***2019*** ***US$'000***	***2018*** ***US$'000***	***Total project costs to December 31, 2019*** [1] ***US$'000***
HIV screening rapid test	2,587	1,657	8,474
Premier Instrument for Haemoglobin A1c testing	1,930	2,653	32,027
Autoimmune Smart Reader	1,325	746	2,071
Syphilis point-of-care test	870	454	1,324
Uni-Gold antigen improvement	691	453	2,362
G-6-PDH test	582	850	2,244
Uni-gold test enhancement	376	796	4,718
Tri-stat Point-of-Care instrument	361	727	9,029

[1] Cumulative costs to December 31, 2019 are shown before deduction of amortization and impairment losses.

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.

The following table sets forth the estimated cost to complete each of the main development projects which were underway in 2019 and not yet completed. The total estimated completion costs are anticipated to be incurred evenly up to the completion date of the relevant project.

Product Name	***Total estimated cost to complete*** ***US$'000***	***Estimated date for completion***
Premier Instrument for Haemoglobin A1c testing[2]	900	2020
HIV screening rapid test	1,250	2020
Autoimmune Smart Reader	1,315	2021

[2] The cost to complete the Premier Instrument does not include the cost of developing the Premier 9210 v2.0.

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 this phase 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. If major development projects were severely delayed, in the opinion of Trinity Biotech it would not impact significantly on Trinity Biotech's financial position or on the capitalisation criteria. 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 followed by within the United States in early 2012.

As part of our continuous improvement a new monitor, key board and frit housing have been customised and validated. These improvements maintain the competiveness of the instruments. Looking forward, the Premier Hb9210 v2.0 is in the initial stages and design with an expected release date of mid-2021 and will feature a new faster and more advanced column.

Premier Resolution Instrument for Haemoglobin Variant Testing

The company has 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. The company intends submitting it to the FDA for clearance later in 2020. Meanwhile, Premier Resolution continues to be enhanced with unique features such as lot specific gradients, an optimised internally developed 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 being targeted at 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.

Low to Medium throughput Haemoglobin instrument for A1c Testing

The company is 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. The company is targeting a launch date of 2021.

Point-of-Care Development Group

Trinity Biotech is in the process of developing point-of-care tests for the detection of HIV (TrinScreen) for the HIV screening market in Africa. The product which was developed at the company's Carlsbad facility is currently in its clinical trials phase after which the product will be submitted to the World Health Organisation for approval.

Autoimmunity Development Group

IFA Smart Reader Project

The company is 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.

Covid-19 Tests

In response to the Covid-19 pandemic, the company has commenced the development of tests for the detection of antibodies to Covid-19.

Trend Information

For information on trends in future operating expenses and capital resources, see "Results of Operations" and "Liquidity and Capital Resources" under Item 5.

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

Directors

Name	*Age*	*Title*
Ronan O'Caoimh	64	Chairman and Chief Executive Officer
Jim Walsh, PhD	61	Executive Director
Kevin Tansley	49	Executive Director, Chief Financial Officer & Company Secretary
Denis R. Burger, PhD	76	Non Executive Director / Lead Director
Clint Severson	71	Non Executive Director
James D. Merselis	66	Non Executive Director

Board of Directors & Executive Officers

The Directors of the Company as of the date of this Annual Report are:

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 and is a Fellow of the Institute of Chartered Accountants in Ireland. 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 in Chemistry from University College Galway.

Kevin Tansley, Chief Financial Officer, 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. 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 from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland**.**

Denis R. Burger, PhD, Non-executive director, co-founded Trinity Biotech in June 1992 and acted as Chairman from June 1992 to May 1995. He is currently lead director of Aptose Biosciences, Inc, a cancer therapeutics, TSX and NASDAQ listed company. Until March 2007, Dr Burger was the Chairman and Chief Executive Officer of AVI Biopharma Inc, a NASDAQ listed biotechnology company. He was also a co-founder and, from 1981 to 1990, Chairman of Epitope Inc. In addition, Dr Burger has held a professorship in the Department of Microbiology and Immunology and Surgery (Surgical Oncology) at the Oregon Health and Sciences University in Portland. Dr Burger received his degree in Bacteriology and Immunology from the University of California in Berkeley in 1965 and his Master of Science and PhD in 1969 in Microbiology and Immunology from the University of Arizona.

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 experience in the medical diagnostics industry. Mr Severson is also on the board of Cutera.

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 newly formed 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; and Abram Scientific Inc., a coagulation diagnostics company located in Palo Alto, California. 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).

Compensation of Directors and Officers

The basis for the executive directors' remuneration and level of annual bonuses is determined by the Remuneration Committee of the board. In all cases, bonuses and the granting of share options are subject to stringent performance criteria. The Remuneration Committee consists of Dr Denis Burger (committee chairman and lead director), Mr Clint Severson and Mr James Merselis. Directors' remuneration shown below comprises salaries, pension contributions and other benefits and emoluments in respect of executive directors. Non-executive directors are remunerated by fees and the granting of share options. The fees payable to non-executive directors are determined by the board. Each director is reimbursed for expenses incurred in attending meetings of the board of directors.

Total directors and non-executive directors' remuneration, excluding pension, for the year ended December 31, 2019 amounted to US$1,238,000. The pension charge for the year amounted to US$42,000. See Item 18, Note 4 to the consolidated financial statements. The split of directors' remuneration set out by director is detailed in the table below:

Executive Director	*Salary/ Benefits US$'000*	*Performance related bonus US$'000*	*Defined contribution pension US$'000*	*Total 2019 US$'000*	*Total 2018 US$'000*
Ronan O'Caoimh[1]	425	—	—	425	585
Jim Walsh	—	—	—	—	9
Kevin Tansley	375	213	42	630	523
	800	213	42	1,055	1,117

Non-executive Director	*Fees US$'000*	*Total 2019 US$'000*	*Total 2018 US$'000*
Denis R. Burger	75	75	—
Peter Coyne[2]	—	—	38
James Merselis	75	75	75
Clint Severson	75	75	75
	225	225	188

As at December 31, 2019 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2018: NIL).

The total share-based compensation expense recognised in the consolidated statement of operations in 2019 in respect of options granted to both executive and non-executive directors amounted to US$624,000. See Item 18, Note 11 to the consolidated financial statements.

There were no 'A' share options granted to the directors during 2019.

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

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1 Represents payments to Ronan O'Caoimh for director fees and to Darnick Company in respect of CEO services.
2 Peter Coyne resigned as Non-executive Director on June 5, 2018.

Directors' Service Contracts

The Company has entered into service contracts with its Executive Directors and Officers. These contracts contain certain termination provisions which are summarised below.

On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by an agreement with Darnick Company, a company wholly-owned by members of Mr O'Caoimh's immediate family. Pursuant to the agreement, Darnick Company will provide the Company with the services of Mr O'Caoimh as Chief Executive Officer. The agreement contains certain non-competition and confidentiality provisions. The term of the agreement will continue until such time as it is terminated by either party, subject to the Company providing one year's notice. Where termination occurs within 12 months of a change of control of the Company, two year's notice will apply. Darnick Company may terminate the agreement on six months' notice. Mr O'Caoimh remains as Chairman of the Board of Directors. This arrangement ceased with effect from December 31, 2018 with Ronan O'Caoimh returning as an employee of the company.

Under the terms of his service contract, Kevin Tansley, Chief Financial Officer, is entitled to 12 months salary and benefits in the event of termination by the Company. Where termination arises within 12 months of a change in control of the Company, Mr. Tansley is entitled to 18 months salary and benefits.

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 Dr. Denis Burger (committee chairman and lead director), Mr Clint Severson 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 two of the three 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. The Group's corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process and (b) the Audit Committee of the Group currently consists of two members (both of whom are non-executive directors) – while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee and be comprised only of independent directors.

Employees

During 2019, Trinity Biotech had an average of 579 employees (2018: 575) consisting of 57 research scientists and technicians, 363 manufacturing and quality assurance employees, and 159 finance, administration, sales and marketing staff (2018: 59 research scientists and technicians, 353 manufacturing and quality assurance employees, and 163 finance, administration, sales and marketing staff). Trinity Biotech's future hiring levels will depend on the growth of revenues.

The geographic spread of the Group's average employees is as follows: 334 in our U.S. operations, 215 in Bray, Ireland, 2 in the UK and 28 in Sao Paulo, Brazil.

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 2017 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 February 28, 2020, 10,414,000 (2,603,500 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 Option
Ronan O'Caoimh*	266,667	66,667	2.43	9.73	24/02/2023
	266,667	66,667	2.43	9.73	24/02/2023
	266,666	66,667	2.43	9.73	24/02/2023
	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
Denis Burger	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
	321,000	80,250	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
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
Kevin Tansley	166,667	41,667	2.43	9.73	24/02/2023
	166,667	41,667	2.43	9.73	24/02/2023
	166,666	41,667	2.43	9.73	24/02/2023
	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
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
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

*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 February 28, 2020 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	12,303,990	US$0.46-US$4.36	US$1.83-US$17.45

As of February 28, 2020 there were no warrants to purchase 'A' Ordinary Shares in the Company outstanding.

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

As of February 28, 2020 Trinity Biotech has outstanding 96,162,410 'A' Ordinary shares. Such totals exclude 12,303,990 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2020, the Trinity Biotech 'A' Ordinary Shares beneficially held by (i) each person believed by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and the Company Secretary of Trinity Biotech, and (iii) all directors and the Company Secretary as a group.

Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Group is not controlled by another corporation or government.

	Number of 'A' Ordinary Shares Beneficially Owned	**Number of ADSs Beneficially Owned**	**Percentage 'A' Ordinary Shares (8)**	**Percentage Total Voting Power**
Stonehill Capital Management, LLC	12,010,288	3,002,572	11.1%	11.1%
Paradice Investment Management, LLC	6,172,460	1,543,115	5.7%	5.7%
Hunter Associates, Inc.	5,918,000	1,479,500	5.5%	5.5%
Ronan O'Caoimh	14,161,496(1)	3,540,374	13.1%	13.1%
Jim Walsh	2,303,611(2)	575,903	2.1%	2.1%
Denis Burger	496,000(3)	124,000	0.5%	0.5%
Clint Severson	558,000(4)	139,500	0.5%	0.5%
James Merselis	458,600(5)	114,650	0.4%	0.4%
Kevin Tansley	1,514,000(6)	378,500	1.4%	1.4%
Directors & Co. Secretary as a group (6 persons)	19,491,707(1)(2)(3)(4)(5)(6)(7)	4,872,927	18.0%	18.0%

(1) Includes 7,104,000 'A' Ordinary shares issuable upon exercise of options issued to Darnick Company.
(2) Includes 910,000 'A' Ordinary shares issuable upon exercise of options. Note that 1,200,000 'A' Ordinary shares (300,000 ADSs) of Dr Walsh's shares are held in trust for the benefit of Dr Walsh's immediate family.
(3) Includes 496,000 'A' Ordinary shares issuable upon exercise of options.
(4) Includes 250,000 'A' Ordinary shares issuable upon exercise of options.
(5) Includes 250,000 'A' Ordinary shares issuable upon exercise of options.
(6) Includes 1,364,000 'A' Ordinary shares issuable upon exercise of options.
(7) Percentage 'A' Ordinary shares is based upon total outstanding 'A' Ordinary shares and total number of shares issuable upon exercise of options.

Related Party Transactions

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$427,000) 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$883,000) and the annual rent for the warehouse is €144,000 (US$162,000). 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.

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.

Darnick Company is wholly-owned by members of Mr. O'Caoimh's immediate family. 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. Pursuant to the agreement, Darnick Company provides Trinity Biotech with the services of Mr O'Caoimh as Chief Executive Officer. In 2019, the Group paid US$425,000 to Darnick Company in respect of compensation for provision of CEO services.

Rayville Limited, an Irish registered company, which is wholly owned by the three executive directors and certain other executives of the Group, owns all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries. The 'B' shares do not entitle the holders thereof to receive any assets of the company on a winding up. All of the 'A' voting ordinary shares in Trinity Research Limited are held by the Group. Trinity Research Limited may, from time to time, declare dividends to Rayville Limited and Rayville Limited may declare dividends to its shareholders out of those amounts. Any such dividends paid by Trinity Research Limited are ordinarily treated as a compensation expense by the Group in the consolidated financial statements prepared in accordance with IFRS, notwithstanding their legal form of dividends to minority interests, as this best represents the substance of the transactions.

The last dividend paid by Trinity Research Limited to Rayville Limited was in June 2009 for US$2,830,000. At the time, this amount was immediately lent back by Rayville Limited to Trinity Research Limited. Since then US$1,788,000 of these loans have been repaid and recognised as a compensation expense by the Group. As of December 31, 2017 and December 31, 2018, the remaining amount of the loan was US$1,042,000. As this remaining amount of the original dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2017 and 2018 consolidated financial statements. During 2019, Trinity Research Limited repaid loans to Rayville Limited of US$159,000 in order to meet its obligations under a tax settlement arising from a tax audit.

The amount of payments to Rayville included in compensation expense was US$Nil for 2019, 2018, 2017 and 2016. There were no dividends payable to Rayville Limited as at December 31, 2019, 2018, 2017 or 2016.

Arising out of a tax audit in one of the jurisdictions in which the company operates, the Company reached a tax settlement of US$6,442,000 in the year end December 31, 2019. The tax audit concluded in late December 2019 and the payment of the settlement amount was made prior to the financial year end. 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. Interest was US$1,000,000 and penalties were US$273,000. The total settlement of US$6,442,000 was partially offset by a provision of US$400,000, resulting in an expense of US$6,042,000. Darnick Company agreed to contribute US$1,231,000 to the above settlement and this amount was outstanding at December 31, 2019 and treated as a contingent asset at year end.

Item 8 ***Financial Information***

Legal Proceedings

In 2017, a dispute arose over the application of the terms of a licence agreement to which the Company is a party. Rather than undergo a lengthy and costly legal dispute, both parties reached a mutually acceptable agreement. In 2018, both parties signed an agreement that extends the term of the licence and settles the dispute in relation to past royalties. The settlement costs were included in consolidated statement of operations in the year ended December 31, 2017.

In 2008 Trinity Biotech filed a civil suit with a New York court against the former shareholders of Primus Corporation. Trinity Biotech claimed that the defendants unjustly received an overpayment of US$512,000 based on the fraudulent and wrongful calculation of the earnout payable to the shareholders of Primus Corporation. Trinity Biotech also alleged that one of the former shareholders, Mr Thomas Reidy, failed to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of a US$3 million promissory note given to the defendants by Trinity Biotech as part of compensation under the share purchase agreement for acquiring Primus. During 2009, all of the defendants with the exception of Mr. Reidy settled the legal action. The US District Court, Southern District of New York granted a judgment against Mr. Reidy ordering him to pay Trinity damages of US$200,000 plus interest and to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of the US$3 million promissory note. Mr Reidy has paid Trinity Biotech US$5,000 to date.

There are also a small number of legal cases being brought against the Group by certain of its former employees. There is a provision for cases where payment is considered by management to be probable.

The ultimate resolution of the aforementioned proceedings is not expected to have a material adverse effect on our financial position, results of operations or cash flows.

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

Trinity Biotech's ADSs are listed on the NASDAQ Global Market under the symbol "TRIB". In 2005, Trinity Biotech adjusted the ratio of ADSs to Ordinary Shares and changed its NASDAQ Listing from the NASDAQ Small Capital listing to a NASDAQ National Market Listing. The ratio of ADSs to underlying Ordinary Shares has changed from 1 ADS : 1 Ordinary Share to 1 ADS : 4 Ordinary Shares and all historical data has been restated as a result.

