

TRINITY BIOTECH PLC  
Form 20-F  
April 09, 2014  
Table of Contents

**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, 2013**

**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 988**

**SIDA 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:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>None</b>	<b>None</b>

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

**American Depositary Shares (each representing 4 A Ordinary Shares, par value US\$0.0109)**

**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:

**92,296,506 Class A Ordinary Shares**

(as of December 31, 2013)

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

Other

by the International Accounting Standards Board

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form S-8 File No. 33-76384, 333-220, 333-5532, 333-7762, 333-124384 and 333-166590.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>General</u>	1
<u>Forward-Looking Statements</u>	1
<b>PART I</b>	
Item 1 <u>Identity of Directors, Senior Management and Advisors</u>	1
Item 2 <u>Offer statistics and Expected timetable</u>	1
Item 3 <u>Selected Consolidated Financial Data</u>	1
Item 4 <u>Information on the Company</u>	7
Item 5 <u>Operating and Financial Review and Prospects</u>	16
Item 6 <u>Directors and Senior Management</u>	36
Item 7 <u>Major Shareholders and Related Party Transactions</u>	42
Item 8 <u>Financial Information</u>	44
Item 9 <u>The Offer and Listing</u>	44
Item 10 <u>Memorandum and Articles of Incorporation</u>	46
Item 11 <u>Qualitative and Quantitative Disclosures about Market Risk</u>	57
Item 12 <u>Description of Securities other than Equity Securities</u>	58
<b>PART II</b>	
Item 13 <u>Defaults, Dividend Arrearages and Delinquencies</u>	58
Item 14 <u>Material Modification to the Rights of Security Holders and Use of Proceeds</u>	58
Item 15 <u>Control and Procedures</u>	58
Item 16A <u>Audit Committee Financial Expert</u>	60
Item 16B <u>Code of Ethics</u>	60
Item 16C <u>Principal Accounting Fees and Services</u>	60
Item 16D <u>Exemptions from the Listing Requirements and Standards for Audit Committee</u>	61
Item 16E <u>Purchase of Equity Securities by the Issuer and Affiliated Purchasers</u>	61
Item 16F <u>Change in Registrant's Certifying Accountant</u>	61
Item 16G <u>Corporate Governance</u>	61
<b>PART III</b>	
Item 17 <u>Consolidated Financial Statements</u>	62
Item 18 <u>Consolidated Financial Statements</u>	62
Item 19 <u>Exhibits</u>	131

---

## **Table of Contents**

### **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 2013. 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 harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates, anticipates, projects, plans, seeks, may, will, expects, intends, believes, should and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors please refer to the risk factors in Item 3 for a more comprehensive outline of these risks and the threats which they pose to the Company and its results.

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

Not applicable.

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

Not applicable.

### **Item 3 Selected Consolidated Financial Data**

The following selected consolidated financial data of Trinity Biotech as at December 31, 2013 and 2012 and for each of the years ended December 31, 2013, 2012 and 2011 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, 2011, 2010 and 2009 and for the years ended December 31, 2010 and December 31, 2009 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.

**Table of Contents****CONSOLIDATED STATEMENT OF OPERATIONS DATA**

	<i>Year ended December, 31</i>				
	2013	2012	2011	2010	2009
	<i>Total</i> <i>US\$ 000</i>	<i>Total</i> <i>US\$ 000</i>	<i>Total</i> <i>US\$ 000</i>	<i>Total</i> <i>US\$ 000</i>	<i>Total</i> <i>US\$ 000</i>
<b>Revenues</b>	<b>91,216</b>	<b>82,510</b>	<b>77,948</b>	<b>89,635</b>	<b>125,907</b>
Cost of sales*	(45,996)	(40,257)	(37,820)	(45,690)	(68,891)
<b>Gross profit</b>	<b>45,220</b>	<b>42,253</b>	<b>40,128</b>	<b>43,945</b>	<b>57,016</b>
Other operating income	532	468	910	1,616	437
Research and development expenses	(3,691)	(3,130)	(3,206)	(4,603)	(7,341)
<b>Total research and development expenses</b>	<b>(3,691)</b>	<b>(3,130)</b>	<b>(3,206)</b>	<b>(4,603)</b>	<b>(7,341)</b>
Selling, general and administrative expenses	(33,066)	(22,425)	(22,048)	(26,929)	(36,013)
<b>Total selling, general and administrative expenses</b>	<b>(33,066)</b>	<b>(22,425)</b>	<b>(22,048)</b>	<b>(26,929)</b>	<b>(36,013)</b>
Net gain on divestment of business and restructuring expenses				<b>46,474</b>	
<b>Operating profit</b>	<b>8,995</b>	<b>17,166</b>	<b>15,784</b>	<b>60,503</b>	<b>14,099</b>
Financial income	1,276	2,280	2,428	1,352	8
Financial expenses	(51)	(88)	(12)	(495)	(1,192)
<b>Net financing income/(costs)</b>	<b>1,225</b>	<b>2,192</b>	<b>2,416</b>	<b>857</b>	<b>(1,184)</b>
<b>Profit before tax</b>	<b>10,220</b>	<b>19,358</b>	<b>18,200</b>	<b>61,360</b>	<b>12,915</b>
Income tax expense	(574)	(2,017)	(2,607)	(942)	(1,091)
<b>Profit for the year (all attributable to owners of the parent)</b>	<b>9,646</b>	<b>17,341</b>	<b>15,593</b>	<b>60,418</b>	<b>11,824</b>
Basic earnings per ADS (US Dollars)	0.44	0.81	0.73	2.85	0.57
Diluted earnings per ADS (US Dollars)	0.41	0.77	0.70	2.79	0.57
Basic earnings per A ordinary share (US Dollars)	0.11	0.20	0.18	0.71	0.14
Diluted earnings per A ordinary share (US Dollars)	0.10	0.19	0.18	0.70	0.14
Weighted average number of shares used in computing basic EPS per A ordinary share	87,746,588	85,675,284	85,171,494	84,734,378	83,737,884
Weighted average number of shares used in computing diluted EPS per A ordinary share	93,712,698	89,773,616	88,912,596	86,661,535	83,772,094

\* Cost of sales for 2013 includes Medical Device Excise Tax of US\$691,000 (2012: US\$Nil).

**Table of Contents****Consolidated Balance Sheet Data**

	December 31, 2013	December 31, 2012	December 31, 2011	December 31, 2010	December 31, 2009
	US\$ 000	US\$ 000	US\$ 000	US\$ 000	US\$ 000
Net current assets (current assets less current liabilities)	55,766	97,531	101,684	89,068	42,835
Non-current liabilities	(22,499)	(15,061)	(6,838)	(7,331)	(27,500)
Total assets	226,486	197,407	171,499	160,874	132,445
Capital stock	1,170	1,134	1,106	1,092	1,080
Shareholders' equity	183,011	169,380	151,332	141,287	79,344

A final dividend of 20 cents per ADS was paid in 2013 in respect of the financial year 2012 (15 cents per ADS paid in 2012 in respect of the financial year 2011 and 10 cents per ADS paid in 2011 in respect of the financial year 2010, no dividends were declared in the period ended December 31, 2009). The dividend payable in respect of the 2013 financial year will be proposed by the Directors prior to the next AGM, to be held in June 2014.

**Risk Factors**

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

***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. We are committed to significant expenditure on R&D. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. Development of new diagnostic tests is subject to very stringent regulatory control and very significant costs in research, development and marketing. Failure to introduce new products could significantly slow our growth and adversely affect our market share.

***Technological advances in the industry could render our products obsolete.***

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 ), Alere Inc. (Determine , Wampole , Athena ), 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, Enzygno®), Siemens Bayer (Centaur ), Siemens DPC (Immulite ), Thermo Fisher (Konelab ) and Tosoh (G8 ).

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

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 licences or proprietary or patented technologies in the future, or that licences granted to us by third parties will not be granted to other third parties who could potentially compete with us.





## **Table of Contents**

***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. 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. If found to infringe, we may attempt to obtain a licence to such intellectual property; however, we may be unable to do so on favorable terms, or at all. Additionally, if our products are found to infringe on third-party intellectual property, we may be required to pay damages for past infringement and lose the ability to sell certain products, causing our revenues to decrease. Any substantial loss resulting from such a claim could 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.

***Our business is heavily regulated and non-compliance with applicable regulations could reduce revenues and profitability.***

Our manufacturing and marketing of diagnostic test kits are subject to government regulation in the United States of America by the Food and Drug Administration ( FDA ), and by comparable regulatory authorities in other jurisdictions. The approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive. Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting approval from these regulatory authorities. There is no certainty that such approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process.

We are required to comply with extensive post market regulatory requirements. Non-compliance with applicable regulatory requirements of the FDA or comparable foreign regulatory bodies can result in enforcement action which may include recalling products, ceasing product marketing, paying significant fines and penalties, and similar actions that could limit product sales, delay product shipment, and adversely affect profitability.

***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. Changes in the healthcare industry delivery system have resulted in major consolidation among reference laboratories and in 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.

***Future acquisitions may be less successful than expected, 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. There can be no guarantees that recent or future acquisitions can be successfully assimilated or that projected growth in revenues or synergies in operating costs can be achieved. Our ability to integrate future acquisitions may also be adversely affected by inexperience in dealing with new technologies, and changes in regulatory or competitive environments. Additionally, even during a successful integration, the investment of management's time and resources in the new enterprise may be detrimental to the consolidation and growth of our existing business.

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

Trinity Biotech currently distributes its product portfolio through distributors in approximately 110 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.



---

**Table of Contents**

***Our patent applications could be rejected or the existing patents could be challenged; our technologies could be subject to patent infringement claims; and trade secrets and confidential know-how could be obtained by competitors.***

We can provide no assurance that the patents Trinity Biotech may apply for will be obtained or that existing patents will not be challenged. The patents owned by Trinity Biotech and its subsidiaries may be challenged by third parties through litigation and could adversely affect the value of our patents. We can provide no assurance that our patents will continue to be commercially valuable.

Trinity Biotech currently owns 13 US patents with remaining patent lives varying from two years to 17 years.

Also, our technologies could be subject to claims of infringement of patents or proprietary technology owned by others. The cost of enforcing our patent and technology rights against infringers or defending our patents and technologies against infringement charges by others may be high and could adversely affect our business.

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.

***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 resulting from its products or services. Trinity Biotech has global product liability insurance in place for its manufacturing subsidiaries up to a maximum of 6,500,000 (US\$8,962,000) for any one accident, limited to a maximum of 6,500,000 (US\$8,962,000) 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.

***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, Newmarket and Cambridge, UK, Jamestown and Buffalo, New York, Kansas City, Missouri and Carlsbad, California comprised approximately 84% of revenues in 2013. 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. 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, 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. 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 could adversely affect our operations.***

Trinity Biotech's success is dependent on certain key management personnel. Our key employees at December 31, 2013 were Ronan O Caoimh, our CEO and Chairman, Rory Nealon, our COO, Jim Walsh, our Chief Scientific Officer and Kevin Tansley, our CFO/Company Secretary. If such key employees were to leave and we were unable to obtain adequate replacements, our operating results could be adversely affected.

***We are dependent on suppliers for the primary raw materials required for its 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. Although Trinity Biotech does not expect to be dependent upon any one source for these 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.

---

**Table of Contents**

*We could be adversely affected by healthcare reform legislation.*

Third-party payers 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. Following years of increasing pressure, during 2010 the U.S. government enacted comprehensive healthcare reform. At present, given the infancy of the enacted reform, we are unable to predict what effect the legislation might ultimately have on reimbursement rates for our products. If reimbursement amounts for diagnostic testing services are decreased in the future, such decreases may reduce the amount that will be reimbursed to hospitals or physicians 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. In addition, this legislation established a 2.3% excise tax on the sales of medical devices beginning in calendar year 2013.

Other elements of this and other future legislation could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

*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 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. 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.

*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 Fiom 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 Krona and Sterling.

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

The total share options and warrants exercisable at December 2013, as described in Item 18, Note 18 to the consolidated financial statements, are convertible into American Depositary Shares (ADSs), 1 ADS representing 4 Class A Ordinary Shares. The exercise of the share options exercisable and of the warrants 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 and warrant holders of the 3,018,915 A Ordinary shares (754,729 ADSs) exercisable at December 31, 2013 be exercised, Trinity Biotech would have to issue 3,018,915 additional A ordinary shares (754,729 ADSs). On the basis of 92,296,506 A ordinary shares outstanding at December 31, 2013, this would effectively dilute the ownership interest of the existing shareholders by approximately 3%.

*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 judgements. The laws of Ireland do however, as a general rule, provide that the judgements of the courts of the United States have in Ireland the same validity

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

as if rendered by Irish Courts. Certain important requirements must be satisfied before the Irish Courts will recognise the United States judgement. The originating court must have been a court of competent jurisdiction, the judgement may not be recognised if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgement obtained in contravention of the rules of natural justice will not be enforced in Ireland.

## **Table of Contents**

### **Item 4 *Information on the Company History and Development of the Company***

Trinity Biotech ( the Group ) develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and Point-of-Care ( POC ) 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. The Group is also a significant provider of raw materials to the life sciences industry. The Group sells worldwide in approximately 110 countries through its own sales force and a network of international distributors and strategic partners.

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

The Group, which has its headquarters in Bray, Ireland, employs approximately 571 people worldwide and markets its portfolio of almost 400 products to customers in approximately 110 countries around the world. Trinity Biotech markets its products in the US through a direct sales force and in the rest of the world through a combination of direct selling and a network of distributors. Trinity Biotech has manufacturing facilities in Bray, Ireland, in Cambridge and Newmarket in the UK, in Jamestown and Buffalo, New York, Carlsbad, California and Kansas City, Missouri in the USA.

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 was 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 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 US-based hospitals and reference laboratories. For more information please refer to Item 18, Note 22.

#### *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 is 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.

#### *Acquisition of Fiom Diagnostics AB*

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

Fiom, which is based in Uppsala, Sweden, is developing a range of point-of-care cardiac assays based on micro-pillar technology. 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. For more information please refer to Item 18, Note 22.

In January 2014, Trinity received CE marking/EU regulatory approval of a Troponin I point-of-care test, the first test on this platform, which will be marketed under the name Meritas.





**Table of Contents**

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

**Principal Markets**

The primary market for Trinity Biotech's tests remains the Americas. During fiscal year 2013, the Group sold 60% (US\$54.8 million) (2012: 60% or US\$49.6 million) (2011: 66% or US\$51.4 million) of product in the Americas. Sales to non-Americas (principally European and Asian/African) countries represented 40% (US\$36.4 million) for fiscal year 2013 (2012: 40% or US\$32.9 million) (2011: 34% or US\$26.5 million).

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

**Principal Products**

Trinity Biotech develops, acquires, manufactures and markets a wide range of clinical in-vitro diagnostic products. This product portfolio, firstly split by point of use, is then subdivided on the basis of application.

Product portfolio sub-division with associated established brand names:

Point-Of-Care			Clinical Laboratory			
Infectious Disease	Emergency Medicine	Autoimmune	Infectious Disease	Haemoglobins	Clinical Chemistry	Blood Bank
UniGold	Meritas®	ImmuBlot	Bartels®	Premier	EZ	Captia
Recombigen®		ImmuGlo	MarDx®	Ultra <sup>2</sup> ™		MicroTrak
		ImmuLisa	MarBlot®			
		OTOblot	MycXtra®			
			MycAssay			

Trinity Biotech also sells raw materials to the life sciences industry and research institutes globally through the Company subsidiary, Fitzgerald Industries.

Trinity Biotech products are sold through our direct sales organizations in the USA and through our network of principal distributors and Non-governmental bodies into approximately 110 countries globally.

**Point of Care (POC)**

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

*UniGold HIV*

Trinity Biotech makes a very significant contribution to the global effort to meet the challenge of HIV. The Group's principal product is UniGold HIV. In Africa, UniGold HIV has been used for several years in voluntary counselling and testing centres (VCTs) in the sub-Saharan region where they provide a cornerstone to early detection and treatment intervention. The UniGold HIV brand is recognised for its quality and reliability.

In the USA, the Centres for Disease Control (CDC) recommend the use of rapid tests to control the spread of HIV/AIDS. As part of this, UniGold HIV is used in public health facilities, hospitals and other outreach facilities.

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

During 2013, the Group received FDA approval for a HIV-2 claim for the UniGold<sup>®</sup> Recombigen<sup>®</sup> product. The approval will expand the US HIV sales potential as this product can now participate in certain health programs previously not open to it and compete more effectively in the hospital market.

## **Table of Contents**

### *The Future of Point-Of-Care at Trinity Biotech*

Point-Of-Care is strategically key to the growth of Trinity Biotech in the future. The product development teams in the USA and Ireland at the end of 2013 released a number of products from the pipeline to market. The key products are Uni-Gold *S. pneumoniae*, Uni-Gold *Legionella*, Uni-Gold *C. difficile* and Uni-Gold Syphilis. All products are 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.

The new point-of-care products are sold through the Trinity Biotech sales and marketing organization to clinical and reference laboratories directly in the UK and through independent distributors and strategic partners in other countries.

### ***Clinical Laboratory***

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

Autoimmune diseases;

Infectious diseases: Bacterial, fungal, parasitic and viral diseases;

HbA1c for diabetes monitoring and diagnosis; Hb Variants for the detection of Hemoglobinopathies; and

Clinical Chemistry: Liver & kidney disease and haemolytic anaemia.

#### *Autoimmune*

In 2013, Trinity Biotech acquired Immco Diagnostics, an autoimmunity company known for novel assay development and extensive contributions to autoimmune disease research. Immco develops, manufactures and distributes products in immunofluorescence assay (IFA), enzyme-linked immunosorbent assay (ELISA), western blot (WB) and line immunoassay (LIA) formats for diagnosis of autoimmune diseases. As a complement to the product range, the automation offering includes ELISA and IFA processors and the Immco IFA reading system, iSight. In terms of range, breadth and technical performance, the Immco IFA range is best on the market, while the EIA range is of the highest quality and very competitive with the market leaders. The Immco products are a seamless fit for the instrumentation platforms currently marketed by Trinity Biotech for ELISA and WB assays. The vast majority of the product line is FDA cleared for sale in the USA and CE marked in Europe.

The diagnostic product line is complemented by a specialized reference laboratory offering services in diagnostic immunology, pathology and immunogenetics, and marketed to US-based reference laboratories and hospitals.

The Immco product line addresses the high growth (over 10% p.a.), 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 and Graves disease.

The Immco products are sold through the Trinity Biotech sales and marketing organization to clinical and reference laboratories directly in the USA and via distributors in other countries. Distribution in the key European markets is through our partner Menarini Diagnostics; currently a European market leader in autoimmune testing. Products are sold in over 100 countries, with the focus on Europe and North America.

#### *Infectious Diseases*

Trinity Biotech manufactures products for niche/specialized 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 niche/specialist disease areas served by the Trinity Biotech products include: (1) Lyme disease, (2) Sexually transmitted diseases: Syphilis, Chlamydia and Herpes simplex virus (3) Respiratory infections: *Legionella*, Flu A&B, (4) Epstein Barr Virus, (5) fungal pathogens and (6) other viral pathogens, e.g. Measles,

Mumps, Rubella and Varicella.

Trinity Biotech develops, manufactures and distributes products in immunofluorescence (IFA), enzyme-linked immunosorbent (ELISA), western blot (WB), real-time PCR 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 is FDA cleared for sale in the USA and CE marked in Europe. Products are sold in approximately 110 countries, with the focus on North America, Europe and Asia. The infectious disease products are sold through the Trinity Biotech sales and marketing organization to clinical and reference laboratories directly in the USA and UK and through independent distributors and strategic partners in other countries.

## **Table of Contents**

### *Clinical Chemistry*

The Trinity Biotech speciality clinical chemistry business includes reagent products such as ACE, Bile Acids, Lactate, Oxalate and Glucose-6-Phosphate Dehydrogenase (G6PDH) that are clearly differentiated in the marketplace. These products are suitable for both manual and automated testing and have proven performance in the diagnosis of many disease states from liver and kidney disease to G6PDH deficiency which is an indicator of haemolytic anaemia.

### *Haemoglobins: HbA1c and Hb Variants*

Primus Corporation, a Trinity Biotech company, focuses on products for the in-vitro diagnostic testing for haemoglobin A1c (HbA1c) used in the monitoring and diagnosis of diabetes and Hb Variants for the detection of Haemoglobinopathies. Primus manufactures a range of instrumentation using patented boronate affinity for HPLC and POC platforms as follows:

HbA1c: These products are the most accurate and precise methods available for diagnosis/monitoring of diabetic. A1C is also used to identify those at risk of becoming diabetic;

Haemoglobin Variants: The Primus Ultra<sup>2</sup> instrument is the most 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. The Ultra<sup>2</sup> is unparalleled in the number of different variants it is able to detect; and

Neonatal Haemoglobin: The GeneSys system, 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. Distribution is through our European partner Menarini Diagnostics, currently the European market leader in Haemoglobin testing. FDA approval was obtained in quarter 4 of 2011. In the USA, the Premier Hb9210 is being sold by our direct sales organization and our distribution partner Thermo Fisher. The Premier's unique features, cost structure and core technology enables it to compete in most economies and settings.

The current Primus products are sold through the Trinity Biotech sales and marketing organization to clinical and reference laboratories directly in the USA and via distributors in other countries.

### ***Blood Bank***

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 Organization (WHO) 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 (OEM) agreements for top 10 IVD businesses. The business has strong market share in Europe and is targeting growth in the United States through internal synergies and external relationships.

## **Table of Contents**

### ***Emergency Medicine***

Emergency Medicine refers to acute care testing, critical time-sensitive diagnostic tests which are performed in emergency rooms, STAT labs, pre/post operative units, physician office labs (POL s) and the central laboratory.

Emergency Medicine is a strategic cornerstone of key growth for Trinity Biotech in the future. Following the acquisition of Fiom Diagnostics, Trinity has developed a high sensitivity Troponin test capable of delivering laboratory based quality in the Emergency Room environment. The objective 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, and CE marking/EU regulatory approval was received in January 2014 with FDA submission expected to be made later in the year. With the launch and CE marking of the Meritas Troponin test these objectives have now been achieved. Thus Trinity Biotech is the first company to commercialise a fully guideline compliant product for use in the \$350m Emergency Room Cardiac market. A top priority for Trinity Biotech is to expand the offering on the Meritas POC Analyzer. The focus of development is to expand the test menu to include assays for (a) heart failure; (b) pulmonary embolism; and (c) other highly valuable areas of need in Emergency Medicine.

Trinity Biotech is first launching the Meritas Troponin product for sale in Europe and other selected markets through its specialist Cardiology Distributor network.

### ***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 clinical chemistry, point of care, infectious disease, Haemoglobins and clinical chemistry products.

Through its sales and marketing organisation in Ireland, Trinity Biotech sells:

Its Clinical Chemistry product range directly to hospitals and laboratories in Germany and France;

All products directly to hospitals and laboratories in the UK; and

All product lines through independent distributors and strategic partners in a further 110 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

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

---

## **Table of Contents**

### *Licences*

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

In 2013, Trinity Biotech entered into a License Agreement with a leading market participant, giving the Group access to a significant HIV-2 patent portfolio on a non-exclusive, worldwide basis. 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.

In 2012 Trinity Biotech entered into a License Agreement with the Centre for Disease Control (CDC) in Atlanta, GA, USA for the rights to use their Cardiophilin technology in developing and producing a Syphilis rapid test.

In 2005 Trinity Biotech obtained a licence from the University of Texas for the use of Lyme antigen (Vlse), thus enabling the inclusion of this antigen in the Group's Lyme diagnostic products. Trinity also entered a Biological Materials License Agreement with the Centre for Disease Control (CDC) in Atlanta, GA, USA for the rights to produce and sell the CDC developed HIV Incidence assay.

In 2002, Trinity Biotech obtained the Unipath and Carter Wallace lateral flow licences under agreement with Inverness Medical Innovations (IMI). In 2006, Trinity Biotech renewed its license agreement with Inverness Medical Innovations covering IMI's most up to date broad portfolio of lateral flow patents, and expanded the field of use to include over the counter (OTC) for HIV products, thus ensuring Trinity Biotech's freedom to operate in the lateral flow market with its UniGold technology. As a platform technology, the lateral flow licences obtained from Inverness Medical Innovations also apply to the new Point-of-Care range which is in development at our Carlsbad facility.

