TRINITY BIOTECH PLC
Form 20-F
April 14, 2011

Table of Contents

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549
FORM 20-F

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

OR

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

For the fiscal year ended December 31, 2010

OR

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

For the transition period from _____ to _____

o **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:

84,116,865 Class A Ordinary Shares and 700,000 Class B Shares

(as of December 31, 2010)

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

Yes o No þ

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 o No þ

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 þ No o

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 o Accelerated filer þ Non-accelerated filer o

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

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

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 o Item 18 o

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 o No þ

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

TABLE OF CONTENTS

PART III

Table of Contents

General

As used herein, references to we , us , Trinity Biotech or the Group in this form 20-F shall mean Trinity Biotech 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 subsequently adopted by the European Union (EU). The IFRS applied are those effective for accounting periods beginning on or after 1 January 2010. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. All references in this annual report to Dollars and $ are to US Dollars, and all references to Euro or are to European Union Euro. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

Forward-Looking Statements

This Annual Report on Form 20-F contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates , anticipates , projects , plans , seeks , may , wi 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, 2010 and 2009 and for each of the years ended December 31, 2010, 2009 and 2008 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, 2008, 2007 and 2006 and for the years ended December 31, 2007 and December 31, 2006 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

Table of Contents

CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December, 31				
	2010 Total US$ 000	*2009 Total US$ 000*	*2008 Total US$ 000*	*2007 Total US$ 000*	*2006 Total US$ 000*
Revenues	**89,635**	**125,907**	**140,139**	**143,617**	**118,674**
Cost of sales	(45,690)	(68,891)	(77,645)	(75,643)	(62,090)
Cost of sales restructuring expenses				(953)	
Cost of sales inventory write off / provision				(11,772)	(5,800)
Total cost of sales	**(45,690)**	**(68,891)**	**(77,645)**	**(88,368)**	**(67,890)**
Gross profit	**43,945**	**57,016**	**62,494**	**55,249**	**50,784**
Other operating income	1,616	437	1,173	413	275
Research and development expenses	(4,603)	(7,341)	(7,544)	(6,802)	(6,696)
Research and development restructuring expenses				(6,907)	
Total research and development expenses	**(4,603)**	**(7,341)**	**(7,544)**	**(13,709)**	**(6,696)**
Selling, general and administrative expenses	(26,929)	(36,013)	(47,816)	(51,010)	(42,422)
Selling, general and administrative impairment charges and restructuring expenses			(87,882)	(20,315)	
Total selling, general and administrative expenses	**(26,929)**	**(36,013)**	**(135,698)**	**(71,325)**	**(42,422)**
Net gain on divestment of business and restructuring expenses	**46,474**				
Operating profit/(loss)	**60,503**	**14,099**	**(79,575)**	**(29,372)**	**1,941**
Financial income	1,352	8	65	457	1,164
Financial expenses	(495)	(1,192)	(2,160)	(3,148)	(2,653)

Net financing income/(costs)	**857**	**(1,184)**	**(2,095)**	**(2,691)**	**(1,489)**
Profit/(loss) before tax	**61,360**	**12,915**	**(81,670)**	**(32,063)**	**452**
Income tax (expense)/ credit	(942)	(1,091)	3,892	(3,309)	2,824
Profit/(loss) for the year (all attributable to owners of the parent)	**60,418**	**11,824**	**(77,778)**	**(35,372)**	**3,276**
Basic earnings/(loss) per A ordinary share (US Dollars)	0.71	0.14	(0.96)	(0.47)	0.05
Basic earnings/(loss) per B ordinary share (US Dollars)	1.43	0.28	(1.91)	(0.94)	0.10
Diluted earnings/(loss) per A ordinary share (US Dollars)	0.70	0.14	(0.96)	(0.47)	0.05
Diluted earnings/(loss) per B ordinary share (US Dollars)	1.39	0.28	(1.91)	(0.94)	0.10
Basic earnings/(loss) per ADS (US Dollars)	2.85	0.57	(3.82)	(1.86)	0.19
Diluted earnings/(loss) per ADS (US Dollars)	2.79	0.57	(3.82)	(1.86)	0.19
Weighted average number of shares used in computing basic EPS	84,734,378	83,737,884	81,394,075	76,036,579	70,693,753
Weighted average number of shares used in computing diluted EPS	86,661,535	83,772,094	81,394,075	76,036,579	72,125,740

Table of Contents

Consolidated Balance Sheet Data	*December 31, 2010 US$ 000*	*December 31, 2009 US$ 000*	*December 31, 2008 US$ 000*	*December 31, 2007 US$ 000*	*December 31, 2006 US$ 000*
Net current assets (current assets less current liabilities)	89,068	42,835	39,494	36,298	60,996
Non-current liabilities	(7,331)	(27,500)	(27,897)	(35,623)	(45,928)
Total assets	160,874	132,445	129,509	215,979	249,131
Capital stock	1,092	1,080	1,070	991	978
Shareholders equity	141,287	79,344	65,905	136,845	167,262

No dividends were declared in any of the periods from December 31, 2006 to December 31, 2009. The Board have proposed a final dividend of 10 cent per ADR in respect of 2010 and this proposal will be submitted to shareholders for their approval at the next Annual General Meeting of the Company. As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars.

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 Siemens (Immulite , Enzygnost®), Inverness Medical Innovations, Inc. (Determine , Wampole , Athena), Diasorin Inc. (Liasion , ETIMAX), Abbott Diagnostics (AxSYM , IMx), Bio-Rad (ELISA, WB, Bioplex & A1c), Roche Diagnostics (COBAS AMPLICOR , Ampliscreen , Accutrend) and OraSure Technologies, Inc (OraQuick®).

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.

Table of Contents

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

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

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

Our business could be adversely affected by changing market conditions.

The diagnostics industry is in transition with a number of changes that affect the market for diagnostic test products. Changes in the healthcare industry delivery system have resulted in major consolidation among reference laboratories and in the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. There can be no assurance that we will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers.

Future acquisitions may be less successful than expected, and therefore, growth may be limited.

Trinity Biotech has historically grown organically and through the acquisition of, and investment in, other companies, product lines and technologies. There can be no guarantees that recent or future acquisitions can be successfully assimilated or that projected growth in revenues or synergies in operating costs can be achieved. Our ability to integrate future acquisitions may also be adversely affected by inexperience in dealing with new technologies, and changes in regulatory or competitive environments. Additionally, even during a successful integration, the investment of management s time and resources in the new enterprise may be detrimental to the consolidation and growth of our existing business.

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

Trinity Biotech currently distributes its product portfolio through distributors in approximately 75 countries worldwide. Our continuing economic success and financial security is dependent on our ability to secure effective channels of distribution on favourable trading terms with suitable distributors.

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

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

Trinity Biotech currently owns 6 US patents with remaining patent lives varying from less than one year to 16 years. In addition to these US patents, Trinity Biotech owns a total of 5 additional non-US patents with expiration dates varying between the years 2011 and 2023.

Table of Contents

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$8,679,000) for any one accident, limited to a maximum of 6,500,000 (US$8,679,000) 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 76% of revenues in 2010. 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, 2010 were Ronan O Caoimh, our CEO and Chairman, Rory Nealon, our COO, Jim Walsh, our Chief Scientific Officer and Kevin Tansley, our CFO/Company Secretary. If such key employees were to leave and we were unable to obtain adequate replacements, our operating results could be adversely affected.

We are dependent on suppliers for the primary raw materials required for its test kits.

The primary raw materials required for Trinity Biotech s test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. Although Trinity Biotech does not expect to be dependent upon any one source for these raw materials, alternative sources of antibodies with the characteristics and quality desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

Table of Contents

We could be adversely affected by healthcare reform legislation.

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. The newly enacted Patient Protection and Affordable Care Act imposes a new 2.3% excise tax on medical device makers beginning in 2013, which could have a material negative impact on our results of operations and our cash flows. At present, given the infancy of the enacted reform, we are unable to predict what effect the legislation might ultimately have on reimbursement rates for our products. If reimbursement amounts for diagnostic testing services are decreased in the future, such decreases may reduce the amount that will be reimbursed to hospitals or physicians for such services and consequently could place constraints on the levels of overall pricing, which could have a material effect on our sales and/or results of operations. Other elements of this legislation could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

Global economic conditions may have a material adverse impact on our results.

We currently generate significant operating cash flows, which combined with access to the credit markets provides us with discretionary funding capacity for research and development and other strategic activities. Current uncertainty in global economic conditions poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. If global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers.

Our sales and operations are subject to the risks of fluctuations in currency exchange rates.

A substantial portion of our operations are in Ireland and Europe is one of our main sales territories. As a result, changes in the exchange rate between the U.S. dollar and the euro can have significant effects on our results of operations.

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

The warrants issued in 2008 and 2010 and the total share options exercisable at December 2010, as described in Item 18, note 19 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 Class A Ordinary Shares. The exercise of the share options exercisable and of the warrants will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders. For instance, should the options and warrant holders of the 5,226,413 A Ordinary shares (1,306,603 ADSs) exercisable at December 31, 2010 be exercised, Trinity Biotech would have to issue 5,226,413 additional A ordinary shares (1,306,603 ADSs). On the basis of 84,116,865 A ordinary shares outstanding at December 31, 2010, this would effectively dilute the ownership interest of the existing shareholders by approximately 6%.

It could be difficult for US holders of ADSs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.

At present, no treaty exists between the United States and Ireland for the reciprocal enforcement of foreign judgements. The laws of Ireland do however, as a general rule, provide that the judgements of the courts of the United States have in Ireland the same validity as if rendered by Irish Courts. Certain important requirements must be satisfied before the Irish Courts will recognize the United States judgement. The originating court must have been a court of competent jurisdiction, the judgement may not be recognized if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgement obtained in contravention of the rules of natural justice will not be enforced in Ireland.

