TRINITY BIOTECH PLC
Form 20-F
April 15, 2010

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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, 2009

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:

82,952,037 Class A Ordinary Shares and 700,000 Class B Shares

(as of December 31, 2009)

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 F-3 File No. 333-113091, 333-112568, 333-116537, 333-103033, 333-107363 and 333-114099 and our Registration Statements on Form S-8 File No. 33-76384, 333-220, 333-5532, 333-7762 and 333-124384.

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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 2009. 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.

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, 2009 and 2008 and for each of the years ended December 31, 2009, 2008 and 2007 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, 2007, 2006 and 2005 and for the years ended December 31, 2006 and December 31, 2005 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

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CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Year ended December, 31				
	2009 Total US$ 000	*2008 Total US$ 000*	*2007 Total US$ 000*	*2006 Total US$ 000*	*2005 Total US$ 000*
Revenues	**125,907**	**140,139**	**143,617**	**118,674**	**98,560**
Cost of sales	(68,891)	(77,645)	(75,643)	(62,090)	(51,378)
Cost of sales restructuring expenses			(953)		
Cost of sales inventory write off / provision			(11,772)	(5,800)	
Total cost of sales	**(68,891)**	**(77,645)**	**(88,368)**	**(67,890)**	**(51,378)**
Gross profit	**57,016**	**62,494**	**55,249**	**50,784**	**47,182**
Other operating income	437	1,173	413	275	161
Research and development expenses	(7,341)	(7,544)	(6,802)	(6,696)	(6,070)
Research and development restructuring expenses			(6,907)		
Total research and development expenses	**(7,341)**	**(7,544)**	**(13,709)**	**(6,696)**	**(6,070)**
Selling, general and administrative expenses	(36,013)	(47,816)	(51,010)	(42,422)	(34,651)
Selling, general and administrative impairment charges and restructuring expenses		(87,882)	(20,315)		
Total selling, general and administrative expenses	**(36,013)**	**(135,698)**	**(71,325)**	**(42,422)**	**(34,651)**
Operating profit/(loss)	**14,099**	**(79,575)**	**(29,372)**	**1,941**	**6,622**
Financial income	8	65	457	1,164	389
Financial expenses	(1,192)	(2,160)	(3,148)	(2,653)	(1,058)
Net financing costs	**(1,184)**	**(2,095)**	**(2,691)**	**(1,489)**	**(669)**
Profit/(loss) before tax	**12,915**	**(81,670)**	**(32,063)**	**452**	**5,953**
Income tax (expense)/ credit	(1,091)	3,892	(3,309)	2,824	(673)

Profit/(loss) for the year (all attributable to owners of the parent)	**11,824**	**(77,778)**	**(35,372)**	**3,276**	**5,280**
Basic earnings/(loss) per A ordinary share (US Dollars)	0.14	(0.96)	(0.47)	0.05	0.09
Basic earnings/(loss) per B ordinary share (US Dollars)	0.28	(1.91)	(0.94)	0.10	0.18
Diluted earnings/(loss) per A ordinary share (US Dollars)	0.14	(0.96)	(0.47)	0.05	0.09
Diluted earnings/(loss) per B ordinary share (US Dollars)	0.28	(1.91)	(0.94)	0.10	0.18
Basic earnings/(loss) per ADS (US Dollars)	0.57	(3.82)	(1.86)	0.19	0.36
Diluted earnings/(loss) per ADS (US Dollars)	0.57	(3.82)	(1.86)	0.19	0.35
Weighted average number of shares used in computing basic EPS	83,737,884	81,394,075	76,036,579	70,693,753	58,890,084
Weighted average number of shares used in computing diluted EPS	83,772,094	81,394,075	76,036,579	72,125,740	67,032,382

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Consolidated Balance Sheet Data

	December 31, 2009 US$ 000	*December 31, 2008 US$ 000*	*December 31, 2007 US$ 000*	*December 31, 2006 US$ 000*	*December 31, 2005 US$ 000*
Net current assets (current assets less current liabilities)	42,835	39,494	36,298	60,996	44,964
Non-current liabilities	(27,500)	(27,897)	(35,623)	(45,928)	(19,083)
Total assets	132,445	129,509	215,979	249,131	184,602
Capital stock	1,080	1,070	991	978	830
Shareholders equity	79,344	65,905	136,845	167,262	133,618

No dividends were declared in any of the periods from December 31, 2005 to December 31, 2009.

Risk Factors

Before you invest in our shares, you should be aware that there are various risks, which are described below. You should consider carefully these risks together with all of the other information included in this annual report before you decide to purchase our shares.

Trinity Biotech s operating results may be subject to fluctuations.

Trinity Biotech s operating results may fluctuate as a result of many factors related to its business, including the competitive conditions in the industry, major reorganisations of the Group s activities, loss of significant customers, delays in the development of new products and currency fluctuations, as described in more detail below, and general factors such as the size and timing of orders, the prevalence of various diseases and general economic conditions. In the event of lower operating profits, this could have a negative impact on cash generated from operations and also negatively impact shareholder value.

A need for capital might arise in the future if Trinity Biotech s capital requirements increase or revenues decrease.

Up to now Trinity Biotech has funded its operations through the sale of its shares and securities convertible into shares, cashflows from operations and bank borrowings. Trinity Biotech expects that the proceeds of equity financings, bank borrowings, lease financing, current working capital and sales revenues will fund its existing operations and payment obligations. However, if our capital requirements are greater than expected, or if our revenues do not generate sufficient cashflows to fund our operations, we may need to find additional financing which may not be available on attractive terms or at all. Any future financing could have an adverse effect on our current shareholders or the price of our shares in general.

Trinity Biotech s acquisition strategy 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.

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The diagnostics industry is highly competitive, and Trinity Biotech s research and development could be rendered obsolete by technological advances of competitors.

Trinity Biotech s principal business is the supply of medical diagnostic test kits and related diagnostic instrumentation. The diagnostics industry is extremely competitive. Trinity Biotech is competing directly with companies which have greater capital resources and larger marketing and business organisations than Trinity Biotech. Trinity Biotech s ability to grow revenue and earnings may be adversely impacted by competitive product and pricing pressures and by its inability to gain or retain market share as a result of the action of competitors.

We have invested in research and development (R&D) 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 (Sysmex® CA, D-Dimer plus, Enzygnost®), Inverness Medical Innovations, Inc. (Determine , Wampole , Athena), Diasorin Inc. (Liasion , ETI), Abbott Diagnostics (AxSYM , IMx), Diagnostic Products Corp. DPC (Immulite), Bio-Rad (ELISA, WB, Bioplex & A1c), Roche Diagnostics (COBAS AMPLICOR , Ampliscreen , Accutrend) and OraSure Technologies, Inc (OraQuick ®).

Trinity Biotech is highly dependent on suitable 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.

Trinity Biotech s business could be adversely affected by changing market conditions resulting in the reduction of the number of institutional customers.

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.