The Group's 'A' Ordinary Shares were also listed and traded on the Irish Stock Exchange until November 2007, whereby the Company de-listed from the Irish Stock Exchange. The Group's depository bank for ADSs is The Bank of New York Mellon. On February 28, 2020, the reported closing sale price of the ADSs was US$1.43 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech's ADSs for (a) the years ended December 31, 2015, 2016, 2017, 2018 and 2019; (b) the quarters ended March 31, June 30, September 30 and December 31, 2018; March 31, June 30, September 30 and December 31, 2019; and (c) the months of March, April, May, June, July, August, September, October, November and December 2019 and January and February 2020 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

ADSs

Year Ended December 31	High	Low
	US$	US$
2015	20.24	10.74
2016	13.68	5.76
2017	7.04	4.50
2018	6.06	2.14
2019	3.22	0.69

ADSs

2019	High	Low
	US$	US$
Quarter ended March 31	3.22	2.31
Quarter ended June 30	3.02	1.57
Quarter ended September 30	2.59	1.21
Quarter ended December 31	1.20	0.69

ADSs

Month Ended	High	Low
March 31, 2019	3.22	2.40
April 30, 2019	3.02	2.68
May 31, 2019	2.83	2.15
June 30, 2019	2.16	1.57
July 31, 2019	2.59	1.63
August 31, 2019	2.22	1.30
September 30, 2019	1.42	1.21
October 31, 2019	1.20	0.69
November 30, 2019	1.03	0.80
December 31, 2019	1.09	0.92
January 31, 2020	1.47	1.03
February 28, 2020	1.43	0.95
March 31, 2020	1.40	0.62
April 30, 2020	1.59	0.88
May 31, 2020	1.77	1.26

The number of record holders of Trinity Biotech's ADSs as at February 28, 2020 amounts to 439, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clients (with each such brokerage house and/or clearing house being considered as one holder).

Item 10 ***Additional Information***

The following is a summary of certain provisions of the Articles of Association of Trinity Biotech plc. This summary does not purport to be complete and is qualified in its entirety by reference to the complete text of the Articles, which are 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 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 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. 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, that shareholder or person may be served with a disenfranchisement notice and may thereby be restricted from transferring the shares and exercising the voting rights or receiving any sums in respect of the shares (except in the case of a liquidation).

In addition, if cheques in respect of the last three dividends paid to a shareholder 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, 21 clear days' notice of the meeting is required and in any other case 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 "Exchange Controls" below. 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.

The Company incorporates by reference all other information concerning its Memorandum and Articles of Association from the Registration Statement on Form F-1 on June 12, 1992.

Irish Law

As required by the Companies Act 2014, all of Trinity Biotech's private limited companies incorporated in Ireland (refer to Item 18, Note 32) have been converted into the new form of private limited company. 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 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 financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the Company (changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office (the "CRO") in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be 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.

Ordinarily, our directors owe their duties only to Trinity Biotech and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to Trinity Biotech. Those duties include duties to act in good faith towards Trinity Biotech in any transaction, not to make use of any money or other property of Trinity Biotech, not to gain directly or indirectly any improper advantage for himself at the expense of Trinity Biotech, to act bona fide in the interests of Trinity Biotech and exercise powers for the proper purpose. A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. 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 fiduciary 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 lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to Trinity Biotech for profit made and restriction of the director from acting as a director in the future.

Material Contracts

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

Acquisition of Immco Diagnostics Inc

In 2013, the Group purchased 100% of the common stock of Immco Diagnostics Inc for a total consideration of US$32.88m. Immco, which is headquartered in Buffalo, New York, is a diagnostic company specialising in the development, manufacture and sale of autoimmune test kits on a worldwide basis.

The key terms of the acquisition are as follows:

- Cash consideration of US$31,652,000;
- Issuance of share option as at the acquisition date with a fair value of US$1,121,000; and
- The transfer of 5,566 Trinity Biotech ADSs as at the acquisition date (fair value of US$110,000).

Acquisition of Fiomi Diagnostics AB

In 2012, the Group purchased 100% of the common stock of Fiomi Diagnostics AB for a total consideration of US$12.9 million (including US$3.2m of contingent payments – net of interest of US$0.2m).

The key terms of the acquisition are as follows:

- An up-front cash payment of US$5.6m;
- The transfer of 408,000 Trinity Biotech ADSs as at the acquisition date (fair value of US$4.1m); and
- Contingent cash consideration (net present value) of US$3.2m.

Exchange Controls and Other Limitations Affecting Security Holders

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of Ireland dealing in domestic securities, which includes shares or depositary receipts of Irish companies such as Trinity Biotech. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to make provision for the restriction of financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of ADSs or ADRs representing shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition.

At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People's Republic of Korea (North Korea), Iran, Iraq, Côte d'Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbour 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 by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. We do not anticipate that orders under the Financial Transfers Act, 1992 or United Nations sanctions implemented into Irish law will have a material effect on our business.

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 will 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 statements expressed 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 a resident of the United States; a corporation created or organised in or under the laws of the United States 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 United States and the control of 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 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 voting shares, 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 which 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 such 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 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 ordinary shares 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 2018, it is 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 in the year in which the excess distribution is made, but it would be subject to tax at the highest tax rate applicable to the U.S. Holder in the prior tax year or years. 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 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 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, will be treated as capital, and the interest penalty will not be imposed. This election is not made by Trinity Biotech, but by each U.S. Holder. Trinity Biotech must provide certain information to the U.S. Holder in order to qualify as a QEF. U.S. Holders should contact their tax advisor for further information on this area.

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 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 depreciated below the U.S. Holders 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. individuals (and, under proposed regulations, certain entities) 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 our ordinary shares.

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 National 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.

Dividend Policy

In 2011, the Board decided that it was an appropriate time to pay a dividend for the first time in the Company's history. The Board proposed a final dividend of 22 cents per ADS in respect of the 2014 financial year and this proposal was approved by the shareholders at the 2015 Annual General Meeting of the Company and subsequently paid during the course of 2015. A dividend of 22 cents per ADS was approved and paid in 2014, in respect of the 2014 financial year. A dividend of 20 cents per ADS was approved and paid in 2013, in respect of the 2012 financial year. A dividend of 15 cents per ADS was approved and paid in 2012, in respect of the 2011 financial year. A dividend of 10 cents per ADS was approved and paid in 2011, in respect of the 2010 financial year. Dividends or other distributions are declared and paid in US Dollars. Any future cash dividends will depend upon the Company's results of operations, financial condition, cash requirements, availability of surplus and such other factors as the Board of Directors may deem relevant, and will be subject to approval by the Company's shareholders. Accordingly, there can be no assurance that a dividend will be declared each year or that, if a dividend is declared, it will be comparable with the one declared the previous year. In March 2016, the Company announced that it was suspending its dividend and that a share buyback program would be commenced.

Documents on Display

This annual report and the exhibits thereto and any other document that we have to file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549; and on the Securities and Exchange Commission Internet site (http://www.sec.gov). You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the Securities and Exchange Commission at 1-800-SEC-0330 or by visiting the Securities and Exchange Commission's website at http://www.sec.gov, and may obtain copies of our filings from the public reference room by calling (202) 551-8090. The Exchange Act file number for our Securities and Exchange Commission filings is 000-22320. The information on our website is not incorporated by reference into this annual report.

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 loss before tax for 2019 by approximately 0.3%.

Exchange rate sensitivity

At year-end 2019, 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$7,282,000. In previous years, this amount has typically been a net asset, but the adoption of IFRS 16*, Leases*, has resulted in significant Euro-denominated liabilities being included on the Balance Sheet for the first time.

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 2019 year-end net worth by US$728,000.

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, 2019 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, 2019 year-end borrowings totalled US$102,174,000 (2018: US$82,344,000) (2017: US$93,841,000) at interest rates of 4.00% to 5.51% (2018: 4.00% to 5.51%) (2017: 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. At December 31, 2014 the Group had no borrowings. See Item 18, Note 29.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$78,000 (2018: US$234,000) and would not affect the interest expense in 2019 or 2018; resulting in an increase in interest income of US$78,000 (2018: US$234,000).

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro and Brazilian Real denominated expenses as a result of the movement in the exchange rate between the US Dollar and those currencies. 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 cashflow 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, 2019.

The Group had foreign currency denominated cash balances equivalent to US$4,045,000 at December 31, 2019 (2018: US$3,052,000).

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

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, 2019.

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, 2019.

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, 2019.

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

16A 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.

This determination is made on the basis that Mr Merselis has extensive experience in advising public and private groups on all aspects of corporate strategy.

16B Code of Ethics

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

16C Principal Accountant Fees and Services

Fees Billed by Independent Public Accountants

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

	Year ended December 31, 2019		*Year ended December 31, 2018*	
	US$'000	*US$'000*	*US$'000*	*%*
Audit	508	67%	562	97%
Audit-related	-	-%	-	-%
Tax	248	33%	17	3%
Total	756		579	

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 due diligence related to acquisitions and any special procedures required to meet certain regulatory requirements. Tax fees consist of fees for professional services for tax compliance and tax advice.

Pre-Approval Policies and Procedures

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

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

16D Exemptions from the Listing Standards for Audit Committees

Not applicable.

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

On March 3, 2011 the Company announced its intention to commence a Share Buyback Program for the first time in the Company's history. Under the authority given by the passing of Resolution 4 at the 2018 AGM, the maximum number of shares that may yet be purchased by Trinity Biotech or on the Group's behalf at December 31, 2019 was 20,901,703 (5,225,426 ADSs) (2018: 20,901,703 (5,225,426 ADSs)).

Share Buyback

Trinity Biotech did not purchase any of its own shares during 2019. During 2018, 107,740 shares 'A' Ordinary Shares (26,935 ADSs) were purchased by Trinity Biotech or on the Group's behalf (2017: 5,374,692).

16 F Change in Registrant's Certifying Accountant

Not applicable.

16 G Corporate Governance

As 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. The Group's corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process. At present, the Board as a whole address the nominations process; and (b) the Audit Committee of the Group currently consists of two members (both of whom are independent non-executive directors) – while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee.

16 H Mine Safety Disclosure

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***

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 statement of financial position of Trinity Biotech plc and its subsidiaries (the "Company") as of December 31, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 supporting 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.

/s/ GRANT THORNTON

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

Dublin, Ireland

June 15, 2020

CONSOLIDATED STATEMENT OF OPERATIONS

	Notes	Year ended December 31 2019 Total US$'000	2018 Total US$'000	2017 Total US$'000
Revenues	2	**90,435**	**97,035**	**99,140**
Cost of sales		**(52,315)**	**(55,586)**	**(57,250)**
Gross profit		**38,120**	**41,449**	**41,890**
Other operating income	5	**91**	**102**	**100**
Research and development expenses		**(5,325)**	**(5,369)**	**(5,657)**
Selling, general and administrative expenses		**(27,661)**	**(29,477)**	**(32,246)**
Selling, general and administrative expenses – tax audit settlement	6	**(5,042)**	**-**	**-**
Impairment charges	7	**(24,295)**	**(26,932)**	**(41,755)**
Operating loss		**(24,112)**	**(20,227)**	**(37,668)**
Financial income	2,8	**697**	**2,124**	**3,198**
Financial expenses	2, 8	**(6,582)**	**(5,080)**	**(5,405)**
Net financing expense		**(5,885)**	**(2,956)**	**(2,207)**
Loss before tax	11	**(29,997)**	**(23,183)**	**(39,875)**
Total income tax credit	2, 9	**1,006**	**525**	**1,214**
Loss for the year on continuing operations	2	**(28,991)**	**(22,658)**	**(38,661)**
Profit/(Loss) for the year on discontinued operations	10	**77**	**568**	**(1,609)**
Loss for the year (all attributable to owners of the parent)	2	**(28,914)**	**(22,090)**	**(40,270)**
Basic loss per ADS (US Dollars) – continuing operations	12	(1.39)	(1.08)	(1.79)
Diluted loss per ADS (US Dollars) – continuing operations	12	(1.39)	(1.08)	(1.79)
Basic loss per 'A' ordinary share (US Dollars) –continuing operations	12	(0.35)	(0.27)	(0.45)
Diluted loss per 'A' ordinary share (US Dollars) – continuing operations	12	(0.35)	(0.27)	(0.45)
Basic loss per ADS (US Dollars) – group	12	(1.38)	(1.06)	(1.86)
Diluted loss per ADS (US Dollars) – group	12	(1.38)	(1.06)	(1.86)
Basic loss per 'A' ordinary share (US Dollars) – group	12	(0.35)	(0.26)	(0.47)
Diluted loss per 'A' ordinary share (US Dollars) –group	12	(0.35)	(0.26)	(0.47)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Year ended December 31		
	Notes	*2019 US$'000*	*2018 US$'000*	*2017 US$'000*
Loss for the year	2	(28,914)	(22,090)	(40,270)
Other comprehensive (loss)/income				
Items that will be reclassified subsequently to profit or loss				
Foreign exchange translation differences		(167)	(520)	3,086
Other comprehensive (loss)/income		(167)	(520)	3,086
Total Comprehensive Loss (all attributable to owners of the parent)		**(29,081)**	**(22,610)**	**(37,184)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	At December 31 2019 US$'000	At December 31 2018 US$'000
ASSETS			
Non-current assets			
Property, plant and equipment	13	9,290	5,362
Goodwill and intangible assets	14	43,654	52,951
Deferred tax assets	15	6,252	6,127
Other assets	16	485	558
Total non-current assets		**59,681**	**64,998**
Current assets			
Inventories	17	32,021	30,359
Trade and other receivables	18	20,987	24,441
Income tax receivable		1,982	1,584
Cash and cash equivalents	19	15,231	30,277
Short term investments	20	1,169	-
Total current assets		**71,390**	**86,661**
TOTAL ASSETS	2	**131,071**	**151,659**
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the parent			
Share capital	21	1,213	1,213
Share premium	21	16,187	16,187
Treasury shares	21	(24,922)	(24,922)
Accumulated surplus	21	16,145	55,319
Translation reserve	21	(3,933)	(3,766)
Other reserves	21	23	23
Total equity		**4,713**	**44,054**
Current liabilities			
Income tax payable		48	210
Trade and other payables	23	16,947	16,908
Provisions	24	50	50
Lease liabilities	26	2,404	436
Total current liabilities		**19,449**	**17,604**
Non-current liabilities			
Exchangeable notes	25	82,021	81,382
Derivative financial instruments	25	4	238
Lease liabilities	26	17,745	526
Deferred tax liabilities	15	7,139	7,855
Total non-current liabilities		**106,909**	**90,001**
TOTAL LIABILITIES	2	**126,358**	**107,605**
TOTAL EQUITY AND LIABILITIES		**131,071**	**151,659**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

					Other reserves			
	Share capital 'A' ordinary shares US$'000	*Share premium US$'000*	*Treasury Shares US$'000*	*Translation reserve US$'000*	*Warrant reserve US$'000*	*Hedging reserves US$'000*	*Accumulated surplus US$'000*	*Total US$'000*
Balance at January 1, 2017	1,213	16,187	(17,327)	(6,332)	4,529	23	110,434	108,727
Loss for the period	-	-	-	-	-	-	(40,270)	(40,270)
Other comprehensive income	-	-	-	3,086	-	-	-	3,086
Total comprehensive income/(loss)	-	-	-	3,086	-	-	(40,270)	(37,184)
Transfer of warrant reserve (Note 22)	-	-	-	-	(4,529)	-	4,529	-
Share-based payments (Note 22)	-	-	-	-	-	-	1,109	1,109
Shares purchased (Note 21)	-	-	(7,456)	-	-	-	-	(7,456)
Balance at December 31, 2017	**1,213**	**16,187**	**(24,783)**	**(3,246)**	**-**	**23**	**75,802**	**65,196**
Balance at January 1, 2018	1,213	16,187	(24,783)	(3,246)	-	23	75,802	65,196
Loss for the period	-	-	-	-	-	-	(22,090)	(22,090)
Other comprehensive income	-	-	-	(520)	-	-	-	(520)
Total comprehensive loss	-	-	-	(520)	-	-	(22,090)	(22,610)
Share-based payments (Note 22)	-	-	-	-	-	-	1,607	1,607
Shares purchased (Note 21)	-	-	(139)	-	-	-	-	(139)
Balance at December 31, 2018	**1,213**	**16,187**	**(24,922)**	**(3,766)**	**-**	**23**	**55,319**	**44,054**
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 (Note 22)	-	-	-	-	-	-	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**