Table of Contents

Item 4

Information on the Company

History and Development of the Company

Trinity Biotech (the Group) develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care (POC) segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. The Group is also a significant provider of raw materials to the life sciences industry. The Group sells worldwide in over 75 countries through its own sales force and a network of international distributors and strategic partners.

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

The Group, which has its headquarters in, Bray Ireland, employs approximately 345 people worldwide and markets its portfolio of over 350 products to customers in 75 countries around the world. Trinity Biotech markets its products in the US through a direct sales force and in the rest of the world through a combination of direct selling and a network of national and international distributors. Trinity Biotech has manufacturing facilities in Bray, Ireland, in Jamestown, New York, Carlsbad, California and Kansas City, Missouri in the USA.

In May 2010, the Group sold its worldwide Coagulation business 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 the immuno-technology business of Cortex Biochem Inc

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

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

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

Principal Markets

The primary market for Trinity Biotech s tests remains the USA. During fiscal year 2010, the Group sold 60% (US$54.0 million) (2009: 54% or US$68.1 million) (2008: 50% or US$69.9 million) of product in the USA. Sales to non-US (principally European and Asian/ African) countries represented 40% (US$35.6 million) for fiscal year 2010 (2009: 46% or US$57.8 million) (2008: 50% or US$70.2 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.

Table of Contents

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®	Primus	EZ
Recombigen®	Captia		
	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 organisations in USA and through our network of principal distributor partners into approximately 75 countries in the rest of the world.

Point of Care (POC)

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

UniGold HIV

Trinity Biotech makes a very significant contribution to the global effort to meet the challenge of HIV. The Group s principal product is UniGold HIV.

In Africa, UniGold HIV has been used for several years in voluntary counselling and testing centres (VCTs) in the sub-Saharan region where they provide a cornerstone to early detection and treatment intervention. The UniGold HIV brand is recognized for its quality and reliability. These same factors are the springboard in some countries for national testing algorithm changes in favour of wider usage of UniGold HIV.

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

The Future of Point-Of-Care at Trinity Biotech

Point-Of-Care is strategically key to the growth of Trinity Biotech in the future. The company has already invested in establishing 3 new product development teams in the US 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) 1 & 2 and HIV combination assay (1 & 2 + Antigen)

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

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 and Hb Variant: Diabetes and Haemoglobin disorders.

Clinical Chemistry: Liver & kidney disease and haemolytic anaemia.

Table of Contents

Infectious Diseases

Trinity Biotech manufactures products for niche/specialised applications in Infectious Disease and Autoimmune disorders. The products are used with patient samples and the results generated help physicians to guide diagnosis for a broad range of infectious diseases. The key niche/specialist disease areas served by the Trinity Biotech products include: (1) Lyme disease, (2) Sexually transmitted diseases: Syphilis, Chlamydia and Herpes simplex, (3) Respiratory infections: Legionella, Flu A&B, (4) Epstein Barr Virus, (5) other viral pathogens, e.g. Measles, Mumps, Rubella and Varicella, (6) Autoimmune disorders (e.g. lupus, celiac and rheumatoid arthritis).

The vast majority of the infectious diseases product line is FDA cleared for sale in the USA and CE marked in Europe. Products are sold in over 75 countries, with the focus on North America, Europe and Asia.

HbA1c and Hb Variants

The Primus Corporation, a Trinity Biotech company, focuses on products for the *in-vitro* diagnostic testing for haemoglobin A1c (HbA1c) used in the monitoring of diabetes. Primus manufactures a range of instrumentation using patented HPLC (high pressure liquid chromatography) technology.

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

Haemoglobin Variants: The Primus Ultra^2 instrument is the most accurate and 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.

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

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

In preparation for the planned 2011 launch of a new high throughput HbA1c instrument, the Premier Hb 9210 (formerly known as Pdx), Trinity Biotech has entered into a distribution agreement with Menarini Diagnostics, for Europe. The US launch is expected later in 2011. This new instrument will also give access to markets not previously open to Trinity Biotech due to instrument price and test capability.

Clinical Chemistry

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

Sales and Marketing

Trinity Biotech sells its product through its own direct sales-force in the United States. Our sales team in the United States is responsible for marketing and selling the Trinity Biotech range of clinical chemistry, point of care, infectious disease, Primus and clinical chemistry products.

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

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

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

All product lines through independent distributors and strategic partners in a further 75 countries.

Table of Contents

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, Roche, Abbott, Johnson & Johnson, Siemens (from the combined acquisitions of Bayer Diagnostics, Dade-Behring and DPC), Beckman Coulter, Inverness Medical Innovations, Inc., Bio-Rad and Thermo Fisher.

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.

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 8.5% of sales. The total amount paid by Trinity Biotech under key licensing arrangements in 2010 was US$1,233,000 (2009: US$899,000).

Table of Contents

Government Regulation

The preclinical and clinical testing, manufacture, labelling, distribution, and promotion of Trinity Biotech s products are subject to extensive and rigorous government regulation in the United States and in other countries in which Trinity Biotech s products are sought to be marketed. The process of obtaining regulatory clearance varies, depending on the product categorisation and the country, from merely notifying the authorities of intent to sell, to lengthy formal approval procedures which often require detailed laboratory and clinical testing and other costly and time-consuming processes. The main regulatory bodies which require extensive clinical testing are the Food and Drug Administration (FDA) in the US, the Irish Medicines Board (as the authority over Trinity Biotech in Europe) and Health Canada. The process in each country varies considerably depending on the nature of the test, the perceived risk to the user and patient, the facility at which the test is to be used and other factors. As 60% of Trinity Biotech s 2010 revenues were generated in the US and the US represents approximately 43% 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 application (PMA) approval 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 2010 is in the region of US$200,000.

510(k) Clearance Pathway. To obtain 510(k) clearance, Trinity Biotech must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a predicate device either a previously cleared class I or II device or a class III preamendment device, for which the FDA has not called for PMA applications. The FDA s 510(k) clearance pathway usually takes from 3 to 9 months, but it can take longer. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could even require a PMA approval.

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

Although the FDA is not bound by the advisory panel decision, the panel s recommendation is important to the FDA s overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. It generally takes from one to three years or even longer. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. As noted above, the FDA has recently implemented substantial fees for the submission and review of PMA applications.

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

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

11

Table of Contents

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 clinica 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.

Table of Contents

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, Co. Wicklow, Ireland while its research and development, manufacturing and marketing activities are principally conducted at Trinity Biotech Manufacturing Limited, based in Bray, Co. Wicklow, Ireland and at Trinity Biotech (USA), MarDx Diagnostics Inc, Primus Corporation and Biopool US Inc. based in Jamestown, New York State, Carlsbad, California, Kansas City, Missouri and Jamestown, New York State respectively. The Group s distributor of raw materials for the life sciences industry, Fitzgerald Industries, is based in Acton, Massachusetts and Bray, Co. Wicklow, Ireland.

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, Co. Wicklow, 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.

Until the divestiture of our Coagulation business in May 2010, our facilities and offices in Ireland were located in four buildings at IDA Business Park, Bray, Co. Wicklow. Following the divestiture, the lease on one of these buildings was assigned to Diagnostica Stago and the lease on another of the buildings is currently in the process of being assigned to Diagnostica Stago. Upon completion of this assignment, the Company will have leases on the remaining two buildings at IDA Business Park, Bray, Co. Wicklow. The lease to be transferred to Diagnostica Stago in 2011 relates to the manufacturing and research and development facility consisting of approximately 45,000 square feet. This facility is ISO 9001 approved and was purchased in December 1997. The facility includes offices, research and development laboratories, production laboratories, cold storage and drying rooms and warehouse space. The annualised rent on this facility is 479,000(US$639,000). Diagnostica Stago has been reimbursing the Company for the payments made on this lease since the divestiture of the Coagulation business in May 2010.

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 at IDA Business Park, Bray, Co. Wicklow, Ireland. In July 2000, Trinity Biotech entered into a 20 year lease with JRJ for a 25,000 square foot warehouse adjacent to the existing facility at a current annual rent of 275,000 (US$367,000). As described above, this was the lease which was assigned to Diagnostica Stago during 2010.

In November 2002, 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$509,000), payable from 2004. In December 2007, the Group entered into an agreement with Mr O Caoimh and Dr Walsh pursuant to which the Group took a lease on an additional 43,860 square foot manufacturing facility in Bray, Ireland at a rate of 17.94 per square foot (including fit out) giving a total annual rent of 787,000 (US$1,051,000). See Item 7 Major Shareholders and Related Party Transactions.

Trinity Biotech USA operates from a 24,000 square foot FDA and ISO 9001 approved facility in Jamestown, New York. The facility was purchased by Trinity Biotech USA in 1994. Additional warehousing space is also leased in upstate New York at an annual rental charge of US$133,000.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,500 square feet and is the subject of a five year lease, renewed in 2009, at an annual rental cost of US$255,978. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, amended in 2009, at an annual rental cost of US$172,356.

13

Table of Contents

Trinity Biotech sold its facility located in Lemgo, Germany during 2010 as part of the Sale of its Coagulation business see Item 18, note 3 for further information.

The Group also had leases on premises in the UK and France which were transferred to Diagnostica Stago in May 2010, following the sale of the Coagulation business. These consisted of two units in Berkshire, UK, at an annual rent of £91,000 (US$141,000) and a lease for a 5,750 square foot premises in Paris, France, at an annual rent of 46,000 (US$61,000).

