

TRINITY BIOTECH PLC  
Form 20-F  
April 02, 2008

Table of Contents

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

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

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

**For the fiscal year ended December 31, 2007**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

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

Date of event requiring this shell company report .....

**Commission file number: 0-22320**

**Trinity Biotech plc**

(Exact Name of Registrant as specified in its charter  
and translation of Registrant's name into English)

**Ireland**

(Jurisdiction of incorporation or organization)

**IDA Business Park, Bray, Co. Wicklow, Ireland**

(Address of principal executive offices)

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 \$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:

**74,756,765 Class A Ordinary Shares and 700,000 Class B Shares**

(as of December 31, 2007)

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F

Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐

Indicate by check mark which financial statement item the registrant has elected to follow:

Item 17 ☐ Item 18 ☐

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

Yes ☐ No ☐

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form F-3 File No. 333-113091, 333-112568, 333-116537, 333-103033, 333-107363, 333-114099 and 333-124385 and our Registration Statements on Form S-8 File No. 33-76384, 333-220, 333-5532, 333-7762 and 333-124384.

---

## TABLE OF CONTENTS

	<b>Page</b>
<b>PART I</b>	
<u>Item 1</u> <u>Identity of Directors, Senior Management and Advisors</u>	1
<u>Item 2</u> <u>Offer statistics and Expected timetable</u>	1
<u>Item 3</u> <u>Selected Consolidated Financial Data</u>	1
<u>Item 4</u> <u>Information on the Company</u>	7
<u>Item 5</u> <u>Operating and Financial Review and Prospects</u>	14
<u>Item 6</u> <u>Directors and Senior Management</u>	35
<u>Item 7</u> <u>Major Shareholders and Related Party Transactions</u>	38
<u>Item 8</u> <u>Financial Information</u>	40
<u>Item 9</u> <u>The Offer and Listing</u>	40
<u>Item 10</u> <u>Memorandum and Articles of Association</u>	42
<u>Item 11</u> <u>Qualitative and Quantitative Disclosures about Market Risk</u>	52
<u>Item 12</u> <u>Description of Securities other than Equity Securities</u>	53
<b>PART II</b>	
<u>Item 13</u> <u>Defaults, Dividend Arrangements and Delinquencies</u>	54
<u>Item 14</u> <u>Material Modification to the Rights of Security Holders and Use of Proceeds</u>	54
<u>Item 15</u> <u>Control and Procedures</u>	54
<u>Item 16A</u> <u>Audit Committee Financial Expert</u>	55
<u>Item 16B</u> <u>Code of Ethics</u>	55
<u>Item 16C</u> <u>Principal Accounting Fees and Services</u>	55
<b>PART III</b>	
<u>Item 17</u> <u>Consolidated Financial Statements</u>	56
<u>Item 18</u> <u>Consolidated Financial Statements</u>	56

Item 19   Exhibits

125

Exhibit 12.1

Exhibit 12.2

Exhibit 13.1

Exhibit 13.2

Exhibit 15.1

---

**Table of Contents**

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 2007. 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.

During the year, a resolution was passed by the shareholders of Trinity Biotech at an Extraordinary General Meeting held on October 1, 2007 to de-list from the Irish Stock Exchange with effect from expiry of the relevant notice to the Irish Stock Exchange, being November 5, 2007. The Company's shares continue to be traded on the NASDAQ National Market Listing.

**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, 2007 and 2006 and for each of the years ended December 31, 2007, 2006 and 2005 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, 2005 and 2004 and for the year ended December 31, 2004 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

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

	<i>Year ended December, 31</i>			
	<i>2007</i>	<i>2006</i>	<i>2005</i>	<i>2004</i>
	<i>Total</i>	<i>Total</i>	<i>Total</i>	<i>Total</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b>Revenues</b>	<b>143,617</b>	<b>118,674</b>	<b>98,560</b>	<b>80,008</b>
Cost of sales	(75,643)	(62,090)	(51,378)	(40,047)
Cost of sales restructuring expenses	(953)			
Cost of sales inventory write off/ provision	(11,772)	(5,800)		
<b>Total cost of sales</b>	<b>(88,368)</b>	<b>(67,890)</b>	<b>(51,378)</b>	<b>(40,047)</b>
<b>Gross profit</b>	<b>55,249</b>	<b>50,784</b>	<b>47,182</b>	<b>39,961</b>
Other operating income	413	275	161	302
Research and development expenses	(6,802)	(6,696)	(6,070)	(4,744)
Research and development restructuring expenses	(6,907)			
<b>Total research and development expenses</b>	<b>(13,709)</b>	<b>(6,696)</b>	<b>(6,070)</b>	<b>(4,744)</b>
Selling, general and administrative expenses	(51,010)	(42,422)	(34,651)	(29,332)
Selling, general and administrative restructuring expenses (including goodwill impairment of US\$19,156,000)	(20,315)			
<b>Total selling, general and administrative expenses</b>	<b>(71,325)</b>	<b>(42,422)</b>	<b>(34,651)</b>	<b>(29,332)</b>
<b>Operating (loss)/ profit</b>	<b>(29,372)</b>	<b>1,941</b>	<b>6,622</b>	<b>6,187</b>
Financial income	457	1,164	389	302
Financial expenses	(3,148)	(2,653)	(1,058)	(824)
<b>Net financing costs</b>	<b>(2,691)</b>	<b>(1,489)</b>	<b>(669)</b>	<b>522</b>
<b>(Loss)/ profit before tax</b>	<b>(32,063)</b>	<b>452</b>	<b>5,953</b>	<b>5,665</b>
Income tax (expense)/ credit	(3,309)	2,824	(673)	49
	<b>(35,372)</b>	<b>3,276</b>	<b>5,280</b>	<b>5,714</b>

**(Loss)/ profit for the year (all attributable to equity holders)**

Basic (loss)/ earnings per A ordinary share (US Dollars)	(0.47)	0.05	0.09	0.10
Basic (loss)/ earnings per B ordinary share (US Dollars)	(0.94)	0.10	0.18	0.20
Diluted (loss)/ earnings per A ordinary share (US Dollars)	(0.47)	0.05	0.09	0.09
Diluted (loss)/ earnings per B ordinary share (US Dollars)	(0.94)	0.10	0.18	0.18
Basic (loss)/ earnings per ADS (US Dollars)	(1.86)	0.19	0.36	0.41
Diluted (loss)/ earnings per ADS (US Dollars)	(1.86)	0.19	0.35	0.37
Weighted average number of A shares used in computing basic EPS	76,036,579	70,693,753	58,890,084	55,132,024
Weighted average number of A shares used in computing diluted EPS	76,036,579	72,125,740	67,032,382	65,527,802



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

	<i>December 31,2007 US\$ 000</i>	<i>December 31,2006 US\$ 000</i>	<i>December 31, 2005 US\$ 000</i>	<i>December 31, 2004 US\$ 000</i>
Net current assets (current assets less current liabilities)	36,298	61,435	44,964	53,448
Non current liabilities	(35,623)	(45,928)	(19,083)	(16,636)
Total assets	215,979	249,131	184,602	156,040
Capital stock	991	978	830	776
Shareholders' equity	136,845	167,262	133,618	118,894

No dividends were declared in any of the periods from December 31, 2004 to December 31, 2007.

***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 Groups 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.

***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.



## **Table of Contents**

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 Dade-Behring (Sysmex® CA, D-Dimer plus, Enzygnost®), Zeus Scientific Inc. (Zeus EIA, IFA), Diasorin Inc. (ETI ), Abbott Diagnostics (AxSYM , IMx ), Diagnostic Products Corp. DPC (Immulite ), Bio-Rad (ELISA, WB & 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 80 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.

