TRINITY BIOTECH PLC
Form 20-F
April 08, 2016
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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

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

For the fiscal year ended December 31, 2015

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:

95,840,138 Class A Ordinary Shares

(as of December 31, 2015)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

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 x

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 x 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 x Non-accelerated filer ¨

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 x 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 x

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form S-8 File Nos. 333-7762, 333-124384, 333-166590, 333-182279 and 333-195232, and Registration Statement on Form F-3, No. 333-203555.

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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 1 January 2015. 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 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.

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, 2015 and 2014 and for each of the years ended December 31, 2015, 2014 and 2013 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, 2013, 2012 and 2011 and for the years ended December 31, 2012 and December 31, 2011 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.

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CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December 31,				
	2015	*2014*	*2013*	*2012*	*2011*
	US$ 000	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Revenues	**100,195**	**104,872**	**91,216**	**82,510**	**77,948**
Cost of sales	(53,950)	(54,525)	(45,996)	(40,257)	(37,820)
Gross profit	**46,245**	**50,347**	**45,220**	**42,253**	**40,128**
Other operating income	288	424	532	468	910
Research and development expenses	(5,069)	(4,291)	(3,691)	(3,130)	(3,206)
Selling, general and administrative expenses	(28,016)	(28,441)	(33,066)	(22,425)	(22,048)
Operating profit	**13,448**	**18,039**	**8,995**	**17,166**	**15,784**
Financial income	13,491	97	1,276	2,280	2,428
Financial expenses	(4,063)	(69)	(51)	(88)	(12)
Net financing income	**9,428**	**28**	**1,225**	**2,192**	**2,416**
Profit before tax	**22,876**	**18,067**	**10,220**	**19,358**	**18,200**
Income tax expense	(1,080)	(853)	(574)	(2,017)	(2,607)
Profit for the year (all attributable to owners of the parent)	**21,796**	**17,214**	**9,646**	**17,341**	**15,593**
Basic earnings per ADS (US Dollars)	0.94	0.76	0.44	0.81	0.73
Diluted earnings per ADS (US Dollars)	0.46	0.73	0.41	0.77	0.70
Basic earnings per A ordinary share (US Dollars)	0.24	0.19	0.11	0.20	0.18
Diluted earnings per A ordinary share (US Dollars)	0.12	0.18	0.10	0.19	0.18
Weighted average number of shares used in computing basic EPS per ADS	23,161,773	22,749,726	21,936,647	21,418,821	21,292,874
Weighted average number of shares used in computing diluted EPS per ADS	27,407,793	23,717,747	23,428,175	22,443,404	22,228,149
Weighted average number of shares used in computing basic EPS per A ordinary share	92,647,091	90,998,904	87,746,588	85,675,284	85,171,494
Weighted average number of shares used in computing diluted EPS per A ordinary share	109,631,172	94,870,988	93,712,698	89,773,616	88,912,596

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Consolidated Balance Sheet Data

	December 31, 2015	*December 31, 2014*	*December 31, 2013*	*December 31, 2012*	*December 31, 2011*
	US$ 000	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Net current assets (current assets less current liabilities)	143,085	46,888	55,766	97,531	101,684
Non-current liabilities	(129,646)	(23,809)	(22,499)	(15,061)	(6,838)
Total assets	363,683	242,838	226,486	197,407	171,499
Capital stock	1,209	1,192	1,170	1,134	1,106
Shareholders equity	213,892	196,972	183,011	169,380	151,332

A final dividend of 22 cents per ADS was paid in 2015 in respect of the fiscal year 2014 (22 cents per ADS paid in 2014 in respect of the fiscal year 2013, 20 cents per ADS paid in 2013 in respect of the fiscal year 2012, 15 cents per ADS paid in 2012 in respect of the fiscal year 2011 and 10 cents per ADS paid in 2011 in respect of the fiscal year 2010).

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 in which we have invested substantial time and money. During the fiscal years ended December 31 2015, 2014 and 2013, we incurred US$19.7 million, US$20.3 million and US$18.4 million, respectively, in capitalized 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 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 utilizing our Meritas platform, such as Troponin I and Brain Natriuretic Peptide (BNP). If FDA clearance is delayed or not achieved for these products, it could have a material impact on the future growth of our business.

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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 Triage®, Architect), Alere (HA-8180), Bio-Rad (ELISA, WB, Bioplex , Variant II, Turbo and D10), Diasorin Inc. (Liasion , ETIMAX), Johnson & Johnson 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 Troponin I and BNP 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, FDA 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. 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.

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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.

The 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 our Troponin I test and BNP test, as well as other possible 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.

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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 facility 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.

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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 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.

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.

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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 states may restrict our ability to sell products in those states. 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. 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.

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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 have agreed to file new 510(k) notifications to obtain clearance for these indications. We are currently in ongoing discussions with the FDA regarding the data that FDA will require to support new 510(k) clearances to support the modified indications for these products. Although the FDA has informed us that we may continue marketing these products pending submission and clearance of new 510(k) notifications, there is no guarantee that we will be able to obtain new 510(k) clearances on a timely basis, or at all or that the FDA will not withdraw its authorisation to continue marketing the products pending new 510(k) clearance. If we are not able to obtain new 510(k) clearances, or if the FDA withdraws its authorisation, we may be required to cease marketing for the currently-marketed indications and remove these products from U.S. commercial distribution.

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.

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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.

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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 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

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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, pursuant to draft legislation being prepared by the German government, may make 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.

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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.

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.

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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 business unless suitable alternatives were timely 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$7,090,000) for any one accident, limited to a maximum of 6,500,000 (US$7,090,000) in any one year period of insurance. A deductible of US$25,000 is applicable to each insurance event that may arise.

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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 83% of revenues during the fiscal year ended December 31, 2015. 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

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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, 2015 were Ronan O Caoimh, our CEO and Chairman, Jim Walsh, Business Development Director, and Kevin Tansley, our CFO/Company Secretary. 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.

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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.

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. Since the acquisition of Fiomi Diagnostics AB in 2012 and the blood bank screening business of Lab21 Ltd in 2013, the Group also has a currency exposure to the Swedish Kroner and Sterling. The Group also has an exposure to the Brazilian Real through its Brazilian entity.

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, 2015, as described in Item 18, Note 18 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 4,679,323 A Ordinary Shares (1,169,831 ADSs) exercisable at

December 31, 2015 be exercised, Trinity Biotech would have to issue 4,679,323 additional A Ordinary Shares (1,169,831ADSs). On the basis of 95,840,138 A Ordinary Shares outstanding at December 31, 2015, this would effectively dilute the ownership interest of the existing shareholders by approximately 5%.