Additional office space is leased by the Group in Ireland, Kansas City, Missouri and Acton, Massachusetts at an annual cost of 115,000(US$154,000), US$100,000 and US$86,000 respectively.

At present we have sufficient productive capacity to cover demand for our product range. We continue to review our level of capacity in the context of future revenue forecasts. In the event that these forecasts indicate capacity constraints, we will either obtain new facilities or expand our existing facilities.

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

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

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

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

Carlsbad, California this facility specializes in the development and manufacture of products utilizing Western Blot technology. Our Lyme suite of products is manufactured at this facility.

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 29 with regard to the acquisition of Phoenix Bio-tech Corp. in 2011 and to Item 18, note 3 concerning the divestiture of the Coagulation business 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, 2010, December 31, 2009 and December 31, 2008, 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.

Table of Contents

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, 2010 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 350 different diagnostic products in approximately 75 countries. In addition, the Group manufactures its own and distributes third party infectious disease diagnostic instrumentation. The Group, through its Fitzgerald operation, is also a significant provider of raw materials to the life sciences industry.

Factors affecting our results

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

Our revenues are directly related to our ability to identify high potential products while they are still in development and to bring them to market quickly and effectively. Efficient and productive research and development is crucial in this environment as we, like our competitors, search for effective and cost-efficient solutions to diagnostic problems. The growth in new technology will almost certainly have a fundamental effect on the diagnostics industry as a whole and upon our future development.

The comparability of our financial results for the years ended December 31, 2010, 2009, 2008, 2007 and 2006 have been impacted by acquisitions made by the Group in two of the five years and by the divestiture of the Coagulation business in 2010. There were no acquisitions made in 2010, 2009 or 2008. In 2007, the Group acquired the immuno-technology assets of Cortex and certain components of the distribution business of Sterilab. In 2006, the Group acquired the coagulation business of bioMerieux (subsequently divested) and a direct selling entity in France.

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

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.

Table of Contents

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 commercial production starts.

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, 2010 the carrying value of capitalised development costs was US$10,073,000 (2009: US$12,785,000) (see Item 18, note 12 to the consolidated financial statements). The decrease in 2010 was as a result of development costs of US$5,887,000 being capitalised in 2010 which were more than offset by amortisation of US$297,000 and reductions associated with the divestment of the Coagulation business; which had a net book value of US$8,289,000.

Impairment of intangible assets and goodwill

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

Significant underperformance relative to expected, historical or projected future operating results;

Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;

Obsolescence of products;

Significant decline in our stock price for a sustained period; and

Our market capitalisation relative to net book value.

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

The recoverable amount of goodwill and intangible assets contained in each of the Group s CGU s is determined based on the greater of the fair value less cost to sell and value in use calculations. The Group operates in one market sector (namely diagnostics) and accordingly the key assumptions are similar for all CGU s. The value in use calculations use cash flow projections based on the 2011 budget and projections for a further four years using projected revenue and cost growth rates of between 3% and 5%. At the end of the five year forecast period, terminal values for each CGU, based on a long term growth rate are used in the value in use calculations. The cashflows and terminal values for the CGU s are discounted using pre-tax discount rates which range from 18% to 32%.

16

Table of Contents

The value in use calculation is subject to significant estimation, uncertainty and accounting judgements and are particularly sensitive in the following areas. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2010:

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, 2010:

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 2008, 2009 or 2010 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2010 our allowance for slow moving and obsolete inventory was US$6,400,000 which represents approximately 26.7% of gross inventory value. This compares with US$12,566,000, or approximately 24.3% of gross inventory value, at December 31, 2009 (see Item 18, note 15 to the consolidated financial statements) and US$16,461,000, or approximately 28.0% of gross inventory value, at December 31, 2008. There has been a small increase in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2010 and 2009. In the case of finished inventory, the size of this provision has been calculated based on the expected future sales of products which are being rationalised. 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$480,000 at December 31, 2010 (2009: US$1,035,000) (2008: US$1,176,000) 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 2010 or 2009 which would have an impact on the carrying values of receivables in these periods. At December 31, 2010, the allowance was US$1,443,000 which represents approximately 1.6% of Group revenues. This compares with US$855,000 at December 31, 2009 which represents approximately 0.7% of Group revenues (see Item 18, note 16 to the consolidated financial statements) and to US$619,000 at December 31, 2008, which represents approximately 0.4% 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$359,000 at December 31, 2010 (2009: US$504,000) (2008: US$561,000) 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.

Table of Contents

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 2010. 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 2010, 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).

Table of Contents

Subsequent Events

Acquisition of Phoenix Bio-tech Corp.

On January 4, 2011, the Group purchased 100% of the common stock of Phoenix Bio-tech Corporation for US$2.5 million. Phoenix Bio-tech manufactures and sells products for the detection of syphilis. This acquisition has not been reflected in the financial statements for the year ended December 31, 2010 as it was completed subsequent to the financial year end. The fair values of the acquired assets and liabilities have not been established yet.

Phoenix Bio-tech was founded in 1992 and is based in Toronto, Canada. It sells its products under the TrepSure and TrepCheck labels. Phoenix s annual revenues are approximately US$1.25 million. Prior to the acquisition, Trinity Biotech distributed Phoenix Bio-tech s syphilis products on a non-exclusive basis in the USA.

The key terms of the acquisition are as follows:

Consideration of US$2,500,000. US$1,000,000 was payable on closing and the remaining US$1,500,000 is payable in four instalments in the period April 2011 to January 2012.

The consideration of US$2,500,000 includes acquired net working capital of approximately US$500,000.

As the initial accounting and fair value assessment for the business combination is incomplete at the time that these financial statements were authorised for issue the following disclosures cannot be made but will be reported if relevant in the Form 20-F for the period ended December 31, 2011:

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

Details of the indemnification assets,

Details of acquired receivables,

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

Details of contingent liabilities recognised; and

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

Dividend

In 2011 the Company announced that it intended to commence a dividend policy, to be paid once a year. In this regard, the Board of Directors has proposed a final dividend of 10 cent per ADR in respect of 2010 and this proposal will be submitted to shareholders for their approval at the next Annual General Meeting of the Company. As provided in the Articles of Association of the Company, dividends or other distributions are declared and paid in US Dollars.

Table of Contents

Results of Operations

Year ended December 31, 2010 compared to the year ended December 31, 2009

The following compares our results in the year ended December 31, 2010 to those of the year ended December 31, 2009 under IFRS. Our analysis is divided as follows:

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

1. Overview

In 2010, Trinity Biotech divested its coagulation business and this was the main reason for the US$36.3 million decline in revenues compared to 2009. Excluding coagulation revenues, the decrease was US$4.8 million, representing a reduction of 6% compared to 2009. In 2010, point-of-care revenues declined by 11%, largely due to the company s decision not to ship to a major HIV customer beginning in the second half of 2009 and continuing into 2010 due to credit related issues. Lower levels of public expenditure on testing in the US market also caused the reduction in point-of-care revenues. Clinical laboratory revenues (excluding coagulation) declined by just under 5%.

The gross margin is 49% for 2010, which is 3.7% higher than the gross margin for 2009. The increase in gross margin this year is primarily attributable to the divestiture of the coagulation business. Due to the costly instrument servicing requirements in the coagulation business, it was the Group s least profitable product line.

The divestiture of the coagulation business resulted in a once-off gain of US$46.8 million.

The table hereunder compares the profit before tax for year ended December, 2010 to the previous financial year.

	Year ended December 31,		
	2010	**2009**	
	US$ 000	**US$ 000**	**%Change**
Profit before Tax	61,360	12,915	
Profit before Tax (2010 figure shown before net gain on divestment of business and restructuring expenses)	14,886	12,915	15.3%

The profit before tax is US$61.4 million for the year ended December 31, 2010 which compares to a profit before tax of US$12.9 million for the year ended December 31, 2009. Excluding the gain on the divestiture of the coagulation business 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 15.3% in 2010. The US$2.0 million increase in profit before tax was primarily due to the elimination of bank debt, causing the net interest expense of US$1.2m in 2009 to become net interest income of US$0.9m in 2010.

The profit for the year ended December 31, 2010 was US$60.4 million which compares to a profit for the year ended December 31, 2009 of US$11.8 million. Excluding the gain on the divestiture of the coagulation business and the impact of restructuring expenses in 2010, the profit for 2010 would have been US$13.6 million.

2. Revenues

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

Table of Contents

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 located at customer premises.

Revenues by Product Line

Trinity Biotech s revenues for the year ended December 31, 2010 were US$89,635,000 compared to revenues of US$125,907,000 for the year ended December 31, 2009, which represents a decrease of US$36,272,000 or 29%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2010 US$ 000	2009 US$ 000	% Change
Revenues			
Clinical Laboratory	73,553	107,778	(31.8%)
Point of Care	16,082	18,129	(11.3%)
Total	**89,635**	**125,907**	**(28.8%)**

Clinical Laboratory

In 2010 Clinical Laboratory revenues decreased by US$34,225,000 which equates to a 32% decline. The decrease was largely due to the divestiture of the coagulation product line in May 2010. Excluding coagulation, clinical laboratory revenues decreased by US$2.8 million when compared to 2009. This represents a decrease of 4.5%.

The decrease was caused by four main factors:

- a slower lyme season due to weather conditions in the USA;
- lower sales of antibodies and antigens by our Fitzgerald business due to the fact that 2009 sales of antibodies and antigens benefitted from the incidence of H1N1;
- the move from selling direct in France and Germany to a distribution selling model; and
- changes in exchange rates, principally the strengthening of the US Dollar against the Euro.