Trinity Biotech s long-term success depends on its ability to develop new products subject to stringent regulatory control. Even if new products are successfully developed, Trinity Biotech s proprietary know-how, manufacturing techniques and trade secrets may be copied by competitors. Furthermore, Trinity Biotech s patents have a limited life time and are thereafter subject to competition with generic products. Also, competitors might claim an exclusive patent for products Trinity Biotech plans to develop.

We are committed to significant expenditure on research and development (R&D). However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. Our organic growth and long-term success is dependent on our ability to develop and market new products but this work 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.

Even when products are successfully developed and marketed, Trinity Biotech s ownership of the technology behind these products has a finite life. In general, generic competition, which can arise through replication of the Trinity Biotech s proprietary know-how, manufacturing techniques and trade secrets or after the expiration of a patent, can have a detrimental effect on a product s revenue, profitability and market share. There can be no guarantee that the net income and financial position of Trinity Biotech will not be adversely affected by competition from generic products. Conversely, on occasion, certain companies have claimed exclusive patent, copyright and other intellectual property rights to technologies in the diagnostics industry. If these technologies relate to Trinity Biotech s planned products, Trinity Biotech would be obliged to seek licences to use this technology and, in the event of being unable to obtain such licences or it being obtainable on grounds that would be materially disadvantageous to Trinity Biotech, we would be precluded from marketing such products, which

could adversely impact our revenues, sales and financial position.

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Trinity Biotech s 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 15 US patents with remaining patent lives varying from less than one year to 13 years. In addition to these US patents, Trinity Biotech owns a total of 7 additional non-US patents with expiration dates varying between the years 2010 and 2023.

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 s 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.

Trinity Biotech s success is dependent on certain key management personnel.

Trinity Biotech s success is dependent on certain key management personnel. Our key employees at December 31, 2009 were Ronan O Caoimh, our CEO and Chairman, Rory Nealon, our COO and Kevin Tansley, our CFO and Company Secretary. Competition for qualified employees among biotechnology companies is intense, and the loss of such personnel or the inability to attract and retain the additional highly skilled employees required for the expansion of our activities, could adversely affect our business. In the USA, the UK, France and Germany we have been able to attract and retain qualified personnel. In Ireland, we have experienced some difficulties in attracting and retaining staff due to competition from other employers in our industry.

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Trinity Biotech is dependent on its 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.

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$9,382,000) for any one accident, limited to a maximum of 6,500,000 (US$9,382,000) 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.

Currency fluctuations may adversely affect our earnings and assets.

Trinity Biotech records its transactions primarily in US Dollars and Euro and prepares its financial statements in US Dollars. A substantial portion of our expenses are denominated in Euro. However, Trinity Biotech s revenues are primarily denominated in US Dollars. As a result, the Group is affected by fluctuations in currency exchange rates, especially the exchange rate between the US dollar and the Euro, which may adversely affect our earnings and assets. The percentage of 2009 consolidated revenue denominated in US Dollars was approximately 72%. Of the remaining 28%, 22% relates to revenue denominated in Euro and 6% relates to sterling and yen denominated revenues. Thus, a 10% decrease in the value of the Euro would have approximately a 2% adverse impact on consolidated revenues.

As part of the process of mitigating foreign exchange risk, the principal exchange risk identified by Trinity Biotech is with respect to fluctuations in the Euro. This is attributable to the level of Euro denominated expenses exceeding the level of Euro denominated revenues thus creating a Euro deficit. 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. In the medium term, our objective is to increase the level of non-US Dollar denominated revenue, thus creating a natural hedge of the non-US Dollar expenditure.

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

The warrants issued in 2004 and 2008 and the total share options exercisable at December 2009, 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 6,915,952 A Ordinary shares (1,728,988 ADSs) exercisable at December 31, 2009 be exercised, Trinity Biotech would have to issue 6,915,952 additional A ordinary shares (1,728,988 ADSs). On the basis of 82,952,037 A ordinary shares outstanding at December 31, 2009, this would effectively dilute the ownership interest of the existing shareholders by approximately 8%.

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

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

Item 4

Information on the Company

History and Development of the Company

Trinity Biotech (the Group) develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care (POC) segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the blood, 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 in excess of 650 people worldwide and markets its portfolio of over 500 products to customers in 75 countries around the world. Trinity Biotech markets its products in the US and the rest of the world through a combination of direct selling and a network of national and international distributors. The Group has established direct sales forces in the US, Germany, France and the UK. Trinity Biotech has manufacturing facilities in Bray, Ireland and Lemgo, Germany, in Europe and in Jamestown, New York, Carlsbad, California and Kansas City, Missouri in the USA.

In 2010 the Group signed an agreement to sell its worldwide coagulation business to Diagnostica Stago for US$90 million. Diagnostica Stago have agreed to purchase the share capital of Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH and Trinity Biotech SARL, 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, 320 Trinity employees will transfer their employment to Diagnostica Stago. The transaction is expected to close during quarter 2, 2010.

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.

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Principal Markets

The primary market for Trinity Biotech s tests remains the USA. During fiscal year 2009, the Group sold 54% (US$68.1 million) (2008: 50% or US$69.9 million) (2007: 48% or US$68.4 million) of product in the USA. Sales to non-US (principally European and Asian/ African) countries represented 46% (US$57.8 million) for fiscal year 2009 (2008: 50% or US$70.2 million) (2007: 52% or US$75.2 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.

Principal Products

Trinity Biotech develops, acquires, manufactures and markets a wide range of clinical in-vitro diagnostic products. The complete portfolio is divided into 2 product lines which are sold under the following established brand names:

Clinical Laboratory			Point of Care
Coagulation	**Infectious Diseases**	**Clinical Chemistry**	
Trini™	Bartels®	Primus	UniGold
Biopool®	CAPTIA	EZ	Capillus
Amax	MarDx®		Recombigen®
Destiny	MicroTrak		
	MarBlot®		

These products are sold through our direct sales organisations in USA, UK, France and Germany and through our network of over 75 principal distributor partners in the rest of the world.

Clinical Laboratory

Trinity Biotech supplies the clinical laboratory segment of the market with a range of diagnostic tests and instrumentation which detect infectious diseases, sexually transmitted diseases, blood coagulation and autoimmune disorders. We also sell raw materials to the life sciences industry. Within the clinical laboratory product line, there are three product portfolios, namely coagulation, infectious diseases and clinical chemistry.

Coagulation

The coagulation product line comprises test kits and instrumentation used in the detection of blood coagulation and clotting disorders. The market for blood clotting and bleeding tests continues to grow due to an aging population and improvement in healthcare systems. Trinity Biotech s instrumentation and assays for coagulation are recognized as being among the highest quality available. The comprehensive product offering is marketed globally to hospitals, clinical laboratories, commercial reference laboratories and research institutions.

In 2008 we commenced the rationalization of the three existing coagulation brands of Amax, Biopool and Destiny under a single brand name called Trini . At the end of 2008 we launched the Destiny MAX instrument, which is specifically designed to service the high throughput segment of the market. This market segment is valued at approximately US$500 million per year. Prior to the launch of the Destiny MAX, this segment was not served by the existing Trinity Biotech instrument product range. During 2009, Destiny MAX has been CE marked for distribution in Europe and has obtained a 510k approval from the FDA. In 2010, the Group has signed an agreement to sell its worldwide coagulation business to Diagnostica Stago please refer to Item 18, note 28 for further details on this proposed sale.

