TRINITY BIOTECH PLC
Form 20-F
April 06, 2012

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, 2011

OR

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

For the transition period from to

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

Date of event requiring this shell company report

Commission file number: 0-22320

Trinity Biotech plc

(Exact name of Registrant as specified in its charter

and translation of Registrant s name into English)

Ireland

(Jurisdiction of incorporation or organization)

IDA Business Park, Bray, Co. Wicklow, Ireland

(Address of principal executive offices)

Kevin Tansley

Chief Financial Officer

Tel: +353 1276 9800

Fax: +353 1276 9888

IDA Business Park, Bray, Co. Wicklow, Ireland

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Name of each exchange on which registered
None	**None**

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:

85,321,081 Class A Ordinary Shares and 700,000 Class B Shares

(as of December 31, 2011)

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

Yes ¨ No x

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

Yes ¨ No x

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

Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

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

U.S. GAAP ¨ **International Financial Reporting Standards as issued by the International Accounting Standards Board** x **Other** ¨

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

Item 17 ¨ Item 18 ¨

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

Yes ¨ No x

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

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General

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

Our financial statements are presented in US Dollars and are prepared in accordance with International Financial Reporting Standards (IFRS) both as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union (EU). The IFRS applied are those effective for accounting periods beginning on or after 1 January 2011. 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 , wi 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, 2011 and 2010 and for each of the years ended December 31, 2011, 2010 and 2009 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, 2009, 2008 and 2007 and for the years ended December 31, 2008 and December 31, 2007 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December, 31				
	2011 Total	*2010 Total*	*2009 Total*	*2008 Total*	*2007 Total*
	US$ 000	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Revenues	**77,948**	**89,635**	**125,907**	**140,139**	**143,617**
Cost of sales	(37,820)	(45,690)	(68,891)	(77,645)	(75,643)
Cost of sales restructuring expenses					(953)
Cost of sales inventory write off / provision					(11,772)
Total cost of sales	**(37,820)**	**(45,690)**	**(68,891)**	**(77,645)**	**(88,368)**
Gross profit	**40,128**	**43,945**	**57,016**	**62,494**	**55,249**
Other operating income	910	1,616	437	1,173	413
Research and development expenses	(3,206)	(4,603)	(7,341)	(7,544)	(6,802)
Research and development restructuring expenses					(6,907)
Total research and development expenses	**(3,206)**	**(4,603)**	**(7,341)**	**(7,544)**	**(13,709)**
Selling, general and administrative expenses	(22,048)	(26,929)	(36,013)	(47,816)	(51,010)
Selling, general and administrative impairment charges and restructuring expenses				(87,882)	(20,315)
Total selling, general and administrative expenses	**(22,048)**	**(26,929)**	**(36,013)**	**(135,698)**	**(71,325)**
Net gain on divestment of business and restructuring expenses		**46,474**			
Operating profit/(loss)	**15,784**	**60,503**	**14,099**	**(79,575)**	**(29,372)**
Financial income	2,428	1,352	8	65	457
Financial expenses	(12)	(495)	(1,192)	(2,160)	(3,148)
Net financing income/(costs)	**2,416**	**857**	**(1,184)**	**(2,095)**	**(2,691)**
Profit/(loss) before tax	**18,200**	**61,360**	**12,915**	**(81,670)**	**(32,063)**
Income tax (expense)/ credit	(2,607)	(942)	(1,091)	3,892	(3,309)
Profit/(loss) for the year (all attributable to owners of the parent)	**15,593**	**60,418**	**11,824**	**(77,778)**	**(35,372)**
Basic earnings/(loss) per ADS (US Dollars)	0.73	2.85	0.57	(3.82)	(1.86)
Diluted earnings/(loss) per ADS (US Dollars)	0.70	2.79	0.57	(3.82)	(1.86)
Basic earnings/(loss) per A ordinary share (US Dollars)	0.18	0.71	0.14	(0.96)	(0.47)
Diluted earnings/(loss) per A ordinary share (US Dollars)	0.18	0.70	0.14	(0.96)	(0.47)
Basic earnings/(loss) per B ordinary share (US Dollars)	0.37	1.43	0.28	(1.91)	(0.94)
Diluted earnings/(loss) per B ordinary share (US Dollars)	0.35	1.39	0.28	(1.91)	(0.94)
Weighted average number of shares used in computing basic EPS per A ordinary share	85,171,494	84,734,378	83,737,884	81,394,075	76,036,579
Weighted average number of shares used in computing diluted EPS per A ordinary share	88,912,596	86,661,535	83,772,094	81,394,075	76,036,579

Consolidated Balance Sheet Data	*December 31, 2011*	*December 31, 2010*	*December 31, 2009*	*December 31, 2008*	*December 31, 2007*
	US$ 000	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Net current assets (current assets less current liabilities)	101,684	89,068	42,835	39,494	36,298
Non-current liabilities	(6,838)	(7,331)	(27,500)	(27,897)	(35,623)
Total assets	171,499	160,874	132,445	129,509	215,979
Capital stock	1,106	1,092	1,080	1,070	991
Shareholders equity	151,332	141,287	79,344	65,905	136,845

No dividends were declared in any of the periods from December 31, 2007 to December 31, 2009. A final dividend of 10 cents per ADS was paid in 2011 in respect of the financial year 2010. The dividend payable in respect of the 2011 financial year will be proposed by the Directors prior to the next AGM, to be held in May 2012.