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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 recognize the United States judgment. The originating court must have been a court of competent jurisdiction, the judgment may not be recognized 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.

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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.

As directed by the Sarbanes-Oxley Act of 2002, we are required to include a report in our Annual Reports on Form 20-F that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

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.

If, during any year, our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, operated, tested or assessed, then it may issue a report that is qualified. We also 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.

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.

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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 8 U.S. patents with remaining patent lives varying from one month to 16 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.

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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 recently 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.

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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.

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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

We could be adversely affected by healthcare reform legislation and other changes in coverage and reimbursement for our tests by third-party payors.

Third-party payors for medical products and services, including state and federal governments, are increasingly concerned about escalating health care costs and can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. During 2010, following years of increasing pressure, the U.S. government enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act. The Affordable Care Act, among other things, established a 2.3% excise tax on the sales of medical devices beginning in calendar year 2013. In addition, it provided that payments under the Medicare Clinical Laboratory Fee Schedule (CLFS), received a negative 1.75% annual adjustment through 2015 and a productivity adjustment pursuant to the CLFS, further reducing payment rates. The Consolidated Appropriations Act, 2016, signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2017.

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Some commercial payors are guided by the CLFS in establishing their reimbursement rates. In February 2012, the Middle Class Tax Relief and Job Creation Act of 2012 was signed into law, which, in part, reduced the potential future cost-based increases to the CLFS by 2%. Because some of our revenue is currently derived from the Medicare program, any changes in Medicare reimbursement may adversely impact our business. We cannot predict whether Medicare and other third-party payor reimbursement rates that mirror Medicare s will be sufficient to make our tests commercially attractive.

Further, with respect to the CLFS, the Protecting Access to Medicare Act of 2014 (PAMA) will make significant changes to the way that Medicare will pay for clinical laboratory services. Under the new law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. 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 private payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). 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. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is too early to predict the impact on reimbursement for our products.

Also under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS must publicly report payment for the tests no later than January 1, 2016. We cannot determine at this time the full impact of the new law on our business, financial condition and results of operations.

Other Medicare policy changes may include competitive bidding by clinical laboratories for the provision of services, which was the subject of a CMS demonstration project pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). In July 2008, the Patients and Providers Act of 2008 was enacted, which, among other things, repealed the competitive bidding demonstration project for clinical laboratory services. If competitive bidding is implemented in the future, competitive bidding could decrease our reimbursement rates for clinical laboratory tests.

Healthcare legislative reforms affecting providers generally also include the Budget Control Act of 2011, which, 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 US$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. On April 1, 2013, the cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including our diagnostic tests, which, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to providers such as hospitals, imaging centres and cancer treatment centres, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of future diagnostic tests, increase costs, divert management s attention and adversely affect our ability to generate revenue and achieve profitability. Additionally, on several occasions, Congress has considered imposing a 20% co-insurance amount for clinical laboratory services, which would require beneficiaries to pay a portion of the cost of their clinical laboratory testing. Although that requirement has not been enacted at this time, Congress could decide to impose such an obligation at some point in the future, which would make it more difficult for us and our customers to collect adequate reimbursement for, and increase use of, our tests. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

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Finally, some private insurers and other third-party payors link their rates to Medicare s reimbursement rates, and a reduction in Medicare reimbursement rates for clinical laboratory services could result in a corresponding reduction in the reimbursements we or our customers receive from such third-party payors. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any such initiatives or reductions in reimbursement levels for our tests may reduce the amount that will be reimbursed to us and our customers for such services and consequently could place constraints on the levels of overall pricing, which could have a material effect on our sales and/or results of operations.

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 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 acquisitions made by Trinity Biotech in recent years:

Acquisition of Phoenix Bio-tech Corp.

In 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation for US$2.5 million of cash consideration and expected contingent consideration of US$172,000. US$120,000 of this contingent consideration had been paid as at December 31, 2015. Phoenix Bio-tech manufactures and sells products for the detection of syphilis.

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Phoenix Bio-tech was founded in 1992 and it sells its products under the TrepSure and TrepChek labels. Prior to the acquisition, Trinity Biotech distributed Phoenix Bio-tech s syphilis products on a non-exclusive basis in the U.S.

Acquisition of Fiomi Diagnostics AB

In 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB (Fiomi) for US$12.9m.

Fiomi, which is based in Uppsala, Sweden, is developing a range of point-of-care cardiac assays based on micro-pillar technology which will be marketed under the name Meritas. This technology is capable of providing extremely sensitive, highly reproducible, quantitative, multiplexed results making it significantly more accurate than the current established point-of-care tests in the market. In January 2014, Trinity received CE marking/EU regulatory approval of a Troponin I point-of-care test, the first test on this platform. In September 2014, CE marking/EU regulatory approval was received for a BNP point-of-care test. The Troponin I test was submitted for FDA review in December 2015, while the BNP test is currently undergoing clinical trials.

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. For more information please refer to Item 18, Note 24.

Acquisition of Blood Bank Screening Business

In 2013, the Group acquired the blood bank screening business of Lab21 Ltd for US$7.45m.

The blood bank screening business acquired consists of a range of products for the screening of syphilis, malaria and cytomegalovirus (CMV), and was, at the time of acquisition based in Cambridge and Newmarket, UK. The business includes very high quality TPHA and ELISA products. For more information please refer to Item 18, Note 24.

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 2015, 62% (US$62.4 million) (2014: 58% or US$61.1 million) (2013: 60% or US$54.8 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 38% (US$37.8 million) of total sales for fiscal year 2015 (2014: 42% or US$43.7 million) (2013: 40% or US$36.4 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.

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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	**Emergency Medicine**	**Infectious Diseases**	**Haemoglobin**	**Autoimmune**	**Clinical Chemistry**	**Blood Bank Screening**
UniGold	Meritas®	Bartels®	Premier	ImmuBlot	EZ	Captia
Recombigen®		MarDx®	Ultra2™	ImmuGlo		MicroTrak
		MarBlot®		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 the United Kingdom, and 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 several years in voluntary counselling and testing centres in the sub-Saharan region where it provides a cornerstone to early detection and treatment intervention.

In the U.S., the Centers for Disease Control (CDC) recommend the use of rapid tests to control the spread of HIV/AIDS. As part of this, Uni-Gold HIV is used in public health facilities, hospitals and other outreach facilities.