On December 20, 1999 Trinity Biotech obtained a non-exclusive commercial licence from the National Institute of Health (NIH) in the US 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.

Trinity Biotech has also entered into a number of licence/supply agreements for key raw materials used in the manufacture of its products.

Each of the key licensing arrangements terminates on the expiry 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 requires the Group to pay a royalty to the licence holder which is based on sales of the products which utilize the relevant technology being licensed. The royalty rates vary from 2% to 10% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2013 was US\$1,105,000 (2012: US\$1,145,000).

### ***Government Regulation***

The preclinical and clinical testing, manufacture, labelling, 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 regulatory clearance 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 Food and Drug Administration (FDA) in the US, the Irish Medicines Board (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 60% of Trinity Biotech's 2013 revenues were generated in the Americas (with a large concentration of this in the USA) and as the USA represents a substantial proportion of the worldwide diagnostics market, an overview of FDA regulation has been included below.

#### *FDA Regulation*

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. The FDA's regulations govern, among other things, the following activities: product development, testing, labelling, storage, pre-market clearance or approval, advertising and promotion and sales and distribution.





---

## **Table of Contents**

*Access to US Market.* Each medical device that Trinity Biotech may wish to commercially distribute in the US will require either pre-market notification (more commonly known as 510(k)) clearance or pre-market approval ( PMA ) application prior to commercial distribution. Devices intended for use in blood bank environments fall under even more stringent review and require a Blood Licence Application ( BLA ). Some low risk devices are exempted from these requirements. The FDA has introduced fees for the review of 510(k) and PMA applications. The fee for a PMA or BLA in 2013 is in the region of US\$260,000.

*510(k) Clearance Pathway.* To obtain 510(k) clearance, Trinity Biotech must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a predicate device either a previously cleared class I or II device or a class III preamendment device, for which the FDA has not called for PMA applications. The FDA's 510(k) clearance pathway usually takes from 3 to 9 months, but it can take longer. 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.

*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. A PMA application must provide extensive 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 committee made up of clinicians and/or other appropriate experts is typically convened to evaluate the application and make recommendations to the FDA as to whether the device should be approved. It generally takes from one to three years but can take longer.

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. It generally takes from one to three years or even longer. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. As noted above, the FDA has recently implemented substantial fees for the submission and review of PMA applications.

*BLA approval pathway.* BLA approval is required for some products intended for use in a blood bank environment, where the blood screened using these products may be administered to an individual following processing. This approval pathway involves even more stringent review of the product.

*Clinical Studies.* A clinical study is required to support a PMA application and is required for a 510(k) pre-market notification. Such studies generally require submission of an application for a Pre-Submission (Pre-Sub) Program showing that it is safe to test the device in humans and that the testing protocol is scientifically sound.

### *Post-market Regulation*

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply, including the Quality System Regulation ( QSR ), which requires manufacturers to follow comprehensive testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting ( MDR ) regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Trinity Biotech is subject to inspection by the FDA to determine compliance with regulatory requirements. 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.

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.

## **Table of Contents**

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.

### *CLIA classification*

Purchasers of Trinity Biotech's clinical diagnostic products 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.

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 authorization 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.

### *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;

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

The Group's distributor of raw materials for the life sciences industry, 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.

## Table of Contents

### *Property, Plant and Equipment*

Trinity Biotech has seven manufacturing sites worldwide, four in the US (Buffalo and Jamestown, NY, Kansas City, MO and Carlsbad, CA), two in the UK (Newmarket and Cambridge), and one in Bray, Ireland. An additional facility is owned in Burlington, Canada which serves as a distribution centre and also carries out some research and development activities. The US 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\$506,000), 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\$1,044,000). 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\$147,000.

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\$238,000. 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\$173,000.

Fioni 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 2,500,000 SEK (US\$384,000).

Immco Diagnostics Inc. operates from a 15,200 square foot facility in Amherst, New York 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 operates 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 expires in March, 2014, and the Newmarket facility is subject to a 3 month rolling lease.

Additional office 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\$152,000), 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.

We do not currently have any plans to expand or materially improve our facilities.

In relation to products produced at our facilities these are as follows:

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

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



---

## **Table of Contents**

**Carlsbad, California** this facility specializes in the development and manufacture of products utilizing 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 A1c range of products.

**Amherst, New York** this site is responsible for the manufacture of autoimmune test kits and the majority of R&D activities for Immco Diagnostics.

**Buffalo, New York** this site contains the reference laboratory business of Immco Diagnostics.

**Cambridge, UK** this site is responsible for the manufacture of blood bank and EIA products, and also includes R&D activities.

**Newmarket, UK** this site is responsible for the manufacture of blood bank and EIA products.

We are fully in compliance with all environmental legislation 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, the acquisition of Fiom Diagnostics AB in 2012 and the acquisition of Phoenix Bio-tech Corp. in 2011.

## **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, 2013, December 31, 2012 and December 31, 2011, 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 (US GAAP) as at and for the three year period ended December 31, 2013 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. The Group markets almost 400 different diagnostic products in approximately 110 countries. In addition, the Group manufactures its own and distributes third party infectious disease diagnostic instrumentation. The Group, through its Fitzgerald operation, is also a significant provider of raw materials to the life sciences industry.

### ***Factors affecting our results***

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





---

## **Table of Contents**

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, 2013, 2012, 2011, 2010 and 2009 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 2010 or 2009. 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 Fiom Diagnostics AB. Fiom 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.

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.

---

## **Table of Contents**

### *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 commercializing our programs, we could incur significant charges in the period in which the impairment occurs. The valuation techniques utilized in performing impairment tests incorporate significant assumptions and judgments to estimate the fair value, as described above. The use of different valuation techniques or different assumptions could result in materially different fair value estimates.

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, 2013 the carrying value of capitalised development costs was US\$51,648,000 (2012: US\$33,704,000) (see Item 18, Note 11 to the consolidated financial statements). The increase in 2013 was mainly as a result of development costs of US\$18,390,000 being capitalised. These additions were partially offset by amortisation of US\$446,000.

### *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.

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

The value-in-use calculations use cash flow projections based on the 2014 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. 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 13% to 25% (2012: 15% to 27%).

---

## **Table of Contents**

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, 2013:

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, 2013:

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 2013, 2012 or 2011 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2013 our allowance for slow moving and obsolete inventory was US\$4,462,000 which represents approximately 13.1% of gross inventory value. This compares with US\$5,348,000, or approximately 20.5% of gross inventory value, at December 31, 2012 (see Item 18, Note 14 to the consolidated financial statements) and US\$5,930,000, or approximately 23.0% of gross inventory value, at December 31, 2011. There has been a decrease in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2013 and 2012. 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\$683,000 at December 31, 2013 (2012: US\$522,000) (2011: US\$515,000) 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 2013, 2012 or 2011 which would have an impact on the carrying values of receivables in these periods. At December 31, 2013, the allowance was US\$2,150,000 which represents approximately 2.4% of Group revenues. This compares with US\$1,520,000 at December 31, 2012 which represented approximately 1.8% of Group revenues (see Item 18, Note 15 to the consolidated financial statements) and to US\$1,507,000 at December 31, 2011 which represented approximately 1.9% 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\$456,000 at December 31, 2013 (2012: US\$413,000) (2011: US\$390,000) would result.

*Accounting for income taxes*

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

## **Table of Contents**

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 2013. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. During 2013, 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(xxvii).



**Table of Contents**

**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.



---

## **Table of Contents**

### ***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:*

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

#### ***1. 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 were 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 were 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.

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

### **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.

**Table of Contents**

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,		% Change
	2013	2012	
	US\$ '000	US\$ '000	
<b>Revenues</b>			
<b>Clinical Laboratory</b>	71,462	63,356	12.8%
<b>Point-of-Care</b>	19,754	19,154	3.1%
<b>Total</b>	<b>91,216</b>	<b>82,510</b>	<b>10.6%</b>

*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<sup>®</sup>, 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,		% Change
	2013	2012	
	US\$ '000	US\$ '000	
<b>Revenues</b>			
Americas	54,761	49,638	10.3%
Europe	12,394	10,214	21.3%
Asia/Africa	24,061	22,658	6.2%

<b>Total</b>	<b>91,216</b>	<b>82,510</b>	<b>10.6%</b>
--------------	---------------	---------------	--------------

**Table of Contents**

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.

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 analyzer 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 analyzer 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.

**3. Operating Profit**

The following table sets forth the Group's operating profit:

	Year ended December 31,		% Change
	2013	2012	
	US\$ '000	US\$ '000	
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	<b>8,995</b>	<b>17,166</b>	<b>(47.6%)</b>

*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 1<sup>st</sup> 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.

**Table of Contents***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.

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

	Year ended December 31,		Increase/(Decrease)	% Change
	2013	2012		
	US\$ 000	US\$ 000	US\$ 000	
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%
<b>Total</b>	<b>33,066</b>	<b>22,425</b>	<b>10,641</b>	<b>47%</b>

*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.



**Table of Contents***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.

**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,		% Change
	2013	2012	
	US\$ 000	US\$ 000	
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%)
<b>Profit of the year</b>	<b>9,646</b>	<b>17,341</b>	<b>(44%)</b>

*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%.

## **Table of Contents**

### ***Results of Operations***

#### ***Year ended December 31, 2012 compared to the year ended December 31, 2011***

*The following compares our results in the year ended December 31, 2012 to those of the year ended December 31, 2011 under IFRS. Our analysis is divided as follows:*

5. *Overview*

6. *Revenues*

7. *Operating Profit*

8. *Profit for the year*

#### **5. Overview**

In 2012, revenues increased by US\$4.6 million to US\$82.5 million, which represented a growth rate of 6%. Most of the revenue growth was attributable to the point-of-care products, in particular the HIV rapid test.

Geographically, 60% of our sales were generated in the Americas, 28% in Africa/Asia and 12% in Europe.

The gross margin is 51.2% for 2012, which is 0.3% lower than the gross margin for 2011. The reduction in gross margin is explained by a high level of sales of A1c instruments, following the launch of the Premier analyzer. Instruments have lower margins than the accompanying reagents and consumables.

The operating profit is US\$17.2 million for the year ended December 31, 2012 which compares to US\$15.8 million for the year ended December 31, 2011. The operating margin is 20.8% in 2012, compared to 20.2% in 2011. The increase in the operating margin is due to the impact of a 6% increase in revenues coupled with strong budgetary control over Sales, General & Administrative (SG&A) costs, which increased by just under 2%.

Net financial income decreased from US\$2.4 million to US\$2.2 million, mainly due to a reduction in deposit interest rates.

The profit after tax for the year ended December 31, 2012 was US\$17.3 million which compares to a profit after tax for the year ended December 31, 2011 of US\$15.6 million.

In 2012 the Group acquired Fiom Diagnostics, a company based in Sweden which is developing a range of cardiac assays. Fiom has not yet commenced selling its products.

#### **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.

The Group also derives a portion of its revenues from leasing infectious diseases diagnostic instruments to customers. In cases where the risks and rewards of ownership of the instrument passes to the customer, the fair value of the instrument is recognised at the time of sale 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. In certain markets, the Group also earns revenue from servicing infectious diseases instruments located at customer premises.

**Table of Contents***Revenues by Product Line*

Trinity Biotech's revenues for the year ended December 31, 2012 were US\$82,510,000 compared to revenues of US\$77,948,000 for the year ended December 31, 2011, which represents an increase of US\$4,562,000 or 6%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		% Change
	2012	2011	
	US\$ '000	US\$ '000	
<b>Revenues</b>			
<b>Clinical Laboratory</b>	63,356	61,386	3.2%
<b>Point-of-Care</b>	19,154	16,562	15.7%
<b>Total</b>	<b>82,510</b>	<b>77,948</b>	<b>5.9%</b>

*Clinical Laboratory*

In 2012 Clinical Laboratory revenues increased by US\$1,970,000 which equates to 3.2%.

The increase of 3.2% is attributable to three main factors:

the full year effect of the Premier analyzer which tests for haemoglobin A1c and haemoglobin variants and was launched towards the end of 2011. In excess of 200 Premier instruments were sold in 2012 and there was a related increase in sales of the accompanying reagents;

growth in Infectious Diseases revenues in China; and

a stronger Lyme season in the USA in 2012.

These increases were partially offset by a decrease in our Clinical Chemistry range of products which test for liver and kidney disease and haemolytic anaemia.

*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\$2,592,000, which represents an increase of just under 16%. This increase was due to higher revenues in Africa offset by slightly lower revenues in the USA.

*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,		% Change
	2012	2011	
	US\$ '000	US\$ '000	

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

<b>Revenues</b>			
Americas	49,638	51,352	(3.3%)
Europe	10,214	9,423	8.4%
Asia/Africa	22,658	17,173	31.9%
<b>Total</b>	<b>82,510</b>	<b>77,948</b>	<b>5.9%</b>

**Table of Contents**

In the Americas, the 3% decrease amounting to US\$1,714,000 is primarily attributable to a reduction in point-of-care revenues due to less government funding for HIV testing in USA. This reduction was largely offset by strong growth in our Lyme s disease and haemoglobin A1c products.

Revenues in Europe increased by US\$791,000, or 8% compared to 2011. The increase was due to the full year effect of the Premier analyzer which was launched towards the end of 2011.

Asia/Africa revenues increased by 32%, or US\$5,485,000 compared to 2011. 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 analyzer 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,		% Change
	2012	2011	
	US\$ 000	US\$ 000	
Revenues	82,510	77,948	5.9%
Cost of sales	(40,257)	(37,820)	6.4%
Gross profit	42,253	40,128	5.3%
Other operating income	468	910	(48.6%)
Research & development	(3,130)	(3,206)	(2.4%)
SG&A expenses	(22,425)	(22,048)	1.7%
Operating profit	<b>17,166</b>	<b>15,784</b>	<b>8.8%</b>

*Cost of sales*

Total cost of sales increased by US\$2,437,000 from US\$37,820,000 for the year ended December 31, 2011 to US\$40,257,000, for the year ended December 31, 2012, an increase of 6%. The increase in cost of sales in 2012 is broadly in line with the increase in revenues.

*Gross margin*

The gross margin of 51.2% in 2012 compares to a gross margin of 51.5% in 2011. The decrease in gross margin in 2011 is largely attributable to a high level of sales of A1c instruments, following the launch of the Premier analyzer. Instruments have lower margins than the accompanying reagents and consumables

*Other operating income*

Other operating income comprises rental income from sublet properties and income from the provision of services to Diagnostica Stago under a Transition Services Agreement (TSA). TSA income 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 were short term arrangements which ceased by the middle of 2011 and this is the main reason explaining the reduction in Other operating income in 2012.

*Research and development expenses*

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Research and development ( R&D ) expenditure reduced from US\$3,206,000 in 2011 to US\$3,130,000 in 2012. The decrease of 2% was due to higher capitalisations of salary costs into development projects. For details of the Company's various R&D projects see Research and Products under Development in Item 5 below.

### *Selling, General & Administrative expenses (SG&A)*

Total SG&A expenses increased by US\$377,000 from US\$22,048,000 for the year ended December 31, 2011 to US\$22,425,000 for the year ended December 31, 2012. The increase is primarily due an increase in the share-based payments.

**Table of Contents**

The following table outlines the breakdown of SG&A expenses in 2012 compared to 2011.

	Year ended December 31,		Increase/(Decrease)	
	2012	2011		
	US\$ 000	US\$ 000	US\$ 000	% Change
SG&A (excl. share-based payments and amortisation)	19,268	19,386	(118)	(0.6%)
Share-based payments	1,675	1,235	440	35.6%
Amortisation	1,482	1,427	55	3.9%
<b>Total</b>	<b>22,425</b>	<b>22,048</b>	<b>377</b>	<b>1.7%</b>

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

SG&A expenses excluding share-based payments and amortisation decreased from US\$19,386,000 for the year ended December 31, 2011 to US\$19,268,000 for the year ended December 31, 2012, which represents a decrease of 1%. The decrease this year of US\$118,000 is mainly due to the impact of foreign exchange rates, specifically a 7% strengthening of the US dollar versus the euro. This saving was partially offset by acquisition costs related to the purchase of Fiom Diagnostics.

*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\$1,713,000 (2011: US\$1,269,000). The increase of US\$444,000 in the total share-based payments expense is due to the full year effect of share options granted to employees and directors during 2011 and the impact of new share options granted during 2012. The total charge is shown in the following expense headings in the statement of operations: US\$38,000 (2011: US\$34,000) was charged against cost of sales and US\$1,675,000 (2011: US\$1,235,000) 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\$1,427,000 for the year ended December 31, 2011 to US\$1,482,000 for the year ended December 31, 2012. The increase of US\$55,000 is mainly due to the full year effect of the amortisation of amounts related to the development of the Premier instrument.

**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,		% Change
	2012	2011	
	US\$ 000	US\$ 000	
Operating profit	17,166	15,784	8.8%
Net financing income	2,192	2,416	(9.3%)
Profit before tax	19,358	18,200	6.4%



## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Income tax expense	(2,017)	(2,607)	(22.6%)
<b>Profit of the year</b>	<b>17,341</b>	<b>15,593</b>	<b>11.2%</b>

### *Net Financing income*

Net financing income is US\$2,192,000 for year-end December 31, 2012 compared to US\$2,416,000 in 2011. Financial expenses increased from US\$12,000 for year-end December 31, 2011 to US\$88,000 in 2012. The increase is mainly due to the implicit interest on the deferred consideration due as part of the acquisition of Fiom Diagnostics. Financial income decreased from US\$2,428,000 for year-end December 31, 2011 to US\$2,280,000 in 2012 due to the fall in deposit interest rates.

## **Table of Contents**

### *Taxation*

The Group recorded a tax charge of US\$2,017,000 for the year ended December 31, 2012 compared to US\$2,607,000 for the year ended December 31, 2011. The 2012 tax charge comprises US\$338,000 of current tax and US\$1,679,000 of deferred tax. The decrease in the total tax charge in 2012 is primarily due to a greater proportion of the Group's income being earned in lower tax jurisdictions. For further details on the Group's tax charge please refer to Item 18, Note 8 and Note 12 to the consolidated financial statements.

### *Profit for the year*

The profit for the year amounted to US\$17,341,000, which represents an increase of US\$1,748,000 when compared to US\$15,593,000 in 2011, representing an increase of 11.2%.

### *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)).

#### *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, 2013, Trinity Biotech's consolidated cash and cash equivalents were US\$22,317,000. This compares to cash and cash equivalents of US\$74,947,000 at December 31, 2012.

Cash generated from operations for the year ended December 31, 2013 amounted to US\$8,766,000 (2012: US\$18,822,000), a decrease of US\$10,056,000. The decrease in cash generated from operations of US\$10,056,000 is attributable to a decrease in operating cash flows before changes in working capital of US\$2,432,000 in addition to increases in working capital outflows of US\$7,624,000. The decrease in operating cash flows before changes in working capital of US\$2,432,000 is primarily driven by the decrease in profit during the current financial year. The working capital outflow increase, when compared to the prior year, is partly due to the increase in the cash outflows for trade and other receivables of US\$4,973,000 (mainly due to increased revenues and a slight increase in debtor days) and increase in cash outflows of US\$5,884,000 for inventories. This has been offset partially by the increase in cash inflows from trade and other payables, when compared to the

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

prior year, of US\$3,233,000. The cash generated from operations was attributable to an operating profit of US\$8,995,000 (2012: US\$17,166,000), as adjusted for non cash items of US\$10,806,000 (2012: US\$5,067,000) plus cash outflows due to changes in working capital of US\$11,035,000 (2012: cash outflows of US\$3,411,000).

The increase in other non cash charges from US\$5,067,000 for the year ended December 31, 2012 to US\$10,806,000 for the year ended December 31, 2013 is mainly attributable to once-off charges incurred in the year relating to restructuring and new license agreements entered into.

---

## **Table of Contents**

The net cash outflows in 2013 due to changes in working capital of US\$11,035,000 are due to the following:

An increase in trade and other receivables of US\$7,032,000 due to the increase in revenues and the increase, year on year, in the debtors days number;

An increase in inventory of US\$7,258,000 due to the strategic build up of certain stock 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\$3,255,000 due to increased production requirements.

Net interest received amounted to US\$1,292,000 (2012: US\$2,186,000). This consisted of interest received of US\$1,292,000 (2012: US\$2,189,000) on the Group's cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2013 amounted to US\$61,193,000 (2012: outflows of US\$9,960,000) which were principally made up as follows:

Payments of US\$39,424,000 to acquire Immco Diagnostics Inc and the blood bank screening business of Lab21 Ltd, partially offset by cash received with acquired subsidiary of US\$1,407,000;

Payments to acquire intangible assets of US\$18,687,000 (2012: US\$12,631,000), 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\$4,489,000 (2012: US\$2,665,000) incurred as part of the Group's investment programme for its manufacturing and distribution activities.

Net cash outflows from financing activities for the year ended December 31, 2013 amounted to US\$798,000 (2012: US\$6,193,000). The principal reason for the decrease in outflows in 2013 is due to the fact that the Group did not purchase any Treasury shares during the year when compared to 2012. The main area of cash outflow from financing activities for the year was the annual dividend payment of US\$4,373,000 (2012: US\$3,224,000). Other cash outflows included expenses paid in connection with share issues and debt financing of US\$87,000 (2012: US\$22,000). These outflows were partially offset by the receipt of US\$3,662,000 from the issue of ordinary shares in 2013 (2012: US\$2,505,000). Ordinary shares issued in 2013 and 2012 are as a result of share options and warrants 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 based on expectations of future exchange rate exposure, implements a hedging policy which may include covering a portion of this exposure through the use of forward contracts. When used, these forward contracts are cashflow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions.

As at December 31, 2013 and December 31, 2012 there was no interest-bearing debt outstanding. Cash and cash equivalents were US\$22,317,000 (2012: US\$74,947,000). 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 Qualitative and Quantitative Disclosures about Market Risk .

### ***Contractual obligations***

The following table summarises our minimum contractual obligations and commercial commitments, including interest, as of December 31, 2013:

	Payments due by Period				
	Total	less than 1 year	1-3 Years	4-5 Years	more than 5 years
<b>Contractual Obligations</b>	US\$ 000	US\$ 000	US\$ 000	US\$ 000	US\$ 000
Operating lease obligations	32,461	3,510	5,498	3,620	19,833
Total	32,461	3,510	5,498	3,620	19,833

## **Table of Contents**

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 considerable 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. If this were the case, there can be no assurance that financing will be available at attractive terms, or at all. The Group believes that success in raising additional capital or obtaining profitability will be dependent on the viability of its products and their success in the market place.

### ***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. Trinity Biotech's revenues are primarily denominated in US Dollars and its expenses are incurred principally in US Dollars and Euro. 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 and the US Dollar may impact on the Group's Euro monetary assets and liabilities and on Euro 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 2013, 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 2013 was US\$2,894,000 (2012: US\$1,910,000).

### ***Research and Products under Development***

#### ***History***

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

#### ***Centres of Excellence***

Trinity Biotech has research and development groups focusing separately on Point-of-Care products, Diabetes products and Western Blot products. These groups are located in Ireland and the USA and largely mirror the production capability at each production site, hence creating a centre of excellence for each product type. 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.



**Table of Contents****Principal Development Projects**

The following table sets forth for each of the main development projects, the costs incurred during each period presented and the cumulative costs incurred as at 31 December 2013:

<i>Product Name</i>	<i>2013</i> <i>US\$ 000</i>	<i>2012</i> <i>US\$ 000</i>	<i>Total project costs to December 31, 2013</i> <i>US\$ 000</i>
Troponin I assay and reader	7,200	5,048	12,248
Premier Instrument for Haemoglobin A1c testing	3,861	3,854	15,748
Brain Natriuretic Peptide (BNP) assay	1,204		1,204
Syphilis Rapid Point-of-Care test	859	750	2,405
Genesys/Resolution column enhancement	685		685
C. Difficile Rapid Point-of-Care test	580	700	1,464
H Pylori Rapid Point-of-Care test	499	146	700
Tristat Point-of-Care instrument	481	440	5,348
Strep pneumonia Rapid Point-of-Care test	342	339	876

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 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 2013. The total estimated completion costs are anticipated to be incurred evenly up to the completion date of the relevant project.