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, Enzygnost®), 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 licenses or proprietary or patented technologies in the future.

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 market conditions.

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 75 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.

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 5 US patents with remaining patent lives varying from three years to 11 years. In addition to these US patents, Trinity Biotech owns a total of 4 additional non-US patents with expiration dates varying between the years 2012 and 2023.

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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$8,416,000) for any one accident, limited to a maximum of 6,500,000 (US$8,416,000) 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, Jamestown, New York, Kansas City, Missouri and Carlsbad, California comprised approximately 84% of revenues in 2011. 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, 2011 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.

We could be adversely affected by healthcare reform legislation.

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. The Patient Protection and Affordable Care Act, enacted in 2010, imposes a new 2.3% excise tax on medical device makers beginning in 2013, which could have a material negative impact on our results of operations and our cash flows. 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. Other elements of this 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. Current 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 are 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.

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

The warrants issued in 2008 and 2010 and the total share options exercisable at December 2011, as described in Item 18, Note 19 to the consolidated financial statements, are convertible into American Depository 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 5,085,431 A Ordinary shares (1,271,357 ADSs) exercisable at December 31, 2011 be exercised, Trinity Biotech would have to issue 5,085,431 additional A ordinary shares (1,271,357 ADSs). On the basis of 85,321,081 A ordinary shares outstanding at December 31, 2011, this would effectively dilute the ownership interest of the existing shareholders by approximately 6%.

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

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 over 75 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 364 people worldwide and markets its portfolio of over 275 products to customers in 75 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 Jamestown, New York, Carlsbad, California and Kansas City, Missouri in the USA.

In April 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 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 following the sale.

The following represents the acquisitions made by Trinity Biotech in recent years.

Acquisition of Phoenix Bio-tech Corp.

In January 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation for US$2,500,000 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 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 USA. For more information please refer to Item 18, Note 24.

Acquisition of the immuno-technology business of Cortex Biochem Inc

In September 2007, the Group acquired the immuno-technology business of Cortex Biochem Inc (Cortex) for a total consideration of US$2,925,000, consisting of cash consideration of US$2,887,000 and acquisition expenses of US$38,000.

Acquisition of certain components of the distribution business of Sterilab Services UK

In October 2007, the Group acquired certain components of the distribution business of Sterilab Services UK (Sterilab), a distributor of Infectious Diseases products, for a total consideration of US$1,489,000, consisting of cash consideration of US$1,480,000 and acquisition expenses of US$9,000.

Principal Markets

The primary market for Trinity Biotech s tests remains the Americas. During fiscal year 2011, the Group sold 66% (US$51.4 million) (2010: 60% or US$54.0 million) (2009: 54% or US$68.1 million) of product in the Americas. Sales to non-Americas (principally European and Asian/ African) countries represented 34% (US$26.5 million) for fiscal year 2011 (2010: 40% or US$35.6 million) (2009: 46% or US$57.8 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.

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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	Infectious Disease	Clinical Laboratory HbA1c + Hb Variant	Clinical Chemistry
UniGold	Bartels®	Premier	EZ
Recombigen®	Captia	Ultra2TM	
	MarDx®		
	MarBlot®		
	MicroTrak		

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 USA and through our network of principal distributor partners into approximately 75 countries in the rest of the world.

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 counseling 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 recognized for its quality and reliability. These same factors are the springboard in some countries for national testing algorithm changes in favour of wider usage of UniGold HIV.

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.

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 company has already invested in establishing 3 product development teams in the USA and Ireland to provide a product pipeline for future growth. In phase one, the areas of development focus include rapid tests for:

Sexually transmitted diseases: Building on the existing success with HIV, the products will include rapid tests for Syphilis, Herpes simplex (HSV) 2 and HIV combination assay (1 & 2 + Antigen);

Enteric pathogens: Separate products for Clostridium toxin A&B, Giardia and Cryptosporidium; and

Respiratory pathogens: Flu A&B, Streptococcus pneumonia.