Infectious Diseases

The infectious diseases product line is the most diverse within Trinity Biotech. The products are used to perform tests on patient samples and the results generated are reported to physicians to guide diagnosis for a broad range of infectious diseases. This product line has grown to include diagnostic kits for autoimmune diseases (e.g. lupus, celiac and rheumatoid arthritis), hormonal imbalances, sexually transmitted diseases (syphilis, chlamydia and herpes), intestinal infections, lung/bronchial infections, cardiovascular and a wide range of other diseases.

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

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The main drivers of expansion and opportunity for the product line have been:

1. The increased Trinity Biotech instrumentation offering/portfolio through collaboration with Dynex and implementation of a system sell (i.e. combining instruments and reagents) strategy;

2. Focus on key accounts in affiliate markets;

3. Expansion of product portfolio to meet market demands; and

4. Increase in our geographical spread with new partnerships in major markets in Asia-Pacific.

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.

In 2005, Trinity Biotech acquired Primus Corporation, a leader in the field of in-vitro diagnostic testing for haemoglobin A1c used in the monitoring of diabetes. Primus manufactures a range of instrumentation using patented HPLC (high pressure liquid chromatography) technology. These products are the most accurate and precise methods available for detection and monitoring the patient status and overall diabetic control. The Primus product range also includes HPLC equipment specifically designed to detect haemoglobin variants which is important for screening populations for genetic abnormalities that can lead to conditions such as sickle cell anaemia. Primus sells the products to physicians offices and reference laboratories directly in the USA and via a distribution network in other countries. In addition, the group developed the GeneSys system for assay and detection of Haemoglobin variants in neo-natal screening and the system was FDA cleared and launched in the US in May 2008. Since the launch of the GeneSys system in the US, four state laboratory services had adopted the method for their state-wide screening programs for all neonates. Primus, as part of its research and development, continues to focus on developing a sub one minute assay for A1c determination. Primus is also involved in the development of a new HPLC instrument to replace the current PDQ analyzer. 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 2009 and is expected to launch initially in the non US market in late 2010.

Point of Care (POC)

Point of Care refers to diagnostic tests which are carried out in the presence of the patient. Trinity Biotech s current range of POC tests principally test for the presence of HIV antibodies. The Group s principal product is UniGold HIV. UniGold HIV has been used for several years in voluntary counselling and testing centres (VCTs) in sub-Saharan Africa where they provide a cornerstone to early detection and treatment intervention. 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. Trinity Biotech make a very significant contribution to the global effort to meet the challenge of HIV.

In November 2007, Trinity Biotech received FDA clearance on the TRIstat point-of-care system, which will be used in physician laboratories, diabetes clinics and health centres for the rapid determination of Haemoglobin A1c. The TRIstat system is currently undergoing the completion of CLIA (Clinical Laboratory Improvement Act) clinical trials for the definition of ease of use.

In June 2007, Trinity Biotech launched its Uni-Gold LUA kit. The product is a rapid lateral flow test for the qualitative detection of Legionella pneumophilia in urine from patients with symptoms of pneumonia. Development of this product continued in 2009, with verification completed in early Q4 and then entered into validation stage with the production of validation lots of product. The new product started clinical studies in 2010 and is expected to launch during 2010.

Sales and Marketing

Trinity Biotech sells its product through its own direct sales-force in four countries: the United States, Germany, France and the United Kingdom. In the United States there are approximately 93 sales and marketing professionals

responsible for the sale of the Trinity Biotech range of coagulation reagents and instrumentation, clinical chemistry, point of care and infectious disease products. The Group also has sales forces of 17 in Germany, 5 in France and 16 in the UK. In addition to our direct sales operations, Trinity Biotech also operates in approximately 75 countries, through over 300 independent distributors and strategic partners.

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Manufacturing and Raw Materials

Trinity Biotech uses a wide range of biological and non-biological raw materials. The primary raw materials required for Trinity Biotech s test kits consist of antibodies, antigens, human plasma, latex beads, rabbit brain phospholipids, bovine source material, other reagents, glass fibre and packaging materials. The reagents used as raw materials have been acquired for the most part from third parties. Although Trinity Biotech is not dependent upon any one source for such raw materials, alternative sources of antibodies and antigens with the specificity and sensitivity desired by Trinity Biotech may not be available from time to time. Such unavailability could affect the supply of its products and its ability to meet orders for specific products, if such orders are obtained. Trinity Biotech s growth may be limited by its ability to obtain or develop the necessary quantity of antibodies or antigens required for specific products. Thus, Trinity Biotech s strategy is, whenever possible, to establish alternative sources of supply of antibodies.

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. 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.

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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 54% of Trinity Biotech s 2009 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 2009 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.

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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.

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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, Trinity Biotech (UK Sales) Limited, based in Berkshire England, Trinity Biotech GmbH, based in Lemgo, Germany, 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 Berkeley Heights, New Jersey 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 30 to the consolidated financial statements.

Property, Plant and Equipment

Trinity Biotech has five manufacturing sites worldwide, three in the US (Jamestown, NY, Kansas City, MO and Carlsbad, CA), one in Bray, Co. Wicklow, Ireland and one in Lemgo, Germany. The US and Irish facilities are each FDA and ISO registered facilities. As part of its ongoing commitment to quality, Trinity Biotech was granted the latest ISO 9001: 2000 and ISO 13485: 2003 certification. This certificate was granted by the Underwriters Laboratory, an internationally recognised notified body. It serves as external verification that Trinity Biotech has an established an effective quality system in accordance with an internationally recognised standard. By having an established quality system there is a presumption that Trinity Biotech will consistently manufacture products in a controlled manner. To achieve this certification Trinity Biotech performed an extensive review of the existing quality system and implemented any additional regulatory requirements.

Trinity Biotech s facilities and offices in Ireland are located in four buildings at IDA Business Park, Bray, Co. Wicklow. The first of these buildings is 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. Trinity Biotech spent US$4.2 million buying and fitting out this facility. In December 1999, the Group sold this facility for net proceeds of US$5.2 million and leased it back from the purchaser for 20 years. The current annual rent, which is reviewed every five years, is set at 479,000 (US$691,000).

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$397,000). 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$550,000), 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$1,136,000). 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$128,000.

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 2006, at an annual rental cost of US$259,000. The second adjacent facility comprises 14,500 square feet and is the subject of a three year lease, amended in 2009, at an annual rental cost of US$170,000.

Trinity Biotech closed its facility located in Umea, Sweden during 2008.

Trinity Biotech GmbH owns an ISO 9001 approved manufacturing and office facility of 78,000 square feet in Lemgo, Germany.

Trinity Biotech also has sales and marketing functions which operate from additional premises in the UK and France. Trinity Biotech leases two units in Berkshire, UK, at an annual rent of £91,000 (US$147,000). In 2006, Trinity Biotech entered into a lease for a 5,750 square foot premises in Paris, France, at an annual rent of 46,000 (US$66,000).