<i>Product Name</i>	<i>Total costs to complete</i> <i>US\$ 000</i>	<i>Estimated date for completion</i>
Troponin I assay and reader <sup>1</sup>	6,900	2015
Brain Natriuretic Peptide (BNP) assay	2,500	2015
Premier Instrument for Haemoglobin A1c testing <sup>2</sup>	7,200	2015
Unigold Recombigen HIV Rapid enhancement	2,000	2015
HIV Ag-Ab rapid test	1,500	2015
Malaria Point-of-Care test	1,000	2015
HIV 1/2	1,000	2015
US Striped Lyme	800	2014
Syphilis Rapid Point-of-Care test	750	2014
H Pylori Rapid Point-of-Care test	500	2014
Parvo	420	2014
IgM Captia	400	2015
West Nile Virus assay	300	2014

<sup>1</sup> The estimated total development costs for the Troponin I assay and reader have increased significantly since last year's estimate due to the project taking longer than expected and an increase in clinical trial costs.

<sup>2</sup> In the next two years, the Premier Instrument development project aims to expand the current offering to include an Ion exchange version, a neo-natal instrument and an instrument with total laboratory automation (TLA) capability.

There are inherent risks and uncertainties associated with completing development projects on schedule. In our experience 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.





---

## **Table of Contents**

We acknowledge that some aspects of a new product development are to an extent outside of the control of the Group. Notwithstanding the uncertainty surrounding these external factors, we believe the planned completion dates of these projects are realistic and achievable. If major development projects were severely delayed, in our opinion it would not impact significantly on Trinity Biotech's financial position or on the capitalization 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 R&D groups within Trinity Biotech:

### **Point-of-Care ( POC ) Development Group**

During 2010, the company commissioned and staffed a new POC product development unit at its Carlsbad, CA facility. This facility has been equipped with state-of-the-art POC assay development equipment and the Group 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. We are also developing tests for the detection of treponemal and non-treponemal Syphilis antibodies in human whole blood, H. pylori antigen and strep pneumoniae. The company is currently in the process of obtaining CE marking for these products after which FDA approval will be sought.

### **A1c Development Group**

#### *Premier Hb9210 Instrument for Haemoglobin A1c Testing*

This project entails the development of a new High Performance Liquid Chromatography (HPLC) instrument for testing haemoglobin A1c (HbA1c). This is a measure of a patient's average blood sugar control over the last two to three months. 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 in the non-US market in 2011 followed by the USA in early 2012.

The Premier Hb9210 analyser is a best in class instrument with the following key advantages:

Patented boronate affinity technology on an HPLC platform (only one in the market) eliminating interference from common haemoglobin variants;

Results available in 1 minute enabling fastest patient result turnaround times;

State-of-the-art software using touch screen technology to facilitate ease of use with operators; and

Modular instrument which will significantly reduce the cost of on-site maintenance.

HbA1c testing is one of the fastest growing markets in the diagnostics industry. 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 laboratory HbA1c market worldwide is approximately US\$300 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 A1c and haemoglobin variants. This product is expected to be launched in 2014.

### **Emergency Medicine Development Group**

During 2012, the company acquired Fiom Diagnostics AB, a Swedish based company which was founded to develop diagnostic tests for the point of care cardiac market. Fiom is currently at an advanced stage of developing 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

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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 2014. Using the same platform, the company is also developing a test for BNP which is a marker for heart failure. CE marking for this product is expected in mid-2014 with submission for FDA approval to follow later that year. The point-of-care cardiac market is currently estimated to be \$650m and is growing rapidly. The vast majority of this market is based on Troponin I and BNP related products.

**Table of Contents**

In addition to cardiac tests, the company believes that diagnostic tests in a range of other fields are capable of being developed using the same platform.

**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 and Senior Management****Directors**

<i>Name</i>	<i>Age</i>	<i>Title</i>
Ronan O Caoimh	58	Chairman and Chief Executive Officer
Rory Nealon	46	Director, Chief Operations Officer
Jim Walsh, PhD	55	Director, Chief Scientific Officer
Denis R. Burger, PhD	70	Non Executive Director
Peter Coyne	54	Non Executive Director
Clint Severson	65	Non Executive Director
James D. Merselis	60	Non Executive Director

**Executive Officer**

Kevin Tansley	43	Chief Financial Officer & Company Secretary
---------------	----	---

**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 an agreement with Darnick Company.

**Rory Nealon, Chief Operations Officer**, joined Trinity Biotech as Chief Financial Officer and Company Secretary in January 2003. He was appointed Chief Operations Officer in November 2007. Prior to joining Trinity Biotech, he was Chief Financial Officer of Conduit plc, an Irish directory services provider with operations in Ireland, the UK, Austria and Switzerland. Prior to joining Conduit he was an Associate Director in AIB Capital Markets, a subsidiary of AIB Group plc, the Irish banking group. Mr Nealon holds a Bachelor of Commerce degree from University College Dublin, is a Fellow of the Institute of Chartered Accountants in Ireland, a member of the Institute of Taxation in Ireland and a member of the Institute of Corporate Treasurers in the UK.

---

**Table of Contents**

**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 was Chairman from June 1992 to May 1995. He is currently Chairman of AMES technology, a private medical device company, and is also non-executive director of Lorus Therapeutics, Inc, a cancer therapeutics, TSX 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 30 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 of Biosensia Ltd; a point-of-care diagnostics company located in Dublin, Ireland and is on the boards of Abram Scientific Inc. located in Mountain View, CA, and Cardiac Designs Inc. located in Austin, TX. Mr. Merselis has more than thirty-seven 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).

**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.

**Table of Contents****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 independent 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. Non-executive directors who perform additional services on the Audit Committee or Remuneration Committee receive additional fees. 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, 2013 amounted to US\$2,155,000. The pension charge for the year amounted to US\$60,000. 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:

<i>Executive Director</i>	<i>Salary/ Benefits US\$ '000</i>	<i>Performance related bonus US\$ '000</i>	<i>Defined contribution pension US\$ '000</i>	<i>Total</i>	
				<i>2013 US\$ '000</i>	<i>2012 US\$ '000</i>
Ronan O Caoimh <sup>1</sup>	684	193		877	816
Rory Nealon	387	119	38	544	506
Jim Walsh	320	136	22	478	460
	1,391	448	60	1,899	1,782

  

<i>Non-executive director</i>	<i>Fees US\$ '000</i>	<i>Total</i>	
		<i>2013 US\$ '000</i>	<i>2012 US\$ '000</i>
Denis R. Burger	84	84	80
Peter Coyne	84	84	80
James Merselis	74	74	70
Clint Severson	74	74	70
	316	316	300

<i>Chief Financial Officer &amp; Company Secretary</i>	<i>Salary/ Benefits US\$ '000</i>	<i>Performance related bonus US\$ '000</i>	<i>Defined contribution pension US\$ '000</i>	<i>Total</i>	
				<i>2013 US\$ '000</i>	<i>2012 US\$ '000</i>
Kevin Tansley	353	119	35	507	476

As at December 31, 2013 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2012: NIL).

The total share-based compensation expense recognised in the consolidated statement of operations in 2013 in respect of options granted to both executive and non-executive directors and the Company Secretary amounted to US\$2,499,000. See Item 18, Note 5 to the consolidated financial statements.

2,540,000 A share options (equivalent to 635,000 ADS options) were granted to the directors and the Company Secretary during 2013, 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 2012.

<sup>1</sup> Includes payments made to Darnick Company

**Table of Contents****Share Options Granted in 2013:**

<b>Director/Executive Officer</b>	<b>Number of Options Granted</b>	<b>Exercise Price of Options Granted</b>	<b>Date of Option Grant*</b>
Ronan O Caoimh	800,000 A shares (200,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Rory Nealon	500,000 A shares (125,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Jim Walsh	500,000 A shares (125,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Kevin Tansley	500,000 A shares (125,000ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Denis Burger	60,000 A shares (15,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Peter Coyne	60,000 A shares (15,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
Clint Severson	60,000 A shares (15,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013
James Merselis	60,000 A shares (15,000 ADS)	US\$4.21 per A share (US\$16.25 per ADS)	24 May 2013

\* 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 month's notice. Mr. O Caoimh remains as Chairman of the Board of Directors.

Under the terms of his service contract, Rory Nealon, Chief Operations 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. Nealon is entitled to 18 months salary and benefits.



## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

---

**Table of Contents**

***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 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 Mr Rory Nealon. The Compensation Committee administers the Employee Share Option Plan. The Committee determines the exercise price and the term of the options. Options granted to the members of the Committee are approved by the Remuneration Committee and individual option grants in excess of 30,000 shares are approved by the full board of directors. 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, 2013, Trinity Biotech had 571 employees (2012: 394) consisting of 113 research scientists and technicians, 313 manufacturing and quality assurance employees, and 145 finance, administration, sales and marketing staff (2012: 61 research scientists and technicians, 220 manufacturing and quality assurance employees, and 113 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: 354 in our US operations, 130 in Bray, Ireland, 31 in Uppsala, Sweden, 51 in the UK and 5 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 a Compensation Committee designated 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 Compensation Committee. The term of an option will be determined by the Compensation Committee, provided that the term may not exceed ten years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with 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.

**Table of Contents**

As of February 28, 2014, 7,188,752 (1,797,188 ADS equivalent) of the options outstanding were held by the directors and Company Secretary of Trinity Biotech as follows:

Director/Company	Number of Options A Shares	Number of Options ADS Equivalent	Exercise Price (Per A Share)	Exercise Price (Per ADS)	Expiration Date of Options
Secretary Ronan O Caoimh	43,752	10,938	US\$ 1.07	US\$ 4.28	18 March 2015
	600,000	150,000	US\$ 1.52	US\$ 6.07	21 May 2017
	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
Rory Nealon	500,000	125,000	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
Denis Burger	15,000	3,750	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
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
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
Clint Severson	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
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
Kevin Tansley	75,000	18,750	US\$ 2.24	US\$ 8.96	07 March 2014 18 March 2015

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

150,000	37,500	US\$ 1.07	US\$ 4.28	21 May 2017
500,000	125,000	US\$ 1.52	US\$ 6.07	7 March 2019
500,000	125,000	US\$ 2.52	US\$10.09	24 May 2020
500,000	125,000	US\$ 4.21	US\$16.85	

As of February 28, 2014 the following 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	9,449,533	US\$ 0.66-US\$4.79	US\$ 2.63-US\$19.15

As of February 28, 2014 there were no warrants to purchase A Ordinary Shares in the Company outstanding.

**Table of Contents****Item 7 Major Shareholders and Related Party Transactions**

As of February 28, 2014 Trinity Biotech has outstanding 92,428,378 A Ordinary shares. Such totals exclude 9,449,533 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2014, 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 (9)	Percentage Total Voting Power
Fidelity Mgt. & Research Co.	10,590,028	2,647,507	10.4%	10.4%
Ronan O Caoimh	6,081,252(1)	1,520,313	6.0%	6.0%
Rory Nealon	1,700,000(2)	425,000	1.7%	1.7%
Jim Walsh	2,508,612(3)	627,153	2.5%	2.5%
Denis Burger	207,000(4)	51,750	0.2%	0.2%
Peter Coyne	245,600(5)	61,400	0.2%	0.2%
Clint Severson	348,000(6)	87,000	0.3%	0.3%
James Merselis	303,600(7)	75,900	0.3%	0.3%
Kevin Tansley	1,725,000(8)	431,250	1.7%	1.7%
Directors & Co. Secretary as a group (8 persons)	13,119,064 (1)(2)(3)(4)(5)(6)(7)(8)	3,279,766	12.9%	12.9%

(1) Includes 2,243,752 shares issuable upon exercise of options.

(2) Includes 1,500,000 shares issuable upon exercise of options.

(3) Includes 1,115,000 shares issuable upon exercise of options.

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

(4) Includes 135,000 shares issuable upon exercise of options.

(5) Includes 240,000 shares issuable upon exercise of options.

(6) Includes 115,000 shares issuable upon exercise of options.

(7) Includes 115,000 shares issuable upon exercise of options.

(8) Includes 1,725,000 shares issuable upon exercise of options.

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

---

**Table of Contents**

***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\$506,000) 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\$1,044,000).

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 an 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 2013, the Group paid US\$877,000 to Darnick Company in respect of Director s compensation. There is no balance payable to or receivable from Darnick Company as at December 31, 2013.

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 2013 and there were no loan balances payable to or receivable from directors at January 1, 2013 and at December 31, 2013.

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\$231,000 and US\$1,422,000 for 2013, 2012 and 2011 respectively, of which US\$Nil, US\$206,000 and US\$1,395,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2013, 2012 or 2011.

**Table of Contents****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.

There are also a small number of legal cases being brought against the Group by certain of its former employees in the previously owned French subsidiary, Trinity Biotech France S.à r.l.

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 American Depositary Shares (ADSs) are listed on the NASDAQ Global Market under the symbol TRIB. In 2005, Trinity Biotech adjusted the ratio of American Depositary Shares (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, 2014, the reported closing sale price of the ADSs was US\$26.49 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, 2009, 2010, 2011, 2012 and 2013; (b) the quarters ended March 31, June 30, September 30 and December 31, 2012; March 31, June 30, September 30 and December 31, 2013; and (c) the months of March, April, May, June, July, August, September, October, November and December 2013 and January and February 2014 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**

<b>Year Ended December 31</b>	<b>High</b>	<b>Low</b>
2009	US\$ 5.70	US\$ 1.05
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

**Table of Contents****ADSs**

<b>2012</b>	<b>High</b>	<b>Low</b>
Quarter ended March 31	US\$ 10.80	US\$ 8.81
Quarter ended June 30	US\$ 12.03	US\$ 10.50
Quarter ended September 30	US\$ 12.87	US\$ 11.58
Quarter ended December 31	US\$ 15.75	US\$ 13.01

**ADSs**

<b>2013</b>	<b>High</b>	<b>Low</b>
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**

<b>Month Ended</b>	<b>High</b>	<b>Low</b>
March 31, 2013	US\$ 19.00	US\$ 16.15
April 30, 2013	US\$ 16.77	US\$ 15.12
May 31, 2013	US\$ 17.92	US\$ 15.76
June 30, 2013	US\$ 17.75	US\$ 16.60
July 31, 2013	US\$ 20.20	US\$ 16.40
August 31, 2013	US\$ 21.21	US\$ 18.77
September 30, 2013	US\$ 22.00	US\$ 18.80
October 31, 2013	US\$ 25.20	US\$ 21.28
November 30, 2013	US\$ 25.63	US\$ 24.34
December 31, 2013	US\$ 25.57	US\$ 22.01
January 31, 2014	US\$ 28.00	US\$ 23.40
February 28, 2014	US\$ 27.38	US\$ 24.00

The number of record holders of Trinity Biotech's ADSs as at February 28, 2014 amounts to 527, 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).



---

## **Table of Contents**

### **Item 10 *Memorandum and Articles of Association***

#### ***Objects***

The Company's objects, detailed in Clause 3 of its Memorandum of Association, are varied and wide ranging and include principally researching, manufacturing, buying, selling and distributing all kinds of patents, pharmaceutical, medicinal and diagnostic preparations, equipment, drugs and accessories. 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***

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 Group). 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 Group to borrow money but it is obliged to restrict these 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 (both terms as defined in the Articles of Association). However, no lender or other person dealing with the Group 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.

All of the above mentioned powers of directors may be varied by way of a special resolution of the shareholders.

#### ***Rights, Preferences and Restrictions Attaching to Shares***

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 disenfranchised and thereby restricted from transferring the shares and voting rights or receiving any sums in respect thereof (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.

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.

## **Table of Contents**

One third of the directors other than an executive director 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 is one, that director shall retire. The directors to retire at each annual general meeting shall be the ones 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.

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. 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.

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 directors resolve to authorise such call.

The Articles do not contain any provisions discriminating against any existing or prospective holder of securities as a result of such shareholder owning a substantial number of shares.

### ***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.

### ***Calling of AGM s and EGM s 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 Ireland unless all of the members entitled to attend and vote at it 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.

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 it is seven clear days notice. Notice must be given in writing to all members and to the auditors 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 in the Companies Acts, 1963 to 2013 of Ireland, extended notice is required. These include removal of a director. 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 addresses outside Ireland and the US but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the 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.

---

**Table of Contents**

***Other Provisions of the Memorandum and Articles of Association***

The Memorandum and Articles of Association do not contain any 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.

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.

## **Table of Contents**

### ***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 \$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 ADS s as at the acquisition date (fair value of US\$110,000).

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

#### **Acquisition of Fiom Diagnostics AB**

In 2012, the Group purchased 100% of the common stock of Fiom 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). Fiom, 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 ADS s 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.

The Group received consideration of US\$68.4 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.

---

**Table of Contents**

*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 US 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 US Holder of ordinary shares or ADSs.

This summary does not discuss all aspects of Irish and US 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-US taxpayers) and it does not discuss any tax consequences arising under the laws of taxing jurisdictions other than the Republic of Ireland and the US 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.

**Table of Contents*****US Federal Income Tax Consequences to US Holders***

The following is a summary of certain material US federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADSs, in the case of a purchaser of such ADSs who is a US Holder (as defined below) and who holds the ADSs as capital assets. This summary is based on the US 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 US Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organized in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to US 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 US persons or (b) has a valid election in effect under applicable US Treasury regulations to be treated as a US 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 US holder in light of such holder's particular circumstances or to US holders subject to special rules, including persons that are non-US 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 US or taxpayers whose functional currency is not the 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 a partnership or an entity treated as a partnership for US federal income tax purposes owns ADSs, the US 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 US federal income tax consequences of holding and disposing of ADSs.

This summary does not address the effect of any US federal taxation other than US 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 US federal, state and local tax considerations of an investment in ADSs.

For US federal income tax purposes, US Holders of Trinity Biotech ADSs will be treated as owning the underlying Class A Ordinary Shares represented by the ADSs held by them. The gross amount of any distribution made by Trinity Biotech to US 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 US federal income tax purposes as a dividend to the extent of Trinity Biotech's current and accumulated earnings and profits, as determined for US 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 US Holder's tax basis in the holder's ADSs, and any amount of the distribution remaining after the holder's tax basis has been reduced to zero will constitute capital gain. The capital gain will be treated as a long-term or short-term capital gain depending on whether or not the 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 US corporate shareholders.

Subject to complex limitations, any Irish withholding tax imposed on such dividends will be a foreign income tax eligible for credit against a US Holder's US 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 Internal Revenue 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 US 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 US Holders, general category income for US foreign tax credit purposes under certain look through rules. 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.

**Table of Contents**

A US Holder will be denied a foreign tax credit with respect to Irish income tax withheld from dividends received on the ordinary shares to the extent such US Holder has not held the ordinary shares 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 US Holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a US Holder has substantially diminished its risk of loss on the ordinary shares are not counted toward meeting the 16-day holding period required by the Internal Revenue Code. 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 US federal income tax liability.

Subject to certain limitations, qualified dividend income received by a noncorporate US Holder in tax years beginning on or after January 1, 2013 will be subject to tax at a reduced maximum tax rate of 15%, with a 20% rate applying only to income which would fall into the highest 39.6% tax bracket. Distributions taxable as dividends paid on the ordinary shares should qualify for the 15% rate provided that either: (i) we are entitled to benefits under the income tax treaty between the United States and Ireland (the Treaty) or (ii) the ADSs are readily tradable on an established securities market in the US 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 US. 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 US 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. US Holders of Trinity Biotech ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

Upon a sale or exchange of ADSs, a US Holder will recognize a gain or loss for US federal income tax purposes in an amount equal to the difference between the amount realized on the sale or exchange and the 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 US Holder has held the ADSs sold or exchanged for more than one year at the time of the sale or exchange.

For US 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 it is not currently subject to treatment as a PFIC. However, no assurance can be given that changes will not occur in Trinity Biotech's business operations, assets and income that might cause it to be treated as a PFIC at some future time.

If Trinity Biotech were to become a PFIC, a US Holder of Trinity Biotech ADSs would be required to allocate to each day in the holding period for such holder's ADSs a pro rata portion of any distribution received (or deemed to be received) by the holder from Trinity Biotech, to the extent the distribution so received constitutes an excess distribution, as defined under US federal income tax law. Generally, a distribution received during a taxable year by a US Holder with respect to the underlying shares represented by any of the 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 holder during the taxable year with respect to such underlying shares, is greater than 125% of the average annual distributions received by the holder with respect to such underlying shares during the three preceding years (or during such shorter period as the US 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 US 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 holder in the prior tax year or years. The 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 recognized on a sale or other disposition of a US Holder's ADSs, including any gain recognized 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.



**Table of Contents**

Finally, the 15% reduced US federal income tax rate otherwise applicable to dividend income as discussed above, will not apply to any distribution made by Trinity Biotech in any taxable year in which it is a PFIC (or made in the taxable year following any such year), whether or not the distribution is an excess distribution .

If Trinity Biotech became a PFIC, a US Holder may make a qualifying electing fund election in the year Trinity Biotech first becomes a PFIC or in the year the holder acquires the shares, whichever is later. This election provides for a current inclusion of Trinity Biotech's ordinary income and capital gain income in the US Holder's US taxable income. In return, any gain on sale or other disposition of a US 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 US Holder. The PFIC must provide certain information to the IRS in order to qualify as a Qualified Electing Fund. US Holders should contact their tax advisor for further information on this area.

Alternatively, if the ADSs are considered marketable stock a US Holder may elect to mark-to-market its ADSs, and such US Holder would not be subject to the rules described above. Instead, such US 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 US Holders adjusted basis at the close of the tax year, the US 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 US Holder included in income with respect to such ADSs in prior years. Income recognized 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 US Holder included in income with respect to such ordinary shares in prior years). However, gain or loss from the disposition of ordinary shares (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 Trinity Biotech were to become a CFC, each US Holder treated as a US Ten-percent Shareholder would be required to include in income each year such US Ten-percent Shareholder's pro rata share of Trinity Biotech's undistributed Subpart F income. For this purpose, Subpart F income generally would include interest, original issue discount, dividends, net gains from the disposition of stocks or securities, net gains on forward and option contracts, receipts with respect to securities loans and net payments received with respect to equity swaps and similar derivatives.

Any undistributed Subpart F income included in a US Holder's income for any year would be added to the tax basis of the US Holder's ADSs. Amounts distributed by Trinity Biotech to the US Holder in any subsequent year would not be subject to further US federal income tax in the year of distribution, to the extent attributable to amounts so included in the US Holder's income in prior years under the CFC rules but would be treated, instead, as a reduction in the tax basis of the US Holder's ADSs, the PFIC rules discussed above would not apply to any undistributed Subpart F income required to be included in a US Holder's income under the CFC rules, or to the amount of any distributions received from Trinity Biotech that were attributable to amounts so included.

Distributions made with respect to underlying shares represented by ADSs may be subject to information reporting to the US Internal Revenue Service and to US backup withholding tax at a rate equal to the fourth lowest income tax rate applicable to individuals (which, under current law, is 28%). Backup withholding will not apply, however, if the 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 US Holder's US tax liability, and a US Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service.

Any US Holder who holds 10% or more in vote or value of Trinity Biotech will be subject to certain additional United States information reporting requirements.

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

---

## **Table of Contents**

### ***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 **US 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; to be paid once a year. 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% 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% and Pay Related Social Insurance contribution of up to 4% in respect of their dividend income.

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

an individual resident in the US (or certain other countries with which Ireland has a double taxation treaty) and who is neither resident nor ordinarily resident in Ireland; or

a US 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 US (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

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

---

## **Table of Contents**

Special DWT arrangements are available in the case of shares in Irish companies held by US 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 US 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 US 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 US.

Where the above procedures have not been complied with and DWT is withheld from dividend payments to US Holders of ordinary shares or ADSs evidenced by ADSs, such US 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 US Holders is reduced to 5% under the terms of the Treaty for corporate US Holders holding 10% or more of voting shares and to 15% for other US Holders. While this will, subject to the application of Article 23 of the Treaty, generally entitle US Holders to claim a partial refund of DWT from the Irish Revenue Commissioners, US Holders will, in most circumstances, likely prefer to seek a full refund of DWT under Irish domestic legislation (see above).

### Disposals of Ordinary Shares or ADSs

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

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

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

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

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

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

---

## **Table of Contents**

US 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, US 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 disponent 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 US 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.

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 if the transfer form contains an appropriate certification.

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

Transfers of ordinary shares from the Depository or the Depository'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 Depository or the Depository'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.

---

**Table of Contents**

**Dividend Policy**

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, to be paid once a year. The Board proposed a final dividend of 20 cents per ADS in respect of the 2012 financial year and this proposal was approved by the shareholders at the 2013 Annual General Meeting of the Company and subsequently paid during the course of 2013. 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.