These decreases were partially offset by a growth in sales of our clinical chemistry product line.

Table of Contents

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 decreased by US$2,047,000, which represents a decline of 11%.

Point of Care revenues in the USA decreased by 10% mainly due to lower levels of public expenditure on testing in the US market. In Africa, revenues decreased by 7% largely due to the company s decision not to ship to a major HIV customer due to credit related issues beginning in the second half of 2009 and continuing into 2010.

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,		
	2010	2009	
	US$ 000	US$ 000	% Change
Revenues			
Americas	53,993	68,130	(21%)
Europe	15,890	32,389	(51%)
Asia/Africa	19,752	25,388	(22%)
Total	**89,635**	**125,907**	(29**%)**

In the Americas, the 21% decrease amounting to US$14,137,000 is primarily attributable to a reduction in coagulation revenue due to the divestiture of this business in May 2010. The other main factor was a slower lyme season due to weather conditions in the USA.

Revenues in Europe decreased by US$16,499,000, or 51% compared to 2009. The decrease was mainly due to the divestiture of the coagulation product line and the move to a distributor selling model for non-coagulation products in Germany and France in the post-divestiture period. Part of the decrease was due to the weakening of the Euro against the US Dollar.

Asia/Africa revenues experienced a decline of 22%, or US$5,636,000 compared to 2009. There were two main reasons for the decrease in Asia/Africa revenues. Firstly, coagulation sales ceased in April 2010 as a result of the divestiture of the coagulation product line. Secondly, there were lower sales of Trinity s Unigold rapid HIV tests following Trinity s decision not to ship to a major customer in Africa due to the credit related issues.

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

Table of Contents

3. Operating Profit

The following table sets forth the Group s operating profit

	Year ended December 31,		
	2010	2009	
	US$ 000	US$ 000	%Change
Revenues	89,635	125,907	(29%)
Cost of sales	(45,690)	(68,891)	(34%)
Gross profit	43,945	57,016	(23%)
Other operating income	1,616	437	270%
Research & development	(4,603)	(7,341)	(37%)
SG&A expenses	(26,929)	(36,013)	(25%)
Net gain on divestment of business and restructuring expenses	46,474		
Operating profit	**60,503**	**14,099**	**329%**

Cost of sales

Total cost of sales decreased by US$23,201,000 from US$68,891,000 for the year ended December 31, 2009 to US$45,690,000, for the year ended December 31, 2010, a decrease of 34%. The main reasons for the decrease in cost of sales in 2010 were the lower revenues following the divestiture of the coagulation business and the transfer of approximately 190 coagulation production employees to Diagnostica Stago in May 2010.

Gross margin

The gross margin of 49.0% in 2010 compares to a gross margin of 45.3% in 2009. The increase in gross margin in 2010 is attributable to the divestiture of the coagulation business, 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 May 2010 and it accounts for the increase of US$1,179,000 compared to the year ended December 31, 2009. A variety of services were provided to Stago including accounting, information technology and logistics support and warehousing services.

Research and development expenses

Research and development (R&D) expenditure reduced from US$7,341,000 in 2009 to US$4,603,000 in 2010. The decrease was caused by the transfer of approximately 46 coagulation specialists to Diagnostica Stago in May 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$9,084,000 from US$36,013,000 for the year ended December 31, 2009 to US$26,929,000 for the year ended December 31, 2010. 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

This comprises the gain on the sale of the worldwide coagulation business of US$46.8 million and a charge for restructuring expenses of US$0.3 million. There were no equivalent gains or expenses in 2009. 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 employees located in Ireland.

23

Table of Contents

The following table outlines the breakdown of SG&A expenses in 2010 compared to 2009.

	Year ended December 31, 2010 US$ 000	2009 US$ 000	(Decrease) US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	24,260	33,567	(9,307)	(28%)
Share-based payments	1,080	487	593	122%
Amortisation	1,589	1,959	(370)	(19%)
Total	**26,929**	**36,013**	**(9,084)**	**(25%)**

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

SG&A expenses excluding share-based payments and amortisation decreased from US$33,567,000 for the year ended December 31, 2009 to US$24,260,000 for the year ended December 31, 2009, which represents a decrease of 28%.

The decrease this year of US$9,307,000 is mainly due to the transfer of approximately 48% of the Group s selling, general and administrative employees to Diagnostica Stago in May, 2010. Stago purchased Trinity s UK, German and French operations employing 43 selling, general and administrative employees. A further 42 selling, general and administrative employees in Ireland and USA were transferred to Stago.

SG&A costs also reduced in 2010 due to the full year effect of the cost reduction measures implemented during 2009 (for a summary of these measures please refer to last year s analysis of the results of operations), including the rationalisation of the Group s US finance function and overhead savings in communications, utilities and professional fees. The Group continued its cost reduction program in 2010 with the notable initiatives being the introduction of remote working arrangements for all US sales staff which allowed the closure of a sales office in New Jersey and the rationalisation of the customer service function in the US.

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$1,109,000 (2009 : US$521,000). The increase of US$588,000 in the total share-based payments expense is due to the granting of new share options to employees and directors during 2009 and 2010. The total charge is shown in the following expense headings in the statement of operations: US$29,000 (2009:US$19,000) was charged against cost of sales, US$31,000 (2009: US$15,000) was charged against research and development expenses and US$1,049,000 (2009 : US$487,000) was charged against selling, general and administrative expenses.

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

Amortisation

Amortisation reduced from US$1,959,000 for the year ended December 31, 2009 to US$1,589,000 for the year ended December 31, 2010. The decrease of US$370,000 is mainly due to the divestiture of all coagulation intangible assets, including the Destiny range of instruments, to Diagnostica Stago as part of the divestiture of the coagulation business.

Table of Contents

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,		
	2010	**2009**	
	US$ 000	**US$ 000**	**% Change**
Operating profit	60,503	14,099	329%
Net financing income/(costs)	857	(1,184)	172%
Profit before tax	61,360	12,915	375%
Income tax expense	(942)	(1,091)	(14%)
Profit of the year	**60,418**	**11,824**	**411%**

Net Financing income/(costs)

Net financing income is US$857,000 for year end December 31, 2010 compared to a net financing cost of US$1,184,000 in 2009. Financial expenses decreased from US$1,192,000 for year end December 31, 2009 to US$495,000 in 2010. The decrease is due to the repayment of all bank loans from the proceeds of sale of the coagulation business. Financial income increased from US$8,000 for year end December 31, 2009 to US$1,352,000 in 2010 due to higher balances on deposit and due to the interest income earned on the deferred consideration. The deposit balances totalled US$55.6 million at December 31, 2010 compared to US$1.4 million at December 31, 2009.

Taxation

The Group recorded a tax charge of US$942,000 for the year ended December 31, 2010 compared to US$1,091,000 for the year ended December 31, 2009. The decrease is due to a lower deferred tax charge in respect of temporary differences as a result of the sale of the Group s coagulation property, plant, equipment and intangible assets. This decrease was partially offset by an increase in current year taxable profits in the Group s Irish operations. The 2010 tax charge comprises US$847,000 of current tax and US$95,000 of deferred tax. 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$60,418,000 which represents an increase of US$48,594,000 when compared to US$11,824,000 in 2009. Excluding the after tax impact of the gain on the sale of the coagulation business 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 2010 of US$1,766,000 compared to 2009, excluding once-off gains and expenses, represents an increase of 14.9%.

Table of Contents

Results of Operations

Year ended December 31, 2009 compared to the year ended December 31, 2008

The following compares our results in the year ended December 31, 2009 to those of the year ended December 31, 2008 under IFRS. Our analysis is divided as follows:

5. *Overview*
6. *Revenues*
7. *Operating Profit/(loss)*
8. *Profit/(loss) for the year*

1. Overview

Group revenues declined by US$14.2 million to US$125.9 million, representing a decrease of 10% compared to 2008. The decrease was mainly due to an 11% decrease in Clinical Laboratory revenues. The main reason for the decrease in Clinical Laboratory revenues was a decrease in coagulation revenues, caused by a reduction in the number of installed instruments and by the strengthening of the US Dollar against both the Euro and Sterling. Point of Care revenues decreased by 5%, largely due to the company s decision not to ship to a major HIV customer due to credit related issues in the second half of 2009.

The gross margin for the year ended December 31, 2009 is 45.3%, which is 0.7% higher than the gross margin for 2008. The increase in gross margin this year is primarily attributable to a reduction in overheads and payroll costs following a cost reduction program, lower depreciation charges and the more favourable Euro exchange rate compared to the previous financial year.

In 2008, Trinity Biotech recognised an impairment charge of US$85.8 million relating to the carrying value of goodwill and other intangible assets, property, plant and equipment and prepayments, in the statement of operations. Additionally in 2008, restructuring expenses of US$2.1 million were recognised. The total effect of these once-off charges on the 2008 results was a reduction in profit before tax of US$87.9 million and a reduction of US$83.1m in profit after tax.

The table hereunder compares the operating profit/(loss) and profit after tax for year ended December, 2009 to the previous financial year.

	Year ended December 31,		
	2009	**2008**	
	US$ 000	**US$ 000**	**%Change**
Operating Profit/(loss)	14,099	(79,575)	
Operating Profit (2008 figure shown before impairment and restructuring charges)	14,099	8,307	70%
Profit/(loss) after Tax	11,824	(77,778)	
Profit after Tax (2008 figure shown before impairment and restructuring charges)	11,824	5,353	121%

The operating profit is US$14.1 million for the year ended December 31, 2009 which compares to an operating loss of US$79.6 million for the year ended December 31, 2008. Excluding the impact of impairment charges and restructuring expenses in 2008, the operating profit would have been US$8.3 million in 2008. On a like-for-like basis, there was therefore an increase in operating profit of 70% in 2009. The increase in operating profit was due to the impact of significant cost reduction measures more than offsetting the negative effect of a 10% fall in revenues. The profitability in 2009 was also helped by a reduction in depreciation and amortisation charges and by more favourable Euro versus US Dollar exchange rates.

