# SECURITIES AND EXCHANGE COMMISSION

**Washington D.C. 20549**

# FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

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

**For the fiscal year ended December 31, 2012**

**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:

**88,994,069 Class 'A' Ordinary Shares**
(as of December 31, 2012)

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 by the International Accounting Standards Board ☒ Other ☐

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. 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.

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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 2012. 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, 2012 and 2011 and for each of the years ended December 31, 2012, 2011 and 2010 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, 2010, 2009 and 2008 and for the years ended December 31, 2009 and December 31, 2008 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* | | | | |
|---|---|---|---|---|---|
| | *2012 Total US$'000* | *2011 Total US$'000* | *2010 Total US$'000* | *2009 Total US$'000* | *2008 Total US$'000* |
| **Revenues** | **82,510** | **77,948** | **89,635** | **125,907** | **140,139** |
| Cost of sales | (40,257) | (37,820) | (45,690) | (68,891) | (77,645) |
| **Gross profit** | **42,253** | **40,128** | **43,945** | **57,016** | **62,494** |
| Other operating income | 468 | 910 | 1,616 | 437 | 1,173 |
| Research and development expenses | (3,130) | (3,206) | (4,603) | (7,341) | (7,544) |
| **Total research and development expenses** | **(3,130)** | **(3,206)** | **(4,603)** | **(7,341)** | **(7,544)** |
| Selling, general and administrative expenses | (22,425) | (22,048) | (26,929) | (36,013) | (47,816) |
| Selling, general and administrative – impairment charges and restructuring expenses | — | — | — | — | (87,882) |
| **Total selling, general and administrative expenses** | **(22,425)** | **(22,048)** | **(26,929)** | **(36,013)** | **(135,698)** |
| Net gain on divestment of business and restructuring expenses | **—** | **—** | **46,474** | **—** | **—** |
| **Operating profit/(loss)** | **17,166** | **15,784** | **60,503** | **14,099** | **(79,575)** |
| Financial income | 2,280 | 2,428 | 1,352 | 8 | 65 |
| Financial expenses | (88) | (12) | (495) | (1,192) | (2,160) |
| **Net financing income/(costs)** | **2,192** | **2,416** | **857** | **(1,184)** | **(2,095)** |
| **Profit/(loss) before tax** | **19,358** | **18,200** | **61,360** | **12,915** | **(81,670)** |
| Income tax (expense)/ credit | (2,017) | (2,607) | (942) | (1,091) | 3,892 |
| **Profit/(loss) for the year (all attributable to owners of the parent)** | **17,341** | **15,593** | **60,418** | **11,824** | **(77,778)** |
| Basic earnings/(loss) per ADS (US Dollars) | 0.81 | 0.73 | 2.85 | 0.57 | (3.82) |
| Diluted earnings/(loss) per ADS (US Dollars) | 0.77 | 0.70 | 2.79 | 0.57 | (3.82) |
| Basic earnings/(loss) per 'A' ordinary share (US Dollars) | 0.20 | 0.18 | 0.71 | 0.14 | (0.96) |
| Diluted earnings/(loss) per 'A' ordinary share (US Dollars) | 0.19 | 0.18 | 0.70 | 0.14 | (0.96) |
| Weighted average number of shares used in computing basic EPS per 'A' ordinary share | 85,675,284 | 85,171,494 | 84,734,378 | 83,737,884 | 81,394,075 |
| Weighted average number of shares used in computing diluted EPS per 'A' ordinary share | 89,773,616 | 88,912,596 | 86,661,535 | 83,772,094 | 81,394,075 |

***Consolidated Balance Sheet Data***

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* | *December 31, 2009 US$'000* | *December 31, 2008 US$'000* |
|---|---|---|---|---|---|
| Net current assets (current assets less current liabilities) | 97,531 | 101,684 | 89,068 | 42,835 | 39,494 |
| Non-current liabilities | (15,061) | (6,838) | (7,331) | (27,500) | (27,897) |
| Total assets | 197,407 | 171,499 | 160,874 | 132,445 | 129,509 |
| Capital stock | 1,134 | 1,106 | 1,092 | 1,080 | 1,070 |
| Shareholders' equity | 169,380 | 151,332 | 141,287 | 79,344 | 65,905 |

No dividends were declared in either of the periods ended December 31, 2008 or December 31, 2009. A final dividend of 15 cents per ADS was paid in 2012 in respect of the financial year 2011 (10 cents per ADS paid in 2011 in respect of the financial year 2010). The dividend payable in respect of the 2012 financial year will be proposed by the Directors prior to the next AGM, to be held in May 2013.

## *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.

***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 license 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.

***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 two years to 10 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$8,576,000) for any one accident, limited to a maximum of €6,500,000 (US$8,576,000) 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 83% of revenues in 2012. 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, 2012 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.***

- 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. At the present time it is believed that little, if any, of this cost can be passed on to customers.
- 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. 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. Since the acquisition of Fiomi Diagnostics AB in February 2012, the Group also has a currency exposure to the Swedish Krona.

***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 2012, 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 4,389,052 'A' Ordinary shares (1,097,263 ADSs) exercisable at December 31, 2012 be exercised, Trinity Biotech would have to issue 4,389,052 additional 'A' ordinary shares (1,097,263 ADSs). On the basis of 88,994,069 'A' ordinary shares outstanding at December 31, 2012, this would effectively dilute the ownership interest of the existing shareholders by approximately 5%.

***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 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 394 people worldwide and markets its portfolio of over 278 products to customers in 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 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 Fiomi Diagnostics AB*

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

Fiomi, which is based in Uppsala, Sweden, is 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. For more information please refer to Item 18, Note 24.

*Acquisition of Phoenix Bio-tech Corp.*

In January 2011, the Group acquired 100% of the common stock of Phoenix Bio-tech Corporation for US$2.5 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 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.

### *Principal Markets*

The primary market for Trinity Biotech's tests remains the Americas. During fiscal year 2012, the Group sold 60% (US$49.6 million) (2011: 66% or US$51.4 million) (2010: 60% or US$54.0 million) of product in the Americas. Sales to non-Americas (principally European and Asian/ African) countries represented 40% (US$32.9 million) for fiscal year 2012 (2011: 34% or US$26.5 million) (2010: 40% or US$35.6 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:

| | Clinical Laboratory | | |
|---|---|---|---|
| **Point-Of-Care** | **Infectious Disease** | **HbA1c + Hb Variant** | **Clinical Chemistry** |
| UniGold™ | Bartels® | Premier™ | EZ™ |
| Recombigen® | Captia™ | Ultra$^{2}$™ | |
| | 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 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 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.

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 pneumoniae.

***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 virus (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 110 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 performance 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 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.

*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, 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.

***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 2012 was US$1,145,000 (2011: US$800,000).

***Government Regulation***

The preclinical and clinical testing, manufacture, labeling, 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 2012 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 2012 is in the region of US$62,000.

*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 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.

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, Biopool US Inc. and Fiomi Diagnostics AB based in Jamestown, New York, Carlsbad, California, Kansas City, Missouri, Jamestown, New York, USA and Uppsala, Sweden 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$503,000), 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$1,038,000). 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$144,000.

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 2012, at an annual rental cost of US$245,000. 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$174,000.

Fiomi Diagnostics AB operates from a 12,500 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 2,000,000 SEK (US$307,000).

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$28,000 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 Fiomi Diagnostics AB in 2012, 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, 2012, December 31, 2011 and December 31, 2010, 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, 2012 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 278 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.

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, 2012, 2011, 2010, 2009 and 2008 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 2012, the Group acquired 100% of the common stock of Fiomi Diagnostics AB. Fiomi is at an advanced stage in 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 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.

At December 31, 2012 the carrying value of capitalised development costs was US$33,704,000 (2011: US$16,630,000) (see Item 18, Note 12 to the consolidated financial statements). The increase in 2012 was as a result of two factors: (1) development costs of US$13,064,000 being capitalised and (2) additions to development costs through business combinations of US$4,348,000. These additions were partially offset by amortisation of US$338,000.

*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.

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

The value-in-use calculations at December 31, 2012 used cash flow projections based on the 2013 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 15% to 27% (2011: 18% to 33%).

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2012:

- 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, 2012:

- 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 2010, 2011 or 2012 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2012 our allowance for slow moving and obsolete inventory was US$5,348,000 which represents approximately 20.5% of gross inventory value. This compares with US$5,930,000, or approximately 23.0% of gross inventory value, at December 31, 2011 (see Item 18, Note 15 to the consolidated financial statements) and US$6,400,000, or approximately 26.7% of gross inventory value, at December 31, 2010. There has been a small decrease in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2012 and 2011. 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$522,000 at December 31, 2012 (2011: US$515,000) (2010: US$480,000) 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 2012 or 2011 which would have an impact on the carrying values of receivables in these periods. At December 31, 2012, the allowance was US$1,520,000 which represents approximately 1.8% of Group revenues. This compares with US$1,507,000 at December 31, 2011 which represented approximately 1.9% of Group revenues (see Item 18, Note 16 to the consolidated financial statements) and to US$1,443,000 at December 31, 2010 which represented approximately 1.6% 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$330,000 at December 31, 2012 (2011: US$312,000) (2010: US$359,000) 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 2012. 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 2012, 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**

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.

***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:*

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

***1. 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 Fiomi Diagnostics, a company based in Sweden which is developing a range of cardiac assays. Fiomi has not yet commenced selling its products.

***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.

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.

*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, 2012 US$'000 | 2011 US$'000 | % Change |
|---|---|---|---|
| **Revenues** | | | |
| **Clinical Laboratory** | 63,356 | 61,386 | 3.2% |
| **Point-of-Care** | 19,154 | 16,562 | 15.7% |
| **Total** | **82,510** | **77,948** | **5.9%** |

*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, 2012 US$'000 | 2011 US$'000 | % Change |
|---|---|---|---|
| **Revenues** | | | |
| Americas | 49,638 | 51,352 | (3.3%) |
| Europe | 10,214 | 9,423 | 8.4% |
| Asia/Africa | 22,658 | 17,173 | 31.9% |
| **Total** | **82,510** | **77,948** | **5.9%** |

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".

***3. Operating Profit***

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

| | Year ended December 31, 2012 US$'000 | 2011 US$'000 | % Change |
|---|---|---|---|
| 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 | **17,166** | **15,784** | **8.8%** |

*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*

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.

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

| | Year ended December 31, 2012 US$'000 | 2011 US$'000 | Increase/(Decrease) 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% |
| **Total** | **22,425** | **22,048** | **377** | **1.7%** |

*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 Fiomi 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 19 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.

***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, | | |
|---|---|---|---|
| | 2012 US$'000 | 2011 US$'000 | % Change |
| 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% |
| Income tax expense | (2,017) | (2,607) | (22.6%) |
| Profit of the year | **17,341** | **15,593** | **11.2%** |

*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 Fiomi 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.

*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 9 and Note 13 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%.

***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:*

5. *Overview*
6. *Revenues*
7. *Operating Profit*
8. *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.

| | Year ended December 31, 2011 US$'000 | 2010 US$'000 | % Change |
|---|---|---|---|
| Profit before Tax | 18,200 | 61,360 | |
| Profit before Tax (2010 figure shown before net gain on divestment of business and restructuring expenses) | 18,200 | 14,886 | 22.3% |

The profit before tax is US$18.2 million for the year ended December 31, 2011 which compares to a profit before tax of US$61.4 million for the year ended December 31, 2010. Excluding the gain on the divestiture of the Coagulation product line and the impact of restructuring expenses in 2010, the profit before tax would have been US$14.9 million in 2010. On a like-for-like basis, there was therefore an increase in profit before tax of 22.3% in 2011. The US$3.3 million increase in profit before tax was due to (a) increased Point-of-Care and Infectious Diseases revenues (b) improved gross margin due to the divestiture of the Coagulation product line and (c) the elimination of bank debt during 2010, causing the net interest income to increase by US$1.6 million in 2011.

The profit after tax for the year ended December 31, 2011 was US$15.6 million which compares to a profit after tax for the year ended December 31, 2010 of US$60.4 million. Excluding the gain on the divestiture of the Coagulation product line and the impact of restructuring expenses in 2010, the profit for 2010 would have been US$13.6 million (representing an increase of 14.7% in 2011).

***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.

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.

*Revenues by Product Line*

Trinity Biotech's revenues for the year ended December 31, 2011 were US$77,948,000 compared to revenues of US$89,635,000 for the year ended December 31, 2010, which represents a decrease of US$11,687,000 or 13%. The following table sets forth selected sales data for each of the periods indicated.

| | Year ended December 31, 2011 US$'000 | 2010 US$'000 | % Change |
|---|---|---|---|
| **Revenues** | | | |
| Clinical Laboratory | 61,386 | 73,553 | (16.5%) |
| Point-of-Care | 16,562 | 16,082 | 3.0% |
| **Total** | **77,948** | **89,635** | **(13.0%)** |

*Clinical Laboratory*

In 2011 Clinical Laboratory revenues decreased by US$12,167,000 which equates to a 16.5% decline. The decrease was due to the divestiture of the Coagulation product line in April 2010. Excluding Coagulation, clinical laboratory revenues increased by US$3.6 million when compared to 2010. This represents an increase of 6.3%.

The increase of 6.3% is attributable to three main factors:

- demand for in vitro diagnostic tests for haemoglobin A1c and haemoglobin variants grew strongly, particularly in the USA. Revenues were also helped by the launch of the new Premier analyzer towards the end of 2011;
- growth in Infectious Diseases revenues, particularly driven by the stronger Lyme season in the USA in 2011 and increased sales of syphilis tests due to the acquisition of Phoenix Bio-tech in quarter 1, 2011; and
- higher sales of our Clinical Chemistry range of products which test for liver and kidney disease and haemolytic anaemia.

These increases were partially offset by a fall in revenues in our Fitzgerald business due to lower influenza antibody sales.

*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$480,000, which represents an increase of 3%. This increase was mainly due to higher 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, 2011 US$'000 | 2010 US$'000 | % Change |
|---|---|---|---|
| **Revenues** | | | |
| Americas | 51,352 | 53,993 | (5%) |
| Europe | 9,423 | 15,890 | (41%) |
| Asia/Africa | 17,173 | 19,752 | (13%) |
| **Total** | **77,948** | **89,635** | **(13%)** |

In the Americas, the 5% decrease amounting to US$2,641,000 is primarily attributable to a reduction in Coagulation revenue due to the divestiture of this product line in April 2010. This reduction was largely offset by strong growth in our Lyme's disease and haemoglobin A1c products.

Revenues in Europe decreased by US$6,467,000, or 41% compared to 2010. The decrease was due to the divestiture of the Coagulation product line in 2010.

Asia/Africa revenues experienced a decline of 13%, or US$2,579,000 compared to 2010. The main reason for this decline was due to the fact that Coagulation sales ceased in April 2010 as a result of the divestiture of the Coagulation product line.

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, 2011 US$'000 | 2010 US$'000 | % Change |
|---|---|---|---|
| Revenues | 77,948 | 89,635 | (13%) |
| Cost of sales | (37,820) | (45,690) | (17%) |
| Gross profit | 40,128 | 43,945 | (9%) |
| Other operating income | 910 | 1,616 | (44%) |
| Research & development | (3,206) | (4,603) | (30%) |
| SG&A expenses | (22,048) | (26,929) | (18%) |
| Net gain on divestment of business and restructuring expenses | — | 46,474 | (100%) |
| Operating profit | **15,784** | **60,503** | **(74%)** |

*Cost of sales*

Total cost of sales decreased by US$7,870,000 from US$45,690,000 for the year ended December 31, 2010 to US$37,820,000, for the year ended December 31, 2011, a decrease of 17%. The main reasons for the decrease in cost of sales in 2011 were the lower revenues following the divestiture of the Coagulation product line and the transfer of approximately 190 Coagulation production employees to Diagnostica Stago in April 2010.

*Gross margin*

The gross margin of 51.5% in 2011 compares to a gross margin of 49.0% in 2010. The increase in gross margin in 2010 is largely attributable to the divestiture of the Coagulation product line, which was the product line with the lowest gross margin.

*Other operating income*

Other operating income comprises income from the provision of services to Diagnostica Stago under a Transition Services Agreement (TSA) and rental income from sublet properties. 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 either during 2010 or in early 2011 and this is the reason for the 44% decrease in other operating income in 2011.

*Research and development expenses*

Research and development ("R&D") expenditure reduced from US$4,603,000 in 2010 to US$3,206,000 in 2011. The decrease was caused by the transfer of approximately 46 Coagulation specialists to Diagnostica Stago in April 2010. 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 decreased by US$4,881,000 from US$26,929,000 for the year ended December 31, 2010 to US$22,048,000 for the year ended December 31, 2011. The decrease is primarily due to the transfer of approximately 85 Coagulation employees and the transfer of our UK, German and French premises to Diagnostica Stago.

*Net gain on divestment of business and restructuring expenses*

In 2010, this comprised the gain on the sale of the worldwide Coagulation product line of US$46.8 million and a charge for restructuring expenses of US$0.3 million. There were no equivalent gains or expenses in 2011. The gain comprised consideration of US$89.9 million less US$43.1 million for Coagulation net assets and other attributable costs such as professional fees. For further information on the divestiture, refer to Item 18, Note 3.

The restructuring expenses related to a re-organisation of the Group's HIV manufacturing activities and comprised termination payments of US$0.3 million for certain employees located in Ireland.