CONSOLIDATED STATEMENT OF CASH FLOWS

	Notes	Year ended December 31, 2019 US$'000	2018 US$'000	2017 US$'000
Cash flows from operating activities				
Loss for the year		(28,914)	(22,090)	(40,270)
Adjustments to reconcile net loss to cash provided by operating activities:				
Depreciation	11	2,526	1,296	1,896
Amortisation	11,14	2,368	2,825	3,303
Income tax (credit) / expense		(1,006)	(1,115)	(374)
Financial income	8	(697)	(2,124)	(3,198)
Financial expense	8	6,582	5,080	5,405
Share-based payments	22	758	1,369	928
Foreign exchange (gains)/losses on operating cash flows		(93)	311	307
Loss on disposal or retirement of property, plant and equipment	11	17	15	3
Movement in inventory provision	17	1,567	300	2,275
Impairment of prepayments	7, 18	1,376	1,608	1,651
Impairment of property, plant and equipment	7, 13	6,349	6,112	10,437
Impairment of intangible assets	7, 14	16,570	19,212	29,667
Provision for closure costs	10	-	-	(1,794)
Other non-cash items		835	570	(728)
Operating cash flows before changes in working capital		**8,238**	**13,369**	**9,508**
(Increase) / decrease in trade and other receivables		445	(5,960)	306
Decrease / (increase) in inventories		(2,959)	1,988	(2,461)
(Decrease) / increase in trade and other payables		151	(3,419)	2,017
Cash generated from operations		**5,875**	**5,978**	**9,370**
Interest paid		(1,000)	(39)	(53)
Interest received		560	874	776
Income taxes received / (paid)		(18)	416	(843)
Net cash generated by operating activities		**5,417**	**7,229**	**9,250**
Cash flows from investing activities				
Payments to acquire intangible assets		(9,718)	(9,863)	(10,229)
Acquisition of property, plant and equipment		(2,118)	(7,528)	(4,839)
Disposal of property, plant and equipment		(17)		
Licence fees	23	-	-	(1,112)
Net cash used in investing activities		**(11,853)**	**(17,391)**	**(16,180)**
Cash flows from financing activities				
Share buyback		-	(434)	(7,799)
Interest payment on exchangeable notes	30	(3,996)	(4,503)	(4,600)
Purchase of exchangeable notes	30	-	(12,042)	-
Proceeds from sale & leaseback transactions		-	481	51
Payment of lease liabilities	30	(3,533)	(374)	(295)
Net cash used in financing activities		**(7,529)**	**(16,872)**	**(12,643)**
Decrease in cash and cash equivalents and short term investments		(13,965)	(27,034)	(19,573)
Effects of exchange rate movements on cash held		88	(296)	71
Cash and cash equivalents and short-term investments at beginning of year		30,277	57,607	77,109
Cash and cash equivalents and short term investments at end of year	19,20	**16,400**	**30,277**	**57,607**

1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies adopted by Trinity Biotech plc ("the Company") and its subsidiaries ("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, 2019. 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 2019 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 32.

The directors have considered the Group's current financial position and cashflow projections, taking into account all known events and developments including the Covid-19 pandemic. While acknowledging that there will be a temporary decrease in revenues due to Covid-19, the company has taken measures to reduce expenditure, to obtain government pandemic supports in Ireland and USA and to exploit sales opportunities of products related to coronavirus. (For more information on the impact of Covid-19 – refer to Subsequent Events in Note 31). The directors believe that the Group will be able to continue in operational existence for at least the next 12 months from the date of approval of these consolidated financial statements and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

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

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

iv) Basis of consolidation

Subsidiaries

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

Transactions eliminated on consolidation

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

v) Property, plant and equipment

Owned assets

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

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

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

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

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:

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

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

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.

Accounting policy applicable before 1 January 2019

Leased assets – as lessee

Leases under terms of which the Group assumes substantially all the risks and rewards of ownership are classified as finance leases. Property, plant and equipment acquired by way of finance lease is stated at an amount equal to the lower of its fair value and present value of the minimum lease payments at inception of the lease, less accumulated depreciation and any impairment losses. Lease payments are apportioned between finance charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognised in financial expenses in the statement of operations.

Depreciation is calculated in order to write-off the amounts capitalised over the estimated useful lives of the assets, or the lease term if shorter, by equal annual instalments. The excess of the total rentals under a lease over the amount capitalised is treated as interest, which is charged to the statement of operations in proportion to the amount outstanding under the lease. Leased assets are reviewed for impairment (see Note 1(viii)).

Leases other than finance leases are classified as "operating leases", and the rentals thereunder are charged to the statement of operations on a straight-line basis over the period of the leases. Lease incentives are recognised in the statement of operations on a straight-line basis over the lease term.

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

Leased assets – as lessor

Leases where the Group substantially transfers the risks and benefits of ownership of the asset to the customer are classified as finance leases within finance lease receivables. The Group recognises the amount receivable from assets leased under finance leases at an amount equal to the net investment in the lease. Finance lease income is recognised as revenue in the statement of operations reflecting a constant periodic rate of return on the Group's net investment in the lease.

Assets provided to customers under leases other than finance leases are classified as operating leases and carried in property, plant and equipment at cost and are depreciated on a straight-line basis over the useful life of the asset or the lease term, if shorter.

Subsequent costs

The Group recognises in the carrying amount of an item of property, plant and equipment the cost of replacing part of such an item when that cost is incurred if it is probable that the future economic benefits embodied within the item will flow to the Group and the cost of the replaced item can be measured reliably. All other costs are recognised in the statement of operations as an expense as incurred.

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, licensed, 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 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 many 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, 2018 and December 31, 2019. See Note 14.

In-process research and development (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 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 each individual debtor taking into account 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

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 or the possible return of goods. 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 apply.

The Group operates a licensed 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.

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

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 24 for details.

Other operating income

Other operating income mainly comprises income recognised under Transitional Services Agreements (TSA) with Diagnostica Stago. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

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, 2019.

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 IASB and IFRIC have issued additional standards and interpretations which are effective for periods starting after January 1, 2019, all of which have not yet been adopted by the EU. IFRS as adopted by the EU differ in certain respects from IFRS as issued by the IASB. However, the Group's consolidated financial statements for the financial years presented would be no different had IFRS as issued by the IASB been applied. The following standards and interpretations have yet to be adopted by the Group:

International Financial Reporting Standards (IFRS/IAS)		***Effective date***
IFRS 3	Business Combinations	January 1, 2020 (issued by the IASB with effectivity date of January 1, 2020)
IFRS 8	Operating Segments	January 1, 2020 (issued by the IASB with effectivity date of January 1, 2020)
IFRS 9	Financial Instruments	January 1, 2020 (issued by the IASB with effectivity date of January 1, 2020)
IAS 39	Financial Instruments	January 1, 2020 (issued by the IASB with effectivity date of January 1, 2020)

The IASB also issued 'Amendments to References to the Conceptual Framework in IFRS Standards'. The amendments in the table above are effective for annual periods beginning on or after 1 January 2020.

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

The IASB issued amendments to IFRS 3 in October 2018 regarding the definition of a business. The amendments clarify that the process required to meet the definition of a business must be substantive; and, that the inputs and process must together significantly contribute to creating outputs. The definition of outputs has been narrowed to focus on goods and services provided to customers and other income from ordinary activities. In addition, the amendments indicate that an acquisition of primarily a single asset or group of similar assets is unlikely to meet the definition of a business. The amendments will be applied prospectively for business combinations and asset acquisitions occurring on or after January 1, 2020. The Group is finalising its review of the impact of this amendment, but does not expect the clarification to have a material impact on the value of acquisitions or additions to property, plant and equipment.

In September 2019, the IASB issued amendments to IFRS 9, IAS 39 Financial Instruments: Recognition and Measurement and IFRS 7 Financial Instruments: Disclosures, which concludes phase one of its work to respond to the effects of Interbank Offered Rates (IBOR) reform on financial reporting. The changes relate to hedge accounting and Group does not expect the amendment to have a material impact.

In 2019, the Group has adopted the new accounting pronouncements which have become effective this year, and are as follows:

IFRS 16 ‘Leases’ IFRS 16 ‘Leases’ replaces IAS 17 ‘Leases’ along with three Interpretations (IFRIC 4 ‘Determining whether an Arrangement contains a Lease’, SIC 15 ‘Operating Leases-Incentives’ and SIC 27 ‘Evaluating the Substance of Transactions Involving the Legal Form of a Lease’).

The adoption of this new Standard has resulted in the Group recognising a right-of-use asset and related lease liability in connection with each former operating lease except for those identified as low-value or having a remaining lease term of less than 12 months from the date of initial application.

The new Standard has been applied using the modified retrospective approach, with the cumulative effect of adopting IFRS 16 being recognised in equity as an adjustment to the opening balance of retained earnings for the current period. Prior periods have not been restated. Right-of-use assets have been assessed for impairment on transition by applying IAS 36, Impairment as at January 1, 2019. This resulted in an adjustment on transition to IFRS 16 of US$11,099,000, which reduces the value of the assets recorded in property, plant and equipment, with a corresponding movement in Accumulated Surplus. See Note 13.

The Group has elected not to include initial direct costs in the measurement of the right-of-use asset for operating leases in existence at the date of initial application of IFRS 16, being 1 January 2019. At this date, the Group has also elected to measure the right-of-use assets at an amount equal to the lease liability adjusted for any prepaid or accrued lease payments that existed at the date of transition.

On transition, for leases previously accounted for as operating leases with a remaining lease term of less than 12 months and for leases of low-value assets the Group has applied the optional exemptions to not recognise right-of-use assets but to account for the lease expense on a straight line basis over the remaining lease term.

For those leases previously classified as finance leases, the right-of-use asset and lease liability are measured at the date of initial application at the same amounts as under IAS 17 immediately before the date of initial application.

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

The following is a reconciliation of the financial statement line items from IAS 17 to IFRS 16 at January 1, 2019:

	Carrying amount at December 31, 2018	*Re-measurement*	*Impairment*	*IFRS 16 carrying amount at January 1, 2019*
	US$000	*US$000*	*US$000*	*US$000*
Property, plant & equipment	5,362	21,185	(11,099)	15,448
Lease liabilities	(962)	(21,185)	-	(22,147)
Retaining earnings	(55,319)	-	11,099	(44,220)
Total	**(50,919)**	**-**	**-**	**(50,919)**

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. 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, 2019	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*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

		Rest of World			
	Americas	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Revenue from external customers	65,863	31,172	-	-	97,035
Inter-segment revenue	38,665	2,899	-	(41,564)	-
Total revenue	104,528	34,071	-	(41,564)	97,035

2. SEGMENT INFORMATION (CONTINUED)

		Rest of World			
Year ended December 31, 2017	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Eliminations US$'000*	*Total US$'000*
Revenue from external customers	66,092	33,048	-	-	99,140
Inter-segment revenue	42,147	3,587	-	(45,734)	-
Total revenue	108,239	36,635	-	(45,734)	99,140

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

Revenue	*December 31, 2019 US$'000*	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Americas	52,183	57,559	59,539
Asia / Africa	27,686	29,466	27,131
Europe (including Ireland) *	10,566	10,010	12,470
	90,435	97,035	99,140

* 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, 2019 US$'000*	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Clinical laboratory	68,127	71,618	73,366
Point-of-Care	11,393	14,836	16,774
Laboratory services	10,915	10,581	9,000
	90,435	97,035	99,140

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

Revenue	*December 31, 2019 US$'000*	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Revenue from contracts with customers (a)	90,435	97,035	99,140
Revenue from other sources	-	-	-
	90,435	97,035	99,140

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

Timing of revenue recognition	*Americas*	*Ireland*	*Other*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At a point in time	64,941	31,172	—	96,113
Over time	922	—	—	922
Total	65,863	31,172	—	97,035

Timing of revenue recognition	*Americas*	*Ireland*	*Other*	*Total*
Year ended December 31, 2017	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At a point in time	65,164	33,048	—	98,212
Over time	928	—	—	928
Total	66,092	33,048	—	99,140

(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	*Americas*	*Asia / Africa*	*Europe*	*Total*
Year ended December 31, 2019	*US$'000*	*US$'000*	*US$'000*	*US$'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

Timing of revenue recognition	*Americas*	*Asia / Africa*	*Europe*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*
At a point in time	56,637	29,466	10,010	96,113
Over time	922	—	—	922
Total	57,559	29,466	10,010	97,035

2. SEGMENT INFORMATION (CONTINUED)

Timing of revenue recognition *Year ended December 31, 2017*	*Americas* *US$'000*	*Asia / Africa* *US$'000*	*Europe* *US$'000*	*Total* *US$'000*
At a point in time	58,611	27,131	12,470	98,212
Over time	928	-	-	928
Total	59,539	27,131	12,470	99,140

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

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
Year ended December 31, 2019	*US$'000*	*US$'000*	*US$'000*	*US$'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)

		Rest of World		
	Americas	*Ireland*	*Other*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Result before impairment and unallocated expenses	5,514	1,900	(44)	7,370
Impairment	(19,095)	(7,837)	—	(26,932)
Result after impairment	(13,581)	(5,937)	(44)	(19,562)
Unallocated expenses *				(665)
Operating loss				(20,227)
Net financing expense (Note 8)				(2,956)
Loss before tax				(23,183)
Income tax credit (Note 9)				525
Loss for the year on continuing operations				(22,658)
Loss for the year on discontinued operations (Note 10)				568
Loss for the year				(22,090)

2. SEGMENT INFORMATION (CONTINUED)

Year ended December 31, 2017	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Result before exceptional expenses	3,744	1,125	(44)	4,825
Impairment	(9,194)	(32,561)	—	(41,755)
Result after exceptional expenses	(5,450)	(31,436)	(44)	(36,930)
Unallocated expenses *				(738)
Operating profit				(37,668)
Net financing expense (Note 8)				(2,207)
Loss before tax				(39,875)
Income tax credit (Note 9)				1,214
Loss for the year on continuing operations				(38,661)
Loss for the year on discontinued operations (Note 10)				(1,609)
Loss for the year				(40,270)

* 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, 2019	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Assets and liabilities				
Segment assets	69,224	37,212	1	106,437
Unallocated assets:				
Income tax assets (current and deferred)				8,234
Cash and cash equivalents and short-term investments				16,400
Total assets as reported in the Group balance sheet				131,071
Segment liabilities	14,575	104,396	200	119,171
Unallocated liabilities:				
Income tax liabilities (current and deferred)				7,187
Total liabilities as reported in the Group balance sheet				126,358

		Rest of World		
As at December 31, 2018	*Americas US$'000*	*Ireland US$'000*	*Other US$'000*	*Total US$'000*
Assets and liabilities				
Segment assets	75,658	38,009	4	113,671
Unallocated assets:				
Income tax assets (current and deferred)				7,711
Cash and cash equivalents and short-term investments				30,277
Total assets as reported in the Group balance sheet				151,659
Segment liabilities				
Unallocated liabilities:	8,946	90,444	150	99,540
Income tax liabilities (current and deferred)				8,065
Total liabilities as reported in the Group balance sheet				107,605

2. SEGMENT INFORMATION (CONTINUED)

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), by geographical area was as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Rest of World – Ireland	14,626	14,864
Americas	38,803	44,007
	53,429	58,871

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Depreciation:			
Rest of World – Ireland	322	74	1,186
Americas	2,208	1,301	1,238
	2,530	1,375	2,424
Amortisation:			
Rest of World – Ireland	642	655	1,164
Americas	1,726	2,170	2,139
	2,368	2,825	3,303

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Rest of World – Ireland	659	1,265	841
Americas	99	104	87
	758	1,369	928
Share based-payments – discontinued operations	—	—	—
	758	1,369	928

See Note 22 for further information on share-based payments.