## **Table of Contents**

***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 30 US patents with remaining patent lives varying from less than one year to 16 years. In addition to these US patents, Trinity Biotech owns a total of 7 additional non-US patents with expiration dates varying between the years 2008 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, 2007 were Ronan O Caoimh, our Executive Chairman, Brendan Farrell, our CEO, Rory Nealon, our COO, Jim Walsh, Director and Kevin Tansley, our CFO and 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, Germany and Sweden 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 and due to the strength of the Irish economy.

***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.



## **Table of Contents**

### ***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\$9,569,000) for any one accident, limited to a maximum of 6,500,000 (US\$9,569,000) 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 in US Dollars, euro and Swedish Kroner and prepares its financial statements in US Dollars. A substantial portion of our expenses is 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 2007 consolidated revenue denominated in US Dollars was approximately 65%. Of the remaining 35% revenue, 27% relates to revenue denominated in Euro and 8% relates to sterling, yen and Swedish Kroner denominated revenues. Thus, a 10% decrease in the value of the euro would have approximately a 3% 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 the total share options exercisable at December 2007, as described in Item 18, note 20 to the consolidated financial statements, are convertible into American Depositary Shares (ADSs), 1 ADS representing 4 Class A Ordinary Shares. The exercise of the share options exercisable and of the warrants will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders. For instance, should the options and warrant holders of the 6,417,223 A Ordinary shares (1,604,306 ADSs) exercisable at December 31, 2007 be exercised, Trinity Biotech would have to issue 6,417,223 additional A ordinary shares (1,604,306 ADSs). On the basis of 74,756,765 A ordinary shares outstanding at December 31, 2007, this would effectively dilute the ownership interest of the existing shareholders by approximately 8%.

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

## **Table of Contents**

### **Item 4 Information on the Company**

#### ***History and Development of the Company***

Trinity Biotech ( the Group ) develops, acquires, manufactures and markets medical diagnostic products for the clinical laboratory and point-of-care ( POC ) segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the 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 80 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 officers 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 750 people worldwide and markets its portfolio of over 500 products to customers in 80 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, Umea, Sweden and Lemgo, Germany, in Europe and in Jamestown, New York, Carlsbad, California and Kansas City, Missouri in the USA.

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.

#### ***Acquisition of Haemostasis business of bioMerieux Inc***

In June 2006, Trinity Biotech acquired the haemostasis business of bioMerieux Inc. ( bioMerieux ) for a total consideration of US\$44.4 million, consisting of cash consideration of US\$38.2 million, deferred consideration of US\$5.5 million (net of discounting) and acquisition expenses of US\$0.7 million. At December 31, 2006, Trinity Biotech had accrued US\$5,688,000 for the deferred consideration to be paid in June 2007 and June 2008 (see Item 18, note 24 to the consolidated financial statements). Deferred consideration of US\$3,208,000 was paid to bioMerieux in June 2007. At December 31, 2007, the Group has accrued deferred consideration US\$2,725,000 (net of discounting) to be paid in June 2008.

#### ***Acquisition of the distribution business of Laboratoires Nephrotek SARL***

In October, 2006, Trinity Biotech acquired the French distribution business of Laboratoires Nephrotek SARL ( Nephrotek ) for a total consideration of US\$1,175,000, consisting of cash consideration of US\$1,060,000 and acquisition expenses of US\$115,000.

#### ***Acquisition of Primus Corporation***

In July 2005, Trinity Biotech completed the acquisition of Primus Corporation for US\$14.3 million before costs, consisting of a cash consideration of US\$8.6 million and a one year promissory note of US\$3.0 million. An additional US\$2.7 million of additional consideration was paid to the shareholders in 2006 based on the growth of the business during 2005 less an adjustment for the working capital at the date of acquisition. Primus Corporation is a leader in the field of providing tests for the detection and monitoring of diabetes patients.

#### ***Acquisition of Research Diagnostics Inc***

In March 2005, Trinity Biotech purchased the assets of Research Diagnostics Inc ( RDI ) for US\$4.2 million in cash. RDI provides a comprehensive range of immunodiagnostic products to pharmaceutical companies, diagnostic manufacturers and research facilities worldwide.





**Table of Contents*****Principal Markets***

The primary market for Trinity Biotech's tests remains the US. During fiscal year 2007, the Group sold 48% (US\$68.4 million) (2006: 51% or US\$60.7 million) (2005: 51% or US\$50.6 million) of product in the US. Sales to non-US (principally European and Asian/ African) countries represented 52% (US\$75.2 million) for fiscal year 2007 (2006: 49% or US\$57.9 million) (2005: 49% or US\$47.9 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 diagnostic products. The complete portfolio is divided into 4 product lines which are sold under the following established brand names:

<b>Haemostasis</b>	<b>Infectious Diseases</b>	<b>Clinical Chemistry</b>	<b>Point of Care</b>
Biopool®	Bartels®	Primus	UniGold
Amax	CAPTIA	EZ	Capillus
Destiny	MarDx®		Recombigen®
	MicroTrak		
	MarBlot®		

In December 2007, the haemostasis, infectious diseases and clinical chemistry product lines were amalgamated into a single product line, Clinical Laboratory.

***Haemostasis***

The haemostasis product line comprises of test kits and instrumentation used for the detection of blood disorders. Trinity Biotech has two established ranges of haemostasis products, Biopool® and Amax, which were acquired by the Group in 2001 and 2002 respectively. The Amax range of products includes a portfolio of diagnostic instrumentation including the Destiny range.

Following the acquisition of the bioMerieux haemostasis product line in 2006, the haemostasis product line has been rationalised into a single core Trini brand and has become the largest product line in revenue terms within Trinity Biotech. The acquisition of bioMerieux has significantly increased the market share of Trinity Biotech within the haemostasis market. In particular, the acquisition has strengthened the Group's position in our direct selling markets in the USA, the UK, France and Germany.

The haemostasis market continues to grow, driven by increasing demands for blood clotting and bleeding tests due to an aging population and improvement in healthcare systems.

Trinity Biotech instrumentation and assays for haemostasis are recognised as being among the highest quality available. The comprehensive product offering is marketed globally to hospitals, clinical laboratories, commercial reference laboratories and research institutions.

As part of the Group restructuring announced in December 2007, a number of Haemostasis products were identified to be culled (See item 18, note 3, Restructuring expenses and impairment).

***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. The Trinity Biotech 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.

## **Table of Contents**

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

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

1. The increased Trinity Biotech instrumentation offering/portfolio through collaboration with Adaltis and 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.

As part of the Group restructuring announced in December 2007, a number of Infectious Diseases products were identified to be culled (See item 18, note 3, Restructuring expenses and impairment).

### ***Clinical Chemistry***

The Trinity Biotech speciality clinical chemistry business includes products such as ACE, Bile Acids, Lactate, Oxalate and 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 and haemoglobin variants, used in the detection 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. 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 is in the process of developing a variant haemoglobin assay for neo-natal screening and a sub one minute HbA1c test.

### ***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 products are UniGold and Capillus.

UniGold and Capillus products have 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, through both UniGold and Capillus, 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.

### ***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 97 sales and marketing professionals responsible for the sale of the Trinity Biotech range of haemostasis reagents and instrumentation, clinical chemistry, point of care and infectious disease products. The Group also has sales forces of 26 in Germany, 11 in France and 16 in the UK. In addition to our direct sales operations, Trinity Biotech also operates in approximately 80 countries, through over 300 independent distributors and strategic partners.

