TRINITY BIOTECH PLC
Form 20-F
March 25, 2015
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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, 2014

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:

94,308,358 Class A Ordinary Shares

(as of December 31, 2014)

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.

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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 2014. 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, 2014 and 2013 and for each of the years ended December 31, 2014, 2013 and 2012 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, 2012, 2011 and 2010 and for the years ended December 31, 2011 and December 31, 2010 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				
	2014	*2013*	*2012*	*2011*	*2010*
	Total US$ 000	*Total US$ 000*	*Total US$ 000*	*Total US$ 000*	*Total US$ 000*
Revenues	**104,872**	**91,216**	**82,510**	**77,948**	**89,635**
Cost of sales*	(54,525)	(45,996)	(40,257)	(37,820)	(45,690)
Gross profit	**50,347**	**45,220**	**42,253**	**40,128**	**43,945**
Other operating income	424	532	468	910	1,616
Research and development expenses	(4,291)	(3,691)	(3,130)	(3,206)	(4,603)
Selling, general and administrative expenses	(28,441)	(33,066)	(22,425)	(22,048)	(26,929)
Net gain on divestment of business and restructuring expenses					46,474
Operating profit	**18,039**	**8,995**	**17,166**	**15,784**	**60,503**
Financial income	97	1,276	2,280	2,428	1,352
Financial expenses	(69)	(51)	(88)	(12)	(495)
Net financing income	**28**	**1,225**	**2,192**	**2,416**	**857**
Profit before tax	**18,067**	**10,220**	**19,358**	**18,200**	**61,360**
Income tax expense	(853)	(574)	(2,017)	(2,607)	(942)
Profit for the year (all attributable to owners of the parent)	**17,214**	**9,646**	**17,341**	**15,593**	**60,418**
Basic earnings per ADS (US Dollars)	0.76	0.44	0.81	0.73	2.85
Diluted earnings per ADS (US Dollars)	0.73	0.41	0.77	0.70	2.79
Basic earnings per A ordinary share (US Dollars)	0.19	0.11	0.20	0.18	0.71
Diluted earnings per A ordinary share (US Dollars)	0.18	0.10	0.19	0.18	0.70
Weighted average number of shares used in computing basic EPS per A ordinary share	90,998,904	87,746,588	85,675,284	85,171,494	84,734,378
Weighted average number of shares used in computing diluted EPS per A ordinary share	94,870,988	93,712,698	89,773,616	88,912,596	86,661,535
Weighted average number of shares used in computing basic EPS per ADS	22,749,726	21,936,647	21,418,821	21,292,874	21,183,595
Weighted average number of shares used in computing diluted EPS per ADS	23,717,747	23,428,175	22,443,404	22,228,149	21,665,684

* Medical Device Excise Tax (MDET) was introduced in the USA on January 1, 2013. Cost of sales for 2014 includes MDET of US$547,000 (2013: US$691,000).

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Consolidated Balance Sheet Data

	December 31, 2014	*December 31, 2013*	*December 31, 2012*	*December 31, 2011*	*December 31, 2010*
	US$ 000	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Net current assets (current assets less current liabilities)	46,888	55,766	97,531	101,684	89,068
Non-current liabilities	(23,809)	(22,499)	(15,061)	(6,838)	(7,331)
Total assets	242,838	226,486	197,407	171,499	160,874
Capital stock	1,192	1,170	1,134	1,106	1,092
Shareholders equity	196,972	183,011	169,380	151,332	141,287

A final dividend of 22 cents per ADS was 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 2014, 2013 and 2012, we incurred US$20.3 million, US$18.4 million and US$13.0 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 BNP. We expect to submit these products for FDA clearance later in 2015. 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®), Alere Inc. (Determine , Wampole , Athena , Biosite Triage®), Arkray (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, or FDCA, or is the subject of an approved premarket approval application, or 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, or 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 test and BNP test, as well as other possible future products under development, will be 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 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, or 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, or 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 Orion, as the 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, or 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 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, 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.

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

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

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

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

the Physician Self-Referral Law, also known as the Stark Law , which provides for strict liability for referrals by physicians to entities with which they or their immediate family members have a financial arrangement for certain designated health services, including clinical laboratory services provided by our CLIA-certified laboratory owned and operated by 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;

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

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

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

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

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

We have not yet developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are or may become subject. Although the development and implementation of such compliance programs can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, or any other laws that may apply to us, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other laws and regulations that apply to us, we could receive adverse publicity, face enforcement action and be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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;

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We may not be able to accurately forecast the performance or ultimate impact of an acquired business;

An acquisition and subsequent integration activities may require greater capital and other resources than originally anticipated at the time of acquisition;

An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;

An acquisition may result in the loss of our or the acquired company s key personnel, customers, distributors or suppliers;

An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations, and our inability to successfully assimilate differences in foreign business practices or overcome language or cultural barriers; and

Our ability to integrate future acquisitions may be adversely affected by inexperience in dealing with new technologies.

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

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

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

The loss or termination of our relationship with these key distributors could significantly disrupt our 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.

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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$7,899,000) for any one accident, limited to a maximum of 6,500,000 (US$7,899,000) in any one year period of insurance. A deductible of US$25,000 is applicable to each insurance event that may arise. There can be no assurance that our product liability insurance is sufficient to protect us against liability that could have a material adverse effect on our business. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

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

Products manufactured at our facilities in Bray, Ireland, Jamestown and Buffalo, New York, Kansas City, Missouri and Carlsbad, California comprised approximately 86% of revenues during the fiscal year ended December 31, 2014. 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;

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we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and

our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

The operations of our facilities or these third-party manufacturing facilities could be adversely affected by fire, power failures, natural or other disasters, such as earthquakes, floods, or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead-time. There can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

If any of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products. If we are unable to satisfy commercial demand for our products in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors products. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our products that are subject to FDA and other regulatory clearances or approvals. We may also be required to assess the new manufacturer s compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Any significant interruption in the Group s or third-party manufacturing capabilities could materially and adversely affect our operating results.

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

Trinity Biotech s success is dependent to a large extent upon the contributions of certain key management personnel. Our key employees at December 31, 2014 were Ronan O Caoimh, our CEO and Chairman, Jim Walsh, our Chief Scientific Officer 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.

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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.

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.

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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, 2014, 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 4,056,991 A Ordinary Shares (1,014,248 ADSs) exercisable at December 31, 2014 be exercised, Trinity Biotech would have to issue 4,056,991 additional A Ordinary Shares (1,014,248 ADSs). On the basis of 94,308,358 A Ordinary Shares outstanding at December 31, 2014, this would effectively dilute the ownership interest of the existing shareholders by approximately 4%.

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.

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

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

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

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

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

We may require future additional capital.

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

The costs and timing of expansion of sales and marketing activities;

The timing and success of the commercial launch of new products;

The extent to which we gain or expand market acceptance for existing, new or enhanced products;

The costs and timing of the expansion of our manufacturing capacity;

The success of our research and product development efforts;

The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;

The magnitude of capital expenditures;

Changes in existing and potential relationships with distributors and other business partners;

The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;

The costs and liability associated with patent infringement or other types of litigation;

Competing technological and market developments; and

The scope and timing of strategic acquisitions.

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

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

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.

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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.

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.

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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 six months 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.

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.

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Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have an adverse effect on our business and financial condition.

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

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

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

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

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

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

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

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

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

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, can cause all or portions of our websites to be unavailable, create system disruptions, shutdowns, erasure of critical data and software or unauthorised disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks and we have implemented solutions, processes, and procedures to help mitigate these risks, such as encryption, virus protection, security firewalls and comprehensive information security and privacy policies. However, despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. The age of our information technology systems, as well as the level of our protection and business continuity or disaster recovery capability, varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent further security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data, which could have a material adverse impact on our business, financial condition and results of operations. While we currently expend resources to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

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

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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, or CLFS, are to receive a negative 1.75% annual adjustment through 2015 and a productivity adjustment pursuant to the CLFS, further reducing payment rates. 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, or 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, or 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.

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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.

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, or 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.

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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.

In 2010, the Group sold its worldwide Coagulation product line to Diagnostica Stago for US$90 million. Diagnostica Stago purchased the share capital of Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH and Trinity Biotech S.à r.l., along with Coagulation assets of Biopool US Inc. and Trinity Biotech Manufacturing Limited. Included in the sale were Trinity s lists of Coagulation customers and suppliers, all Coagulation inventory, intellectual property and developed technology. In total, 321 Trinity employees transferred their employment to Diagnostica Stago following the sale.

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. Phoenix Bio-tech manufactures and sells products for the detection of syphilis.

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 is currently undergoing clinical trials, while trials for the BNP test will commence in 2015 with FDA submission for both tests expected during 2015. For more information please refer to Item 18, Note 22.

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 22.

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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 screening. For more information please refer to Item 18, Note 22.

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 2014, 58% (US$61.1 million) (2013: 60% or US$54.8 million) (2012: 60% or US$49.6 million) of the Group s total revenues were derived from products sold in the Americas. Sales in the non-Americas (principally European, Asian and African countries) represented 42% (US$43.7 million) of total sales for fiscal year 2014 (2013: 40% or US$36.4 million) (2012: 40% or US$32.9 million).

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

Principal Products

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

Point-Of-Care		Clinical Laboratory				
Infectious Diseases	**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.

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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 based quality in the emergency room environment for the detection of heart attacks. 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 (2007 guideline) with a testing time of no more than 15 minutes. CE marking/EU regulatory approval for this product was received in January 2014. The product is currently undergoing clinical trials with a view to submitting to the FDA later in 2015.

Trinity has also developed a Brain Natriuretic Peptide (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. Clinical trials for the product are anticipated to commence in 2015. Once approved, the BNP assay will run side by side, on the same platform as Trinity s Troponin product. An FDA submission is also expected to be made later in 2015.

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, and
- Autoimmune diseases

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

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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.