The dividend payable in respect of the 2013 financial year will be proposed by the Directors prior to the next AGM, to be held in June 2014.

As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars.

**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.

**Item 11 Qualitative and Quantitative Disclosures about Market Risk**  
**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, 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\$223,000 (2012: US\$749,000) and would not affect the interest expense in 2013 or 2012; resulting in an increase in interest income of US\$223,000 (2012: US\$749,000).

## **Table of Contents**

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 denominated expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, where considered necessary, the Group pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions. 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, 2013.

The Group had foreign currency denominated cash balances equivalent to US\$1,624,000 at December 31, 2013 (2012: US\$1,316,000).

## **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 2013 by approximately 2.2%.

### **Exchange rate sensitivity**

At year-end 2013, approximately 6.9% of the Group's US\$183,011,000 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the Euro, Canadian Dollar, Swedish Krona 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 2013 year-end net worth by US\$1,262,000.

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

Not applicable.

## **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 *Control 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

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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, 2013.



---

## **Table of Contents**

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 authorization of management and the directors of Trinity Biotech; and provide reasonable assurance regarding prevention or timely detection of unauthorised acquisition, use or disposition of Trinity Biotech's assets that could have a material effect on our financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. It is not always possible to conduct an assessment of an acquired business's internal control over financial reporting in the period between the purchase date and the date of management's assessment. In such cases, management will note that it has excluded the acquired business or businesses from its report on internal control over financial reporting. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, and that the degree of compliance with the policies or procedures may deteriorate.

In 2013, the Company acquired Immco Diagnostics, Inc., Nova Century Scientific, Inc. and a business in the UK which was incorporated as Trinity Biotech (UK) Ltd. These three entities have been excluded from management's assessment of the internal controls. These acquisitions constituted 20% of total assets, as of 31 December 2013 and 9% of revenue for the financial year then ended.

Management has assessed the effectiveness of internal control over financial reporting, excluding entities acquired in 2013, based on criteria established in the 1992 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, 2013.

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, 2013 (see Item 18).

### ***Changes in Internal Controls 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.

**Table of Contents****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 request. 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 Accounting fees and services******Fees Billed by Independent Public Accountants***

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

	Year ended December 31,		Year ended December 31,	
	2013		2012	
	US\$ '000	%	US\$ '000	%
Audit	574	85%	451	82%
Audit-related	16	2%	22	4%
Tax	89	13%	79	14%
Total	679		552	

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.



**Table of Contents****16D Exemptions from the Listing Requirements and Standards for Audit Committee**

Not applicable.

**16 E Purchase 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, 2013 was 7,244,556 (1,811,139 ADS's) (2012: 7,244,556 (1,811,139 ADS's)).

**2013 Share Buyback**

There were no shares purchased by Trinity Biotech or on the Group's behalf in the year ended December 31, 2013.

**2012 Share Buyback**

Period	Total Number of ADS's Purchased	Average Price Paid per ADS (US\$)	Total Number of ADS's Purchased as part of Publicly Announced Plans or Programs	Maximum Number of ADS's that May Yet Be Purchased.
March 1-31, 2012	96,805	10.44	96,805	1,506,679
May 1-31, 2012	145,500	11.39	145,500	2,026,156
August 1-31, 2012	56,660	12.42	56,660	1,969,496
September 1-30, 2012	58,357	12.42	58,357	1,911,139
October 1-31, 2012	100,000	12.47	100,000	1,811,139
<b>Total</b>	<b>457,322</b>	<b>11.68</b>	<b>457,322</b>	<b>1,811,139</b>

**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.

**Table of Contents**

**Part III**

**Item 17**    *Financial Statements*

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

**Item 18**    *Financial Statements*

**Table of Contents**

**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, 2013, based on criteria established in the 1992 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 (Management’s Report). Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. Our audit of, and opinion on, the Company’s internal control over financial reporting does not include the internal control over financial reporting of wholly-owned subsidiaries, Immco Diagnostics, Inc., Nova Century Scientific Inc. and Trinity Biotech (UK) Ltd. whose financial statements reflect total assets and revenues constituting 20 and 9 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2013. As indicated in Management’s Report, Immco Diagnostics, Inc., Nova Century Scientific, Inc. and a business in the UK which was incorporated as Trinity Biotech (UK) Ltd. were acquired during 2013. Management’s assertion on the effectiveness of the Company’s internal control over financial reporting excluded internal control over financial reporting of these subsidiaries.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in the 1992 Internal Control – Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2013, and our report dated April 9, 2014 expressed an unqualified opinion on those financial statements.

Grant Thornton

Dublin, Ireland

April 9, 2014

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited the accompanying consolidated statements of financial position of Trinity Biotech plc and subsidiaries (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income, changes in equity, and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Trinity Biotech plc and subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and International Financial Reporting Standards as adopted by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2013, based on criteria established in the 1992 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated April 9, 2014, expressed an unqualified opinion.

Grant Thornton

Dublin, Ireland

April 9, 2014

**Table of Contents****CONSOLIDATED STATEMENT OF OPERATIONS**

	Notes	Year ended December, 31		
		2013 Total US\$ 000	2012 Total US\$ 000	2011 Total US\$ 000
<b>Revenues</b>	2	<b>91,216</b>	<b>82,510</b>	<b>77,948</b>
<b>Cost of sales</b>		<b>(45,996)</b>	<b>(40,257)</b>	<b>(37,820)</b>
<b>Gross profit</b>		<b>45,220</b>	<b>42,253</b>	<b>40,128</b>
<b>Other operating income</b>	4	<b>532</b>	<b>468</b>	<b>910</b>
<b>Research and development expenses</b>		<b>(3,691)</b>	<b>(3,130)</b>	<b>(3,206)</b>
<b>Selling, general and administrative expenses</b>		<b>(33,066)</b>	<b>(22,425)</b>	<b>(22,048)</b>
<b>Operating profit</b>		<b>8,995</b>	<b>17,166</b>	<b>15,784</b>
Financial income	2, 3	1,276	2,280	2,428
Financial expenses	2, 3	(51)	(88)	(12)
<b>Net financing income</b>		<b>1,225</b>	<b>2,192</b>	<b>2,416</b>
<b>Profit before tax</b>	5	<b>10,220</b>	<b>19,358</b>	<b>18,200</b>
Total income tax expense	2, 8	(574)	(2,017)	(2,607)
<b>Profit for the year (all attributable to owners of the parent)</b>	2	<b>9,646</b>	<b>17,341</b>	<b>15,593</b>
Basic earnings per ADS (US Dollars)	9	0.44	0.81	0.73
Diluted earnings per ADS (US Dollars)	9	0.41	0.77	0.70
Basic earnings per A ordinary share (US Dollars)	9	0.11	0.20	0.18
Diluted earnings per A ordinary share (US Dollars)	9	0.10	0.19	0.18



**Table of Contents****CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

		<i>Year ended December 31,</i>		
		<i>2013</i>	<i>2012</i>	<i>2011</i>
	<i>Notes</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Profit for the year	2	9,646	17,341	15,593
<b>Other comprehensive income</b>				
<b>Items that will be reclassified subsequently to profit or loss</b>				
Foreign exchange translation differences		194	127	
<i>Cash flow hedges:</i>				
Effective portion of changes in fair value			6	(6)
Deferred tax on income and expenses recognised directly in equity			1	(1)
<i>Other comprehensive income</i>		194	134	(7)
<b>Total Comprehensive Income (all attributable to owners of the parent)</b>		<b>9,840</b>	<b>17,475</b>	<b>15,586</b>

**Table of Contents****CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

		<i>At December, 31</i>	
		<i>2013</i>	<i>2012</i>
	<i>Notes</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	10	12,991	8,883
Goodwill and intangible assets	11	128,547	73,046
Deferred tax assets	12	7,044	4,073
Other assets	13	1,162	908
<b>Total non-current assets</b>		<b>149,744</b>	<b>86,910</b>
<b>Current assets</b>			
Inventories	14	29,670	20,757
Trade and other receivables	15	24,268	14,457
Income tax receivable		487	336
Cash and cash equivalents	16	22,317	74,947
<b>Total current assets</b>		<b>76,742</b>	<b>110,497</b>
<b>TOTAL ASSETS</b>	<b>2</b>	<b>226,486</b>	<b>197,407</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to the equity holders of the parent</b>			
Share capital		1,170	1,134
Share premium		8,842	5,138
Treasury Shares	17	(7,367)	(7,367)
Accumulated surplus		176,037	166,340
Translation reserve		(223)	(417)
Other reserves		4,552	4,552
<b>Total equity</b>		<b>183,011</b>	<b>169,380</b>
<b>Current liabilities</b>			
Income tax payable		770	1,092
Trade and other payables	19	20,131	11,824
Provisions	20	75	50
<b>Total current liabilities</b>		<b>20,976</b>	<b>12,966</b>
<b>Non-current liabilities</b>			
Other payables	21	4,596	4,318
Deferred tax liabilities	12	17,903	10,743
<b>Total non-current liabilities</b>		<b>22,499</b>	<b>15,061</b>
<b>TOTAL LIABILITIES</b>	<b>2</b>	<b>43,475</b>	<b>28,027</b>

**TOTAL EQUITY AND LIABILITIES**

**226,486**

**197,407**

**Table of Contents****CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

	<i>Share capital</i>		<i>Share premium</i>	<i>Treasury Shares</i>	<i>Translation reserve</i>	<i>Warrant reserve</i>	<i>Hedging reserves</i>	<i>Accumulated surplus/ (deficit)</i>	<i>Total</i>
	<i>A</i>	<i>B</i>							
	<i>ordinary shares</i>	<i>ordinary shares</i>							
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Balance at January 1, 2011	1,080	12	161,599		(544)	4,529	23	(25,412)	141,287
Profit for the period								15,593	15,593
Other comprehensive income							(7)		(7)
Total comprehensive income							(7)	15,593	15,586
Share-based payments								1,547	1,547
Options/warrants exercised	14		1,175						1,189
Share issue expenses			(38)						(38)
Share Premium Transfer (Note 17)			(160,000)					160,000	
Dividends								(2,145)	(2,145)
Treasury Shares acquired during the year				(6,094)					(6,094)
<b>Balance at December 31, 2011</b>	<b>1,094</b>	<b>12</b>	<b>2,736</b>	<b>(6,094)</b>	<b>(544)</b>	<b>4,529</b>	<b>16</b>	<b>149,583</b>	<b>151,332</b>
Balance at January 1, 2012	1,094	12	2,736	(6,094)	(544)	4,529	16	149,583	151,332
Profit for the period								17,341	17,341
Other comprehensive income					127		7		134
Total comprehensive income					127		7	17,341	17,475
Share-based payments								2,640	2,640
Options/warrants exercised	27		2,478						2,505
Share issue expenses			(76)						(76)
B share conversion	13	(12)							1
Dividends (Note 26)								(3,224)	(3,224)
Treasury Shares acquired during the year				(5,343)					(5,343)
Treasury Shares re-issued				4,070					4,070
<b>Balance at December 31, 2012</b>	<b>1,134</b>		<b>5,138</b>	<b>(7,367)</b>	<b>(417)</b>	<b>4,529</b>	<b>23</b>	<b>166,340</b>	<b>169,380</b>
Balance at January 1, 2013	1,134		5,138	(7,367)	(417)	4,529	23	166,340	169,380
Profit for the period								9,646	9,646
Other comprehensive income					194				194
Total comprehensive income					194			9,646	9,840
Share-based payments								3,303	3,303
Options/warrants exercised	36		3,626						3,662
Share issue expenses			(32)						(32)
Shares/options issued as consideration			110					1,121	1,231
Dividends (Note 26)								(4,373)	(4,373)
<b>Balance at December 31, 2013</b>	<b>1,170</b>		<b>8,842</b>	<b>(7,367)</b>	<b>(223)</b>	<b>4,529</b>	<b>23</b>	<b>176,037</b>	<b>183,011</b>

**Table of Contents****CONSOLIDATED STATEMENT OF CASH FLOWS**

	Notes	Year ended December 31,		
		2013	2012	2011
		US\$ 000	US\$ 000	US\$ 000
<b>Cash flows from operating activities</b>				
Profit for the year		9,646	17,341	15,593
<i>Adjustments to reconcile net profit to cash provided by operating activities:</i>				
Depreciation		1,688	1,349	1,166
Amortisation	11	1,902	1,482	1,427
Income tax expense	8	574	2,017	2,607
Financial income	3	(1,276)	(2,280)	(2,428)
Financial expense	3	51	88	12
Share-based payments	18	2,014	1,713	1,269
Foreign exchange gains on operating cash flows		46	(60)	(10)
Loss on disposal / retirement of property, plant and equipment		1	5	
Licence fees	19, 21	4,135		
Other non-cash items		1,020	578	302
<b>Operating cash flows before changes in working capital</b>		<b>19,801</b>	<b>22,233</b>	<b>19,938</b>
(Increase)/decrease in trade and other receivables		(7,032)	(2,059)	1,276
(Increase) in inventories		(7,258)	(1,374)	(2,409)
Increase/(decrease) in trade and other payables		3,255	22	(33)
<b>Cash generated from operations</b>		<b>8,766</b>	<b>18,822</b>	<b>18,772</b>
Interest paid			(3)	(12)
Interest received		1,292	2,189	2,013
Income taxes paid		(701)	(1,047)	(317)
<b>Net cash generated by operating activities</b>		<b>9,357</b>	<b>19,961</b>	<b>20,456</b>
<b>Cash flows from investing activities</b>				
Payments to acquire subsidiaries		(39,424)	(5,958)	(2,166)
Cash received with acquired subsidiary		1,407	44	21
Proceeds from divestiture of Coagulation product line			11,250	11,250
Payments to acquire intangible assets		(18,687)	(12,631)	(6,799)
Acquisition of property, plant and equipment		(4,489)	(2,665)	(2,436)
<b>Net cash used in investing activities</b>		<b>(61,193)</b>	<b>(9,960)</b>	<b>(130)</b>
<b>Cash flows from financing activities</b>				
Proceeds from issue of ordinary share capital	17	3,662	2,505	1,189
Purchase of Treasury Shares	17		(5,343)	(6,094)
Expenses paid in connection with share issue and debt financing		(87)	(22)	(38)
Dividends paid to equity holders of the parent	26	(4,373)	(3,224)	(2,145)
Payment of finance lease liabilities			(109)	(159)
<b>Net cash used in financing activities</b>		<b>(798)</b>	<b>(6,193)</b>	<b>(7,247)</b>
(Decrease)/increase in cash and cash equivalents		(52,634)	3,808	13,079
Effects of exchange rate movements on cash held		4	54	4
Cash and cash equivalents at beginning of year		74,947	71,085	58,002

<b>Cash and cash equivalents at end of year</b>	16	22,317	74,947	71,085
---	----	--------	--------	--------

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

**1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES**

The principal accounting policies adopted by Trinity Biotech plc and its subsidiaries ( the Group ) are as follows:

*i) Statement of compliance*

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ( IFRS ) both as issued by the International Accounting Standards Board ( IASB ) and as subsequently adopted by the European Union ( EU ) (together IFRS ). The IFRS applied are those effective for accounting periods beginning 1 January 2013. 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.

*ii) Basis of preparation*

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

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

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

Judgements made by management that have a significant effect on the financial statements and estimates with a significant risk of material adjustment in the next year are discussed in Note 28.

Having considered the Group s current financial position and its cashflow projections, the directors believe that the Group will be able to continue in operational existence for at least the next 12 months from the date of approval of these consolidated financial statements and that it is appropriate to continue to prepare the consolidated financial statements on a going concern basis.

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

*iii) Basis of consolidation*

***Subsidiaries***

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

statements from the date that control commences until the date that control ceases.

***Transactions eliminated on consolidation***

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



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)***iv) Property, plant and equipment****Owned assets***

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

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

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

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

***Leased assets as lessee***

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

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

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

***Leased assets as lessor***

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

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

*Subsequent costs*

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

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

v) *Business combinations*

All business combinations are accounted for by applying the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred (excluding amounts relating to the settlement of pre-existing relationships), the amount of any non-controlling interest in the acquiree and, in a business combination achieved in stages, the acquisition-date fair value of the acquirer's previously-held equity interest in the acquiree. Acquisition-related costs of the combination are recorded as an expense in the statement of operations and any contingent consideration is measured at fair value at the acquisition date. If the contingent consideration arrangement gives rise to a financial liability, any subsequent changes are generally recognised in profit or loss. Assets and liabilities assumed are measured at their acquisition date fair values.

vi) *Goodwill*

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

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

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

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

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

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

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

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

embodied in the specific asset to which it relates.

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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****1. BASIS OF PREPARATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)**

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

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

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

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

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

***Amortisation***

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

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

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

- (a) once a diagnostic test becomes established, customers are reluctant to change to new technology until it is fully proven, thus resulting in relatively long product life cycles. There is also reluctance in customers to change to a new product as it can be costly both in terms of the initial changeover cost and as new technology is typically more expensive.
- (b) demand for the diagnostic tests is enduring and robust within a wide geographic base. The diseases that the products diagnose are widely prevalent (HIV, Diabetes and Chlamydia being just three examples) in many countries. There is a general consensus that these diseases will continue to be widely prevalent in the future.
- (c)

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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

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

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

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

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

*viii) Impairment*

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

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

For goodwill, assets that have an indefinite useful life and intangible assets that are not yet available for use, the recoverable amount is estimated at each balance sheet date at the cash generating unit level. The goodwill and indefinite-lived assets were reviewed for impairment at December 31, 2011, December 31, 2012 and December 2013. See Note 11.

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

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

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

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

An impairment loss in respect of goodwill is not reversed.

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

*ix) Inventories*

Inventories are stated at the lower of cost and net realisable value. Cost is based on the first-in, first-out principle and includes all expenditure which has been incurred in bringing the products to their present location and condition, and includes an appropriate allocation of manufacturing

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

overhead based on the normal level of operating capacity. Net realisable value is the estimated selling price of inventory on hand in the ordinary course of business less all further costs to completion and costs expected to be incurred in selling these products.

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



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

*x) Trade and other receivables*

Trade and other receivables are stated at their amortised cost less impairment losses incurred. Cost approximates fair value given the short dated nature of these assets.

*xi) Trade and other payables*

Trade and other payables are stated at cost. Cost approximates fair value given the short dated nature of these liabilities.

*xii) Cash and cash equivalents*

Cash and cash equivalents comprise cash balances and short-term deposits. The Group has no short-term bank overdraft facilities. Where restrictions are imposed by third parties, such as lending institutions, on cash balances held by the Group these are treated as financial assets in the financial statements.

*xiii) Share-based payments*

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

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

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

*xiv) Government grants*

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



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

*xv) 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 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.

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. See also Note 1(iv).

***Other operating income***

Rental income from sub-leasing premises under operating leases, where the risks and rewards of the premises remain with the lessor, is recognised in the statement of operations as other operating income on a straight-line basis over the term of the lease.

Other income also comprises income recognised under Transitional Services Agreements (TSA) with Lab 21 Limited and Diagnostica Stago. As part of the acquisition of the blood bank screening business in July 2013 from Lab 21 Limited, the Group entered into a TSA. The services provided by the Group to Lab 21 under the TSA comprise of mainly facilities and information technology. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

*xvi) Employee benefits*

***Defined contribution plans***

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

***Other long-term benefits***

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

*Termination benefits*

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

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

*xvii) Foreign currency*

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

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

Where Euro or Sterling amounts have been referenced in this document, their corresponding US Dollar equivalent has also been included and these equivalents have been calculated with reference to the foreign exchange rates prevailing at December 31, 2013.

*xviii) Derivative financial instruments*

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

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

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

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

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

*xix) Segment reporting*

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Board of Directors.

*xx) Tax (current and deferred)*

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

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

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

Current tax represents the expected tax payable (or recoverable) on the taxable profit for the year using tax rates enacted or substantively enacted at the balance sheet date and taking into account any adjustments stemming from prior years.

Deferred tax is provided on the basis of the balance sheet liability method on all temporary differences at the balance sheet date which is defined as the difference between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred tax assets and liabilities are not subject to discounting and are measured at the tax rates that are anticipated to apply in the period in which the asset is realised or the liability is settled based on tax rates and tax laws that have been enacted or substantively enacted at the balance sheet date. Deferred tax assets are recognised when it is probable that future taxable profits will be available to utilize the associated losses or temporary differences. The amount of deferred tax provided is based on the expected manner of realisation or settlement of the carrying amount of assets and liabilities.

Deferred tax assets and liabilities are recognised for all temporary differences (that is, differences between the carrying amount of the asset or liability and its tax base) with the exception of the following:

- i. Where the deferred tax liability arises from goodwill not deductible for tax purposes or the initial recognition of an asset or a liability in a transaction that is not a business combination and affects neither the accounting profit nor the taxable profit or loss at the time of the transaction; and
- ii. Where, in respect of temporary differences associated with investments in subsidiary undertakings, the timing of the reversal of the temporary difference is subject to control and it is probable that the temporary difference will not reverse in the foreseeable future.

Where goodwill is tax deductible, a deferred tax liability is not recognised on initial recognition of goodwill. It is recognised subsequently for the taxable temporary difference which arises when the goodwill is amortised for tax with no corresponding adjustment to the carrying value of the goodwill.

The carrying amounts of deferred tax assets are subject to review at each balance sheet date and are derecognised to the extent that future taxable profits are considered to be inadequate to allow all or part of any deferred tax asset to be utilised.

*xxi) Provisions*

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

*xxii) Cost of sales*

Cost of sales comprises product cost including manufacturing and payroll costs, quality control, shipping, handling, and packaging costs and the cost of services provided.

*xxiii) Finance income and costs*

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Financing expenses comprise interest costs payable on leases. Interest payable on finance leases is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability. Financing expenses also includes the financing element of long term liabilities which have been discounted.

Finance income includes interest income on deposits and is recognised in the statement of operations as it accrues, using the effective interest method. Finance income also includes interest on the deferred consideration due to the Group as part of the divestiture of the Coagulation product line in 2010.

### *xxiv) Warrant reserve*

The Group calculates the fair value of warrants at the date of issue taking the amount directly to equity. The fair value is calculated using a recognised valuation methodology for the valuation of financial instruments (that is, the trinomial model). The fair value which is assessed at the grant date is calculated on the basis of the contractual term of the warrants.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

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

*xxv) Treasury shares*

Own equity instruments that are reacquired (treasury shares) are recognised at cost and deducted from equity. No gain or loss is recognised in the statement of operations on the purchase, sale, issue or cancellation of the Group's own equity instruments. Any difference between the carrying amount and the consideration, if reissued, is recognised in share premium. Voting rights related to treasury shares are nullified for the Group and no dividends are allocated to them.

*xxvi) Fair values*

For financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2: valuation techniques for which the lowest level of inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly

Level 3: valuation techniques for which the lowest level of inputs that have a significant effect on the recorded fair value are not based on observable market data

*xxvii) New IFRS Standards and Interpretations not applied*

The IASB and IFRIC have issued additional standards and interpretations which are effective for periods starting after January 1, 2013, all of which have not yet been adopted by the EU. The following standards and interpretations have yet to be adopted by the Group:

<i>International Financial Reporting Standards (IFRS/IAS)</i>	<i>Effective date</i>
IAS 16 Property, Plant and Equipment (Amendment)	July 1, 2014 (not yet adopted by the EU)
IAS 19 Employee Benefits (Amendment)	July 1, 2014 (not yet adopted by the EU)
IAS 24 Related Party Disclosures (Amendment)	July 1, 2014 (not yet adopted by the EU)
IAS 27 Separate Financial Statements (Amendment)	January 1, 2014 (not yet adopted by the EU)
IAS 32 Financial Instruments: Presentation (Amendment)	January 1, 2014 (not yet adopted by the EU)
IAS 36 Impairment of Assets (Amendment)	January 1, 2014 (not yet adopted by the EU)
IAS 38 Intangible Assets (Amendment)	July 1, 2014 (not yet adopted by the EU)
IAS 39 Financial Instruments: Recognition and Measurement (Amendment)	January 1, 2014 (not yet adopted by the EU)
IAS 40 Investment Property (Amendment)	July 1, 2014 (not yet adopted by the EU)
IFRIC 21 Levies	January 1, 2014 (not yet adopted by the EU)
IFRS 2 Share Based Payments (Amendment)	July 1, 2014 (not yet adopted by the EU)

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

IFRS 3	Business Combinations (Amendment)	July 1, 2014 (not yet adopted by the EU)
IFRS 8	Operating Segments (Amendment)	July 1, 2014 (not yet adopted by the EU)
IFRS 9	Financial Instruments – Classification and Measurement	January 1, 2018 (not yet adopted by the EU)
IFRS 10	Consolidated Financial Statements (Amendment)	January 1, 2014 (not yet adopted by the EU)
IFRS 12	Disclosure of Interest in Other Entities (Amendment)	January 1, 2014 (not yet adopted by the EU)
IFRS 13	Fair Value Measurement (Amendment)	July 1, 2014 (not yet adopted by the EU)
IFRS 14	Regulatory Deferral Accounts	January 1, 2016 (not yet adopted by the EU)

The Group does not anticipate that the adoption of these standards and interpretations will have a material effect on its financial statements on initial adoption.