### ***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.

## **Table of Contents**

### ***Competition***

The diagnostic industry is very competitive. There are many companies, both public and private, engaged in the sale of medical diagnostic products and diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. The Group's competition includes several large companies such as, but not limited to, Roche, Abbott, Johnson & Johnson, Bayer and Dade-Behring.

### ***Patents and Licences***

#### ***Patents***

Many of the 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.

### ***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 48% of Trinity Biotech's 2007 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.



## **Table of Contents**

### *FDA Regulation*

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. The FDA's regulations govern, among other things, the following activities: product development, testing; labelling, storage, premarket 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 premarket 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 2007 is in excess of US\$280,000.

*510(k) Clearance Pathway.* To obtain 510(k) clearance, Trinity Biotech must submit a premarket 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. 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) premarket 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.

### *Postmarket 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.



## **Table of Contents**

Unanticipated changes in existing regulatory requirements or adoption of new requirements could have a material adverse effect on the Group. Any failure to comply with applicable QSR or other regulatory requirements could have a material adverse effect on the Group's revenues, earnings and financial standing.

There can be no assurances that the Group will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not have a material adverse effect upon the Group's revenues, earnings and financial standing.

### ***CLIA classification***

Purchasers of Trinity Biotech's clinical diagnostic products in the United States may be regulated under The Clinical Laboratory Improvements Amendments of 1988 ( CLIA ) and related federal and state regulations. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA established three levels of diagnostic tests ( waived , moderately complex and highly complex ) and the standards applicable to a clinical laboratory depend on the level of the tests it performs.

Export of products subject to 510(k) notification requirements, but not yet cleared to market, are permitted without FDA export approval, if statutory requirements are met. Unapproved products subject to PMA requirements can be exported to any country without prior FDA approval provided, among other things, they are not contrary to the laws of the destination country, they are manufactured in substantial compliance with the QSR, and have been granted valid marketing authorisation in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or member countries of the European Union or of the European Economic Area ( EEA ). FDA approval must be obtained for exports of unapproved products subject to PMA requirements if these export conditions are not met.

There can be no assurance that Trinity Biotech will meet statutory requirements and/or receive required export approval on a timely basis, if at all, for the marketing of its products outside the United States.

### ***Regulation outside the United States***

Distribution of Trinity Biotech's products outside of the United States is also subject to foreign regulation. Each country's regulatory requirements for product approval and distribution are unique and may require the expenditure of substantial time, money, and effort. There can be no assurance that new laws or regulations will not have a material adverse effect on Trinity Biotech's business, financial condition, and results of operation. The time required to obtain needed product approval by particular foreign governments may be longer or shorter than that required for FDA clearance or approval. There can be no assurance that Trinity Biotech will receive on a timely basis, if at all, any foreign government approval necessary for marketing its products.

### ***Organisational Structure***

Trinity Biotech plc and its subsidiaries ( the Group ) is a manufacturer of diagnostic test kits and instrumentation for sale and distribution worldwide. Trinity Biotech's executive offices are located at Bray, 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 Concord, Massachusetts and Bray, Co. Wicklow, Ireland.

For a more comprehensive schedule of the subsidiary undertakings of the Group please refer to Item 18, note 32 to the consolidated financial statements.



## **Table of Contents**

### ***Property, Plant and Equipment***

Trinity Biotech has six manufacturing sites worldwide, three in the US (Jamestown, NY, Kansas City, MO and Carlsbad, CA), one in Bray, Co. Wicklow, Ireland, one in Umea, Sweden 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 Irish manufacturing and research and development facilities consisting of approximately 45,000 square feet are located at IDA Business Park, Bray, Co. Wicklow. This facility is ISO 9001 approved and was purchased in December 1997. The facilities include 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 the facility. In December 1999, the Group sold the facility for net proceeds of US\$5.2 million and leased it back from the third party purchaser for 20 years. The current annual rent, which is reviewed every five years, is set at 479,000 (US\$705,000).

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 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\$405,000). 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\$561,000), 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\$1,158,000). 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\$118,000.

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\$251,000. The second adjacent facility comprises 14,500 square feet and is the subject of a five year lease, renewed in 2006, at an annual rental cost of US\$165,000.

Trinity Biotech also operates from an additional facility located in Umea, Sweden. The Umea facility is 8,712 square feet and the annual rental is US\$129,000. The lease, renewed in December 2006, expires in December 2008. This lease will not be renewed in December 2008, as the closure of Swedish manufacturing operation will be completed during 2008 (See Item 18, Note 3, Restructuring expenses and impairment).

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\$182,000). 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\$69,000).

Additional office space is leased by the Group in Ireland, Kansas City, Missouri, Concord, Massachusetts and Berkeley Heights, New Jersey at an annual cost of US\$170,000, US\$100,000, US\$109,000 and US\$266,000, respectively.

### ***Capital expenditures and divestitures***

Trinity Biotech has no divestitures or significant capital expenditures in progress.



## **Table of Contents**

### ***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, 2007, December 31, 2006 and December 31, 2005, 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).

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, 2007 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 80 countries. In addition, the Group manufactures its own and distributes third party haemostasis 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, 2007, 2006, 2005 and 2004 have been impacted by acquisitions made by the Group in each of the four years. 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 Haemostasis business of bioMerieux and a direct selling entity in France. In 2005, Group acquired Primus Corporation and Research Diagnostics Inc. In 2004, the Group acquired Fitzgerald Industries International inc (Fitzgerald) and certain components of Adaltis US Inc.

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.



## **Table of Contents**

### *Research and development expenditure*

We write-off research and development expenditure as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalised at cost within intangible assets and amortised over its expected useful life of 15 years, which commences when 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.

In December 2007, as part of an overall restructuring announced the Group announced its intention to focus on a smaller number of R&D projects, with a particular focus on projects which will make the greatest contribution to the strategic growth and development of the Group. This decision was made independently of and in advance of the Group's annual impairment review. As part of the Group restructuring it was decided to terminate or suspend a number of projects. As a result, US\$5,134,000 of development costs were written off for the year ended December 31, 2007. The write off of capitalised developments costs in 2007 relates to a number of specific projects, the two most significant being the HIV over-the-counter (OTC) product and the development of the HIV Western Blot confirmatory test which account for US\$2,772,000 of the total amount of capitalised development costs written off of US\$5,134,000. The decision to suspend the HIV OTC project is based on the latest assessment of expected market size for this product. The Group's market assessment, carried out at the time of the Group restructuring, indicated that the market opportunity for this product was significantly less than was originally envisaged. The Group's decision to suspend the development of its HIV Western Blot confirmatory test is also due to changes in the marketplace. In particular the emergence of specific information in late 2007 indicating that Western Blot technology would no longer be required for carrying out confirmatory testing for HIV was a major factor in this assessment. The remaining development projects, which account for US\$2,631,000 of the total capitalised development costs being written off in 2007 have resulted from the strategic decision made by the Group in 2007 to focus on a smaller number of R&D projects.

At December 31, 2007 the carrying value of capitalised development costs was US\$19,150,000 (2006: US\$17,290,000) (see Item 18, note 12 to the consolidated financial statements). The increase in 2007 was attributable to development costs of US\$7,508,000 being capitalised during 2007, foreign exchange movements of US\$33,000 and partially offset by the write-off of capitalised development costs for the year ended December 31, 2007 of US\$5,134,000, referred to above, arising from the decision taken by the Group to suspend development of a number of on-going projects (See Item 18, note 3, Restructuring expenses and impairment) and amortisation of US\$547,000. Given the level or amount of expected cash flows that will result from the successful conclusion of the Company's on-going development projects when compared to their respective carrying values, any reasonably possible change in estimate of cashflows would not result in a change to these carrying values. In the event that any of the projects cannot be completed this would result in a write off of the balance in question. The projects which are currently in progress have a range of carrying values up to US\$5,988,000.