Diabetes and haemoglobinapothies

Primus Corporation, a Trinity Biotech company, focuses on products for in-vitro diagnostic testing for haemoglobin A1c used in the monitoring and diagnosis of diabetes and Hb Variants for the detection of haemoglobinapothies. Haemoglobinapothies are genetic defects that results in abnormal structure of the haemoglobin molecule, the iron-containing oxygen-transport metalloprotein in the red blood cells. Haemoglobinapathies include sickle-cell diseases and are among the most common genetic disorders in the world.

Primus manufactures a range of instruments that use patented boronate affinity technology for point-of-care platforms and for high-performance liquid chromotography, or HPLC, platforms, as follows:

- Haemoglobin A1c, or HbA1c, is a measure of a patient s average blood sugar control over the last two to three months. HbA1c is a highly accurate biomarker available for the diagnosis of diabetes and is a strong indicator of a diabetics glycemic control. HbA1c is also used to identify those at risk of becoming diabetic; often referred to as impaired glucose tolerance;
- Haemoglobin Variants: The Primus Ultra^2 instrument is an accurate, precise method for detection of haemoglobin variants which is important for screening populations for genetic abnormalities that can lead to conditions such as sickle cell anaemia and thalassemia. With over 200 variants in its library The Primus Ultra^2 is in a leading position to address this complex yet common disorder;

Neonatal Haemoglobin: The GeneSys system is designed for the detection of Haemoglobin variants in neonatal patients. This is a growing segment as more countries around the world expand their newborn screening programs.

The Premier Hb9210 was launched in Europe in the second half of 2011. Trinity Biotech distributes Premier Hb9210 through its European partner Menarini Diagnostics. FDA approval was obtained in the fourth quarter of 2011. In the U.S., 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 is currently developing an ion exchange version of the Premier Hb9210 which will be capable of detecting both HbA1c and haemoglobin variants. This product, Premier Resolution, is expected to launch in 2015.

The current Primus products are sold through the Trinity Biotech sales and marketing organisation to clinical and reference laboratories directly in the U.S. and Brazil. Elsewhere the products are sold through Trinity Biotech s network of distribution partners.

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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 specialised reference laboratory offering 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.

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 (or 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 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 in the United States 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.

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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 approximately.

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, Alere Inc., 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. 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.

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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, except in the case of one of the agreements which expires in 2015. 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 10% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2014 was US$1,049,000 (2013: US$1,105,000).

Government Regulation

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

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

The process in each country varies considerably depending on the nature of the test, the perceived risk to the user and patient, the facility at which the test is to be used and other factors. As 58% of Trinity Biotech s 2014 revenues were generated in the Americas (with a large concentration of this in the United States) and as the United States represents a substantial proportion of the worldwide diagnostics market, an overview of FDA regulation has been included below.

Food and Drug Administration

All of our products sold in the United States are medical devices subject to the Federal Food, Drug, and Cosmetic Act (FDCA), as implemented and enforced by the U.S. Food and Drug Administration (FDA). Certain of our products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. Other of our 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 on PMA approvals that have already been granted;

refusal to grant export approval for our products; or

criminal prosecution.

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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 US 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 procedure. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees.

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

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

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

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

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

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

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

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

Although the FDA is not bound by the advisory panel decision, the panel s recommendation is important to the FDA s overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application , although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process.

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

Clinical Studies.

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

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

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Most clinical studies of IVDs (all of which technically involve investigational use only, or 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, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

post-approval restrictions or conditions, including post-approval study commitments;

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

the FDA s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

regulations pertaining to voluntary recalls; and

notices of corrections or removals.

We have registered our facility with the FDA as a medical device manufacturer. 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.

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

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

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

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

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

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Federal Oversight of Laboratory Developed Tests and Research Use Only Products

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

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

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

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

Product Exports

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

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

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Healthcare Reform

The Protecting Access to Medicare Act of 2014, or 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, enacted in March 2010, among other things:

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

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

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

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

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

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

State and Federal Privacy and Security Laws

Under the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of individually identifiable health information, also known as protected health information, or 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.

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

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

Federal and State Anti-Kickback Laws

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

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

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

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

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

Physician Self-Referral Prohibitions

In addition to the Anti-Kickback Statute, a federal law directed at physician self-referral, commonly known as the Stark Law, prohibits, among other things, physicians who personally or through an immediate family member, have a financial relationship, including an investment, ownership or compensation relationship with an entity, including clinical laboratories, from referring Medicare patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies.

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In addition, the clinical laboratory is prohibited from billing for any tests performed pursuant to a prohibited referral. Recent court cases have extended the Stark law s prohibition to referral of Medicaid patients as well. A person who engages in a scheme to circumvent the Stark Law s referral prohibition may be fined up to US$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to US$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states also have anti- self-referral and other laws that are not limited to Medicare and Medicaid referrals.

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

Civil Monetary Penalties Law

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

Other Federal and State Fraud and Abuse Laws

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

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

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

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

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

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

New York Laboratory Licensing

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

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

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

Other States Laboratory Licensing

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

Regulation outside the United States

Distribution of Trinity Biotech s products outside of the United States is also subject to foreign regulation. Each country s regulatory requirements for product approval and distribution are unique and may require the expenditure of substantial time, money, and effort. There can be no assurance that new laws or regulations will not have a material adverse effect on Trinity Biotech s business, financial condition, and results of operation. The time required to obtain needed product approval by particular foreign governments may be longer or shorter than that required for FDA clearance or approval. There can be no assurance that Trinity Biotech will receive on a timely basis, if at all, any foreign government approval necessary for marketing its products.

Organisational Structure

Trinity Biotech plc and its subsidiaries (the Group) is a manufacturer of diagnostic test kits and instrumentation for sale and distribution worldwide. Trinity Biotech s executive offices are located at Bray, Ireland while its research and development, manufacturing and marketing activities are principally conducted at the following:

Trinity Biotech Manufacturing Limited, based in Bray, Ireland;

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; and

Fiomi Diagnostics AB based in Uppsala.

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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 29 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. 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 and ISO registered facilities. As part of its ongoing commitment to quality, Trinity Biotech was granted the latest ISO 9001: 2000 and ISO 13485: 2003 certification. This certificate was granted by the Underwriters Laboratory, an internationally recognised notified body. It 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 Trinity Biotech 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 16,700 square feet of offices at an annual rent of 381,000 (US$463,000), 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$956,000). 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$155,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,436 square feet and is the subject of a three year lease, renewed in 2012, at an annual rental cost of US$244,000. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, amended in 2012, at an annual rental cost of US$176,000.

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$429,000).

Immco Diagnostics Inc. operates from a 15,200 square foot facility and a 4,000 square foot facility in Buffalo, New York, subject to leases expiring in 2017 and 2015 respectively. The annual rent for these facilities is US$531,000. An additional 4,200 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$140,000), US$100,000, US$91,000 and US$29,000 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.

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We do not currently have any plans to expand our facilities. We intend to improve production efficiency in the next twelve months at our Bray, Ireland facility by introducing more automation into the production process.

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.

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 22 with regard to the acquisition of Immco Diagnostics Inc and the blood bank screening business in 2013 and the acquisition of Fiomi Diagnostics AB in 2012.

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

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

Trinity Biotech s consolidated financial statements include the attributable results of Trinity Biotech plc and all its subsidiary undertakings collectively. This discussion covers the years ended December 31, 2014, December 31, 2013 and December 31, 2012, 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, 2014 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.

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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 high potential 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, 2014, 2013, 2012, 2011 and 2010 have been impacted by acquisitions made by the Group in three of the five years and by the divestiture of the Coagulation product line in 2010. There were no acquisitions made in 2014 or 2010. 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.

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 shipment terms. Where the shipment terms do not permit revenue to be recognised as of the date of shipment, revenue is recognised when the Group has satisfied all of its 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.

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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, 2014 the carrying value of capitalised development costs was US$70,662,000 (2013: US$51,648,000) (see Item 18, Note 11 to the consolidated financial statements). The increase in 2014 was mainly as a result of development costs of US$20,323,000 being capitalised. These additions were partially offset by amortisation of US$562,000.

Impairment of intangible assets and goodwill

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

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

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

Goodwill and other intangibles are subject to impairment testing on an annual basis. The recoverable amount of each of the cash-generating units (CGU) is determined based on a value-in-use computation, which is the only methodology applied by the Group and which has been selected due to the impracticality of obtaining fair value less costs to sell measurements for each reporting period. For the purpose of the annual impairment tests, goodwill is allocated to the relevant CGU.

The 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 15%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate, 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.

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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% (2013: 13% to 25%).

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

1. 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, the following impairment loss/write back would be recorded at December 31, 2014:

No reversal of impairment in the event of a 10% increase in the growth in revenues.

No impairment loss in the event of a 10% decrease in the growth in revenues.

2. Similarly if there was a 10% variation in the discount rate used to calculate the potential impairment of the carrying values, which would represent a reasonably likely range of outcomes, there would be the following impairment loss/write back would be recorded at December 31, 2014:

No reversal of impairment in the event of a 10% decrease in the discount rate.

No impairment loss in the event of a 10% increase in the discount rate.

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 2014, 2013 or 2012 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2014 our allowance for slow moving and obsolete inventory was US$4,636,000 which represents approximately 12.1% of gross inventory value. This compares with 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) and US$5,348,000, or approximately 20.5% of gross inventory value, at December 31, 2012. There has been a decrease in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2014 and 2013. 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$763,000 at December 31, 2014 (2013: US$683,000) (2012: US$522,000) 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 2014, 2013 or 2012 which would have an impact on the carrying values of receivables in these periods. At December 31, 2014, the allowance was US$2,205,000

which represents approximately 2.1% of Group revenues. This compares with US$2,150,000 at December 31, 2013 which represented approximately 2.4% of Group revenues (see Item 18, Note 15 to the consolidated financial statements) and to US$1,520,000 at December 31, 2012 which represented approximately 1.8% of Group revenues. In the event that this estimate 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$524,000 at December 31, 2014 (2013: US$456,000) (2012: US$413,000) would result.