Clinical Laboratory

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

Infectious diseases: bacterial and viral diseases and autoimmune disorders;

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

Clinical Chemistry: Liver & kidney disease and haemolytic anaemia.

Infectious Diseases

Trinity Biotech manufactures products for niche/specialized applications in Infectious Disease and Autoimmune disorders. 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, (3) Respiratory infections: Legionella, Flu A&B, (4) Epstein Barr Virus, (5) other viral pathogens, e.g. Measles, Mumps, Rubella and Varicella and (6) Autoimmune disorders (e.g. lupus, celiac and rheumatoid arthritis).

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 over 75 countries, with the focus on North America, Europe and Asia.

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 Hemoglobinapothies. Primus manufactures a range of instrumentation using patented HPLC (high pressure liquid chromatography) technology.

HbA1c: These products are the most accurate and precise methods available for detection and monitoring the patient status and overall glycemic control.

Haemoglobin Variants: The Primus Ultra^2 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^2 is unparalleled in the number of different variants it is able to detect.

Neonatal Haemoglobin: The most recent addition, the GeneSys system, designed for assay and detection of Haemoglobin variants in neo-natal screening, addresses the largest segment of this niche area, i.e. the reference laboratories (responsible for state-wide screening of newborns).

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 distribution in other countries.

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. Commercial activities have also started in Brazil, Russia, India and China (BRIC Countries) as well as other emerging economies. The Premier s unique features, cost structure and core technology enables it to compete in most economies and settings.

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.

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, Primus 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 75 countries.

Competition

The diagnostic industry is very competitive. There are many companies, both public and private, engaged in the sale of medical diagnostic products and diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. Innovation in the market is rare but significant advantage can be made with the introduction of new disease markers or innovative techniques with patent protection. The Group s competition includes several large companies such as, but not limited to: Abbott Diagnostics, Alere Inc., Arkray, Bio-Rad, Diasorin Inc., Johnson & Johnson, OraSure Technologies Inc., Roche Diagnostics, Siemens (from the combined acquisitions of Bayer, Beckman Coulter, Dade-Behring and DPC), Thermo Fisher and Tosoh.

Patents and Licences

Patents

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

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

Licences

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

In 2005 Trinity Biotech obtained a license 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 license 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 2011 was US$800,000 (2010: US$1,233,000).

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 66% of Trinity Biotech s 2011 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, labeling, storage, pre-market clearance or approval, advertising and promotion and sales and distribution.

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 2011 is in the region of US$220,000.

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 labeling. 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 an Investigational Device Exemption (IDE) 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.

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 Trinity Biotech Manufacturing Limited, based in Bray, Ireland and at Trinity Biotech (USA), MarDx Diagnostics Inc, Primus Corporation and Biopool US Inc. based in Jamestown, New York, Carlsbad, California, Kansas City, Missouri and Jamestown, New York, USA respectively. 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 31 to the consolidated financial statements.

Property, Plant and Equipment

Trinity Biotech has four manufacturing sites worldwide, three in the US (Jamestown, NY, Kansas City, MO and Carlsbad, CA) and one in Bray, Ireland. 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 an 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 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$493,000), 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 rate of 17.94 per square foot (including fit out) giving a total annual rent of 787,000 (US$1,019,000). 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 upstate New York at an annual rental charge of US$139,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,436 square feet and is the subject of a five year lease, renewed in 2009, at an annual rental cost of US$257,000. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, amended in 2009, at an annual rental cost of US$173,000.

Additional office space is leased by the Group in Ireland, Kansas City, Missouri and Acton, Massachusetts at an annual cost of 115,000 (US$149,000), US$100,000 and US$86,000 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, Immunoflourescence and Clinical Chemistry products are manufactured at this site.

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

Carlsbad, California this facility specializes in the development and manufacture of products utilizing Western Blot technology. Our Lyme suite of products is manufactured at this facility. Our new Point-of-Care range will be manufactured at this site.

Kansas City, Missouri this site is responsible for the manufacture of the Group s A1c range of 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 24 with regard to the acquisition of Phoenix Bio-tech Corp. in 2011 and to Item 18, Note 3 concerning the divestiture of the Coagulation product line during 2010.

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, 2011, December 31, 2010 and December 31, 2009, 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, 2011 as Trinity Biotech is a foreign private issuer and 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).

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 over 275 different diagnostic products in approximately 75 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.

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, 2011, 2010, 2009, 2008 and 2007 have been impacted by acquisitions made by the Group in two of the five years and by the divestiture of the Coagulation product line in 2010. There were no acquisitions made in 2010, 2009 or 2008. 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. In 2007, the Group acquired the immuno-technology assets of Cortex and certain components of the distribution business of Sterilab.

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 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.

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.

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.