The following table outlines the breakdown of SG&A expenses in 2011 compared to 2010.

| | Year ended December 31, 2011 US$'000 | 2010 US$'000 | (Decrease) US$'000 | % Change |
|---|---|---|---|---|
| SG&A (excl. share-based payments and amortisation) | 19,386 | 24,260 | (4,874) | (20%) |
| Share-based payments | 1,235 | 1,080 | 155 | 14% |
| Amortisation | 1,427 | 1,589 | (162) | (10%) |
| **Total** | **22,048** | **26,929** | **(4,881)** | **(18%)** |

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

SG&A expenses excluding share-based payments and amortisation decreased from US$24,260,000 for the year ended December 31, 2010 to US$19,386,000 for the year ended December 31, 2011, which represents a decrease of 20%.

The decrease this year of US$4,874,000 is mainly due to the following main factors:

- the transfer of 85 of the Group's selling, general and administrative employees to Diagnostica Stago in April 2010. Diagnostica Stago purchased Trinity Biotech's UK, German and French operations employing 43 selling, general and administrative employees. At the same time a further 42 selling, general and administrative employees in Ireland and USA were transferred to Diagnostica Stago;
- in the post-divestiture period, certain SG&A costs associated with the provision of services to Diagnostica Stago under a Transition Services Agreement were eliminated when some of those services were terminated;
- cost saving initiatives in I.T., finance and administration contributed to the overall reduction in SG&A costs;
- these reductions were partially offset by foreign exchange movements as the weakening of the US Dollar against the Euro caused our Irish operation's SG&A costs to increase by approximately 5% compared to 2010.

*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$1,269,000 (2010: US$1,109,000). The increase of US$160,000 in the total share-based payments expense is due to the granting of new share options to employees and directors during 2010 and 2011. The total charge is shown in the following expense headings in the statement of operations: US$34,000 (2010:US$29,000) was charged against cost of sales and US$1,235,000 (2010: US$1,080,000) was charged against selling, general & administrative expenses.

For further details refer to Item 18, Note 19 to the consolidated financial statements.

*Amortisation*

Amortisation reduced from US$1,589,000 for the year ended December 31, 2010 to US$1,427,000 for the year ended December 31, 2011. The decrease of US$162,000 is mainly due to the divestiture of all Coagulation intangible assets in 2010 to Diagnostica Stago partially offset by higher amortisation charges as new products, notably the Premier instrument, were launched.

***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, 2011 US$'000 | 2010 US$'000 | % Change |
|---|---|---|---|
| Operating profit | 15,784 | 60,503 | (74%) |
| Net financing income | 2,416 | 857 | 182% |
| Profit before tax | 18,200 | 61,360 | (70%) |
| Income tax expense | (2,607) | (942) | 177% |
| Profit of the year | 15,593 | 60,418 | (74%) |

*Net Financing income*

Net financing income is US$2,416,000 for year-end December 31, 2011 compared to US$857,000 in 2010. Financial expenses decreased from US$495,000 for year-end December 31, 2010 to US$12,000 in 2011. The decrease is due to the repayment of all bank loans from the proceeds of sale of the Coagulation product line. Financial income increased from US$1,352,000 for year-end December 31, 2010 to US$2,428,000 in 2011 due to the full year effect of the interest income earned on the proceeds of sale of the Coagulation product line.

*Taxation*

The Group recorded a tax charge of US$2,607,000 for the year ended December 31, 2011 compared to US$942,000 for the year ended December 31, 2010. The 2011 tax charge comprises US$1,402,000 of current tax and US$1,205,000 of deferred tax. The increase in the total tax charge in 2011 is primarily due to a higher deferred tax charge. In 2010, the deferred tax charge was reduced significantly by the release of deferred tax liabilities following the sale of the Group's Coagulation property, plant, equipment and intangible assets. The current tax charge has also increased in 2011 mainly due to higher taxable income in our Irish operation. For further details on the Group's tax charge please refer to Item 18, Note 9 and Note 13 to the consolidated financial statements.

*Profit for the year*

The profit for the year amounted to US$15,593,000 which represents a decrease of US$44,825,000 when compared to US$60,418,000 in 2010. Excluding the after tax impact of the gain on the sale of the Coagulation product line of US$47,129,000 and the restructuring expenses of US$301,000, the 2010 profit for the year would be US$13,590,000. The increase in profits in 2011 of US$2,003,000 compared to 2010, excluding once-off gains and expenses, represents an increase of 14.7%.

***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 25(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, 2012, Trinity Biotech's consolidated cash and cash equivalents were US$74,947,000. This compares to cash and cash equivalents of US$71,085,000 at December 31, 2011.

Cash generated from operations for the year ended December 31, 2012 amounted to US$18,822,000 (2011: US$18,772,000), an increase of US$50,000. The increase in cash generated from operations of US$50,000 is attributable to an increase in operating cash flows before changes in working capital of US$2,295,000 being offset to a large degree by increases in working capital outflows of US$2,245,000. The increase in operating cash flows before changes in working capital of US$2,295,000 is primarily driven by the increase in profit during the current financial year. The working capital outflow increase, when compared to the prior year, is primarily due to the effect of the cash outflows for trade and other receivables of US$3,335,000 (mainly due to increased revenues and a slight increase in debtor days). This has been offset partially by cash inflows from inventories, when compared to the prior year, of US$1,035,000 and cash inflows from trade and other payables of US$55,000. The cash generated from operations was attributable to a profit before interest and taxation of US$17,166,000 (2011: US$15,784,000, as adjusted for non cash items of US$5,067,000 (2011: US$4,154,000) plus cash outflows due to changes in working capital of US$3,411,000 (2011: cash outflows of US$1,166,000).

The increase in other non cash charges from US$4,154,000 for the year ended December 31, 2011 to US$5,067,000 for the year ended December 31, 2012 is mainly attributable to the movement in the share based payment charge along with the slight increase in the expense in relation to provisions and other non-cash items.

The net cash outflows in 2012 due to changes in working capital of US$3,411,000 are due to the following:

- An increase in accounts receivable of US$2,059,000 due to the increase in revenues and the increase, year on year, in the debtors days number;
- An increase in inventory of US$1,374,000 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
- A broadly flat trade and other payables balance (increase of US$22,000).

Net interest received amounted to US$2,186,000 (2011: US$2,001,000). This consisted of interest received of US$2,189,000 (2011: US$2,013,000) on the Group's cash deposits and interest payments of US$3,000 (2011: US$12,000) on the Group's finance leases.

Net cash outflows from investing activities for the year ended December 31, 2012 amounted to US$9,960,000 (2011: outflows of US$130,000) which were principally made up as follows:

- Proceeds from the divestiture of the Coagulation product line (deferred consideration payment) of US$11,250,000 (2011: US$11,250,000);
- Payments to acquire intangible assets of US$12,631,000 (2011: US$6,799,000), which principally related to development expenditure capitalised as part of the Group's on-going product development activities;
- Acquisition of property, plant and equipment of US$2,665,000 (2011: US$2,436,000) incurred as part of the Group's investment programme for its manufacturing and distribution activities; and
- Payments made to acquire subsidiary undertakings during the year (net of cash acquired) of US$5,914,000 (2011: US$2,145,000).

Net cash outflows from financing activities for the year ended December 31, 2012 amounted to US$6,193,000 (2011: US$7,247,000). The principal reason for the decrease in outflows in 2012 is due to the fact that the Group purchased fewer Treasury shares during the year when compared to 2011. The main areas of cash outflow from financing activities for the year were the purchase of Treasury Shares for US$5,343,000 (2011: US$6,094,000) and the annual dividend payment of US$3,224,000 (2011: US$2,145,000). Other cash outflows included expenses paid in connection with share issues and debt financing of US$22,000 (2011: US$38,000) and payments in respect of finance lease liabilities of US$109,000 (2011: US$159,000). These outflows were partially offset by the receipt of US$2,505,000 from the issue of ordinary shares in 2012 (2011: US$1,189,000). Ordinary shares issued in 2012 and 2011 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, 2012 there was no interest-bearing debt outstanding (2011: total interest-bearing debt, consisting entirely of finance leases, was US$108,000). Cash and cash equivalents were US$74,947,000 (2011: US$71,085,000). 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, 2012:

| | Payments due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | Total US$'000 | less than 1 year US$'000 | 1-3 Years US$'000 | 3-5 Years US$'000 | more than 5 years US$'000 |
| Operating lease obligations | 30,938 | 2,699 | 4,442 | 3,277 | 20,520 |
| Total | 30,938 | 2,699 | 4,442 | 3,277 | 20,520 |

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 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 26 to the consolidated financial statements.

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

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

During 2012, 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 2012 was US$1,910,000 (2011: US$558,000).

***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.

***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 2012:

| *Product Name* | *2012* *US$'000* | *2011* *US$'000* | *Total project costs to December 31, 2012* *US$'000* |
|---|---|---|---|
| Troponin I assay and reader | *5,048* | — | *5,048* |
| Premier Hb9210 Instrument for Haemoglobin A1c testing | *3,854* | *3,652* | *11,887* |
| Syphilis Rapid Point-of-Care test | *750* | *611* | *1,546* |
| C. Difficile rapid Point-of-Care test | *700* | *171* | *884* |
| Tristat Point-of-Care instrument | *440* | *333* | *4,867* |
| Cryptosporidium rapid Point-of-Care test | *376* | *520* | *916* |
| Giardia rapid Point-of-Care test | *342* | *513* | *883* |
| Strep pneumonia rapid Point-of-Care test | *339* | *194* | *534* |
| Unigold Recombigen HIV Rapid enhancement | *354* | *247* | *2,109* |
| HIV Ag-Ab rapid test | *150* | *421* | *818* |

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 2012. The total estimated completion costs are anticipated to be incurred evenly up to the completion date of the relevant project.

| *Product Name* | *Total costs to complete* *US$'000* | *Estimated date for completion* |
|---|---|---|
| Troponin I assay and reader | *9,700* | *2014* |
| Premier Hb9210 Instrument for Haemoglobin A1c testing* | *5,739* | *2014* |
| HIV Ag-Ab rapid test | *1,000* | *2014* |
| H Pylori Rapid Point-of-Care test | *1,000* | *2013* |
| IgM Captia | *1,000* | *2015* |
| C. Difficile rapid Point-of-Care test | *500* | *2013* |
| Strep pneumonia rapid Point-of-Care test | *400* | *2013* |
| Tristat Point-of-Care instrument | *400* | *2013* |
| Syphilis Rapid Point-of-Care test | *200* | *2013* |

* The Premier instrument was launched in 2011, however, the Premier project is on-going and there will be various enhancements and upgrades including an Ion Exchange version of the instrument.

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.

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 Chromotography (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, therefore eliminating interference from 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,
- 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 and the number of diabetic patients is expected to reach 430 million in 2030. In the U.S. alone some 20.8 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.

During 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 haemogloblin variants. This product is expected to be launched in mid-2013.

**Cardiac Development Group**

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

The company is targeting CE marking this product in late 2013, after which it will be submitted for FDA approval in early 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 early 2014 with submission for FDA approval to follow later that year. The point of care cardiac market is currently estimated to be $900m and is growing rapidly. The vast majority of this market is based on Troponin I and BNP related products.

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", "Liquidity and Capital Resources" and "Impact of Inflation" under Item 5.

## Item 6 *Directors and Senior Management*

### Directors

| *Name* | *Age* | *Title* |
|---|---|---|
| Ronan O'Caoimh | 57 | Chairman and Chief Executive Officer |
| Rory Nealon | 45 | Director, Chief Operations Officer |
| Jim Walsh, PhD | 54 | Director, Chief Scientific Officer |
| Denis R. Burger, PhD | 69 | Non Executive Director |
| Peter Coyne | 53 | Non Executive Director |
| Clint Severson | 64 | Non Executive Director |
| James D. Merselis | 59 | Non Executive Director |
| **Executive Officer** | | |
| Kevin Tansley | 42 | 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.

**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 was previously a director of AIB Corporate Finance and has extensive experience in advising public and private groups on all aspects of corporate strategy. Mr Coyne trained as a chartered accountant and was a senior manager in Arthur Andersen's Corporate Financial Services practice. Mr Coyne holds a Bachelor of Engineering degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

**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 has been a consultant to a range of healthcare companies. Mr Merselis has more than thirty-six years experience in healthcare, with the first twenty-two years at Boehringer Mannheim Diagnostics (now Roche Diagnostics). At Boehringer Mannheim he held a series of increasingly responsible executive positions, including Managing Director of Boehringer Mannheim UK. Mr Merselis has since 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 included: Nexus Dx (now Samsung), Alverix, Inc. and Micronics, Inc. (now SONY).

**Kevin Tansley, Chief Financial Officer**, joined Trinity Biotech in June 2003 and was appointed Chief Financial Officer and Secretary to the Board of Directors in November 2007. Prior to joining Trinity Biotech in 2003, Mr Tansley held a number of financial positions in the Irish electricity utility ESB. Mr Tansley holds a Masters of Accounting from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

### *Compensation of Directors and Officers*

The basis for the executive directors' remuneration and level of annual bonuses is determined by the Remuneration Committee of the board. In all cases, bonuses and the granting of share options are subject to stringent performance criteria. The Remuneration Committee consists of Dr Denis Burger (committee chairman and senior 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, 2012 amounted to US$1,812,000. The pension charge for the year amounted to US$270,000. See Item 18, Note 6 to the consolidated financial statements. The split of directors' remuneration set out by director is detailed in the table below:

| *Executive Director* | *Salary/ Benefits US$'000* | *Performance related bonus US$'000* | *Defined contribution pension US$'000* | *Total 2012 US$'000* | *Total 2011 US$'000* |
|---|---|---|---|---|---|
| Ronan O'Caoimh [1] | 650 | 166 | — | 816 | 881 |
| Rory Nealon | 296 | 100 | 110 | 506 | 576 |
| Jim Walsh | 185 | 115 | 160 | 460 | 448 |
| | 1,131 | 381 | 270 | 1,782 | 1,905 |

| *Non-executive director* | *Fees US$'000* | *Total 2012 US$'000* | *Total 2011 US$'000* |
|---|---|---|---|
| Denis R. Burger | 80 | 80 | 85 |
| Peter Coyne | 80 | 80 | 85 |
| James Merselis | 70 | 70 | 68 |
| Clint Severson | 70 | 70 | 68 |
| | 300 | 300 | 306 |

| *Chief Financial Officer & Company Secretary* | *Salary/ Benefits US$'000* | *Performance related bonus US$'000* | *Defined contribution pension US$'000* | *Total 2012 US$'000* | *Total 2011 US$'000* |
|---|---|---|---|---|---|
| Kevin Tansley | 342 | 100 | 34 | 476 | 444 |

As at December 31, 2012 there was no accrual by the Company to provide pension, retirement or similar benefits for the directors (2011: NIL).

The total share-based compensation expense recognised in the consolidated statement of operations in 2012 in respect of options granted to both executive and non-executive directors and the Company Secretary amounted to US$1,865,000. See Item 18, Note 6 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 2012, the terms of which are set out below. Neither the directors nor the Company Secretary were granted options during 2011.

[1] Includes payments made to Darnick Company

**Share Options Granted in 2012:**

| Director/Executive Officer | Number of Options Granted | Exercise Price of Options Granted | Date of Option Grant* |
|---|---|---|---|
| Ronan O'Caoimh | 800,000 'A' shares (200,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Rory Nealon | 500,000 'A' shares (125,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Jim Walsh | 500,000 'A' shares (125,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Kevin Tansley | 500,000 'A' shares (125,000ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Denis Burger | 60,000 'A' shares (15,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Peter Coyne | 60,000 'A' shares (15,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| Clint Severson | 60,000 'A' shares (15,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |
| James Merselis | 60,000 'A' shares (15,000 ADS) | US$2.52 per 'A' share (US$10.09 per ADS) | 7 March 2012 |

* 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.

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.