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Accounting for income taxes

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

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

While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable.

The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. In management s opinion, adequate provisions for income taxes have been made.

Item 18, Note 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.

Impact of Recently Issued Accounting Pronouncements

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) both as issued by the International Accounting Standards Board (IASB) and as subsequently adopted by the European Union (EU) (together IFRS). The IFRS applied are those effective for accounting periods beginning 1 January 2014. 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.

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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 2014, 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).

Subsequent Events

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, 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:

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

1. 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.

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, CIF (carriage including freight) and FOB (free on board), 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.

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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 .

3. 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	Increase/(Decrease)	
	US$ 000	US$ 000	US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	24,583	29,186	(4,603)	(15.8%)
Share-based payments	1,478	1,978	(500)	(25.3%)
Amortisation	2,380	1,902	478	25.1%
Total	**28,441**	**33,066**	(4,625)	(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 22 to the consolidated financial statements.

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,		
	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)	49%
Profit of the year	**17,214**	**9,646**	**78%**

Net Financing income

Net financing income was US$28,000 for year-end December 31, 2014 compared to US$1,225,000 in 2013. Financial expenses remained broadly the same at US$69,000. Financial income decreased from US$1,276,000 for the year-end December 31, 2013 to US$97,000 in 2014 due to the fall in deposit interest rates and a reduction in the amount of cash on deposit following two acquisitions in 2013.

Taxation

The Group recorded a tax charge of US$853,000 for the year ended December 31, 2014 compared to US$574,000 for the year ended December 31, 2013. The 2014 tax charge comprises US$123,000 of current tax credit and US$976,000 of deferred tax charge. The increase in the total tax charge in 2014 is primarily due to a 77% increase in profit before tax. The effective tax rate was broadly consistent in 2013 and 2014 at 4.7%. 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$17,214,000, which represents an increase of US$7,568,000 when compared to US$9,646,000 in 2013, representing an increase of 78%.

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Results of Operations

Year ended December 31, 2013 compared to the year ended December 31, 2012

The following compares our results in the year ended December 31, 2013 to those of the year ended December 31, 2012 under IFRS. Our analysis is divided as follows:

5. *Overview*

6. *Revenues*

7. *Operating Profit*

8. *Profit for the year*

5. Overview

In 2013, revenues were US$91.2 million, which represented an increase of US$8.7 million (11%) compared to 2012. Point-of-care revenues increased by over 3% from US$19.2 million in 2012 to US$19.8 million in 2013. This growth was due to the continuing strength of HIV sales in Africa. Meanwhile, Clinical Laboratory revenues grew by almost 13% due to higher diabetes sales driven by increased Premier placements, the impact of the Immco Diagnostics and blood bank screening acquisitions made during the year and higher sales of infectious diseases products in China. These was partly offset by lower Lyme sales due to the impact of adverse weather conditions in eastern USA, particularly in the first half of 2013.

Geographically, 60% of our sales were generated in the Americas, 26% in Africa/Asia and 14% in Europe.

The gross margin is 49.6% for 2013, which is 1.6% lower than the gross margin for 2012. The reduction in gross margin is due to several factors, the main ones being the new medical devices excise tax introduced by the US government in 2013 and a higher level of sales of A1c instruments. There was also higher running costs associated with the two blood bank screening manufacturing facilities in the UK. These facilities will be closed in 2014, following the transfer of manufacturing to the Group s existing facilities in Ireland and New York.

The operating profit is US$9.0 million for the year ended December 31, 2013 which compares to US$17.2 million for the year ended December 31, 2012. In addition to the factors discussed above, several other significant charges contributed to a reduction in operating profit in 2013, as follows:

- a licence to a significant HIV-2 patent portfolio cost US$5.4 million including associated legal fees and net of implicit interest,
- a charge of US$0.7 million was recognised for redundancy costs associated with the closure of the two UK operations acquired as part of the blood bank screening business, and
- acquisition costs of US$0.3 million were incurred in relation to the two business combinations.

Net financial income decreased from US$2.2 million to US$1.2 million, mainly due to a combination of reduced deposit interest rates and lower cash on deposit following two acquisitions in 2013.

The profit after tax for the year ended December 31, 2013 was US$9.6 million which compares to a profit after tax for the year ended December 31, 2012 of US$17.3 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 (carriage including freight) and FOB (free on board), 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.

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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, 2013 were US$91,216,000 compared to revenues of US$82,510,000 for the year ended December 31, 2012, which represents an increase of US$8,706,000 or 11%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31, 2013	2012	
	US$ 000	US$ 000	% Change
Revenues			
Clinical Laboratory	71,462	63,356	12.8%
Point-of-Care	19,754	19,154	3.1%
Total	**91,216**	**82,510**	**10.6%**

Clinical Laboratory

In 2013 Clinical Laboratory revenues increased by US$8,106,000 which equates to 12.8%.

The increase is mainly attributable to the two acquisitions in our Clinical Laboratory division, which generated incremental revenues of US$8,444,000 in 2013. Immco Diagnostics sells autoimmune tests, while the blood bank screening business has a particular emphasis on syphilis and malaria testing. This increase was partly offset by a decrease of US$253,000 in Lyme sales 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 remain underground, thus reducing the risk of contraction by humans.

Point-of-Care

Our principal Point-of-Care product is Unigold , which tests for the presence of HIV antibodies. Our two main markets for Point-of-Care tests are USA and Africa. Point-of-Care revenues increased by US$600,000, which represents an increase of 3.1%. This increase was due to a 4% increase in revenues in Africa, due to higher international and governmental funding in Nigeria, Tanzania and Zambia. This was partly offset by a 3% decrease in revenues in the USA due to lower federal funding for HIV testing programmes.

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, 2013	2012	
	US$ 000	US$ 000	% Change
Revenues			
Americas	54,761	49,638	10.3%
Europe	12,394	10,214	21.3%
Asia/Africa	24,061	22,658	6.2%

Total	**91,216**	**82,510**	10.6%

In the Americas, the 10% increase amounting to US$5,123,000 is primarily attributable to the Immco acquisition. This increase was partly offset by a reduction in sales of Lyme s disease products.

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Revenues in Europe increased by US$2,180,000, or 21% compared to 2012. The increase was due to growth in sales of the Premier analyser and the impact of acquisitions in 2013.

Asia/Africa revenues increased by 6%, or US$1,403,000 compared to 2012. The main reason for this is the strong growth in sales of Trinity s Unigold rapid HIV test in Africa. Higher sales of infectious diseases tests in China and the new Premier analyser also contributed to the growth.

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, 2013	2012	
	US$ 000	**US$ 000**	**% Change**
Revenues	91,216	82,510	10.6%
Cost of sales	(45,996)	(40,257)	14.3%
Gross profit	45,220	42,253	7.0%
Other operating income	532	468	13.7%
Research & development	(3,691)	(3,130)	17.9%
SG&A expenses	(33,066)	(22,425)	47.5%
Operating profit	**8,995**	**17,166**	**(47.6%)**

Cost of sales and gross margin

Total cost of sales increased by US$5,739,000 from US$40,257,000 for the year ended December 31, 2012 to US$45,996,000, for the year ended December 31, 2013, an increase of 14%. The gross margin of 49.6% in 2013 compares to a gross margin of 51.2% in 2012.

The increase in cost of sales and the decrease in gross margin in 2013 is largely attributable to (a) the introduction of a medical devices excise tax by the US government on 1st January 2013, which resulted in additional costs of US$691,000, (b) a higher level of sales of A1c instruments (instruments have lower margins than the accompanying reagents and consumables) and (c) the margin earned by the new blood bank screening business acquired in H2 2013 was lower than average due to high running costs associated with the two manufacturing facilities in the UK. These facilities will be closed in mid-2014, following the transfer of manufacturing to Trinity Biotech s facilities in Ireland and New York.

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). TSA income from Diagnostica Stago commenced in April 2010 and comprised a variety of services including accounting, information technology and logistics support and warehousing services. The majority of the TSA services derived from Diagnostica Stago were short term arrangements which ceased by the middle of 2012. TSA income from Lab21 Ltd commenced in 2013 and comprises facilities and information technology services.

Research and development expenses

Research and development (R&D) expenditure recorded in the Statement of Operations increased from US$3,130,000 in 2012 to US$3,691,000 in 2013. The increase of US$561,000 was mainly due to the impact of two acquisitions during 2013 and an increase in headcount in our US technical support team. 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 increased by US$10,641,000 from US$22,425,000 for the year ended December 31, 2012 to US$33,066,000 for the year ended December 31, 2013.

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The following table outlines the breakdown of SG&A expenses in 2013 compared to 2012.

	Year ended December 31, 2013	2012	Increase/(Decrease)	
	US$ 000	US$ 000	US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	29,186	19,268	9,918	51%
Share-based payments	1,978	1,675	303	18%
Amortisation	1,902	1,482	420	28%
Total	**33,066**	**22,425**	**10,641**	**47%**

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

SG&A expenses excluding share-based payments and amortisation increased from US$19,268,000 for the year ended December 31, 2012 to US$29,186,000 for the year ended December 31, 2013, which represents an increase of 51%. The increase of US$9,918,000 is attributable to the following main reasons:

- the combined Selling General & Administrative Expenditure incurred by the two acquired businesses was US$3,900,000, excluding share-based payments, amortisation costs and restructuring charges;

- in 2013, the Group acquired the blood bank screening business of Lab21 Ltd. In order to drive significant operational synergies and efficiencies, the production activities of the blood bank screening business will be transferred from its current UK premises to our existing manufacturing facilities in Bray, Ireland and Jamestown, New York during 2014. This will result in redundancies in the UK and we have recognised a restructuring charge in 2013 of US$690,000;

- a cost of US$5,415,000 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. The cost of the licence has been charged to the Statement Of Operations in 2013 as management have determined that the Company will not generate any incremental cash flows or otherwise generate any future economic benefit from the license. The Company recently received approval from the FDA for the HIV-2 claim on its Uni-gold HIV kit in the USA. Future growth in HIV revenues in the USA will result from the granting of the HIV-2 claim by the FDA, rather than from the HIV-2 licence itself.