During 2013, Trinity Biotech received approval from the FDA for a HIV-2 claim for the Uni-Gold Recombigen® product. The approval will expand the sales potential of the Uni-Gold Recombigen® product in the United States as this product can now participate in certain health programs previously not open to it and compete more effectively in the hospital market.

The Future of Point-Of-Care at Trinity Biotech

Point-of-care is strategically key to the growth of Trinity. During 2013, Trinity Biotech introduced Uni-Gold S. pneumoniae, Uni-Gold Legionella, Uni-Gold C. difficile and Uni-Gold Syphilis. All of these products are Conformité Européenne (CE) marked and submissions for FDA clearance for the relevant products are in preparation. Future additions to this portfolio will include; *Helicobacter pylori* antigen, Malaria and HIV.

These new 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 and through independent distributors and strategic partners in other countries.

Emergency Medicine

Emergency medicine diagnostics refers to acute care testing which is critical time-sensitive diagnostic tests performed in emergency rooms, STAT labs, pre/post-operative units, physician office labs and the central laboratory.

Emergency medicine is a strategic cornerstone of the future growth of Trinity Biotech. Following the acquisition of Fiomi Diagnostics AB in 2012, Trinity Biotech has developed a high sensitivity test for Troponin I under the Meritas brand capable of delivering laboratory-quality results for the detection of heart attacks in the emergency room environment. Troponin I is a recognised marker for detecting acute myocardial infarctions. The objective in developing this product was to produce a test capable of meeting the Third Universal Definition of Myocardial

Infarction (2012 guideline) with a testing time of less than 15 minutes. CE marking/EU regulatory approval for this product was received in January 2014, and the product has been submitted for FDA review in Q4 2015.

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Trinity has also developed a BNP test on the same platform. BNP is a biomarker utilised in aiding the diagnosis of and determining the clinical severity of acute and chronic heart failure. In addition, BNP can be useful in a wide range of clinical applications including risk stratification and monitoring of patients with heart failure and heart attacks. CE marking and EU regulatory approval was received for this product in September 2014. US clinical studies for the product commenced in 2015, and submission to the FDA is anticipated in mid-2016. Once approved, the BNP assay will run side by side, on the same platform as Trinity s Troponin product.

Once the combined product offering is approved for commercialisation, Trinity will be positioned to successfully target and compete in the combined BNP and Troponin point-of-care market. The cardiac point-of-care market is estimated to be US$1 billion per year.

A top priority for Trinity Biotech is to expand its offering on the Meritas POC Analyser. The focus of our development efforts is to continue to expand the test menu to include assays for deep vein thrombosis and pulmonary embolism (D-dimer), and other highly valuable areas of need in emergency medicine.

Currently, Trinity Biotech offers the Meritas Troponin and BNP products for sale in Europe and other selected markets through its specialist Cardiology Distributor network. Trinity Biotech will launch the products in the U.S. following FDA clearance.

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,
- Haemoglobin, haemoglobin variants and glycated haemoglobin used in monitoring diabetes, and
- Autoimmune diseases

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

Infectious Diseases

Trinity Biotech manufactures products for niche and specialised applications in infectious diseases. The products are used with patient samples and the results generated help physicians to guide diagnosis for a broad range of infectious diseases. The key disease areas that Trinity Biotech serves include:

- Lyme disease,
- sexually transmitted diseases, including Syphilis, Chlamydia and Herpes simplex virus,
- respiratory infections, including legionella and influenza,
- Epstein Barr virus, and
- other viral pathogens, including measles, mumps, rubella and varicella.

Trinity Biotech develops, manufactures and distributes products in immunofluorescence (IFA), enzyme-linked immunosorbent (ELISA), western blot (WB) and cytotoxicity assay formats for diagnosis of infectious diseases. As a complement to the product range, the automation offering includes ELISA and western blot processors.

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, 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.

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Diabetes and haemoglobinapothies

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 boronte affinity technology to test for HbA1c which is a measure of a patient s average blood sugar control over the last two to three months. 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.

Trinity Biotech manufactures its own A1c instrument, the Premier Hb9210, which was launched in Europe and obtained FDA approval in late 2011. Trinity Biotech distributes Premier Hb9210 through its European partner Menarini Diagnostics. In the U.S. and Brazil, Trinity Biotech sells the Premier Hb9210 through its direct sales organisation. The Premier s unique features, cost structure and core technology enables it to compete in most economies and settings.

Trinity Biotech also develops and commercialises products for haemoglobin variants, primarily through the Ultra^2 instrument. This is used for the detection of haemoglobinapothies. Haemoglobinapothies are genetic defects that result in abnormal structure of the haemoglobin molecule. Haemoglobinapathies include sickle-cell diseases, alpha and beta thalassemia and are amongst the most common genetic disorders in the world.

Trinity is currently developing an ion exchange version of the Premier Hb9210, the Premier Resolution, which is expected to go to market in 2016. It combines the best of the Premier Hb9210 and the Ultra^2, and is a next generation integrated platform for detection of haemoglobin variants.

Autoimmune Diseases

Autoimmune diseases are diseases that involve immune responses of a body against its own cells and tissues.

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

- IFA,
- ELISA,
- WB and
- line immunoassay, or LIA.

As a complement to the product range, the automation offering includes ELISA and IFA processors and the Immco IFA reading system, iSight.

The Immco products are a seamless fit for the instrumentation platforms that Trinity Biotech continues to market for ELISA and WB assays. The majority of Immco s product line is FDA cleared for sale in the United States and CE marked in Europe.

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.

The Immco product line addresses the high growth, lower throughput, speciality 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.

The Immco products are sold through Trinity Biotech s sales and marketing organisation to clinical and reference laboratories directly in the U.S. and via distributors in other countries. Menarini Diagnostics, a European market leader in autoimmune testing, distributes Immco products in the key European markets.

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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 s blood bank screening business was acquired from Lab21 Ltd in July 2013. The business unit manufactures a number of products to screen donated blood for transfusion-transmissible infections.

The World Health Organisation estimates that there were 107 million blood donations in 2011 and half of these were within high income countries. In these countries it is mandatory to screen for HIV, HBV, HCV and Syphilis by nucleic acid or immunoassay testing and the WHO recommends testing for other pathogens (e.g. CMV, malaria, chagas and HTLV) based on territory.

Trinity Biotech manufactures immunoassays for the detection of Syphilis, CMV and Malaria. These products are sold through direct and distributor sales channels and are manufactured under original equipment manufacturer agreements for other major third party diagnostic companies. The business has strong market share in Europe and while not currently operating in the United States, Trinity Biotech is planning for operations there through internal synergies and external relationships.