### *Impairment of intangible assets and goodwill*

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

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

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

Obsolescence of products;

Significant decline in our stock price for a sustained period; and our market capitalisation relative to net book value.



## **Table of Contents**

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. As part of the impairment review for 2007, updated estimates of cash flows from sales were employed based on the latest sales and forecast information available. These revised estimates resulted in an impairment loss of US\$19,156,000 on goodwill being recognised in 2007, which represented the excess of the carrying value over the discounted future cashflows. The Group has also recognised a specific impairment loss of US\$1,094,000 against the carrying value of the technology assets acquired from bioMerieux in 2006. The impairment loss represents 25% of the carrying value of the technology assets at the date of the group restructuring, as the products being culled represent approximately 25% of sales of those products acquired from bioMerieux. The remaining useful economic life of the remaining 75% of the carrying value of the technology asset is unaffected and was amortised on a straight line basis, through December 31, 2007. No other assets were impaired as a direct result of the product rationalisation (See Item 18, note 11 to the consolidated financial statements).

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, there would be the following impact on the level of the goodwill impairment loss recorded at December 31, 2007:

An increase in goodwill impairment of US\$23.5 million in the event of a 10% decrease in the growth in revenues.

A decrease in goodwill impairment of US\$18.6 million in the event of a 10% increase in the growth in revenues.

Similarly if there was a 10% variation in the discount rate used to calculate the potential goodwill impairment of the carrying values, which would represent a reasonably likely range of outcomes, there would be the following impact on the level of the goodwill impairment loss recorded at December 31, 2007:

An increase in goodwill impairment of US\$18.0 million in the event of a 10% increase in the discount rate.

A decrease in goodwill impairment of US\$16.3 million in the event of a 10% decrease in the discount rate.

The impairment reviews carried out at December 31, 2006 and December 31 2005 did not result in any impairment of intangible assets, non-current assets or related goodwill. A 10% variation in the discount rate or growth in revenues used to calculate the potential impairment of the carrying values would not have resulted in an impairment of assets at December 31, 2006 or December 31, 2005.

### *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 2005, 2006 or 2007 which would have an impact on the carrying values of inventory during those periods, except as discussed below.

At December 31, 2007 our allowance for slow moving and obsolete inventory was US\$18,234,000 which represents approximately 29.1% of gross inventory value. This compares with US\$7,284,000, or approximately 13.8% of gross inventory value, at December 31, 2006 (see Item 18, note 15 to the consolidated financial statements) and US\$3,564,000, or approximately 9.1% of gross inventory value, at December 31, 2005. The change in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory in 2007 compared to 2006 was principally due to a US\$11,772,000 provision recorded in 2007 arising from the rationalisation of the Group's haemostasis and infectious diseases product lines announced as part of the Group's restructuring of its business in December 2007 (See Item 18, note 3 to the consolidated financial statements). 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. The change in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory in 2006 compared to 2005 was principally due a provision put in place during 2006 in relation to the discontinuation of a number of haemostasis products following the acquisition of the haemostasis business of bioMerieux. 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\$1,253,000 at December 31, 2007 (2006: US\$1,057,000) (2005: US\$802,000) would result.



**Table of Contents***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 2007 or 2006 which would have an impact on the carrying values of receivables in these periods. At December 31, 2007, the allowance was US\$657,000 which represents approximately 0.5% of Group revenues. This compares with US\$1,074,000 at December 31, 2006 which represents approximately 0.9% of Group revenues (see Item 18, note 16 to the consolidated financial statements) and to US\$587,000 at December 31, 2005, which represents approximately 0.6% of Group revenues. In the event that this estimate was to increase or decrease by 0.4% of Group revenues, which would represent a reasonably likely range of outcomes, then a change in the allowance of US\$574,000 at December 31, 2007 (2006: US\$475,000) (2005: US\$394,000) 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 substantially 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 derecognized deferred tax assets arising on unused tax losses except to the extent that there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity which will result in taxable amounts against which the unused tax losses can be utilised before they expire. The derecognition of these deferred tax assets was considered appropriate in light of the increased tax losses caused by the restructuring and uncertainty over the timing of the utilisation of the tax losses. Except for the derecognition of deferred tax assets there were no material changes in estimates used to calculate the income tax expense provision during 2007, 2006 or 2005.

**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 2007. 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 2007, the IASB and the International Financial Reporting Interpretations Committee ( IFRIC ) issued additional standards, interpretations and amendments to existing standards which are effective for periods starting after the date of these financial statements. A list of these additional standards, interpretations and amendments, and the potential impact on the financial statements of the Group, is outlined in Item 18, note 1(z).

**Table of Contents*****Results of Operations******Year ended December 31, 2007 compared to the year ended December 31, 2006***

*The following compares our results in the year ended December 31, 2007 to those of the year ended December 31, 2006 under IFRS. Our analysis is divided as follows:*

- 1. Overview*
- 2. Revenues*
- 3. Operating Expenses*
- 4. Retained Profit*

***1. Overview***

The financial results for the year ended December 31, 2007 are impacted by the announcement made by Trinity Biotech in December 2007 to restructure its business. The restructuring included the following elements:

the rationalisation of the Haemostasis and Infectious Diseases reagent and instrumentation product lines resulting in an inventory write off of US\$11,772,000;

the closure of the Group's operation in Sweden, resulting in an inventory write off of US\$147,000 (included in the total inventory write off in 2007 of US\$11,772,000), a write down of property, plant & equipment of US\$42,000, termination payments of US\$332,000 and accrued lease obligations of US\$116,000;

the streamlining of the Group's development activities which resulted in a write off of capitalised development and license costs of US\$6,667,000 and,

the reorganisation of the US sales force coupled with a redundancy programme to reduce headcount across the Group resulting in additional termination payments of US\$1,703,000 (exclusive of termination payments made as part of the closure of the Swedish manufacturing operation of US\$332,000). Total termination payments for the year amounted to US\$2,035,000 of which US\$2,016,000 has been accrued at December 31, 2007.

In addition, in accordance with IAS 36, *Impairment of Assets*, the Group also recognised an impairment provision of US\$19,156,000 against goodwill. A further US\$1,094,000 was written off technology intangible assets acquired from BioMerieux and this charge is included in research and development expenses as part of the total amount written off for capitalised development and license costs of US\$6,667,000. Please refer to Item 18, note 3 to the consolidated financial statements for a more comprehensive discussion on the restructuring in 2007.

The impact of this restructuring and goodwill impairment is a charge to the statement of operations after tax of US\$38,363,000 for the year ended December 31, 2007.

	<i>Restructuring</i> <i>US\$ '000</i>	<i>Impairment</i> <i>US\$ '000</i>	<i>Total</i> <i>US\$ '000</i>
<i>Cost of sales</i>			
Inventory provision	11,772		11,772
Termination payments	953		953
	12,725		12,725
<i>Research &amp; development</i>			
Write-off of capitalised development and license costs	6,667		6,667
Termination payments	240		240

	6,907		6,907
<i>Selling, general &amp; administration expenses</i>			
Impairment of goodwill		19,156	19,156
Termination payments	842		842
Lease obligation provision	116		116
Other	201		201
	1,159	19,156	20,315
<b>Total restructuring expenses and goodwill impairment before tax</b>	<b>20,791</b>	<b>19,156</b>	<b>39,947</b>
Income tax impact of restructuring expenses and goodwill impairment	(1,584)		(1,584)
<b>Total restructuring expenses and goodwill impairment after tax</b>	<b>19,207</b>	<b>19,156</b>	<b>38,363</b>

## **Table of Contents**

In 2007 Group revenues increased by US\$24.9 million, which represents a growth rate of 21%. In 2007 haemostasis continues to be the Group's most significant product line representing 42% of product revenues. Haemostasis revenues increased by 31% in 2007, primarily due to the full year impact of the acquisition of the haemostasis business of BioMerieux in 2006. The remaining revenues came from the infectious diseases (29%), point of care (12%) and clinical chemistry (17%) product lines. Geographically, 48% of sales were generated in the Americas, 30% in Europe and 22% in the rest of the world.