Table of Contents

The profit for the year ended December 31, 2009 was US$11.8 million which compares to a loss for the year ended December 31, 2008 of US$77.8 million. Excluding the after tax impact of the restructuring expenses and goodwill impairment, the profit for 2008 would have been US$5.4 million.

2. Revenues

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

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

The Group also derives a portion of its revenues from leasing infectious diseases and coagulation 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 and coagulation instrumentation located at customer premises.

Revenues by Product Line

Trinity Biotech s revenues for the year ended December 31, 2009 were US$125,907,000 compared to revenues of US$140,139,000 for the year ended December 31, 2008, which represents a decrease of US$14,232,000 or 10%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2009	**2008**	
	US$ 000	**US$ 000**	% Change
Revenues			
Clinical Laboratory	107,778	121,143	(11%)
Point of Care	18,129	18,996	(5%)
Total	**125,907**	**140,139**	(10%)

Clinical Laboratory

In 2009 Clinical Laboratory revenues decreased by US$13,365,000 which equates to an 11% decline. The decrease was mainly due to a decline in sales of coagulation products in advance of the worldwide launch of the Destiny Max instrument.

The decrease in coagulation revenues was caused by a reduction in the installed customer base and by movements in foreign exchange rates. The installed base of MDA instruments in the US and UK declined in advance of the launch of the newly developed Destiny Max instrument. The Destiny Max was launched in all markets by July 2009 and is the designated replacement for the MDA. 5% of the overall decrease was caused by changes in exchange rates, principally the strengthening of the US Dollar against the Euro.

Table of Contents

Point of Care

Our principal Point of Care product is Unigold , which tests for the presence of HIV antibodies. Sales of Point of Care tests decreased by US$867,000, which equates to a 5% decline.

Our two main markets for Point of Care tests are Africa and USA. Sales of HIV tests in Africa decreased by 18% largely due to the company s decision not to ship to a major HIV customer due to credit related issues in the second half of 2009. Point of Care revenues continued to show strong growth in the USA with an increase this year of 17% compared to 2008. Outside of our two main Point of Care markets, revenues increased by 4% in 2009, with most of this increase coming from Latin America.

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,		
	2009	2008	
	US$ 000	US$ 000	% Change
Revenues			
Americas	68,130	69,915	(3%)
Europe	32,389	43,481	(26%)
Asia/Africa	25,388	26,743	(5%)
Total	**125,907**	**140,139**	(10%)

The 3% decrease in the Americas amounting to US$1,785,000 is primarily attributable to a reduction in coagulation revenue arising from an erosion of the MDA customer base. This reduction was largely offset by growth in the sales of the Unigold rapid HIV test, higher sales of infectious diseases tests mainly Lyme disease and higher revenues for diabetes related tests.

European revenues experienced a decline of US$11,092,000, or 26% compared to 2008. 9% of the decrease was due to the weakening of both Euro and Sterling against the US Dollar. The remaining 17% decrease was mainly due to a reduction in coagulation revenues arising from an erosion of the installed customer base of medium and high throughput analyzers, particularly in UK and Germany.

A US$1,355,000 decrease in Asia/Africa revenues is largely due to lower sales of Trinity s Unigold rapid HIV tests following Trinity s decision not to ship to a major customer in Africa due to the credit related issues.

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

Table of Contents

3. Operating Profit/(loss)

The following table sets forth the Group s operating profit/(loss)

	Year ended December 31,		
	2009	2008	
	US$ 000	US$ 000	%Change
Revenues	125,907	140,139	(10%)
Cost of sales	(68,891)	(77,645)	(11%)
Gross profit	57,016	62,494	(9%)
Other operating income	437	1,173	(63%)
Research & development	(7,341)	(7,544)	(3%)
SG&A expenses	(36,013)	(47,816)	(25%)
SG&A expenses impairment charges and restructuring expenses		(87,882)	(100%)
Operating profit/(loss)	**14,099**	**(79,575)**	

Cost of sales

Total cost of sales decreased by US$8,754,000 from US$77,645,000 for the year ended December 31, 2008 to US$68,891,000, for the year ended December 31, 2009, a decrease of 11%. The main reasons for the decrease in cost of sales in 2009 were the lower revenues, the savings achieved by a cost reduction program and the change in the Euro exchange rate compared to the previous financial year.

The cost reduction program succeeded in reducing a wide range of direct costs including wages and salaries, utilities and freight costs. Depreciation charges decreased also in 2009.

A significant proportion of the Group s Cost of Sales is denominated in Euro. During 2009 the average Euro versus US Dollar exchange rate was 6% lower than in 2008 and this had the effect of reducing Cost of Sales.

Gross margin

The gross margin of 45.3% in 2009 compares to a gross margin of 44.6% in 2008. The increase in gross margin in 2009 is primarily attributable to a reduction in overheads and payroll costs following the cost reduction program, lower depreciation charges and the slightly more favourable Euro exchange rate compared to the previous financial year.

Other operating income

Other operating income comprises government grants and rental income from sublet properties. The 63% reduction in 2009 is mainly due to lower government grants following the completion of the related grant-aided activity.

Research and development expenses

Research and development (R&D) expenditure reduced from US$7,544,000 in 2008 to US$7,341,000 in 2009. The main reason for the decrease was the change in the US Dollar to Euro exchange rate, which caused research and development costs incurred in our Irish and German operations to decrease by approximately 6%. This decrease was partly offset by an increase in average R&D headcount from 57 in 2008 to 61 in 2009. 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$99,685,000 from US$135,698,000 for the year ended December 31, 2008 to US$36,013,000 for the year ended December 31, 2009. The decrease is primarily due to the impairment charges and restructuring expenses of US$87,882,000 incurred in 2008.

Table of Contents

The following table outlines the breakdown of SG&A expenses in 2009 compared to 2008.

	Year ended December 31, 2009 US$ 000	2008 US$ 000	(Decrease) US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	33,567	43,314	(9,747)	(23%)
SG&A impairment charges and restructuring expenses		87,882	(87,882)	(100%)
Share-based payments	487	886	(399)	(45%)
Amortisation	1,959	3,616	(1,657)	(46%)
Total	**36,013**	**135,698**	**(99,685)**	**(73%)**

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

SG&A expenses excluding share-based payments and amortisation decreased from US$43,314,000 for the year ended December 31, 2008 to US$33,567,000 for the year ended December 31, 2009, which represents a decrease of 23%. The decrease this year of US$9,747,000 is mainly attributable to cost reductions as follows:

- a cost reduction program involving a headcount reduction was announced in December 2008, which delivered payroll cost savings in SG&A of approximately US$5,100,000 in 2009. The headcount reduction also had the effect of reducing travel and other employee expenses by almost US$1,000,000.
- other headcount reductions implemented in 2009 contributed to a further reduction in SG&A payroll costs of US$700,000. These headcount reductions mainly involved the rationalisation of the French sales and US finance functions.
- a salary reduction for directors and senior managers was implemented in early 2009 and resulted in a cost saving of approximately US$700,000.
- a significant proportion of the Group s SG&A expenses are denominated in Euro. During 2009 the average US dollar versus Euro exchange rate was 6% lower compared to 2008 and this had the effect of reducing SG&A expenses by about US$1,100,000. The US dollar also strengthened versus Sterling in 2009 and this had the effect of reducing the reported SG&A costs for our UK selling entity by just over US$350,000.
- through strict cost control the Group succeeded in reducing its selling overheads and administrative expenses by about US$750,000 in 2009. A wide range of overhead savings were achieved, including communications, utilities, travel costs, legal and professional fees and recruitment fees.

SG&A impairment charges and restructuring expenses

No impairment charges or restructuring expenses were recorded in 2009. In 2008, an impairment charge of US$85,793,000 was recognized arising from the annual impairment review of the asset valuations included on the balance sheet. The Company recognized an impairment loss against goodwill and other intangible assets (US$71,684,000), property, plant and equipment (US$13,095,000) and prepayments (US$1,014,000).

Restructuring expenses of US$2,089,000 were recorded in SG&A in year ended December 31, 2008. This was made up of US$1,465,000 arising from the resignation of the Company s former Chief Executive and US$589,000 in relation to costs associated with the implementation of headcount reductions. Other restructuring costs amounted to US$35,000.

Share-based payments

The expense represents the 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 and the risk free rate.

The Group recorded a total share-based payments charge of US$521,000 (2008: US$1,166,000). The total charge is shown in the following expense headings in the statement of operations: US$19,000 (2008: US$51,000) was charged

against cost of sales, US$15,000 (2008: US$48,000) was charged against research and development expenses and US$487,000 (2008: US$886,000) was charged against selling, general and administrative expenses. In 2008 a further share option charge of US$181,000 was included within the selling, general and administrative expenses restructuring charge relating to the share option cost associated with the resignation of the former Chief Executive Officer.

Table of Contents

The decrease of US$645,000 in the total share-based payments expense is primarily because share option holders ended their employment with the company and thereby forfeited their share options. For further details refer to Item 18, note 19 to the consolidated financial statements.

Amortisation

Amortisation reduced from US$3,616,000 for the year ended December 31, 2008 to US$1,959,000 for the year ended December 31, 2009. The decrease of US$1,657,000 is partially due to the reduction resulting from the prior year write down of the carrying value of intangible assets following the annual impairment review carried out at December 31, 2008.