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

The Group has adopted the following standards and amendments during the year:

IAS 1 Presentation of Financial Statements (Amendment)

IAS 19 Employee Benefits (Amendment)

IFRS 10 Consolidated Financial Statements

IFRS 13 Fair Value Measurement

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

The application of the above standards did not result in material changes in the Group's consolidated accounts.

**2. SEGMENT INFORMATION**

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

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

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

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

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

Rest of World Other revenue from external customers commenced in 2013 following the acquisition of the blood bank screening business located in the UK.

<b>Revenue</b>	<i>Rest of World</i>			<i>Eliminations</i>	<i>Total</i>
	<i>Americas</i>	<i>Ireland</i>	<i>Other</i>		
<i>Year ended December 31, 2013</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Revenue from external customers	48,679	40,616	1,921		91,216
Inter-segment revenue	35,474	7,525	10,996	(53,995)	
<b>Total revenue</b>	<b>84,153</b>	<b>48,141</b>	<b>12,917</b>	<b>(53,995)</b>	<b>91,216</b>

<i>Year ended December 31, 2012</i>	<i>Rest of World</i>			<i>Eliminations</i>	<i>Total</i>
	<i>Americas</i>	<i>Ireland</i>	<i>Other</i>		
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Revenue from external customers	42,029	40,481			82,510
Inter-segment revenue	32,466	7,655	5,558	(45,679)	
<b>Total revenue</b>	<b>74,495</b>	<b>48,136</b>	<b>5,558</b>	<b>(45,679)</b>	<b>82,510</b>

<i>Year ended December 31, 2011</i>	<i>Americas</i>	<i>Rest of World</i>		<i>Eliminations</i>	<i>Total</i>
	<i>US\$ 000</i>	<i>Ireland</i>	<i>Other</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Revenue from external customers	40,226	37,722			77,948
Inter-segment revenue	26,169	7,856		(34,025)	
<b>Total revenue</b>	<b>66,395</b>	<b>45,578</b>		<b>(34,025)</b>	<b>77,948</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 2. SEGMENT INFORMATION (CONTINUED)

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

<b>Revenue</b>	<i>December 31, 2013</i> US\$ 000	<i>December 31, 2012</i> US\$ 000	<i>December 31, 2011</i> US\$ 000
Americas	54,761	49,638	51,352
Europe (including Ireland) *	12,394	10,214	9,423
Asia / Africa	24,061	22,658	17,173
	91,216	82,510	77,948

\* Revenue for customers in Ireland is not disclosed separately due to the immateriality of these revenues.

iii) The distribution of revenue by major product group was as follows:

<b>Revenue</b>	<i>December 31, 2013</i> US\$ 000	<i>December 31, 2012</i> US\$ 000	<i>December 31, 2011</i> US\$ 000
Clinical laboratory	71,462	63,356	61,386
Point-of-Care	19,754	19,154	16,562
	91,216	82,510	77,948

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

<i>Year ended December 31, 2013</i>	<i>Rest of World</i>			<i>Total</i> US\$ 000
	<i>Americas</i> US\$ 000	<i>Ireland</i> US\$ 000	<i>Other</i> US\$ 000	
<b>Result</b>	5,730	5,014	(968)	9,776
Unallocated expenses *				(781)
Operating profit				8,995
Net financing income (Note 3)				1,225
Profit before tax				10,220
Income tax expense (Note 8)				(574)
Profit for the year				9,646

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

<i>Year ended December 31, 2012</i>	<i>Americas</i>	<i>Rest of World</i>		<i>Total</i>
	<i>US\$ 000</i>	<i>Ireland</i>	<i>Other</i>	<i>US\$ 000</i>
<b>Result</b>	6,299	11,739	(39)	17,999
Unallocated expenses *				(833)
Operating profit				17,166
Net financing income (Note 3)				2,192
Profit before tax				19,358
Income tax expense (Note 8)				(2,017)
Profit for the year				17,341

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 2. SEGMENT INFORMATION (CONTINUED)

<i>Year ended December 31, 2011</i>	<i>Americas</i> <i>US\$ 000</i>	<i>Rest of World</i>		<i>Total</i> <i>US\$ 000</i>
		<i>Ireland</i> <i>US\$ 000</i>	<i>Other</i> <i>US\$ 000</i>	
<b>Result</b>	5,840	10,922	(80)	16,682
Unallocated expenses *				(898)
Operating profit				15,784
Net financing income (Note 3)				2,416
Profit before tax				18,200
Income tax expense (Note 8)				(2,607)
Profit for the year				15,593

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

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

<i>As at December 31, 2013</i>	<i>Americas</i> <i>US\$ 000</i>	<i>Rest of World</i>		<i>Total</i> <i>US\$ 000</i>
		<i>Ireland</i> <i>US\$ 000</i>	<i>Other</i> <i>US\$ 000</i>	
<b>Assets and liabilities</b>				
Segment assets	92,470	83,044	21,124	196,638
<i>Unallocated assets:</i>				
Income tax assets (current and deferred)				7,531
Cash and cash equivalents				22,317
Total assets as reported in the Group balance sheet				226,486
Segment liabilities	8,598	10,762	5,442	24,802
<i>Unallocated liabilities:</i>				
Income tax liabilities (current and deferred)				18,673
Total liabilities as reported in the Group balance sheet				43,475

<i>As at December 31, 2012</i>	<i>Americas</i> <i>US\$ 000</i>	<i>Rest of World</i>		<i>Total</i> <i>US\$ 000</i>
		<i>Ireland</i> <i>US\$ 000</i>	<i>Other</i> <i>US\$ 000</i>	
<b>Assets and liabilities</b>				



Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Segment assets	46,434	55,346	16,271	118,051
<i>Unallocated assets:</i>				
Income tax assets (current and deferred)				4,409
Cash and cash equivalents				74,947
Total assets as reported in the Group balance sheet				197,407
Segment liabilities	4,401	6,332	5,459	16,192
<i>Unallocated liabilities:</i>				
Income tax liabilities (current and deferred)				11,835
Total liabilities as reported in the Group balance sheet				28,027

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 2. SEGMENT INFORMATION (CONTINUED)

- vi) The distribution of long-lived assets, which are property, plant and equipment, goodwill and intangible assets and other non-current assets (excluding deferred tax assets), by geographical area was as follows:

		<i>December 31, 2013</i>	<i>December 31, 2012</i>
		<i>US\$ 000</i>	<i>US\$ 000</i>
Rest of World	Ireland	59,160	38,996
Rest of World	Other	18,458	16,049
Americas		65,082	27,792
		142,700	82,837

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

		<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
		<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b><i>Depreciation:</i></b>				
Rest of World	Ireland	447	408	325
Rest of World	Other	95	32	
Americas		1,316	1,023	841
		1,858	1,463	1,166
<b><i>Amortisation:</i></b>				
Rest of World	Ireland	1,272	1,174	1,258
Rest of World	Other			
Americas		630	308	169
		1,902	1,482	1,427

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

		<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
		<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Rest of World	Ireland	1,791	1,482	1,099
Rest of World	Other	20		
Americas		203	231	170

2,014

1,713

1,269

See Note 18 for further information on share-based payments.

83

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 2. SEGMENT INFORMATION (CONTINUED)

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

<b>Interest Income</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2013</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Income Earned	2		1,274		1,276
Inter-segment Interest Income			3,930	(3,930)	
<b>Total</b>	<b>2</b>		<b>5,204</b>	<b>(3,930)</b>	<b>1,276</b>

<b>Interest Expense</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2013</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Expense					
Interest on Deferred Consideration			51		51
Inter-segment Interest Expense	3,930			(3,930)	
<b>Total</b>	<b>3,930</b>		<b>51</b>	<b>(3,930)</b>	<b>51</b>

<b>Interest Income</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2012</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Income Earned		2	2,166		2,168
Interest on Deferred Consideration	25	87			112
Inter-segment Interest Income			3,270	(3,270)	
<b>Total</b>	<b>25</b>	<b>89</b>	<b>5,436</b>	<b>(3,270)</b>	<b>2,280</b>

<b>Interest Expense</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2012</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Expense	1	2			3
Interest on Deferred Consideration			85		85
Inter-segment Interest Expense	3,270			(3,270)	

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Total	3,271	2	85	(3,270)	88
-------	-------	---	----	---------	----

<b>Interest Income</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2011</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Income Earned		326	1,657		1,983
Interest on Deferred Consideration	99	346			445
Inter-segment Interest Income			2,040	(2,040)	
Total	99	672	3,697	(2,040)	2,428

<b>Interest Expense</b>	<i>Americas</i>	<i>Rest of World</i>			<i>Total</i>
		<i>Ireland</i>	<i>Other</i>	<i>Eliminations</i>	
<i>Year ended December 31, 2011</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Interest Expense	2	10			12
Inter-segment Interest Expense	2,040			(2,040)	
Total	2,042	10		(2,040)	12

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 2. SEGMENT INFORMATION (CONTINUED)

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Rest of World Ireland	(22)	(880)	(1,295)
Rest of World Other	18	(80)	(10)
Americas	(570)	(1,057)	(1,302)
	(574)	(2,017)	(2,607)

xi) During 2013, 2012 and 2011 there were no customers generating 10% or more of total revenues.

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Rest of World Ireland	15,790	10,140
Rest of World Other	8,493	16,006
Americas	38,892	5,608
	63,175	31,754

## 3. FINANCIAL INCOME AND EXPENSES

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Financial income:			
Interest income	1,276	2,168	1,983
Other interest income		112	445
	1,276	2,280	2,428
Financial expense:			
Finance lease interest		(2)	(10)

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Other interest expense	(51)	(86)	(2)
	(51)	(88)	(12)
Net Financing Income	1,225	2,192	2,416

Other interest income recognised in 2012 and 2011 is comprised of interest income relating to the deferred consideration due to the Company as a result of the sale of the Coagulation product line in 2010.

Other interest expense for 2013 includes US\$51,000 (2012: US\$85,000) (2011: US\$Nil) related to the deferred consideration arising as a result of the acquisition of Fiom Diagnostics AB by the Group in 2012 (see Note 22).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 4. OTHER OPERATING INCOME

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Rental income from premises	250	243	245
Other income	282	225	665
	<b>532</b>	<b>468</b>	<b>910</b>

Other income mainly comprises income recognised under Transitional Services Agreements (TSA) with Lab 21 Limited and Diagnostica Stago. As part of the acquisition of the blood bank screening business in July 2013 from Lab 21 Limited, the Group entered into a TSA. The services provided by the Group to Lab 21 under the TSA comprise of mainly facilities and information technology. As part of the divestiture of the Coagulation product line in April 2010, the Group entered into a TSA. The services provided by the Group to Stago under the TSA comprise canteen services. This income has not been treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

## 5. PROFIT BEFORE TAX

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Directors' emoluments (including non-executive directors):			
Remuneration	2,155	1,812	2,086
Pension	60	270	111
Share based payments	2,008	1,499	786
Other			14
Auditors' remuneration			
Audit fees	586	506	510
Non audit fees	123	99	31
Depreciation - leased assets*	14	12	13
Depreciation - owned assets*	1,674	1,337	1,153
Amortisation	1,902	1,482	1,427
Loss on the disposal of property, plant and equipment		5	
Net foreign exchange differences	224	(41)	(69)
Restructuring costs	690		
Operating lease rentals:			
Land and buildings	2,980	2,447	2,654
Other equipment	6	9	19



Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

- \* Note that US\$170,000 of depreciation was charged to research and development projects during 2013 in line with the Group's capitalisation policy for Intangible projects.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****6. PERSONNEL EXPENSES**

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Wages and salaries	22,504	19,066	18,470
Social welfare costs	2,162	1,842	1,718
Pension costs	704	669	658
Share-based payments	2,014	1,713	1,269
Restructuring costs	690		
	28,074	23,290	22,115

Personnel expenses are shown net of capitalisations. Total personnel expenses, inclusive of amounts capitalised for wages and salaries, social welfare costs and pension costs, for the year ended December 31, 2013 amounted to US\$37,455,000 (2012: US\$29,181,000) (2011: US\$25,304,000). Total share based payments, inclusive of amounts capitalised in the balance sheet, amounted to US\$3,303,000 for the year ended December 31, 2013 (2012: US\$2,640,000) (2011: US\$1,547,000). See Note 18.

Restructuring costs for the year ended December 31, 2013 amounted to US\$690,000 (2012: US\$Nil) (2011: US\$Nil) and relate to UK operations.

The average number of persons employed by the Group in the financial year was 496 (2012: 385) (2011: 357) and is analysed into the following categories:

	<i>December 31,</i>	<i>December 31,</i>	<i>December 31,</i>
	<i>2013</i>	<i>2012</i>	<i>2011</i>
Research and development	95	57	47
Administration and sales	274	110	102
Manufacturing and quality	127	218	208
	496	385	357

**7. PENSION SCHEMES**

The Group operates defined contribution pension schemes for certain of its full time employees. The benefits under these schemes are financed by both Group and employee contributions. Total contributions made by the Group in the financial year and charged against income amounted to US\$711,000 (2012: US\$837,000) (2011: US\$658,000) (Note 6). The pension accrual for the Group at December 31, 2013 was US\$333,000 (2012: US\$213,000), (2011: US\$184,000).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 8. INCOME TAX EXPENSE

- (a) The charge for tax based on the profit comprises:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<i>Current tax expense</i>			
Irish Corporation tax	(400)	316	984
Foreign taxes (a)	252	176	431
Adjustment in respect of prior years	(27)	(154)	(13)
<b>Total current tax expense</b>	<b>(175)</b>	<b>338</b>	<b>1,402</b>
<i>Deferred tax expense (b)</i>			
Origination and reversal of temporary differences (see Note 12)	3,235	2,599	1,293
Origination and reversal of net operating losses (see Note 12)	(2,486)	(920)	(88)
<b>Total deferred tax expense</b>	<b>749</b>	<b>1,679</b>	<b>1,205</b>
<b>Total income tax charge in statement of operations</b>	<b>574</b>	<b>2,017</b>	<b>2,607</b>

- (a) The foreign taxes relate primarily to USA, Canada and Luxembourg.
- (b) In 2013 there was a deferred tax charge of US\$393,000 (2012: US\$561,000; 2011: US\$326,000) recognised in respect of Ireland and a deferred tax charge of US\$356,000 (2012: US\$1,118,000; 2011: US\$879,000) recognised in respect of overseas tax jurisdictions.

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<i>Effective tax rate</i>			
Profit before taxation	10,220	19,358	18,200
As a percentage of profit before tax:			
Current tax	(1.72%)	1.75%	7.70%
Total (current and deferred)	5.61%	10.42%	14.32%

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 8. INCOME TAX EXPENSE (CONTINUED)

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
Irish corporation tax	12.50%	12.50%	12.50%
Effect of tax rates on overseas earnings(a)	(5.10%)	(0.66%)	1.69%
Effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised(b)	5.13%	0.82%	(0.98%)
Effect of Irish income taxable at higher tax rate	0.12%	0.13%	0.35%
R&D tax credits	(4.03%)	(0.17%)	(0.12%)
Adjustments in respect of prior years	(0.27%)	(0.80%)	(0.36%)
Other items(c)	(2.74%)	(1.40%)	1.24%
Effective tax rate	5.61%	10.42%	14.32%

- (a) Taxes incurred in foreign jurisdictions had the impact of reducing the overall effective rate of taxation in both 2013 and 2012. This is a result of a higher proportion of the Group's income being earned in lower tax rate jurisdictions.
- (b) The effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised is analyzed further in the table below (see also Note 12). No deferred tax asset was recognised because there was no reversing deferred tax liability in the same jurisdiction reversing in the same period and no future taxable income in the same jurisdiction.

	<b>Effect in 2013 US\$ '000</b>	<b>Percentage effect in 2013</b>	<b>Effect in 2012 US\$ '000</b>	<b>Percentage effect in 2012</b>
Unrecognised deferred tax assets				
Temporary differences arising in USA	8	0.08%	26	0.13%
Net operating losses arising in Brazil	208	2.04%	52	0.27%
Net operating losses arising in UK	73	0.71%		
Net operating losses arising in Sweden	235	2.30%	90	0.47%
Net operating losses arising in Canada		0.00%	(11)	(0.05%)
	<b>524</b>	<b>5.13%</b>	<b>157</b>	<b>0.82%</b>

- (c) Other items comprise items not chargeable to tax/expenses not deductible for tax.

**Deferred tax recognised directly in equity**

*December 31, 2013*      *December 31, 2012*      *December 31, 2011*

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Relating to forward contracts as hedged instruments		1	(1)
		1	(1)

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 8. INCOME TAX EXPENSE (CONTINUED)

a. The distribution of profit before taxes by geographical area was as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Rest of World Ireland	4,233	10,992	10,686
Rest of World Other	4,185	5,313	3,617
Americas	1,802	3,053	3,897
	10,220	19,358	18,200

b. At December 31, 2013, the Group had unutilised net operating losses as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
USA	9,795	5,444	2,634
Ireland	8,073		
Brazil	768	156	
UK	317		
Sweden	1,249	347	
Canada			36
	20,202	5,947	2,670

In the USA, the utilisation of net operating loss carryforwards is limited to future profits in the USA. The net operating losses for USA have a maximum carryforward of 20 years. In respect of the USA, US\$1,004,000 will expire by December 31, 2026, US\$1,120,000 will expire by December 31, 2027, US\$907,000 will expire by December 31, 2031, US\$2,408,000 will expire by December 31, 2032 and US\$4,356,000 will expire by December 31, 2033.

At December 31, 2013, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
USA unused tax credits	381	373	347
Brazil unused tax losses	261	52	
Sweden unused tax losses	325	90	
UK unused tax losses	73		

Canada	unused tax losses			11
--------	-------------------	--	--	----

Unrecognised Deferred Tax Asset	1,040	515	358
---------------------------------	-------	-----	-----

The accounting policy for deferred tax is to calculate the deferred tax asset that is deemed recoverable, considering all sources for future taxable profits. The deferred tax assets in the above table have not been recognised due to uncertainty regarding the full utilization of these losses in the related tax jurisdiction in future periods. Only when it is probable that future profits will be available to utilize the forward losses or temporary differences is a deferred tax asset recognised. When there is a reversing deferred tax liability in that jurisdiction that reverses in the same period, the deferred tax asset is restricted so that it equals the reversing deferred tax liability.

The Group has US state credit carryforwards of US\$381,000 at December 31, 2013 (2012: US\$373,000; 2011: US\$347,000). A deferred tax asset of US\$381,000 (2012: US\$373,000; 2011: US\$347,000) in respect of US state credit carryforwards was not recognised in 2013 due to uncertainties regarding future full utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****9. EARNINGS PER SHARE***Basic earnings per ordinary share*

Basic earnings per ordinary share for the Group is computed by dividing the profit after taxation of US\$9,646,000 (2012: US\$17,341,000) (2011: US\$15,593,000) for the financial year by the weighted average number of A ordinary shares and B ordinary shares in issue. As at December 31, 2013, this amounted to 87,746,588 shares (2012: 85,675,284 shares) (2011: 85,171,494 shares). As at December 31, 2011, 1,400,000 of the total weighted average shares used as the EPS denominator related to the 700,000 B ordinary shares which were in issue at that time. At an EGM held in September 2012, it was resolved that the B ordinary shares would be converted to A ordinary Shares (see below). Prior to this conversion, the B ordinary shares were treated the same as A ordinary shares except for the fact that they had two voting rights per share, rights to participate in any liquidation or sale of the Group and to receive dividends as if each Class B ordinary share were two Class A ordinary shares. Hence the earnings per share for a B ordinary share was exactly twice the earnings per share of an A ordinary share.

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
A ordinary shares	87,746,588	85,675,284	83,771,494
B ordinary shares (multiplied by 2)			1,400,000
<b>Basic earnings per share denominator</b>	<b>87,746,588</b>	<b>85,675,284</b>	<b>85,171,494</b>
<i>Reconciliation to weighted average earnings per share denominator:</i>			
Number of A ordinary shares at January 1 (Note 17)	88,994,069	85,321,081	84,116,865
Number of B ordinary shares at December 31 (multiplied by 2)*			1,400,000
Weighted average number of shares issued during the year**	(1,247,481)	354,203	(345,371)
<b>Basic earnings per share denominator</b>	<b>87,746,588</b>	<b>85,675,284</b>	<b>85,171,494</b>

\* At an Extraordinary General Meeting of the Company, held in September 2012, two resolutions were ratified by the shareholders which allowed for the conversion of the existing B ordinary shares into A ordinary shares. This conversion took place at an effective rate of 1 B ordinary share : 1.7 A ordinary shares. These resolutions also granted the cancellation of B ordinary shares subsequent to the aforementioned conversion.

\*\* The weighted average number of shares issued during the year is calculated by taking the number of shares issued multiplied by the number of days in the year each share is in issue, divided by 365 days. In 2012, this includes the 700,000 B ordinary shares (equivalent to 1,400,000 A ordinary shares) up to the date of their conversion into A ordinary shares on the 27 September 2012. Following on from the B share conversion, 1,190,000 A ordinary shares were included in their place. In 2012 and 2011, the weighted average number has been impacted by the Company's repurchase of its own shares (see Note 17). There were no repurchases of treasury shares in 2013.

*Diluted earnings per ordinary share*

Diluted earnings per ordinary share is computed by dividing the profit after tax of US\$9,646,000 (2012: US\$17,341,000) (2011: US\$15,593,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 93,712,698 (2012: 89,773,616) (2011: 88,912,596).

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



Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
Basic earnings per share denominator (see above)	87,746,588	85,675,284	85,171,494
Issuable on exercise of options and warrants	5,966,110	4,098,332	3,741,102
Diluted earnings per share denominator	93,712,698	89,773,616	88,912,596

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 9. EARNINGS PER SHARE (CONTINUED)

*Earnings per ADS*

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

Basic earnings per ADS for the Group is computed by dividing the profit after taxation of US\$9,646,000 (2012: US\$17,341,000) (2011: US\$15,593,000) for the financial year by the weighted average number of ADS in issue of 21,936,647 (2012: 21,418,821); (2011: 21,292,873).

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
A ordinary shares ADS	21,936,647	21,418,821	20,942,873
B ordinary shares ADS			350,000
<b>Basic earnings per share denominator</b>	<b>21,936,647</b>	<b>21,418,821</b>	<b>21,292,873</b>

Diluted earnings per ADS for the Group is computed by dividing the profit after taxation of US\$9,646,000 (2012: US\$17,341,000) (2011: US\$15,593,000) for the financial year, by the diluted weighted average number of ADS in issue of 23,428,175 (2012: 22,443,404) (2011: 22,228,149).