2. SEGMENT INFORMATION (CONTINUED)

x) The distribution of interest income and interest expense by geographical area was as follows:

		Rest of World			
Interest Income	*Americas*	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2019	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Interest income earned	47	417	—	—	464
Non-cash financial income	—	233	—	—	233
Inter-segment interest income	—	—	4,853	(4,853)	—
Total	47	650	4,853	(4,853)	697

		Rest of World			
Interest Expense	*Americas*	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2019	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Interest on finance leases	294	653	—	—	947
Interest on tax audit settlement (Note 6)	—	1,000	—	—	1,000
Cash interest on exchangeable notes	—	3,996	—	—	3,996
Non-cash interest on exchangeable notes (Note 25)	—	639	—	—	639
Inter-segment interest expense	4,853	—	—	(4,853)	—
Total	5,147	6,288	—	(4,853)	6,582

		Rest of World			
Interest Income	*Americas*	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Interest income earned	32	704	—	—	736
Non-cash financial income	—	1,388	—	—	1,388
Inter-segment interest income	—	—	4,853	(4,853)	—
Total	32	2,092	4,853	(4,853)	2,124

		Rest of World			
Interest Expense	*Americas*	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2018	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Interest on finance leases	7	32	—	—	39
Cash interest on exchangeable notes	—	4,352	—	—	4,352
Non-cash interest on exchangeable notes (Note 25)	—	689	—	—	689
Inter-segment interest expense	4,853	—	—	(4,853)	—
Total	4,860	5,073	—	(4,853)	5,080

		Rest of World			
Interest Income	*Americas*	*Ireland*	*Other*	*Eliminations*	*Total*
Year ended December 31, 2017	*US$'000*	*US$'000*	*US$'000*	*US$'000*	*US$'000*
Interest income earned	44	764	—	—	808
Non-cash financial income	—	2,390	—	—	2,390
Inter-segment interest income	—	—	4,853	(4,853)	—
Total	44	3,154	4,853	(4,853)	3,198

2. SEGMENT INFORMATION (CONTINUED)

Interest Expense *Year ended December 31, 2017*	*Americas* *US$'000*	*Rest of World* *Ireland* *US$'000*	*Rest of World* *Other* *US$'000*	*Eliminations* *US$'000*	*Total* *US$'000*
Interest on deferred consideration and licence fee	—	40	—	—	40
Interest on finance leases	—	42	—	—	42
Cash interest on exchangeable notes	—	4,600	—	—	4,600
Non-cash interest on exchangeable notes (Note 25)	—	723	—	—	723
Inter-segment interest expense	4,853	—	—	(4,853)	—
Total	4,853	5,405	—	(4,853)	5,405

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Rest of World – Ireland	831	(59)	192
Rest of World – Other	—	(3)	(81)
Americas	175	587	1,103
	1,006	525	1,214

xii) During 2019, 2018 and 2017 there were no customers generating 10% or more of total revenues.

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Rest of World – Ireland	20,758	7,148
Rest of World – Other	-	1,746
Americas	12,863	8,911
	33,621	17,805

3. PERSONNEL EXPENSES

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Wages and salaries	25,885	26,475	26,316
Social welfare costs	2,538	2,585	2,424
Pension costs	503	490	459
Tax settlement (Note 6)	5,094	—	—
Share-based payments	758	1,369	928
	34,778	30,919	30,127

Personnel expenses are shown net of capitalisations. Total personnel expenses, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2019 amounted to US$36,288,000 (2018: US$38,002,000) (2017: US$37,351,000). Total share based payments, inclusive of amounts capitalised in the balance sheet, amounted to US$838,000 for the year ended December 31, 2019 (2018: US$1,607,000) (2017: US$1,109,000). See Note 22 for further details.

3. PERSONNEL EXPENSES (CONTINUED)

The average number of persons employed by the Group in the financial year was 579 (2018: 575) (2017: 556) and is analysed into the following categories:

	December 31, 2019	*December 31, 2018*	*December 31, 2017*
Research and development	57	59	60
Administration and sales	159	163	162
Manufacturing and quality	363	353	334
	579	575	556

4. PENSION SCHEMES

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$503,000 (2018: US$490,000) (2017: US$458,000). The pension accrual for the Group at December 31, 2019 was US$43,000 (2018: US$45,000), (2017: US$33,000).

5. OTHER OPERATING INCOME

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Rental income from premises	3	3	-
Other income	88	99	100
	91	102	100

Other income mainly comprises income recognised under Transitional Services Agreements (TSA) with Diagnostica Stago. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

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

Arising out of a tax audit in one of the jurisdictions in which the company operates, the Company reached a tax settlement of US$6,442,000 in the year ended December 31, 2019. The tax audit concluded in late December 2019 and the payment of the settlement amount was made prior to the financial year end. 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, which is shown as Selling, general and administrative expenses – tax audit settlement.

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 recognised in the consolidated statement of financial position at year-end.

7. IMPAIRMENT CHARGES

In accordance with IAS 36, *Impairment of Assets*, the Group carries out an annual impairment review of the asset valuations. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. A number of factors affected this calculation including:

- The Company's market capitalisation at the end of the year that was lower when compared to the end of 2018.
- The inclusion of the latest cash flow projections and net asset values for each cash generating unit; and
- Increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

The impact of the above items on the statement of operations for the year ended December 31, 2019, December 31, 2018 and December 31, 2017 was as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Selling, general & administration expenses			
Impairment of PP&E (Note 13)	6,349	6,112	10,437
Impairment of goodwill and other intangible assets (Note 14)	16,570	19,212	29,667
Impairment of prepayments (Note 18)	1,376	1,608	1,651
Total impairment loss	**24,295**	**26,932**	**41,755**
Income tax impact of impairment loss	148	(1,752)	(517)
Total impairment loss after tax	**24,443**	**25,180**	**41,238**

8. FINANCIAL INCOME AND EXPENSES

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Financial income:			
Non-cash financial income	233	1,388	2,390
Interest income	464	736	808
	697	2,124	3,198
Financial expense:			
Interest on leases	(947)	(39)	(42)
Interest on tax audit settlement (Note 6)	(1,000)	-	-
Cash interest on exchangeable notes	(3,996)	(4,352)	(4,600)
Non-cash interest on exchangeable notes (Note 25)	(639)	(689)	(723)
Interest on deferred consideration and licence fee	-	-	(40)
	(6,582)	(5,080)	(5,405)
Net Financing Expense	(5,885)	(2,956)	(2,207)

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 25.

9. INCOME TAX CREDIT

The tax credit based on the loss comprises:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Current tax (credit)/expense			
Irish Corporation tax	(312)	(258)	(51)
Foreign taxes (a)	197	195	358
Adjustment in respect of prior years	(50)	(56)	150
Total current tax (credit)/expense	(165)	(119)	457
Deferred tax credit (b)			
Origination and reversal of temporary differences (see Note 15)	(841)	(2,031)	(5,969)
Origination and reversal of net operating losses (see Note 15)	-	1,625	4,298
Total deferred tax credit	(841)	(406)	(1,671)
Total income tax credit on continuing operations in statement of operations	(1,006)	(525)	(1,214)
Tax (credit)/charge on discontinued operations (see Note 10)	-	(590)	323
Total tax credit	(1,006)	(1,115)	(891)

(a) In 2019, the foreign taxes relate primarily to Canada.
(b) In 2019, there was a deferred tax credit of US$444,000 (2018: charge of US$369,000; 2017: credit of US$170,000) recognised in respect of Ireland and a deferred tax credit of US$397,000 (2018: credit of US$775,000; 2017: credit of US$1,501,000) recognised in respect of overseas tax jurisdictions.

Effective tax rate	*December 31, 2019 US$'000*	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Loss before taxation	(29,997)	(23,183)	(39,875)
As a percentage of loss before tax:			
Current tax	(0.55)%	(0.51)%	1.14%
Total (current and deferred)	(3.36)%	(2.26)%	(3.05)%

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

	December 31, 2019	*December 31, 2018*	*December 31, 2017*
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)	13.21%	15.76%	12.05%
Effect of tax rates on overseas earnings	(3.05)%	(6.10)%	(2.09)%
Effect of Irish income taxable at higher tax rate	0.04%	0.05%	-
Adjustments in respect of prior years	(0.17)%	0.94%	0.38%
Effect of changes in US tax code (b)	-	-	(1.89)%
R&D tax credits	(2.69)%	(1.70)%	(0.17)%
Other items (c)	1.80%	1.29%	1.17%
Effective tax rate	(3.36)%	(2.26)%	(3.05)%

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

(a) The effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised is analyzed further in the table below (see also Note 15). No deferred tax asset was recognised because there was no reversing deferred tax liability in the same jurisdiction reversing in the same period and no future taxable income in the same jurisdiction.

(b) In 2017, a number of changes were made to the USA tax code, the most significant of which was the reduction in the federal corporation tax rate to 21%. This resulted in a once-off tax credit in 2017 of US$753,000 arising from the reduction in deferred tax balances due to the tax rate change, partially offset by the effect of mandatory deemed repatriation of certain deferred foreign earnings. The other changes to the USA tax code did not have a material impact on the Group.

(c) Other items comprise items not chargeable to tax/expenses not deductible for tax purposes. In 2019, other items mainly comprise the tax audit settlement recorded in Selling, General and Administrative expenses (see also Note 6), which is not deductible for tax. Additionally, the movement in the exchangeable notes' embedded derivatives value and the accretion of notional interest on the Loan Note's host contract, both of which are exempt from deferred taxation recognition under IAS 12, Income Taxes.

Unrecognised deferred tax assets – continuing operations	**Effect in 2019 US$'000**	**Percentage effect in 2019**	**Effect in 2018 US$'000**	**Percentage effect in 2018**
Increase in net operating losses arising in US	1,117	3.72%	2,174	9.38%
Temporary differences arising in US	129	0.43%	19	0.08%
Decrease in net operating losses arising in Brazil	608	2.03%	(20)	(0.09)%
Increase in net operating losses arising in Ireland	2,110	7.03%	1,482	6.39%
	3,964	13.21%	3,655	15.76%

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Rest of World – Ireland	(20,318)	(9,590)	(35,821)
Rest of World – Other	4,760	4,809	4,809
Americas	(14,439)	(18,402)	(8,863)
	(29,997)	(23,183)	(39,875)

At December 31, 2019, the Group had unutilised net operating losses as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
USA	1,034	2,382	7,737
Ireland	73,754	60,629	57,206
Brazil	5,789	4,001	4,060
	80,577	67,012	69,003

In the USA, the utilisation of net operating loss carryforwards is limited to future profits in the USA. All of the net operating losses for the USA arose prior to January 1, 2018 and have a maximum carryforward of 20 years. In respect of the US, US$994,000 will expire by December 31, 2036, and US$40,000 will expire by December 31, 2037.

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

At December 31, 2019, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Ireland – unused tax losses	12,062	9,953	8,471
US – unused tax losses	3,291	2,174	-
US – unused tax credits	493	364	345
Brazil – unused tax losses	1,968	1,360	1,380
Unrecognised deferred tax asset	17,814	13,851	10,196

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.

The Group has US state credit carryforwards of US$624,000 at December 31, 2019 (2018: US$461,000; 2017: US$436,000). A deferred tax asset of US$493,000 (2018: US$364,000; 2017: US$345,000) in respect of US state credit carryforwards was not recognised due to uncertainties regarding future full utilisation of these state credit carryforwards in the related tax jurisdiction in future periods

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

In 2016, management decided to cease the development of Cardiac point-of-care tests on the Meritas platform. These products were being developed by the Group's subsidiary Fiomi Diagnostics ("Fiomi") located in Sweden. 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. PROFIT/(LOSS) FOR THE YEAR ON DISCONTINUED OPERATION (CONTINUED)

In 2017, settlements were negotiated with a number of counterparties that were lower than had been estimated in the previous years' financial statements. The resultant excess provision for closure costs was released to the Consolidated Statement of Operations. During 2017, all remaining employees and all operating lease obligations were terminated. The loss on discontinued operations in 2017 also included a charge in relation to foreign translation reserves that had been recognised in previous periods as a reserve movement. In 2018, taxes paid to the Swedish tax authorities were recovered and there was a resulting tax credit of US$590,000.

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Revenues	—	—	—
Operating loss	—	—	—
Loss for the year	—	—	—
Profit/(Loss) on re-measurement of assets and liabilities:			
Closure costs	(8)	(22)	1,794
Foreign currency translation reserve	85	—	(3,080)
Tax credit/(expense)	—	590	(323)
Total profit/(loss)	77	568	(1,609)
Profit/(Loss) for the year from discontinued operations	**77**	**568**	**(1,609)**

Basic earnings per ordinary share – discontinued operations

Basic earnings/(loss) per ordinary share for discontinued operations is computed by dividing the profit after taxation on discontinued operations of US$77,000 (2018: profit US$568,000) (2017: loss US$1,609,000) for the financial year by the weighted average number of 'A' ordinary shares in issue. As at December 31, 2019, this amounted to 83,606,810 shares (2018: 83,612,908 shares) (2017: 86,486,409 shares), see note 12 for further details.

Diluted earnings per ordinary share – discontinued operations

Diluted earnings/(loss) per ordinary share for discontinued operations is computed by dividing the profit/(loss) after taxation on discontinued operations of US$77,000 (2018: profit US$568,000) (2017: loss US$1,609,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 101,870,064 (2018: 103,508,820) (2017: 107,510,179), 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 earnings/(loss) per ADS for discontinued operations is computed by dividing the profit after taxation on discontinued operations of US$77,000 (2018: profit US$568,000) (2017: loss US$1,609,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2018: 20,903,227); (2017: 21,621,602), see note 12 for further details.

Diluted earnings/(loss) per ADS for discontinued operations is computed by dividing the profit after taxation on discontinued operations of US$77,000 (2018: profit US$568,000) (2017: loss US$1,609,000) for the financial year, by the diluted weighted average number of ADS in issue of 25,467,516 (2018: 25,877,205) (2017: 26,877,544), see note 12 for further details.

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

	December 31, 2019	*December 31, 2018*	*December 31, 2017*
Basic earnings/(loss) per ADS (US Dollars) – discontinued operations	0.00	0.03	(0.07)
Diluted earnings/(loss per ADS (US Dollars) – discontinued operations	0.00	0.02	(0.07)
Basic earnings/(loss) per 'A' share (US Dollars) – discontinued operations	0.00	0.01	(0.02)
Diluted earnings/(loss) per 'A' share (US Dollars) – discontinued operations	0.00	0.01	(0.02)

Cash flows

The cash flows attributable to discontinued operations are as follows:

	December 31, 2019 US$000	*December 31, 2018 US$000*	*December 31, 2017 US$000*
Cash flows from operating activities	(5)	527	(2,847)
Cash flows from investing activities	-	-	-

There were no cash flows from financing activities attributable to discontinued operations for the years ended December 31, 2019, 2018 or 2017.

11. LOSS BEFORE TAX

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Directors' emoluments (including non- executive directors):			
Remuneration	1,238	1,261	1,800
Pension	42	44	44
Share based payments	624	1,204	727
Auditor's remuneration			
Audit fees	523	506	568
Tax fees	172	15	73
Other non-audit fees	-	-	-
Depreciation*	2,526	1,296	1,896
Amortisation	2,368	2,825	3,303
Loss on the disposal of property, plant and equipment	17	15	3
Net foreign exchange differences**	(179)	344	(17)

* Note that US$4,000 (2018: US$79,000) (2017: US$528,000) of depreciation was capitalised to research and development projects during 2019 in line with the Group's capitalisation policy for Intangible projects.

** The net foreign exchange differences in 2017 do not include US$440,000 which were included in the operating expenses that were stated in Note 10 in respect of the discontinued operations in Fiomi.

12. LOSS PER SHARE

Basic earnings per ordinary share

Basic earnings per ordinary share for the group is computed by dividing the loss after taxation of US$28,914,000 (2018: loss of US$22,090,000) (2017: loss of US$40,270,000) for the financial year by the weighted average number of 'A' ordinary shares in issue. Basic earnings per ordinary share for continuing operations is computed by dividing the loss after taxation for continued operations of US$28,991,000 (2018: loss of US$22,658,000) (2017: loss of US$38,661,000) for the financial year by the weighted average number of 'A' ordinary shares in issue.