4. Profit/(loss) for the year

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

	Year ended December 31,		
	2009	**2008**	
	US$ 000	**US$ 000**	**%Change**
Operating profit/(loss)	14,099	(79,575)	118%
Net financing costs	(1,184)	(2,095)	(43%)
Profit/(Loss) before tax	12,915	(81,670)	116%
Income tax (expense)/credit	(1,091)	3,892	128%
Profit/(Loss) of the year	**11,824**	**(77,778)**	**115%**

Net Financing Costs

Net financing costs decreased by US$911,000 from US$2,095,000 in 2008 to US$1,184,000 in 2009. The decrease is primarily due to a combination of lower interest bearing loan balances outstanding and lower interest rates. The interest bearing loan balances at December 31, 2008 were US$36,121,000 compared to US$31,856,000 at December 31, 2009. The interest rate for the majority of the Group s borrowings is based on LIBOR rates, which reduced significantly during 2009. The deposit interest earned during the year reduced from US$65,000 to US$8,000 due to lower cash balances and lower interest rates.

Taxation

The Group recorded a tax charge of US$1,091,000 for the year ended December 31, 2009 compared to a net tax credit of US$3,892,000 for the year ended December 31, 2008. The 2009 tax charge comprises US$1,000 of current tax and US$1,090,000 of deferred tax. In 2008, the net tax credit was primarily attributable to the impairment of goodwill and other intangible assets, property, plant and equipment. For further details on the impairment please refer to Item 18, note 28 and 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/(loss) for the year

The profit for the year amounted to US$11,824,000 which represents an increase of US$89,602,000 when compared to the loss for the year of US$77,778,000 in 2008. Excluding the after tax impact of the restructuring expenses and impairment loss of US$83,131,000, the 2008 profit for the year would have been US$5,353,000. The increase in profits in 2009 of US$6,471,000 compared to 2008, excluding once-off charges, represents an increase of 121%.

Table of Contents

Liquidity and Capital Resources

Financing

During 2010 the Group repaid in full the outstanding portion of its US$48,340,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Limited (the banks) using the proceeds from the divestiture of the coagulation business. The facility consisted of a US Dollar floating interest rate term loan of US$41,340,000 and a one year revolver of US$7,000,000. This facility had been secured on the assets of the Group (see Item 18, note 25(c)).

The balance on this facility at December 31, 2010 was therefore US$NIL (December 31, 2009:US$29,327,000, net of unamortised funding costs of US$180,000).

During 2008, the Group issued 7,260,816 A Ordinary shares as part of a private placement. These shares were issued for a consideration of US$7,115,600, settled in cash. The Group incurred costs of US$438,000 in connection with the issue of these shares.

Working capital

In the Group s 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;
- Successful working capital management in the context of a growing group.

The Group has some finance lease obligations outstanding at December 31, 2010 and the expected maturity dates of these are set out in more detail in Item 11.

Cash management

As at December 31, 2010, Trinity Biotech s consolidated cash and cash equivalents were US$58,002,000. This compares to cash and cash equivalents of US$6,078,000 at December 31, 2009.

Cash generated from operations for the year ended December 31, 2010 amounted to US$22,973,000 (2009: US$15,533,000), an increase of US$7,440,000. The increase in cash generated from operations of US$7,440,000 is attributable to an increase in operating cash flows before changes in working capital of US$1,433,000 and favourable working capital movements of US$6,007,000. The increase in operating cash flows before changes in working capital of US$1,433,000 is primarily due to higher net profits arising in 2010 from improved gross margin following the divestiture of the coagulation business. The favourable working capital movements are primarily due to the effect of the substantial cash inflow from trade and other payables of US$11,983,000 being partially offset by the increase in cash outflows for trade and other receivables of US$778,000 and inventory of US$5,198,000. The cash generated from operations was attributable to a profit before interest, taxation and gain on divestiture of business of US$13,728,000 (2009: US$14,099,000), as adjusted for non cash items of US$7,403,000 (2009: US$5,599,000) plus cash inflows due to changes in working capital of US$1,842,000 (2009: cash outflows of US$4,165,000).

The increase in other non cash charges from US$5,599,000 for the year ended December 31, 2009 to US$7,403,000 for the year ended December 31, 2010 is mainly attributable to the movement in items including inventory provisions and the share option expense.

The net cash inflows in 2010 due to changes in working capital of US$1,842,000 are due to the following:

- A decrease in accounts receivable of US$3,094,000 due to a decrease in debtors days in the year as a result of better collections;
- An increase in inventory of US$2,826,000 due to the strategic build up of certain stock items during the course of the year; and
- An increase in trade and other payables of US$1,574,000 due mainly to the timing of payments to suppliers.

32

Table of Contents

Net interest received amounted to US$339,000 (2009: net interest paid of US$871,000). This consisted of interest received of US$842,000 (2009: US$12,000) on the Group s cash deposits and interest payments of US$503,000 (2009: US$883,000) on the Group s interest bearing debt; including bank loans and finance leases. The movement from a net interest payment amount in 2009 to a net interest received amount in 2010 was brought about by the elimination of bank debt in 2010 and the placing of funds on deposit following the sale of the coagulation business.

Net cash inflows from investing activities for the year ended December 31, 2010 amounted to US$56,885,000 (2009: net cash outflows of US$10,335,000) which were principally made up as follows:

Proceeds from the divestiture of the coagulation business, net of associated costs, of US$65,886,000

Payments to acquire intangible assets of US$6,233,000 (2009: US$8,103,000), 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$2,784,000 (2009: US$2,481,000) incurred as part of the Group s investment programme for its manufacturing and distribution activities;

Proceeds from the disposal of property, plant and equipment of US$16,000 (2009: US$249,000).

Net cash outflows from financing activities for the year ended December 31, 2010 amounted to US$27,984,000 (2009: US$3,512,000). The main driver of the cash outflow in 2010 was the repayment of long-term debt of US$29,775,000 (2009: US$5,400,000). This payment in 2010 has resulted in all bank debt being eliminated from the Group balance sheet as at December 31, 2010. Other cash outflows included expenses paid in connection with share issues and debt financing of US$74,000 (2009: US$68,000) and payments in respect of finance lease liabilities of US$638,000 (2009: US$546,000). These outflows were partially offset by the receipt of US$1,023,000 from the issue of ordinary shares in 2010 (2009: US$897,000). Ordinary shares issued in 2010 and 2009 are as a result of share options and warrants exercised during the course of the year. The Group also received US$1,480,000 from the proceeds of new finance leases (2009: US$1,298,000). The Group did not receive any proceeds from long-term debt in 2010 (2009: US$307,000).

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 on 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, 2010, total interest-bearing debt, consisting entirely of leases, was US$273,000 (2009: US$31,856,000 consisting of bank loans and leases) and cash and cash equivalents were US$58,002,000 (2009: US$6,078,000). For a more comprehensive discussion of the Group s level of borrowings at the end of 2010, the maturity profile of the borrowings, 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, 2010:

		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
Capital (finance) lease obligations	285	172	113		
Operating lease obligations	36,556	2,411	4,527	4,320	25,298
Total	36,841	2,583	4,640	4,320	25,298

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 business in 2010, the Group has now 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.

Table of Contents

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.

In 2005 a software development company based in France was contracted to develop and enhance the software in the Destiny Max instrument. Under the terms of the contract, all software developed by the software development company is the property of Trinity Biotech. Fees were agreed for each separate software development task and payment was made once a specific project milestone had been achieved. A total of 271,000 (US$362,000) was paid to this software development company in 2010. Additionally, a number of individuals acted as third party consultants working principally on the Destiny Max, Premier Hb9210 and Tristat instruments. The total amount paid to R&D consultants in 2010 was US$960,000.

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. There were no significant development projects in their research phase during 2010.

Centres of Excellence

Trinity Biotech has research and development groups focusing separately on Western Blot products, Clinical Chemistry products and Point-of-Care products. These groups are located in Ireland and the US 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 US and Europe.

Table of Contents

Principal Development Projects

The following table sets forth for each of the main development projects, the costs incurred during each period presented and the cumulative costs incurred as at 31 December 2010:

Product Name	*2010 US$ 000*	*2009 US$ 000*	*Total project costs to December 31, 2010 US$ 000*
Premier Hb 9210 Instrument for Haemoglobin A1c testing	*2,569*	*1,023*	*4,381*
Destiny Max coagulation instrument*	*956*	*3,234*	*14,686*
Bordetella Pertussis Western Blot test	*337*	*156*	*493*
Tristat point of care instrument	*318*	*1,072*	*4,094*
HIV Ag-Ab rapid test	*247*		*247*
Syphilis Rapid point-of-care test	*185*		*185*
Unigold Recombigen HIV Rapid enhancement	*142*	*456*	*2,157*

* *Note that this and other coagulation projects ceased in May 2010 following the divestiture of the Coagulation Business see Item 18, note 3.*

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 2010. 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 US$ 000*
Various point-of-care rapid tests	*1,400*	*2012*
Premier Hb 9210 Instrument for Haemoglobin A1c testing	*1,172*	*2011*
HIV Ag-Ab rapid test	*1,000*	*2013*
Syphilis Rapid point-of-care test	*750*	*2012*
Unigold Recombigen HIV Rapid enhancement	*500*	*2011*
IgM CAPITA	*400*	*2012*
Tristat point of care instrument	*330*	*2011*

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.

35

Table of Contents

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 and Cryptosporidium antigens in human stool samples. We have also commenced development of a test for the detection of treponemal and nontreponemal Syphilis antibodies in human whole blood. It is envisaged some tests will reach clinical trial stage and be submitted to the FDA for 510k approval later in 2011.