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
Basic earnings per share denominator (see above)	21,936,647	21,418,821	21,292,873
Issuable on exercise of options and warrants	1,491,528	1,024,583	935,276
<b>Diluted earnings per share denominator</b>	<b>23,428,175</b>	<b>22,443,404</b>	<b>22,228,149</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 10. PROPERTY, PLANT AND EQUIPMENT

	<i>Freehold land and buildings</i>	<i>Leasehold improvements</i>	<i>Computers, fixtures and fittings</i>	<i>Plant and equipment</i>	<i>Total</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b><u>Cost</u></b>					
At January 1, 2012	2,091	2,410	4,761	15,603	24,865
Acquisitions through business combinations (Note 22)				43	43
Other additions	6	50	235	2,395	2,686
Disposals / retirements			(175)	(209)	(384)
Exchange adjustments			1	15	16
<b>At December 31, 2012</b>	<b>2,097</b>	<b>2,460</b>	<b>4,822</b>	<b>17,847</b>	<b>27,226</b>
At January 1, 2013	2,097	2,460	4,822	17,847	27,226
Acquisitions through business combinations (Note 22)	560	42	358	421	1,381
Other additions		241	322	4,051	4,614
Disposals / retirements			(193)	(1,893)	(2,086)
Exchange adjustments	(22)	3	2	15	(2)
<b>At December 31, 2013</b>	<b>2,635</b>	<b>2,746</b>	<b>5,311</b>	<b>20,441</b>	<b>31,133</b>
<b><u>Accumulated depreciation and impairment losses</u></b>					
At January 1, 2012	(841)	(2,030)	(3,924)	(10,444)	(17,239)
Charge for the year	(61)	(105)	(236)	(1,061)	(1,463)
Disposals / retirements			159	201	360
Exchange adjustments				(1)	(1)
<b>At December 31, 2012</b>	<b>(902)</b>	<b>(2,135)</b>	<b>(4,001)</b>	<b>(11,305)</b>	<b>(18,343)</b>
At January 1, 2013	(902)	(2,135)	(4,001)	(11,305)	(18,343)
Charge for the year	(71)	(133)	(296)	(1,358)	(1,858)
Disposals / retirements			192	1,868	2,060
Exchange adjustments				(1)	(1)
<b>At December 31, 2013</b>	<b>(973)</b>	<b>(2,268)</b>	<b>(4,105)</b>	<b>(10,796)</b>	<b>(18,142)</b>
<b><u>Carrying amounts</u></b>					
At December 31, 2013	1,662	478	1,206	9,645	12,991
At December 31, 2012	1,195	325	821	6,542	8,883

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

The annual impairment review performed at December 31, 2013 and December 31, 2012, showed that the carrying value of the Group's assets did not exceed the amount that could be recovered through their use or sale and, on that basis, there was no impairment in 2013 or 2012.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 10. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)

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

Included in the carrying amount of property, plant and equipment are a number of assets included in plant and equipment which generate operating lease revenue for the Group. The net book value of these assets as at December 31, 2013 is US\$749,000 (2012: US\$525,000). Depreciation charged on these assets in 2013 amounted to US\$347,000 (2011: US\$239,000).

Included in disposals/retirements in 2013 is US\$26,000 (2012: US\$18,000) relating to the net book value of leased instruments reclassified as inventory on return from customers.

*Assets held under finance leases*

Included in the carrying amount of property, plant and equipment is an amount for capitalised leased assets of US\$98,000 (2012: US\$114,000). The leased equipment secures the lease obligations. The depreciation charge in respect of capitalised leased assets for the year ended December 31, 2013 was US\$14,000 (2012: US\$12,000). This is split as follows:

	<i>Leasehold improvements</i>	<i>Computers, fixtures and fittings</i>	<i>Plant and equipment</i>	<i>Total</i>
<i>At December 31, 2013</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Depreciation charge			14	14
<i>Carrying value</i>				
At December 31, 2013			98	98

	<i>Leasehold improvements</i>	<i>Computers, fixtures and fittings</i>	<i>Plant and equipment</i>	<i>Total</i>
<i>At December 31, 2012</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Depreciation charge			12	12
<i>Carrying value</i>				
At December 31, 2012			114	114

*Property, plant and equipment under construction*

Included in plant and equipment at December 31, 2013 is an amount of US\$3,044,000 (2012: US\$728,000) relating to assets in the course of construction.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 11. GOODWILL AND INTANGIBLE ASSETS

	<i>Goodwill</i>	<i>Development costs</i>	<i>Patents and licences</i>	<i>Other</i>	<i>Total</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b><i>Cost</i></b>					
At January 1, 2012	49,055	34,660	6,426	20,637	110,778
Acquisitions through business combinations (Note 22)	7,061	4,348	4,130		15,539
Other additions		13,029	307	150	13,486
Disposals / retirements				(2)	(2)
Exchange Adjustments	57	35	21		113
<b>At December 31, 2012</b>	<b>56,173</b>	<b>52,072</b>	<b>10,884</b>	<b>20,785</b>	<b>139,914</b>
At January 1, 2013	56,173	52,072	10,884	20,785	139,914
Acquisitions through business combinations (Note 22)	26,428			12,339	38,767
Other additions		18,390		109	18,499
Exchange Adjustments	76		61		137
<b>At December 31, 2013</b>	<b>82,677</b>	<b>70,462</b>	<b>10,945</b>	<b>33,233</b>	<b>197,317</b>
<b><i>Accumulated amortisation and Impairment losses</i></b>					
At January 1, 2012	(29,426)	(18,030)	(5,918)	(12,014)	(65,388)
Charge for the year		(338)	(58)	(1,086)	(1,482)
Disposals / retirements				2	2
<b>At December 31, 2012</b>	<b>(29,426)</b>	<b>(18,368)</b>	<b>(5,976)</b>	<b>(13,098)</b>	<b>(66,868)</b>
At January 1, 2013	(29,426)	(18,368)	(5,976)	(13,098)	(66,868)
Charge for the year		(446)	(93)	(1,363)	(1,902)
<b>At December 31, 2013</b>	<b>(29,426)</b>	<b>(18,814)</b>	<b>(6,069)</b>	<b>(14,461)</b>	<b>(68,770)</b>
<b><i>Carrying amounts</i></b>					
At December 31, 2013	53,251	51,648	4,876	18,772	128,547
At December 31, 2012	26,747	33,704	4,908	7,687	73,046

Included within development costs are costs of US\$26,264,000 which were not amortised in 2013 (2012: US\$17,322,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at December 31, 2013 or at December 31, 2012. As at December 31, 2013 these projects are expected to be completed during the period from February 1, 2014 to December 31, 2015 at an expected further cost of approximately US\$19,360,000.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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

Product Name	2013	2012
	US\$ 000	US\$ 000
Troponin I assay and reader <sup>1</sup>	7,200	5,048
Premier Instrument for Haemoglobin A1c testing <sup>2</sup>	3,861	3,854
Brain Natriuretic Peptide (BNP) assay	1,204	
Syphilis Rapid Point-of-Care test	859	750
Genesys/Resolution column enhancement	685	
C. Difficile Rapid Point-of-Care test	580	700
H Pylori Rapid Point-of-Care test	499	146
Tristat Point-of-Care instrument	481	440
Unigold Recombigen HIV Rapid enhancement	463	354
IgM Captia	363	96
Strep pneumonia Rapid Point-of-Care test	342	339
US Striped Lyme	230	12
Liquid Clinical Chemistry	230	190
Anti-nuclear Antibodies HEp-2 IFA	224	
Uni-Gold antigen improvement	166	
Dengue fever assay	151	
Cryptosporidium Rapid Point-of-Care test	138	376
HIV Ag-Ab rapid test	121	150
Giardia Rapid Point-of-Care test	120	342
Other projects with spend less than US\$100,000	473	232
<b>Total capitalized development costs</b>	<b>18,390</b>	<b>13,029</b>

- The Troponin I assay and reader project commenced in 2012 following the acquisition of Fiom Diagnostics AB in February 2012 (see Note 22). The amount of US\$7,200,000 incurred in 2013 represents the costs incurred on this project during the year and, as the project is not yet complete, no amortisation has been charged to date.
- The Premier project entails the development of a High Performance Liquid Chromatography (HPLC) instrument for testing haemoglobin A1c (HbA1c). Several versions of the instrument are being developed including an Ion Exchange version. At December 31, 2013 this project had a total carrying amount of \$14,637,000. Amortisation will occur over a 15 year period, commencing on commercialization of each version of the instrument.

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

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



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

- (b) A technical feasibility study is undertaken in advance of every project. The feasibility study for each project is reviewed by the R&D team leader, and by other senior management depending on the size of the project. The feasibility study occurs in the initial research phase of the project and costs in this phase are not capitalized.
- (c) Nearly all of our new product developments involve the transfer of our existing product know-how to a new application. The Group does not engage in pure research. Every development project is undertaken with the intention of bringing a particular new product to market for which there is a known demand.
- (d) The commercial feasibility of each new product is established prior to commencement of a project by ensuring it is projected to achieve an acceptable income after applying appropriate discount rates.

**Other intangible assets**

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

**Amortisation**

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

**Impairment testing for intangibles including goodwill and indefinite lived assets**

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 annual impairment analysis is based on a valuation technique involving level 3 inputs, see Note 1 (xxvi).

The value-in-use calculations use cash flow projections based on the 2014 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. 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 13% to 25% (2012: 15% to 27%).

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, 2013:

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, 2013:

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.

**Significant Goodwill and Intangible Assets with Indefinite Useful Lives**

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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 11. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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

	<i>Immco Diagnostics</i>		<i>Fitzgerald Industries</i>	
	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2013</i>	<i>December 31, 2012</i>
Carrying amount of goodwill (US\$ '000)	20,365		12,592	12,592
Discount rate applied (real pre-tax)	19.40%		12.85%	14.90%
Excess value-in-use over carrying amount (US\$ '000)	12,748		25,363	13,906
% EBITDA would need to decrease for an impairment to arise	24.30%		53.90%	38.90%

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

<b>Intangible Assets with Indefinite Useful lives</b>	<i>December 31, 2013</i>	<i>December 31, 2012</i>
<b>(included in other intangibles)</b>	<i>US\$ '000</i>	<i>US\$ '000</i>
<b>Fitzgerald Industries International CGU</b>		
Fitzgerald trade name	970	970
RDI trade name	560	560
<b>Primus Corporation CGU</b>		
Primus trade name	670	670
<b>Immco Diagnostic CGU</b>		
Immco Diagnostic trade name	3,393	
<b>Total</b>	<b>5,593</b>	<b>2,200</b>

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

## 12. DEFERRED TAX ASSETS AND LIABILITIES

**Recognised deferred tax assets and liabilities**

Deferred tax assets and liabilities of the Group are attributable to the following:

	<i>Assets</i>		<i>Liabilities</i>		<i>Net</i>	
	<i>2013</i>	<i>2012</i>	<i>2013</i>	<i>2012</i>	<i>2013</i>	<i>2012</i>
	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>
Property, plant and equipment	129	170	(806)	(571)	(677)	(401)
Intangible assets			(16,048)	(9,516)	(16,048)	(9,516)
Inventories	659	647			659	647

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Provisions	800	575			800	575
Other items	1,116	827	(1,049)	(656)	67	171
Tax value of loss carryforwards recognised	4,340	1,854			4,340	1,854
Deferred tax assets/(liabilities)	7,044	4,073	(17,903)	(10,743)	(10,859)	(6,670)

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****12. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)**

The deferred tax asset in 2013 is mainly due to deductible temporary differences relating to net operating losses, share-based payments, inventory and the elimination of unrealised intercompany inventory profit. The deferred tax asset increased by US\$2,971,000 in 2013 principally due to an increase in net operating losses.

The deferred tax liability is caused by the net book value of non-current assets being greater than the tax written down value of non-current assets, temporary differences due to the acceleration of the recognition of certain charges in calculating taxable income permitted in Ireland and the USA and deferred tax recognised on fair value asset uplifts in connection with business combinations. The deferred tax liability increased by US\$7,160,000 in 2013, principally because of the acquisition of Immco Diagnostics and the blood bank screening business of Lab21 Ltd., and increased temporary differences between the carrying value of assets and their asset base due to the capital expenditure incurred during 2013.

Deferred tax assets and liabilities are only offset when the entity has a legally enforceable right to set off current tax assets against current tax liabilities and where the intention is to settle current tax liabilities and assets on a net basis or to realise the assets and settle the liabilities simultaneously. At December 31, 2013 and at December 31, 2012 no deferred tax assets and liabilities are offset as it is not certain as to whether there is a legally enforceable right to set off current tax assets against current tax liabilities and it is also uncertain as to what current tax assets may be set off against current tax liabilities and in what periods.

**Unrecognised deferred tax assets**

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ '000</i>	<i>US\$ '000</i>
Capital losses	8,513	8,513
Net operating losses	2,334	503
US state credit carryforwards	381	373
	11,228	9,389

There was an increase of US\$1,839,000 in the unrecognised deferred tax assets during the year ended December 31, 2013. For comments on the uncertainty prompting less than full recognition refer to Note 8. The movement in the unrecognised deferred tax assets during the year ended December 31, 2013 is analysed as follows:

	<b>Increase</b>	<b>Applicable tax rate</b>	<b>Tax effect</b>
	<b>US\$ '000</b>	<b>%</b>	<b>US\$ '000</b>
Movement in Unrecognised deferred tax assets			
Net operating losses Brazil	611	34%	208
Net operating losses UK	317	23%	73
Net operating losses Sweden	903	26%	235
US state credit carryforwards	8	n/a	8

A deferred tax asset of US\$381,000 (2012: US\$373,000) in respect of US state credit carryforwards was not recognised due to uncertainties regarding the timing of the utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

Deferred tax assets of US\$261,000, US\$325,000 and US\$73,000 were not recognised in respect of net operating losses in Brazil, Sweden and UK respectively. The entity in Brazil was incorporated in 2012 and the entities in Sweden were acquired as part of the Fiom Diagnostics acquisition in 2012. The UK entity was incorporated in 2013 and carries on the blood bank manufacturing business acquired in 2013. The deferred tax assets have not been recognised for Brazil, Sweden and UK due to uncertainty regarding the full utilization of these losses in the related tax jurisdiction in future periods. Only when it is probable that future profits will be available to utilize the forward losses or temporary differences is a deferred tax asset recognised.

No deferred tax asset is recognised in respect of a capital loss forward of US\$8,513,000 (2012: US\$8,513,000) in Ireland as it is not probable that there will be future capital gains against which to offset these capital losses.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 12. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

**Unrecognised deferred tax liabilities**

At December 31, 2013 and 2012, there was no recognised or unrecognised deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Company is able to control the timing of the reversal of the temporary differences of its subsidiaries and it is probable that these temporary differences will not reverse in the foreseeable future.

**Movement in temporary differences during the year**

	<i>Balance</i>				<i>Balance</i>
	<i>January, 1 2013</i>	<i>Recognised in income</i>	<i>Recognised in goodwill</i>	<i>Recognised in equity</i>	<i>December 31, 2013</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Property, plant and equipment	(401)	(276)			(677)
Intangible assets	(9,516)	(3,092)	(3,440)		(16,048)
Inventories	647	12			659
Provisions	575	225			800
Other items	171	(104)			67
Tax value of loss carryforwards recognised	1,854	2,486			4,340
	(6,670)	(749)	(3,440)		(10,859)

	<i>Balance</i>				<i>Balance</i>
	<i>January, 1 2012</i>	<i>Recognised in income</i>	<i>Recognised in goodwill</i>	<i>Recognised in equity</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Property, plant and equipment	(246)	(155)			(401)
Intangible assets	(5,916)	(2,461)	(1,139)		(9,516)
Inventories	951	(304)			647
Provisions	296	279			575
Other items	130	42		(1)	171
Tax value of loss carryforwards recognised	934	920			1,854
	(3,851)	(1,679)	(1,139)	(1)	(6,670)

## 13. OTHER ASSETS

December 31, 2013

December 31, 2012

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

	<i>US\$ 000</i>	<i>US\$ 000</i>
Finance lease receivables (see Note 15)	1,084	832
Other assets	78	76
	1,162	908

The Group leases instruments as part of its business. For details of future minimum finance lease receivables with non-cancellable terms, please refer to Note 15.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 14. INVENTORIES

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Raw materials and consumables	8,514	6,083
Work-in-progress	6,136	5,335
Finished goods	15,020	9,339
	29,670	20,757

All inventories are stated at the lower of cost or net realisable value. Total inventories for the Group are shown net of provisions of US\$4,462,000 (2012: US\$5,348,000). Cost of sales in 2013 includes inventories expensed of US\$46,037,000 (2012: US\$39,784,000), (2011: US\$37,383,000).

The movement on the inventory provision for the three year period to December 31, 2013 is as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Opening provision at January 1	5,348	5,930	6,400
Charged during the year	123	824	617
Utilised during the year	(845)	(1,055)	(907)
Released during the year	(164)	(351)	(180)
Closing provision at December 31	4,462	5,348	5,930

During 2013 US\$164,000 (2012: US\$351,000), (2011: US\$180,000) of inventory provision relating to net realisable value was released to the statement of operations following a current year review of inventory usage.

## 15. TRADE AND OTHER RECEIVABLES

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Trade receivables, net of impairment losses	19,762	12,615
Prepayments	3,106	1,216
Value added tax	886	219
Finance lease receivables	514	391
Other receivables	16	16

24,268

14,457

Trade receivables are shown net of an impairment losses provision of US\$2,150,000 (2012: US\$1,520,000) (see Note 25).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 15. TRADE AND OTHER RECEIVABLES (CONTINUED)

*Leases as lessor**(i) Finance lease commitments Group as lessor*

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

	<i>December 31, 2013</i>		
	<i>US\$ 000</i>		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	839	325	514
Between one and five years (Note 13)	1,869	785	1,084
	2,708	1,110	1,598

	<i>December 31, 2012</i>		
	<i>US\$ 000</i>		
	Gross investment	Unearned income	Minimum payments receivable
Less than one year	604	213	391
Between one and five years (Note 13)	1,341	509	832
	1,945	722	1,223

The Group classified future minimum lease receivables between one and five years of US\$1,084,000 (2012: US\$832,000) as Other Assets, see Note 13. Under the terms of the lease arrangements, no contingent rents are receivable.

*(ii) Operating lease commitments Group as lessor*

The Group has leased a facility consisting of 9,000 square feet in Dublin, Ireland. This property has been sub-let by the Group. The lease contains a clause to enable upward revision of the rent charge on a periodic basis. The Group also leases instruments under operating leases as part of its business.

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

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

December 31, 2013

	<i>US\$ '000</i>		
	Land and buildings	Instruments	Total
Less than one year	232	5,627	5,859
Between one and five years	403	1,210	1,613
More than five years			
	635	6,837	7,472

December 31, 2012

	<i>US\$ '000</i>		
	Land and buildings	Instruments	Total
Less than one year	232	4,641	4,873
Between one and five years	636	2,323	2,959
More than five years			
	868	6,964	7,832

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 16. CASH AND CASH EQUIVALENTS

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ '000</i>	<i>US\$ '000</i>
Cash at bank and in hand	9,034	11,482
Short-term deposits	13,283	63,465
<b>Cash and cash equivalents in the statements of cash flows</b>	<b>22,317</b>	<b>74,947</b>

## 17. CAPITAL AND RESERVES

*Share capital*

<i>In thousands of shares</i>	<i>Class A Ordinary shares 2013</i>	<i>Class A Ordinary shares 2012</i>
In issue at January 1	88,994	85,321
Issued for cash	3,280	2,483
Issued as part of acquisition consideration	22	
Conversion of B shares during the year		700
Bonus issue arising on B share conversion		490
<b>In issue at December 31</b>	<b>92,296</b>	<b>88,994</b>

<i>In thousands of shares</i>	<i>Class B Ordinary shares 2013</i>	<i>Class B Ordinary shares 2012</i>
In issue at January 1		700
Issued for cash		
Conversion to A shares during the year		(700)
<b>In issue at December 31</b>		

<i>In thousands of shares</i>	<i>Class A Treasury shares 2013</i>	<i>Class A Treasury shares 2012</i>
Balance at January 1	2,635	2,437
Purchased during the year		1,829
Issued as part of acquisitions made during the year		(1,631)

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Balance at December 31

2,635

2,635

The Group had authorised share capital of 200,700,000 A ordinary shares of US\$0.0109 each (2012: 200,700,000 A ordinary shares of US\$0.0109 each) and Nil B ordinary shares (2012: Nil B ordinary shares of US\$0.0109 each) as at December 31, 2013.

- (a) During 2013, the Group issued 3,280,000 A Ordinary shares from the exercise of warrants and employee options for a consideration of US\$3,662,000 settled in cash. The Group incurred costs of US\$32,000 in connection with the issue of shares.
- (b) The Group acquired Immco Diagnostics Inc (see Note 22) during the year. As part of the purchase consideration, the Group issued 22,264 A Ordinary Shares (5,566 ADS s).
- (c) Following shareholder approval at the 2013 AGM, the Board approved the payment of a final dividend of 20 cents per ADS in respect of the 2012 financial year (15 cents per ADS in respect of the 2011 financial year). As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars (see Note 26 for further information).

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

17. CAPITAL AND RESERVES (CONTINUED)

(d) During 2012, the Group purchased 1,829,000 A Ordinary shares (457,000 ADS s) Treasury shares . The total cost of these shares was US\$5,343,000. There was no purchase of treasury shares in 2013.

(e) An Extraordinary General Meeting ( EGM ) of the Company was held on 27 September 2012 and, at this meeting, it was approved by the shareholders that the 700,000 existing B Ordinary Shares be redesignated as A Ordinary Shares. It was further approved that a bonus issue of 490,000 A Ordinary Shares be allocated to the existing B Ordinary Shareholders on the basis of 7,000 A Ordinary Shares per existing holding of 10,000 B Ordinary Shares and that, following this, the Class B Shareholding be cancelled.

Prior to this EGM, the B Ordinary Shares had two votes per share and had the right to participate in any liquidation or sale of the Group and to receive dividends as if each Class B Ordinary Share were two Class A Ordinary Shares.

***Share Premium***

Following the passing of a Special Resolution of the Company in September 2010 and the approval of a petition placed before the High Court of Ireland, the Company was permitted to reduce its share premium in the amount of US\$160,000,000 during 2011. This amount was, therefore, transferred to retained earnings in the 2011 financial statements.

***Currency translation reserve***

The currency translation reserve comprises all foreign exchange differences arising from the translation of the financial statements of foreign currency denominated operations of the Group since January 1, 2004.

***Warrant reserve***

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

In accordance with IFRS 2, 3,477,068 warrants with a fair value of US\$4,529,000 (2012: 3,477,068 warrants with a fair value of US\$4,529,000) have been classified as a separate reserve. There were no new warrants issued by the Group in 2013 or 2012.

***Hedging reserve***

The hedging reserve comprises the effective portion of the cumulative net change in the fair value of cash flow hedging instruments related to hedged transactions entered into but not yet crystallised.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****18. SHARE OPTIONS AND SHARE WARRANTS*****Warrants***

There were no warrants granted in either 2013 or 2012.

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>Class A Ordinary Shares</i>	<i>Class A Ordinary Shares</i>
Outstanding at beginning of year	933,120	1,321,744
Exercised	(924,120)	(388,624)
Expired	(9,000)	
Outstanding at end of year		933,120

***Options***

Under the terms of the Company's Employee Share Option Plans, options to purchase 9,781,409 A Ordinary Shares were outstanding at December 31, 2013. Under the Plans, options are granted to officers, employees and consultants of the Group at the discretion of the Compensation Committee (designated by the board of directors), under the terms outlined below.

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

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

***Vesting conditions***

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

***Contractual life***

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



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

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

	Options and warrants A Ordinary Shares	Weighted- average exercise price		Range	
		US\$		US\$	
		Per	A Ordinary Share	Per	A Ordinary Share
Outstanding January 1, 2011	10,953,671	1.44	0.66	4.00	
Granted	514,000	2.40	2.14	2.52	
Exercised	(1,368,896)	1.16	0.66	1.78	
Forfeited	(1,076,421)	2.59	0.87	4.00	
Outstanding at end of year	9,022,354	1.40	0.66	2.80	
Exercisable at end of year	5,085,431	1.39	0.66	2.80	
Outstanding January 1, 2012	9,022,354	1.40	0.66	2.80	
Granted	4,098,000	2.59	2.50	3.27	
Exercised	(2,663,636)	1.17	0.66	2.23	
Forfeited	(30,000)	1.57	1.52	1.65	
Outstanding at end of year	10,426,718	1.93	0.66	3.27	
Exercisable at end of year	4,389,052	1.43	0.66	2.80	
Outstanding January 1, 2013	10,426,718	1.93	0.66	3.27	
Granted	3,027,652	3.93	1.66	4.79	
Exercised	(3,625,961)	1.44	0.66	2.80	
Forfeited	(47,000)	1.52	1.39	1.78	
Outstanding at end of year	9,781,409	2.73	0.66	4.79	
Exercisable at end of year	3,018,915	1.89	0.66	3.27	
		Weighted- average exercise price		Range	
	Options and warrants ADS Equivalent	US\$		US\$	
		Per	ADS	Per	ADS

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Outstanding January 1, 2011	2,738,418	5.76	2.63	16.00
Granted	128,500	9.60	8.56	10.08
Exercised	(342,224)	4.64	2.63	7.12
Forfeited	(269,105)	10.36	3.48	16.00
Outstanding at end of year	2,255,589	5.60	2.63	11.20
Exercisable at end of year	1,271,358	5.56	2.63	11.20
Outstanding January 1, 2012	2,255,589	5.60	2.63	11.20
Granted	1,024,500	10.36	10.00	13.08
Exercised	(665,909)	4.68	2.63	8.92
Forfeited	(7,500)	6.28	6.08	6.60
Outstanding at end of year	2,606,680	7.72	2.63	13.08
Exercisable at end of year	1,097,263	5.72	2.63	11.20
Outstanding January 1, 2013	2,606,680	7.72	2.63	13.08
Granted	756,912	15.71	6.64	19.15
Exercised	(906,490)	5.74	2.63	11.20
Forfeited	(11,750)	6.08	5.54	7.12
Outstanding at end of year	2,445,352	10.92	2.63	19.15
Exercisable at end of year	754,729	7.56	2.63	13.08

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The weighted average share price per A Ordinary share at the date of exercise for options exercised in 2013 was: US\$5.10 (\$20.40 per ADS), 2012: US\$3.13 per A Ordinary share (US\$12.52 per ADS) and 2011: US\$2.48 per A Ordinary share (US\$9.92 per ADS).