Sales and Marketing

Trinity Biotech sells its product 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 disease, Haemoglobins, autoimmune and clinical chemistry products.

Through its sales and marketing organisation 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 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. Innovation in the market is rare but significant advantage can be made with the introduction of new disease markers or innovative techniques with patent protection.

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

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.

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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:

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. The Company recently received approval from the FDA for the HIV-2 claim on its Uni-gold HIV kit in the USA.

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 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. In 2005, Trinity also entered a Biological Materials License Agreement with the CDC for the rights to produce and sell the CDC developed HIV Incidence assay.

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 the new Point-of-Care range which is in development at our Carlsbad facility.

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% to 12.5% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2015 was US$846,000 (2014: US$1,049,000)

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 62% of Trinity Biotech s 2015 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.

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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.

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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.

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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 noninvasive;
- 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;

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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. 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.

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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.

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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.

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

State and Federal Privacy and Security Laws

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

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

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

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

Federal and State Anti-Kickback Laws

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

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

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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.

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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.

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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;

Trinity Biotech (USA), based in Jamestown, New York;

MarDx Diagnostics Inc, based in Carlsbad, California;

Primus Corporation, based in Kansas City;

Biopool US Inc, based in Jamestown, New York;

Immco Diagnostics Inc, based in Amherst and Buffalo, New York;

Nova Century Scientific Inc, based in Burlington, Canada;

Fiomi Diagnostics AB based in Uppsala; and

Trinity Biotech Brazil based in Sao Paulo.

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 31 to the consolidated financial statements.

Property, Plant and Equipment

Trinity Biotech has five manufacturing sites worldwide, four in the United States. (Buffalo and Jamestown, NY, Kansas City, MO and Carlsbad, CA), and one in Bray, Ireland, as well as a research and development facility in Uppsala, Sweden. The site in Uppsala currently has a manufacturing facility under construction. 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 9001: 2008 and ISO 13485: 2003 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.

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 and Dr Walsh, to provide current and potential future needs for the Group s manufacturing and research and development facilities, located in Bray, Ireland. In November 2004, Trinity Biotech 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$423,000), payable from 2004. In December 2007, the Group entered into an agreement with Mr O Caoimh and Dr Walsh pursuant to which the Group took a lease on an additional 43,860 square foot manufacturing facility in Bray, Ireland at a total annual rent of 787,000 (US$874,000). 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$161,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,436 square feet and is the subject of a five year lease, renewed in 2015, at an annual rental cost of US$248,000. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, renewed in 2015, at an annual rental cost of US$179,000.

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Fiomi Diagnostics AB operates from a 15,500 square foot facility based in Uppsala, in Sweden. This facility is the subject of a 3 year operating lease. The annual rent on this facility is 2,924,000 SEK (US$348,000).

Immco Diagnostics Inc. operates from a 19,250 square foot facility and a 2,436 square foot facility in Buffalo, New York, subject to leases expiring in 2017. The annual rent for these facilities is US$559,000. An additional 5,120 square foot facility is owned in Burlington, Canada.

Trinity Biotech (UK) Ltd operated from a 20,000 square foot facility in Cambridge, UK and a 10,000 square foot facility in Newmarket, UK. The lease for the Cambridge facility expired in March, 2014, and the Newmarket facility was subject to a 3 month rolling lease and is now also expired. Trinity Biotech vacated both the Cambridge and Newmarket premises in 2014.

Additional office and factory space is leased by the Group in Ireland, Kansas City, Missouri, Acton, Massachusetts and Sao Paulo, Brazil at an annual cost of 115,000 (US$128,000), US$104,000, US$94,000 and US$19,000 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. We do not currently have any plans to expand our 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.

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.

Uppsala, Sweden this site is responsible for the R&D activities related to our cardiac products, and a manufacturing facility is also currently under construction here.

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

Capital expenditures and divestitures

Please refer to Item 18, Note 24 with regard to the acquisition of Immco Diagnostics Inc and the blood bank screening business in 2013.

Item 4A ***Unresolved Staff Comments***
Not applicable.

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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, 2015, December 31, 2014 and December 31, 2013, 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, 2015 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, 2015, 2014, 2013, 2012 and 2011 have been impacted by acquisitions made by the Group in three of the five years. There were no acquisitions made in 2015 or 2014. In 2013, the Group acquired 100% of the common stock of Immco Diagnostics Inc. Immco specialises in the development, manufacture and sale of autoimmune test kits on a worldwide basis. In 2013, the Group also acquired the blood bank screening business of Lab21 Ltd, a UK based company. The acquired business generates revenues from syphilis and malaria products. In 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB. Fiomi is developing a range of point-of-care cardiac assays. In 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation. Phoenix Bio-tech manufactures and sells products for the detection of syphilis.

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.

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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

Revenue from the sale of goods is recognised in the statement of operations when the significant risks and rewards of ownership have been transferred to the buyer. Revenue from products is generally recorded as of the date of shipment, consistent with our typical ex-works shipping terms. Where the shipping 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 obligations to the customer in accordance with the shipping terms.

Revenue, including any amounts invoiced for shipping and handling costs, represents the value of goods supplied to external customers, net of discounts and excluding sales taxes.

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.

Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group, that the risks and rewards of ownership have passed to the buyer 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.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass 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. In the case of operating leases revenue is recognised over the life of the lease.

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, 2015 the carrying value of capitalised development costs was US$89,244,000 (2014: US$70,662,000) (see Item 18, Note 11 to the consolidated financial statements) of which US$31,084,000 relates to cardiac products developed by Fiomi Diagnostics. The increase in 2015 was mainly as a result of development costs of US$19,708,000 being capitalised. These additions were partially offset by amortisation of US$823,000.