In response to the increased incidence of the new strain of HIV called HIV-2, we are developing a new assay for the simultaneous detection of p24 HIV Antigen (Ag) and Antibodies (Ab) to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect p24 HIV antigen and antibodies to HIV-1/HIV-2 from infected individuals.

Western Blot Development Group

A Western Blot kit is a test where antigens (usually proteins) from a specific bacteria or virus are transferred onto a nitrocellulose strip. When a patient s plasma is added to the strip, if antibodies to that bacteria or virus are present in a patient s sample, then they will bind to the specific antigens on the strip. If antibodies to any of the antigens are present in sufficient concentration, coloured bands corresponding to one or more of those antigens will be visible on the reacted nitrocellulose strip.

Pertussis Western Blot

During 2010, a project was undertaken to further develop the Bordetella pertussis Western Blot product by adding an additional stripe for Adenylate Cyclase per assay kit. This work finished in 2010 when the newly developed product was transferred into production and launched onto the European market.

Clinical Chemistry Development Group

Premier Hb 9210 Instrument for Haemoglobin A1c Testing

This project entails the development of a new High Performance Liquid Chromotography (HPLC) instrument for testing haemoglobin A1c. 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 (A1c and variant). Development was initiated in late 2007, continued through 2010 and is expected to launch initially in the non-US market in the first half of 2011.

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 370 million in 2030. In the U.S. alone some 20.8 million Americans (7 percent of the population) have the disease with a full 54 million Americans considered to be pre-diabetic. The total laboratory HbA1c market worldwide is expected to reach $272 million by 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.

Table of Contents

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	55	Chairman and Chief Executive Officer
Rory Nealon	43	Director, Chief Operations Officer
Jim Walsh, PhD	52	Director, Chief Scientific Officer
Denis R. Burger, PhD	67	Non Executive Director
Peter Coyne	51	Non Executive Director
Clint Severson	62	Non Executive Director
James D. Merselis	57	Non Executive Director

Executive Officer

Kevin Tansley	40	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 Limited.

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

Table of Contents

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

Denis R. Burger, PhD, Non-executive director, co-founded Trinity Biotech in June 1992 and was Chairman from June 1992 to May 1995. He is currently Chairman of BioCurex, Inc, a cancer diagnostics, OTC:BB listed company and is also non-executive Chairman 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 is 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. Since November 2006, Mr. Severson has also served on the Board of Directors of CytoCore, Inc. 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. Mr. Merselis is currently President and CEO of ITC Nexus Dx Holding Company, Inc, a privately held, New Jersey-based diagnostics company working to improve patient care by providing rapid and reliable point of care (POC) medical test information. Prior to this Mr. Merselis served as President and CEO of Alverix, Inc., a privately held company developing portable medical diagnostic instruments , HemoSense, Inc. (NASDAQ: HEM), a point-of-care diagnostics company and Micronics, Inc., a microfluidics company. Over twenty-two years, Mr. Merselis held a series of increasingly responsible executive positions with Boehringer Mannheim Diagnostics (now Roche Diagnostics).

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 Bachelor of Commerce degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

Table of Contents

Compensation of Directors and Officers

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

Total directors and non-executive directors remuneration, excluding pension, for the year ended December 31, 2010 amounted to US$2,082,000. The pension charge for the year amounted to US$127,000. 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 2010 US$ 000*	*Total 2009 US$ 000*
Ronan O Caoimh	560	450	82	1,092	644
Rory Nealon	377	300	37	714	419
Jim Walsh*	77		8	85	
	1,014	750	127	1,891	1,063

Non-executive director	*Fees US$ 000*	*Other US$ 000*	*Total 2010 US$ 000*	*Total 2009 US$ 000*
Denis R. Burger	73		73	70
Peter Coyne	73		73	70
James Merselis	63		63	53
Clint Severson	63		63	60
Jim Walsh*	46	39	85	60
	318	39	357	313

* Dr. Jim Walsh is included as a non-executive director of the Company up until his appointment as Chief Scientific Officer in October 2010 and accordingly his remuneration after that point has been categorised with the two other executive directors.

Chief Financial Officer & Company Secretary	*Salary/ Benefits US$ 000*	*Performance related bonus US$ 000*	*Defined contribution pension US$ 000*	*Total 2010 US$ 000*	*Total 2009 US$ 000*
Kevin Tansley	285	300	28	613	317

As at December 31, 2010 an amount of $58,000 was accrued by a Company subsidiary to provide pension, retirement or similar benefits for the directors.

The total share-based compensation expense recognised in the consolidated statement of operations in 2010 in respect of options granted to both executive and non executive directors and the Company Secretary amounted to US$814,000. See Item 18, note 6 to the consolidated financial statements.

Table of Contents

The directors and Company Secretary were granted 2,500,000 share options during 2010 and were granted 2,220,000 share options during 2009 the terms of which are as follows:

2010 Share Options Granted:

Director/Executive Officer	Number of Options Granted	Exercise Price of Options Granted	Date of Option Grant*
Ronan O Caoimh	800,000 A shares	US$ 1.52 per A share	21 May 2010
Rory Nealon	500,000 A shares	US$ 1.52 per A share	21 May 2010
Denis Burger	60,000 A shares	US$ 1.52 per A share	21 May 2010
Peter Coyne	60,000 A shares	US$ 1.52 per A share	21 May 2010
Jim Walsh	60,000 A shares	US$ 1.52 per A share	21 May 2010
Clint Severson	60,000 A shares	US$ 1.52 per A share	21 May 2010
James Merselis	60,000 A shares	US$ 1.52 per A share	21 May 2010
Jim Walsh	400,000 A shares	US$ 1.57 per A share	4 October 2010
Kevin Tansley	500,000 A shares	US$ 1.52 per A share	21 May 2010

* All options issued are subject to a 7 year life from date of grant.

2009 Share Options Granted:

Director/Executive Officer	Number of Options Granted	Exercise Price of Options Granted	Date of Option Grant*
Ronan O Caoimh	800,000 A shares	US$ 0.66 per A share	8 May 2009
Rory Nealon	500,000 A shares	US$ 0.66 per A share	8 May 2009
Denis Burger	60,000 A shares	US$ 0.66 per A share	8 May 2009
Peter Coyne	60,000 A shares	US$ 0.66 per A share	8 May 2009
Jim Walsh	60,000 A shares	US$ 0.66 per A share	8 May 2009
Clint Severson	120,000 A shares	US$ 0.66 per A share	8 May 2009
James Merselis	120,000 A shares	US$ 0.66 per A share	8 May 2009
Kevin Tansley	500,000 A shares	US$ 0.66 per A share	8 May 2009

* 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 Limited, a company wholly-owned by members of Mr. O Caoimh s immediate family. Pursuant to the agreement, Darnick Limited 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 Limited may terminate the agreement on six month s notice. Mr. O Caoimh will remain as Chairman of the Board of Directors.

40

Table of Contents

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, entered into in October 2010, 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 way; the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process.

Employees

As of December 31, 2010, Trinity Biotech had 343 employees (2009: 658) consisting of 29 research scientists and technicians, 210 manufacturing and quality assurance employees, and 104 finance, administration, sales and marketing staff (2009: 60 research scientists and technicians, 422 manufacturing and quality assurance employees, and 176 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 was as follows: 121 in Bray, Co. Wicklow, Ireland and 222 in its US operations.

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 2006 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.

41

Table of Contents

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 seven 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, 2011, 7,352,086 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)	Exercise Price (Per A Share)	Expiration Date of Options
Ronan O Caoimh	450,000	US$ 2.56	26 August 2011
	250,000	US$ 1.67	2 November 2012
	350,000	US$ 2.09	13 December 2013
	175,000	US$ 1.07	18 March 2015
	66,666	US$ 0.74	16 September 2015
	533,334	US$ 0.66	8 May 2016
	800,000	US$ 1.52	21 May 2017
Rory Nealon	175,000	US$ 2.56	26 August 2011
	100,000	US$ 1.67	2 November 2012
	150,000	US$ 2.09	13 December 2013
	200,000	US$ 1.07	18 March 2015
	240,000	US$ 0.74	16 September 2015
	500,000	US$ 0.66	8 May 2016
	500,000	US$ 1.52	21 May 2017
Denis Burger	60,000	US$ 2.56	26 August 2011
	25,000	US$ 1.67	2 November 2012
	25,000	US$ 2.09	13 December 2013
	60,000	US$ 0.66	8 May 2016
	60,000	US$ 1.52	21 May 2017
Jim Walsh	168,750	US$ 2.56	26 August 2011
	50,000	US$ 1.67	2 November 2012
	25,000	US$ 2.09	13 December 2013
	60,000	US$ 0.66	8 May 2016
	60,000	US$ 1.52	21 May 2017
	400,000	US$ 1.57	4 October 2017
Peter Coyne	60,000	US$ 2.56	26 August 2011
	25,000	US$ 1.67	2 November 2012
	25,000	US$ 2.09	13 December 2013
	60,000	US$ 0.66	8 May 2016
	60,000	US$ 1.52	21 May 2017
Clint Severson	120,000	US$ 0.66	8 May 2016
	60,000	US$ 1.52	21 May 2017
James Merselis	120,000	US$ 0.66	8 May 2016
	60,000	US$ 1.52	21 May 2017
Kevin Tansley	20,000	US$ 2.79	19 May 2011
	20,000	US$ 1.59	16 August 2012
	30,000	US$ 1.78	26 July 2013

75,000	US$	2.24	07 March 2014
150,000	US$	1.07	18 March 2015
150,000	US$	0.74	16 September 2015
333,336	US$	0.66	8 May 2016
500,000	US$	1.52	21 May 2017

Table of Contents

As of February 28, 2011 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	9,266,102	US$ 0.66-US$4.00	US$ 2.63-US$16.00

In April 2010, the Company granted warrants to purchase 40,000 Class A Ordinary Shares (vesting immediately). These warrants were issued at an exercise price of US$1.50 per ordinary share and have a term of seven years. As of February 28, 2011 there were warrants to purchase 1,672,244 A Ordinary Shares in the Company outstanding.