The opening share price per A Ordinary share at the start of the financial year was US\$3.64 or US\$14.55 per ADS (2012: US\$2.54 or US\$10.15 per ADS) (2011: US\$2.20 or US\$8.80 per ADS) and the closing share price at December 31, 2013 was US\$6.28 or US\$25.14 per ADS (2012: US\$3.61 or US\$14.42 per ADS) (2011: US\$2.55 or US\$10.18 per ADS). The average share price for the year ended December 31, 2013 was US\$4.79 per A Ordinary share or US\$19.15 per ADS.

A summary of the range of prices for the Company's stock options and warrants for the year ended December 31, 2013 follows:

Exercise price range	Outstanding			Exercisable		
	No. of options/warrants	Weighted-average exercise price	Weighted-average contractual life remaining (years)	No. of options/warrants	Weighted-average exercise price	Weighted-average contractual life remaining (years)
US\$0.66-US\$0.99	74,008	0.69	2.23	74,008	0.69	2.23
US\$1.00-US\$2.05	2,511,073	1.50	3.31	1,757,242	1.49	3.26
US\$2.06-US\$2.99	4,348,328	2.54	5.05	1,071,665	2.49	4.64
US\$3.00-US\$4.79	2,848,000	4.16	6.35	116,000	3.25	5.39
	9,781,409			3,018,915		

Exercise price range	Outstanding			Exercisable		
	No. of options/warrants	Weighted-average exercise price	Weighted-average contractual life remaining (years)	No. of options/warrants	Weighted-average exercise price	Weighted-average contractual life remaining (years)
US\$2.63-US\$3.96	18,502	2.76	2.23	18,502	2.76	2.23
US\$4.00-US\$8.20	627,768	6.00	3.31	439,311	5.96	3.26
US\$8.24-US\$11.96	1,087,082	10.16	5.05	267,916	9.96	4.64
US\$12.00-US\$19.16	712,000	16.64	6.35	29,000	13.00	5.39
	2,445,352			754,729		

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The weighted-average remaining contractual life of options and warrants outstanding at December 31, 2013 was 4.96 years (2012: 4.34 years).

A summary of the range of prices for the Company's stock options and warrants for the year ended December 31, 2012 follows:

Exercise price range	Outstanding			Exercisable		
	No. of options/warrants	Weighted average exercise price	Weighted-average contractual life remaining (years)	No. of options/warrants	Weighted average exercise price	Weighted-average contractual life remaining (years)
US\$0.66 - US\$0.99	944,014	0.73	3.06	877,346	0.71	2.98
US\$1.00 - US\$2.05	4,206,372	1.46	3.25	2,660,706	1.43	2.55
US\$2.06 - US\$2.99	5,112,332	2.49	5.40	851,000	2.21	1.57
US\$3.00 - US\$4.00	164,000	3.21	6.48			
	10,426,718			4,389,052		

Exercise price range	Outstanding			Exercisable		
	No. of options/warrants	Weighted average exercise price	Weighted-average contractual life remaining (years)	No. of options/warrants	Weighted average exercise price	Weighted-average contractual life remaining (years)
US\$2.63 - US\$3.96	236,004	2.92	3.06	219,337	2.84	2.98
US\$4.00 - US\$8.20	1,051,593	5.84	3.25	665,176	5.72	2.55
US\$8.24 - US\$11.96	1,278,083	9.96	5.40	212,750	8.84	1.57
US\$12.00 - US\$16.00	41,000	12.84	6.48			
	2,606,680			1,097,263		

The recognition and measurement principles of IFRS 2 have been applied to share options granted under the Company's Share Option Plans since November 7, 2002 which have not vested by January 1, 2005 in accordance with IFRS 2.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 18. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

**Charge for the year under IFRS 2**

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

The fair value of the options is expensed over the vesting period of the option. US\$2,014,000 was charged to the statement of operations in 2013, (2012: US\$1,713,000), (2011: US\$1,269,000) split as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>	<i>December 31, 2011</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Share-based payments cost of sales	36	38	34
Share-based payments selling, general and administrative	1,978	1,675	1,235
<b>Total</b>	<b>2,014</b>	<b>1,713</b>	<b>1,269</b>

The total share based payments charge for the year was US\$3,303,000. However, a total of US\$1,289,000 (2012: US\$927,000) (2011: US\$278,000) of share based payments were capitalised in intangible development project assets during the year.

The fair value of services received in return for share options granted are measured by reference to the fair value of share options granted. The estimate of the fair value of services received is measured based on a trinomial model. The following are the input assumptions used in determining the fair value of share options granted in 2013, 2012 and 2011:

	<b>Key management personnel 2013</b>	<b>Other employees 2013</b>	<b>Key management personnel 2012</b>	<b>Other employees 2012</b>	<b>Key management personnel 2011</b>	<b>Other employees 2011</b>
Weighted average fair value at measurement date per A share / (per ADS)	US\$1.64 / (US\$6.56)	US\$2.69 / (US\$10.76)	US\$1.21 / (US\$4.84)	US\$1.18 / (US\$4.72)	US\$1.25 / (US\$5.00)	
Total A share options granted / (ADS s equivalent)	2,540,000 / (635,000)	487,652 / (121,913)	2,540,000 / (635,000)	1,558,000 / (389,500)	514,000 / (128,500)	
Weighted average share price per A share / (per ADS)	US\$4.21 / (US\$16.85)	US\$4.75 / (US\$19.00)	US\$2.52 / (US\$10.08)	US\$2.67 / (US\$10.68)	US\$2.37 / (US\$9.48)	
Weighted average exercise price per A share / (per ADS)	US\$4.21 / (US\$16.85)	US\$2.45 / (US\$9.80)	US\$2.52 / (US\$10.08)	US\$2.67 / (US\$10.68)	US\$2.37 / (US\$9.48)	
Weighted average expected volatility	49.69%	12.06%	62.54%	62.02%	66.30%	
Weighted average expected life	4.80	4.09	4.88	4.18	4.52	

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Weighted average risk free interest rate	0.90%	0.27%	0.87%	0.61%	1.50%
Expected dividend yield	1%	1%	1%	1%	1%

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility is based on the historic volatility (calculated based on the expected life of the options). The Group has considered how future experience may affect historical volatility. The profile and activities of the Group are not expected to change in the immediate future and therefore Trinity Biotech would expect estimated volatility to be consistent with historical volatility.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 19. TRADE AND OTHER PAYABLES

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Trade payables	8,154	4,525
Payroll taxes	310	283
Employee related social insurance	208	202
Accrued liabilities	9,362	6,564
Deferred consideration	1,953	151
Deferred income	144	99
	<b>20,131</b>	<b>11,824</b>

The deferred consideration payable arises as a result of the acquisition of Fiom Diagnostics AB in 2012 and Phoenix Biotech in 2011, and is shown net of deferred interest expense of US\$11,000.

Accrued liabilities include US\$1,080,000 relating to contracted licence payments for HIV-2 licence.

## 20. PROVISIONS

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Provisions	75	50

Movement on provisions during the year is as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Balance at January 1	50	50
Additional provisions related to acquisitions	25	
Balance at December 31	<b>75</b>	<b>50</b>

During 2013 the Group experienced no significant product warranty claims. However, the Group believes that it is appropriate to retain a product warranty provision to cover any future claims. The provision at December 31, 2013 represents the estimated cost of product warranties, the exact amount which cannot be determined. US\$75,000 represents management's best estimate of these obligations at December 31, 2013.

## 21. OTHER PAYABLES DUE AFTER ONE YEAR

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Other payables	3,055	1,000
Deferred Consideration	1,541	3,318
	4,596	4,318

The deferred consideration payable arises as a result of the acquisition of Fiom Diagnostics AB in 2012 and is shown net of deferred interest expense of US\$36,000. For further information on the acquisition of Fiom Diagnostics, please refer to Note 22.

Other payables in 2013 are entirely comprised of amounts relating to contracted licence payments for HIV-2 licence.

Other payables in 2012 are entirely comprised of amounts relating to contracted technology licence payments arising as a result of the Fiom Diagnostics acquisition (see note 22).



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****22. BUSINESS COMBINATIONS****2013 Acquisitions**

In 2013, the Group acquired Immco Diagnostics ( Immco ) and the Blood bank screening business of Lab21 Ltd.

**Immco Diagnostics**

The Group acquired 100% of the common stock of Immco Diagnostics Inc. for US\$32,883,000. Immco is headquartered in Buffalo, New York, and employs 90 people. It specializes in the development, manufacture and sale of autoimmune test kits on a worldwide basis. This product line is complemented by specialized reference laboratory services in diagnostic immunology, pathology and immunogenetics, marketed to US-based reference laboratories and hospitals. Immco has a wholly-owned Canadian subsidiary, Nova Century Scientific Inc.

Autoimmune diseases are now the second leading cause of chronic illness and the leading cause of death amongst women over 65. Immco is positioned in the lower throughput, speciality autoimmune segment of the market, where the competition is limited to a small number of key players, principally Bio-Rad, Werfen-Inova and Phadia. Immco offers a comprehensive range of more than 120 products across all the main autoimmune segments. The principal autoimmune conditions in this segment are Rheumatoid Arthritis, Vasculitis, Lupus, Celiac and Crohn's disease, Ulcerative Colitis, Neuropathy, Hashimoto's and Graves disease. Meanwhile, the two key technologies employed are Immunofluorescence (IFA) and Immunoassay (EIA). Prior to acquisition by Trinity Biotech, Immco sold its products through a network of distributors, mainly outside the US. Immco's very low level of sales in the US was due to a lack of FDA product approvals and a sales force. However, Immco has in the last two years succeeded in harmonizing its complete IFA and EIA product ranges, virtually all of which have now been FDA 510K cleared.

The consideration comprised the following:

An up-front cash payment of US\$31,652,000,

Share options in Trinity Biotech ADSs which vested immediately and were in the money upon vesting. The fair value was US\$1,121,000 as at the acquisition date and,

5,566 Trinity Biotech ADSs with a fair value of US\$110,000 as at the acquisition date.

Goodwill recognised during 2013 in respect of the Immco acquisition amounted to US\$20,365,000 and comprised:

	Book values	Fair value adjustments	Fair value	Purchase Consideration*	Goodwill
	US\$ '000	US\$ '000	US\$ '000	US\$ '000	US\$ '000
<b>Immco Diagnostic</b>					
Property, plant & equipment	1,632	(355)	1,277		
Intangible assets	356	10,211	10,567		
Trade & other receivables	3,437	(549)	2,888		
Inventory	2,538	(927)	1,611		

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Cash	2,282		2,282
Deferred tax asset	9	(9)	
	10,254	8,371	18,625
Trade & other payables	(1,686)		(1,686)
Taxes payable	(403)		(403)
Loan liabilities	(955)		(955)
Deferred tax liability		(3,063)	(3,063)
	(3,044)	(3,063)	(6,107)
Total identifiable net assets at fair value			<b>12,518</b>
			<b>32,883</b>
			<b>20,365</b>
<b>*Purchase Consideration</b>	US\$ 000		
Cash Paid	31,652		
Shares and share options transferred as part of consideration	1,231		
Total Purchase Consideration	32,883		

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****22. BUSINESS COMBINATIONS (CONTINUED)**

The gross contractual value of trade and other receivables as at the date of acquisition amounted to US\$3,730,000. The fair value of these receivables is US\$2,888,000 (all of which is expected to be recoverable) and is inclusive of an aggregate allowance for impairment of US\$841,000.

The fair value of intangible assets was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the intangible assets reflects significant assumptions regarding the estimates a market participant would make, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The Group recognised US\$10,567,000 of intangible assets as part of the Immco acquisition.

The principal factor contributing to the recognition of goodwill of US\$20,365,000 on acquisition is the realisation of synergies with existing entities in the Group which do not qualify for separate recognition as intangible assets. In particular, there is a major opportunity to grow Immco's revenues in the US by leveraging both the Group's existing installed base and its sales force. Secondly, the combination of the Group's existing infectious diseases products with Immco's autoimmune products will create a portfolio effect which will be to the benefit of both product lines. Lastly, the addition of the reference laboratory will be beneficial for new product introduction and obtaining human samples. None of the goodwill recognised is expected to be deductible for income tax purposes.

Transaction costs of US\$153,000 have been expensed during the year and are included within selling, general and administrative expenses. No contingent liabilities were recognised on the acquisition.

Immco has recorded post-acquisition revenue, including revenues for existing Trinity Biotech products, of US\$5,999,000 and a profit of US\$95,000. The revenues and profit of the Group for the financial year determined in accordance with IFRS as though the acquisition had been at the beginning of the year would have been as follows:

	<i>US\$ '000</i>
Revenues	99,396
Group Profit for the financial year	9,983

**Blood bank screening business of Lab21 Ltd**

The blood bank screening business of Lab21 Ltd was acquired by a newly incorporated Group entity, Trinity Biotech (UK) Ltd., for cash consideration of US\$7,456,000. The business consists of a range of products for the screening of syphilis, malaria and cytomegalovirus (CMV) in blood donations. Located in Cambridge and Newmarket in the United Kingdom, the business employs 45 people between the two sites. The products, comprising very high quality TPHA, RPR and ELISA tests, have an excellent balance between sensitivity and specificity and compete in a market which has limited competition. The syphilis products have a market share of over 75% of the syphilis blood bank markets in the UK, France, Germany, Netherlands, Switzerland, Austria and Belgium. The malaria test is well positioned to avail of the increase in malaria blood bank testing in the developed world given the increased prevalence of malaria as a result of foreign travel. The CMV product was launched in late 2012 and has excellent revenue growth prospects. The Group plans to replicate the European success in other countries and more particularly in the US, where it intends to immediately submit the products for FDA approval.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 22. BUSINESS COMBINATIONS (CONTINUED)

Goodwill recognised during 2013 in respect of the blood bank screening business acquisition amounted to US\$6,063,000 and comprised:

	Book values	Fair value adjustments	Fair value	Purchase Consideration	Goodwill
	US\$ 000	US\$ 000	US\$ 000	US\$ 000	US\$ 000
<b>Blood bank screening business</b>					
Property, plant & equipment	153	(49)	104		
Intangible assets		1,772	1,772		
Inventory	76	9	85		
	229	1,732	1,961		
Trade & other payables		(199)	(199)		
Deferred tax liability		(369)	(369)		
		(568)	(568)		
<b>Total identifiable net assets at fair value</b>			<b>1,393</b>	<b>7,456</b>	<b>6,063</b>

The fair value of intangible assets was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the intangible assets reflects significant assumptions regarding the estimates a market participant would make, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The Group recognised US\$1,772,000 of intangible assets as part of the blood banking business acquisition.

The principal factor contributing to the recognition of goodwill of US\$6,063,000 on acquisition is the realisation of cost savings and other synergies with existing entities in the Group which do not qualify for separate recognition as intangible assets. In 2014, the production activities of the business will be transferred from its existing manufacturing facilities in the UK to the Group's current facilities in Bray, Ireland and Jamestown, New York. This will result in significant operational synergies and efficiencies.

Transaction costs of US\$163,000 have been expensed during the year and are included within selling, general and administrative expenses. No contingent liabilities were recognised on the acquisition.

The blood bank screening business has recorded post-acquisition revenues of US\$2,445,000 and a loss of US\$1,054,000. The revenues and profit of the Group for the financial year determined in accordance with IFRS as though the acquisition had been at the beginning of the year would have been as follows:

	<i>US\$ 000</i>
Revenues	94,125
Group Profit for the financial year	9,069

***2012 Acquisition***

In February, 2012, the Group acquired 100% of the common stock of Fiom Diagnostics AB ( Fiom ).

Fiom, which is based in Uppsala, Sweden, is at an advanced stage in developing a range of point-of-care cardiac assays based on micro-pillar technology. 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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 22. BUSINESS COMBINATIONS (CONTINUED)

Goodwill recognised during 2012 in respect of the Fiom Diagnostics AB acquisition amounted to US\$7,061,000 and comprised:

	Book values	Fair value adjustments	Fair value	Purchase Consideration*	Goodwill
	US\$ 000	US\$ 000	US\$ 000	US\$ 000	US\$ 000
<b>Fiom Diagnostics AB</b>					
Property, plant & equipment	43		43		
Intangible assets	4,130	4,348	8,478		
Trade & other receivables	78		78		
Cash	44		44		
	4,295	4,348	8,643		
Trade & other payables	(646)		(646)		
Other non-current liabilities	(1,000)		(1,000)		
Deferred tax liability		(1,131)	(1,131)		
	(1,646)	(1,131)	(2,777)		
<b>Total identifiable net assets at fair value</b>			<b>5,866</b>	<b>12,927</b>	<b>7,061</b>
<b>*Purchase Consideration</b>	US\$ 000				
Cash Paid	5,624				
Shares Transferred as part of consideration	4,070				
Contingent consideration liability (net present value)	3,233				
<b>Total Purchase Consideration</b>				<b>12,927</b>	

Under the terms of the purchase agreement, the previous owners of Fiom are entitled to additional consideration which is based on the CE Marking, FDA submission and approval of a Troponin I assay. At the acquisition date, the net present value of this contingent consideration was estimated to be US\$3,233,000 (net of interest of \$182,000) and this remains the most likely outcome as at December 31, 2013.

The fair value of the in-process research and development (IPR&D) intangible asset was estimated using the discounted cash flow method of the income approach. Under this method, an intangible asset's fair value is equal to the present value of the after-tax cash flows attributable solely to the intangible asset over its remaining useful life. To calculate fair value, we estimated the present value of cash flows discounted at rates commensurate with the inherent risks associated with that type of asset. The valuation model used to estimate the fair value of the IPR&D reflects significant assumptions regarding the estimates a market participant would make in order to evaluate a diagnostic assay development asset, including (a) the estimated net revenues, (b) market size and market growth projections, (c) royalty percentage, and (d) a discount rate. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk and regulatory risk. The Group recognised US\$4,348,000 of IPR&D as part of the Fiom acquisition.

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Development of the Troponin I cardiac assay requires various levels of in-house and external testing, clinical trials and approvals from the FDA or comparable foreign regulatory authorities before it could be commercialized in the U.S. or other territories. Assuming successful results in clinical trials and regulatory approval, the Group expects to commercially launch the cardiac assay in 2014. The estimated costs to complete the project represent management's best estimate of expected costs, but are subject to change based on additional information to be received as development activities advance.

IPR&D is tested annually for impairment (see Note 1(viii)). We did not recognise any impairment charges related to IPR&D during the years ended December 31, 2013, 2012 and 2011.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****22. BUSINESS COMBINATIONS (CONTINUED)**

The fair value of the trade and other receivables amounted to US\$78,000 (i.e. the book value on the date of acquisition). None of the trade and other receivables was impaired as all of these receivables were collected by the Company.

Trade and other payables were valued at US\$646,000 and other non-current liabilities, comprising contracted licence fees for technology, were valued at US\$1,000,000.

The goodwill of US\$7,061,000 represented the future economic benefits arising from the acquisition that have not been individually identified and separately recognised. None of the goodwill recognised is expected to be deductible for income tax purposes.

Transaction costs of US\$90,000 were expensed in 2012 and are included within selling, general and administrative expenses.

During 2013, Fiomis was engaged entirely in the development of its point-of-care cardiac marker assays and, as such, all costs incurred by Fiomis during the year were capitalised to these projects. Fiomis has yet to make its first commercial sale and did not contribute to the Group's revenue in 2012 or 2013. As a result of these factors, Fiomis did not contribute to the Group's profit for the years ended December 31, 2013 and December 31, 2012.

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 ADS's as at the acquisition date (fair value of US\$4.1m); and

Contingent cash consideration of US\$3.4m.

***2011 Acquisition***

In January 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.

Phoenix Bio-tech was founded in 1992 and is based in Toronto, Canada. 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 US. The acquisition of Phoenix Bio-tech strengthens Trinity Biotech's existing range of tests for sexually-transmitted diseases and allows the Company to exploit synergies in both manufacturing and distribution.

Goodwill recognised during 2011 in respect of the Phoenix Bio-tech acquisition amounted to US\$1,801,000 and comprised:

Book values	Fair value adjustments	Fair value	Purchase	Goodwill
US\$ 000	US\$ 000	US\$ 000	Consideration*	US\$ 000



US\$ 000

<b>Phoenix Bio-tech</b>			
Property, plant & equipment	261	(102)	159
Intangible assets		490	490
Inventory	348	(138)	210
Trade & other receivables	167		167
Cash	21		21
	797	250	1,047
Trade & other payables	(26)	(13)	(39)
Deferred tax liability		(137)	(137)
	(26)	(150)	(176)
<b>Total identifiable net assets at fair value</b>		<b>871</b>	<b>2,672</b>
			<b>1,801</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 22. BUSINESS COMBINATIONS (CONTINUED)

<b>*Purchase Consideration</b>	US\$ 000
Cash Payable	2,500
Contingent consideration liability	172
 Total Purchase Consideration	 2,672

Under the terms of the purchase agreement, the previous owners of Phoenix Bio-tech are entitled to additional consideration based on the growth of the acquired products in the 5 year period after the date of acquisition. At the acquisition date, the net present value of this contingent consideration was estimated to be US\$172,000. The contingent consideration liability reduced by US\$22,000 during 2012 to US\$150,000 due to a payment made in respect of 2011 sales. The contingent consideration liability reduced by US\$25,000 during 2013 to US\$125,000 due to a payment made in respect of 2012 sales. As at December 31, 2013 there was no change in the range of outcomes expected in respect of the contingent consideration.

## 23. COMMITMENTS AND CONTINGENCIES

(a) *Capital Commitments*

The Group has no capital commitments authorised and contracted for as at December 31, 2013 (2012: US\$Nil).

(b) *Leasing Commitments*

The Group leases a number of premises under operating leases. The leases typically run for periods up to 25 years. Lease payments are reviewed periodically (typically on a 5 year basis) to reflect market rentals. Operating lease commitments payable during the next 12 months amount to US\$3,510,000 (2012: US\$2,699,000) payable on leases of buildings at Dublin and Bray, Ireland, Jamestown, Buffalo and Amherst, New York, Acton, Massachusetts, Carlsbad, California, Uppsala, Sweden, Cambridge and Newmarket, UK, and Sao Paulo, Brazil. US\$328,000 (2012: US\$317,000) of these operating lease commitments relates to leases whose remaining term will expire within one year, US\$881,000 (2012: US\$123,000) relates to leases whose remaining term expires between one and two years, US\$692,000 (2012: US\$719,000) between two and five years and the balance of US\$1,610,000 (2012: US\$1,540,000) relates to leases which expire after more than five years. See Note 24 for related party leasing arrangements.

Future minimum operating lease commitments with non-cancellable terms in excess of one year are as follows:

	<i>Year ended 2013 Operating leases US\$ 000</i>
2014	3,510
2015	2,961
2016	2,537
2017	2,010
2018	1,610

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Later years	19,833
Total lease obligations	32,461

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 23. COMMITMENTS AND CONTINGENCIES (CONTINUED)

	<i>Year ended 2012</i>
	<i>Operating leases US\$ 000</i>
2013	2,699
2014	2,371
2015	2,071
2016	1,737
2017	1,540
Later years	20,520
<b>Total lease obligations</b>	<b>30,938</b>

**(c) Bank Security**

The Group repaid in full its bank borrowings in April 2010, at which point all previous charges against Group assets were released. The Group had no bank borrowings as at December 31, 2013.