The gross margin for the year ended December 31, 2007 was 38%. In 2007, as part of the overall restructuring expense, the Group recognised US\$11,772,000 in cost of sales for inventory written off relating to those haemostasis and infectious diseases products and instruments being rationalised for the year ended December 31, 2007. The Group also recognised an additional charge of US\$953,000 in cost of sales for termination payments for the year ended December 31, 2007. Excluding the impact of the US\$12.7 million for the restructuring expenses, the gross margin would be 47% which is broadly consistent with the gross margin for the year ended December 31, 2006, excluding the impact of the inventory provision of US\$5.8 million, of 48%.

The operating loss was US\$29,372,000 for the year ended December 31, 2007 which compares to an operating profit of US\$1,941,000 for the year ended December 31, 2006. The movement is primarily due to the impact of the US\$39.9 million for restructuring expenses and goodwill impairment. Excluding the impact of the restructuring expenses and goodwill impairment in 2007 and the inventory provision of US\$5.8 million in 2006, the operating profit increased by 37% primarily due to increased sales, of which US\$13,523,000 relates to the impact of acquisitions made in 2007 and 2006 and US\$11,420,000 is as a result of organic growth. However, the impact of increased sales, which grew by 21%, was offset by increased selling, general & administrative (SG&A) and research and development (R&D) costs. This resulted in an operating margin, excluding the impact of the restructuring expenses and goodwill impairment, of 7%. In 2006, the operating margin, excluding the impact of the US\$5.8 million inventory provision was also 7%.

The loss for the year ended December 31, 2007 was US\$35,372,000 which compares to a profit for the year ended December 31, 2006 of US\$3,276,000. Excluding the after tax impact of the restructuring expenses and goodwill impairment, the profit for the year would be US\$2,991,000, which represents a decrease in profit for the year of 9% (compared to an increase in operating profit of 37%). Although profit before tax increased in 2007, the profit after tax was lower than 2006. This is due to the impact of the derecognition of deferred tax assets of US\$3,780,000 in relation to unused tax losses and higher net interest financing costs in 2007.

## **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 on 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 haemostasis 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 haemostasis instrumentation located at customer premises.

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

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

	Year ended December 31,		% Change
	2007 US\$ 000	2006 US\$ 000	
<b>Revenues</b>			
Infectious diseases	41,293	42,051	(2%)
Haemostasis	60,759	46,476	31%
Clinical Chemistry	17,061	14,868	15%
Point of Care	24,504	15,279	60%
<b>Total</b>	<b>143,617</b>	<b>118,674</b>	<b>21%</b>

Trinity Biotech's consolidated revenues for the year ended December 31, 2007 were US\$143,617,000 compared to consolidated revenues of US\$118,674,000 for the year ended December 31, 2006, which represents an overall increase of US\$24,943,000.

*Infectious Diseases Revenues*

Sales of infectious diseases products have decreased by US\$758,000. This decrease is principally due to a reduction in sales of flu anti-bodies through our Fitzgerald business due to a poor flu season principally attributable to mild winter conditions in Fitzgerald's US and Asian markets. This was partially offset by improved Lyme sales in the US, increased sales in the Group's direct selling operation in France during its first full year of trading and the impact of the acquisition of Sterilab in the United Kingdom.

*Haemostasis Revenues*

The net increase in haemostasis revenues of US\$14,283,000 is principally attributable to increased sales arising from the full year impact of the acquisition of the haemostasis business of BioMerieux in 2006 (US\$12,224,000). The remaining increase is attributable to the 8% growth in the Group's Amax and Biopool product ranges (US\$2,059,000).

*Clinical Chemistry Revenues*

The increase in clinical chemistry revenues of US\$2,193,000 is principally due to international sales of the Primus products. Primus specialises in the field of in vitro diagnostic testing for haemoglobin A1c and haemoglobin variants (used in the detection and monitoring of diabetes patients).

*Point of Care*

Sales of Point of Care products have increased by US\$9,225,000 which is primarily attributable to increased sales of Trinity's Unigold rapid HIV test in Africa and the US.

*Revenues by Geographical Region*

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

	Year ended December 31,		% Change
	2007 US\$ 000	2006 US\$ 000	
<b>Revenues</b>			
Americas	68,481	60,748	13%
Europe	43,631	34,452	27%
Asia/Africa	31,505	23,474	34%
<b>Total</b>	<b>143,617</b>	<b>118,674</b>	<b>21%</b>



**Table of Contents**

The US\$7,733,000 increase in the Americas is primarily attributable to the following factors:

An increase in haemostasis sales including the full year impact of bioMerieux haemostasis products which was acquired in June 2006 (US\$12,224,000);

the growth in the sales of Trinity's Unigold rapid HIV test.

The US\$9,179,000 increase in Europe is primarily due to increased sales arising from the full year impact of the acquisition of BioMerieux and sales of Infectious Diseases products in France.

The US\$8,031,000 increase in Asia/Africa is primarily due to increased sales of Trinity's Unigold rapid HIV tests in Africa.

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

**3. Operating Expenses**

The following table sets forth the Group's operating expenses.

	<b>Year ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	
	<b>US\$ '000</b>	<b>US\$ '000</b>	<b>% Change</b>
Revenues	143,617	118,674	21%
Cost of sales	(75,643)	(62,090)	22%
Cost of sales restructuring expenses	(953)		100%
Cost of sales inventory write off/ provision	(11,772)	(5,800)	103%
Gross profit	55,249	50,784	9%
Other operating income	413	275	50%
Research & development	(6,802)	(6,696)	2%
Research & development restructuring expenses	(6,907)		100%
SG&A expenses	(51,010)	(42,422)	20%
SG&A expenses restructuring expenses	(20,315)		100%
Operating (loss)/ profit	<b>(29,372)</b>	<b>1,941</b>	<b>(1614%)</b>

*Cost of sales*

Total cost of sales increased by US\$20,478,000 from US\$67,890,000 for the year ended December 31, 2006 to US\$88,368,000, for the year ended December 31, 2007, an increase of 30%. The increase is primarily attributable to the restructuring expenses of US\$12,725,000 recognised in cost of sales in 2007, partially offset by the inventory provision in 2006 of US\$5.8 million. Cost of sales, excluding the impact of the restructuring expenses of US\$12.7 million in 2007 and the US\$5.8 million inventory provision in 2006, increased by US\$13,553,000 from US\$62,090,000 for the year ended December 31, 2006 to US\$75,643,000, for the year ended December 31, 2007, an increase of 22%. This increase in cost of sales is broadly in line with the increase in revenues for the Group. Cost of sales excluding the US\$12.7 million for the inventory write off and restructuring expenses for the year represents 53% of revenues, which is broadly in line with the cost of sales excluding the US\$5.8 million inventory provision as a percentage of revenue in 2006 (52%). See Revenues section above for details on movements in revenues during 2007. Included in cost of sales for the year ended December 31, 2007 is US\$12,725,000 for the inventory write off and restructuring expenses, resulting from a decision taken by the Board of Directors of Trinity Biotech during 2007 to restructure the business. Under the restructuring plan, Trinity Biotech undertook to reduce the number of products and instruments within the two key product lines of haemostasis and infectious diseases. As a result, the Group has recognised US\$11,772,000 for inventory written off relating to those haemostasis 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.