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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 value-in-use calculations use cash flow projections based on the 2015 budget and projections for a further four years using projected revenue and cost growth rates of between 3% and 10%. 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 12% to 24% (2014: 12% to 24%). 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 11 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 no impairment loss recorded at December 31, 2015.
- In the event there was a 10% increase in the discount rate used to calculate the potential impairment of the carrying values, which would represent a reasonably likely range of outcomes, there would be the following impairment losses recorded at December 31,

2015:

	Theoretical Impairment loss US$000
Trinity Biotech Manufacturing Limited	1,808
Immco Diagnostics Inc.	1,287
Fiomi Diagnostics AB	3,473
Total	6,568

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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 has reached 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 2015, 2014 or 2013 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2015 our allowance for slow moving and obsolete inventory was US$4,822,000 which represents approximately 12.1% of gross inventory value. This compares with US$4,636,000, or approximately 12.1% of gross inventory value, at December 31, 2014 and US$4,462,000, or approximately 13.1% of gross inventory value, at December 31, 2013 (see Item 18, Note 14 to the consolidated financial statements). The estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory has remained consistent between 2015 and 2014. 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$799,000 at December 31, 2015 (2014: US$763,000) (2013: US$683,000) 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 2015, 2014 or 2013 which would have an impact on the carrying values of receivables in these periods. At December 31, 2015, the allowance was US$2,812,000 which represents approximately 2.8% of Group revenues. This compares with US$2,205,000 at December 31, 2014 which represented approximately 2.1% of Group revenues (see Item 18, Note 15 to the consolidated financial statements) and to US$2,150,000 at December 31, 2013 which represented approximately 2.4% of Group revenues. The increase in the allowance for impairment of receivables in the year ended December 31, 2015 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$501,000 at December 31, 2015 (2014: US$524,000) (2013: US$456,000) 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.

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Item 18, Note 12 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 22 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 2015. 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 2015, 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(xxviii).

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Subsequent Events

On March 3, 2016, the Group announced that it was suspending the payment of dividends and would commence a share buyback program. Based on a resolution passed at its most recent annual general meeting (AGM), the Company is currently authorized to repurchase up to 10% of its own shares. The Company s ability to buy back shares will be determined by available liquidity and general market conditions and will be carried out in accordance with applicable securities laws and regulations.

There are no other matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

The entity s operations in future financial years;

The results of those operations in future financial years; or

The entity s state of affairs in future financial years.

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Results of Operations

Year ended December 31, 2015 compared to the year ended December 31, 2014

The following compares our results in the year ended December 31, 2015 to those of the year ended December 31, 2014 under IFRS. Our analysis is divided as follows:

1. *Overview*
2. *Revenues*
3. *Operating Profit*
4. *Profit for the year*

1. Overview

In 2015, revenues decreased from US$104.9 million in 2014 to US$100.2 million, representing a decrease of 4.5%. This reduction was mainly attributable to the impact of the strengthening US dollar on the Company s foreign currency denominated revenues. In particular, the weakness of the Euro, Brazilian Real, Canadian dollar and Sterling resulted in a reduction in our US dollar denominated revenues. Other factors included lower Lyme sales due to weather related factors and unusually low HIV sales in Q2 2015. These were partly offset by underlying growth in Premier and Immco revenues for the year. Geographically, 62% of our sales were generated in the Americas, 23% in Africa/Asia and 15% in Europe.

The gross margin is 46.2% for 2015 compared to 48.0% in 2014. The reduction in gross margin is due to the strengthening US dollar, and lower Lyme and HIV sales. The operating profit is US$13.4 million for the year which compares to US$18.0 million for 2014. The decrease of US$4.5m in operating profit in 2015 is mainly attributable to the lower gross profit, higher Research & Development expenses and, in 2014, there was the release of a contingent consideration accrual of US$2.0 million. The contingent consideration accrual was written off in 2014 when the deadline for a milestone for Troponin I was not met and the deadline for a future milestone was not expected to be met.

In 2015, net financing income increased by US$9.4 million compared to 2014 due to the revaluation of elements of exchangeable notes issued in April 2015. The revaluation of embedded derivatives at fair value at 31 December 2015 resulted in a non-cash financial income of US$13.0 million. This was partly offset by interest on the exchangeable senior notes of US$3.9 million, of which US$0.5 million was the non-cash element.

Profit after tax for the year was US$21.8 million though this includes non-cash financial income of US$12.5 million recognised in relation to the exchangeable senior notes. Excluding this, profit after tax would have been US$9.3m compared with US$17.2m in 2014.

2. Revenues

The Group s revenues consist of the sale of diagnostic kits and related instrumentation and the sale of raw materials to the life sciences industry. Revenues from the sale of the above products are generally recognised on the basis of shipment to customers. The Group ships its products on a variety of freight terms, including ex-works, carriage including freight (CIF) and free on board (FOB), depending on the specific terms agreed with customers. In cases where the Group ships on terms other than ex-works, the Group does not recognise the revenue until its obligations have been fulfilled in accordance with the shipping terms.

No right of return exists in relation to product sales except in instances where demonstrable product defects occur. The Group has defined procedures for dealing with customer complaints associated with such product defects as they arise.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass 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. In the case of operating leases of instruments which typically involve commitments by the customer to pay a fee per test run on the instruments, revenue is recognised on the basis of customer usage of the instruments.

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Revenues by Product Line

Trinity Biotech s revenues for the year ended December 31, 2015 were US$100,195,000 compared to revenues of US$104,872,000 for the year ended December 31, 2014, which represents a decrease of US$4,677,000 or 4.5%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31, 2015	2014	
	US$ 000	US$ 000	% Change
Revenues			
Clinical Laboratory	73,576	77,240	(4.7%)
Point-of-Care	18,810	20,036	(6.1%)
Laboratory Services	7,809	7,596	2.8%
Total	**100,195**	**104,872**	**(4.5%)**

Clinical Laboratory

In 2015 Clinical Laboratory revenues decreased by US$3,664,000 which equates to a reduction of 4.7%.

This reduction was mainly attributable to the impact of the strengthening US dollar on the Company s foreign currency denominated revenues. In particular, the weakness of the Euro, Brazilian Real, Canadian dollar and Sterling, all of which represent significant currencies in which the Company invoices sales, resulted in a reduction in our US dollar reported revenues. This was accentuated by weakness in the currencies of other countries such as Turkey, Russia and a number of South American countries where the Company invoices in US dollars. In such countries the dollar s strength served to erode our competitiveness, which had a negative effect on our revenues. Other factors included lower Lyme disease sales due to weather related factors.

These were partly offset by underlying growth in Premier and Immco revenues for the year. Our sales prices tend to be relatively stable as we are unable to pass on sales price increases to our customers due to competitive factors.

Point-of-Care

Point-of-Care revenues decreased by US$1,226,000, which represents a reduction of 6.1%. Unlike Clinical Laboratory revenue, currency movements had a negligible impact on Point-of-Care revenues as a large proportion of sales are invoiced in US dollar. Revenues for our Unigold HIV test were US$17.2 million in 2015 compared to US$19.3 million in 2014. Sales prices were relatively stable during 2015 and the reduction in HIV revenues was due to lower sales volumes in Africa in Q2 2015, due to unusual ordering patterns. These revenues immediately rebounded in the third and fourth quarters to normal levels.