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Additional office space is leased by the Group in Ireland, Kansas City, Missouri, Acton, Massachusetts and Berkeley Heights, New Jersey at an annual cost of US$170,000, US$100,000, US$109,000 and US$274,000, 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 please also refer to Item 18, note 28.

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

Bray, Ireland this is the principal coagulation manufacturing site within the Group. Clinical Chemistry, Point of Care/HIV and Immunoflourescence products are also manufactured at this site.

Lemgo, Germany this facility is responsible for the production of our coagulation instrumentation and the associated plastic consumables for use with these instruments.

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

Trinity Biotech has no significant capital expenditures in progress. Please refer to Item 18, note 28 with regard to details of the Group s proposed disposal of its coagulation business to Diagnostica Stago.

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, 2009, December 31, 2008 and December 31, 2007, 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.

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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, 2009 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 500 different diagnostic products in approximately 75 countries. In addition, the Group manufactures its own and distributes third party coagulation and infectious diseases 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, 2009, 2008, 2007, 2006 and 2005 have been impacted by acquisitions made by the Group in three of the five years. There were no acquisitions made in 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 and a direct selling entity in France. In 2005, Group acquired Primus Corporation and Research Diagnostics Inc (RDI).

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.

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.

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At December 31, 2009 the carrying value of capitalised development costs was US$12,785,000 (2008: US$5,338,000) (see Item 18, note 12 to the consolidated financial statements). The increase in 2009 was as a result of development costs of US$7,845,000 being capitalised in 2009 and offset partially by amortisation of US$401,000.

In December 2008, an impairment loss of US$21,480,000 was incurred on the Group s capitalised development costs. This loss arose as part of the Group s annual impairment review (see Item 18, note 3 to the consolidated financial statements).

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 business segment and accordingly the key assumptions are similar for all CGU s. The value in use calculations use cash flow projections based on the 2010 budget and projections for a further four years using a projected revenue growth rate of between 3% and 5% and a cost growth rate of 3% to 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 33%.

The value in use calculation is subject to significant estimation, uncertainty and accounting judgements and are particularly sensitive in the following areas. In the event that there was a variation of 10% in the assumed level of future growth in revenues, which would represent a reasonably likely range of outcomes, the following impairment loss/write back would be recorded at December 31, 2009:

A net reversal of impairment loss of US$2.5 million in the event of a 10% increase in the growth in revenues.

An impairment loss of US$2.1 million 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, 2009:

A reversal of impairment loss of US$8.0 million in the event of a 10% decrease in the discount rate.

An impairment loss of US$7.7 million 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 2007, 2008 or 2009 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

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At December 31, 2009 our allowance for slow moving and obsolete inventory was US$12,566,000 which represents approximately 24.3% of gross inventory value. This compares with US$16,461,000, or approximately 28.0% of gross inventory value, at December 31, 2008 (see Item 18, note 15 to the consolidated financial statements) and US$18,234,000, or approximately 29.1% of gross inventory value, at December 31, 2007. There has been no significant change in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory between 2008 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$1,035,000 at December 31, 2009 (2008: US$1,176,000) (2007: US$1,253,000) 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 2009 or 2008 which would have an impact on the carrying values of receivables in these periods. At December 31, 2009, the allowance was US$855,000 which represents approximately 0.7% of Group revenues. This compares with US$619,000 at December 31, 2008 which represents approximately 0.4% of Group revenues (see Item 18, note 16 to the consolidated financial statements) and to US$657,000 at December 31, 2007, which represents approximately 0.5% 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$504,000 at December 31, 2009 (2008: US$561,000) (2007: US$574,000) would result.

Accounting for income taxes

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

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

Item 18, note 13 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and includes details of the unrecognized deferred tax assets at year end. The Group does not recognize deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilised before they expire.

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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 2009. 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 2009, 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).

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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:

1. *Overview*
2. *Revenues*
3. *Operating Profit/(loss)*
4. *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.

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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.

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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 .

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3. Operating Profit/(loss)

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

	Year ended December 31, 2009 US$ 000	2008 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.

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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, 2008, 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.

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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 2009, 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 3 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%.

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Results of Operations

Year ended December 31, 2008 compared to the year ended December 31, 2007

The following compares our results in the year ended December 31, 2008 to those of the year ended December 31, 2007 under IFRS. Our analysis is divided as follows:

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

1. Overview

In 2008, Trinity Biotech recognised an impairment charge of US$85.8 million in the statement of operations relating to the carrying value of goodwill and other intangible assets, property, plant and equipment and prepayments. This non-cash impairment charge, which was triggered by a comparison of our market capitalisation versus the book value of our net assets as required under IFRS accounting standards, contributed to the company recording a loss for the year of US$77.8 million.

Additionally in December 2008, we recognised restructuring expenses of US$2.1 million. This is made up of US$1.5 million in relation to the resignation of the Company s former Chief Executive and US$0.6 million in relation to costs associated with the implementation of headcount reductions as part of a cost cutting programme announced in December 2008.

Before the impact of these impairment and restructuring charges the Company would have recorded a profit before tax of US$6.2 million.

The following table sets forth a breakdown of impairment charges and restructuring expenses incurred in the current financial year:

	Year ended December 31, 2008		
	Impairment	*Restructuring*	*Total*
	US$ 000	*US$ 000*	*US$ 000*
Selling, general & administration expenses			
Impairment of property, plant and equipment (Item 18, note 11)	13,095		13,095
Impairment of goodwill and other intangible assets (Item 18, note 12)	71,684		71,684
Impairment of prepayments (Item 18, note 16)	1,014		1,014
Employee termination payments		589	589
Director s compensation for loss of office and share option expense		1,465	1,465
Other restructuring expenses		35	35
Total impairment loss and restructuring expenses before tax	**85,793**	**2,089**	**87,882**
Income tax impact of impairment loss and restructuring expenses (Item 18, note 9)	(4,536)	(215)	(4,751)
Total impairment loss and restructuring expenses after tax	**81,257**	**1,874**	**83,131**

For the year ended December 31, 2007, the impact of restructuring expenses and a goodwill impairment was a charge to the statement of operations after tax of US$38.4 million.

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Group revenues decreased by US$3.5 million in 2008, representing a decline of 2%. This was mainly attributable to lower Point of Care revenues. During 2008 revenues from HIV products grew in the USA but this was more than offset by lower revenue for HIV tests in Africa. The latter was due to particularly strong sales in 2007 with the result that the return to more normal sales levels resulted in a decline in overall Point of Care revenues.

The gross margin for the year ended December 31, 2008 was approximately 45%. In 2007, excluding the impact of US$12.7 million restructuring expenses and write-offs, the gross margin would have been 47%. The lower gross margin in 2008 reflects the impact of lower sales of Uni-Gold HIV products, as these products typically command higher margins. Gross margins were also adversely impacted by the weaker US dollar during 2008 compared to 2007.