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 and the risk free rate.

The Group recorded a total share-based payments charge of US$2,014,000 (2012: US$1,713,000). The increase of US$301,000 in the total share-based payments expense is due to the full year effect of share options granted to employees and directors during 2012 and the impact of new share options granted during 2013. The total charge is shown in the following expense headings in the statement of operations: US$36,000 (2012: US$38,000) was charged against cost of sales and US$1,978,000 (2012: US$1,675,000) 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$1,482,000 for the year ended December 31, 2012 to US$1,902,000 for the year ended December 31, 2013. The increase of US$420,000 is mainly due to the amortisation charged on intangibles acquired in 2013 as part of the Immco Diagnostics and blood bank screening acquisitions and higher amortisation charges as new products were launched. For further details of these business combinations refer to Item 18, Note 22 to the consolidated financial statements.

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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, 2013	2012	
	US$ 000	**US$ 000**	**% Change**
Operating profit	8,995	17,166	(48%)
Net financing income	1,225	2,192	(44%)
Profit before tax	10,220	19,358	(47%)
Income tax expense	(574)	(2,017)	(72%)
Profit of the year	**9,646**	**17,341**	**(44%)**

Net Financing income

Net financing income is US$1,225,000 for year-end December 31, 2013 compared to US$2,192,000 in 2012. Financial expenses remained broadly the same at US$51,000. Financial income decreased from US$2,280,000 for the year-end December 31, 2012 to US$1,276,000 in 2013 due to the fall in deposit interest rates and a reduction in the amount of cash on deposit following two acquisitions in 2013.

Taxation

The Group recorded a tax charge of US$574,000 for the year ended December 31, 2013 compared to US$2,017,000 for the year ended December 31, 2012. The 2013 tax charge comprises US$175,000 of current tax credit and US$749,000 of deferred tax charge. The decrease in the total tax charge in 2013 is primarily due to lower profits in our Irish operations and a higher R&D tax credit in 2013. 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$9,646,000, which represents a decrease of US$7,695,000 when compared to US$17,341,000 in 2012, representing a decrease of 44%.

Liquidity and Capital Resources

Financing

The Group has no bank borrowings. During 2010 the Group repaid in full the outstanding portion of its US$48,340,000 club banking facility with AIB plc and Bank of Scotland (Ireland) Limited (the banks) using the proceeds from the divestiture of the Coagulation product line. This facility had been secured on the assets of the Group (see Item 18, Note 23(c)).

Bank Facility

In February 2015, the Group entered into an overall facility agreement with Allied Irish Bank which consists of separate revolver, overdraft and leasing facilities amounting to approximately US$15 million.

Working capital

In the Directors opinion the Group will have access to sufficient funds to support its existing operations for at least the next 12 months by utilising existing cash resources and cash generated from operations.

The amount of cash generated from operations will depend on a number of factors which include the following:

The ability of the Group to continue to generate revenue growth from its existing product lines;

The ability of the Group to generate revenues from new products following the successful completion of its development projects;

The extent to which capital expenditure is incurred on additional property plant and equipment;

The level of investment required to undertake both new and existing development projects; and

Successful working capital management in the context of a growing business.

Cash management

As at December 31, 2014, Trinity Biotech s consolidated cash and cash equivalents were US$9,102,000. This compares to cash and cash equivalents of US$22,317,000 at December 31, 2013.

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Cash generated from operations for the year ended December 31, 2014 amounted to US$15,690,000 (2013: US$8,766,000), an increase of US$6,924,000. The increase in cash generated from operations of US$6,924,000 is attributable to an increase in operating cash flows before changes in working capital of US$481,000 in addition to a decrease in working capital outflows of US$6,443,000. The increase in operating cash flows before changes in working capital of US$481,000 is primarily driven by the increase in profit during the current financial year. The working capital outflow decrease, when compared to the prior year, is partly due to the decrease in the cash outflows for trade and other receivables of US$6,303,000 and decrease in cash outflows of US$2,771,000 for inventories. This has been offset partially by the decrease in cash inflows from trade and other payables, when compared to the prior year, of US$2,631,000. The cash generated from operations was attributable to an operating profit of US$18,039,000 (2013: US$8,995,000), as adjusted for non cash items of US$2,243,000 (2013: US$10,806,000) plus cash outflows due to changes in working capital of US$4,592,000 (2013: cash outflows of US$11,035,000).

The decrease in other non cash charges from US$10,806,000 for the year ended December 31, 2013 to US$2,243,000 for the year ended December 31, 2014 is mainly attributable to once-off charges incurred in 2013 relating to restructuring and new license agreements entered into, as well as a reduction of US$2,057,000 in the estimated contingent consideration payable relating to the acquisition of Fiomi Diagnostics AB. Refer to Item 18, Note 22 for further detail.

The net cash outflows in 2014 due to changes in working capital of US$4,592,000 are due to the following:

- An increase in trade and other receivables of US$729,000 due to the increase in revenues and the increase, year on year, in the debtors days number;
- An increase in inventory of US$4,487,000 due to the strategic build up of certain inventory items during the course of the year (most notably in relation to the Premier Hb9210 Instrument); and
- An increase in trade and other payables balance of US$624,000 due to timing of payments.

Net interest received amounted to US$96,000 (2013: US$1,292,000). This consisted of interest received of US$96,000 (2013: US$1,292,000) on the Group s cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2014 amounted to US$27,756,000 (2013: outflows of US$61,193,000) which were principally made up as follows:

- Payments to acquire intangible assets of US$19,486,000 (2013: US$18,687,000), which principally related to development expenditure capitalised as part of the Group s on-going product development activities; and
- Acquisition of property, plant and equipment of US$8,270,000 (2013: US$4,489,000) incurred as part of the Group s investment programme for its manufacturing and distribution activities, and placement of instruments.
- There were no acquisitions of subsidiaries in the current year (2013: US$39,424,000).

Net cash outflows from financing activities for the year ended December 31, 2014 amounted to US$1,427,000 (2013: US$798,000). The increase in outflows in 2014 is due to the fact that the Group paid higher dividends in 2014 compared to 2013. The main area of cash outflow from financing activities for the year was the annual dividend payment of US$5,029,000 (2013: US$4,373,000). Other cash outflows included expenses paid in connection with share issues and debt financing of US$40,000 (2013: US$87,000). These outflows were partially offset by the receipt of US$3,642,000 from the issue of ordinary shares in 2014 (2013: US$3,662,000). Ordinary shares issued in 2014 and 2013 are as a result of share options exercised during the course of the year.

The majority of the Group s transactions are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group s Euro denominated expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Trinity Biotech

continuously monitors its exposure to foreign currency movements and expectations of future exchange rate exposure and, if deemed necessary, will cover a portion of this exposure through the use of forward contracts. When used, these forward contracts are cash flow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions.

As at December 31, 2014 and December 31, 2013 there was no interest-bearing debt outstanding. Cash and cash equivalents were US$9,102,000 (2013: US$22,317,000).

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

Contractual obligations

The following table summarises our minimum contractual obligations and commercial commitments, including interest, as of December 31, 2014:

	Payments due by Period				
Contractual Obligations	Total US$ 000	less than 1 year US$ 000	1-3 Years US$ 000	4-5 Years US$ 000	more than 5 years US$ 000
Operating lease obligations	26,743	3,109	4,586	2,986	16,062
Total	26,743	3,109	4,586	2,986	16,062

In the past, Trinity Biotech incurred debt and raised equity to pursue its policy of growth through acquisition. However, since the divestiture of the Coagulation product line in 2010, the Group has eliminated bank debt and has adequate cash resources. The Group intends to grow organically for the foreseeable future and Trinity Biotech believes that it will have sufficient funds to meet its capital commitments and continue existing operations in to the future, in excess of 12 months. If the Group was to make a large and unanticipated cash outlay, the Group would have further funding requirements which could be met from drawing down on the Company s existing bank facilities or through access to equity and debt markets.

Impact of Currency Fluctuation

Trinity Biotech s revenue and expenses are affected by fluctuations in currency exchange rates especially the exchange rate between the US Dollar and the Euro, Swedish Kroner and the Brazilian Real. Trinity Biotech s revenues are primarily denominated in US Dollars and its expenses are incurred principally in US Dollars, Euro, Swedish Kroner and Brazilian Real. The weakening of the US Dollar could have an adverse impact on future profitability. Management are actively seeking to reduce the mismatch in this regard to mitigate this risk. The revenues and costs incurred by US subsidiaries are denominated in US Dollars.

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

Off-Balance Sheet Arrangements

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

Leases with Related Parties

The Group has entered into lease arrangements for premises in Ireland with JRJ Investments (JRJ), a partnership currently owned by Mr O Caoimh and Dr Walsh, directors of Trinity Biotech plc, and directly with Mr O Caoimh and Dr Walsh. Independent valuers have advised Trinity Biotech that the rent fixed with respect to these leases represents a fair market rent. Details of these leases with related parties are set out in Item 4 Information on the Company , Item 7 Major Shareholders and Related Party Transactions and Item 18, Note 24 to the consolidated financial statements.

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

Certain R&D activities of the Group have been outsourced to third parties. These activities are carried out in the normal course of business with these companies.

During 2014, a number of individuals acted as third party consultants and contractors; working principally on the Troponin I and Premier projects. The total amount paid to these R&D consultants and contractors in 2014 was US$994,000 (2013: US$2,894,000).