As at December 31, 2019, this amounted to 83,606,810 shares (2018: 83,612,908 shares) (2017: 86,486,409 shares).

	December 31, 2019	*December 31, 2018*	*December 31, 2017*
'A' ordinary shares	83,606,810	83,612,908	86,486,409
Basic earnings per share denominator	83,606,810	83,612,908	86,486,409
Reconciliation to weighted average earnings per share denominator:			
Number of 'A' ordinary shares at January 1 (Note 21)	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)	(12,549,502)	(9,676,001)
Basic earnings per share denominator	83,606,810	83,612,908	86,486,409

*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 per ordinary share for the group is computed by dividing the adjusted loss after tax of US$24,512,000 (2018: loss of US$18,437,000) (2017: loss of US$37,337,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 101,870,064 (2018: 103,508,820) (2017: 107,510,179). Diluted earnings per ordinary share for continuing operations is computed by dividing the adjusted loss after tax on continuing operations of US$24,590,000 (2018: loss of US$19,005,000) (2017: loss of US$35,728,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 101,870,064 (2018: 103,508,820) (2017: 107,510,179). The adjusted loss 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 earnings per ordinary share.

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, 2019	*December 31, 2018*	*December 31, 2017*
Basic earnings per share denominator (see above)	83,606,810	83,612,908	86,486,409
Issuable on exercise of options and warrants	-	22,359	-
Issuable on conversion of exchangeable notes	18,263,254	19,873,553	21,023,770
Diluted earnings per share denominator	101,870,064	103,508,820	107,510,179

12. LOSS PER SHARE (CONTINUED)

The 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, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Loss after tax for the year	(28,914)	(22,090)	(40,270)
Non-cash financial income (Note 8)	(233)	(1,388)	(2,390)
Cash interest expense (Note 8)	3,996	4,352	4,600
Non-cash interest on exchangeable notes (Note 8)	639	689	723
Adjusted loss after tax	(24,512)	(18,437)	(37,337)

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 loss after taxation of US$28,914,000 (2018: loss of US$22,090,000) (2017: loss of US$40,270,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2018: 20,903,227); (2017: 21,621,602). Basic earnings per ADS for continuing operations is computed by dividing the loss after taxation of US$28,991,000 (2018: loss of US$22,658,000) (2017: loss of US$38,661,000) for the financial year by the weighted average number of ADS in issue of 20,901,703 (2018: 20,903,227); (2017: 21,621,602).

	December 31, 2019	*December 31, 2018*	*December 31, 2017*
ADS	20,901,703	20,903,227	21,621,602
Basic earnings per share denominator	20,901,703	20,903,227	21,621,602
Reconciliation to weighted average earnings per share denominator:			
Number of ADS at January 1 (Note 21)	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)	(3,137,375)	(2,419,000)
Basic earnings per share denominator	20,901,703	20,903,227	21,621,602

Diluted earnings per ADS for the Group is computed by dividing the adjusted loss after taxation of US$24,512,000 (2018: loss of US$18,437,000) (2017: loss of US$37,337,000) for the financial year, by the diluted weighted average number of ADS in issue of 25,467,516 (2018: 25,877,205) (2017: 26,877,544).

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

*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, 2019	*December 31, 2018*	*December 31, 2017*
Basic earnings per share denominator (see above)	20,901,703	20,903,227	21,621,602
Issuable on exercise of options and warrants	-	5,590	-
Issuable on conversion of exchangeable notes	4,565,814	4,968,388	5,255,942
Diluted earnings per share denominator	25,467,517	25,877,205	26,877,544

13. PROPERTY, PLANT AND EQUIPMENT

	Land and buildings US$'000	*Leasehold improvements US$'000*	*Computers, fixtures and fittings US$'000*	*Plant and equipment US$'000*	*Total US$'000*
Cost					
At January 1, 2018	2,624	3,004	5,894	37,895	49,417
Additions	19	1,609	829	5,068	7,525
Disposals or retirements	—	(1)	(131)	(1,804)	(1,936)
Exchange adjustments	(38)	(52)	(7)	(1,095)	(1,192)
At December 31, 2018	2,605	4,560	6,585	40,064	53,814
At January 1, 2019	2,605	4,560	6,585	40,064	53,814
Adjustment on transition to IFRS 16	20,961	—	149	75	21,185
Additions	681	71	168	1,905	2,825
Disposals or retirements	—	(1,626)	(2,610)	(3,314)	(7,550)
Exchange adjustments	22	—	—	(54)	(32)
At December 31, 2019	24,269	3,005	4,292	38,676	70,242
Accumulated depreciation and impairment losses					
At January 1, 2018	(1,283)	(2,659)	(5,308)	(34,367)	(43,617)
Charge for the year	(80)	(47)	(185)	(1,063)	(1,375)
Impairment loss	(578)	(543)	(423)	(4,568)	(6,112)
Disposals or retirements	—	—	130	1,679	1,809
Exchange adjustments	7	6	3	827	843
At December 31, 2018	(1,934)	(3,243)	(5,783)	(37,492)	(48,452)
At January 1, 2019	(1,934)	(3,243)	(5,783)	(37,492)	(48,452)
Charge for the year	(1,545)	(105)	(200)	(680)	(2,530)
Adjustment on transition to IFRS 16	(10,984)	—	(40)	(75)	(11,099)
Impairment loss as at December 31, 2019	(4,024)	(233)	(276)	(1,816)	(6,349)
Disposals or retirements	—	1,544	2,618	3,331	7,493
Reallocations / reclassifications	—	—	—	(5)	(5)
Exchange adjustments	(6)	—	(1)	(3)	(10)
At December 31, 2019	(18,493)	(2,037)	(3,682)	(36,740)	(60,952)
Carrying amounts					
At December 31, 2019	5,776	968	610	1,936	9,290
At December 31, 2018	671	1,317	802	2,572	5,362

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

The following is a reconciliation of the financial statement line items from IAS 17 to IFRS 16 at January 1, 2019:

	Carrying amount at December 31, 2018 US$000	*Remeasurement US$000*	*Impairment US$000*	*IFRS 16 carrying amount at January 1, 2019 US$000*
Property, plant & equipment	5,362	21,185	(11,099)	15,448
Lease liabilities	(962)	(21,185)	-	(22,147)
Retaining earnings	(55,319)	-	11,099	(44,220)
Total	**(50,919)**	**-**	**-**	**(50,919)**

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

	Carrying amount At December 31, 2019 *US$000*	Depreciation Year ended December 31, 2019 *US$000*	Impairment Year ended December 31, 2019 *US$000*
Buildings	5,220	(1,523)	(3,913)
Computer equipment	7	(39)	(63)
	5,227	(1,562)	(3,976)

Income from sub-letting right-of-use buildings amounted to US$3,000 in the year ended December 31, 2019.

13. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

Right-of-Use assets	*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	13	1 to 14	5	1	-	2	4
Vehicle	9	1 to 2	1	-	9	-	9
I.T. and office equipment	11	1 to 2	2	-	-	-	1

The annual impairment review performed at December 31, 2019 showed that the carrying value of the Group's assets exceeded the amount to be recovered through use or sale of the assets by a total of US$76,740,000. 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$6,349,000 was allocated to property, plant and equipment as at December 31, 2019. The recoverable amount of property, plant and equipment was determined to be the value in use of each cash generating unit.

The annual impairment review performed at December 31, 2018 showed that the carrying value of the Group's assets exceeded the amount to be recovered through use or sale of the assets by a total of US$57,794,000. 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$6,112,000 was allocated to property, plant and equipment in 2018. 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, 2019 and 2018 is US$Nil following full write down of the assets due to group impairment (refer to Note 14). Depreciation charged on these assets in 2019 amounted to US$7,000 (2018: US$8,000).

Included in disposals/retirements in 2019 is US$Nil (2018: US$12,000) relating to the net book value of leased instruments reclassified as inventory on return from customers.

Property, plant and equipment under construction

There were no assets under contraction included in property, plant and equipment at December 31, 2019 (2018: US$204,000).

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, 2018	81,689	136,918	9,947	33,818	262,372
Additions	—	9,871	—	410	10,281
Disposals	—	—	—	—	—
Exchange adjustments	—	(17)	—	—	(17)
At December 31, 2018	81,689	146,772	9,947	34,228	272,636
At January 1, 2019	81,689	146,772	9,947	34,228	272,636
Additions	—	9,569	4	38	9,611
Disposals	—	—	—	—	—
Reclassification	—	—	—	—	—
Exchange adjustments	—	36	—	—	36
At December 31, 2019	81,689	156,377	9,951	34,266	282,283
Accumulated amortisation and Impairment losses					
At January 1, 2018	(63,791)	(102,140)	(9,728)	(21,959)	(197,618)
Charge for the year	—	(1,564)	—	(1,261)	(2,825)
Disposals	—	—	—	—	—
Impairment losses	(1,757)	(16,773)	(86)	(596)	(19,212)
Exchange adjustments	—	(30)	—	—	(30)
At December 31, 2018	(65,548)	(120,507)	(9,814)	(23,816)	(219,685)
At January 1, 2019	(65,548)	(120,507)	(9,814)	(23,816)	(219,685)
Charge for the year	—	(1,182)	(2)	(1,184)	(2,368)
Disposals	—	—	—	—	—
Impairment losses	(3,550)	(11,904)	(3)	(1,113)	(16,570)
Exchange adjustments	—	(6)	—	—	(6)
At December 31, 2019	(69,098)	(133,599)	(9,819)	(26,113)	(238,629)
Carrying amounts					
At December 31, 2019	12,591	22,778	132	8,153	43,654
At December 31, 2018	16,141	26,265	133	10,412	52,951

Included within development costs are costs of US$3,719,000 which were not amortised in 2019 (2018: US$4,192,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at December 31, 2019 or at December 31, 2018. As at December 31, 2019 these projects are expected to be completed during the period from January 1, 2020 to December 31, 2022 at an expected further cost of approximately US$5,557,000.

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	2019 US$'000	2018 US$'000
HIV screening rapid test	2,587	1,657
Premier Instrument for Haemoglobin A1c testing	1,930	2,653
Autoimmune Smart Reader	1,325	746
Syphilis point-of-care test	870	454
Uni-Gold antigen improvement	691	453
G-6-PDH test	582	850
Uni-gold test	376	796
Tri-stat Point-of-Care instrument	361	727
Ultra Genesys	237	263
Column enhancement	236	292
Sjogrens tests	135	414
Other projects	239	566
Total capitalised development costs	**9,569**	**9,871**

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 a known 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 an annual basis. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. A number of factors impacted this calculation including:

- the Company's market capitalisation at the end of the year, which was lower when compared to the end of 2018,
- the inclusion of the latest cash flow projections and net asset values for each cash generating unit; and
- increased volatility in the Company's share price and higher market interest rates which resulted in a higher discount factor being applied to the Company's expected future cash flows.

As the future discounted cash flows for a number of cash generating units ("CGUs") was below the carrying value of their net assets, the Group recognised a non-cash impairment charge of US$24,295,000 at December 31, 2019.

The impairment test performed as at December 31, 2019 identified a total impairment loss of US$76,740,000 in seven CGUs, of which US$24,295,000 has been recorded in the 2019 financial statements. Not all of the total impairment loss was recorded in the financial statements due to the allocation method proscribed in IAS 36, *Impairment of Assets.* According to this accounting standard, the impairment loss for each CGU is first allocated to reduce the carrying amount of any goodwill allocated to the CGU, then to other assets of the unit pro rata on the basis of the carrying amount of each asset in the CGU. The full impairment loss for Biopool US Inc, Trinity Biotech Manufacturing Limited, Clark Laboratories Inc,, Mardx Diagnostics Inc and Trinity Biotech Do Brasil could not be reflected in the 2019 financial statements for these entities because each of these entities had insufficient assets to write down after excluding those assets with a known recoverable amount. The amount of impairment loss that could not be recorded for Biopool US Inc, Trinity Biotech Manufacturing Limited, Clark Laboratories Inc,, Mardx Diagnostics Inc and Trinity Biotech Do Brasil was US$29,423,000, US$7,707,000, US$33,000,US$5,817,000 and US$9,465,000 respectively. As a result, the impairment loss that was recorded in the 2019 financial statements was US$24,295,000, being the total impairment loss of US$76,740,000 less the amounts which could not be recorded.

The impairment loss arose from the impairment review performed on Biopool US Inc,, Trinity Biotech Manufacturing Limited, Clark Laboratories Inc,, Mardx Diagnostics Inc, Immco Diagnostics, Primus Corp. and Trinity Biotech Do Brasil. An impairment loss arose in these entities due to the carrying value of their net assets exceeding the entity's discounted future cashflows. The recoverable amount of each of the CGUs is determined based on a value-in-use computation, which is the only methodology applied by the Group and which has been selected due to the impracticality of obtaining fair value less costs to sell measurements for each reporting period. For the purpose of the annual impairment tests, goodwill is allocated to the relevant CGU. The annual impairment analysis is based on a valuation technique involving level 3 inputs, see Note 1 (xxix).

The value-in-use calculations use cash flow projections based on the 2020 projections for each CGU and a further four years projections using estimated revenue and cost growth rates of between 0% and 7%. 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 key assumptions employed in arriving at the estimates of future cash flows are subjective and include projected EBITDA, net cash flows, discount rates and the duration of the discounted cash flow model. The assumptions and estimates used were derived from a combination of internal and external factors based on historical experience. The pre-tax discount rates used range from 20% to 27% (2018: 20% to 35%)

14. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Trinity Biotech Manufacturing Limited	9,732	7 ,837
Immco Diagnostics Inc	6,332	-
Primus Corp	5,321	12,424
Trinity Biotech Do Brasil	1,253	2,785
Clark Laboratories Inc.	727	3,377
Mardx Diagnostics Inc.	720	-
Biopool US Inc.	210	509
Total impairment loss	**24,295**	**26,932**

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Goodwill and other intangible assets (see Note 14)	16,570	19,212
Property, plant and equipment (see Note 13)	6,349	6,112
Prepayments (see Note 18)	1,376	1,608
Total impairment loss	**24,295**	**26,932**

The impairment loss at December 31, 2019 allocated to goodwill arose in Immco Diagnostics Inc. The impairment loss at December 31, 2018 allocated to goodwill arose in Clark Laboratories Inc.

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas;

- In the event that there was a variation 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 an additional impairment loss of US$743,000 at December 31, 2019.

- In the event there was a 10% variation 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 an additional impairment loss of US$5,420,000 at December 31, 2019.

The annual impairment test only takes into account conditions existing at the end of the reporting period. COVID-19 began to impact the population of Wuhan, China in December 2019 and initially the outbreak was largely concentrated in China. It was declared a pandemic by the World Health Organization in March 2020. The Company's impairment test as at December 31, 2019 therefore does not reflect the downturn in economic activity or the aforementioned impacts on the Company's revenues and expenditure caused by the Covid-19 pandemic. If the impairment test was reperformed using projections which take into account the aforementioned impacts on revenues and expenditure, the impairment loss as at December 31, 2019 for Primus Corp. and Immco Diagnostics would be higher by US$1.8 million and US$1.7 million respectively.