### *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, 2012, Trinity Biotech had 394 employees (2011: 364) consisting of 61 research scientists and technicians, 220 manufacturing and quality assurance employees, and 113 finance, administration, sales and marketing staff (2011: 49 research scientists and technicians, 213 manufacturing and quality assurance employees, and 102 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: 248 in our US operations, 127 in Bray, Ireland, 17 in Uppsala, Sweden and 2 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 2011 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. As of February 28, 2013, 6,703,752 (1,675,938 ADS equivalent) of the options outstanding were held by the directors and Company Secretary of Trinity Biotech as follows:

| Director/Company Secretary | Number of Options 'A' Shares | Number of Options ADS Equivalent | Exercise Price (Per 'A' Share) | Exercise Price (Per ADS) | Expiration Date of Options |
|---|---|---|---|---|---|
| Ronan O'Caoimh | 350,000 | 87,500 | US$2.09 | US$ 8.36 | 13 December 2013 |
| | 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 |
| Rory Nealon | 150,000 | 37,500 | US$2.09 | US$ 8.36 | 13 December 2013 |
| | 200,000 | 50,000 | US$1.07 | US$ 4.28 | 18 March 2015 |
| | 240,000 | 60,000 | US$0.74 | US$ 2.96 | 16 September 2015 |
| | 166,668 | 41,667 | US$0.66 | US$ 2.63 | 8 May 2016 |
| | 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 |
| Denis Burger | 25,000 | 6,250 | US$2.09 | US$ 8.36 | 13 December 2013 |
| | 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 |
| Jim Walsh | 25,000 | 6,250 | US$2.09 | US$ 8.36 | 13 December 2013 |
| | 60,000 | 15,000 | US$1.52 | US$ 6.07 | 21 May 2017 |
| | 400,000 | 100,000 | US$1.57 | US$ 6.26 | 4 October 2017 |
| | 500,000 | 125,000 | US$2.52 | US$10.09 | 7 March 2019 |
| Peter Coyne | 25,000 | 6,250 | US$2.09 | US$ 8.36 | 13 December 2013 |
| | 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 |
| Clint Severson | 30,000 | 7,500 | US$1.52 | US$ 6.07 | 21 May 2017 |
| | 60,000 | 15,000 | US$2.52 | US$10.09 | 7 March 2019 |
| James Merselis | 120,000 | 30,000 | 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 |
| Kevin Tansley | 30,000 | 7,500 | US$1.78 | US$ 7.12 | 26 July 2013 |
| | 75,000 | 18,750 | US$2.24 | US$ 8.96 | 07 March 2014 |
| | 150,000 | 37,500 | US$1.07 | US$ 4.28 | 18 March 2015 |
| | 150,000 | 37,500 | US$0.74 | US$ 2.96 | 16 September 2015 |
| | 83,332 | 20,833 | US$0.66 | US$ 2.63 | 8 May 2016 |
| | 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 |

As of February 28, 2013 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 | 9,357,258 | US$0.66-US$3.27 | US$2.63-US$13.09 |

As of February 28, 2013 there were warrants to purchase 933,120 'A' Ordinary Shares in the Company outstanding.

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

As of February 28, 2013 Trinity Biotech has outstanding 89,130,409 'A' Ordinary shares. Such totals exclude 10,290,378 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2013, 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 | Percentage Outstanding 'A' Ordinary Shares | Percentage Total Voting Power |
|---|---|---|---|
| Heartland Advisors, Inc. | 8,118,900 | 9.1% | 9.1% |
| Fidelity Mgt. & Research Co. | 6,197,364 | 7.0% | 7.0% |
| Ronan O'Caoimh | 4,431,252(1) | 4.9% | 4.9% |
| Rory Nealon | 1,206,668(2) | 1.3% | 1.3% |
| Jim Walsh | 1,648,612(3) | 1.8% | 1.8% |
| Denis R. Burger | 140,000(4) | 0.2% | 0.2% |
| Peter Coyne | 120,600(5) | 0.1% | 0.1% |
| Clint Severson | 198,000(6) | 0.2% | 0.2% |
| James Merselis | 153,600(7) | 0.2% | 0.2% |
| Kevin Tansley | 738,332(8) | 0.8% | 0.8% |
| Directors & Co. Secretary as a group (8 persons) | 8,637,064(1)(2)(3)(4)(5)(6)(7)(8) | 9.4% | 9.4% |

(1) Includes 593,756 shares issuable upon exercise of options.
(2) Includes 1,006,668 shares issuable upon exercise of options.
(3) Includes 255,000 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 55,000 shares issuable upon exercise of options.
(5) Includes 115,000 shares issuable upon exercise of options.
(6) Includes NIL shares issuable upon exercise of options.
(7) Includes 150,000 shares issuable upon exercise of options.
(8) Includes 738,332 shares issuable upon exercise of options.

***Related Party Transactions***

The Group has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of Trinity Biotech, and directly with Mr O'Caoimh 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$503,000) 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$1,038,000).

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.

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 2012 and there were no loan balances payable to or receivable from directors at January 1, 2012 and at December 31, 2012.

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 2011 & 2012 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US$2,149,000, US$1,422,000 and US$231,000 for 2010, 2011 and 2012 respectively, of which US$1,431,000, US$1,395,000 and US$206,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2012, 2011 or 2010. All of the US$231,000 of payments made to Rayville Limited in 2012 represented repayments of the loan to Trinity Research Limited referred to above.

**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 claim that certain instruments supplied by Trinity Biotech did not operate properly in the field. Trinity Biotech will be defending the claim.

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 Depository Shares ("ADSs") are listed on the NASDAQ Global Market under the symbol "TRIB". In 2005, Trinity Biotech adjusted the ratio of American Depository 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, 2013, the reported closing sale price of the ADSs was US$16.91 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, 2008, 2009, 2010, 2011 and 2012; (b) the quarters ended March 31, June 30, September 30 and December 31, 2011; March 31, June 30, September 30 and December 31, 2012; and (c) the months of March, April, May, June, July, August, September, October, November and December 2012 and January and February 2013 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

**ADSs**

| Year Ended December 31 | High | Low |
|---|---|---|
| 2008 | US$ 6.95 | US$1.25 |
| 2009 | US$ 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 |

**ADSs**

| 2011 | High | Low |
|---|---|---|
| Quarter ended March 31 | US$ 9.90 | US$8.00 |
| Quarter ended June 30 | US$11.00 | US$8.94 |
| Quarter ended September 30 | US$10.94 | US$8.40 |
| Quarter ended December 31 | US$10.50 | US$8.54 |

**ADSs**

| 2012 | High | Low |
|---|---|---|
| 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**

| Month Ended | High | Low |
|---|---|---|
| March 31, 2012 | US$10.80 | US$ 9.84 |
| April 30, 2012 | US$11.75 | US$10.50 |
| May 31, 2012 | US$11.75 | US$10.81 |
| June 30, 2012 | US$12.03 | US$10.89 |
| July 31, 2012 | US$12.76 | US$11.58 |
| August 31, 2012 | US$12.87 | US$11.80 |
| September 30, 2012 | US$12.77 | US$12.07 |
| October 31, 2012 | US$14.49 | US$13.01 |
| November 30, 2012 | US$14.75 | US$13.55 |
| December 31, 2012 | US$15.75 | US$14.00 |
| January 31, 2013 | US$16.15 | US$14.30 |
| February 29, 2013 | US$17.10 | US$15.90 |

The number of record holders of Trinity Biotech's ADSs as at February 28, 2013 amounts to 534, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clients (with each such brokerage house and/or clearing house being considered as one holder).

**Item 10** ***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.

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 2012 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 2012 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 2012 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.

***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 (new share capital issues, changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office (the "CRO") in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the Company carrying the right of voting at general meetings of the Company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the Company. Any shareholder who complains that the affairs of the Company are being conducted or that the powers of the directors of the Company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the Company.

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

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

### *Material Contracts*

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

**Acquisition of Fiomi Diagnostics AB**

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

The key terms of the acquisition are as follows:

- An up-front cash payment of US$5.6m;
- The transfer of 408,000 Trinity Biotech 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 24 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 (see Item 18, Note 3). 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.

### *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 harbor 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.

#### *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 organised 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.

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 before December 31, 2012 will be subject to tax at a reduced maximum tax rate of 15%. 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 recognise a gain or loss for US federal income tax purposes in an amount equal to the difference between the amount realised 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 recognised on a sale or other disposition of a US Holder's ADSs, including any gain recognised on a liquidation of Trinity Biotech, would be treated in the same manner as an excess distribution. Any such gain would be treated as ordinary income rather than as capital gain. 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.

***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 their 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 their 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 10% 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) are substantially or regularly traded on a recognised stock exchange; or

is otherwise entitled to an exemption from DWT.

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

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

Special DWT arrangements are available in the case of shares held by US resident holders in Irish companies 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 while 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 our 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. A rate of 30% applied to disposals made between 7 December 2011 and 5 December 2012 while a rate of 25% applied to disposals made between 8 April 2009 and 6 December 2011. Indexation of the base cost of the ordinary shares or ADSs will only be 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 a tax return 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 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 a 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.

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

The Estate Tax Convention between Ireland and the United States generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited, in whole or in part, against tax payable in the United States, in the case where an inheritance of ordinary shares or ADSs is subject to both Irish capital acquisitions tax and 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 Depositary or the Depositary's custodian upon surrender of ADSs for the purposes of withdrawing the underlying ordinary shares from the ADS system, and transfers of ordinary shares to the Depositary or the Depositary's custodian for the purposes of transferring ordinary shares onto the ADS system, will be stampable at the ad valorem rate of 1% of the value of the shares transferred if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of ordinary shares. Such transfers will be exempt from Irish stamp duty if the transfer does not relate to or involve any change in the beneficial ownership in the underlying ordinary shares and the transfer form contains the appropriate certification.

The person accountable for the payment of stamp duty is the transferee or, in the case of a transfer by way of gift or for consideration less than the market value, both parties to the transfer. Stamp duty is normally payable within 30 days after the date of execution of the transfer. Late or inadequate payment of stamp duty will result in liability for interest, penalties, surcharge and fines.

## Dividend Policy

In 2011, the Board decided that it was an appropriate time to 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 15 cents per ADS in respect of the 2011 financial year and this proposal was approved by the shareholders at the 2012 Annual General Meeting of the Company and subsequently paid during the course of 2012. 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 2012 financial year will be proposed by the Directors prior to the next AGM, to be held in May 2013.

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, 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 27.

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$749,000 (2011: US$711,000) and would not affect the interest expense in 2012 or 2011; resulting in an increase in interest income of US$749,000 (2011: US$711,000).

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro 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, 2012.

The Group had foreign currency denominated cash balances equivalent to US$1,316,000 at December 31, 2012 (2011: US$413,000).

**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 2012 by approximately 3.9%.

**Exchange rate sensitivity**

At year-end 2012, approximately 1.2% of the Group's US$169,380,000 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the Euro and Swedish Krona.

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 2012 year-end net worth by US$207,000.

**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 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, 2012.

In designing and evaluating our disclosure controls and procedures, our management, with the participation of the Chief Executive Officer and Chief Financial Officer, recognized 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. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, and that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of internal control over financial reporting based on criteria established in the 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, 2012.

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, 2012 (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.

**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, 2012* | | *Year ended December 31, 2011* | |
|---|---|---|---|---|
| | *US$'000* | *%* | *US$'000* | *%* |
| Audit | 451 | 82% | 561 | 91% |
| Audit-related | 22 | 4% | 6 | 1% |
| Tax | 79 | 14% | 48 | 8% |
| Total | 552 | | 615 | |

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

***Pre-Approval Policies and Procedures***

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

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

### *16D Exemptions from the Listing 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, 2012 was 4,311,824 (1,077,956 ADS's) (2011: 6,009,520 (1,502,380 ADS's)).

**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 |
| **Total** | **457,322** | **11.68** | **457,322** | **1,811,139** |

**2011 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, 2011 | 112,337 | 9.53 | 112,337 | 1,963,026 |
| July 1-31, 2011 | 86,500 | 10.62 | 86,500 | 2,013,990 |
| August 1-31, 2011 | 127,800 | 10.46 | 127,800 | 1,886,190 |
| September 1-30, 2011 | 90,721 | 9.65 | 90,721 | 1,795,469 |
| October 1-31, 2011 | 66,000 | 9.42 | 66,000 | 1,729,469 |
| November 1-30, 2011 | 67,648 | 9.80 | 67,648 | 1,661,821 |
| December 1-31, 2011 | 58,337 | 10.40 | 58,337 | 1,603,484 |
| **Total** | **609,343** | **10.00** | **609,343** | **1,603,484** |

### *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.

**Part III**

**Item 17** ***Financial Statements***

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

**Item 18** ***Financial Statements***

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders 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, 2012, based on criteria established in 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, appearing under Item 15 in this Annual Report on Form 20-F. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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, 2012, based on criteria established in 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 December 31, 2012 and 2011 and for each of the years in the three year period ended December 31, 2012 and our report dated April 5, 2013 expressed an unqualified opinion on those consolidated financial statements.

Grant Thornton

Dublin, Ireland
April 5, 2013

## 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, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, changes in equity, and cash flows for each of the years in the three year period ended December 31, 2012. 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, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2012, 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, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated April 5, 2013, expressed an unqualified opinion.

Grant Thornton

Dublin, Ireland
April 5, 2013

**CONSOLIDATED STATEMENT OF OPERATIONS**

| | | Year ended December, 31 | | |
|---|---|---|---|---|
| | Notes | 2012 Total US$'000 | 2011 Total US$'000 | 2010 Total US$'000 |
| **Revenues** | 2 | **82,510** | **77,948** | **89,635** |
| **Cost of sales** | | **(40,257)** | **(37,820)** | **(45,690)** |
| **Gross profit** | | **42,253** | **40,128** | **43,945** |
| **Other operating income** | 5 | **468** | **910** | **1,616** |
| **Research and development expenses** | | **(3,130)** | **(3,206)** | **(4,603)** |
| **Selling, general and administrative expenses** | | **(22,425)** | **(22,048)** | **(26,929)** |
| Net gain on divestment of business and restructuring expenses | 3 | — | — | 46,474 |
| **Operating profit** | | **17,166** | **15,784** | **60,503** |
| Financial income | 2, 4 | 2,280 | 2,428 | 1,352 |
| Financial expenses | 2, 4 | (88) | (12) | (495) |
| **Net financing income** | | **2,192** | **2,416** | **857** |
| **Profit before tax** | 6 | **19,358** | **18,200** | **61,360** |
| Total income tax expense | 2, 9 | (2,017) | (2,607) | (942) |
| **Profit for the year (all attributable to owners of the parent)** | 2 | **17,341** | **15,593** | **60,418** |
| Basic earnings per ADS (US Dollars) | 10 | 0.81 | 0.73 | 2.85 |
| Diluted earnings per ADS (US Dollars) | 10 | 0.77 | 0.70 | 2.79 |
| Basic earnings per 'A' ordinary share (US Dollars) | 10 | 0.20 | 0.18 | 0.71 |
| Diluted earnings per 'A' ordinary share (US Dollars) | 10 | 0.19 | 0.18 | 0.70 |

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

| | | Year ended December 31, | | |
|---|---|---|---|---|
| | Notes | 2012 US$'000 | 2011 US$'000 | 2010 US$'000 |
| Profit for the year | 2 | 17,341 | 15,593 | 60,418 |
| **Other comprehensive income:** | | | | |
| Foreign exchange translation differences | | 127 | — | (750) |
| *Cash flow hedges*: | | | | |
| Effective portion of changes in fair value | | 6 | (6) | 70 |
| Deferred tax on income and expenses recognised directly in equity | | 1 | (1) | 6 |
| ***Other comprehensive income*** | | 134 | (7) | (674) |
| ***Total Comprehensive Income (all attributable to owners of the parent)*** | | **17,475** | **15,586** | **59,744** |

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

| | Notes | At December, 31 2012 US$'000 | 2011 US$'000 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | 11 | 8,883 | 7,626 |
| Goodwill and intangible assets | 12 | 73,046 | 45,390 |
| Deferred tax assets | 13 | 4,073 | 2,977 |
| Other assets | 14 | 908 | 493 |
| **Total non-current assets** | | **86,910** | **56,486** |
| **Current assets** | | | |
| Inventories | 15 | 20,757 | 19,838 |
| Trade and other receivables | 16 | 14,457 | 23,973 |
| Income tax receivable | | 336 | 117 |
| Cash and cash equivalents | 17 | 74,947 | 71,085 |
| **Total current assets** | | **110,497** | **115,013** |
| **TOTAL ASSETS** | 2 | **197,407** | **171,499** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity attributable to the equity holders of the parent** | | | |
| Share capital | | 1,134 | 1,106 |
| Share premium | | 5,138 | 2,736 |
| Treasury Shares | 18 | (7,367) | (6,094) |
| Accumulated surplus | | 166,340 | 149,583 |
| Translation reserve | | (417) | (544) |
| Other reserves | | 4,552 | 4,545 |
| **Total equity** | | **169,380** | **151,332** |
| **Current liabilities** | | | |
| Interest-bearing loans and borrowings | 20 | — | 108 |
| Income tax payable | | 1,092 | 1,582 |
| Trade and other payables | 21 | 11,824 | 11,589 |
| Provisions | 22 | 50 | 50 |
| **Total current liabilities** | | 12,966 | 13,329 |
| **Non-current liabilities** | | | |
| Other payables | 23 | 4,318 | 10 |
| Deferred tax liabilities | 13 | 10,743 | 6,828 |
| **Total non-current liabilities** | | **15,061** | **6,838** |
| **TOTAL LIABILITIES** | 2 | **28,027** | **20,167** |
| **TOTAL EQUITY AND LIABILITIES** | | **197,407** | **171,499** |