**Table of Contents**

In 2006, the Group made a US\$5.8 million inventory provision resulting from the acquisition of the haemostasis business of bioMerieux in 2006. This arose from the process of combining the acquired bioMerieux range of products with the Group's existing product range. As part of this process it was decided to discontinue various existing products, hence the requirement for the inventory provision.

*Gross margin*

The gross margin for 2007 was 38% which compares to a gross margin in 2006 of 43%. The decrease in gross margin in 2007 is primarily attributable to the impact of the restructuring expenses and goodwill impairment. Excluding the impact of the US\$12.7 million restructuring expenses, the gross margin would have been 47%, which is broadly in line with the 2006 gross margin excluding the impact of the US\$5.8 million inventory provision of 48%.

*Research and development expenses*

Research and development ( R&D ) expenditure increased to US\$13,709,000 in 2007 compared to expenditure of US\$6,696,000 in 2006. The increase in research and development expenditure is primarily attributable to the total restructuring expenses recognised in R&D in 2007 of US\$6,907,000. The total R&D restructuring expenses of US\$6,907,000 consists of US\$5,134,000 of development costs written off, US\$439,000 for license costs written off and a further US\$1,094,000 written off technology intangible assets acquired from BioMerieux. Termination payments included in R&D amounted to US\$240,000. Research and development expenditure, excluding the impact of the write-off of capitalised development and license costs of US\$6,667,000 and termination payments of US\$240,000 resulting from the restructuring activities, increased to US\$6,802,000 in 2007 compared to expenditure of US\$6,696,000 in 2006. This represents 5% of consolidated revenues, which is consistent with 2006. 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)*

The following table outlines the breakdown of SG&A expenses in 2007 compared to a similar breakdown for 2006.

	<b>Year ended December 31, 2007</b>	<b>2006</b>	<b>Increase/ (decrease)</b>	
	<b>US\$ '000</b>	<b>US\$ '000</b>	<b>US\$ '000</b>	<b>% Change</b>
SG&A (excl. share-based payments and amortisation)	46,368	38,719	7,649	20%
SG&A restructuring expenses and goodwill impairment	20,315		20,315	100%
Share-based payments	1,224	1,016	208	20%
Amortisation	3,418	2,687	731	27%
<b>Total</b>	<b>71,325</b>	<b>42,422</b>	<b>28,903</b>	<b>68%</b>

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

Total SG&A expenses increased from US\$42,422,000 for the year ended December 31, 2006 to US\$71,325,000 for the year ended December 31, 2007, which represents an increase of US\$28,903,000. The increase is primarily due to the restructuring expenses and an increase in SG&A expenses excluding share-based payments and amortisation. Total SG&A expenses excluding share-based payments and amortisation increased from US\$38,719,000 for the year ended December 31, 2006 to US\$66,683,000 for the year ended December 31, 2007, which represents an increase of 72%. Of the total increase of US\$38,719,000, US\$20,315,000 relates to restructuring expenses incurred in 2007. SG&A expenses (excluding restructuring expenses, goodwill impairment, share-based payments and amortisation) increased 20% or by US\$7,649,000 from US\$38,719,000 to US\$46,368,000, which compares to revenue growth of 21% during the same period.

## **Table of Contents**

The principal reasons for the increase in SG&A expenses (excluding restructuring expenses, goodwill impairment, share-based payments and amortisation) of US\$7,649,000 in 2007, are as follows:

Increased SG&A costs in the Head Office/Irish operations of US\$4,327,000. This is mainly due to a combination of strengthening of the Group's marketing and central administration functions in conjunction with increased professional fees associated with the implementation of Sarbanes Oxley;

An increase of US\$2,057,000 in the Group's European operations (excluding Ireland). Of this increase, US\$1,465,000 related to the full year impact of the direct sales operation in France acquired in 2006. The remaining increase of US\$592,000 arose principally in the UK mainly due to the increase in employee numbers and related costs associated with the expansion of this entity following the acquisition of the haemostasis business of bioMerieux in 2006.

Increased SG&A costs of US\$1,265,000 in the USA. This is primarily due to the full year impact of the increased personnel and related costs following the acquisition of the haemostasis business of bioMerieux in June 2006.

### *SG&A restructuring expenses and goodwill impairment*

Arising from the 2007 impairment review, a goodwill impairment loss of US\$19,156,000 was recognised in the consolidated statement of operations for the year ended December 31, 2007. This impairment loss arose in Trinity Biotech Manufacturing Limited, one of the Group's cash generating units (CGUs). Trinity Biotech Manufacturing Limited manufactures haemostasis, infectious diseases, point of care and clinical chemistry products at its plant in Bray, Ireland, which are then sold to third party distributors and other selling entities within the Group. A further US\$1,094,000 was written off technology intangible assets acquired by BioMerieux and this charge is included in research and development expenses as part of the total amount written off for capitalised development and license costs of US\$6,667,000. The remaining restructuring expenses of US\$1,159,000 included in SG&A primarily relate 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 Group recorded a total charge to the statement of operations in 2007 of US\$1,403,000 (2006: US\$1,141,000) for share-based payments. Of the 2007 charge US\$71,000 (2006: US\$89,000) was charged against cost of sales. Of the remaining US\$1,332,000, US\$108,000 (2006: US\$36,000) was charged against research and development expenses and US\$1,224,000 (2006: US\$1,016,000) was charged against selling general and administrative expenses.

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 expense for 2007 is broadly in line with that of 2006 and is due to the impact of the newly issued options being offset by a reduction in the expense resulting from forfeiture of previous share options, granted to employees and key management personnel but not vested at the time of forfeiture. For further details refer to Item 18, note 20 to the consolidated financial statements.

### *Amortisation*

The increase in amortisation of US\$731,000 from US\$2,687,000 to US\$3,418,000 is largely attributable to the impact of amortisation of intangible assets acquired as part of the Group's acquisitions in 2007 and 2006 (see Item 18, note 27 to the consolidated financial statements). The Group acquired the haemostasis business of BioMerieux and a direct selling operation in France in 2006 and the full year impact of these acquisitions on the 2007 amortisation charge was US\$579,000. A further US\$56,000 was amortised in relation to intangible assets valued on the acquisition of the immuno-technology business of Cortex and certain components of the distribution business of Sterilab, a distributor of Infectious Diseases products, in 2007.

The remaining increase of US\$96,000 is mainly attributable to amortisation of development costs which were capitalised and are now being amortised over the expected life of the products to which they related.



**Table of Contents****4. ( Loss)/ profit for the year**

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

	<b>Year ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	
	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>% Change</b>
Operating (loss)/ profit	(29,372)	1,941	(1613%)
<b>Net financing costs</b>	<b>(2,691)</b>	<b>(1,489)</b>	<b>81%</b>
(Loss)/ profit before tax	(32,063)	452	(7194%)
<b>Income tax (expense)/ credit</b>	<b>(3,309)</b>	<b>2,824</b>	<b>(217%)</b>
(Loss)/ profit of the year	(35,372)	3,276	(1180%)

***Net Financing Costs***

Net financing costs increased to US\$2,691,000 compared to US\$1,489,000 in 2006. This increase is primarily due to the impact of the additional debt financing taken on by the Group during 2006 and 2007. The loan facility was amended in July 2006, increasing the original loan facility by US\$30 million from US\$13,340,000 to US\$43,340,000 due to the acquisition of the haemostasis business of bioMerieux. In October 2007, the revolver loan element of the facility increased by US\$5 million from US\$2,000,000 to US\$7,000,000 to fund the acquisition of Cortex and Sterilab in 2007. The increased interest expense in relation to this additional debt was offset by lower interest charges in relation the Group's convertible notes as they were being repaid during 2006. Deposit interest earned during the year decreased from US\$1,164,000 in 2006 to US\$457,000 due to lower cash balances held on deposit.