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 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, 2019*	*December 31, 2018*
Carrying amount of goodwill (US$'000)	12,592	12,592
Discount rate applied (real pre-tax)	20.42%	19.80%
Excess value-in-use over carrying amount (US$'000)	2,385	8,847
% EBITDA would need to decrease for an impairment to arise	12.11%	32.6%
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, 2019 US$'000*	*December 31, 2018 US$'000*
Fitzgerald Industries International CGU		
Fitzgerald trade name	970	970
RDI trade name	560	560
Primus Corporation CGU		
Primus trade name	500	547
Immco Diagnostic CGU		
Immco Diagnostic trade name	2,938	3,393
Total	**4,968**	**5,470**

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 2019, impairment losses of US$47,000 and US$455,000 were allocated against the Primus trade name and the Immco Diagnostic trade name respectively as the carrying value of the related CGUs' net assets exceeded their 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*	
	2019 US$000	*2018 US$'000*	*2019 US$'000*	*2018 US$'000*	*2019 US$'000*	*2018 US$'000*
Property, plant and equipment	1,027	815	(9)	(37)	1,018	778
Intangible assets	—	—	(6,099)	(7,189)	(6,099)	(7,189)
Inventories	642	668	—	—	642	668
Provisions	3,838	4,311	—	—	3,838	4,311
Other items	745	333	(1,031)	(629)	(286)	(296)
Deferred tax assets/(liabilities)	6,252	6,127	(7,139)	(7,855)	(887)	(1,728)

The deferred tax asset in 2019 is mainly due to deductible temporary differences relating to provisions, property, plant and equipment, share-based payments and the elimination of unrealised intercompany inventory profit. In 2019, the deferred tax asset increased by US$125,000. Due to the impairment loss in 2019, the amount of deferred tax assets recoverable through the reversal of taxable timing differences is lower because the deferred tax liability relating to impaired assets was significantly reduced. In other words, deferred tax assets were derecognized as they exceeded the amount of reversing deferred tax liabilities.

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 and deferred tax recognised on fair value asset uplifts in connection with business combinations. The deferred tax liability decreased by US$716,000 in 2019, 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, 2019 and at December 31, 2018 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.

The vast majority of temporary differences are expected to reverse after 2021.

Unrecognised deferred tax assets

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

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Capital losses	8,293	8,293
Net operating losses	80,577	67,012
US alternative minimum tax credits	1,928	1,674
Other temporary timing differences	7,399	3,880
US state credit carryforwards	493	364
	98,690	81,223

15. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

There was an increase of US$17,467,000 in the unrecognised deferred tax assets during the year ended December 31, 2019. For comments on the uncertainty prompting less than full recognition refer to Note 9. The movement in the unrecognised deferred tax assets during the year ended December 31, 2019 is analysed as follows:

Movement in unrecognised deferred tax assets	Increase / (decrease) US$'000	Applicable tax rate %	Tax effect US$'000
Net operating losses in US	(1,348)	21%	(283)
Alternative minimum tax credit in US	254	n/a	254
Net operating losses in Brazil	1,788	34%	608
Net operating losses in Ireland	13,125	12.5% -25%	2,353
Other deferred tax assets in Ireland	(1,938)	12.5%	(243)
Other deferred tax assets in US	5,457	21%	1,146
US state credit carryforwards	129	n/a	129
Total – continuing operations	17,467		3,964

A deferred tax asset of US$1,968,000 (2018: US$1,360,000) was not recognised in respect of net operating losses in Brazil. The entity in Brazil was incorporated in 2012 and has cumulative losses to date. The deferred tax asset has not been recognised for Brazil 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.

A deferred tax asset of US$4,820,000 (2018: US$3,564,000) was not recognised in respect of net operating losses of Trinity Biotech Investments Ltd. ("TBIL"). TBIL, which is tax resident in Ireland, issued an exchangeable note of US$115 million in 2015 following its incorporation earlier in that year. To date this entity has recorded cumulative losses, as its interest expenses is greater than its interest income. The deferred tax asset has not been recognised due to uncertainty regarding the full utilization of these losses in future periods. Only when it is probable that future profits will be available to utilize the forward losses is a deferred tax asset recognised. In accordance with IAS 12, Income Taxes, both the movement in the exchangeable note's embedded derivatives value and the movement on the exchangeable note's host contract, being the accretion of notional interest, are exempt from deferred taxation recognition.

A deferred tax asset of US$6,619,000 (2018: US$5,691,000) was not recognised in respect of net operating losses in Trinity Biotech Manufacturing Ltd. An additional US$243,000 (2018: US$485,000) was not recognized in respect of other temporary timing differences. The total unrecognized deferred tax asset is US$6,862,000. The deferred tax assets in respect of net operating losses and other temporary timing differences have not been recognised due to insufficient deferred tax liabilities following the impairment charges relating to fixed assets in this entity. When there is a reversing deferred tax liability in a jurisdiction that reverses in the same period, the deferred tax asset is restricted so that it equals the reversing deferred tax liability.

A deferred tax asset of US$381,000 (2018: US$213,000) was not recognised in respect of net operating losses in Trinity Biotech Plc. The deferred tax asset has not been recognised due to uncertainty regarding the full utilization of these losses 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.

A deferred tax asset of US$3,291,000 (2018: US$2,174,000) was not recognised in respect of net operating losses, alternative minimum tax credits and other deferred tax assets in US. The deferred tax asset has not been recognised due to insufficient deferred tax liabilities following the impairment charge relating to property, plant and equipment and intangible assets. When there is a reversing deferred tax liability in a jurisdiction that reverses in the same period, the deferred tax asset is restricted so that it equals the reversing deferred tax liability. A deferred tax asset of US$493,000 (2018: US$364,000) in respect of US state credit carryforwards was also not recognised due to uncertainties regarding the timing of the utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

No deferred tax asset is recognised in respect of a capital loss forward of US$8,293,000 (2018: US$8,293,000) in Ireland as it is not probable that there will be future capital gains against which to offset these capital losses.

15. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

Unrecognised deferred tax liabilities

At December 31, 2019 and 2018, there was no recognised or unrecognised deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Company is able to control the timing of the reversal of the temporary differences of its subsidiaries and it is probable that these temporary differences will not reverse in the foreseeable future.

Movement in temporary differences during the year

	Balance January, 1 2019 US$'000	*Recognised in income US$'000*	*Balance December 31, 2019 US$'000*
Property, plant and equipment	778	240	1,018
Intangible assets	(7,189)	1,090	(6,099)
Inventories	668	(26)	642
Provisions	4,311	(473)	3,838
Other items	(296)	10	(286)
	(1,728)	841	(887)

	Balance January, 1 2018 US$'000	*Recognised in income US$'000*	*Balance December 31, 2018 US$'000*
Property, plant and equipment	350	428	778
Intangible assets	(9,443)	2,254	(7,189)
Inventories	1,006	(338)	668
Provisions	3,510	801	4,311
Other items	818	(1,114)	(296)
Tax value of loss carryforwards recognised	1,625	(1,625)	—
	(2,134)	406	(1,728)

16. OTHER ASSETS

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Finance lease receivables (see Note 18)	403	476
Other assets	82	82
	485	558

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, 2019 US$'000	*December 31, 2018 US$'000*
Raw materials and consumables	12,654	10,556
Work-in-progress	6,940	8,239
Finished goods	12,427	11,564
	32,021	30,359

All inventories are stated at the lower of cost or net realisable value. The replacement cost of inventories does not differ from cost. Total inventories for the Group are shown net of provisions of US$6,716,000 (2018: US$6,299,000). Cost of sales in 2019 includes inventories expensed of US$50,748,000 (2018: US$55,285,000), (2017: US$54,904,000).

The movement on the inventory provision for the three year period to December 31, 2019 is as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Opening provision at January 1	6,299	7,543	10,017
Charged during the year	1,567	480	2,561
Utilised during the year	(1,150)	(1,544)	(4,749)
Released during the year	-	(180)	(286)
Closing provision at December 31	6,716	6,299	7,543

During 2019, US$Nil (2018: US$180,000), (2017: US$286,000) of inventory provision relating to net realisable value was released to the statement of operations following a current year review of inventory usage.

18. TRADE AND OTHER RECEIVABLES

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Trade receivables, net of impairment losses	17,754	21,318
Prepayments	576	807
Contract assets	2,317	1,894
Value added tax	59	63
Finance lease receivables	281	359
	20,987	24,441

Trade receivables are shown net of an impairment losses provision of US$5,443,000 (2018: US$4,202,000) (see Note 29). Prepayments are shown net of impairment of US$1,376,000 (2018: US$1,608,000) (see Note 7).

Contract assets have increased compared to the prior year as the Group shipped more product to customers with cost per test contracts in the last month 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, 2019 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	523	242	281
Between one and five years (Note 16)	805	402	403
	1,328	644	684

	December 31, 2018 US$'000		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	617	258	359
Between one and five years (Note 16)	888	412	476
	1,505	670	835

The Group classified future minimum lease receivables between one and five years of US$403,000 (2018: US$476,000) 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, 2019 *US$'000*	
	Instruments	Total
Less than one year	3,528	3,528
Between one and five years	27	27
	3,555	3,555

	December 31, 2018 *US$'000*	
	Instruments	Total
Less than one year	3,498	3,498
Between one and five years	32	32
	3,530	3,530

19. CASH AND CASH EQUIVALENTS

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Cash at bank and in hand	6,275	6,854
Short-term deposits	8,956	23,423
Cash and cash equivalents	15,231	30,277

20. SHORT-TERM INVESTMENTS

All liquid investments with a maturity greater than six months are considered to be short-term investments.

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Investments (deposits)	1,169	-
	1,169	-

21. CAPITAL AND RESERVES

Share capital

In thousands of shares	*Class 'A' Ordinary shares 2019*	*Class 'A' Ordinary shares 2018*
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 2019*	*ADS 2018*
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 2019*	*Class 'A' Treasury shares 2018*
Balance at January 1	12,556	12,448
Purchased during the year	-	108
Balance at December 31	12,556	12,556

In thousands of ADSs	*ADS Treasury shares 2019*	*ADS Treasury shares 2018*
Balance at January 1	3,139	3,112
Purchased during the year	-	27
Balance at December 31	3,139	3,139

21. CAPITAL AND RESERVES (CONTINUED)

The Group had authorised share capital of 200,700,000 'A' ordinary shares of US$0.0109 each (2018: 200,700,000 'A' ordinary shares of US$0.0109 each) as at December 31, 2019.

(a) During 2019, the Group did not issue any shares from the exercise of employee options (2018: nil). At December 31, 2019, there were no amounts receivable on issuance share capital (2018: US$nil) relating to the exercise of share options.

(b) During 2019, the Group did not repurchase any 'A' ordinary shares under its share buyback program. (2018: 107,740 'A' ordinary shares or 26,935 ADS's).

(c) There were no dividends paid during 2019 in respect of the 2018 financial year, (nil in respect of the 2017 financial year), (nil in respect of the 2016 financial year). As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars.

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.

Warrant reserve

The Group calculates the fair value of warrants at the date of issue taking the amount directly to a separate reserve within equity. The fair value is calculated using the trinomial model. The fair value which is assessed at the grant date is calculated on the basis of the contractual term of the warrants.

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 warrant and hedging reserves form Other Reserves in the Consolidated Statement of Financial Position.

Treasury shares

During 2019, the Group did not purchase any (2018: 107,740) 'A' Ordinary shares (2018: 26,935 ADS's) 'Treasury shares'. The total cost of these shares in 2018 was US$139,000.

22. SHARE OPTIONS AND SHARE WARRANTS

Warrants

There were no warrants outstanding at the beginning of 2019, and there were no warrants granted in either 2019 or 2018. As there were no warrants outstanding, the warrant reserve was transferred to the accumulated surplus reserve during 2017.

Options

Under the terms of the Company's Employee Share Option Plans, options to purchase 12,303,990 'A' Ordinary Shares (3,075,998 ADS's) were outstanding at December 31, 2019. 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.

22. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

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.

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, 2017	9,830,183	3.19	0.66 –4.47
Granted	5,630,000	1.31	1.24 –1.44
Exercised	-	-	-
Forfeited	(4,732,807)	3.86	0.75 –4.47
Outstanding at end of year	10,727,376	1.92	1.24 –4.36
Exercisable at end of year	3,268,707	2.57	1.66 –4.36
Outstanding January 1, 2018	10,727,376	1.92	1.24 –4.36
Granted	720,000	1.07	0.67 –1.37
Exercised	-	-	-
Forfeited	(539,176)	2.50	1.34 –4.23
Outstanding at end of year	10,908,200	1.83	0.67 –4.36
Exercisable at end of year	6,091,864	2.09	1.24 –4.36
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

22. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

	Options and warrants 'ADS' Equivalent	Weighted-average exercise price US$ Per 'ADS'	Range US$ Per 'ADS'
Outstanding January 1, 2017	2,457,546	12.76	2.64 - 17.88
Granted	1,407,500	5.25	4.95 – 5.75
Exercised	-	-	-
Forfeited	(1,183,202)	10.26	3.00 –17.88
Outstanding at end of year	2,681,844	7.69	4.96–17.44
Exercisable at end of year	817,179	10.29	6.64 –17.45
Outstanding January 1, 2018	2,681,844	7.69	4.96 - 17.44
Granted	180,000	4.28	2.68 – 5.48
Exercised	-	-	-
Expired / Forfeited	(134,794)	10.00	5.36 – 16.92
Outstanding at end of year	2,727,050	7.32	2.68–17.44
Exercisable at end of year	1,522,966	8.36	4.96 –17.44
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

There were no share options exercised during 2019, 2018 or 2017.

The opening share price per 'A' Ordinary share at the start of the financial year was US$0.57 or US$2.29 per ADS (2018: US$1.28 or US$5.10 per ADS) (2017: US$1.73 or US$6.93 per ADS) and the closing share price at December 31, 2019 was US$0.26 or US$1.03 per ADS (2018: US$0.57 or US$2.29 per ADS) (2017: US$1.28 or US$5.10 per ADS). The average share price for the year ended December 31, 2019 was US$0.49 per 'A' Ordinary share or US$1.95 per ADS.

A summary of the range of prices for the Company's stock options for the year ended December 31, 2019 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$0.46-US$0.99	4,600,000	0.69	6.42	-	-	-
US$1.00-US$2.05	5,613,990	1.35	4.69	4,542,667	1.34	4.68
US$2.06-US$2.99	1,980,000	2.48	3.13	1,970,000	2.48	3.13
US$3.00 -US$4.36	110,000	4.19	2.07	110,000	4.19	2.07
	12,303,990			6,622,667		

22. SHARE OPTIONS AND SHARE WARRANTS (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$1.84-US$3.96	1,150,000	2.75	6.42	-	-	-
US$4.00-US$8.20	1,403,498	5.40	4.69	1,135,667	5.38	4.68
US$8.24-US$11.96	495,000	9.92	3.13	492,500	9.91	3.13
US$12.00-US$17.45	27,500	16.75	2.07	27,500	16.75	2.07
	3,075,998			1,655,667		

The weighted-average remaining contractual life of options outstanding at December 31, 2019 was 5.06 years (2018: 4.33 years).

A summary of the range of prices for the Company's stock options for the year ended December 31, 2018 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$0.66-US$0.99	430,000	0.88	6.79	-	-	-
US$1.00-US$2.05	6,111,800	1.35	5.64	2,476,133	1.35	5.57
US$2.06-US$2.99	4,168,400	2.51	2.23	3,437,731	2.51	1.83
US$3.00-US$4.47	198,000	4.20	2.97	178,000	4.20	2.93
	10,908,200			6,091,864		

	Outstanding			Exercisable		
Exercise price range	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)	No. of options 'ADS equivalent'	Weighted–average exercise price	Weighted-average contractual life remaining (years)
US$2.64-US$3.96	107,500	3.52	6.79	-	-	-
US$4.00-US$8.20	1,527,950	5.40	5.64	619,033	5.40	5.57
US$8.24-US$11.96	1,042,100	10.04	2.23	859,433	10.04	1.83
US$12.00-US$17.88	49,500	16.80	2.97	44,500	16.80	2.93
	2,727,050			1,522,966		

22. SHARE OPTIONS AND SHARE WARRANTS (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$758,000 was charged to the statement of operations in 2019, (2018: US$1,369,000), (2017: US$928,000) split as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*	*December 31, 2017 US$'000*
Share-based payments – cost of sales	26	34	35
Share-based payments – selling, general and administrative	732	1,335	893
Total – continuing operations	758	1,369	928
Share-based payments – discontinued operations	-	-	-
Total	758	1,369	928

The total share based payments charge for the year was US$839,000 (2018: US$1,607,000) (2017: US$1,109,000). However, a total of US$80,000 (2018: US$238,000) (2017: US$181,000) 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. The following are the input assumptions used in determining the fair value of share options granted in 2019, 2018 and 2017:

	Key management personnel 2019	**Other employees 2019**	**Key management personnel 2018**	**Other employees 2018**	**Key management personnel 2017**	**Other employees 2017**
Weighted average fair value at measurement date per 'A' share / (per ADS)	US$0.14 / (US$0.56)	US$0.25 / (US$1.02)	-	US$0.41 / (US$1.64)	US$0.43 / (US$1.72)	US$0.44 / (US$1.76)
Total 'A' share options granted / (ADS's equivalent)	4,060,000 / (1,015,000)	310,000 / (77,500)	-	720,000 / (180,000)	5,150,000/ (1,287,500)	480,000 / (120,000)
Weighted average share price per 'A' share / (per ADS)	US$0.46 / (US$1.84)	US$0.64 / (US$2.53)	-	US$1.07 / (US$4.28)	US$1.34 / (US$5.36)	US$1.31 / (US$5.24)
Weighted average exercise price per 'A' share / (per ADS)	US$0.69 / (US$2.74)	US$0.64 / (US$2.53)	-	US$1.07 / (US$4.28)	US$1.34 / (US$5.36)	US$1.31 / (US$5.24)
Weighted average expected volatility	51.18%	47.31%	-	42.69%	40.62%	40.48%
Weighted average expected life	4.15	4.42	-	4.55	4.45	4.69
Weighted average risk free interest rate	1.84%	2.23%	-	2.72%	1.59%	1.91%
Expected dividend yield	-	-	-	-	0.81%	0.81%

22. SHARE OPTIONS AND SHARE WARRANTS (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.

23. TRADE AND OTHER PAYABLES

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Trade payables	7,833	8,116
Payroll taxes	519	448
Employee related social insurance	170	154
Accrued liabilities	8,133	7,878
Deferred income	292	312
	16,947	16,908

Accrued liabilities include US$1,307,000 (2018: US$1,207,000) relating to contracted licence payments.