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At December 31, 2011 the carrying value of capitalised development costs was US$16,630,000 (2010: US$10,073,000) (see Item 18, Note 12 to the consolidated financial statements). The increase in 2011 was as a result of development costs of US$6,829,000 being capitalised in 2011 which were partially offset by amortisation of US$272,000.

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, 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.

The recoverable amount of goodwill and intangible assets contained in each of the Group s CGU s is determined based on the greater of the fair value less cost to sell and value in use calculations. The Group operates in one market sector (namely diagnostics) and accordingly the key assumptions are similar for all CGU s. The value in use calculations use cash flow projections based on the 2012 budget and projections for a further four years using projected revenue and cost growth rates of between 3% and 10%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate are used in the value in use calculations. The cashflows and terminal values for the CGU s are discounted using pre-tax discount rates which range from 18% to 33%.

The value in use calculation is subject to significant estimation, uncertainty and accounting judgements and are particularly sensitive in the following areas. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2011:

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

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

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, 2011:

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

No impairment loss or reversal of impairment 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 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. 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 2009, 2010 or 2011 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2011 our allowance for slow moving and obsolete inventory was US$5,930,000 which represents approximately 23.0% of gross inventory value. This compares with US$6,400,000, or approximately 26.7% of gross inventory value, at December 31, 2010 (see Item 18, Note 15 to the consolidated financial statements) and US$12,566,000, or approximately 24.3% of gross inventory value, at December 31, 2009. There has been a small decrease in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2011 and 2010. 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$515,000 at December 31, 2011 (2010: US$480,000) (2009: US$1,035,000) 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 2011 or 2010 which would have an impact on the carrying values of receivables in these periods. At December 31, 2011, the allowance was US$1,507,000 which represents approximately 1.9% of Group revenues. This compares with US$1,443,000 at December 31, 2010 which represents approximately 1.6% of Group revenues (see Item 18, Note 16 to the consolidated financial statements) and to US$855,000 at December 31, 2009 which represents approximately 0.7% of Group revenues. In the event that this estimate was to increase or decrease by 0.4% of Group revenues, which would represent a reasonably likely range of outcomes, then a change in the allowance of US$312,000 at December 31, 2011 (2010: US$359,000) (2009: US$504,000) would result.

Accounting for income taxes

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

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

Item 18, Note 13 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and includes details of the unrecognized deferred tax assets at year end. The Group does not recognize 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). The IFRS applied are those effective for accounting periods beginning on or after 1 January 2011. 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 2011, 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(z).

Subsequent Events

Acquisition of Fiomi Diagnostics AB

In Quarter 1 of 2012, the Group purchased 100% of the common stock of Fiomi Diagnostics AB for a total consideration of US$13.1 million (including US$3.4m of contingent payments). Fiomi, which is based in Uppsala, Sweden, is at an advanced stage in developing a panel of Point-of-Care cardiac marker assays.

This acquisition has not been reflected in the financial statements for the year ended December 31, 2011 as it was completed subsequent to the financial year end. The fair values of the acquired assets and liabilities have not been established yet.

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.

As the initial accounting and fair value assessment for the business combination is incomplete at the time that these financial statements were authorised for issue, the following disclosures cannot be made but will be reported if relevant in the Form 20-F for the period ended December 31, 2012:

A qualitative description of the factors that make up the goodwill to be recognised,

Details of the indemnification assets,

Details of acquired receivables,

The amounts recognised as of the acquisition date for each major class of asset acquired and liability assumed,

Details of contingent liabilities recognised; and

The total amount of goodwill that is expected to be deductible for tax purposes.

Results of Operations

Year ended December 31, 2011 compared to the year ended December 31, 2010

The following compares our results in the year ended December 31, 2011 to those of the year ended December 31, 2010 under IFRS. Our analysis is divided as follows:

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

1. Overview

In 2011, revenues decreased by US$11.7 million to US$77.9 million due to the Coagulation product line being divested in 2010. Excluding Coagulation revenues, revenues increased by US$4.1 million in 2011, representing an increase of 4% in total, comprising growth of 3% in Point-of-Care revenues and 6% in Clinical Laboratory revenues.

Geographically, 66% of our sales were generated in the Americas, 22% in Africa/Asia and 12% in Europe.

The gross margin is 51.5% for 2011, which is 2.5% higher than the gross margin for 2010. The improved gross margin in 2011 primarily reflected the divestiture of the Coagulation product line, which was historically the Group s product line with the lowest gross margin. Other reasons for the improvement in gross margin are better operating efficiencies and increased leverage of our manufacturing cost base as continuing revenues have risen compared to 2010.

The divestiture of the Coagulation product line resulted in a once-off gain in 2010 of US$46.8 million.

The table hereunder compares the profit before tax for year ended December, 2011 to the previous financial year.