Table of Contents

Item 7

Major Shareholders and Related Party Transactions

As of February 28, 2011 Trinity Biotech has outstanding 84,252,189 A Ordinary shares and 700,000 B Ordinary shares. Such totals exclude 10,938,346 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2011, the Trinity Biotech A Ordinary Shares and B 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	Number of B Ordinary Shares Beneficially Owned	Percentage Outstanding B Ordinary Shares	Percentage Total Voting Power
William Blair & Company Investment Management	11,763,664	14.0%			13.7%
Goldman Capital Management, Inc.	6,714,000	8.0%			7.8%
Heartland Advisors, Inc.	5,888,000	7.0%			6.9%
Ronan O Caoimh	4,974,995(1)	5.8%			5.7%
Rory Nealon	1,051,666(2)	1.2%			1.2%
Jim Walsh	1,657,362(3)	2.0%			1.9%
Denis R. Burger	130,000(4)	0.2%			0.2%
Peter Coyne	130,000(5)	0.2%			0.2%
Clint Severson	88,000(6)	0.1%			0.1%
James Merselis	40,000(7)	0.1%			0.1%
Kevin Tansley	353,252(8)	0.4%			0.4%
Potenza Investments Inc.			500,000(9)	71.4%	1.2%
	8,425,275(1)(2)(3)(4)(5)(6)(7)(8)	9.7%			9.5%

Directors & Co.
Secretary as a group (8
persons)

(1) Includes 1,137,499 shares issuable upon exercise of options.

(2) Includes 851,666 shares issuable upon exercise of options.

(3) Includes 263,750 shares issuable upon exercise of options.

(4) Includes 130,000 shares issuable upon exercise of options.

(5) Includes 130,000 shares issuable upon exercise of options.

(6) Includes 40,000 shares issuable upon exercise of options.

(7) Includes 40,000 shares issuable upon exercise of options.

(8) Includes 301,252 shares issuable upon exercise of options.

(9) These B shares have two votes per share.

Table of Contents

Related Party Transactions

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

In July 2000, Trinity Biotech entered into an agreement with JRJ pursuant to which the Group took a lease of a 25,000 square foot premises adjacent to the existing facility for a term of 20 years at a rent of 7.62 per square foot for an annual rent of 190,000 (US$254,000). During 2006, the rent on this property was reviewed and increased to 11.00 per square foot, resulting in an annual rent of 275,000 (US$367,000). The lease on this property was assigned to Diagnostica Stago in May, 2010 following the divestiture of the coagulation business.

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$509,000) 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$1,051,000).

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 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 four 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 2010 and there were no loan balances payable to or receivable from directors at January 1, 2010 and at December 31, 2010.

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 2009 & 2010 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US$1,866,000, US$1,071,000 and US$2,149,000 for 2008, 2009 and 2010 respectively, of which US$1,610,000, US$887,000 and US$1,431,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as of December 31, 2010 or 2009. Dividends payable to Rayville at December 31, 2008 amounted to US$60,000. Of the US$2,149,000 of payments made to Rayville Limited in 2010, US$565,000 represented repayments of the loan to Trinity Research Limited referred to above.

Table of Contents

Item 8

Financial Information

Legal Proceedings

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

In 2010, Laboratoires Nephrotek, formerly a distributor for Trinity Biotech, took a legal action in France against the Group, claiming damages of US$0.8 million. They claim that certain instruments supplied by Trinity Biotech did not operate properly in the field. No court hearings have occurred in relation to this case yet. 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 National Cap Market under the symbol TRIB . In 2005, the 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, 2011, the reported closing sale price of the ADSs was US$8.89 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, 2006, 2007, 2008, 2009 and 2010; (b) the quarters ended March 31, June 30, September 30 and December 31, 2009; March 31, June 30, September 30 and December 31, 2010; and (c) the months of March, April, May, June, July, August, September, October, November and December 2010 and January and February 2011 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**	
2006	US$	9.54	US$	7.09
2007	US$	11.75	US$	5.72
2008	US$	6.95	US$	1.25
2009	US$	5.70	US$	1.05
2010	US$	8.93	US$	3.76

Table of Contents

ADSs

2009	**High**		**Low**	
Quarter ended March 31	US$	2.35	US$	1.05
Quarter ended June 30	US$	4.84	US$	1.50
Quarter ended September 30	US$	5.70	US$	3.06
Quarter ended December 31	US$	4.43	US$	3.33

ADSs

2010	**High**		**Low**	
Quarter ended March 31	US$	6.24	US$	3.76
Quarter ended June 30	US$	6.67	US$	5.26
Quarter ended September 30	US$	6.67	US$	5.71
Quarter ended December 31	US$	8.93	US$	6.15

ADSs

Month Ended	**High**		**Low**	
March 31, 2010	US$	6.24	US$	4.71
April 30, 2010	US$	6.24	US$	5.47
May 31, 2010	US$	6.67	US$	5.26
June 30, 2010	US$	6.60	US$	5.81
July 31, 2010	US$	6.42	US$	5.79
August 31, 2010	US$	6.45	US$	5.71
September 30, 2010	US$	6.67	US$	5.90
October 31, 2010	US$	7.16	US$	6.15
November 30, 2010	US$	8.69	US$	7.04
December 31, 2010	US$	8.93	US$	7.60
January 31, 2011	US$	8.83	US$	8.00
February 28, 2011	US$	9.19	US$	8.03

The number of record holders of Trinity Biotech s ADSs as at February 28, 2011 amounts to 693, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech s securities for their clients (with each such brokerage house and/or clearing house being considered as one holder).

Table of Contents

Item 10

Memorandum and Articles of Association

Objects

The Company s objects, detailed in Clause 3 of its Memorandum of Association, are varied and wide ranging and include principally researching, manufacturing, buying, selling and distributing all kinds of patents, pharmaceutical, medicinal and diagnostic preparations, equipment, drugs and accessories. They also include the power to acquire shares or other interests or securities in other companies or businesses and to exercise all rights in relation thereto. The Company s registered number in Ireland is 183476.

Powers and Duties of Directors

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

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

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

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

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

Rights, Preferences and Restrictions Attaching to Shares

The A Ordinary Shares and the B Ordinary Shares rank pari passu in all respects save that the B Ordinary Shares have two votes per share and the right to receive dividends and participate in the distribution of the assets of the Company upon liquidation or winding up at a rate of twice that of the A Ordinary Shares.

Where a shareholder or person who appears to be interested in shares fails to comply with a request for information from the Company in relation to the capacity in which such shares or interest are held, who is interested in them or whether there are any voting arrangements, that shareholder or person may be disenfranchised and thereby restricted from transferring the shares and voting rights or receiving any sums in respect thereof (except in the case of a liquidation). In addition, if cheques in respect of the last three dividends paid to a shareholder remain uncashed, the Company is, subject to compliance with the procedure set out in the Articles of Association, entitled to sell the shares of that shareholder.

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

the joint holding) who tendered a vote, whether in person or by proxy, shall be accepted to the exclusion of votes of the other joint holders.

Table of Contents

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

The Company may, subject to the provisions of the Companies Acts, 1963 to 2009 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 2009 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 2009 of Ireland, extended notice is required. These include removal of a director. No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum.

The Company is not obliged to serve notices upon members who have addresses outside Ireland and the US but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in the Company.

However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in Exchange Controls below. In addition, Irish competition law may restrict the acquisition by a party of shares in the

Company but this does not apply on the basis of nationality or residence.

Table of Contents

Other Provisions of the Memorandum and Articles of Association

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

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

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

Irish Law

Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept at the registered office of the Company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper books of account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the Company (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.

Table of Contents

Material Contracts

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

Divestiture of Coagulation business to Diagnostica Stago SAS

In May 2010, the Group sold its worldwide Coagulation business 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 business.

The Group received consideration of US$67.4 million and interest on deferred consideration of US$1.0 million in 2010. A further US$11.25 million will be received from Diagnostica Stago in May 2011 and the remaining US$11.25 million will be received in May 2012. No conditions or earnout provisions will apply to this deferred element of the consideration, which is supported by a bank guarantee.

Acquisition of the immuno-technology business of Cortex Biochem Inc

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

The main terms and conditions in the Cortex purchase agreement were as follows:

1. Trinity Biotech acquired Cortex s lists of customers and suppliers, inventory of immuno reagents, certain accounts receivable and accounts payable balances and the Cortex Biochem website.
2. The vendor undertook not to compete directly with the Cortex business for a period of three years after the sale of the business to Trinity
3. All of the purchase consideration was payable on signing of the contract.

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

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

The main terms and conditions in the Sterilab purchase agreement were as follows:

1. Trinity Biotech acquired a list of customers, inventory of infectious diseases and autoimmune products and all diagnostic instruments placed with Sterilab s customers.
2. The vendor undertook not to compete directly with Trinity s infectious disease business in the United Kingdom for a period of one year after the sale of the Sterilab business to Trinity.
3. All of the purchase consideration was payable on signing of the contract.

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.

51

Table of Contents

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, Usama 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, Uzbekistan, Sudan, Somalia, Republic of Guinea, 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.

52

Table of Contents

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 r