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Research and Products under Development

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

Principal Development Projects

The following table sets forth for each of Trinity Biotech s main development projects, the costs incurred during each period presented and the cumulative costs incurred as at 31 December 2014:

Product Name	*2014 US$ 000*	*2013 US$ 000*	*Total project costs to December 31, 2014 US$ 000*
Brain Natriuretic Peptide (BNP) assay	*4,400*	*1,204*	*5,604*
Premier Instrument for Haemoglobin A1c testing	*3,375*	*3,861*	*19,123*
Troponin I assay and reader	*3,370*	*7,200*	*15,618*
Genesys/Resolution column enhancement	*725*	*685*	*1,410*
Tristat Point-of-Care instrument	*689*	*481*	*6,037*
US Striped Lyme	*684*	*230*	*936*
Uni-Gold test enhancement	*675*		*675*
HIV 1/2 rapid screening test	*587*	*121*	*708*
Malaria Point-of-Care screening test	*485*	*23*	*508*
H Pylori Rapid Point-of-Care screening test	*462*	*499*	*1,162*

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

The following table sets forth the estimated cost to complete each of the main development projects which were underway in 2014. The total estimated completion costs are anticipated to be incurred evenly up to the completion date of the relevant project.

Product Name	*Total estimated cost to complete US$ 000*	*Estimated date for completion*
Premier Resolution	*3,265*	*2015*
Troponin I assay and reader	*3,000*	*2017*
Brain Natriuretic Peptide (BNP) assay	*2,000*	*2016*
TPHA enhancement	*1,500*	*2017*
P24 development	*1,200*	*2016*
D-Dimer development	*1,000*	*2017*
HIV 1/2 rapid screening test	*1,000*	*2016*
US Striped Lyme	*985*	*2016*
Syphilis Rapid Point-of-Care test	*800*	*2016*
Malaria Point-of-Care screening test	*800*	*2016*
IgM Captia	*700*	*2016*
Unigold test enhancement	*600*	*2015*
Tristat Point-of-Care instrument	*501*	*2015*
Meritas analyser	*500*	*2015*
Genesys/Resolution column enhancement	*363*	*2015*

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

Some aspects of the development of a new product are outside of the control of Trinity Biotech. Notwithstanding the uncertainty surrounding these external factors, Trinity Biotech believes the planned completion dates of these projects are realistic and achievable. If major development projects were severely delayed, in the opinion of Trinity Biotech it would not impact significantly on Trinity Biotech s financial position or on the capitalisation criteria. As the manufacturing lead time for these new products is relatively short, it is anticipated that material cash inflows will commence shortly after each of the project s planned completion date.

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

Emergency Medicine Development Group

During 2012, Trinity Biotech acquired Fiomi Diagnostics AB, a Swedish based company which was founded to develop diagnostic tests for the point of care cardiac market. Trinity Biotech has developed a point of care test for Troponin I, which is a recognised marker for detecting acute myocardial infarctions. The technology, which uses micro-pillar technology, is capable of providing extremely sensitive, highly reproducible, quantitative, multiplexed results which give more accurate results than the established point-of-care tests currently in the market.

CE marking for this product was received in January 2014, and is expected to be submitted for FDA approval during 2015. Using the same platform, the company has developed a test for BNP which is a marker for heart failure. CE marking for this product was received in 2014 with clinical trials expected to be completed in 2015. The point-of-care cardiac market is currently estimated to be US$1 billion.

In the CE marking trials our Troponin I product exhibited sensitivity rates with a detection of 19ng/L of whole blood and a CV of 10% at 36ng/L, which corresponds to the 99th percentile of the reference population. Time zero sensitivity was shown to be 60%.

Clinical Performance

In July 2014, results of an Independent clinical performance study were published at the American Association Clinical Chemistry Conference in Chicago. This study, carried out by Dr. Fred Apple at Hennepin County Medical Centre in Minneapolis demonstrated excellent clinical performance. Time zero whole blood sensitivity was 75% with corresponding specificity of 93.6%.

In addition to cardiac tests, we believe that diagnostic tests in a range of other fields are capable of being developed using the same platform. A D-dimer test is currently in development with other tests to follow.

Haemoglobin Development Group

Premier Hb9210 Instrument for Haemoglobin A1c Testing

This project entails the development of a new HPLC instrument for testing HbA1c. The new instrument will allow access to markets not previously open to Trinity Biotech due to instrument price and test capability. Development was initiated in late 2007, and was launched outside of the United States in 2011 followed by within the United States in early 2012.

In response to increased lab automation as well as workstation consolidation, the Premier 9210 TLA project was initiated at the end of 2014. TLA (total lab automation) capability will enable the Premier 9210 to be interfaced with many of the TLA systems currently available.

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HbA1c testing is rapidly growing due to the increased utility as a method for diagnosis and identification of pre-diabetics. Diabetes is the fourth leading cause of death by disease in the world. In 2013, 5.1 million people died due to diabetes. Every 6 seconds a person dies from the disease. The number of diabetic patients is expected to reach 592 million in 2035. In the U.S. alone some 24.4 million Americans (7 percent of the population) have the disease with a further 54 million Americans considered to be pre-diabetic. The total HbA1c market worldwide is estimated to be approximately US$900 million.

Since 2012, the company focussed on the development of an ion exchange version of the Premier Hb9210 which will be capable of detecting both HbA1c and haemoglobin variants. This product is expected to be launched in 2015. The Premier Resolution combines the best of the Premier 9210 and Ultra 2 to offer customers of Trinity Biotech what we believe to be an even better solution for the expanding haemoglobinopathy market.

The Premier Genesys system is also currently under development. The Genesys system is designed to meet the growing demand for neonatal screening of sickle cell disease and Alpha and Beta Thallasemia in newborns.

Point-of-Care (POC) Development Group

During 2010, Trinity Biotech commissioned and staffed a new POC product development unit at its Carlsbad, California facility. This facility has been equipped with state-of-the-art POC assay development equipment and Trinity Biotech has commenced development of a portfolio of point-of-care / lateral flow infectious disease tests. Initial tests include an enteric panel of assays for the detection of giardia, cryptosporidium and C. difficile antigens in human stool samples. Trinity Biotech also is developing tests for the detection of treponemal and non-treponemal syphilis antibodies in human whole blood, H. pylori antigen and strep pneumoniae. Trinity Biotech is currently in the process of obtaining CE marking for these products after which FDA approval will be sought.

Trend Information

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

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

Directors

Name	*Age*	*Title*
Ronan O Caoimh	59	Chairman and Chief Executive Officer
Jim Walsh, PhD	56	Director, Chief Scientific Officer
Denis R. Burger, PhD	71	Non Executive Director
Peter Coyne	55	Non Executive Director
Clint Severson	66	Non Executive Director
James D. Merselis	61	Non Executive Director
Executive Officer		
Kevin Tansley	44	Chief Financial Officer & Company Secretary

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Board of Directors & Executive Officers

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

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

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

Peter Coyne, Non-executive director, joined the board of Trinity Biotech in November 2001 as a non-executive director. Mr. Coyne trained as a chartered accountant in the Corporate Financial Services practice of Arthur Andersen & Co. Mr. Coyne was previously a director of AIB Corporate Finance and has extensive experience of advising boards on mergers and acquisitions and corporate strategy. Mr. Coyne is a partner of VISION Consulting, an international consulting firm delivering breakthrough solutions in customer service and leadership development. Mr. Coyne is a non-executive director of Ark Life Assurance Company Limited. Mr. Coyne holds a bachelor of engineering degree from University College Dublin, is a fellow of the Institute of Chartered Accountants in Ireland and is a CEDR Accredited Mediator.

Clint Severson, Non-executive director, joined the board of Trinity Biotech in November 2008 as a non-executive director. Mr. Severson is currently Chairman, President and CEO of Abaxis Inc., a NASDAQ traded diagnostics company based in Union City, California. From February 1989 to May 1996, Mr. Severson served as President and Chief Executive Officer of MAST Immunosystems, Inc., a privately-held medical diagnostic company and to date he has accumulated over 40 years experience in the medical diagnostics industry.

James D. Merselis, Non-executive director, joined the board of Trinity Biotech in February 2009 as a non-executive director. He is currently CEO and Director of Biosensia Ltd; a point-of-care diagnostics company located in Dublin, Ireland and is on the board of Abram Scientific Inc. located in Mountain View, California. Mr. Merselis has more than thirty-eight years experience in healthcare, with the first twenty-two years at Boehringer Mannheim Diagnostics (now Roche Diagnostics). Mr. Merselis has led a number of healthcare diagnostic start-ups. From 2002 to 2007, he served as President and CEO of HemoSense, Inc., a point-of-care diagnostics company providing patients and physicians with rapid test results to help manage the risk of stroke with the use of Warfarin or Coumadin. During this time he successfully took the company public (NASDAQ:HEM) followed two years later by its acquisition by Alere (NYSE:ALR). His leadership at other start-ups has included: Nexus Dx (now Samsung), Alverix, Inc. (now Becton Dickenson), and Micronics, Inc. (now SONY).

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Kevin Tansley, Chief Financial Officer, joined Trinity Biotech in March 2003 and was appointed Chief Financial Officer and Secretary to the Board of Directors in November 2007. Mr. Tansley trained as a chartered accountant in the Corporate Financial Services practice of Arthur Andersen & Co. Prior to joining Trinity Biotech in 2003, Mr. Tansley held a number of financial positions in the Irish electricity utility ESB. Mr. Tansley holds a Masters of Accounting from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

Compensation of Directors and Officers

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

Total directors and non-executive directors remuneration, excluding pension, for the year ended December 31, 2014 amounted to US$2,353,000. The pension charge for the year amounted to US$87,000. See Item 18, Note 5 to the consolidated financial statements. The split of directors remuneration set out by director is detailed in the table below:

Executive Director	*Salary/ Benefits US$ 000*	*Performance related bonus US$ 000*	*Defined contribution pension US$ 000*	*Total 2014 US$ 000*	*Total 2013 US$ 000*
Ronan O Caoimh	773	176		949	877
Rory Nealon[2]	378	110	35	523	544
Jim Walsh	426	110	52	588	478
	1,577	396	87	2,060	1,899

Non-executive director	*Fees US$ 000*	*Total 2014 US$ 000*	*Total 2013 US$ 000*
Denis R. Burger	96	96	84
Peter Coyne	96	96	84
James Merselis	94	94	74
Clint Severson	94	94	74
	380	380	316

Chief Financial Officer & Company Secretary	*Salary/ Benefits US$ 000*	*Performance related bonus US$ 000*	*Defined contribution pension US$ 000*	*Total 2014 US$ 000*	*Total 2013 US$ 000*
Kevin Tansley	410	118	45	573	507

As at December 31, 2014 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2013: NIL).