The decrease in HIV revenues was partly offset by growth in sales volumes of (a) newly-developed point-of-care tests for diseases such as streptococcus pneumonia and Legionella and (b) higher sales of our rapid syphilis test which received a CLIA waiver from the FDA in December 2014. The waiver allows the test to be performed by untrained healthcare workers in a variety of non-traditional laboratory sites such as emergency rooms, health department clinics, community-based organisations, physicians offices and other free standing counselling and testing locations in the U.S.

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Laboratory Services

In 2015, Laboratory Services revenues increased by US$213,000 which equates to growth of 2.8%. The increase was attributable to the laboratory of Immco Diagnostics, which was acquired in 2013. The increase in laboratory service revenues was driven by the growing demand for autoimmune diagnostic testing in the U.S., with our Sjögrens Syndrome test continuing to be the highest in revenue terms.

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, 2015	2014	
	US$ 000	US$ 000	% Change
Revenues			
Americas	62,421	61,142	2.1%
Asia/Africa	22,346	25,161	(11.2%)
Europe	15,428	18,569	(16.9%)
Total	**100,195**	**104,872**	(4.5%)

In the Americas, the 2.1% increase amounting to US$1,279,000 was primarily attributable to strong sales growth in our diabetes business in Brazil (although this was dampened by the weakness in the Brazilian currency), increased services revenues from our autoimmune laboratory in the U.S. and higher sales of our rapid syphilis test which received a CLIA waiver from the FDA in December 2014. These increases were partly offset by a reduction in sales of Lyme s disease products and the negative impact of the strengthening of the US dollar on Canadian revenues.

Asia/Africa revenues decreased by 11.2%, or US$2,815,000 compared to 2014. The main reasons for this were the decrease in Unigold HIV revenue in Africa and lower sales of the Premier and Tri-stat analysers particularly in Asia.

Revenues in Europe decreased by US$3,141,000, or 16.9% compared to 2014. The decrease was almost entirely due to currency movements. The Euro/US dollar exchange rate weakened by 16.5% on average in 2015 compared to 2014, while the Sterling/US dollar exchange also deteriorated by 7.3% on average in 2015 compared to 2014.

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

3. Operating Profit

The following table sets forth the Group s operating profit:

	Year ended December 31, 2015	2014	
	US$ 000	US$ 000	% Change
Revenues	100,195	104,872	(4.5%)
Cost of sales	(53,950)	(54,525)	(1.1%)
Gross profit	46,245	50,347	(8.1%)
Other operating income	288	424	(32.1%)
Research & development	(5,069)	(4,291)	18.1%
SG&A expenses	(28,016)	(28,441)	(1.5%)

Operating profit	**13,448**	**18,039**	(25.5%)

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Cost of sales and gross margin

Total cost of sales decreased by US$575,000 from US$54,525,000 for the year ended December 31, 2014 to US$53,950,000, for the year ended December 31, 2015, a decrease of 1.1%. The gross margin of 46.2% in 2015 compares to a gross margin of 48.0% in 2014.

The decrease in gross margin in 2015 is largely attributable to (a) the strengthening US dollar which contributed to a reduction in foreign currency denominated revenues and (b) lower sales of the high margin Lyme and HIV products.

Other operating income

Other operating income comprises rental income from sublet properties and income from the provision of services to Diagnostica Stago under Transition Services Agreements (TSAs). Other operating income decreased by US$136,000 from US$424,000 for the year ended December 31, 2014 to US$288,000, for the year ended December 31, 2014. The decrease is due to the strengthening US dollar against the Euro, the ending of TSA services being provided to Lab21 Ltd and the expiration of a rental sub lease.

Research and development expenses

Research and development expenditure recorded in the Statement of Operations increased from US$4,291,000 in 2014 to US$5,069,000 in 2015. The increase of US$778,000 was due to an increase in the technical support costs for our products partly offset by a) a reduction in Euro denominated costs due to the strengthening of the US dollar and b) the saving from the closure of the UK offices and the associated reduction in R&D headcount during 2014. 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$425,000 from US$28,441,000 for the year ended December 31, 2014 to US$28,016,000 for the year ended December 31, 2015.

The following table outlines the breakdown of SG&A expenses in 2015 compared to 2014.

	Year ended December 31, 2015	2014	
	US$ 000	US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	23,822	24,583	(3.1%)
Share-based payments	1,541	1,478	4.3%
Amortisation	2,653	2,380	11.5%
Total	**28,016**	**28,441**	(1.5%)

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

SG&A expenses excluding share-based payments and amortisation decreased from US$24,583,000 for the year ended December 31, 2014 to US$23,822,000 for the year ended December 31, 2015, which represents a decrease of 3.1%. The decrease of US$761,000 is mainly attributable to the impact of the strengthening US dollar on SG&A costs denominated in Euro, Brazilian Real, Canadian Dollar and and Sterling. This was partly offset by a non-recurring credit in 2014 being the release of a contingent consideration accrual of US$1,956,000. The contingent consideration was payable to the previous owners of Fiomi Diagnostics on the expected timing of certain development milestones for a Troponin I assay. The reversal of the contingent consideration liability reduced the SG&A costs in 2014 and occurred when the deadline for a milestone was not met and the deadline for a future milestone was not expected to be met.

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.

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The Group recorded a total share-based payments charge of US$1,550,000 (2014: US$1,496,000). The increase of US$54,000 in the total share-based payments expense is due to the granting of share options to key employees during 2015. The total charge is shown in the following expense headings in the statement of operations: US$9,000 (2014: US$18,000) was charged against cost of sales and US$1,541,000 (2014: US$1,478,000) was charged against selling, general & administrative expenses.

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

Amortisation

Amortisation increased from US$2,380,000 for the year ended December 31, 2014 to US$2,653,000 for the year ended December 31, 2015. The increase of US$273,000 is due to the commencement of amortisation for several internally developed products which were launched during 2015.

4. Profit for the year

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

	Year ended December 31,		
	2015	2014	
	US$ 000	US$ 000	% Change
Operating profit	13,448	18,039	(25.5%)
Net financing income	9,428	28	33571.4%
Profit before tax	22,876	18,067	26.6%
Income tax expense	(1,080)	(853)	26.6%
Profit of the year	**21,796**	**17,214**	**26.6%**

Net Financing income

Net financing income was US$9,428,000 for year-end December 31, 2015 compared to US$28,000 in 2014. Financial expenses increased by US$3,994,000 to US$4,063,000 mainly due to the interest expense for exchangeable senior notes issued in 2015. Financial income increased from US$97,000 for the year-end December 31, 2014 to US$13,491,000 in 2015 due to the revaluation of embedded derivatives at fair value at 31 December 2015 and the increase in bank deposit interest due to the higher cash on hand.