24. PROVISIONS

	December 31, 2019 US$'000	*December 31, 2017 US$'000*
Provisions	50	50

During 2019 and 2018 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, 2019 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, 2019.

25. EXCHANGEABLE NOTES

The Group 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, 2019.

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$463,000 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.

25. EXCHANGEABLE NOTES (CONTINUED)

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 embedded derivatives are summarised as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Non-current assets		
Exchangeable note bond call option	-	-
Non-current liabilities		
Exchangeable note equity conversion option	4	238
Exchangeable note bond put option	-	-
	4	238
Total value of embedded derivatives – net liability	4	238

Financial income in the consolidated statement of operations for the year includes US$234,000 (2018: US$1,388,000) arising from the revaluation of embedded derivatives at fair value at December 31, 2019.

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 carrying value of exchangeable senior notes is calculated as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Balance at 1 January	81,382	92,955
Accretion interest	639	689
Less: purchased during the year at fair value	-	(12,262)
	82,021	81,382

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Exchangeable senior notes	82,021	81,382
Total value of embedded derivatives – liability	4	238
Total non-current liabilities	82,025	81,620

This liability will accrete back to its nominal value of US$99,900,000 over the term of the debt using an effective interest rate methodology. Financial expense in the consolidated statement of operations for the year includes US$639,000 (2018: US$689,000) of accretion interest.

26. 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.

The reconciliation of operating lease commitments at December 31, 2018 to the additional lease liabilities recognized on the initial application of IFRS 16 at January 1, 2019 is as follows:

	US$000
Operating Lease commitments at December, 31, 2018 (Note 27)	27,342
Relief option for short term leases	(130)
Relief option for low value assets	-
Effect of assumed probable lease extension in adoption of IFRS 16	573
Other	(149)
Gross lease liabilities at January 1, 2019	27,636
Discounting	(6,451)
Additional Lease liabilities as a result of the initial application of IFRS 16 at January 1, 2019	21,185

The lease liabilities were discounted at the incremental borrowing rate as at January 1, 2019. The weighted average discount rate was 5.0%.

Lease liabilities

Lease liabilities are payable as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Current liabilities		
Lease liabilities related to Right of Use assets	2,156	-
Sale and leaseback liabilities	248	436
	2,404	436
Non-Current liabilities		
Lease liabilities related to Right of Use assets	17,474	-
Sale and leaseback liabilities	271	526
	17,745	526

26. LEASE LIABILITIES

	December 31, 2019 US$'000 Lease liabilities related to Right of Use assets			*December 31, 2019 US$'000 Sale and leaseback liabilities*		
	Minimum lease payments	Interest	Principal	Minimum lease payments	Interest	Principal
Less than one year	3,017	861	2,156	267	19	248
In more than one year, but not more than two	2,787	775	2,012	107	12	95
In more than two years but not more than five	6,700	1,861	4,840	185	9	176
more than five years	12,748	2,126	10,622	-	-	-
	25,252	5,263	19,630	559	40	519

	December 31, 2018 Operating Leases	*December 31, 2018 US$'000 Sale and leaseback liabilities*		
	Minimum lease payments	Minimum lease payments	Interest	Principal
Less than one year	3,083	473	37	436
In more than one year, but not more than two	2,783	271	19	252
In more than two years but not more than five	6,777	294	20	274
more than five years	14,699	-	-	-
	27,342	1,038	76	962

Lease payments not recognised as a liability

The Group has 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. The expense relating to payments not included in the measurement of the lease liability is as follows:

	December 31, 2019 US$000
Short term leases	130
Leases of low value assets	-
Variable lease payments	-
	130

26. LEASE LIABILITIES (CONTINUED)

Terms and debt repayment schedule

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2019 are as follows:

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	Euro	4.53%	2023	286	286
Sale and leaseback liabilities	USD	5.51%	2023	233	233
Total interest-bearing loans and borrowings				519	519

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2018 were as follows:

Facility	*Currency*	*Nominal interest rate*	*Year of maturity*	*Fair Value*	*Carrying Value*
Sale and leaseback liabilities	Euro	4.53%	2023	648	648
Sale and leaseback liabilities	USD	5.51%	2023	314	314
Total interest-bearing loans and borrowings				962	962

The total paid in respect of lease liabilities in the year ended December 31, 2019 was US$3,533,000 (2018: US$374,000).

27. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has capital commitments authorised and contracted for of US$323,000 as at December 31, 2019 (2018: US$187,000).

(b) Leasing Commitments

The Group's leasing commitments are shown in Note 26.

For future minimum finance lease commitments as at December 31, 2019, in respect of which the lessor has a charge over the related assets, see Note 26. Future minimum non-cancelable operating lease commitments in accordance with IAS 17 as at December 31, 2018 were as follows:

	Year ended 2018 Operating leases US$'000
2019	3,083
2020	2,783
2021	2,512
2022	2,255
2023	2,010
Later years	14,699
Total lease obligations	27,342

27. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(c) ***Bank Security***

The Group repaid in full its bank borrowings in April 2010, at which point all previous charges against Group assets were released. At December 31, 2019, Group borrowings were at fixed rates of interest and consisted Euro and USD denominated borrowings, refer to Note 29. 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, 2019 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 357, Irish Companies Act, 2014. Where the Company enters into these guarantees of the indebtedness of other companies within its Group, the Company considers these to be insurance arrangements and accounts for them as such. The Company treats the guarantee contract as a contingent liability until such time as it becomes probable that the company will be required to make a payment under the guarantee. The Company does not enter into financial guarantees with third parties.

(e) ***Contingent asset***

Arising from the tax audit settlement described in Note 6, Darnick Company agreed to contribute US$1,231,000 towards the settlement. The tax audit was finalised in late December 2019 and the amount due from Darnick Company was outstanding at December 31, 2019. This is a contingent asset at December 31, 2019. In accordance with IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*, the amount owing will be recognised when receipt of payment is virtually certain.

(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, 2019. However if the income were to become repayable, the maximum amounts repayable as at December 31, 2019 would amount to US$2,834,000 (2018: US$2,892,000).

(g) ***Litigation***

There are also a small number of legal cases being brought against the Group by certain of its former employees. There is a provision for cases where payment is considered by management to be probable. The ultimate resolution of the aforementioned proceedings is not expected to have a material adverse effect on the Group's financial position, results of operations or cash flows.

28. RELATED PARTY TRANSACTIONS

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

Leasing arrangements with related parties

The Group has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of Trinity Biotech, and directly with Mr O'Caoimh, to provide 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$427,000) 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.

28. RELATED PARTY TRANSACTIONS (CONTINUED)

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$883,000) and the annual rent for the warehouse is €144,000 (US$162,000). 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.

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.

Compensation of key management personnel of the Group

At December 31, 2019, 2018 and 2017 the key management personnel of the Group were made up of three key personnel: the two executive directors; Mr Ronan O'Caoimh and Dr Jim Walsh and Mr Kevin Tansley, our Chief Financial Officer/Executive Director. Kevin Tansley was appointed to the board in September 2016 as an Executive Director.

Compensation for the year ended December 31, 2019 of these personnel is detailed below:

	December 31, 2019 *US$'000*	December 31, 2018 *US$'000*
Short-term employee benefits	800	863
Performance related bonus	213	210
Post-employment benefits	42	44
Share-based compensation benefits	542	1,041
	1,597	2,158

The amounts disclosed in respect of directors' emoluments in Note 11 includes non-executive directors' fees of US$225,000 (2018: US$188,000) and share-based compensation benefits of US$82,000 (2018: US$313,000). Total directors' remuneration is also included in "personnel expenses" (Note 3) and "loss before tax" (Note 11). In 2019, share-based compensation benefits included in Note 11 exclude capitalised amounts of US$35,000 (2018: US$149,000).

On March 30, 2011, the service agreement with Ronan O'Caoimh as Chief Executive Officer was terminated and replaced by an agreement with Darnick Company, a company wholly-owned by members of Mr O'Caoimh's immediate family. Directors' compensation includes payments made to Darnick Company. This arrangement ceased with effect from December, 31, 2018 with Ronan O'Caoimh returning as an employee of the company.

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

	'A' Ordinary Shares	*Share options*
At January 1, 2019	9,139,706	8,655,004
Shares of retired director	(30,000)	—
Options of retired director	—	(215,000)
Shares purchased during the year	—	—
Shares sold during the year	(32,000)	—
Granted	—	4,060,000
Expired / forfeited	—	(2,086,000)
At December 31, 2019	9,077,706	10,414,004

28. RELATED PARTY TRANSACTIONS (CONTINUED)

	'A' Ordinary Shares	*Share options*
At January 1, 2018	5,719,706	8,770,004
Shares purchased during the year	3,420,000	—
Expired	—	(115,000)
At December 31, 2018	9,139,706	8,655,004

Rayville Limited, an Irish registered company, which is wholly owned by the three executive directors and certain other executives of the Group, owns all of the 'B' non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries. The 'B' shares do not entitle the holders thereof to receive any assets of the company on a winding up. All of the 'A' voting ordinary shares in Trinity Research Limited are held by the Group. Trinity Research Limited may, from time to time, declare dividends to Rayville Limited and Rayville Limited may declare dividends to its shareholders out of those amounts.

Any such dividends paid by Trinity Research Limited are ordinarily treated as a compensation expense by the Group in the consolidated financial statements prepared in accordance with IFRS, notwithstanding their legal form of dividends to minority interests, as this best represents the substance of the transactions.

The last dividend paid by Trinity Research Limited to Rayville Limited was in June 2009 for US$2,830,000. At the time this amount was immediately lent back by Rayville Limited to Trinity Research Limited. Since then US$1,788,000 of these loans have been repaid and recognised as a compensation expense by the Group. As of December 31, 2018 and December 31, 2019, the remaining amount of the loan was US$1,042,000. As this remaining amount of the original dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2018 and 2019 consolidated financial statements. During 2019, Trinity Research Limited repaid loans to Rayville Limited of US$159,000 in order to meet its obligations under a tax settlement arising from a tax audit.

As described in Note 6, a settlement was reached with the tax authority in one of the jurisdictions in which the company operates which included the payment of US$3,863,000 in relation to payments made by Trinity Research Limited to Rayville Limited and US$1,231,000 in relation to payments for CEO services made to Darnick Company. 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 recognised in the consolidated statement of financial position at year-end (refer to Note 27).

29. DERIVATIVES AND FINANCIAL INSTRUMENTS

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 in a cost effective, low-risk manner. 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.

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

Interest rate risk

Effective and repricing analysis

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

As at December 31, 2019	*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*	1.1%	15,231	15,231	—	—	—	—
Short-term investments	*20*	1.3%	1,169	—	1,169	—	—	—
Lease receivable	*16,18*	4.0%	684	157	124	202	201	—
Licence payments	*23*	8.1%	(1,307)	(1,307)	—	—	—	—
Exchangeable note	*25*	4.8%	(82,021)	—	—	—	—	(82,021)
Lease payable on Right of Use assets	*26*	5.0%	(19,630)	(1,136)	(1,020)	(2,012)	(4,840)	(10,622)
Lease payable on sale & leaseback transactions	*26*	5.0%	(519)	(122)	(125)	(95)	(177)	—
Total			(86,393)	12,823	148	(1,905)	(4,816)	(92,643)

As at December 31, 2018	*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*	1.8%	30,277	30,277	—	—	—	—
Short-term investments	*20*	—	—	—	—	—	—	—
Lease receivable	*18*	4.0%	835	191	168	238	238	—
Licence payments	*23*	3.0%	(1,207)	(1,207)	—	—	—	—
Finance lease payable	*26*	4.8%	(962)	(217)	(219)	(252)	(274)	—
Exchangeable note	*25*	4.8%	(81,382)	—	—	—	—	(81,382)
Total			(52,439)	29,044	(51)	(14)	(36)	(81,382)

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$101,000 (2018: US234,000) and would not affect the interest expense (2018: nil) resulting in an increase in net interest income of US$101,000 (2018: increase in net interest income of US$234,000).

Interest rate profile of financial assets / liabilities

The interest rate profile of financial assets/liabilities of the Group was as follows:

	December 31, 2019 US$'000	*December 31, 2018 US$'000*
Fixed rate instruments		
Fixed rate financial liabilities (licence fees)	(1,307)	(1,207)
Fixed rate financial liabilities (exchangeable note)	(82,021)	(81,382)
Fixed rate financial liabilities (lease payables)	(20,149)	(962)
Financial assets (short-term deposits and short-term investments)	10,125	23,423
Financial assets (lease receivables)	684	835
	(92,668)	(59,293)

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

Financial assets comprise cash and cash equivalents and short-term investments as at December 31, 2019 and December 31, 2018 (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, 2019 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, 2019 and December 31, 2018 as all fell due within 6 months.

Liquidity risk

The Group's operations are cash generating. 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, 2019 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	16,947	16,947	16,947	—	—	—	—
Lease payable on Right of Use assets	19,630	19,630	1,136	1,020	2,012	4,840	10,622
Lease payable on sale & leaseback transactions	519	519	122	125	95	177	—
Exchangeable notes	82,021	99,900	—	—	—	—	99,900
Exchangeable note interest	999	101,898	1,998	1,998	3,996	11,988	81,918
	120,116	238,894	20,203	3,143	6,103	17,005	192,440

As at December 31, 2018 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	16,908	16,908	16,908	—	—	—	—
Exchangeable notes	81,382	99,900	—	—	—	—	99,900
Exchangeable note interest	999	105,894	1,998	1,998	3,996	11,988	85,914
	99,289	222,702	18,906	1,998	3,996	11,988	185,814

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

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, 2019.

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, 2019	*EUR US$'000*	*GBP US$'000*	*SEK US$'000*	*CAD US$'000*	*BRL US$'000*	*Other US$'000*
Cash	394	138	10	3,265	238	—
Trade and other receivable	1,247	71	—	337	1,871	—
Trade and other payables	(2,350)	(27)	(142)	(47)	(796)	—
Total exposure	(709)	182	(132)	3,555	1,313	—

As at December 31, 2018	*EUR US$'000*	*GBP US$'000*	*SEK US$'000*	*CAD US$'000*	*BRL US$'000*	*Other US$'000*
Cash	81	122	9	2,512	322	6
Trade and other receivable	894	113	38	430	2,065	6
Trade and other payables	(1,995)	(51)	(146)	(103)	(1,621)	(2)
Total exposure	(1,020)	184	(99)	2,839	766	10

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, 2019 or December 31, 2018.