The total share-based compensation expense recognised in the consolidated statement of operations in 2014 in respect of options granted to both executive and non-executive directors and the Company Secretary amounted to US$2,109,000. See Item 18, Note 5 to the consolidated financial

statements.

[1] Includes payments made to Darnick Company
[2] Rory Nealon resigned from the board of directors on November 15, 2014

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1,700,000 A share options (equivalent to 425,000 ADS options) were granted to the directors and the Company Secretary during 2014, the terms of which are set out below. 2,540,000 A share options (equivalent to 635,000 ADS options) were granted to the directors and the Company Secretary during 2013.

Share Options Granted in 2014:

Director/Executive Officer	Number of Options Granted	Exercise Price of Options Granted	Date of Option Grant*
Ronan O Caoimh	800,000 A shares	US$4.23 per A share	5 December 2014
	(200,000 ADS)	(US$16.90 per ADS)	
Jim Walsh	160,000 A shares	US$4.23 per A share	5 December 2014
	(40,000 ADS)	(US$16.90 per ADS)	
Kevin Tansley	500,000 A shares	US$4.23 per A share	5 December 2014
	(125,000ADS)	(US$16.90 per ADS)	
Denis Burger	60,000 A shares	US$4.23 per A share	5 December 2014
	(15,000 ADS)	(US$16.90 per ADS)	
Peter Coyne	60,000 A shares	US$4.23 per A share	5 December 2014
	(15,000 ADS)	(US$16.90 per ADS)	
Clint Severson	60,000 A shares	US$4.23 per A share	5 December 2014
	(15,000 ADS)	(US$16.90 per ADS)	
James Merselis	60,000 A shares	US$4.23 per A share	5 December 2014
	(15,000 ADS)	(US$16.90 per ADS)	

*All options issued are subject to a 7 year life from date of grant.
In addition, see Item 7 Major Shareholders and Related Party Transactions for further information on the compensation of Directors and Officers.

Directors Service Contracts

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

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

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

Under the terms of his service contract, Jim Walsh, Chief Scientific Officer, is entitled to 12 months salary and benefits in the event of termination by the Company. Where termination arises within 12 months of a change in control of the Company, Dr. Walsh is entitled to 18 months salary and benefits.

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Board Practices

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

The Board of Directors has established Audit, Remuneration and Compensation Committees. The functions and membership of the Remuneration Committee are described above. The Audit Committee reviews the Group s annual and interim financial statements and reviews reports on the effectiveness of the Group s internal controls. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The Audit Committee comprises two of the four independent non-executive directors of the Group, Mr Peter Coyne (Committee Chairman) and Mr James Merselis. The Compensation Committee currently comprises Mr Ronan O Caoimh (Committee Chairman) and Dr Jim Walsh. The Board of Directors administers the Employee Share Option Plan. The Board determines the exercise price and the term of the options. Individual option grants of less than 30,000 shares are approved by the Compensation Committee. Options granted to the members of the Compensation Committee are approved by the Remuneration Committee and share options granted to non-executive directors are decided by the other members of the board.

Because Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 5600 as they apply to U.S. domestic companies. The Group s corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process and (b) the Audit Committee of the Group currently consists of two members (both of whom are independent non-executive directors) while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee and be comprised only of independent directors.

Employees

As of December 31, 2014, Trinity Biotech had 545 employees (2013: 571) consisting of 69 research scientists and technicians, 337 manufacturing and quality assurance employees, and 139 finance, administration, sales and marketing staff (2013: 113 research scientists and technicians, 313 manufacturing and quality assurance employees, and 145 finance, administration, sales and marketing staff). Trinity Biotech s future hiring levels will depend on the growth of revenues.

The geographic spread of the Group s employees is as follows: 360 in our U.S. operations, 131 in Bray, Ireland, 35 in Uppsala, Sweden, 5 in the UK and 14 in Sao Paulo, Brazil.

Stock Option Plans

The Board of Directors have adopted the Employee Share Option Plans (the Plans); with the most recently adopted Share Option Plan being the 2013 Plan. The purpose of these Plans is to provide Trinity Biotech s employees, consultants, officers and directors with additional incentives to improve Trinity Biotech s ability to attract, retain and motivate individuals upon whom Trinity Biotech s sustained growth and financial success depends. These Plans are administered by the Board of Directors. Options under the Plans may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

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

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As of February 28, 2015, 6,185,000 (1,546,250 ADS equivalent) of the options outstanding were held by the directors and Company Secretary of Trinity Biotech as follows:

Director/Company Secretary	Number of Options A Shares	Number of Options ADS Equivalent	Exercise Price (Per A Share)	Exercise Price (Per ADS)	Expiration Date of Options
Ronan O Caoimh	800,000	200,000	US$ 2.52	US$10.09	7 March 2019
	800,000	200,000	US$ 4.21	US$16.85	24 May 2020
	800,000	200,000	US$ 4.23	US$16.90	5 December 2021
Denis Burger	20,000	5,000	US$ 2.52	US$10.09	7 March 2019
	60,000	15,000	US$ 4.21	US$16.85	24 May 2020
	60,000	15,000	US$ 4.23	US$16.90	5 December 2021
Jim Walsh	15,000	3,750	US$ 1.52	US$ 6.07	21 May 2017
	100,000	25,000	US$ 1.57	US$ 6.26	4 October 2017
	500,000	125,000	US$ 2.52	US$10.09	7 March 2019
	500,000	125,000	US$ 4.21	US$16.85	24 May 2020
	160,000	40,000	US$ 4.23	US$16.90	5 December 2021
Peter Coyne	60,000	15,000	US$ 0.66	US$ 2.63	8 May 2016
	60,000	15,000	US$ 1.52	US$ 6.07	21 May 2017
	60,000	15,000	US$ 2.52	US$10.09	7 March 2019
	60,000	15,000	US$ 4.21	US$16.85	24 May 2020
	60,000	15,000	US$ 4.23	US$16.90	5 December 2021
Clint Severson	20,000	5,000	US$ 2.52	US$10.09	7 March 2019
	40,000	10,000	US$ 4.21	US$16.85	24 May 2020
	60,000	15,000	US$ 4.23	US$16.90	5 December 2021
James Merselis	15,000	3,750	US$ 1.52	US$ 6.07	21 May 2017
	40,000	10,000	US$ 2.52	US$10.09	7 March 2019
	60,000	15,000	US$ 4.21	US$16.85	24 May 2020
	60,000	15,000	US$ 4.23	US$16.90	5 December 2021
Kevin Tansley	150,000	37,500	US$ 1.07	US$ 4.28	18 March 2015
	125,000	31,250	US$ 1.52	US$ 6.07	21 May 2017

	500,000	125,000	US$ 2.52	US$10.09	7 March 2019
	500,000	125,000	US$ 4.21	US$16.85	24 May 2020
	500,000	125,000	US$ 4.23	US$16.90	5 December 2021

As of February 28, 2015 the following total options were outstanding:

	Number of A Ordinary Shares Subject to Option	Range of Exercise Price per Ordinary Share	Range of Exercise Price per ADS
Total options outstanding	8,743,325	US$ 0.66-US$4.79	US$ 2.63-US$19.15

As of February 28, 2015 there were no warrants to purchase A Ordinary Shares in the Company outstanding.

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

As of February 28, 2015 Trinity Biotech has outstanding 94,856,690 A Ordinary shares. Such totals exclude 8,743,325 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2015, the Trinity Biotech A Ordinary Shares beneficially held by (i) each person believed by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and the Company Secretary of Trinity Biotech, and (iii) all directors and the Company Secretary as a group.

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

	Number of A Ordinary Shares Beneficially Owned	Number of ADSs Beneficially Owned	Percentage A Ordinary Shares (8)	Percentage Total Voting Power
Ronan O Caoimh	6,037,496(1)	1,509,374	5.8%	5.8%
Jim Walsh	2,668,612(2)	667,153	2.6%	2.6%
Denis Burger	267,000(3)	66,750	0.3%	0.3%
Peter Coyne	305,600(4)	76,400	0.3%	0.3%
Clint Severson	408,000(5)	102,000	0.4%	0.4%
James Merselis	363,600(6)	90,900	0.4%	0.4%
Kevin Tansley	1,775,000(7)	443,750	1.7%	1.7%
Directors & Co. Secretary as a group (7 persons)	11,825,308 (1)(2)(3)(4)(5)(6)(7)	2,956,327	11.4%	11.4%

(1) Includes 2,400,000 A Ordinary shares issuable upon exercise of options.

(2) Includes 1,275,000 A Ordinary shares issuable upon exercise of options.

Note that 1,200,000 A Ordinary shares (300,000 ADSs) of Dr Walsh s shares are held in trust for the benefit of Dr Walsh s immediate family.

(3) Includes 140,000 A Ordinary shares issuable upon exercise of options.

(4) Includes 300,000 A Ordinary shares issuable upon exercise of options.

(5) Includes 120,000 A Ordinary shares issuable upon exercise of options.

(6) Includes 175,000 A Ordinary shares issuable upon exercise of options.

(7) Includes 1,775,000 A Ordinary shares issuable upon exercise of options.