Taxation

The Group recorded a tax charge of US$1,080,000 for the year ended December 31, 2015 compared to US$853,000 for the year ended December 31, 2014. The 2015 tax charge comprises US$627,000 of current tax charge and US$453,000 of deferred tax charge. The effective tax rate for the year (which excludes the impact of non-cash financial income) was 10.4%. This low effective rate of tax is due to the competitive corporation tax rate in Ireland and the availability of research and development tax credits in a number of jurisdictions. For further details on the Group s tax charge please refer to Item 18, Note 8 and Note 12 to the consolidated financial statements.

Profit for the year

The profit for the year amounted to US$21,796,000, which represents an increase of US$4,582,000 when compared to US$17,214,000 in 2014, representing an increase of 26.6%. Excluding the non-cash financial income, profit after tax would have been US$9,315,000 compared with US$17,214,000 in 2014.

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Results of Operations

Year ended December 31, 2014 compared to the year ended December 31, 2013

The following compares our results in the year ended December 31, 2014 to those of the year ended December 31, 2013 under IFRS. Our analysis is divided as follows:

5. *Overview*
6. *Revenues*
7. *Operating Profit*
8. *Profit for the year*

5. Overview

In 2014, revenues increased 15% from US$91.2 million in 2013 to US$104.9 million. Clinical Laboratory revenues grew by almost 19% due to higher diabetes sales driven by increased Premier placements and the full year impact of the Immco Diagnostics and blood bank screening acquisitions made during 2013. These were partly offset by lower Lyme sales due to the impact of adverse weather conditions, particularly in north-eastern USA. Meanwhile, point-of-care revenues increased by 1.4% from US$19.8 million in 2013 to US$20.0 million in 2014. This growth was due to higher sales of new point-of-care tests for streptococcus pneumonia and legionella, and increased demand for our point-of-care A1c analyser, Tri-stat.

Geographically, 58% of our sales were generated in the Americas, 24% in Africa/Asia and 18% in Europe.

The gross margin is 48.0% for 2014, which is 1.6% lower than the gross margin for 2013. The reduction in gross margin is due to several factors, the main ones being a higher level of sales of Premier instruments, lower sales of the high margin Lyme product, and the higher running costs associated with the two blood bank screening manufacturing facilities in the UK. These facilities were closed in Q3 2014, following the transfer of manufacturing to the Group s existing facilities in Ireland and New York.

The operating profit is US$18.0 million for the year ended December 31, 2014 which compares to US$9.0 million for the year ended December 31, 2013. The increase of US$9.0m in operating profit in 2014 is mainly attributable to the increase in revenues, lower share-based payments, release of a contingent consideration accrual and several non-recurring charges in 2013. The non-recurring charges incurred in 2013 were as follows:

- a cost of US$5.4 million was incurred in 2013 to acquire a licence to a significant HIV-2 patent portfolio,
- a restructuring charge of US$0.7 million was recognised in 2013 for the blood bank screening business and,
- transaction costs of US$0.3 million were incurred in 2013 in relation to two acquisitions.

The contingent consideration accrual relates to additional consideration payable to the previous owners of Fiomi Diagnostics on the expected timing of certain milestones in the development of a Troponin I assay. In 2014 there was a reduction in the estimated amount payable amounting to US$2,057,000 when the deadline for a milestone was not met and the deadline for a future milestone is not expected to be met.

Net financial income decreased from US$1.2 million to US$28,000 mainly due to lower cash on deposit following two acquisitions in 2013.

The profit after tax for the year ended December 31, 2014 was US$17.2 million which compares to a profit after tax for the year ended December 31, 2013 of US$9.6 million.

6. Revenues

The Group s revenues consist of the sale of diagnostic kits and related instrumentation and the sale of raw materials to the life sciences industry. Revenues from the sale of the above products are generally recognised on the basis of shipment to customers. The Group ships its products on a variety of freight terms, including ex-works, CIF and FOB, depending on the specific terms agreed with customers. In cases where the Group ships on terms other than ex-works, the Group does not recognise the revenue until its obligations have been fulfilled in accordance with the shipping terms.

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No right of return exists in relation to product sales except in instances where demonstrable product defects occur. The Group has defined procedures for dealing with customer complaints associated with such product defects as they arise.

The Group leases instruments under operating and finance leases as part of its business. In cases where the risks and rewards of ownership of the instrument pass 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. In the case of operating leases of instruments which typically involve commitments by the customer to pay a fee per test run on the instruments, revenue is recognised on the basis of customer usage of the instruments.

Revenues by Product Line

Trinity Biotech s revenues for the year ended December 31, 2014 were US$104,872,000 compared to revenues of US$91,216,000 for the year ended December 31, 2013, which represents an increase of US$13,656,000 or 15%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31, 2014	2013	
	US$ 000	**US$ 000**	**% Change**
Revenues			
Clinical Laboratory	77,240	68,727	12.4%
Point-of-Care	20,036	19,754	1.4%
Laboratory Services	7,596	2,735	177.7%
Total	**104,872**	**91,216**	**15.0%**

Clinical Laboratory

In 2014 Clinical Laboratory revenues increased by US$8,513,000 which equates to growth of 12.4%.

The increase is mainly attributable to the full year impact of the two acquisitions in 2013 in our Clinical Laboratory division. Immco Diagnostics sells autoimmune tests, while the blood bank screening business has a particular emphasis on syphilis and malaria testing. Blood bank screening revenues increased to US$3,583,000 in 2014 (2013: US$2,445,000). The increase due to the two acquisitions was partly offset by a decrease in the volume of Lyme sales, which fell by US$942,000 to US$8,673,000 due to the impact of extreme cold weather conditions in north east USA resulting in the ticks that carry the bacteria which cause Lyme disease to be less active, thus reducing the risk of contraction by humans. Our sales prices tend to be relatively stable as we are unable to pass on sales price increases to our customers due to competitive factors.

Point-of-Care

Point-of-Care revenues increased by US$282,000, which represents an increase of 1.4%. Sales prices were relatively stable during 2014 and therefore the increase is more attributable to growth in sales volumes of (a) our Tri-stat A1c analyser which was launched in 2013 and (b) newly-developed point-of-care tests for diseases such as streptococcus pneumonia and Legionella. Revenues for our Unigold HIV test were US$19.3 million in 2014, which is broadly consistent with 2013.