Sensitivity analysis

A 10% strengthening of the US Dollar against the Euro at December 31, 2019 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, 2019	
Euro	2,282
December 31, 2018	
Euro	1,818

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

A 10% weakening of the US Dollar against the Euro at December 31, 2019 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, 2019	
Euro	(2,790)
December 31, 2018	
Euro	(2,222)

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.

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, 2019 US$'000	*Carrying Value December 31, 2018 US$'000*
Third party trade receivables (Note 18)	17,754	21,318
Finance lease income receivable (Note 18)	684	835
Cash & cash equivalents (Note 19)	15,231	30,277
Short-term investments (Note 20)	1,169	—
	34,838	52,430

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

	Carrying Value December 31, 2019 US$'000	*Carrying Value December 31, 2018 US$'000*
United States	8,647	9,472
Euro-zone countries	786	1,502
United Kingdom	121	132
Other European countries	7	84
Other regions	8,877	10,963
	18,438	22,153

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

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, 2019 US$'000	*Carrying Value December 31, 2018 US$'000*
End-user customers	9,453	9,253
Distributors	7,199	11,860
Non-governmental organisations	1,786	1,040
	18,438	22,153

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

Impairment Losses

The ageing of trade receivables at December 31, 2019 is as follows:

	Gross 2019 US$'000	*Impairment 2019 US$'000*	*Expected Credit Loss Rate 2019 %*	*Gross 2018 US$'000*	*Impairment 2018 US$'000*	*Expected Credit Loss Rate 2018 %*
Not past due	10,924	8	0.1%	13,917	4	—
Past due 0-30 days	3,743	6	0.2%	3,761	17	0.5%
Past due 31-120 days	2,115	27	1.3%	3,438	36	1.0%
Greater than 120 days	6,415	5,402	84.2%	4,404	4,145	94.1%
	23,197	5,443	—	25,520	4,202	—

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

	2019 US$'000	*2018 US$'000*	*2017 US$'000*
Balance at January 1	4,202	3,590	3,171
Charged to costs and expenses	1,276	682	662
Amounts written off during the year	(35)	(70)	(243)
Balance at December 31	5,443	4,202	3,590

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.

Capital Management

The Group's policy is to maintain a strong capital base so as 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.

Following the divestiture of the Coagulation product line in 2010, the Group eliminated all bank debt. In the past, the Group has funded acquisitions using both equity and long term debt depending on the size of the acquisition and the capital structure in place at the time of the acquisition. Although at December 31, 2019 the Group has no bank debt, it maintains a relationship with a number of lending banks and Trinity Biotech is listed on the NASDAQ, which allows the Group to raise funds through equity financing where necessary. During 2015, the Group raised US$115,000,000 through the issuance of 30 year exchangeable senior notes. During 2018 the Group repurchased $15,100,000 of the exchangeable senior notes. The remaining exchangeable senior notes which will mature on April 1, 2045, subject to earlier repurchase, redemption or exchange, the earliest which is April 2022.

The Board of Directors is authorised to purchase its own shares on the market on the following conditions;

- the aggregate nominal value of the shares authorised to be acquired shall not exceed 10% of the aggregate nominal value of the issued share capital of the Company at the close of business on the date of the passing of the resolution:
- the minimum price (exclusive of taxes and expenses) which may be paid for a share shall be the nominal value of that share:

- the maximum price (exclusive of taxes and expenses) which may be paid for a share shall not be more than the average of the closing bid price on NASDAQ in respect of the ten business days immediately preceding the day on which the share is purchased.

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

Fair Values

The table below sets out the Group's classification of each class of financial assets/liabilities, their fair values and under which valuation method they are valued:

	Note	*Level 1 US$'000*	*Level 2 US$'000*	*Total carrying amount US$'000*	*Fair Value US$'000*
December 31, 2019					
Loans and receivables at amortised cost					
Trade receivables	*18*	17,754	—	17,754	17,754
Cash and cash equivalents	*19*	15,231	—	15,231	15,231
Investments (deposits)	*20*	1,169	—	1,169	1,169
Finance lease receivable	*16,18*	684	—	684	684
		34,838	—	34,838	34,838
Liabilities at amortised cost					
Exchangeable note	*25*	—	(82,021)	(82,021)	(82,021)
Lease liabilities	*26*	(20,149)	—	(20,149)	(20,149)
Trade and other payables (excluding deferred income)	*23*	(16,655)	—	(16,655)	(16,655)
Provisions	*24*	(50)	—	(50)	(50)
		(36,854)	(82,021)	(118,875)	(118,875)
Fair value through profit and loss (FVPL)					
Exchangeable note bond call option	*25*	—	—	—	—
Exchangeable note equity conversion option	*25*	—	(4)	(4)	(4)
Exchangeable note bond put option	*25*	—	—	—	—
		—	(4)	(4)	(4)
		(2,016)	(82,025)	(84,041)	(84,041)

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

29. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

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, 2018					
Loans and receivables at amortised cost					
Trade receivables	*18*	21,318	—	21,318	21,318
Cash and cash equivalents	*19*	30,277	—	30,277	30,277
Finance lease receivable	*16,18*	835	—	835	835
		52,430	—	52,430	52,430
Liabilities at amortised cost					
Exchangeable note	*25*	—	(81,382)	(81,382)	(81,382)
Finance lease payable	*26*	(962)	—	(962)	(962)
Trade and other payables (excluding deferred income)	*23*	(16,596)	—	(16,596)	(16,596)
Provisions	*24*	(50)	—	(50)	(50)
		(17,608)	(81,382)	(98,990)	(98,990)
Fair value through profit and loss (FVPL)					
Exchangeable note bond call option	*25*	—	—	—	—
Exchangeable note equity conversion option	*25*	—	(238)	(238)	(238)
Exchangeable note bond put option	*25*	—	—	—	—
		—	(238)	(238)	(238)
		34,822	(81,620)	(46,798)	(46,798)

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.

30. 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 1 January 2019	*25,26*	81,620	962
Cash-flows:			
Interest paid		(3,996)	—
Repayment		—	(3,533)
Non-cash:			
Interest charged		3,996	—
Adoption of IFRS 16 (Note 13)		—	21,185
Additions (related to Right of Use assets)		—	679
Exchange adjustment		—	(91)
Accretion interest		639	947
Fair value		(234)	—
Balance at 31 December 2019	*25,26*	82,025	20,149

	Note	*Borrowings & derivative financial instruments US$'000*	*Lease liabilities US$'000*
Balance at 1 January 2018	*25,26*	95,185	886
Cash-flows:			
Interest paid		(4,503)	—
Repurchase		(12,042)	—
Repayment.		—	(374)
Proceeds		—	481
Non-cash:			
Interest charged		4,352	—
Reduction in accrued interest payable		150	—
Exchange adjustment		—	(31)
Accretion interest		689	—
Fair value		(2,211)	—
Balance at 31 December 2018	*25,26*	81,620	962

31. POST BALANCE SHEET EVENTS

Decision to close Carlsbad manufacturing plant in 2020

The last number of years have 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 at our Carlsbad, California facility (which specialises in Western Blot manufacturing) have declined steadily to the extent that it no longer makes economic sense to continue. Consequently, in the early part of 2020, management decided to close this facility from June 30, 2020.

During the period until closure, final batches of Lyme Western Blot for remaining customers will be produced, whilst simultaneously transferring non-Lyme product manufacturing to other Group facilities. No provision has been reflected in the 2019 financial statements relating to the costs associated with closing this facility, terminating employment contracts, transferring assets to new locations in the Group. The Company recorded a provision of US$2.4 million in its income statement for Q1, 2020 to cover the related closure costs. This primarily includes the write-off of inventory and redundancy costs and is mainly non-cash in nature.

Covid-19 pandemic

Impact on Revenues

Subsequent to the balance sheet date, the Company's revenues have been significantly impacted by the Covid-19 Pandemic with the greater impact being seen from April 2020 onwards. In particular, this resulted in significant reduction in:

- Haemoglobins revenues – including both instrument and consumables revenues with the impact being greater on diabetes (A1c) rather than on haemoglobin variant revenues.
- Autoimmune revenues – 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, Infectious Diseases and Clinical chemistry product sales.

However, there were increases in sales of our transport medium product (used to transport Covid-19 patient samples in a stable environment), respiratory tests for Legionnaire's Disease and Strep Pneumoniae and of coronavirus-related antibodies sold by our life sciences supply business, Fitzgerald.

Covid-19 Expenditure Reduction Measures

All of the company's operations have remained open during the pandemic though at reduced levels of output in line with expected demand. However, in response to the expected reduction in revenues, the company undertook a number cost cutting measures which included the following:

- The company furloughed a large percentage of its work forces in the USA, Ireland and Canada in April, 2020. Meanwhile, in Brazil and other locations, staff costs were also significantly reduced by means of pay cuts.
- The elimination of virtually all travel costs and significant reductions in discretionary sales and marketing expenditure.
- Availing of governmental supports. This included the receipt of US$4.5 million of loans under the U.S. government's Paycheck Protection Program ("PPP"). Under the provisions of the PPP, these loans will be partially or totally forgiven, based on the extent to which a borrower's workforce returns to normal levels in the eight-week period immediately following the loans being granted. Upon receipt of these loans, the Company ended the furloughing of all staff in the USA and therefore expects that a large percentage of these loans will be forgiven later in 2020, once the necessary verification has taken place. In Ireland, the company also availed of economic support mechanisms being provided by the Irish Government though a significant level of furloughing continued into June, 2020, mainly due to the expected lower demand for HIV products for the African market.

31. POST BALANCE SHEET EVENTS (CONTINUED)

Impact on Working Capital

Due to the measures implemented by the company in response to falling demand for products the Company's cash position at May 31, 2020 was similar to that reported in the financial statements as at 31 December, 2019. Furthermore, the Company has not seen any significant deterioration in the recoverability of its inventory and accounts receivables balances as at 31 December, 2019. Meanwhile, the company is continuing to pay its creditors.

Asset Impairment

The annual impairment test on the carrying value of goodwill and other assets was carried out as at December 31, 2019 – see note 14. In determining whether a potential asset impairment exists, a range of internal and external factors are considered. However, the impairment test only takes into account conditions existing at the end of the reporting period. COVID-19 began to impact the population of Wuhan, China in December 2019 and initially the outbreak was largely concentrated in China. It was declared to be a pandemic by the World Health Organization in March 2020. The Company's impairment test as at December 31, 2019 therefore does not reflect the downturn in economic activity or the aforementioned impacts on the Company's revenues and expenditure caused by the Covid-19 pandemic.

If the impairment test was reperformed using projections which take into account the aforementioned impacts on revenues and expenditure, the impairment loss as at December 31, 2019 for Primus Corp. and Immco Diagnostics would be higher by US$1.8 million and US$1.7 million respectively. The reason these two Cash Generating Units are the only units affected is that the other Cash Generating Units' assets were already fully impaired, except Fitzgerald, as at December 31, 2019.

32. 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 22 outlines information regarding the valuation of share options and warrants. Note 25 outlines the valuation techniques used by the Company in determining the fair value of exchangeable notes and the associated embedded derivatives. In Note 29, detailed analysis is given about the interest rate risk, credit risk, liquidity risk and foreign exchange risk of the Group. The Group recognises revenue when it transfers control over a good or service to a customer.

Critical accounting judgements in applying the Group's accounting policies

Certain critical accounting judgements in applying the Group's accounting policies are described below:

Research and development expenditure

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.

32. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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

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

Impairment of intangible assets and goodwill

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment 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. 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. 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. 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. 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. For further information, refer to Note 29.

32. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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 in light of the increased tax losses caused by the restructuring and 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 2019, 2018 or 2017.

IFRS 16

IFRS 16, *Leases*, requires entities to make certain judgements and estimations. Critical judgements was 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.

Revenue Recognition

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 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.

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.

33. 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 plc IDA Business Park, Bray Co. Wicklow, Ireland	Investment and holding company	Ireland	Holding company
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.	Manufacture and sale of diagnostic test kits	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	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 June 15, 2020.

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: June 15, 2020

By: /s/ KEVIN TANSLEY
Mr Kevin Tansley
Company secretary/
Chief Financial Officer

Date: June 15, 2020

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 (File No. 000-22320), filed with the SEC on March 31, 2006).
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 (File No. 333-111946), filed with the SEC on January 15, 2004.)
4.1	Trinity Biotech plc Employee Share Option Plan 2013 (included as Exhibit 4.1 to our Registration Statement on Form S-8 (File No. 333-195232), filed with the SEC on April 11, 2014).
4.2	Trinity Biotech plc Employee Share Option Plan 2011 (included as Exhibit 4 to our Registration Statement on Form S-8 (File No. 333-182279), filed with the SEC on June 22, 2012).
4.3	Credit Facilities Letter dated as of February 6, 2015 between Allied Irish Banks, p.l.c. and Trinity Biotech plc, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited, as Borrowers (included as Exhibit 4.7 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.4	Guarantee Letter to Allied Irish Banks, p.l.c. dated as of February 6, 2015 by Trinity Biotech plc, Trinity Biotech Manufacturing Limited and Trinity Biotech Financial Services Limited, as Borrowers (included as Exhibit 4.8 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.5	Lease agreement dated as of October 18, 2004 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of office premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.1 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 31, 2006).
4.6	Lease agreement dated as of November 26, 2004 between Ronan O'Caoimh, Jonathon O'Connell and Jim Walsh with Trinity Biotech plc in respect of warehouse premises in Bray, Co Wicklow, Ireland (included as Exhibit 4b.2 to our to our Annual Report on Form 20-F (File No. 000-22320), filed with the SEC on 31 March 2006).
4.7	Lease agreement dated as of December 20, 2007 between Ronan O'Caoimh and Jim Walsh with Trinity Biotech Manufacturing Limited in respect of warehouse premises in Bray, Co Wicklow, Ireland (included as Exhibit 4.13 to our Annual Report on Form 20-F (File No. 000-22320), filed with the SEC on March 25, 2015).
4.8	Lease agreement dated as of March 19, 2004 between Livers, LLC with Primus Corporation in respect of office premises in Kansas City, Missouri, U.S.A. (included as Exhibit 4.14 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.9	Lease agreement dated as of May 30, 2001 between Lorrelle S. Johnson and Sharon L. Johnson with Clark Laboratories Inc in respect of office premises in Jamestown, New York, U.S.A. (included as Exhibit 4.15 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.10	Lease agreement dated as of February 13, 2012 between Barco Inv. Inc with Mardx Diagnostics in respect of office premises in San Diego, California, U.S.A. (included as Exhibit 4.16 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).

4.11	Lease agreement dated as of December 1, 2007 between 60 Pineview LLC with Immco Diagnostics Inc in respect of office premises in Amherst, New York, U.S.A. (included as Exhibit 4.17 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.12	CDC Non-Exclusive Patent License Agreement dated as of May 22, 2012 (included as Exhibit 4.19 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.13	The University of Texas System Materials License Agreement dated as of April 18, 2005 (included as Exhibit 4.20 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.14	Inverness Medical Innovations, Inc. Patent License Agreement renewal dated as of August 3, 2006 (included as Exhibit 4.21 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
4.15	National Institute of Health Non-Exclusive Patent License Agreement dated as of December 17, 1999 (included as Exhibit 4.22 to our Annual Report on Form 20-F (File No. 000- 22320), filed with the SEC on March 25, 2015).
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

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.

June 15, 2020

/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, Kevin Tansley, 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.

June 15, 2020

/s/ KEVIN TANSLEY*
Kevin Tansley
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, 2019 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

June 15, 2020

* 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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin Tansley, 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/ KEVIN TANSLEY*
Kevin Tansley
Chief Financial Officer

June 15, 2020

* 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 reports dated June 15, 2020, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Trinity Biotech plc on Form 20-F for the year ended December 31, 2019. We consent to the incorporation by reference of said reports 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

/s/ GRANT THORNTON
Dublin, Ireland

June 15, 2020