(8) Percentage A Ordinary shares is based upon total outstanding A Ordinary shares and total number of shares issuable upon exercise of options.

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Related Party Transactions

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

In November 2002, the Group entered into an agreement for a 25 year lease with JRJ for offices that have been constructed adjacent to its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. The annual rent of 381,000 (US$463,000) is payable from January 1, 2004. There was a rent review performed on this premises in 2009 and further to this review, there was no change to the annual rental charge.

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$956,000).

Independent valuers have advised the Group that the rent in respect of each of the leases represents a fair market rent.

Trinity Biotech and its directors (excepting Mr O Caoimh and Dr Walsh who express no opinion on this point) believe at the time that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises.

Darnick Company is wholly-owned by members of Mr. O Caoimh s immediate family. On March 30, 2011, the service agreement with Ronan O Caoimh as Chief Executive Officer was terminated and replaced by a management agreement with Darnick Company. Pursuant to the agreement, Darnick Company will provide Trinity Biotech with the services of Mr O Caoimh as Chief Executive Officer. In 2014, the Group paid US$696,000 to Darnick Company in respect of Director s compensation. There is no balance payable to or receivable from Darnick Company as at December 31, 2014.

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

There were no director loans advanced during 2014 and there were no loan balances payable to or receivable from directors at January 1, 2014 and at December 31, 2014.

In June 2009, the Board approved the payment of a dividend of US$2,830,000 by Trinity Research Limited to Rayville Limited on the B shares held by it. This amount was then lent back by Rayville to Trinity Research Limited. As the dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2012 & 2013 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US$Nil, US$Nil and US$231,000 for 2014, 2013 and 2012 respectively, of which US$Nil, US$Nil and US$206,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2014, 2013 or 2012.

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Item 8 ***Financial Information***

Legal Proceedings

In 2008 Trinity Biotech filed a civil suit with a New York court against the former shareholders of Primus Corporation. Trinity Biotech claimed that the defendants unjustly received an overpayment of US$512,000 based on the fraudulent and wrongful calculation of the earnout payable to the shareholders of Primus Corporation. Trinity Biotech also alleged that one of the former shareholders, Mr Thomas Reidy, failed to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of a US$3 million promissory note given to the defendants by Trinity Biotech as part of compensation under the share purchase agreement for acquiring Primus. During 2009, all of the defendants with the exception of Mr. Reidy settled the legal action. The US District Court, Southern District of New York granted a judgment against Mr. Reidy ordering him to pay Trinity damages of US$200,000 plus interest and to return stock certificates and collateral pledged by Trinity Biotech as security for the payment of the US$3 million promissory note. Mr Reidy has not yet paid any damages or interest due to Trinity Biotech.

In 2010, Laboratoires Nephrotek, formerly a distributor for Trinity Biotech, took a legal action in France against the Group, claiming damages of US$0.8 million. They claimed that certain instruments supplied by Trinity Biotech did not operate properly in the field. In 2013, Trinity Biotech successfully defended this claim in the French courts. Nephrotek are in the process of appealing this decision.

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

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

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

The Group s A Ordinary Shares were also listed and traded on the Irish Stock Exchange until November 2007, whereby the Company de-listed from the Irish Stock Exchange. The Group s depository bank for ADSs is The Bank of New York Mellon. On February 28, 2015, the reported closing sale price of the ADSs was US$17.76 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech s ADSs for (a) the years ended December 31, 2010, 2011, 2012, 2013 and 2014; (b) the quarters ended March 31, June 30, September 30 and December 31, 2013; March 31, June 30, September 30 and December 31, 2014; and (c) the months of March, April, May, June, July, August, September, October, November and December 2014 and January and February 2015 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

ADSs

Year Ended December 31	High	Low
2010	US$ 8.93	US$ 3.76
2011	US$ 11.00	US$ 8.00
2012	US$ 15.75	US$ 8.81
2013	US$ 25.63	US$ 14.30
2014	US$ 28.06	US$ 14.00

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ADSs

2013	High	Low
Quarter ended March 31	US$ 19.00	US$ 14.30
Quarter ended June 30	US$ 17.92	US$ 15.12
Quarter ended September 30	US$ 22.00	US$ 16.40
Quarter ended December 31	US$ 25.63	US$ 21.28

ADSs

2014	High	Low
Quarter ended March 31	US$ 28.06	US$ 22.58
Quarter ended June 30	US$ 26.00	US$ 22.53
Quarter ended September 30	US$ 24.00	US$ 18.15
Quarter ended December 31	US$ 18.49	US$ 14.00

ADSs

Month Ended	High	Low
March 31, 2014	US$ 28.06	US$ 22.58
April 30, 2014	US$ 26.00	US$ 22.53
May 31, 2014	US$ 24.95	US$ 23.00
June 30, 2014	US$ 24.38	US$ 22.90
July 31, 2014	US$ 24.00	US$ 22.80
August 31, 2014	US$ 23.48	US$ 19.55
September 30, 2014	US$ 22.11	US$ 18.15
October 31, 2014	US$ 18.49	US$ 14.00
November 30, 2014	US$ 18.43	US$ 16.54
December 31, 2014	US$ 18.40	US$ 16.35
January 31, 2015	US$ 20.24	US$ 17.50
February 28, 2015	US$ 19.66	US$ 17.00

The number of record holders of Trinity Biotech s ADSs as at February 28, 2015 amounts to 526, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech s securities for their clients (with each such brokerage house and/or clearing house being considered as one holder).

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Item 10 ***Additional Information***

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

Objects

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

Powers and Duties of Directors

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

A director may enter into a contract and be interested in any contract or proposed contract with the Company either as vendor, purchaser or otherwise and shall not be liable to account for any profit made by him resulting therefrom provided that he has first disclosed the nature of his interest in such a contract at a meeting of the board as required by Section 194 of the Irish Companies Act 1963. Generally, a director must not vote in respect of any contract or arrangement or any proposal in which he has a material interest (otherwise than by virtue of his holding of shares or debentures or other securities in or through the Company). In addition, a director shall not be counted in the quorum at a meeting in relation to any resolution from which he is barred from voting.

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

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

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

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

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Rights, Preferences and Restrictions Attaching to Shares

The Company may, subject to the provisions of the Companies Acts, 1963 to 2013 of Ireland, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution.

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

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

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

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

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

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

Action Necessary to Change the Rights of Shareholders

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

Calling of AGMs and EGMs of Shareholders

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in the Republic of Ireland unless all of the members entitled to attend and vote at such meeting consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2013 of Ireland.

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In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days notice of the meeting is required and in any other case seven clear days notice is required. Notice must be given in writing to all members and to the auditors in accordance with the Articles of Association and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided for in the Companies Acts, 1963 to 2013 of Ireland, extended notice of a general meeting is required. These include a meeting at which a resolution for the removal of a director before the expiration of his term of office is proposed.

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

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

Other Provisions of the Memorandum and Articles of Association

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

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

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

Irish Law

Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept at the registered office of the Company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper books of account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the Company (changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office (the CRO) in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the Company carrying the right of voting at general meetings of the Company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the Company. Any shareholder who complains that the affairs of the Company are being conducted or that the powers of the directors of the Company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the Company.

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Ordinarily, our directors owe their duties only to Trinity Biotech and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to Trinity Biotech. Those duties include duties to act in good faith towards Trinity Biotech in any transaction, not to make use of any money or other property of Trinity Biotech, not to gain directly or indirectly any improper advantage for himself at the expense of Trinity Biotech, to act bona fide in the interests of Trinity Biotech and exercise powers for the proper purpose. A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. When directors, as agents in transactions, make contracts on behalf of the Company, they generally incur no personal liability under these contracts.

It is Trinity Biotech, as principal, which will be liable under them, as long as the directors have acted within Trinity Biotech s objects and within their own authority. A director who commits a breach of his fiduciary duties shall be liable to Trinity Biotech for any profit made by him or for any damage suffered by Trinity Biotech as a result of the breach. In addition to the above, a breach by a director of his duties may lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to Trinity Biotech for profit made and restriction of the director from acting as a director in the future.

Material Contracts

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

Acquisition of Immco Diagnostics Inc

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

The key terms of the acquisition are as follows:

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

Please refer to Item 18, Note 22 for further information.

Acquisition of Fiomi Diagnostics AB

In 2012, the Group purchased 100% of the common stock of Fiomi Diagnostics AB for a total consideration of US$12.9 million (including US$3.2m of contingent payments net of interest of US$0.2m). Fiomi, which is based in Uppsala, Sweden, is at an advanced stage in developing a range of Point-of-Care cardiac assays.

The key terms of the acquisition are as follows:

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

Contingent cash consideration (net present value) of US$3.2m.
Please refer to Item 18, Note 22 for further information.

Divestiture of Coagulation product line to Diagnostica Stago SAS

In April 2010, the Group sold its worldwide Coagulation product line to Diagnostica Stago for US$89.9 million. The gain on the divestiture was US$46.8m. Diagnostica Stago purchased the share capital of Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH and Trinity Biotech S.à r.l., along with Coagulation assets of Biopool US Inc. and Trinity Biotech Manufacturing Limited. As part of the sale, the Group also assigned leasing arrangements on a facility in Bray, Ireland to Diagnostica Stago. Included in the sale are Trinity s lists of Coagulation customers and suppliers, all Coagulation inventory, intellectual property and developed technology. In total, 321 Trinity employees transferred their employment to Diagnostica Stago as part of the divestiture of the Coagulation product line.

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The Group received consideration of US$68.4 million in 2010. A further US$11.25 million was received from Diagnostica Stago in April 2011 and the remaining US$11.25 million was received in April 2012. No conditions or earnout provisions were applied to this deferred element of the consideration, which has now been fully received.

Exchange Controls and Other Limitations

Affecting Security Holders

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

At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People s Republic of Korea (North Korea), Iran, Iraq, Côte d Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbour certain terrorist groups, without the prior permission of the Central Bank of Ireland.