Laboratory Services

In 2014 Laboratory Services revenues increased by US$4,861,000 which equates to growth of 177.7%. The increase is entirely attributable to the laboratory of Immco Diagnostics, which was acquired in H2 2013 and achieved high organic growth in 2014 mainly due to strong demand for Sjögrens Syndrome testing. Revenues for Sjögrens Syndrome testing increased significantly as the year progressed and in Quarter 4, 2014 we recorded Sjögrens revenues of more than US$500,000.

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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, 2014	2013	
	US$ 000	US$ 000	% Change
Revenues			
Americas	61,142	54,761	11.7%
Asia/Africa	25,161	24,061	4.6%
Europe	18,569	12,394	49.8%
Total	**104,872**	**91,216**	15.0%

In the Americas, the 12% increase amounting to US$6,381,000 is primarily attributable to the full year effect of the acquisition of Immco in H2 2013 and strong sales growth in our diabetes business in Brazil. This increase was partly offset by a reduction in sales of Lyme s disease products.

Asia/Africa revenues increased by 5%, or US$1,100,000 compared to 2013. The main reasons for this are the higher sales of the Premier and Tri-stat analysers particularly in Asia.

Revenues in Europe increased by US$6,175,000, or 50% compared to 2013. The increase was due to growth in sales of the Premier analyser and the full year impact of the two acquisitions in 2013.

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

7. Operating Profit

The following table sets forth the Group s operating profit:

	Year ended December 31, 2014	2013	
	US$ 000	US$ 000	% Change
Revenues	104,872	91,216	15.0%
Cost of sales	(54,525)	(45,996)	18.5%
Gross profit	50,347	45,220	11.3%
Other operating income	424	532	(20.3%)
Research & development	(4,291)	(3,691)	16.2%
SG&A expenses	(28,441)	(33,066)	(14.0%)
Operating profit	**18,039**	**8,995**	**100.5%**

Cost of sales and gross margin

Total cost of sales increased by US$8,529,000 from US$45,996,000 for the year ended December 31, 2013 to US$54,525,000, for the year ended December 31, 2014, an increase of 18.5%. The gross margin of 48.0% in 2014 compares to a gross margin of 49.6% in 2013.

The increase in cost of sales and the decrease in gross margin in 2014 is largely attributable to (a) a higher level of sales of Premier instruments (instruments have lower margins than the accompanying reagents and consumables), (b) lower sales of the high margin Lyme product and (c) the margin earned by the blood bank screening business, acquired in 2013, was lower than average due to high running costs associated with the two manufacturing facilities in the UK. These facilities were closed in quarter 3 2014, following the transfer of manufacturing to Trinity Biotech s facilities in Ireland and New York.

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Other operating income

Other operating income comprises rental income from sublet properties and income from the provision of services to Lab21 Ltd and Diagnostica Stago under Transition Services Agreements (TSAs). Other operating income decreased by US$108,000 from US$532,000 for the year ended December 31, 2013 to US$424,000, for the year ended December 31, 2014. The decrease was largely attributable to a decrease in TSA income from Lab21 Ltd. The short term arrangements with Lab21 for the provision of facilities and information technology services commenced in 2013 and finished in quarter 2 of 2014.

Research and development expenses

Research and development expenditure recorded in the Statement of Operations increased from US$3,691,000 in 2013 to US$4,291,000 in 2014. The increase of US$600,000 was due to the full year impact of two acquisitions, Immco Diagnostics and the blood bank screening business of Lab21, during 2013. 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$4,625,000 from US$33,066,000 for the year ended December 31, 2013 to US$28,441,000 for the year ended December 31, 2014.

The following table outlines the breakdown of SG&A expenses in 2014 compared to 2013.

	Year ended December 31, 2014	2013	
	US$ 000	US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	24,583	29,186	(15.8%)
Share-based payments	1,478	1,978	(25.3%)
Amortisation	2,380	1,902	25.1%
Total	**28,441**	**33,066**	**(14.0%)**

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

SG&A expenses excluding share-based payments and amortisation decreased from US$29,186,000 for the year ended December 31, 2013 to US$24,583,000 for the year ended December 31, 2014, which represents a decrease of 16%. The decrease of US$4,603,000 is mainly attributable to the following non-recurring costs incurred in 2013:

a cost of US$5,415,000 was incurred in 2013 to acquire a licence to a significant HIV-2 patent portfolio, including associated legal fees and net of implicit interest to reflect the contractual payment terms. There was no similar cost in 2014.

in 2013, the Group decided to transfer the production activities of the newly acquired blood bank screening business from the UK to our existing manufacturing facilities in Ireland and USA. This resulted in redundancies in the UK and a restructuring charge of US$690,000 was recognised in 2013.

Transaction costs of US$316,000 were incurred in 2013 in relation to the two acquisitions. There were no acquisitions in 2014. SG&A expenses were reduced in 2014 by the release of a contingent consideration accrual of US$1,956,000, with a further US$101,000 being credited to financial expenses. The contingent consideration is payable to the previous owners of Fiomi Diagnostics on the expected timing of certain development milestones for a Troponin I assay. The estimated amount payable reduced when the deadline for a milestone was not met

and the deadline for a future milestone is not expected to be met.

There was a partially offsetting increase of US$3,774,000 in Selling General & Administrative Expenditure mainly relating to sales and marketing costs for the Meritas range of products for which there were no matching revenues, selling and marketing costs for our new Sjögrens test, and the full year effect of the acquisitions in 2013.

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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$1,496,000 (2013: US$2,014,000). The decrease of US$518,000 in the total share-based payments expense is due to the vesting of a significant number of options during 2014. The total charge is shown in the following expense headings in the statement of operations: US$18,000 (2013: US$36,000) was charged against cost of sales and US$1,478,000 (2013: US$1,978,000) was charged against selling, general & administrative expenses.

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

Amortisation

Amortisation increased from US$1,902,000 for the year ended December 31, 2013 to US$2,380,000 for the year ended December 31, 2014. The increase of US$478,000 is due to a full year s amortisation charge on intangibles acquired in 2013 as part of the Immco Diagnostics and blood bank screening acquisitions. For further details of these business combinations refer to Item 18, Note 24 to the consolidated financial statements.

8. Profit for the year

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

	Year ended December 31,		
	2014	2013	
	US$ 000	US$ 000	% Change
Operating profit	18,039	8,995	101%
Net financing income	28	1,225	(98%)
Profit before tax	18,067	10,220	77%
Income tax expense	(853)	(574)	