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

| | *Share capital 'A' ordinary shares US$'000* | *Share capital 'B' ordinary shares US$'000* | *Share premium US$'000* | *Treasury Shares US$'000* | *Translation reserve US$'000* | *Warrant reserve US$'000* | *Hedging reserves US$'000* | *Accumulated surplus/ (deficit) US$'000* | *Total US$'000* |
|---|---|---|---|---|---|---|---|---|---|
| Balance at January 1, 2010 | 1,068 | 12 | 160,683 | — | 206 | 4,498 | (53) | (87,070) | 79,344 |
| Profit for the period | — | — | — | — | — | — | — | 60,418 | 60,418 |
| Other comprehensive income | — | — | — | — | (750) | — | 76 | — | (674) |
| Total comprehensive income | — | — | — | — | (750) | — | 76 | 60,418 | 59,744 |
| Share-based payments | — | — | — | — | — | — | — | 1,240 | 1,240 |
| Options/warrants exercised | 12 | — | 1,011 | — | — | — | — | — | 1,023 |
| Share issue expenses | — | — | (64) | — | — | — | — | — | (64) |
| Fair Value of Warrants issued during the year | — | — | (31) | — | — | 31 | — | — | — |
| **Balance at December 31, 2010** | **1,080** | **12** | **161,599** | **—** | **(544)** | **4,529** | **23** | **(25,412)** | **141,287** |
| 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 | — | — | (160,000) | — | — | — | — | 160,000 | — |
| Dividends (Note 28) | — | — | — | — | — | — | — | (2,145) | (2,145) |
| Treasury Shares acquired during the year | — | — | — | (6,094) | — | — | — | — | (6,094) |
| **Balance at December 31, 2011** | **1,094** | **12** | **2,736** | **(6,094)** | **(544)** | **4,529** | **16** | **149,583** | **151,332** |
| 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 28) | — | — | — | — | — | — | — | (3,224) | (3,224) |
| Treasury Shares acquired during the year | — | — | — | (5,343) | — | — | — | — | (5,343) |
| Treasury Shares re-issued | — | — | — | 4,070 | — | — | — | — | 4,070 |
| **Balance at December 31, 2012** | **1,134** | **—** | **5,138** | **(7,367)** | **(417)** | **4,529** | **23** | **166,340** | **169,380** |

**CONSOLIDATED STATEMENT OF CASH FLOWS**

| | Notes | Year ended December 31, 2012 US$'000 | 2011 US$'000 | 2010 US$'000 |
|---|---|---|---|---|
| **Cash flows from operating activities** | | | | |
| Profit for the year | | 17,341 | 15,593 | 60,418 |
| *Adjustments to reconcile net profit to cash provided by operating activities:* | | | | |
| Depreciation | | 1,349 | 1,166 | 1,230 |
| Amortisation | | 1,482 | 1,427 | 1,589 |
| Income tax expense | 9 | 2,017 | 2,607 | 942 |
| Financial income | 4 | (2,280) | (2,428) | (1,352) |
| Financial expense | 4 | 88 | 12 | 495 |
| Share-based payments | 19 | 1,713 | 1,269 | 1,109 |
| Foreign exchange (gains)/losses on operating cash flows | | (60) | (10) | 351 |
| Loss on disposal / retirement of property, plant and equipment | | 5 | — | 12 |
| Gain on divestment of business | 3 | — | — | (46,775) |
| Other non-cash items | | 578 | 302 | 3,112 |
| **Operating cash flows before changes in working capital** | | **22,233** | **19,938** | **21,131** |
| (Increase)/decrease in trade and other receivables | | (2,059) | 1,276 | 3,094 |
| (Increase)/decrease in inventories | | (1,374) | (2,409) | (2,826) |
| Increase/(decrease) in trade and other payables | | 22 | (33) | 1,574 |
| **Cash generated from operations** | | **18,822** | **18,772** | **22,973** |
| Interest paid | | (3) | (12) | (503) |
| Interest received | | 2,189 | 2,013 | 842 |
| Income taxes paid | | (1,047) | (317) | (239) |
| **Net cash generated by operating activities** | | **19,961** | **20,456** | **23,073** |
| **Cash flows from investing activities** | | | | |
| Proceeds from divestiture of Coagulation product line (net) | 3 | 11,250 | 11,250 | 65,886 |
| Payments to acquire subsidiaries | | (5,958) | (2,166) | — |
| Cash received with acquired subsidiary | | 44 | 21 | — |
| Payments to acquire intangible assets | | (12,631) | (6,799) | (6,233) |
| Proceeds from disposal of property, plant and equipment | | — | — | 16 |
| Acquisition of property, plant and equipment | | (2,665) | (2,436) | (2,784) |
| **Net cash (used in)/generated by investing activities** | | **(9,960)** | **(130)** | **56,885** |
| **Cash flows from financing activities** | | | | |
| Proceeds from issue of ordinary share capital | 18 | 2,505 | 1,189 | 1,023 |
| Purchase of Treasury Shares | 18 | (5,343) | (6,094) | — |
| Expenses paid in connection with share issue and debt financing | | (22) | (38) | (74) |
| Repayment of long-term debt | | — | — | (29,775) |
| Proceeds from new finance leases | | — | — | 1,480 |
| Dividends paid to equity holders of the parent | 28 | (3,224) | (2,145) | — |
| Payment of finance lease liabilities | | (109) | (159) | (638) |
| **Net cash used in financing activities** | | **(6,193)** | **(7,247)** | **(27,984)** |
| Increase in cash and cash equivalents | | 3,808 | 13,079 | 51,974 |
| Effects of exchange rate movements on cash held | | 54 | 4 | (50) |
| Cash and cash equivalents at beginning of year | | 71,085 | 58,002 | 6,078 |
| **Cash and cash equivalents at end of year** | 17 | **74,947** | **71,085** | **58,002** |

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:

*a) 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 on or after 1 January 2012. 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.

*b) 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 30.

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.

Certain comparative amounts have been reclassified to conform with the current year's presentation.

*c) 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.

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

*d) 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(h)). 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, at each balance sheet date.

***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(h)).

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.

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

*e) Business combinations*

All business combinations are accounted for by applying the acquisition method.

The revised standard on business combinations (IFRS 3R) introduced major changes to the accounting requirements for business combinations. It retains the major features of the purchase method of accounting, now referred to as the acquisition method. The most significant changes in IFRS 3R that impact the Group are as follows:

- acquisition-related costs of the combination are recorded as an expense in the statement of operations. Previously, these costs would have been accounted for as part of the cost of the acquisition;
- 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. Previously, contingent consideration was recognised only once its payment was probable and changes were recognised as an adjustment to goodwill ; and
- the measurement of assets acquired and liabilities assumed at their acquisition-date fair values is retained. However, IFRS 3R includes certain exceptions and provides specific measurement rules.

IFRS 3R has been applied prospectively to business combinations for which the acquisition date is on or after 1 January 2010. Business combinations for which the acquisition date is before 1 January 2010 have not been restated and were accounted for by applying the purchase method.

*f) 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(h)).

*g) 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(h)). Definite lived intangible assets are reviewed for indicators of impairment annually while indefinite lived assets and those not yet brought into use are tested for impairment annually, either individually or at the cash generating unit level.

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

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

The technical feasibility of a new product is determined by a specific feasibility study undertaken at the first stage of any development project. The majority of our new product developments involve the transfer of existing product know-how to a new application. Since the technology is already proven in an existing product which is being used by customers, this facilitates the proving of the technical feasibility of that same technology in a new product. The results of the feasibility study are reviewed by a design review committee comprising senior managers. The feasibility study occurs in the initial research phase of a project and costs in this phase are not 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(h)).

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 entry into the industry. The following factors have been considered in estimating the useful life of developed products:

(a) once a diagnostic test becomes established, customers are reluctant to change to new technology until it is fully proven, thus resulting in relatively long product life cycles. There is also reluctance in customers to change to a new product as it can be costly both in terms of the initial changeover cost and as new technology is typically more expensive.

(b) demand for the diagnostic tests is enduring and robust within a wide geographic base. The diseases that the products diagnose are widely prevalent (HIV, Diabetes and Chlamydia being just three examples) in many countries. There is a general consensus that these diseases will continue to be widely prevalent in the future.

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

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

Certain trade names acquired are deemed to have an indefinite useful life.

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.

*h) 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, 2010, December 31, 2011 and December 2012. See Note 12.

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.

*i) Inventories*

Inventories are stated at the lower of cost and net realisable value. Cost is based on the first-in, first-out principle and includes all expenditure which has been incurred in bringing the products to their present location and condition, and includes an appropriate allocation of manufacturing overhead based on the normal level of operating capacity. Net realisable value is the estimated selling price of inventory on hand in the ordinary course of business less all further costs to completion and costs expected to be incurred in selling these products.

The Group provides for inventory, based on estimates of the expected realisability 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.

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

*j) 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.

*k) Trade and other payables*

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

*l) 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.

*m) 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 1(g).

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.

*n) 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.

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

*o) 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. See also Note 1(d).

***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 operating income also comprises income derived from the Transitional Services Agreement (TSA) which the Group entered into with Diagnostica Stago in April 2010. The services provided by the Group under the TSA mainly include: accounting, information technology and logistics support and warehousing services. This income is not treated as revenue since the TSA activities are incidental to the main revenue-generating activities of the Group.

*p) 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.

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

*q) 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 subsidiary in Sweden) principally operate. Thus the functional currency of the Company and its subsidiaries (other than the Swedish subsidiary) is the US Dollar. The functional currency of the Swedish subsidiary is the Swedish Kroner. The presentation currency of the Company and Group is the US Dollar. Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the balance sheet date. The resulting gains and losses are included in the statement of operations. Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

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, 2012.

*r) 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.

*s) Segment reporting*

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

*t) 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.

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.

*u) 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.

*v) 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.

*w) Finance income and costs*

Financing expenses comprise 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.

*x) 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.

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

*y) 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.

*z) 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, 2012, some of which have not yet been adopted by the EU. The following standards and interpretations have yet to be adopted by the Group:

| ***International Financial Reporting Standards (IFRS/IAS)*** | | ***Effective date*** |
|---|---|---|
| IAS 1 | Presentation of Items of Other Comprehensive Income – Amendments to IAS 1 | July 1, 2012 (not yet adopted by the EU) |
| IAS 19 | Employee Benefits (Amendment) | January 1, 2013 (not yet adopted by the EU) |
| IAS 27 | Separate Financial Statements (Revised 2011) | January 1, 2013 (not yet adopted by the EU) |
| IAS 28 | Investments in Associates and Joint Ventures (Revised 2011) | January 1, 2013 (not yet adopted by the EU) |
| IFRS 1 | Government Loans (Amendments to IFRS 1) | January 1, 2013 (not yet adopted by the EU) |
| IFRS 7 | Disclosures – Offsetting Financial Assets & Financial Liabilities (Amendments to IFRS 7) | January 1, 2013 (not yet adopted by the EU) |
| IFRS 9 | Financial Instruments – Classification and Measurement | January 1, 2015 (not yet adopted by the EU) |
| IFRS 10 | Consolidated Financial Statements | January 1, 2013 (not yet adopted by the EU) |
| IFRS 11 | Joint Arrangements | January 1, 2013 (not yet adopted by the EU) |
| IFRS 12 | Disclosure of Interests in Other Entities | January 1, 2013 (not yet adopted by the EU) |
| IFRS 13 | Fair Value Measurement | January 1, 2013 (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. The Group has adopted IAS 12 *Income Taxes (amendment)* and *IFRS 7 Financial Instruments: Disclosures (amendment)* in respect of the 2012 year-end. The application of the above standards and interpretations did not result in material changes in the Group's Consolidated Financial Statements.

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.

2. SEGMENT INFORMATION (CONTINUED)

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.

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

Rest of World Other revenue from external customers ceased in 2010 after the disposal of the Group's UK, French and German operations as part of the divestiture of the Coagulation product line (see Note 3). The acquisition of Fiomi Diagnostics AB (see Note 24) in 2012 has reinstated Inter-segment revenue in this area in the current year.

| | | *Rest of World* | | | |
|---|---|---|---|---|---|
| **Revenue** | *Americas* | *Ireland* | *Other* | *Eliminations* | *Total* |
| *Year ended December 31, 2012* | *US$'000* | *US$'000* | *US$'000* | *US$'000* | *US$'000* |
| Revenue from external customers | 42,029 | 40,481 | — | — | 82,510 |
| Inter-segment revenue | 32,466 | 7,655 | 5,558 | (45,679) | — |
| Total revenue | 74,495 | 48,136 | 5,558 | (45,679) | 82,510 |

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

| | | *Rest of World* | | | |
|---|---|---|---|---|---|
| | *Americas* | *Ireland* | *Other* | *Eliminations* | |
| *Year ended December 31, 2010* | *US$'000* | *US$'000* | *US$'000* | *US$'000* | *US$'000* |
| Revenue from external customers | 37,643 | 45,642 | 6,350 | — | 89,635 |
| Inter-segment revenue | 21,786 | 12,154 | 7,101 | (41,041) | — |
| Total revenue | 59,429 | 57,796 | 13,451 | (41,041) | 89,635 |

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

| **Revenue** | *December 31, 2012* *US$'000* | *December 31, 2011* *US$'000* | *December 31, 2010* *US$'000* |
|---|---|---|---|
| Americas | 49,638 | 51,352 | 53,993 |
| Europe (including Ireland) * | 10,214 | 9,423 | 15,890 |
| Asia / Africa | 22,658 | 17,173 | 19,752 |
| | 82,510 | 77,948 | 89,635 |

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

2. SEGMENT INFORMATION (CONTINUED)

The Group disposed of its Coagulation product line in April 2010 (see Note 3) and thus Coagulation revenue ceased after this point.

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

| **Revenue** | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Clinical laboratory | 63,356 | 61,386 | 73,553 |
| Point-of-Care | 19,154 | 16,562 | 16,082 |
| | 82,510 | 77,948 | 89,635 |

The Group disposed of its Coagulation product line in April 2010 (see Note 3) and thus Coagulation revenue ceased after this point.

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

| | | *Rest of World* | | |
|---|---|---|---|---|
| *Year ended December 31, 2012* | *Americas US$'000* | *Ireland US$'000* | *Other US$'000* | *Total US$'000* |
| Result | 6,299 | 11,739 | (39) | 17,999 |
| Unallocated expenses * | | | | (833) |
| Operating profit | | | | 17,166 |
| Net financing income (Note 4) | | | | 2,192 |
| Profit before tax | | | | 19,358 |
| Income tax expense (Note 9) | | | | (2,017) |
| Profit for the year | | | | 17,341 |

| | | *Rest of World* | | |
|---|---|---|---|---|
| *Year ended December 31, 2011* | *Americas US$'000* | *Ireland US$'000* | *Other US$'000* | *Total US$'000* |
| Result | 5,840 | 10,922 | (80) | 16,682 |
| Unallocated expenses * | | | | (898) |
| Operating profit | | | | 15,784 |
| Net financing income (Note 4) | | | | 2,416 |
| Profit before tax | | | | 18,200 |
| Income tax expense (Note 9) | | | | (2,607) |
| Profit for the year | | | | 15,593 |

2. SEGMENT INFORMATION (CONTINUED)

| *Year ended December 31, 2010* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Total US$'000* |
|---|---|---|---|---|
| **Result before Gain on Sale and Restructuring** | 7,103 | 4,912 | 2,600 | 14,615 |
| Net gain on divestment of business and restructuring expenses (Note 3) | 5,745 | 32,918 | 7,811 | 46,474 |
| Result after Gain on Sale and Restructuring | 12,848 | 37,830 | 10,411 | 61,089 |
| Unallocated expenses * | | | | (586) |
| Operating profit | | | | 60,503 |
| Net financing income (Note 4) | | | | 857 |
| Profit before tax | | | | 61,360 |
| Income tax expense (Note 9) | | | | (942) |
| Profit for the year | | | | 60,418 |

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

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

| *As at December 31, 2012* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Total US$'000* |
|---|---|---|---|---|
| **Assets and liabilities** | | | | |
| Segment assets | 46,434 | 55,346 | 16,271 | 118,051 |
| *Unallocated assets:* | | | | |
| 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 |
| *Unallocated liabilities:* | | | | |
| Income tax liabilities (current and deferred) | | | | 11,835 |
| Total liabilities as reported in the Group balance sheet | | | | 28,027 |

| *As at December 31, 2011* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Total US$'000* |
|---|---|---|---|---|
| **Assets and liabilities** | | | | |
| Segment assets | 44,245 | 53,034 | 41 | 97,320 |
| *Unallocated assets:* | | | | |
| Income tax assets (current and deferred) | | | | 3,094 |
| Cash and cash equivalents | | | | 71,085 |
| Total assets as reported in the Group balance sheet | | | | 171,499 |
| Segment liabilities | 4,645 | 6,989 | 15 | 11,649 |
| *Unallocated liabilities:* | | | | |
| Income tax liabilities (current and deferred) | | | | 8,410 |
| Interest-bearing loans and borrowings (current and non-current) | | | | 108 |
| Total liabilities as reported in the Group balance sheet | | | | 20,167 |

2. SEGMENT INFORMATION (CONTINUED)

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Rest of World – Ireland | 38,996 | 30,402 |
| Rest of World – Other | 16,049 | — |
| Americas | 27,792 | 23,107 |
| | 82,837 | 53,509 |

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| ***Depreciation:*** | | | |
| Rest of World – Ireland | 408 | 325 | 276 |
| Rest of World – Other | 32 | — | 296 |
| Americas | 1,023 | 841 | 658 |
| | 1,463 | 1,166 | 1,230 |
| ***Amortisation:*** | | | |
| Rest of World – Ireland | 1,174 | 1,258 | 1,475 |
| Rest of World – Other | — | — | 55 |
| Americas | 308 | 169 | 59 |
| | 1,482 | 1,427 | 1,589 |

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | 1,482 | 1,099 | 1,032 |
| Rest of World – Other | — | — | 1 |
| Americas | 231 | 170 | 76 |
| | 1,713 | 1,269 | 1,109 |

See Note 19 for further information on share-based payments.

i) The distribution of restructuring expenses by geographical area was as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| ***Restructuring expenses:*** | | | |
| Rest of World – Ireland | — | — | 301 |
| Rest of World – Other | — | — | — |
| Americas | — | — | — |
| | — | — | 301 |

The 2010 restructuring expenses were incurred in connection with a programme involving a re-organisation of the Group's HIV manufacturing activities and comprised termination payments for employees located in Ireland. This restructuring cost is included within net gain on divestment of business and restructuring expenses, on the face of the statement of operations.