The operating loss was US$79.6 million for the year ended December 31, 2008 which compares to an operating loss of US$29.4 million for the year ended December 31, 2007. Excluding the impact of impairment charges and restructuring expenses in both 2007 and 2008, the operating profit would be US$8.3 million in 2008, compared to US$10.6 million in 2007, a decline of 22%. This decline is mainly attributable to the significant decrease in revenue from higher margin HIV tests in Africa and the adverse change in the Euro to US dollar exchange rate. The Group succeeded in significantly offsetting these negative effects by implementing cost reduction measures and by driving revenue growth in its other product lines, principally infectious disease and clinical chemistry.

The loss for the year ended December 31, 2008 was US$77.8 million which compares to a loss for the year ended December 31, 2007 of US$35.4 million. Excluding the after tax impact of the restructuring expenses and goodwill impairment, the profit for 2007 would have been US$3.0 million. Similarly, if the after tax impact of the restructuring expenses and impairment charges is excluded from the 2008 results, the profit for the year would be US$5.3 million. Despite a loss before tax being recorded for the year in ended December 31, 2007, we recorded a tax charge of US$3.3 million due to the derecognition of deferred tax assets of US$3.8 million in relation to unused tax losses.

In December 2008, the Group s new coagulation analyzer, Destiny Max, was launched in markets outside the USA. Destiny Max represents the largest development project ever undertaken by the Group. Its launch represents a major success for the Group. Notwithstanding that the launch came close to the end of the year, the Group was proud to announce it had achieved the first sales of instruments in Japan, Italy and Ireland in 2008. The submission to the FDA for approval of Destiny Max was filed in December 2008. The Group expects to launch Destiny Max in the USA towards the end of quarter 2, 2009.

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.

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Revenues by Product Line

Trinity Biotech s revenues for the year ended December 31, 2008 were US$140,139,000 compared to revenues of US$143,617,000 for the year ended December 31, 2007, which represents a decrease of US$3,478,000 or 2.4%. The following table sets forth selected sales data for each of the periods indicated.

	Year ended December 31,		
	2008	2007	
	US$ 000	US$ 000	% Change
Revenues			
Clinical Laboratory	121,143	119,113	2%
Point of Care	18,996	24,504	(23%)
Total	**140,139**	**143,617**	**(2%)**

Clinical Laboratory

In 2008 Clinical Laboratory revenues increased by US$2,030,000 which equates to a growth rate of 2%. The growth was driven by strong demand for infectious disease tests and clinical chemistry tests, which increased by 8% and 9% respectively. These increases were largely offset by a 5% decline in sales of coagulation products.

Sales of infectious diseases products have increased by US$3,401,000. The 8% increase in 2008 is principally due to higher sales of Lyme kits in the US market, a full year s trading for the Cortex Biochem and Sterilab Services businesses which were acquired in September and October 2007 respectively, and lastly an increase in sales of antibodies by our Fitzgerald business. The Fitzgerald revenues were weakened in 2007 by a poor flu season in that year and 2008 saw a recovery to a more typical level.

Clinical chemistry revenues grew by 9% or US$1,567,000 mainly due to increased sales of diabetes tests in US, Europe and Asia. The demand for in vitro diagnostic tests for haemoglobin A1c and haemoglobin variants continues to grow as diabetes becomes more prevalent.

The decrease in coagulation revenues of US$2,938,000 was mainly caused by a decrease in customers in the installed base of MDA instruments in the US and UK and, to a lesser extent, a reduction in the Amax instrument base in Germany. The MDA and Amax 400 instruments are large scale instruments in the late stage of their life cycles. The newly developed Destiny Max instrument, which was launched in all markets except US in December 2008, is the natural replacement for the MDA and Amax 400 instruments. Its introduction to our product range will help to curtail customer losses in that end of the market. Increased coagulation revenues through our distributor network in Western Europe and Latin America partially offset the effect of the lower revenue in US, UK and Germany.

Point of Care

Our principal Point of Care products are Unigold and Capillus and they test for the presence of HIV antibodies. 2007 was an exceptionally strong year for sales of HIV tests in Africa. Revenues from HIV sales in Africa reverted to more normal levels in 2008 and were 16% higher than in 2006, a more comparable year. Meanwhile in the important US market, Point of Care revenue continues to show strong growth with an increase this year of 18% compared to 2007.

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Revenues by Geographical Region

The following table sets forth selected sales data, analysed by geographic region, based on location of customer:

	Year ended December 31, 2008 US$ 000	2007 US$ 000	% Change
Revenues			
Americas	69,915	68,481	2%
Europe	43,481	43,631	0%
Asia/Africa	26,743	31,505	(15%)
Total	**140,139**	**143,617**	**(2%)**

The 2% increase in the Americas amounting to US$1,434,000 is primarily attributable to the growth in the sales of the Unigold rapid HIV test, higher sales of infectious disease tests mainly Lyme s disease and higher revenues relating to diabetes tests. These increases were largely offset by a reduction in coagulation revenue arising from an erosion of the MDA customer base.

European revenues were consistent with the previous year. A decrease in revenue in the German market was offset by increased sales to distributors in other European markets mainly relating to coagulation products.

A US$4,762,000 decrease in Asia/Africa revenues is primarily due to lower sales of Trinity s Unigold rapid HIV tests in Africa, partly offset by higher coagulation revenues in the region.

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

3. Operating Loss

The following table sets forth the Group s operating loss.

	Year ended December 31, 2008 US$ 000	2007 US$ 000	% Change
Revenues	140,139	143,617	(2%)
Cost of sales	(77,645)	(75,643)	3%
Cost of sales restructuring expenses		(953)	(100%)
Cost of sales inventory write off/ provision		(11,772)	(100%)
Gross profit	62,494	55,249	13%
Other operating income	1,173	413	184%
Research & development	(7,544)	(6,802)	11%
Research & development restructuring expenses		(6,907)	(100%)
SG&A expenses	(47,816)	(51,010)	(6%)
SG&A expenses impairment charges and restructuring expenses	(87,882)	(20,315)	333%
Operating (loss)	**(79,575)**	**(29,372)**	**171%**

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Cost of sales

Total cost of sales decreased by US$10,723,000 from US$88,368,000 for the year ended December 31, 2007 to US$77,645,000, for the year ended December 31, 2008, a decrease of 12%. The decrease is primarily attributable to the restructuring expenses of US$12,725,000 recognised in cost of sales in 2007, partially offset by an increase in cost of sales (excluding once-off items) of US$2,002,000.

Included in cost of sales for the year ended December 31, 2007 was US$11,772,000 for an inventory write off and US$953,000 for restructuring expenses. These charges resulted from a decision taken by the Board of Directors of Trinity Biotech during 2007 to restructure the business. Under the restructuring plan, the company undertook to reduce the number of products and instruments within the two key product lines of coagulation and infectious diseases. As a result, the Group recognised US$11,772,000 for inventory written off relating to those coagulation and infectious diseases products and instruments being rationalised for the year ended December 31, 2007. As part of the restructuring, the Group also recognised an additional amount of US$953,000 in cost of sales for termination payments for the year ended December 31, 2007.