**(d) Section 17 Guarantees**

Pursuant to the provisions of Section 17, Irish Companies (Amendment) Act, 1986, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, Trinity Research Limited, Benen Trading Limited and Trinity Biotech Financial Services Limited subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2013 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 17, Irish Companies (Amendment) Act, 1986. Where the Company enters into these guarantees of the indebtedness of other companies within its Group, the Company considers these to be insurance arrangements and accounts for them as such. The Company treats the guarantee contract as a contingent liability until such time as it becomes probable that the company will be required to make a payment under the guarantee. The Company does not enter into financial guarantees with third parties.

**(e) Government Grant Contingencies**

The Group has received training and employment grant income from Irish development agencies. Subject to existence of certain conditions specified in the grant agreements, this income may become repayable. No such conditions existed as at December 31, 2013. However if the income were to become repayable, the maximum amounts repayable as at December 31, 2013 would amount to US\$3,483,000 (2012: US\$3,333,000).

**(f) Litigation**

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. There are also a small number of legal cases being brought against the Group by certain of its former employees in the previously owned French subsidiary, Trinity Biotech France S.à.r.l. The ultimate resolution of the aforementioned proceedings is not expected to have a material adverse effect on the Group's financial position, results of operations or cash flows.

24. RELATED PARTY TRANSACTIONS

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

*Leasing arrangements with related parties*

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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 24. RELATED PARTY TRANSACTIONS (CONTINUED)

In November 2004, 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\$506,000) 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 rate of 17.94 per square foot (including fit out) giving a total annual rent of 787,000 (US\$1,044,000).

Trinity Biotech and its directors (excepting Mr O Caoimh and Dr Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises. At December 31, 2013 rental payments outstanding amounted to US\$248,000 (2012: US\$Nil).

*Compensation of key management personnel of the Group*

At December 31, 2013 and December 31, 2012 the key management personnel of the Group were made up of four key personnel: the three executive directors; Mr. Ronan O Caoimh, Mr. Rory Nealon and Dr. Jim Walsh and Mr. Kevin Tansley, our Chief Financial Officer/Company Secretary.

Compensation for the year ended December 31, 2013 of these personnel is detailed below:

	December 31, 2013 US\$ '000	December 31, 2012 US\$ '000
Short-term employee benefits	1,938	1,473
Performance related bonus	374	481
Post-employment benefits	95	304
Share-based compensation benefits	2,263	1,689
	4,670	3,947

Note 5 includes non executive directors' fees of US\$315,000 (2012: US\$300,000) and share-based compensation benefits of US\$235,000 (2012: US\$177,000). Note 5 excludes the compensation costs of the Chief Financial Officer comprising total remuneration of US\$507,000 (2012: US\$476,000) and share-based compensation of US\$490,000 (2012: US\$367,000). Total directors' remuneration is also included in personnel expenses (Note 6). On March 30, 2011, the service agreement with Ronan O Caoimh as Chief Executive Officer was terminated and replaced by an agreement with Darnick Company, a company wholly-owned by members of Mr. O Caoimh's immediate family. Directors' compensation includes payments made to Darnick Company.

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

	A Ordinary Shares	Share options
At January 1, 2013	5,723,306	6,703,759
Exercised	220,000	(2,055,000)
Granted		2,540,000

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Expired Options		
Shares purchased/(sold) during the year	(13,000)	
At December 31, 2013	5,930,306	7,188,759
	<i>A Ordinary Shares</i>	<i>Share options</i>
At January 1, 2012	5,534,706	5,753,759
Exercised	235,000	(1,590,000)
Granted		2,540,000
Expired Options		
Shares purchased/(sold) during the year	(46,400)	
At December 31, 2012	5,723,306	6,703,759

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013****24. RELATED PARTY TRANSACTIONS (CONTINUED)**

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 2013 or 2012.

In June 2009, the Board approved the payment of a dividend of \$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 and 2013 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US\$Nil, US\$231,000 and US\$1,422,000 for 2013, 2012 and 2011 respectively, of which US\$Nil, US\$206,000 and US\$1,395,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2013, 2012 or 2011.

**25. DERIVATIVES AND FINANCIAL INSTRUMENTS**

The Group uses a range of financial instruments (including cash, finance leases, receivables, payables and derivatives) to fund its operations. These instruments are used to manage the liquidity of the Group in a cost effective, low-risk manner. Working capital management is a key additional element in the effective management of overall liquidity. The Group does not trade in financial instruments or derivatives. The main risks arising from the utilization of these financial instruments are interest rate risk, liquidity risk and credit risk.

***Interest rate risk******Effective and repricing analysis***

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

		<i>Effective interest</i>	<i>Total</i>	<i>6 mths or less</i>	<i>6-12 mths</i>	<i>1-2 years</i>	<i>2-5 years</i>
<i>As at December 31, 2013</i>	<i>Note</i>	<i>rate</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>
Cash and cash equivalents	16	0.1%	22,317	22,317			
Finance lease receivable	15	4.2%	1,598	267	247	428	656
Deferred Consideration	19, 21	3.1%	(3,369)	(1,828)		(1,541)	
Licence payments	19, 21	3.0%	(4,135)		(1,080)	(1,049)	(2,006)



Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Total			16,411	20,756	(833)	(2,162)	(1,350)
-------	--	--	--------	--------	-------	---------	---------

		<i>Effective interest</i>	<i>Total</i>	<i>6 mths or less</i>	<i>6-12 mths</i>	<i>1-2 years</i>	<i>2-5 years</i>
<i>As at December 31, 2012</i>	<i>Note</i>	<i>rate</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Cash and cash equivalents	16	2.5%	74,947	14,905	60,042		
Finance lease receivable	15	4.1%	1,223	198	193	341	491
Deferred Consideration	19	3.1%	(3,318)			(3,318)	
Total			72,852	15,103	60,235	(2,977)	491

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

Year-end cash and cash equivalents amounted to US\$22,317,000 (2012: US\$74,947,000) which attracted an average rate of interest of 0.1% (2012: 2.5%).

In broad terms, a one-percentage point increase in interest rates would increase interest income by US\$223,000 (2012: US\$749,000) and would not affect the interest expense (2012: nil impact also) resulting in an increase in net interest income of US\$223,000 (2012: increase in net interest income of US\$749,000).

**Interest rate profile of financial assets / liabilities**

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

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ '000</i>	<i>US\$ '000</i>
<b><i>Fixed rate instruments</i></b>		
Fixed rate financial liabilities (deferred consideration)	(3,369)	(3,318)
Fixed rate financial liabilities (licence fees)	(4,135)	
Financial assets (cash and short-term deposits)	13,283	60,042
Financial assets (finance lease receivables)	1,598	1,223
<b><i>Variable rate instruments</i></b>		
Financial assets (cash and short-term deposits)	9,034	14,905
	16,411	72,852

In 2013 and 2012, the fixed rate financial liabilities relating to deferred consideration arises as a result of the Fiomis acquisition (see Note 22). The weighted average interest rate and weighted average period for which the rate is fixed is as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
<b><i>Fixed rate financial liabilities (deferred consideration)</i></b>		
Weighted average interest rate	3.1%	3.1%
Weighted average period for which rate is fixed	0.55 years	1.52 years

Financial assets comprise cash and cash equivalents as at December 31, 2013 and December 31, 2012 (see Note 16).

**Fair value sensitivity analysis for fixed rate instruments**

The Group does not account for any fixed rate financial liabilities at fair value through profit and loss. Therefore a change in interest rates at December 31, 2013 would not affect profit or loss.

**Cash flow sensitivity analysis for variable rate instruments**

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

A change of 100 basis points in interest rates at the reporting date would have no effect on profit or loss for the period. This assumes that all other variables, in particular foreign currency rates, remain constant.

### Interest rates used for determining fair value

The interest rates used to discount estimated cash flows, where applicable, based on observable market rates plus a premium which reflects the risk profile of the Group at the reporting date, were as follows:

	<i>December 31, 2013</i>	<i>December 31, 2012</i>
Deferred Consideration	3.1%	3.1%

There was no significant difference between the fair value and carrying value of the Group's trade receivables and trade and other payables at December 31, 2013 and December, 31 2012 as all fell due within 6 months.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

*Liquidity risk*

The Group's operations are cash generating. Short-term flexibility is achieved through the management of the Group's short-term deposits.

The following are the contractual maturities of financial liabilities, including estimated interest payments:

<i>As at December 31, 2013</i>	<i>Carrying amount</i>	<i>Contractual cash flows</i>	<i>6 mths or less</i>	<i>6 mths</i>		
				<i>12 mths</i>	<i>1-2 years</i>	<i>2-5 years</i>
<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>
<b><i>Financial liabilities</i></b>						
Trade & other payables	24,727	24,727	20,131		4,596	
	24,727	24,727	20,131		4,596	

<i>As at December 31, 2012</i>	<i>Carrying amount</i>	<i>Contractual cash flows</i>	<i>6 mths or less</i>	<i>6 mths</i>		
				<i>12 mths</i>	<i>1-2 years</i>	<i>2-5 years</i>
<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>
<b><i>Financial liabilities</i></b>						
Trade & other payables	16,142	16,142	11,824		4,318	
	16,142	16,142	11,824		4,318	

*Foreign exchange risk*

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 denominated expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, where considered necessary, the Group pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these Euro forecasted transactions. Forward contracts normally have maturities of less than one year after the balance sheet date. There were no forward contracts in place as at December 31, 2013.

Foreign currency short term financial assets and liabilities which expose the Group to currency risk are disclosed below. The amounts shown are those reported to key management translated into US Dollars at the closing rate:

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

<i>As at 31 December 2013</i>	<i>EUR</i>	<i>GBP</i>	<i>SEK</i>	<i>CAD</i>	<i>Other</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Cash	271	416	6	817	114
Trade and other receivable	2,528	1,193	626	522	172
Trade and other payables	(1,673)	(615)	(789)	(104)	(62)
Total exposure	1,126	994	(157)	1,235	224

<i>As at 31 December 2012</i>	<i>EUR</i>	<i>GBP</i>	<i>SEK</i>	<i>CAD</i>	<i>Other</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Cash	958	135	214		8
Trade and other receivable	1,480	210	202		
Trade and other payables	(1,860)	(45)	(2,117)		(12)
Total exposure	578	300	(1,701)		(4)

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

The Group states its forward exchange contracts at fair value in the balance sheet. The Group classifies its forward exchange contracts as hedging forecasted transactions and thus accounts for them as cash flow hedges. During 2013 and 2012, changes in the fair value of these contracts were recognised in equity and then in the case of contracts which were exercised during 2013 and 2012, the cumulative gain or losses were transferred to the statement of operations.

There were no forward exchange contracts in place at December 31, 2013 or December 31, 2012.

**Sensitivity analysis**

A 10% strengthening of the US Dollar against the following currencies at December 31, 2013 would have increased/ (decreased) profit or loss and other equity by the amounts shown below. This analysis assumes that all other variables, in particular interest rates, remain constant.

	<i>Profit or loss</i>	<i>Other equity movements</i>
	<i>US\$ '000</i>	<i>US\$ '000</i>
<b>December 31, 2013</b>		
Euro	2,429	
<b>December 31, 2012</b>		
Euro	1,325	

A 10% weakening of the US Dollar against the above currencies at December 31, 2013 and December 31, 2012 would have the equal but opposite effect on the above currencies to the amounts shown above, on the basis that all other variables remain constant.

**Credit Risk**

The Group has no significant concentrations of credit risk. Exposure to credit risk is monitored on an ongoing basis. The Group maintains specific provisions for potential credit losses. To date such losses have been within management's expectations. Due to the large number of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

With respect to credit risk arising from the other financial assets of the Group, which comprise cash and cash equivalents and deferred consideration, the Group's exposure to credit risk arises from default of the counter-party, with a maximum exposure equal to the carrying amount of these instruments.

The Group maintains cash and cash equivalents and enters into forward contracts, when necessary, with various financial institutions. The Group performs regular and detailed evaluations of these financial institutions to assess their relative credit standing. The carrying amount reported in the balance sheet for cash and cash equivalents and forward contracts approximate their fair value.

**Exposure to credit risk**

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk is as follows:

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

	<i>Carrying Value</i>	<i>Carrying Value</i>
	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
Third party trade receivables	19,762	12,615
Finance lease income receivable	1,598	1,223
Cash & cash equivalents	22,317	74,947
	43,677	88,785

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

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

	<i>Carrying Value</i>	<i>Carrying Value</i>
	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
United States	12,743	7,971
Euro-zone countries	1,452	1,343
UK	582	262
Other European countries	173	112
Other regions	6,410	4,150
	21,360	13,838

The maximum exposure to credit risk for trade receivables and finance lease income receivable by type of customer is as follows:

	<i>Carrying Value</i>	<i>Carrying Value</i>
	<i>December 31, 2013</i>	<i>December 31, 2012</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>
End-user customers	9,738	5,841
Distributors	10,847	7,657
Non-governmental organisations	775	340
	21,360	13,838

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

**Impairment Losses**

The ageing of trade receivables at December 31, 2013 is as follows:

<i>In thousands of US\$</i>	<i>Gross</i>	<i>Impairment</i>	<i>Gross</i>	<i>Impairment</i>
	<i>2013</i>	<i>2013</i>	<i>2012</i>	<i>2012</i>
Not past due	13,913	2	8,554	30
Past due 0-30 days	3,242	1	2,999	5



Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Past due 31-120 days	1,893	43	573	2
Greater than 120 days	2,864	2,104	2,009	1,483
	21,912	2,150	14,135	1,520

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

<i>In thousands of US\$</i>	2013	2012	2011
Balance at January 1	1,520	1,507	1,443
Charged to costs and expenses	62	72	64
Related to acquisitions	700		
Charged to other accounts			499
Amounts recovered during the year			(86)
Amounts written off during the year	(132)	(59)	(413)
Balance at December 31	2,150	1,520	1,507

The allowance for impairment in respect of trade receivables is used to record impairment losses unless the Group is satisfied that no recovery of the account owing is possible. At this point the amount is considered irrecoverable and is written off against the financial asset directly.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

**Capital Management**

The Group's policy is to maintain a strong capital base so as to maintain investor, creditor and market confidence and to sustain future development of the business. The Board of Directors monitors earnings per share as a measure of performance, which the Group defines as profit after tax divided by the weighted average number of shares in issue.

Following the divestiture of the Coagulation product line in 2010, the Group eliminated all bank debt. In the past, the Group has funded acquisitions using both equity and long term debt depending on the size of the acquisition and the capital structure in place at the time of the acquisition.

Although at December 31, 2013 the Group has no debt, it maintains a relationship with a number of lending banks and Trinity Biotech is listed on the NASDAQ which allows the Group to raise funds through equity financing where necessary.

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

the aggregate nominal value of the shares authorised to be acquired shall not exceed 10% of the aggregate nominal value of the issued share capital of the Company at the close of business on the date of the passing of the resolution:

the minimum price (exclusive of taxes and expenses) which may be paid for a share shall be the nominal value of that share:

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

**Fair Values**

The table below sets out the Group's classification of each class of financial assets/liabilities and their fair values:

	<i>Note</i>	<i>Loans and receivables</i>	<i>Liabilities at amortised cost</i>	<i>Total carrying amount</i>	<i>Fair Value</i>
<b>December 31, 2013</b>					
Trade receivables	15	19,762		19,762	19,762
Cash and cash equivalents	16	22,317		22,317	22,317
Finance lease receivable	13, 15	1,598		1,598	1,598
Net Deferred Consideration Payable ( Fiomi )	19, 21		(3,369)	(3,369)	(3,369)
Other Payables	21		(3,055)	(3,055)	(3,055)
Deferred Consideration (Phoenix Bio-tech)	22		(125)	(125)	(125)
Trade and other payables (excluding deferred revenue)	19		(18,034)	(18,034)	(18,034)
Provisions	20		(75)	(75)	(75)

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

43,677 (24,658) 19,019 19,019

At December 31, 2013 consideration payable of US\$3,369,000 and other payables relating to licence fees of US\$3,055,000 are valued using Level 2 inputs. All other items are valued using Level 1 inputs. Valuation methods for Levels 1, 2 and 3 are described in the fair value hierarchy section of the accounting policies, see Note 1(xxvi).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 25. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

	<i>Note</i>	<i>Loans and receivables</i>	<i>Liabilities at amortised cost</i>	<i>Total carrying amount</i>	<i>Fair Value</i>
<b>December 31, 2012</b>					
Trade receivables	15	12,615		12,615	12,615
Cash and cash equivalents	16	74,947		74,947	74,947
Finance lease receivable	13, 15	1,223		1,223	1,223
Net Deferred Consideration Payable ( Fiom )	19, 21		(3,318)	(3,318)	(3,318)
Other Payables	21		(1,000)	(1,000)	(1,000)
Deferred Consideration (Phoenix Bio-tech)	22		(150)	(150)	(150)
Trade and other payables (excluding deferred revenue)	19		(11,574)	(11,574)	(11,574)
Provisions	20		(50)	(50)	(50)
		88,785	(16,092)	72,693	72,693

At December 31, 2012 consideration payable of US\$3,318,000 is valued using Level 2 inputs. All other items are valued using Level 1 inputs. Valuation methods for Levels 1, 2 and 3 are described in the fair value hierarchy section of the accounting policies, see Note 1(xxvi).

## 26. DIVIDENDS PAID

A dividend of 20 cents per ADS was approved and paid during 2013 in respect of the 2012 financial year (15 cents per ADS approved and paid in 2012 in respect of the 2011 financial year).

	2013 US\$ '000	2012 US\$ '000
<b>Declared and paid during the year:</b>		
Dividends on ordinary shares:		
Final dividend in respect of FY 2013: US\$0.05 per A share (US\$0.20 per ADS) (FY 2012: US\$0.15).	<b>4,373</b>	<b>3,224</b>

The dividend payable in respect of the 2013 financial year will be proposed by the Directors prior to the next AGM, to be held in June 2014.

## 27. POST BALANCE SHEET 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.

## **Table of Contents**

### **NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

#### **28. ACCOUNTING ESTIMATES AND JUDGEMENTS**

The preparation of these financial statements requires the Group to make estimates and judgements that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities.

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

#### **Key sources of estimation uncertainty**

Note 11 contains information about the assumptions and the risk factors relating to goodwill impairment. Note 18 outlines information regarding the valuation of share options and warrants. Note 22 outlines the valuation techniques used by the Company in determining the fair value of business combinations. In Note 25, detailed analysis is given about the interest rate risk, credit risk, liquidity risk and foreign exchange risk of the Group.

#### **Critical accounting judgements in applying the Group's accounting policies**

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

##### *Research and development expenditure*

Under IFRS as adopted by the EU, 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 commercial production starts.

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

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

##### *Impairment of intangible assets and goodwill*

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment annually, individually or at the cash generating unit level.

Factors considered important, as part of an impairment review, include the following:

Significant underperformance relative to expected historical or projected future operating results;

## Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

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.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2013**

28. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

*Allowance for slow-moving and obsolete inventory*

We evaluate the realisability of our inventory on a case-by-case basis and make adjustments to our inventory provision based on our estimates of expected losses. We write-off any inventory that is approaching its use-by date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value.

*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.

*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. In management's opinion, adequate provisions for income taxes have been made.

Deferred tax assets and liabilities are determined for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities, using tax rates projected to be in effect for the year in which the differences are expected to reverse. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing whether deferred tax assets can be recognised, there is no assurance that these deferred tax assets may be realisable. The extent to which recognised deferred tax assets are not realisable could have a material adverse impact on our income tax provision and net income in the period in which such determination is made.

Note 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 derecognised deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilized before they expire. The derecognition of these deferred tax assets was considered appropriate in light of the increased tax losses caused by the restructuring and uncertainty over the timing of the utilization of the tax losses. Except for the derecognition of deferred tax assets there were no material changes in estimates used to calculate the income tax expense provision during 2013, 2012 or 2011.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 29. GROUP UNDERTAKINGS

The consolidated financial statements include the financial statements of Trinity Biotech plc and the following principal subsidiary undertakings:

<i>Name and registered office</i>	<i>Principal activity</i>	<i>Principal Country of incorporation and operation</i>	<i>Group % holding Holding company</i>
Trinity Biotech plc  IDA Business Park, Bray  Co. Wicklow, Ireland	Investment and holding company	Ireland	
Trinity Biotech Manufacturing Limited  IDA Business Park, Bray  Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland	100%
Trinity Research Limited  IDA Business Park, Bray  Co. Wicklow, Ireland	Research and development	Ireland	100%
Benen Trading Limited  IDA Business Park, Bray  Co. Wicklow, Ireland	Trading	Ireland	100%
Trinity Biotech Manufacturing Services Limited  IDA Business Park, Bray  Co. Wicklow, Ireland	Engineering services	Ireland	100%
Trinity Biotech Luxembourg Sarl  49, route d Arlon,  L-1140 Luxembourg	Investment and provision of financial services	Luxembourg	100%
Trinity Biotech Inc  Girts Road,  Jamestown,  NY 14702, USA	Holding Company	U.S.A.	100%

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Clark Laboratories Inc	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Trading as Trinity Biotech (USA)			
Girts Road, Jamestown			
NY14702, USA			
Mardx Diagnostics Inc	Manufacture and sale of diagnostic test kits	U.S.A.	100%
5919 Farnsworth Court			
Carlsbad			
CA 92008, USA			
Fitzgerald Industries International, Inc	Management services company	U.S.A.	100%
2711 Centerville Road, Suite 400			
Wilmington, New Castle			
Delaware, 19808, USA			
Biopool US Inc (trading as Trinity Biotech	Sale of diagnostic test kits	U.S.A.	100%
Distribution)			
Girts Road, Jamestown			
NY14702, USA			
Primus Corporation	Manufacture and sale of diagnostic test kits and instrumentation	U.S.A.	100%
4231 E 75 <sup>th</sup> Terrace			
Kansas City,			
MO 64132, USA			

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****DECEMBER 31, 2013**

## 29. GROUP UNDERTAKINGS (CONTINUED)

<i>Name and registered office</i>	<i>Principal activity</i>	<i>Principal Country of incorporation and operation</i>	<i>Group % holding</i>
Phoenix Bio-tech Corp.  1166 South Service Road West  Oakville, ON L6L 5T7  Canada.	Manufacture and sale of diagnostic test kits	Canada	100%
Fioni Diagnostics Holding AB  Dag Hammarskjöldsv 52A  SE-752 37 Uppsala  Sweden	Holding Company	Sweden	100%
Fioni Diagnostics AB  Dag Hammarskjöldsv 52A  SE-752 37 Uppsala  Sweden	Research and development	Sweden	100%
Trinity Biotech Do Brasil  Rua Claudio Soares  Sao Paulo  Brazil	Sale of diagnostic test kits	Brazil	100%
Trinity Biotech (UK) Ltd  184 Cambridge Science Park  Cambridge CB4 0GA  United Kingdom  (Incorporated July 11, 2013)	Manufacture of blood bank screening products	UK	100%
Immco Diagnostics Inc	Manufacture and sale of autoimmune products	U.S.A.	100%

60 Pineview Drive

Buffalo

NY 14228, USA

(Acquired July 26, 2013)

Nova Century Scientific Inc

Manufacture and sale of  
autoimmune products

Canada

100%

5022 South Service Road

Burlington

Ontario

Canada

(Acquired July 26, 2013)

30. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on April 9, 2014.

**Table of Contents**

*Signatures*

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

TRINITY BIOTECH PLC

By: /s/ RONAN O CAOIMH  
Mr Ronan O Caoimh  
Director/  
Chief Executive Officer

Date: April 9, 2014

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

Date: April 9, 2014

**Table of Contents**

**Item 19 Exhibits**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
4.1	Agreement and Plan of Merger dated as of July 26, 2013 with Immco Diagnostics, Inc.
4.2	Fiomi Diagnostics AB Share Purchase Agreement (incorporated by reference to Exhibit 4(a) of Trinity Biotech Plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2011).
10(c)	Purchase and Sale Agreement of the Diagnostic Coagulation Business (incorporated by reference to Exhibit 10c of Trinity Biotech Plc s Annual Report on Form 20-F for the fiscal year ended December 31, 2010).
12.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
12.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
13.1	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm (GT)