2. SEGMENT INFORMATION (CONTINUED)

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

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

| **Interest Expense** *Year ended December 31, 2012* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Eliminations US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| Interest Expense | 1 | 2 | — | — | 3 |
| Interest on Deferred Consideration | — | — | 85 | — | 85 |
| Inter-segment Interest Expense | 3,270 | — | — | (3,270) | — |
| Total | 3,271 | 2 | 85 | (3,270) | 88 |

| **Interest Income** *Year ended December 31, 2011* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Eliminations US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| 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 |

| **Interest Expense** *Year ended December 31, 2011* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Eliminations US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| Interest Expense | 2 | 10 | — | — | 12 |
| Inter-segment Interest Expense | 2,040 | — | — | (2,040) | — |
| Total | 2,042 | 10 | — | (2,040) | 12 |

| **Interest Income** *Year ended December 31, 2010* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Eliminations US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| Interest Income Earned | — | 910 | — | — | 910 |
| Interest on Deferred Consideration | 98 | 344 | — | — | 442 |
| Inter-segment Interest Income | — | 428 | — | (428) | — |
| Total | 98 | 1,682 | — | (428) | 1,352 |

| **Interest Expense** *Year ended December 31, 2010* | *Americas US$'000* | *Rest of World Ireland US$'000* | *Rest of World Other US$'000* | *Eliminations US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| Interest Expense | 85 | 410 | — | — | 495 |
| Inter-segment Interest Expense | 73 | 355 | — | (428) | — |
| Total | 158 | 765 | — | (428) | 495 |

2. SEGMENT INFORMATION (CONTINUED)

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | (880) | (1,295) | 591 |
| Rest of World – Other | (80) | (10) | (815) |
| Americas | (1,057) | (1,302) | (718) |
| | (2,017) | (2,607) | (942) |

l) During 2012, 2011 and 2010 there were no customers generating 10% or more of total revenues.

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Rest of World – Ireland | 10,140 | 4,553 |
| Rest of World – Other | 16,006 | — |
| Americas | 5,608 | 7,891 |
| | 31,754 | 12,444 |

3. NET GAIN ON DIVESTMENT OF BUSINESS AND RESTRUCTURING EXPENSES

In April 2010, the Group sold its worldwide Coagulation product line to Diagnostica Stago for US$89.9 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. As part of the sale, the Group also transferred the leasing arrangements of one of its facilities in Bray, Ireland to Diagnostica Stago. Included in the sale were Trinity's lists of Coagulation customers and suppliers, all Coagulation inventory, intellectual property and developed technology.

The Group received consideration of US$67.4 million and interest on deferred consideration of US$1.0 million in 2010. These proceeds were used in part to repay the Group's bank loans in 2010 and accordingly there were no bank loans outstanding at December 31, 2010, December 31, 2011 or December 31, 2012. 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.

IFRS 5 (Non-current Assets Held for Sale and Discontinued Operations) outlines the disclosures required for a discontinued operation. However, the Coagulation product line falls outside of these criteria, principally owing to the fact that it is not defined as a component of the Group. A component is defined by IFRS 5 as "operations and cashflows that can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the entity." The Group has determined that neither the operations nor the cashflows of the Coagulation product line could be clearly distinguished, operationally or from a financial reporting viewpoint and therefore, on that basis, the Coagulation product line did not meet the definition of a discontinued operation.

Accordingly, the Group has disclosed the Gain on Sale under the heading 'Net gain on divestment of business and restructuring expenses' in the statement of operations, where it is shown net of termination expenses of US$301,000 (see Note 7). The Gain on divestment is also shown separately within the Segment Information Note as required by IFRS 8 (Operating Segments) where appropriate (see Note 2).

3. NET GAIN ON DIVESTMENT OF BUSINESS AND RESTRUCTURING EXPENSES (CONTINUED)

The gain on the divestment is summarised below according to the assets and liabilities which were divested in April 2010 as part of the sale. The effect of the divestment is summarised as follows:

| | 2010 US$'000 | 2010 US$'000 |
|---|---|---|
| Total Consideration | | **89,923** |
| Property, plant and equipment (net book value) | **6,775** | |
| Goodwill and intangible assets | **12,270** | |
| Deferred tax assets | **123** | |
| Inventories (net) | **21,528** | |
| Trade and other receivables | **6,211** | |
| Cash and cash equivalents | **427** | |
| Interest bearing loans and borrowings | **(2,825)** | |
| Income tax payable | **(70)** | |
| Trade and other payables | **(3,463)** | |
| Deferred Tax Liabilities | **(183)** | |
| Net identifiable assets disposed | **40,793** | **(40,793)** |
| Other Costs associated with the Divestiture of Coagulation | | **(2,355)** |
| **Net gain on divestment of business** | | **46,775** |
| **Restructuring Expenses*** | | **(301)** |
| **Net gain on divestment of business and restructuring expenses** | | **46,474** |

* The Restructuring Expenses relate to termination payments resulting from a restructuring programme announced in 2010 (see Note 7).

4. FINANCIAL INCOME AND EXPENSES

| | *Note* | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|---|
| Financial income: | | | | |
| Interest income | | 2,168 | 1,983 | 910 |
| Other interest income | | 112 | 445 | 442 |
| | | 2,280 | 2,428 | 1,352 |
| Financial expense: | | | | |
| Finance lease interest | | (2) | (10) | (67) |
| Interest payable on interest bearing loans and borrowings | *20* | — | — | (425) |
| Other interest expense | | (86) | (2) | (3) |
| | | (88) | (12) | (495) |
| Net Financing Income | | 2,192 | 2,416 | 857 |

Other interest income recognised in 2012, 2011 and 2010 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. For further information, see Note 3.

Other interest expense for 2012 includes $85,000 related to the deferred consideration arising as a result of the acquisition of Fiomi Diagnostics AB by the Group during the year (see Note 24).

5. OTHER OPERATING INCOME

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Rental income from premises | 243 | 245 | 213 |
| Employment / training grants | — | — | (50) |
| Other income | 225 | 665 | 1,453 |
| | 468 | 910 | 1,616 |

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

6. PROFIT BEFORE TAX

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Directors' emoluments (including non-executive directors): | | | |
| Remuneration | 1,812 | 2,086 | 2,082 |
| Pension | 270 | 111 | 127 |
| Share based payments | 1,499 | 786 | 705 |
| Other | — | 14 | 39 |
| Auditors' remuneration | | | |
| Audit fees | 506 | 510 | 628 |
| Non audit fees | 99 | 31 | 31 |
| Depreciation – leased assets* | 12 | 13 | 84 |
| Depreciation – owned assets* | 1,337 | 1,153 | 1,146 |
| Amortisation | 1,482 | 1,427 | 1,589 |
| Gain on divestment of Coagulation product line | — | — | 46,775 |
| Loss on the disposal of property, plant and equipment | 5 | — | 12 |
| Net foreign exchange differences | (41) | (69) | 1,119 |
| Operating lease rentals: | | | |
| Plant and machinery | — | — | 5 |
| Land and buildings | 2,447 | 2,654 | 3,211 |
| Other equipment | 9 | 19 | 130 |

* Note that $114,000 of depreciation was charged to research and development projects during 2012 in line with the Group's capitalisation policy for Intangible projects.

The 2011 and 2010 share based payments amounts have been restated to exclude amounts capitalized in the statement of operations, in order to be consistent with the current year's presentation. In the 2011 financial statements, these amounts were shown as US$551,000 and US$592,000 respectively.

7. PERSONNEL EXPENSES

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Wages and salaries | 19,066 | 18,470 | 25,491 |
| Social welfare costs | 1,842 | 1,718 | 2,279 |
| Pension costs | 669 | 658 | 897 |
| Share-based payments | 1,713 | 1,269 | 1,109 |
| | 23,290 | 22,115 | 29,776 |

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, 2012 amounted to US$29,181,000 (2011: US$25,304,000) (2010: US$32,506,000). Total share based payments, inclusive of amounts capitalised in the balance sheet, amounted to US$2,640,000 for the year ended December 31, 2012 (2011: US$1,547,000) (2010: US$1,240,000). See Note 19.

Included in personnel expenses for the year ended December 31, 2010 is US$301,000 which relates to termination payments resulting from a restructuring programme announced in 2010. This programme involved a re-organisation of the Group's HIV manufacturing activities and comprised termination payments for employees located in Ireland. This restructuring cost is included within net gain on divestment of business and restructuring expenses, on the face of the statement of operations.

The average number of persons employed by the Group in the financial year was 385 (2011: 357) (2010: 452) and is analysed into the following categories:

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| Research and development | 57 | 47 | 37 |
| Administration and sales | 110 | 102 | 130 |
| Manufacturing and quality | 218 | 208 | 285 |
| | 385 | 357 | 452 |

In April 2010, 321 employees transferred to the acquirer of the Coagulation product line (Diagnostica Stago). In 2010, these employees have been included in the average headcount numbers on a pro-rata basis up to their date of departure.

8. 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$837,000 (2011: US$658,000) (2010: US$897,000) (Note 7). The pension accrual for the Group at December 31, 2012 was US$213,000 (2011: US$184,000), (2010: US$228,000).

9. INCOME TAX EXPENSE

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| *Current tax expense* | | | |
| Irish Corporation tax | 316 | 984 | 629 |
| Foreign taxes(a) | 176 | 431 | 356 |
| Adjustment in respect of prior years | (154) | (13) | (138) |
| Total current tax expense | 338 | 1,402 | 847 |
| *Deferred tax expense*(b) | | | |
| Origination and reversal of temporary differences (see Note 13) | 2,599 | 1,293 | 380 |
| Origination and reversal of net operating losses (see Note 13) | (920) | (88) | (285) |
| Total deferred tax expense | 1,679 | 1,205 | 95 |
| Total income tax charge in statement of operations | 2,017 | 2,607 | 942 |

(a) The foreign taxes in 2012 and 2011 relate primarily to USA, Canada and Luxembourg. In 2010, the foreign taxes related primarily to USA.

(b) In 2012 there was a deferred tax charge of US$561,000 (2011: US$326,000; 2010: US$1,093,000 credit) recognised in respect of Ireland and a deferred tax charge of US$1,118,000 (2011: US$879,000; 2010: US$1,188,000) recognised in respect of overseas tax jurisdictions.

| *Effective tax rate* | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Profit before taxation | 19,358 | 18,200 | 61,360 |
| As a percentage of profit before tax: | | | |
| Current tax | 1.75% | 7.70% | 1.38% |
| Total (current and deferred) | 10.42% | 14.32% | 1.53% |

9. 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:

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| Irish corporation tax | 12.50% | 12.50% | 12.50% |
| Effect of tax rates on overseas earnings(a) | (0.66%) | 1.69% | 3.89% |
| Effect of non deductible expenses | 0.24% | 1.24% | 0.32% |
| Effect of Irish income taxable at higher tax rate(b) | 0.13% | 0.35% | (9.35%) |
| Effect of current year net operating losses and temporary differences for which no deferred tax asset was recognised(c) | 0.82% | (0.98%) | (5.55%) |
| R&D tax credit | (0.17%) | (0.12%) | (0.06%) |
| Adjustments in respect of prior years | (0.80%) | (0.36%) | (0.22%) |
| Other(d) | (1.64%) | — | — |
| Effective tax rate | 10.42% | 14.32% | 1.53% |

(a) Taxes incurred in foreign jurisdictions during 2012 had the impact of reducing the overall effective rate of taxation. This is a result of a higher proportion of the Group's income being earned in lower tax rate jurisdictions.

(b) In 2010 the Irish income taxable at a higher tax rate reduced the overall corporation tax rate. This was because the gain arising on sale of the assets and liabilities of the Coagulation product line in Ireland, which was taxable at the higher tax rate of 25%, resulted in a capital loss and consequently no capital gains tax was payable.

(c) The effect of current year net operating losses and temporary differences for which no deferred tax asset was recognized is analyzed further in the table below (see also Note 13). No deferred tax asset was recognized 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.

| Unrecognised deferred tax assets | **Effect in 2012 US$'000** | **Percentage effect in 2012** | **Effect in 2011 US$'000** | **Percentage effect in 2011** |
|---|---|---|---|---|
| Temporary differences arising in USA | 26 | 0.13% | (11) | (0.06%) |
| Net operating losses arising in Brazil | 52 | 0.27% | — | — |
| Net operating losses arising in Sweden | 90 | 0.47% | — | — |
| Net operating losses arising in Ireland | — | — | (177) | (0.98%) |
| Net operating losses arising in Canada | (11) | (0.05%) | 11 | 0.06% |
| | **157** | **0.82%** | **(177)** | **(0.98%)** |

(d) In 2012 there was a credit arising from the tax deduction for share option expense in Ireland.

**Deferred tax recognised directly in equity**

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Relating to forward contracts as hedged instruments | 1 | (1) | 6 |
| | 1 | (1) | 6 |

9. INCOME TAX EXPENSE (CONTINUED)

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Rest of World – Ireland | 10,992 | 10,686 | 38,161 |
| Rest of World – Other | 5,313 | 3,617 | 10,411 |
| Americas | 3,053 | 3,897 | 12,788 |
| | 19,358 | 18,200 | 61,360 |

b. At December 31, 2012, the Group had unutilised net operating losses as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| USA | 5,444 | 2,634 | 1,841 |
| Brazil | 156 | — | — |
| Sweden | 347 | — | — |
| Canada | — | 36 | — |
| Ireland | — | — | 999 |
| | 5,947 | 2,670 | 2,840 |

The utilisation of these 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$906,000 will expire by December 31, 2031 and US$2,414,000 will expire by December 31, 2032.

At December 31, 2012, the Group had unrecognised deferred tax assets in respect of unused tax losses and unused tax credits as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| USA – unused tax credits | 373 | 347 | 358 |
| Brazil – unused tax losses | 52 | — | — |
| Sweden – unused tax losses | 90 | — | — |
| Canada – unused tax losses | — | 11 | — |
| Ireland – unused tax losses | — | — | 177 |
| Unrecognised Deferred Tax Asset | 515 | 358 | 535 |

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 recognized 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 recognized. 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$373,000 at December 31, 2012 (2011: US$347,000; 2010: US$358,000). A deferred tax asset of US$373,000 (2011: US$347,000) in respect of US state credit carryforwards was not recognised in 2012 due to uncertainties regarding future full utilisation of these state credit carryforwards in the related tax jurisdiction in future periods.

10. 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$17,341,000 (2011: US$15,593,000) (2010: US$60,418,000) for the financial year by the weighted average number of 'A' ordinary shares and 'B' ordinary shares in issue. As at December 31, 2012, this amounted to 85,675,284 shares (2011: 85,171,494 shares) (2010: 84,734,378 shares). As at December 31, 2011 and December, 31 2010, 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.

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| 'A' ordinary shares | 85,675,284 | 83,771,494 | 83,334,378 |
| 'B' ordinary shares (multiplied by 2) | — | 1,400,000 | 1,400,000 |
| Basic earnings per share denominator | 85,675,284 | 85,171,494 | 84,734,378 |
| *Reconciliation to weighted average earnings per share denominator:* | | | |
| Number of A ordinary shares at January 1 (Note 18) | 85,321,081 | 84,116,865 | 82,952,037 |
| Number of B ordinary shares at December 31 (multiplied by 2)* | — | 1,400,000 | 1,400,000 |
| Weighted average number of shares issued during the year** | 354,203 | (345,371) | 382,341 |
| Basic earnings per share denominator | 85,675,284 | 85,171,494 | 84,734,378 |

* 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 18). There were no purchases of treasury shares in 2010.

*Diluted earnings per ordinary share*

Diluted earnings per ordinary share is computed by dividing the profit after tax of US$17,341,000 (2011: US$15,593,000) (2010: US$60,418,000) for the financial year by the diluted weighted average number of ordinary shares in issue of 89,773,616 (2011: 88,912,596) (2010: 86,661,535).

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:

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| Basic earnings per share denominator (see above) | 85,675,284 | 85,171,494 | 84,734,378 |
| Issuable on exercise of options and warrants | 4,098,332 | 3,741,102 | 1,927,157 |
| Diluted earnings per share denominator | 89,773,616 | 88,912,596 | 86,661,535 |

10. 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$17,341,000 (2011: US$15,593,000) (2010: US$60,418,000) for the financial year by the weighted average number of ADS in issue of 21,418,821 (2011: 21,292,873); (2010: 21,183,594).

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| 'A' ordinary shares – ADS | 21,418,821 | 20,942,873 | 20,833,594 |
| 'B' ordinary shares – ADS | — | 350,000 | 350,000 |
| Basic earnings per share denominator | 21,418,821 | 21,292,873 | 21,183,594 |

Diluted earnings per ADS for the Group is computed by dividing the profit after taxation of US$17,341,000 (2011: US$15,593,000) (2010: US$60,418,000) for the financial year, by the diluted weighted average number of ADS in issue of 22,443,404 (2011: 22,228,149) (2010: 21,665,383).