Excluding the inventory write off and restructuring expenses incurred, the cost of sales in 2007 would have been US$75,643,000, which is 3% lower than the comparable figure in 2008. The two main reasons for the increase in cost of sales in 2008 were the adverse change in the Euro exchange rate compared to the previous financial year and the change in the sales mix. A significant proportion of the Group s Cost of Sales is denominated in Euro. During 2008 the average Euro versus US Dollar exchange rate was 8% higher than in 2007 and this had the effect of increasing Cost of Sales. The sales mix changed principally because of the decline in revenues from HIV tests in Africa with an increase in revenues for Infectious Disease and Clinical Chemistry revenues.

Gross margin

The gross margin of 45% in 2008 compares to a gross margin of 38% in 2007. The increase in gross margin in 2008 is primarily attributable to the impact of the restructuring expenses and the inventory write off recorded in 2007. Excluding the impact of the US$12.7 million restructuring expenses and inventory write off, the gross margin in 2007 would have been 47%, which is slightly higher than the 2008 gross margin. The main reasons for this reduction are the impact of lower sales of Uni-Gold HIV products, as these products achieve higher margins, and secondly the gross margin was adversely impacted by the weaker US dollar during 2008 compared to 2007.

Research and development expenses

Research and development (R&D) expenditure reduced from US$13,709,000 in 2007 to US$7,544,000 in 2008. In 2007, R&D restructuring expenses of US$6,907,000 were incurred and this is largely the reason for the higher expenditure in 2007. The restructuring expenses in 2007 consisted of US$5,573,000 of development and licence costs written off, US$1,094,000 written off the carrying value of technology intangible assets acquired from BioMerieux and lastly termination payments amounting to US$240,000.

Research and development expenditure, excluding the impact of last year s restructuring expenses, increased by US$742,000 compared to 2007. The main reason for the increase 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 increase by about 8%. The other reason for the increase in R&D expenditure was the increase in average R&D headcount from 51 in 2007 to 57 in 2008. For a consideration of the Company s various R&D projects see Research and Products under Development in Item 5 below.

Selling, General & Administrative expenses (SG&A)

Total SG&A expenses increased by US$64,373,000 from US$71,325,000 for the year ended December 31, 2007 to US$135,698,000 for the year ended December 31, 2008. The increase is primarily due to the higher impairment charges incurred in 2008, which were partially offset by a reduction in SG&A expenses excluding share-based payments and amortisation. The following table outlines the breakdown of SG&A expenses in 2008 compared to 2007.

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	Year ended December 31, 2008 US$ 000	2007 US$ 000	Increase/ (decrease) US$ 000	% Change
SG&A (excl. share-based payments and amortisation)	43,314	46,368	(3,054)	(7%)
SG&A impairment charges and restructuring expenses	87,882	20,315	67,567	333%
Share-based payments	886	1,224	(338)	(28%)
Amortisation	3,616	3,418	198	6%
Total	**135,698**	**71,325**	**64,373**	**90%**

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

SG&A expenses excluding share-based payments and amortisation decreased from US$46,368,000 for the year ended December 31, 2007 to US$43,314,000 for the year ended December 31, 2008, which represents a decrease of 7%. The decrease would have been greater than 7% but for an adverse change in the Euro exchange rate compared to the previous financial year. A significant proportion of the Group s SG&A expenses are denominated in Euro. During 2008 the average Euro versus US dollar exchange rate was 8% higher compared to 2007 and this had the effect of increasing SG&A expenses by about US$1,800,000.

Despite the adverse change in the Euro exchange rate, there was a decrease of US$3,054,000 in SG&A expenses (excluding restructuring expenses, goodwill impairment, share-based payments and amortisation) in 2008 due to cost reductions as follows:

a reorganisation of our sales force mainly in the US was announced in December 2007. As a result, a headcount reduction was implemented which delivered payroll cost savings of about US$1,000,000 in 2008. Other headcount reductions in management and administrative functions reduced SG&A payroll costs by a further US$900,000.

through cost control the Group succeeded in reducing its selling overheads and administrative expenses by about US$2,000,000 in 2008. Further cost cutting measures were announced by the Board in December 2008 but due to timing these measures did not have a significant impact on the 2008 figures. The full benefit of these cost cutting measures, which mainly comprise further headcount reductions in sales, marketing and administration, will be seen in 2009.

a reduction in professional fees including audit fees of approximately US$700,000.

the closure of the plant in Umea, Sweden during 2008 reduced administrative expenses by about US$180,000.

the US dollar strengthened versus Sterling in the second half of 2008 and this had the effect of reducing the reported SG&A costs for our UK selling entity by just over US$100,000.

SG&A impairment charges and restructuring expenses

An impairment charge of US$85,793,000 was recorded in year ended December 31, 2008 arising out of the annual impairment review of the asset valuations included on the balance sheet. The Company has 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). By its nature this adjustment has no cash implications for the Group and does not impact on debt covenants.

Restructuring expenses of US$2,089,000 were recorded in SG&A in year ended December 31, 2008. This is 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 as part of the cost cutting measures announced in December 2008. Other restructuring costs amounted to US$35,000. The restructuring, which consists of a combination of head count and overhead reductions, will generate a saving of approximately US$6 million in 2009. The cash flow benefit will also be approximately US$6 million in 2009. In total the Company s headcount has been reduced by 70 full-time employees which equates to a reduction of approximately 10% of the overall work force.

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In the 2007 statement of operations, a goodwill impairment loss of US$19,156,000 was recognised. Additionally, restructuring expenses of US$1,159,000 were included in SG&A in 2007 primarily relating to termination payments (US$842,000) and onerous lease obligations resulting from the closure of the Swedish manufacturing operation (US$116,000).

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$1,166,000 (2007: US$1,403,000) in 2008. The total charge is shown in the following expense headings in the statement of operations: US$51,000 (2007: US$71,000) was charged against cost of sales, US$48,000 (2007: US$108,000) was charged against research and development expenses and US$886,000 (2007: US$1,224,000) was charged against selling, general and administrative expenses. A further share option charge of US$181,000 has been included within the selling, general and administrative expenses restructuring charge. This amount is related to the share option cost associated with the resignation of the former Chief Executive Officer, Mr Brendan Farrell.

The decrease of US$237,000 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

The increase in amortisation of US$198,000 from US$3,418,000 to US$3,616,000 is primarily due to the full year impact of the amortisation charge relating to the Group s acquisitions in 2007. There was a full year s amortisation charge in 2008 for the intangible assets valued on the acquisition of the immuno-technology business of Cortex Biochem Inc. This business was acquired in September 2007 and the amortisation expense was higher in 2008 by an amount of US$106,000 due to the full year effect. Similarly, there was an increase of US$82,000 in amortisation for the intangible assets valued on the acquisition of the Sterilab Services distribution business which was acquired in October 2007. The remaining increase of US$10,000 is attributable to the amortisation of software assets and capitalised development projects costs, which are being amortised over their expected lives.