***Taxation***

The Group recorded a net tax charge of US\$3,309,000 for the year ended December 31, 2007. This compared to a tax credit of US\$2,824,000 for 2006. This represented a decrease in current tax of US\$98,000 which is more than offset by an increase in deferred tax of US\$6,231,000. The decrease in current tax is primarily attributable to current year losses in the US, Ireland and Germany resulting from the restructuring. The net deferred tax expense is primarily attributable to the derecognition of deferred tax assets in relation to unused tax losses. The derecognition of these deferred tax assets was considered appropriate due to uncertainty over the timing of the utilisation of the unused tax losses. 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)/ profit for the year***

The loss for the year amounted to US\$35,372,000 which represents a decrease of US\$38,648,000 when compared to the profit for year of US\$3,276,000 in 2006. Excluding the after tax impact of the inventory write off, restructuring expenses and goodwill impairment of US\$38,363,000, the profit for the year would have been US\$2,991,000. This compares to a profit for the year ended December 31, 2006, excluding the after tax impact of the US\$5.8 million inventory provision, of US\$3,276,000.

## **Table of Contents**

### ***Year ended December 31, 2006 compared to the year ended December 31, 2005***

*The following compares our results in the year ended December 31, 2006 to those of the year ended December 31, 2005 under IFRS. Our analysis is divided as follows:*

1. *Overview*
2. *Revenues*
3. *Operating Expenses*
4. *Retained Profit*

#### ***1. Overview***

In 2006 consolidated revenues increased by US\$20.1 million, which represents a growth rate of 20.4%. In 2006 haemostasis became the Group's most significant product line representing 39% of product revenues. The remaining revenues came from the infectious diseases (35%), point of care (13%) and clinical chemistry (13%) product lines. Geographically, 51% of sales were generated in the Americas, 29% in Europe and 20% in the rest of the world.

The gross margin for the year ended December 31, 2006 was 43%. Following the acquisition of the haemostasis business of bioMérieux, Trinity Biotech sought to combine the range of products acquired with the Group's existing product range. As part of this process it was decided to discontinue various existing products and this resulted in a US\$5.8 million provision against the existing inventory of the Group. Excluding the impact of the US\$5.8 million inventory provision, the gross margin was 48% which is consistent with the gross margin for the year ended December 31, 2005.

Operating profit decreased by 71%, primarily due to the impact of the US\$5.8 million inventory provision. Excluding the impact of this inventory write-off the operating profit increased by 17% primarily due to increased sales. However, the impact of increased sales, which grew by 20%, was offset by increased selling, general & administrative (SG&A) and research and development (R&D) costs. This caused the operating margin, excluding the impact of the inventory write off, to remain at the 2005 level of 7%.

The profit for the year decreased by 38% primarily due to the impact of the inventory provision (compared to a decrease of 71% in operating profit). The lower level of decrease in profit of the year compared to the level of decrease in operating profit is due to the impact of higher net interest financing costs in 2006 being more than offset by the impact of an overall income tax credit. Excluding the after tax impact of the inventory write-off, the increase in profit for the year ended December 31, 2006 was US\$2,224,000, an increase of 42%.

#### ***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 on 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 haemostasis 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 haemostasis instrumentation located at customer premises.



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

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

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	
	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>% Change</b>
<b>Revenues</b>			
Infectious diseases	42,051	44,078	(5%)
Haemostasis	46,476	29,766	56%
Clinical Chemistry	14,868	11,880	25%
Point of Care	15,279	12,836	19%
<b>Total</b>	<b>118,674</b>	<b>98,560</b>	<b>20%</b>

Trinity Biotech's consolidated revenues for the year ended December 31, 2006 were US\$118,674,000 compared to consolidated revenues of US\$98,560,000 for the year ended December 31, 2005, which represents an overall increase of US\$20,114,000.

*Infectious Diseases*

Sales of infectious diseases products have decreased by US\$2,027,000. This decrease is principally due to a reduction in sales of US\$2,338,000 to Wampole. This decrease was partially offset by an increase of US\$311,000 which is attributable to the net increase in non-Wampole sales over a wide range of infectious diseases products.

*Haemostasis Revenues*

The increase in haemostasis revenues of US\$16,710,000 is principally attributable to the impact of the acquisition of the haemostasis business of bioMerieux in June 2006 (US\$20.9 million), which has been offset by a decline in existing sales compared to 2005.

*Clinical Chemistry Revenues*

The increase in clinical chemistry revenues of US\$2,988,000 is principally due to increased sales arising from the full year impact of the acquisition of Primus in July 2005. Primus specialises in the field of in vitro diagnostic testing for haemoglobin A1c and haemoglobin variants (used in the detection and monitoring of diabetes patients).

*Point of Care*

Sales of Point of Care products have increased by US\$2,443,000 which is primarily attributable to increased sales of Trinity's Unigold rapid HIV test in the USA and to a lesser extent increased sales of rapid HIV products in Africa.

*Revenues by Geographical Region*

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

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	
	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>% Change</b>
<b>Revenues</b>			
Americas	60,748	50,627	20%
Europe	34,452	25,301	36%
Asia/Africa	23,474	22,632	4%
<b>Total</b>	<b>118,674</b>	<b>98,560</b>	<b>20%</b>

The US\$10,121,000 increase in the Americas is primarily attributable to the following factors:

The inclusion of sales of US\$9,822,000 of bioMerieux haemostasis products from the date of acquisition in June 2006;



The full year impact of Primus, which was acquired in July 2005, of US\$3,012,000;

Partially offset by the US\$2,338,000 reduction in sales to Wampole.

**Table of Contents**

The US\$9,151,000 increase in Europe is primarily due to the impact of the acquisition of the haemostasis business of bioMerieux acquired in June 2006.

The US\$842,000 increase in Asia/Africa is primarily due to the impact of the acquisition of the haemostasis business of bioMerieux acquired in June 2006 (US\$1,714,000). This was largely offset by lower sales of US\$658,000 of Fitzgerald products following the particularly strong flu season in 2005.

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

**3. Operating Expenses**

The following table sets forth the Group's operating expenses.

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	
	<b>US\$ '000</b>	<b>US\$ '000</b>	<b>% Change</b>
Revenues	118,674	98,560	20%
Cost of sales	(62,090)	(51,378)	21%
Cost of sales – inventory provision	(5,800)		100%
Gross profit	50,784	47,182	8%
Other operating income	275	161	71%
Research & development	(6,696)	(6,070)	10%
SG&A expenses	(42,422)	(34,651)	23%
Operating profit	<b>1,941</b>	<b>6,622</b>	<b>(71%)</b>

*Cost of sales*

Cost of sales (excluding the impact of the US\$5.8 million inventory provision) increased by US\$10,712,000 from US\$51,378,000 for the year ended December 31, 2005 to US\$62,090,000, for the year ended December 31, 2006, an increase of 21%. This increase in cost of sales is broadly in line with the increase in revenues for the Group. Cost of sales excluding the US\$5.8 million inventory provision for the year represents 52% of revenues, the same level as in 2005. See Revenues section above for details on movements in revenues during 2006.