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

| | *December 31, 2012* | *December 31, 2011* | *December 31, 2010* |
|---|---|---|---|
| Basic earnings per share denominator (see above) | 21,418,821 | 21,292,873 | 21,183,594 |
| Issuable on exercise of options and warrants | 1,024,583 | 935,276 | 481,789 |
| Diluted earnings per share denominator | 22,443,404 | 22,228,149 | 21,665,383 |

11. PROPERTY, PLANT AND EQUIPMENT

| | *Freehold land and buildings US$'000* | *Leasehold improvements US$'000* | *Computers, fixtures and fittings US$'000* | *Plant and equipment US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| *Cost* | | | | | |
| At January 1, 2011 | 2,080 | 2,253 | 4,290 | 13,940 | 22,563 |
| Acquisitions through business combinations (Note 24) | — | — | — | 159 | 159 |
| Other additions | 11 | 157 | 472 | 2,076 | 2,716 |
| Disposals / retirements | — | — | (1) | (572) | (573) |
| At December 31, 2011 | 2,091 | 2,410 | 4,761 | 15,603 | 24,865 |
| At January 1, 2012 | 2,091 | 2,410 | 4,761 | 15,603 | 24,865 |
| Acquisitions through business combinations (Note 24) | — | — | — | 43 | 43 |
| Other additions | 6 | 50 | 235 | 2,395 | 2,686 |
| Disposals / retirements | — | — | (175) | (209) | (384) |
| Exchange adjustments | — | — | 1 | 15 | 16 |
| At December 31, 2012 | 2,097 | 2,460 | 4,822 | 17,847 | 27,226 |
| *Accumulated depreciation and impairment losses* | | | | | |
| At January 1, 2011 | (781) | (1,936) | (3,735) | (10,112) | (16,564) |
| Charge for the year | (60) | (94) | (189) | (823) | (1,166) |
| Disposals / retirements | — | — | — | 491 | 491 |
| At December 31, 2011 | (841) | (2,030) | (3,924) | (10,444) | (17,239) |
| 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) |
| At December 31, 2012 | (902) | (2,135) | (4,001) | (11,305) | (18,343) |
| *Carrying amounts* | | | | | |
| At December 31, 2012 | 1,195 | 325 | 821 | 6,542 | 8,883 |
| At December 31, 2011 | 1,250 | 380 | 837 | 5,159 | 7,626 |

The annual impairment review performed at December 31, 2012 and December 31, 2011, 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 2012 or 2011.

11. 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, 2012 is US$525,000 (2011: US$648,000). Depreciation charged on these assets in 2012 amounted to US$239,000 (2011: US$192,000).

Included in disposals/retirements in 2012 is US$18,000 (2011: US$77,000) 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$114,000 (2011: US$126,000). The leased equipment secures the lease obligations (Note 20). The depreciation charge in respect of capitalised leased assets for the year ended December 31, 2012 was US$12,000 (2011: US$12,000). This is split as follows:

| *At December 31, 2012* | *Leasehold improvements US$'000* | *Computers, fixtures and fittings US$'000* | *Plant and equipment US$'000* | *Total US$'000* |
|---|---|---|---|---|
| Depreciation charge | — | — | 12 | 12 |
| *Carrying value* | | | | |
| At December 31, 2012 | — | — | 114 | 114 |

| *At December 31, 2011* | *Leasehold improvements US$'000* | *Computers, fixtures and fittings US$'000* | *Plant and equipment US$'000* | *Total US$'000* |
|---|---|---|---|---|
| Depreciation charge | — | — | 12 | 12 |
| *Carrying value* | | | | |
| At December 31, 2011 | — | — | 126 | 126 |

***Property, plant and equipment under construction***

Included in plant and equipment at December 31, 2012 is an amount of US$728,000 (2011: US$690,000) relating to assets in the course of construction.

12. GOODWILL AND INTANGIBLE ASSETS

| | *Goodwill US$'000* | *Development costs US$'000* | *Patents and licences US$'000* | *Other US$'000* | *Total US$'000* |
|---|---|---|---|---|---|
| *Cost* | | | | | |
| At January 1, 2011 | 47,254 | 27,831 | 6,426 | 19,698 | 101,209 |
| Acquisitions through business combinations (Note 24) | 1,801 | — | — | 490 | 2,291 |
| Other additions | — | 6,829 | — | 449 | 7,278 |
| At December 31, 2011 | 49,055 | 34,660 | 6,426 | 20,637 | 110,778 |
| At January 1, 2012 | 49,055 | 34,660 | 6,426 | 20,637 | 110,778 |
| Acquisitions through business combinations (Note 24) | 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 |
| At December 31, 2012 | 56,173 | 52,072 | 10,884 | 20,785 | 139,914 |
| *Accumulated amortisation and Impairment losses* | | | | | |
| At January 1, 2011 | (29,426) | (17,758) | (5,859) | (10,918) | (63,961) |
| Charge for the year | — | (272) | (59) | (1,096) | (1,427) |
| At December 31, 2011 | (29,426) | (18,030) | (5,918) | (12,014) | (65,388) |
| 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 |
| At December 31, 2012 | (29,426) | (18,368) | (5,976) | (13,098) | (66,868) |
| *Carrying amounts* | | | | | |
| At December 31, 2012 | 26,747 | 33,704 | 4,908 | 7,687 | 73,046 |
| At December 31, 2011 | 19,629 | 16,630 | 508 | 8,623 | 45,390 |

Included within development costs are costs of US$17,322,000 which were not amortised in 2012 (2011: US$8,295,000). These development costs are not being amortised as the projects to which the costs relate were not fully complete at December 31, 2012 or at December 31, 2011. As at December 31, 2012 these projects are expected to be completed during the period from January 1, 2013 to April 30, 2015 at an expected further cost of approximately US$22.1 million.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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

| Product Name | 2012 US$'000 | 2011 US$'000 |
|---|---|---|
| Troponin I assay and reader* | 5,048 | — |
| Premier Hb9210 Instrument for Haemoglobin A1c testing** | 3,854 | 3,652 |
| Syphilis Rapid Point-of-Care test | 750 | 611 |
| C. Difficile Rapid Point-of-Care test | 700 | 171 |
| Tristat Point-of-Care instrument | 440 | 333 |
| Cryptosporidium Rapid Point-of-Care test | 376 | 520 |
| Unigold Recombigen HIV Rapid enhancement | 354 | 247 |
| Giardia Rapid Point-of-Care test | 342 | 513 |
| Strep pneumonia Rapid Point-of-Care test | 339 | 194 |
| Liquid Clinical Chemistry | 190 | — |
| HIV Ag-Ab rapid test | 150 | 421 |
| H Pylori Rapid Point-of-Care test | 146 | 42 |
| Other projects with spend less than $100,000 | 340 | 125 |
| **Total capitalized development costs** | **13,029** | **6,829** |

* The Troponin I project was undertaken in 2012 following on from the acquisition of Fiomi Diagnostics AB in February 2012 (see Note 24). The amount of US$5,048,000 incurred in 2012 represents the costs incurred on this project since its acquisition and, as the project is not yet complete, no amortisation has been charged to date.

** The Premier Hb9210 project entails the development of a new High Performance Liquid Chromotography (HPLC) instrument for testing haemoglobin A1c (HbA1c). At December 31, 2012 this project had a carrying amount of $11,002,000 and will be amortised over 15 years.

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:

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

(b) A technical feasibility study is undertaken in advance of every project. The feasibility study for each project is reviewed by the R&D team leader, and by other senior management depending on the size of the project. The feasibility study occurs in the initial research phase of the project and costs in this phase are not 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 consist primarily of acquired customer and supplier lists, trade names, website and software costs.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

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 value-in-use calculations use cash flow projections based on the 2013 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 15% to 27% (2011: 18% to 33%).

The value-in-use calculation is subject to significant estimation, uncertainty and accounting judgements and is particularly sensitive in the following areas. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2012:

- 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, 2012:

- 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.

**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. The additional disclosures required for the two CGUs with significant goodwill are as follows:

| | *Fitzgerald Industries* | | *Fiomi Diagnostics* | |
|---|---|---|---|---|
| | *December 31, 2012* | *December 31, 2011* | *December 31, 2012* | *December 31, 2011* |
| Carrying amount of goodwill (US$'000) | 12,592 | 12,592 | 7,061 | — |
| Discount rate applied (real pre-tax) | 14.9% | 18.3% | 21.2% | — |
| Excess value-in-use over carrying amount (US$'000) | 13,906 | 7,830 | 5,225 | — |
| % EBITDA would need to decrease for an impairment to arise | 38.9% | 25.7% | 16.3% | — |

The key assumptions and methodology used in respect of these two CGUs 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.

12. GOODWILL AND INTANGIBLE ASSETS (CONTINUED)

| **Intangible Assets with Indefinite Useful lives (included in other intangibles)** | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| **Fitzgerald Industries International CGU** | | |
| Fitzgerald trade name | 970 | 970 |
| RDI trade name | 560 | 560 |
| **Primus Corporation CGU** | | |
| Primus trade name | 670 | 670 |
| **Total** | **2,200** | **2,200** |

The trade name assets purchased as part of the acquisition of Primus and RDI in 2005 and Fitzgerald in 2004 were valued by an external valuer 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.

13. DEFERRED TAX ASSETS AND LIABILITIES

**Recognised deferred tax assets and liabilities**

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

| | *Assets* | | *Liabilities* | | *Net* | |
|---|---|---|---|---|---|---|
| | *2012 US$'000* | *2011 US$'000* | *2012 US$'000* | *2011 US$'000* | *2012 US$'000* | *2011 US$'000* |
| Property, plant and equipment | 170 | 142 | (571) | (388) | (401) | (246) |
| Intangible assets | — | — | (9,516) | (5,916) | (9,516) | (5,916) |
| Inventories | 647 | 951 | — | — | 647 | 951 |
| Provisions | 575 | 296 | — | — | 575 | 296 |
| Other items | 827 | 654 | (656) | (524) | 171 | 130 |
| Tax value of loss carryforwards recognised | 1,854 | 934 | — | — | 1,854 | 934 |
| Deferred tax assets/(liabilities) | 4,073 | 2,977 | (10,743) | (6,828) | (6,670) | (3,851) |

The deferred tax asset in 2012 is mainly due to deductible temporary differences relating to net operating losses, inventory and the elimination of unrealised intercompany inventory profit. The deferred tax asset increased US$1,096,000 in 2012 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 US$3,915,000 in 2012, principally because of increased temporary differences between the carrying value of assets and their asset base due to the capital expenditure incurred during 2012 and the acquisition of Fiomi Diagnostics.

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, 2012 and at December 31, 2011 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.

13. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

**Unrecognised deferred tax assets**

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

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Capital losses | 8,513 | 8,513 |
| Net operating losses | 503 | 36 |
| US state credit carryforwards | 373 | 347 |
| | 9,389 | 8,896 |

There was an increase of US$493,000 in the unrecognised deferred tax assets during the year ended December 31, 2012. For comments on the uncertainty prompting less than full recognition refer to Note 9. The movement in the unrecognised deferred tax assets during the year ended December 31, 2012 is analysed as follows:

| Movement in Unrecognised deferred tax assets | **Increase/ (decrease) US$'000** | **Applicable tax rate %** | **Tax effect US$'000** |
|---|---|---|---|
| Net operating losses Canada | (36) | 28% | (11) |
| Net operating losses Brazil | 156 | 34% | 52 |
| Net operating losses Sweden | 347 | 26% | 90 |
| US state credit carryforwards | 26 | n/a | 26 |
| | **493** | | **157** |

A deferred tax asset of US$373,000 (2011: US$347,000) 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$52,000 and US$90,000 were not recognised in respect of net operating losses in Brazil and Sweden respectively. The entity in Brazil was incorporated in 2012 and the entities in Sweden were acquired as part of the Fiomi Diagnostics acquisition. The deferred tax assets have not been recognized for Brazil and Sweden 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 recognized.

At December 31, 2011, a deferred tax asset of US$11,000 in respect of net operating losses of US$36,000 in Canada was not recognised due to uncertainties regarding the timing of the utilisation of these losses in the Canadian entity in future periods.

No deferred tax asset is recognised in respect of a capital loss forward of US$8,513,000 (2011: 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.

**Unrecognised deferred tax liabilities**

At December 31, 2012 and 2011, 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.

13. DEFERRED TAX ASSETS AND LIABILITIES (CONTINUED)

**Movement in temporary differences during the year**

| | *Balance January 1, 2012 US$'000* | *Recognised in income US$'000* | *Recognised in goodwill US$'000* | *Recognised in equity US$'000* | *Balance December 31, 2012 US$'000* |
|---|---|---|---|---|---|
| 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) |

| | *Balance January 1, 2011 US$'000* | *Recognised in income US$'000* | *Recognised in goodwill US$'000* | *Recognised in equity US$'000* | *Balance December 31, 2011 US$'000* |
|---|---|---|---|---|---|
| Property, plant and equipment | 1,788 | (2,034) | 0 | 0 | (246) |
| Intangible assets | (6,031) | 252 | (137) | 0 | (5,916) |
| Inventories | 955 | (4) | 0 | 0 | 951 |
| Provisions | 294 | 2 | 0 | 0 | 296 |
| Other items | (362) | 491 | 0 | 1 | 130 |
| Tax value of loss carryforwards recognised | 846 | 88 | 0 | 0 | 934 |
| | (2,510) | (1,205) | (137) | 1 | (3,851) |

14. OTHER ASSETS

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Finance lease receivables (see Note 16) | 832 | 415 |
| Other assets | 76 | 78 |
| | 908 | 493 |

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 16.

15. INVENTORIES

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Raw materials and consumables | 6,083 | 6,753 |
| Work-in-progress | 5,335 | 4,595 |
| Finished goods | 9,339 | 8,490 |
| | 20,757 | 19,838 |

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$5,348,000 (2011: US$5,930,000). Cost of sales in 2012 includes inventories expensed of US$39,784,000 (2011: US$37,383,000).

As a result of an inventory review carried out during the year, the 2011 inventory classifications between Raw materials, Work-in-progress and Finished goods have been altered from US$7,333,000, US$4,053,000 and US$8,452,000 respectively to the amounts shown above. The overall value of inventory has not changed as a result of these classification changes.

The movement on the inventory provision for the three year period to December 31, 2012 is as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Opening provision at January 1 | 5,930 | 6,400 | 12,566 |
| Charged during the year | 824 | 617 | 3,006 |
| Utilised during the year | (1,055) | (907) | (8,440) |
| Released during the year | (351) | (180) | (732) |
| Closing provision at December 31 | 5,348 | 5,930 | 6,400 |

During 2012 US$351,000 of inventory provision relating to net realisable value was released to the statement of operations following a current year review of selling prices and inventory usage.

16. TRADE AND OTHER RECEIVABLES

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Trade receivables, net of impairment losses | 12,615 | 10,700 |
| Deferred consideration (due within 1 year) | — | 11,138 |
| Prepayments | 1,216 | 1,419 |
| Value added tax | 219 | 374 |
| Finance lease receivables | 391 | 266 |
| Other receivables | 16 | 76 |
| | 14,457 | 23,973 |

In 2011, the deferred consideration arose as a result of the sale of the Coagulation product line (see Note 3) and was comprised of US$11,250,000 of a receivable due from Diagnostica Stago – shown net of US$112,000 of deferred interest income.

Trade receivables are shown net of an impairment losses provision of US$1,520,000 (2011: US$1,507,000) (see Note 27).

16. 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:

| | *December 31, 2012 US$'000* | | |
|---|---|---|---|
| | Gross investment | Unearned income | Minimum payments receivable |
| Less than one year | 604 | 213 | 391 |
| Between one and five years (Note 14) | 1,341 | 509 | 832 |
| | 1,945 | 722 | 1,223 |

| | *December 31, 2011 US$'000* | | |
|---|---|---|---|
| | Gross investment | Unearned income | Minimum payments receivable |
| Less than one year | 414 | 148 | 266 |
| Between one and five years (Note 14) | 659 | 244 | 415 |
| | 1,073 | 392 | 681 |

The Group classified future minimum lease receivables between one and five years of US$832,000 (2011: US$415,000) as Other Assets, see Note 14. 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:

| | *December 31, 2012 US$'000* | | |
|---|---|---|---|
| | 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 |

| | *December 31, 2011 US$'000* | | |
|---|---|---|---|
| | Land and buildings | Instruments | Total |
| Less than one year | 252 | 7,495 | 7,747 |
| Between one and five years | 939 | 3,869 | 4,808 |
| More than five years | — | — | — |
| | 1,191 | 11,364 | 12,555 |

17. CASH AND CASH EQUIVALENTS

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Cash at bank and in hand | 11,482 | 3,210 |
| Short-term deposits | 63,465 | 67,875 |
| Cash and cash equivalents in the statements of cash flows | 74,947 | 71,085 |

18. CAPITAL AND RESERVES

***Share capital***

| *In thousands of shares* | *Class 'A' Ordinary shares 2012* | *Class 'A' Ordinary shares 2011* |
|---|---|---|
| In issue at January 1 | 85,321 | 84,117 |
| Issued for cash | 2,483 | 1,204 |
| Conversion of 'B' shares during the year | 700 | — |
| Bonus issue arising on 'B' share conversion | 490 | — |
| In issue at December 31 | 88,994 | 85,321 |

| *In thousands of shares* | *Class 'B' Ordinary shares 2012* | *Class 'B' Ordinary shares 2011* |
|---|---|---|
| In issue at January 1 | 700 | 700 |
| Issued for cash | — | — |
| Conversion to 'A' shares during the year | (700) | |
| In issue at December 31 | — | 700 |

| *In thousands of shares* | *Class 'A' Treasury shares 2012* | *Class 'A' Treasury shares 2011* |
|---|---|---|
| Balance at January 1 | 2,437 | — |
| Purchased during the year | 1,829 | 2,437 |
| Issued as part of acquisitions made during the year | (1,631) | — |
| Balance at December 31 | 2,635 | 2,437 |

The Group had authorised share capital of 200,700,000 'A' ordinary shares of US$0.0109 each (2011: 200,000,000 'A' ordinary shares of US$0.0109 each) and Nil 'B' ordinary shares (2011: 700,000 'B' ordinary shares of US$0.0109 each) as at December 31, 2012.