4. Loss for the year

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

	Year ended December 31,		
	2008	**2007**	
	US$ 000	**US$ 000**	**% Change**
Operating (loss)	(79,575)	(29,372)	171%
Net financing costs	(2,095)	(2,691)	(22%)
(Loss) before tax	(81,670)	(32,063)	155%
Income tax credit/(expense)	3,892	(3,309)	(218%)
(Loss) of the year	**(77,778)**	**(35,372)**	**120%**

Net Financing Costs

Net financing costs decreased by US$596,000 from US$2,691,000 in 2007 to US$2,095,000 in 2008. 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, 2007 were US$42,133,000 compared to US$36,121,000 at December 31, 2008. The interest rate for the Group s borrowings is based on LIBOR rates, which reduced significantly during 2008. The deposit interest earned during the year reduced from US$457,000 to US$65,000 due to lower cash balances and lower interest rates.

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Taxation

The Group recorded a net tax credit of US$3,892,000 for the year ended December 31, 2008. The net deferred tax credit is 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 3 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.

Loss for the year

The loss for the year amounted to US$77,778,000 which represents an increase of US$42,406,000 when compared to the loss for the year of US$35,372,000 in 2007. Excluding the after tax impact of the restructuring expenses and impairment loss of US$83,131,000, the profit for the year would have been US$5,353,000. This compares to a profit for the year ended December 31, 2007 of US$2,991,000, excluding the after tax impact of the inventory write off, restructuring expenses and goodwill impairment of US$38,363,000. A decrease in net financing costs and a decrease in the income tax expense resulted in this increase in profits after tax excluding once off items.

Liquidity and Capital Resources

Financing

Trinity Biotech has a US$48,340,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Limited (the banks). The facility consists of a US Dollar floating interest rate term loan of US$41,340,000, which runs until July 2012, and a one year revolver of US$7,000,000.

The facility was amended in December 2009, with the length of the term remaining unchanged (July 2012). The repayment schedule has been revised to US$2,415,000 payable in January and July 2010 (revised from US$3,215,000). The repayment schedule for January 2011, July 2011 and January 2012 remains unchanged at US$3,215,000 per repayment. However, the final repayment in July 2012 has been revised to US$8,032,000 (previously US$6,432,000). During 2009, amounts of US$2,144,000 and US$3,215,000 were paid in January and July respectively. The revolver loan element of the facility has remained at US$7,000,000. This facility is secured on the assets of the Group (see Item 18, note 25(c)).

Various covenants apply to the Group s bank borrowings. At December 31, 2009, the total amount outstanding under the facility amounted to 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. These funds will consist of the Group s existing cash resources, cash generated from operations and where required debt and/or equity funding or the proceeds of asset disposals.

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.

Where cash generated from operations is not sufficient to meet the Group s obligations, additional debt or equity funding will need to be raised. The cost and availability of debt funding will depend on prevailing interest rates at the time and the size and nature of the funding being provided. The availability of debt and equity will depend on market conditions at the time, which is of relevance at present given the constraints being experienced in international funding markets.

The Group expects that it will have access to sufficient funds to repay the debt obligations which were outstanding at December 31, 2009. These obligations include the repayment of the remaining bank loans and finance leases. The timing of these repayment obligations and the expected maturity dates are set out in more detail in Item 11.

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Cash management

As at December 31, 2009, Trinity Biotech s consolidated cash and cash equivalents were US$6,078,000. This compares to cash and cash equivalents of US$5,184,000 at December 31, 2008.

Cash generated from operations for the year ended December 31, 2009 amounted to US$15,533,000 (2008: US$12,946,000), an increase of US$2,587,000. The increase in cash generated from operations of US$2,587,000 is attributable to an increase in operating cash flows before changes in working capital of US$4,007,000 and unfavourable working capital movements of US$1,420,000. The increase in operating cash flows before changes in working capital of US$4,007,000 is primarily due to higher net profits arising in 2009 from improved gross margin and the positive impact of strict control over indirect costs. The unfavourable working capital movements are primarily due to the effect of an increase in cash flows from trade and other receivables of US$8,003,000 and an increase in cash inflows with respect to inventory of US$310,000 being more than offset by a decrease in trade and other payables of US$9,733,000 and thus resulted in the overall unfavourable movement. The cash generated from operations was attributable to a profit before interest and taxation of US$14,099,000 (2008: loss before interest and taxation of US$79,575,000), as adjusted for non cash items of US$5,599,000 (2008: US$95,266,000) less cash outflows due to changes in working capital of US$4,165,000 (2008: cash outflows of US$2,745,000).

The decrease in other non cash charges from US$95,266,000 for the year ended December 31, 2008 to US$5,599,000 for the year ended December 31, 2009 is mainly attributable to the impairment charge in 2008 (see Item 18, note 3 to the consolidated financial statements). An impairment loss of US$71,684,000 was recognised against the intangible assets of the Group during 2008, with a further impairment of US$13,095,000 and US$1,014,000 being recognised in 2008 against property, plant and equipment and prepayments respectively. In addition to the impairment in 2008, decreased depreciation and amortisation in 2009 has led to a further decrease in other non cash charges of US$2,639,000 and US$1,657,000 respectively.

The net cash outflows in 2009 due to changes in working capital of US$4,165,000 are due to the following:

A decrease in accounts receivable by US$3,872,000 due to a decrease in debtors days in the year;

A decrease in trade and other payables by US$10,409,000 due mainly to the significant reduction in overdue creditor amounts during the year; and

A decrease in inventory by US$2,372,000 due to the continued Group wide emphasis on inventory management.

Net interest paid amounted to US$871,000 (2008: US$2,576,000). This consisted of interest paid of US$883,000 (2008: US$2,639,000) on the Group s interest bearing debt including bank loans and finance leases and was partially offset by interest received of US$12,000 (2008: US$63,000) on the Group s cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2009 amounted to US$10,335,000 (2008: US$14,688,000) which were principally made up as follows:

Payments to acquire intangible assets of US$8,103,000 (2008: US$8,981,000), 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$2,481,000 (2008: US$3,713,000) 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$249,000 (2008: US$808,000).

Net cash outflows from financing activities for the year ended December 31, 2009 amounted to US$3,512,000 (2008: cash inflow of US$481,000). The Group received US$897,000 from its issue of ordinary shares in 2009 (2008: US$7,116,000). Ordinary shares issued in 2009 are solely as a result of share options exercised during the year. The Group also received US$307,000 from the issue of long-term debt (2008: US$NIL) and US$1,298,000 from the proceeds of new finance leases (2008: US$NIL). These inflows were offset by the repayment of debt and other liabilities of US$5,400,000 (2008: US$5,224,000) and expenses paid in connection with share issues and debt financing of US$68,000 (2008: US$624,000). Also offsetting the inflows were payments in respect of finance lease

liabilities of US$546,000 (2008: US$787,000).

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

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As at December 31, 2009, total year end borrowings were US$31,856,000 (2008: US$36,121,000) and cash and cash equivalents were US$6,078,000 (2008: US$5,184,000). For a more comprehensive discussion of the Group s level of borrowings at the end of 2009, 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, 2009:

Contractual Obligations	**Payments due by Period**				
	Total	less than 1 year	1-3 Years	3-5 Years	more than 5 years
	US$ 000	US$ 000	US$ 000	US$ 000	US$ 000
Bank loans	30,556	12,364	18,090	102	
Capital (finance) lease obligations	2,478	909	1,361	208	
Operating lease obligations	53,820	4,289	7,229	6,799	35,503
Total	86,854	17,562	26,680	7,109	35,503

Trinity Biotech incurs debt and raises equity to pursue its policy of growth through acquisition. Trinity Biotech believes that, with further funds generated from operations, it will have sufficient funds to meet its capital commitments and continue existing operations for the foreseeable future, in excess of 12 months. If operating margins on sales were to decline substantially or 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. In December 2009, the Group agreed amendments to its bank facility, for more information see Item 18, note 27.