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

Taxation

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

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

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

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

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

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

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

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

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

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

Dividends and Other Distributions on ADSs

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

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

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

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

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

Dispositions of the ADSs

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

Passive Foreign Investment Company

For U.S. federal income tax purposes, a foreign corporation is treated as a passive foreign investment company (or PFIC) in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable look through rules, either (1) at least 75% of the corporation s gross income is passive income or (2) at least 50% of the average value of the corporation s assets is attributable to assets that produce passive income or are held for the production of passive income. Based on the nature of its present business operations, assets and income, Trinity Biotech believes that for the year 2014, it is not a PFIC. However, no assurance can be given that changes will not occur in Trinity Biotech s business operations, assets and income that might cause it to be treated as a PFIC at some future time.

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

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

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

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

Information Reporting and Backup Withholding

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

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

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Information with Respect to Foreign Financial Assets

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

Medicare Contribution Tax

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

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

Republic of Ireland Taxation

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

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

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

In 2011, the Board decided that it was an appropriate time to commence a dividend policy for the first time in the Company s history. The payment of a dividend is generally subject to dividend withholding tax (DWT) at the standard rate of income tax in force at the time the dividend is paid, currently 20%. Under current legislation, where DWT applies, Trinity Biotech will be responsible for withholding it at source.

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

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

Individual Irish Holders will be subject to income tax on the gross amount of any dividend (that is the amount of the dividend received plus any DWT withheld), at their marginal rate of income tax, currently either 20% or 41% (this upper limit has been reduced to 40% with effect from 1 January 2015) depending on the individual s circumstances excluding PRSI and the universal social charge. Individual Irish Holders will be able to claim a credit against their resulting income tax liability in respect of DWT withheld. Individual Irish Holders may, depending on their circumstances, also be subject to the Irish Universal Social Charge of up to 7% (this upper limit rate has increased to 8% with effect from 1 January 2015, with a further 3% surcharge also arising on certain income in excess of 100,000) and Pay Related Social Insurance contribution of up to 4% in respect of their dividend income.

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

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

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

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

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

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

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

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

Disposals of Ordinary Shares or ADSs

Irish Holders that acquire ordinary shares or ADSs will generally be considered, for Irish tax purposes, to have acquired their ordinary shares or ADSs at a base cost equal to the amount paid for the ordinary shares or ADSs. On subsequent dispositions, ordinary shares or ADSs acquired at an earlier time will generally be deemed, for Irish tax purposes, to be disposed of on a first in first out basis before ordinary shares or ADSs

acquired at a later time. Irish Holders that dispose of their ordinary shares or ADSs will be subject to Irish capital gains tax (CGT) to the extent that the proceeds realised from such disposition exceed the indexed base cost of the ordinary shares or ADSs disposed of and any incidental expenses. The current rate of CGT is 33% and this applies to disposals made on or after 6 December 2012. Indexation of the base cost of the ordinary shares or ADSs is available up to 31 December 2002, and only in respect of ordinary shares or ADSs held for more than 12 months prior to their disposal.

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

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

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

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

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

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

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

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

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

Irish stamp duty, which is a tax imposed on certain documents, is payable on all transfers of ordinary shares of an Irish registered company (other than transfers made between spouses, transfers made between 90% associated companies, or certain other exempt transfers) regardless of where the document of transfer is executed. Irish stamp duty is also payable on electronic transfers of ordinary shares. A transfer of ordinary shares made as part of a sale or gift will generally be stampable at the ad valorem rate of 1% of the value of the consideration received for the transfer, or, if higher, the market value of the shares transferred. Any instrument executed on or after 24 December 2008 which transfers stock or marketable securities on sale where the amount or value of the consideration is 1,000 or less may be exempt from stamp duty. Where the consideration for a sale is expressed in a currency other than Euro, the duty will be charged on the Euro equivalent calculated at the rate of exchange prevailing at the date of the transfer.

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

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

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

Dividend Policy

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

Documents on Display

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

Item 11 Quantitative and Qualitative Disclosures about Market Risk
Quantitative information about Market Risk

Interest rate sensitivity

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

Trinity Biotech estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Group is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be an increase in the profit before tax for 2014 by approximately 0.5%.

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Exchange rate sensitivity

At year-end 2014, approximately 11.5% of the Group s US$196,972,000 net worth (shareholders equity) was denominated in currencies other than the US Dollar, principally the Euro, Canadian Dollar, Swedish Kroner and Brazilian Real.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Group operates, would have the approximate effect of reducing or increasing the Group s 2014 year-end net worth by US$2,272,000.

Qualitative information about Market Risk

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

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

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

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

At December 31, 2014, 2013 and 2012 the Group had no borrowings. At December 31, 2011 Group borrowings were at fixed rates of interest and consisted entirely of Euro denominated finance leases. At December 31, 2011 year-end borrowings totalled US$108,000, at interest rates ranging from 5.02% to 5.29% - see Item 18, Note 25.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$91,000 (2013: US$223,000) and would not affect the interest expense in 2014 or 2013; resulting in an increase in interest income of US$91,000 (2013: US$223,000).

The majority of the Group s activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group s Euro, Swedish Kroner and Brazilian Real denominated expenses as a result of the movement in the exchange rate between the US Dollar and those currencies. Arising from this, where considered necessary, the Group periodically pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro, Kroner and Real expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro, Kroner or Real forecasted transactions. These forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at 31 December, 2014.

The Group had foreign currency denominated cash balances equivalent to US$2,073,000 at December 31, 2014 (2013: US$1,624,000).

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

Fees and Charges Payable by ADS Holders

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

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

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

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

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

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

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

In the event of refusal to pay taxes or other governmental charges by the holder of an ADS, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of such tax or other governmental charge from any distribution to be made to the ADS holder, and the ADS holder would remain liable for any deficiency.

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The disclosure under this heading Fees and Charges Payable by ADS Holders is subject to and qualified in its entirety by reference to the full text of the Deposit Agreement.

Part II

Item 13 ***Defaults, Dividend Arrearages and Delinquencies***
Not applicable.

Item 14 ***Material Modifications to the Rights of Security Holders and Use of Proceeds***
Not applicable.

Item 15 ***Controls and Procedures***
Evaluation of Disclosure Controls and Procedures

The Group s disclosure and control procedures are designed so that information required to be disclosed in reports filed or submitted under the Securities Exchange Act 1934 is prepared and reported on a timely basis and communicated to management, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(d) of the Securities Exchange Act of 1934 as of the end of the period covered by this Form 20-F. The Chief Executive Officer and Chief Financial Officer have concluded that disclosure controls and procedures were effective as of December 31, 2014.

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

Management s Annual Report on Internal Control over Financial Reporting

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

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

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

Management has assessed the effectiveness of internal control over financial reporting based on criteria established in the 2013 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that the Group s internal control over financial reporting was effective as of December 31, 2014.

Our auditor, Grant Thornton, an independent registered public accounting firm, has issued an attestation report on the Group s internal control over financial reporting as of December 31, 2014 (see Item 18).

Changes in Internal Control over Financial Reporting

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

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Item 16

16A Audit Committee Financial Expert

Mr Peter Coyne is an independent director and a member of the Audit Committee.

Our board of directors has determined that Mr Peter Coyne meets the definition of an audit committee financial expert, as defined in Item 401 of Regulation S-K.

This determination is made on the basis that Mr Coyne is a Fellow of the Institute of Chartered Accountants in Ireland and has extensive experience in advising public and private groups on all aspects of corporate strategy. Mr Coyne was formerly a director of AIB Corporate Finance, a subsidiary of AIB Group plc, and was also formerly a senior manager in Arthur Andersen s Corporate Financial Services practice.

16B Code of Ethics

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

16C Principal Accountant Fees and Services

Fees Billed by Independent Public Accountants

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

	Year ended December 31,		*Year ended December 31,*	
	2014		*2013*	
	US$ 000	*%*	*US$ 000*	*%*
Audit	457	88%	574	85%
Audit-related	5	1%	16	2%
Tax	55	11%	89	13%
Total	517		679	

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

Pre-Approval Policies and Procedures

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

Pre-approval may be given as part of the Audit Committee s approval of the scope of the engagement of our independent auditor or on an individual basis. The pre-approval of services may be delegated to one or more of the Audit Committee s members, but the decision must be presented to the full Audit Committee at its next scheduled meeting. The policy prohibits retention of the independent public accountants to

perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the SEC, and also considers whether proposed services are compatible with the independence of the public accountants.

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16D Exemptions from the Listing Standards for Audit Committees

Not applicable.

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

On March 3, 2011 the Company announced its intention to commence a Share Buyback Program for the first time in the Company s history. Under the authority given by the passing of Resolution 6 at the 2012 AGM, the maximum number of shares that may yet be purchased by Trinity Biotech or on the Group s behalf at December 31, 2014 was 7,244,556 (1,811,139 ADSs) (2013: 7,244,556 (1,811,139 ADSs)).

2014 Share Buyback

There were no shares purchased by Trinity Biotech or on the Group s behalf in the year ended December 31, 2014 (2013: Nil).

16 F Change in Registrant s Certifying Accountant

Not applicable.

16 G Corporate Governance

As Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 5600 as they apply to U.S. domestic companies. The Group s corporate governance measures differ in the following significant ways: (a) the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process. At present, the Board as a whole address the nominations process; and (b) the Audit Committee of the Group currently consists of two members (both of whom are independent non-executive directors) while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee.

16 H Mine Safety Disclosure

Not applicable.

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Part III

Item 17 ***Financial Statements***
The registrant has responded to Item 18 in lieu of responding to this item.

Item 18 ***Financial Statements***

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited the internal control over financial reporting of Trinity Biotech plc and subsidiaries (the Company) as of December 31, 2014, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Annual Report on Internal Control over Financial Reporting (Mana