(a) During 2012, the Group issued 2,483,000 'A' Ordinary shares from the exercise of warrants and employee options for a consideration of US$2,505,000 settled in cash. The Group incurred costs of US$76,000 in connection with the issue of shares.

(b) 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.

18. CAPITAL AND RESERVES (CONTINUED)

(c) 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.

(d) The Group acquired Fiomi Diagnostics AB (see Note 24) during the year. As part of the purchase consideration, the Group issued 1,631,000 'A' Ordinary Shares (408,000 ADS's). These shares were issued out of the Group's existing Treasury Share holding.

(e) Following shareholder approval at the 2012 AGM, the Board approved the payment of a final dividend of 15 cents per ADS in respect of the 2011 financial year (10 cents per ADS in respect of the 2010 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 28 for further information).

(f) During 2011, the Group issued 1,204,000 'A' Ordinary shares from the exercise of warrants and employee options for a consideration of US$1,189,000 settled in cash. The Group incurred costs of US$38,000 in connection with the issue of shares.

(g) During 2011, the Group purchased 2,437,000 'A' Ordinary shares (609,000 ADS's) 'Treasury shares' on the open market. The total cost of these shares was US$6,094,000.

***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 (2011: 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 2012 or 2011.

***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.

19. SHARE OPTIONS AND SHARE WARRANTS

***Warrants***

There were no warrants granted in either 2012 or 2011.

| | *December 31, 2012 Class 'A' Ordinary Shares* | *December 31, 2011 Class 'A' Ordinary Shares* |
|---|---|---|
| Outstanding at beginning of year | 1,321,744 | 1,672,244 |
| Exercised | (388,624) | (350,500) |
| Outstanding at end of year | 933,120 | 1,321,744 |

***Options***

Under the terms of the Company's Employee Share Option Plans, options to purchase 9,493,598 (excluding warrants of 933,120) 'A' Ordinary Shares were outstanding at December 31, 2012. 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.

19. 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 US$* Per 'A' Ordinary Share | *Range US$* Per 'A' Ordinary Share |
|---|---|---|---|
| Outstanding January 1, 2010 | 10,648,710 | 1.48 | 0.66 – 4.00 |
| Granted | 3,760,000 | 1.47 | 0.97 – 2.00 |
| Exercised | (1,410,156) | 1.02 | 0.66 – 1.78 |
| Forfeited | (2,044,883) | 1.96 | 0.87 – 4.00 |
| Outstanding at end of year | 10,953,671 | 1.44 | 0.66 – 4.00 |
| Exercisable at end of year | 5,226,413 | 1.70 | 0.66 – 4.00 |
| 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 |

| | Options and warrants 'ADS' Equivalent | Weighted-average exercise price US$ Per 'ADS' | Range US$ Per 'ADS' |
|---|---|---|---|
| Outstanding January 1, 2010 | 2,662,178 | 5.92 | 2.63 – 16.00 |
| Granted | 940,000 | 5.88 | 3.88 – 8.00 |
| Exercised | (352,539) | 4.08 | 2.63 – 7.12 |
| Forfeited | (511,221) | 7.84 | 3.48 –16.00 |
| Outstanding at end of year | 2,738,418 | 5.76 | 2.63 – 16.00 |
| Exercisable at end of year | 1,306,603 | 6.80 | 2.63 – 16.00 |
| 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 |

19. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

The weighted average share price per 'A' Ordinary share at the date of exercise for options exercised in 2012 was: US$3.13 ($12.52 per ADS), 2011: US$2.48 per 'A' Ordinary share (US$9.92 per ADS) and 2010: US$1.65 per 'A' Ordinary share (US$6.60 per ADS).

The opening share price per 'A' Ordinary share at the start of the financial year was US$2.54 or US$10.15 per ADS (2011: US$2.20 or US$8.80 per ADS) (2010: US$1.04 or US$4.15 per ADS) and the closing share price at December 31, 2012 was US$3.61 or US$14.42 per ADS (2011: US$2.55 or US$10.18 per ADS) (2010: US$2.20 or US$8.81 per ADS). The average share price for the year ended December 31, 2012 was US$3.03 per 'A' Ordinary share or US$12.10 per ADS.

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

| | Outstanding | | | Exercisable | | |
|---|---|---|---|---|---|---|
| Exercise price range | 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 | | |

| | Outstanding | | | Exercisable | | |
|---|---|---|---|---|---|---|
| Exercise price range | 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 weighted-average remaining contractual life of options and warrants outstanding at December 31, 2012 was 4.34 years (2011: 3.73 years).

19. SHARE OPTIONS AND SHARE WARRANTS (CONTINUED)

A summary of the range of prices for the Company's stock options and warrants for the year ended December 31, 2011 follows:

| | Outstanding | | | Exercisable | | |
|---|---|---|---|---|---|---|
| Exercise price range | 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 | 2,203,358 | 0.71 | 4.19 | 1,246,685 | 0.71 | 4.04 |
| US$1.00 – US$2.05 | 5,607,996 | 1.49 | 3.55 | 3,141,746 | 1.49 | 2.16 |
| US$2.06 – US$2.99 | 1,211,000 | 2.25 | 3.71 | 697,000 | 2.25 | 2.01 |
| US$3.00 – US$4.00 | — | — | — | — | — | — |
| | 9,022,354 | | | 5,085,431 | | |

| | Outstanding | | | Exercisable | | |
|---|---|---|---|---|---|---|
| Exercise price range | 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 | 550,840 | 2.84 | 4.19 | 311,671 | 2.84 | 4.04 |
| US$4.00 – US$8.20 | 1,401,999 | 5.96 | 3.55 | 785,437 | 5.96 | 2.16 |
| US$8.24 – US$11.96 | 302,750 | 9.00 | 3.71 | 174,250 | 9.00 | 2.01 |
| US$12.00 – US$16.00 | — | — | — | — | — | — |
| | 2,255,589 | | | 1,271,358 | | |

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.

19. 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$1,713,000 was charged to the statement of operations in 2012, (2011: US$1,269,000), (2010: US$1,109,000) split as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* | *December 31, 2010 US$'000* |
|---|---|---|---|
| Share-based payments – cost of sales | 38 | 34 | 29 |
| Share-based payments – selling, general and administrative | 1,675 | 1,235 | 1,080 |
| Total | 1,713 | 1,269 | 1,109 |

The total share based payments charge for the year was US$2,640,000. However, a total of US$927,000 (2011: US$278,000) (2010: US$131,000) 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 2012, 2011 and 2010:

| | **Key management personnel 2012** | **Other employees 2012** | **Key management personnel 2011** | **Other employees 2011** | **Key management personnel 2010** | **Other employees 2010** |
|---|---|---|---|---|---|---|
| Weighted average fair value at measurement date per 'A' share / (per ADS) | US$1.21 / (US$4.84) | US$1.18 / (US$4.72) | — | US$1.25 / (US$5.00) | US$0.86 / (US$3.44) | US$0.72 / (US$2.88) |
| Total 'A' share options granted / (ADS's equivalent) | 2,540,000 / (635,000) | 1,558,000 / (389,500) | — | 514,000 / (128,500) | 2,500,000 / (625,000) | 1,220,000 / (305,000) |
| Weighted average share price per 'A' share / (per ADS) | US$2.52 / (US$10.08) | US$2.67 / (US$10.68) | — | US$2.37 / (US$9.48) | US$1.53 / (US$6.12) | US$1.34 / (US$5.36) |
| Weighted average exercise price per 'A' share / (per ADS) | US$2.52 / (US$10.08) | US$2.67 / (US$10.68) | — | US$2.37 / (US$9.48) | US$1.53 / (US$6.12) | US$1.34 / (US$5.36) |
| Weighted average expected volatility | 62.54% | 62.02% | — | 66.30% | 64.86% | 68.97% |
| Weighted average expected life | 4.88 | 4.18 | — | 4.52 | 5.34 | 4.33 |
| Weighted average risk free interest rate | 0.87% | 0.61% | — | 1.50% | 2.04% | 1.78% |
| Expected dividend yield | 1% | 1% | — | 1% | 0% | 0% |

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.

20. INTEREST-BEARING LOANS AND BORROWINGS

This note provides information about the contractual terms of the Group's interest-bearing loans and borrowings. For more information about the Group's exposure to interest rate and foreign currency risk, see Note 27.

***Bank loans***

During 2010 the Group repaid in full all outstanding bank loans following the receipt of the proceeds from the sale of the Coagulation product line (for further information, please refer to Note 3).

***Finance lease liabilities***

There were no finance lease liabilities as at December 31, 2012.

| | *Note* | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|---|
| **Current liabilities** | | | |
| Finance lease liabilities | | — | 108 |
| | | — | 108 |

| | *December 31, 2011 US$'000* | | |
|---|---|---|---|
| | Minimum lease payments | Interest | Principal |
| Less than one year | 110 | 2 | 108 |
| In more than one year, but not more than two | — | — | — |
| In more than two years but not more than five | — | — | — |
| | 110 | 2 | 108 |

Under the terms of the lease arrangements, no contingent rents are payable.

**Terms and debt repayment schedule**

The terms and conditions of outstanding interest bearing loans and borrowings at December 31, 2012 and December 31, 2011 are as follows:

| *Facility* | *Currency* | *Nominal interest rate* | *Year of maturity* | *Fair Value December 31, 2012* | *Carrying Value December 31, 2012* | *Fair Value December 31, 2011* | *Carrying Value December 31, 2011* |
|---|---|---|---|---|---|---|---|
| Finance lease liabilities | Euro | 5.16% | 2010 – 2012 | — | — | 108 | 108 |
| **Total interest-bearing loans and borrowings** | | | | — | — | 108 | 108 |

21. TRADE AND OTHER PAYABLES

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Trade payables | 4,525 | 3,797 |
| Payroll taxes | 283 | 150 |
| Employee related social insurance | 202 | 191 |
| Accrued liabilities | 6,564 | 7,180 |
| Deferred income | 250 | 271 |
| | 11,824 | 11,589 |

22. PROVISIONS

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Provisions | 50 | 50 |

Movement on provisions during the year is as follows:

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Balance at January 1 | 50 | 50 |
| Provisions released during the year | — | — |
| Balance at December 31 | 50 | 50 |

During 2012 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, 2012 represents the estimated cost of product warranties, the exact amount which cannot be determined. US$50,000 represents management's best estimate of these obligations at December 31, 2012.

23. OTHER PAYABLES DUE AFTER ONE YEAR

| | *December 31, 2012 US$'000* | *December 31, 2011 US$'000* |
|---|---|---|
| Other payables | 1,000 | 10 |
| Deferred Consideration | 3,318 | — |
| | 4,318 | 10 |

The deferred consideration payable arises as a result of the acquisition of Fiomi Diagnostics AB in Q1, 2012 and is shown net of deferred interest expense of $97,000. For further information on the acquisition of Fiomi Diagnostics, please refer to Note 24.

Other payables in 2012 are entirely comprised of amounts relating to contracted technology licence payments arising as a result of the Fiomi Diagnostics acquisition (See Note 24).

24. BUSINESS COMBINATIONS

***2012 Acquisition***

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

Fiomi, 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.

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

| | Book values *US$'000* | Fair value adjustments *US$'000* | Fair value *US$'000* | Purchase Consideration* *US$'000* | Goodwill *US$'000* |
|---|---|---|---|---|---|
| **Fiomi Diagnostics AB** | | | | | |
| 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) | | |
| Total identifiable net assets at fair value | | | **5,866** | **12,927** | **7,061** |

| ***Purchase Consideration** | US$'000 |
|---|---|
| Cash Paid | 5,624 |
| Shares Transferred as part of consideration | 4,070 |
| Contingent consideration liability (net present value) | 3,233 |
| Total Purchase Consideration | 12,927 |

Under the terms of the purchase agreement, the previous owners of Fiomi 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, 2012.

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 Fiomi acquisition.

24. BUSINESS COMBINATIONS (CONTINUED)

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, we expect 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 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 recognized 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. We did not recognize any impairment charges related to IPR&D during the years ended December 31, 2012, 2011 and 2010.

The fair value of the trade and other receivables amounts to US$78,000 (i.e. the book value on the date of acquisition). None of the trade and other receivables have been impaired as all of these receivables have been collected by the Company as at December 31, 2012.

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

The goodwill of US$7,061,000 represents 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 have been expensed during the year and are included within selling, general and administrative expenses.

During the year, Fiomi was engaged entirely in the development of its point-of-care cardiac marker assays and, as such, all costs incurred by Fiomi during the year were capitalised to these projects. Fiomi has yet to make its first commercial sale and did not contribute to the Group's revenue in the current financial year. As a result of these factors, Fiomi did not contribute to the Group's profit for the year ended December 31, 2012 and therefore there is no material difference between the profits and revenue which Fiomi would have contributed, had the acquisition taken place as of the beginning of the financial year.

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.

24. BUSINESS COMBINATIONS (CONTINUED)

***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 USA. 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 *US$'000* | Fair value adjustments *US$'000* | Fair value *US$'000* | Purchase Consideration* *US$'000* | Goodwill *US$'000* |
|---|---|---|---|---|---|
| **Phoenix Bio-tech** | | | | | |
| 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) | | |
| Total identifiable net assets at fair value | | | **871** | **2,672** | **1,801** |

| ***Purchase Consideration** | 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. As at December 31, 2012 there was no change in the range of outcomes expected in respect of the contingent consideration.

*Acquisitions 2010*

There were no acquisitions made by the Group in 2010.

25. COMMITMENTS AND CONTINGENCIES

(a) ***Capital Commitments***

The Group has no capital commitments authorised and contracted for as at December 31, 2012 (2011: 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$2,699,000 (2011: US$2,388,000) payable on leases of buildings at Dublin and Bray, Ireland, Jamestown, New York, Acton, Massachusetts, Carlsbad, California, Uppsala, Sweden and Sao Paulo, Brazil. US$317,000 (2011: US$91,000) of these operating lease commitments relates to leases whose remaining term will expire within one year, US$123,000 (2011: US$Nil) relates to leases whose remaining term expires between one and two years, US$719,000 (2011: US$505,000) between two and five years and the balance of US$1,540,000 (2011: US$1,792,000) relates to leases which expire after more than five years. See Note 26 for related party leasing arrangements.

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

| | *Year ended 2012 Operating leases US$'000* |
|---|---|
| 2013 | 2,699 |
| 2014 | 2,371 |
| 2015 | 2,071 |
| 2016 | 1,737 |
| 2017 | 1,540 |
| Later years | 20,520 |
| Total lease obligations | 30,938 |

| | *Year ended 2011 Operating leases US$'000* |
|---|---|
| 2012 | 2,388 |
| 2013 | 2,315 |
| 2014 | 2,306 |
| 2015 | 2,102 |
| 2016 | 1,733 |
| Later years | 23,365 |
| Total lease obligations | 34,209 |

For future minimum finance lease commitments, in respect of which the lessor has a charge over the related assets, see Note 20.

(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.

25. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(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, 2011 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, 2012. However if the income were to become repayable, the maximum amounts repayable as at December 31, 2012 would amount to US$3,333,000 (2011: US$3,271,000).

(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 claim that certain instruments supplied by Trinity Biotech did not operate properly in the field. Trinity Biotech will be defending the claim. 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.

26. 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.

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$503,000) 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$1,038,000).

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

*Compensation of key management personnel of the Group*

At December 31, 2012 and December 31, 2011 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.

26. RELATED PARTY TRANSACTIONS (CONTINUED)

Compensation for the year ended December 31, 2012 of these personnel is detailed below:

| | December 31, 2012 *US$'000* | December 31, 2011 *US$'000* |
|---|---|---|
| Short-term employee benefits | 1,473 | 1,788 |
| Performance related bonus | 481 | 416 |
| Post-employment benefits | 304 | 145 |
| Share-based compensation benefits | 1,689 | 887 |
| | 3,947 | 3,236 |

Note 6 includes non executive directors' fees of US$300,000 (2011: US$306,000) and share-based compensation benefits of US$177,000 (2011: US$97,000). Note 6 excludes the compensation costs of the Chief Financial Officer comprising total remuneration of US$476,000 (2011: US$444,000) and share-based compensation of US$367,000 (2011: US$198,000). Total directors' remuneration is also included in "personnel expenses" (Note 7). 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, 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 |

| | *'A' Ordinary Shares* | *Share options* |
|---|---|---|
| At January 1, 2011 | 5,531,106 | 7,352,089 |
| Exercised | — | (664,580) |
| Granted | — | — |
| Expired Options | — | (933,750) |
| Shares purchased/(sold) during the year | 3,600 | — |
| At December 31, 2011 | 5,534,706 | 5,753,759 |

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 2012 or 2011.

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 2011 and 2012 consolidated financial statements.