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.

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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 coagulation and clinical chemistry. The Research and Development (R&D) activities of the Group have mirrored this expansion by developing new products in these areas also.

Centres of Excellence

Trinity Biotech has research and development groups focusing separately on Western Blot products, Clinical Chemistry products and Coagulation products. These groups are located in Ireland, Germany 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.

The following is a list of the principal projects which are currently being undertaken by the R&D groups within Trinity Biotech.

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.

US Lyme Western Blot

During 2009, 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 will continue into 2010 where the newly developed product will be transferred into production and launched onto the European market.

Automated Blotting Instrument and Blot Scanner

In 2006 a project was initiated to introduce the use of an automated blotting instrument with Trinity Biotech s Western Blot tests, initially focusing on the US Lyme Western Blot allowing increased throughput for end-users. This work progressed successfully, culminating on the commencement of validation of the system in late 2006. Validation was completed in early 2007 with launch of the system, which is called TrinBlot. In 2008 the Group continued to extend the range of products which can be used on the TrinBlot, in addition to the introduction of an automated scanner to aid in the interpretation of the western blots. This system was validated and launched for use with US Lyme in 2008. In 2009, in tandem with the development of the enhanced Bordatella Pertussis product, work was initiated in developing the Trinblot and automated scanner for use with the enhanced Western Blot product. This new software will be validated and launched with the new Bordatella Pertussis product in 2010.

Clinical Chemistry

TRIstat POC

Trinity Biotech, at its Kansas City site, has developed a point of care test called TRIstat for the measurement of haemoglobin A1c for which FDA approval was obtained in late 2007. The Group continued to enhance this product during 2008 culminating in preparation for CLIA trials in late 2008. CLIA trials were performed in 2009 and the file was submitted to the FDA for review. The company is currently awaiting CLIA approval from the FDA.

Medium throughput HPLC for Haemoglobin testing

This project entails the development of a new HPLC instrument to replace the current PDQ analyzer. 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 2009 and is expected to launch initially in the non US market in late 2010.

Coagulation Development Group

Destiny Max Development Project

During 2009 the Group launched a new high throughput coagulation instrument called the Destiny Max. This instrument has been CE marked for distribution in Europe and has obtained a 510k approval from the FDA. The Destiny Max instrument is intended to meet the requirements of large laboratories, commercial laboratories, reference laboratories and anti-coagulation clinics, i.e. high volume laboratories. Enhancement of the instrument has continued throughout 2009 and into 2010. In 2010 the Group signed an agreement to sell its worldwide Coagulation business to Diagnostica Stago please refer to Item 18, note 28 for further details of this proposed sale.

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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	54	Chief Executive Officer
Rory Nealon	42	Director, Chief Operations Officer
Jim Walsh, PhD	51	Non Executive Director
Denis R. Burger, PhD	66	Non Executive Director
Peter Coyne	50	Non Executive Director
Clint Severson	61	Non Executive Director
James D. Merselis	56	Non Executive Director

Executive Officer

Kevin Tansley	39	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.

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.

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Jim Walsh, PhD, Non-executive director, joined Trinity Biotech in October 1995 as Chief Operations Officer. Dr. Walsh resigned from the role of Chief Operations Officer in 2007. He is currently CEO of Biosensia Ltd., and Stokes Bio Ltd. He also holds non Executive Director positions with PuriCore Plc (LSE: PURI) and BioCurex (OTC: BB: BOCX). 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. Dr Walsh remains on the Board as a non executive director of the Company.

Denis R. Burger, PhD, Non-executive director, co-founded Trinity Biotech in June 1992 and acted as Chairman from June 1992 to May 1995. He is currently Executive 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, a subsidiary of AIB Group plc, the Irish banking group. He has extensive experience in advising public and private groups on all aspects of corporate strategy. Prior to joining AIB, 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 Nexus Dx, Inc, a privately held, San Diego-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. From 2002 to 2007, Mr. Merselis served as President and CEO of HemoSense, Inc. (NASDAQ: HEM), a point-of-care diagnostics company providing patients and physicians with rapid test results to help manage the risk of stroke with the use of warfarin or Coumadin. Prior to his tenure at HemoSense, Mr. Merselis served as President and CEO of Micronics, Inc., a microfluidics company. In addition, Mr. Merselis held a series of increasingly responsible executive positions over twenty-two years with Boehringer Mannheim Diagnostics (now Roche Diagnostics). Mr. Merselis is the Chairman of Akrotome Imaging, a California-based, privately held start-up developing novel imaging agents for cancer diagnosis.

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.

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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, 2009 amounted to US$1,271,000. The pension charge for the year amounted to US$105,000. 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:

Director	*Salary/ Benefits US$ 000*	*Performance related bonus US$ 000*	*Defined contribution pension US$ 000*	*Total 2009 US$ 000*	*Total 2008 US$ 000*
Ronan O Caoimh	579		65	644	593
Rory Nealon	379		40	419	507
Brendan Farrell					1,841
	958		105	1,063	2,941

Non-executive director	*Fees US$ 000*	*Total 2009 US$ 000*	*Total 2008 US$ 000*
Denis R. Burger	70	70	68
Peter Coyne	70	70	68
James Merselis	53	53	
Clint Severson	60	60	5
Jim Walsh	60	60	103*
	313	313	244

* comprised of US$59,000 relating to fees and US$44,000 relating to other amounts.

Chief Financial Officer & Company	*Salary/ Benefits*	*Performance related bonus*	*Defined contribution pension*	*Total 2009*	*Total 2008*

Secretary	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*	*US$ 000*
Kevin Tansley	286		31	317	408
	286		31	317	408

As at December 31, 2009 there are no amounts which are set aside or accrued by the Company or its subsidiaries to provide pension, retirement or similar benefits for the directors.

The total share-based compensation expense recognised in the consolidated statement of operations in 2009 in respect of options granted to both executive and non executive directors amounted to US$422,000. See Item 18, note 6 to the consolidated financial statements.

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The directors were granted 2,220,000 share options during 2009 and were granted 1,665,000 share options during 2008 the terms of which are as follows:

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
Kevin Tansley	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

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

2008 Share Options Granted:

Director/Executive Officer	Number of Options Granted	Exercise Price of Options Granted	Date of Option Grant*
Brendan Farrell	250,000 A shares	US$ 1.07 per A share	18 March 2008
Rory Nealon	200,000 A shares	US$ 1.07 per A share	18 March 2008
Ronan O Caoimh	175,000 A shares	US$ 1.07 per A share	18 March 2008
Kevin Tansley	150,000 A shares		