26. RELATED PARTY TRANSACTIONS (CONTINUED)

The amount of payments to Rayville included in compensation expense was US$2,149,000, US$1,422,000 and US$231,000 for 2010, 2011 and 2012 respectively, of which US$1,431,000, US$1,395,000 and US$206,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as at December 31, 2012, 2011 or 2010. All of the US$231,000 of payments made to Rayville Limited in 2012 represented repayments of the loan to Trinity Research Limited referred to above.

27. 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.

***Effective interest rate and repricing analysis***

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

| *As at December 31, 2012 US$'000* | *Note* | *Effective interest rate* | *Total US$'000* | *6 mths or less US$'000* | *6-12 mths US$'000* | *1-2 years US$'000* | *2-5 years US$'000* |
|---|---|---|---|---|---|---|---|
| Cash and cash equivalents | *17* | 2.5% | 74,947 | 14,905 | 60,042 | — | — |
| Deferred Consideration | *23* | 3.1% | (3,318) | — | — | (3,318) | — |
| Total | | | 71,629 | 14,905 | 60,042 | (3,318) | — |

| *As at December 31, 2011 US$'000* | *Note* | *Effective interest rate* | *Total US$'000* | *6 mths or less US$'000* | *6-12 mths US$'000* | *1-2 years US$'000* | *2-5 years US$'000* |
|---|---|---|---|---|---|---|---|
| Cash and cash equivalents | *17* | 3.0% | 71,085 | 71,085 | — | — | — |
| Deferred Consideration | *14/16* | 3.1% | 11,138 | 11,138 | — | — | — |
| Finance lease liabilities – fixed | *20* | 5.06% | (108) | — | (108) | — | — |
| Total | | | 82,115 | 82,223 | (108) | — | — |

The effective interest rate on all loans and borrowings is the same as the actual interest rates.

***Interest rate risk***

Year-end cash and cash equivalents amounted to US$74,947,000 (2011: US$71,085,000) which attracted an average rate of interest of 2.5% (2011: 3.0%).

In broad terms, a one-percentage point increase in interest rates would increase interest income by US$749,000 (2011: US$711,000) and would not affect the interest expense (2011: nil impact also) resulting in an increase in interest income of US$749,000 (2011: increase in interest income of US$711,000).

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

***Interest rate profile of financial assets / liabilities***

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

| | *December 31, 2012 US$ '000* | *December 31, 2011 US$ '000* |
|---|---|---|
| ***Fixed rate instruments*** | | |
| Fixed rate financial liabilities | (3,318) | (108) |
| Financial assets (deferred consideration) | — | 11,138 |
| Financial assets (cash and short-term deposits) | 60,042 | — |
| ***Variable rate instruments*** | | |
| Financial assets (cash and short-term deposits) | 14,905 | 71,085 |
| | 71,629 | 82,115 |

In 2012, the fixed rate financial liabilities consist of deferred consideration arising as a result of the Fiomi acquisition (see Note 24). In 2011, fixed rate financial liabilities were entirely comprised of finance lease obligations. The weighted average interest rate and weighted average period for which the rate is fixed is as follows:

| | *December 31, 2012* | *December 31, 2011* |
|---|---|---|
| ***Fixed rate financial liabilities*** | | |
| Weighted average interest rate | 3.1% | 5.06% |
| Weighted average period for which rate is fixed | 1.52 years | 0.61 years |

Financial assets comprise cash and cash equivalents as at December 31, 2012 and cash and cash equivalents and deferred consideration as at December 31, 2011 (see Note 16 & 17).

***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, 2012 would not affect profit or loss.

***Cash flow sensitivity analysis for variable rate instruments***

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.

**Fair Values**

The table below sets out the Group's classification of each class of financial assets/liabilities and their fair values:

| | *Note* | *Loans and receivables* | *Liabilities at amortised cost* | *Total carrying amount* | *Fair Value* |
|---|---|---|---|---|---|
| **December 31, 2012** | | | | | |
| Trade receivables | *16* | 12,615 | — | 12,615 | 12,615 |
| Cash and cash equivalents | *17* | 74,947 | — | 74,947 | 74,947 |
| Finance lease receivable | *14, 16* | 1,223 | — | 1,223 | 1,223 |
| Net Deferred Consideration Payable ('Fiomi') | *23* | — | (3,318) | (3,318) | (3,318) |
| Other Payables | *23* | — | (1,000) | (1,000) | (1,000) |
| Deferred Consideration (Phoenix Bio-tech) | *24* | — | (150) | (150) | (150) |
| Trade and other payables (excluding deferred revenue) | *21* | — | (11,574) | (11,574) | (11,574) |
| Provisions | *22* | — | (50) | (50) | (50) |
| | | 88,785 | (16,092) | 72,693 | 72,693 |

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

| | *Note* | *Loans and receivables* | *Liabilities at amortised cost* | *Total carrying amount* | *Fair Value* |
|---|---|---|---|---|---|
| **December 31, 2011** | | | | | |
| Trade receivables | *16* | 10,700 | — | 10,700 | 10,700 |
| Cash and cash equivalents | *17* | 71,085 | — | 71,085 | 71,085 |
| Finance lease receivable | *14,16* | 681 | — | 681 | 681 |
| Net Deferred Consideration Receivable | *14,16* | 11,138 | — | 11,138 | 11,138 |
| Finance lease liabilities | *20* | — | (108) | (108) | (108) |
| Trade and other payables (excluding deferred revenue) | *21* | — | (11,318) | (11,318) | (11,318) |
| Other payables | *23* | — | (10) | (10) | (10) |
| Provisions | *22* | — | (50) | (50) | (50) |
| | | 93,604 | (11,486) | 82,118 | 82,118 |

**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:

| | *December 31, 2012* | *December 31, 2011* |
|---|---|---|
| Deferred Consideration | 3.10% | 3.10% |
| Leases | — | 5.02% - 5.29% |

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, 2012 and December, 31 2011 as all fell due within 6 months.

***Liquidity risk***

The Group's operations are cash generating. Short-term flexibility is achieved through the management of the Group's short-term deposits.

The following are the contractual maturities of financial liabilities, including estimated interest payments:

| *As at December 31, 2012 US$'000* | *Carrying amount US$'000* | *Contractual cash flows US$'000* | *6 mths or less US$'000* | *6 mths – 12 mths US$'000* | *1-2 years US$'000* | *2-5 years US$'000* |
|---|---|---|---|---|---|---|
| ***Financial liabilities*** | | | | | | |
| Trade & other payables | 12,824 | 12,824 | 12,824 | — | — | — |
| | 12,824 | 12,824 | 12,824 | — | — | — |

| *As at December 31, 2011 US$'000* | *Carrying amount US$'000* | *Contractual cash flows US$'000* | *6 mths or less US$'000* | *6 mths – 12 mths US$'000* | *1-2 years US$'000* | *2-5 years US$'000* |
|---|---|---|---|---|---|---|
| ***Financial liabilities*** | | | | | | |
| Finance lease liabilities – fixed | 108 | 110 | 79 | 31 | — | — |
| Trade & other payables | 11,589 | 11,589 | 11,589 | — | — | — |
| | 11,697 | 11,699 | 11,668 | 31 | — | — |

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

***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, 2012.

The Group had foreign currency denominated cash balances equivalent to US$1,316,000 at December 31, 2012 (2011: US$413,000).

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 2012 and 2011, changes in the fair value of these contracts were recognized in equity and then in the case of contracts which were exercised during 2012 and 2011, the cumulative gain or losses were transferred to the statement of operations.

There were no forward exchange contracts in place at December 31, 2012. The fair value of the forward exchange contract in place at December 31, 2011 amounted to a liability of US$7,000.

**Sensitivity analysis**

A 10% strengthening of the US Dollar against the following currencies at December 31, 2012 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.

| | *Profit or loss US$'000* | *Other equity movements US$'000* |
|---|---|---|
| **December 31, 2012** | | |
| Euro | 1,325 | — |
| **December 31, 2011** | | |
| Euro | 1,101 | (140) |

A 10% weakening of the US Dollar against the above currencies at December 31, 2012 and December 31, 2011 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.

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

**Exposure to credit risk**

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk is as follows:

| | *Carrying Value December 31, 2012 US$'000* | *Carrying Value December 31, 2011 US$'000* |
|---|---|---|
| Third party trade receivables | 12,615 | 10,700 |
| Finance lease income receivable | 1,223 | 681 |
| Cash & cash equivalents | 74,947 | 71,085 |
| Net Deferred Consideration | — | 11,138 |
| | 88,785 | 93,604 |

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

| | *Carrying Value December 31, 2012 US$'000* | *Carrying Value December 31, 2011 US$'000* |
|---|---|---|
| United States | 7,971 | 7,105 |
| Euro-zone countries | 1,343 | 665 |
| UK | 262 | 316 |
| Other European countries | 112 | 149 |
| Other regions | 4,150 | 3,146 |
| | 13,838 | 11,381 |

The maximum exposure to credit risk for trade receivables and finance lease income receivable by type of customer is as follows:

| | *Carrying Value December 31, 2012 US$'000* | *Carrying Value December 31, 2011 US$'000* |
|---|---|---|
| End-user customers | 5,841 | 6,947 |
| Distributors | 7,657 | 4,129 |
| Non-governmental organisations | 340 | 305 |
| | 13,838 | 11,381 |

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, 2012 is as follows:

| *In thousands of US$* | *Gross 2012* | *Impairment 2012* | *Gross 2011* | *Impairment 2011* |
|---|---|---|---|---|
| Not past due | 8,554 | 30 | 7,901 | 9 |
| Past due 0-30 days | 2,999 | 5 | 2,392 | 11 |
| Past due 31-120 days | 573 | 2 | 380 | 12 |
| Greater than 120 days | 2,009 | 1,483 | 1,534 | 1,475 |
| | 14,135 | 1,520 | 12,207 | 1,507 |

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (CONTINUED)

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

| *In thousands of US$* | *2012* | *2011* | *2010* |
|---|---|---|---|
| Balance at January 1 | 1,507 | 1,443 | 855 |
| Charged to costs and expenses | 72 | 64 | 717 |
| Charged to other accounts | — | 499 | — |
| Amounts recovered during the year | — | (86) | (13) |
| Amounts written off during the year | (59) | (413) | (116) |
| Balance at December 31 | 1,520 | 1,507 | 1,443 |

The allowance for impairment in respect of trade receivables is used to record impairment losses unless the Group is satisfied that no recovery of the account owing is possible. At this point the amount is considered irrecoverable and is written off against the financial asset directly.

**Capital Management**

The Group's policy is to maintain a strong capital base so as to maintain investor, creditor and market confidence and to sustain future development of the business. The Board of Directors monitors earnings per share as a measure of performance, which the Group defines as profit after tax divided by the weighted average number of shares in issue.

Following the divestiture of the Coagulation product line in 2010, the Group now has significant cash reserves and has 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, 2012 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.

Capital management in the Group has been assisted by the sale of the Coagulation product line to Diagnostica Stago in 2010. The sale allowed the Group to eliminate bank debt and increases cash reserves. These cash reserves are monitored closely and cash deposits are aligned to mature with the capital requirements of the Group.

28. DIVIDENDS PAID

A dividend of 15 cents per ADS was approved and paid during 2012 in respect of the 2011 financial year (10 cents per ADS approved and paid in 2011 in respect of the 2010 financial year).

| | 2012 US$'000 | 2011 US$'000 |
|---|---|---|
| **Declared and paid during the year:** | | |
| Dividends on ordinary shares: | | |
| Final dividend in respect of FY 2011: US$0.0375 per 'A' share (US$0.15 per ADS) (FY 2010: US$0.10). | **3,224** | **2,145** |

The dividend payable in respect of the 2012 financial year will be proposed by the Directors prior to the next AGM, to be held in May 2013.

29. 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.

30. 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 12 contains information about the assumptions and the risk factors relating to goodwill impairment. Note 19 outlines information regarding the valuation of share options and warrants. Note 24 outlines the valuation techniques used by the Company in determining the fair value of business combinations. In Note 27, 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.

30. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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

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

*Impairment of intangible assets and goodwill*

Definite lived intangible assets are reviewed for indicators of impairment annually while goodwill and indefinite lived assets are tested for impairment annually, individually or at the cash generating unit level.

Factors considered important, as part of an impairment review, include the following:

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

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

*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.

30. ACCOUNTING ESTIMATES AND JUDGEMENTS (CONTINUED)

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 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 derecognized 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 2012, 2011 or 2010.

31. GROUP UNDERTAKINGS

The consolidated financial statements include the financial statements of Trinity Biotech plc and the following principal subsidiary undertakings:

| *Name and registered office* | *Principal activity* | *Principal Country of incorporation and operation* | *Group % holding* |
|---|---|---|---|
| Trinity Biotech plc<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland | Investment and holding company | Ireland | Holding company |
| Trinity Biotech Manufacturing Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland | Manufacture and sale of diagnostic test kits | Ireland | 100% |
| Trinity Research Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland | Research and development | Ireland | 100% |
| Benen Trading Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland | Trading | Ireland | 100% |
| Trinity Biotech Manufacturing Services Limited<br>IDA Business Park, Bray<br>Co. Wicklow, Ireland | Engineering services | Ireland | 100% |
| Trinity Biotech Luxembourg Sarl<br>49, route d'Arlon,<br>L-1140 Luxembourg | Investment and provision of financial services | Luxembourg | 100% |
| Trinity Biotech Inc<br>Girts Road, Jamestown,<br>NY 14702 USA | Holding Company | U.S.A. | 100% |
| Clark Laboratories Inc<br>Trading as Trinity Biotech (USA)<br>Girts Road, Jamestown<br>NY14702, USA | Manufacture and sale of diagnostic test kits | U.S.A. | 100% |
| Mardx Diagnostics Inc<br>5919 Farnsworth Court<br>Carlsbad<br>CA 92008, USA | Manufacture and sale of diagnostic test kits | U.S.A. | 100% |
| Fitzgerald Industries International, Inc<br>2711 Centerville Road, Suite 400<br>Wilmington, New Castle<br>Delaware, 19808, USA | Management services company | U.S.A. | 100% |
| Biopool US Inc (trading as Trinity Biotech Distribution)<br>Girts Road, Jamestown<br>NY14702, USA | Sale of diagnostic test kits | U.S.A. | 100% |
| Primus Corporation<br>4231 E 75th Terrace<br>Kansas City,<br>MO 64132, USA | Manufacture and sale of diagnostic test kits and instrumentation | U.S.A. | 100% |

31. GROUP UNDERTAKINGS (CONTINUED)

| *Name and registered office* | *Principal activity* | *Principal Country of incorporation and operation* | *Group % holding* |
|---|---|---|---|
| Phoenix Bio-tech Corp.<br>1166 South Service Road West<br>Oakville, ON L6L 5T7<br>Canada. | Manufacture and sale of diagnostic test kits | Canada | 100% |
| Fiomi Diagnostics Holding AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden | Holding Company | Sweden | 100% |
| Fiomi Diagnostics AB<br>Dag Hammarskjöldsv 52A<br>SE-752 37 Uppsala<br>Sweden | Research and development | Sweden | 100% |
| Trinity Biotech Do Brasil<br>Rua Claudio Soares<br>Sao Paulo<br>Brazil | Sale of diagnostic test kits | Brazil | 100% |

32. AUTHORISATION FOR ISSUE

These Group consolidated financial statements were authorised for issue by the Board of Directors on April 5, 2013.

***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 5, 2013

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

Date: April 5, 2013

**Item 19** ***Exhibits***

| Exhibit No. | Description of Exhibit |
|---|---|
| 4(a) | 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) |

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**Exhibit 12.1**

**CERTIFICATION PURSUANT TO**
**SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002**

I, Ronan O'Caoimh, certify that:

1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarise and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2013

/s/ RONAN O'CAOIMH*
Ronan O'Caoimh
Chief Executive Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

**Exhibit 12.2**

**CERTIFICATION PURSUANT TO**
**SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002**

I, Kevin Tansley, certify that:

1. I have reviewed this annual report on Form 20-F of Trinity Biotech plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the registrant's auditors and the Audit Committee of the registrant's Board of Directors:

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarise and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 5, 2013

/s/ KEVIN TANSLEY *
Kevin Tansley
Chief Financial Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

**Exhibit 13.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronan O'Caoimh, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ RONAN O'CAOIMH*
Ronan O'Caoimh
Chief Executive Officer

April 5, 2013

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

**Exhibit 13.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin Tansley, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ KEVIN TANSLEY*
Kevin Tansley
Chief Financial Officer

April 5, 2013

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

**Exhibit 15.1**

## Consent of Independent Registered Public Accounting Firm

**The Board of Directors**
**Trinity Biotech plc**

We have issued our reports dated April 5, 2013, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Trinity Biotech plc on Form 20-F for the year ended December 31, 2012. We hereby consent to the incorporation by reference of said reports in the following Registration Statements of Trinity Biotech plc:

| Form Type | File Number | Effective Date |
|---|---|---|
| **Form S-8** | 33-76384 | 3/14/1994 |
| **Form S-8** | 333-5532 | 9/9/1996 |
| **Form S-8** | 333-220 | 1/10/1996 |
| **Form S-8** | 333-7762 | 10/10/1997 |
| **Form S-8** | 333-124384 | 4/28/2005 |
| **Form S-8** | 333-166590 | 5/6/2010 |

Grant Thornton
Dublin, Ireland

April 5, 2013