The Group made a US\$5.8 million inventory provision resulting from the acquisition of the haemostasis business of bioMerieux in 2006. This arose from the process of combining the acquired bioMerieux range of products with the Group's existing product range. As part of this process it was decided to discontinue various existing products, hence the requirement for the inventory provision.

*Gross Margin*

The gross margin for 2006 was 43%. Excluding the impact of the US\$5.8 million inventory write-off the gross margin would have been 48%, the same level as in 2005. The gross margin for the first 6 months of 2006 was 49%. This fell to 47% in the second 6 months of 2006. This is largely due to the acquisition of the haemostasis business of bioMerieux Inc., as haemostasis products tend to have a lower margin on average than the other Trinity Biotech product lines.

*Research and development*

Research and development expenditure increased to US\$6,696,000 in 2006 compared to expenditure of US\$6,070,000 in 2005. This represents 6% of consolidated revenues, which is consistent with 2005. For a consideration of the Company's various R&D projects see Research and Products under Development in Item 5 below.

**Table of Contents***Selling, General & Administrative expenses (SG&A)*

The following table outlines the breakdown of SG&A expenses in 2006 compared to a similar breakdown for 2005.

	<b>Year ended December 31,</b>		<b>Increase/</b>	
	<b>2006</b>	<b>2005</b>	<b>(decrease)</b>	
	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>% Change</b>
SG&A (excl. share-based payments and amortisation)	38,719	31,800	6,919	22%
Share-based payments	1,016	1,048	(32)	(3%)
Amortisation	2,687	1,803	884	49%
<b>Total</b>	<b>42,422</b>	<b>34,651</b>	<b>7,771</b>	<b>23%</b>

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

SG&A (excluding share-based payments and amortisation) increased 22% or by US\$6,919,000 from US\$31,800,000 to US\$38,719,000, which compares to revenue growth of 20% during the same period.

The principal reasons for the increase in SG&A expenses of US\$6,919,000 in 2006, is as follows:

Increased SG&A costs of US\$3,901,000 in the USA. This is partially due to the full year impact of Primus which was acquired in July 2005 of US\$2,524,000. The remaining increase of US\$1,377,000 is mainly attributable to increased personnel and related costs following the acquisition of the haemostasis business of bioMerieux;

Increased SG&A costs in the Head Office/Irish operations of US\$1,390,000. This is mainly due to a combination of strengthening of the Group's marketing and central administration functions in conjunction with the increase in scale of the Group and level of activity of the Irish manufacturing operation;

An increase of US\$1,538,000 in the Group's European operations (excluding Ireland). Of this increase US\$363,000 related to the newly established direct sales operation in France. The remaining increase of US\$1,175,000 arose principally in Germany and UK mainly due to the increase in employee numbers and related costs associated with the expansion of these entities following the acquisition of the haemostasis business of bioMerieux.

*Share-based payments*

The Group recorded a total charge to the statement of operations in 2006 of US\$1,141,000 (2005: US\$1,368,000) for share-based payments. Of the 2006 charge US\$89,000 (2005: US\$110,000) was charged against cost of sales. Of the remaining US\$1,052,000, US\$36,000 (2005: US\$210,000) was charged against research and development expenses and US\$1,016,000 (2005: US\$1,048,000) was charged against selling and general administration expenses.

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 expense for 2006 is broadly in line with that of 2005 and is due to the impact of the newly issued options being offset by a reduction in the expense resulting from forfeiture and expiration of previous share options granted to employees and key management personnel.

*Amortisation*

The increase in amortisation of US\$884,000 from US\$1,803,000 to US\$2,687,000 is largely attributable to the amortisation of intangible assets acquired as part of the Group's acquisitions in 2005 and 2006. The impact of the full year of the acquisition of Primus and RDI, both of which were acquired in 2005, was US\$172,000 whilst a further US\$585,000 was amortised in relation to intangible assets valued on the acquisition of the haemostasis business of

bioMerieux and the direct selling operation in France in 2006.

The remaining increase of US\$127,000 is mainly attributable to amortisation of development costs which were capitalised and are now being amortised over the expected life of the products to which they related.

**Table of Contents*****4. Profit for the year***

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

	<b>Year ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	
	<b>US\$ 000</b>	<b>US\$ 000</b>	<b>% Change</b>
Operating Profit	1,941	6,622	(71%)
<b>Net financing costs</b>	<b>(1,489)</b>	<b>(669)</b>	<b>123%</b>
Profit before tax	452	5,953	(92%)
<b>Income tax credit/(expense)</b>	<b>2,824</b>	<b>(673)</b>	<b>(520%)</b>
Profit of the year	3,276	5,280	(38%)

***Net Financing Costs***

Net financing costs increased to US\$1,489,000 compared to US\$669,000 in 2005. This increase is primarily due to the impact of the additional debt financing taken on by the Group during 2006 due to the acquisition of the haemostasis business of bioMerieux. The loan facility was amended in July 2006, increasing the original loan facility by US\$30 million from US\$13,340,000 to US\$43,340,000. The increased interest expense in relation to this additional debt was offset by lower interest charges in relation the Group's convertible notes as they were being repaid during 2006 and an increase in deposit interest earned during the year of US\$775,000 due to a combination of higher cash balances and higher interest rates.

***Taxation***

The Group recorded a net tax credit of US\$2,824,000 in the year ended December 31, 2006. This compared to a tax charge of US\$673,000 for 2005. This represented an increase in current tax of US\$16,000 which is more than offset by a decrease in deferred tax of US\$3,513,000. The increase in current tax is primarily attributable to an increase in current year profits in the Group's Irish operations. The net deferred tax credit is primarily attributable to an increase in deferred tax assets arising from current year losses in certain of the Group's subsidiary undertakings. The increase in deferred tax assets was partially offset by an increase in deferred tax liabilities attributable to an upfront deduction for certain development expenditure and licence fees, primarily in Ireland, for items that have not as yet been expensed in the Group's statement of operations.

***Profit for the year***

Profit for the year decreased by US\$2,004,000, from US\$5,280,000 to US\$3,276,000. Excluding the after tax impact of the inventory provision of US\$5,800,000, the profit for the year was US\$7,504,000, an increase of US\$2,224,000 (42%) and represents 6% of consolidated revenues, which is the same level as in 2005.

***Liquidity and Capital Resources******Financing***

Trinity Biotech has a US\$48,340,000 club banking facility with AIB plc and Bank of Scotland (Ireland) Limited (the banks). The facility consists of a five year term loan of US\$41,340,000 and a one year revolver of US\$7,000,000. The facility was amended in October 2007, increasing the original revolver loan element of the facility by US\$5 million from US\$2,000,000 to US\$7,000,000. The term loan is repayable in ten equal biannual instalments which commenced in January 2007. Two principal repayments of US\$4,134,000 each were paid during 2007. This facility is secured by the assets of the Group (see Item 18, note 28 (c) to the consolidated financial statements). Various covenants apply to the Group's bank borrowings. As at December 31, 2007, the Group was in breach of a number of these covenants which had been waived by the banks. The covenants which were breached concerned the level of earnings before taxation, depreciation and amortisation for the year end December 31, 2007 and the level of the Group's net debt and net assets excluding intangible assets at December 31, 2007. Following these breaches the Group has agreed new covenants with the banks under revised terms and conditions for the facility. These covenants have been calculated based on the expected future results and cash flows of the Group. Given the basis on which these revised covenants

have been calculated and the headroom that they afford, the directors believe that the revised covenants as well as the other terms and conditions of the facility will be complied with by the Group in future periods. In addition to agreeing to revised covenants, since December 31, 2007 the Group has agreed a revised repayment schedule for the outstanding debt, which will result in an extension to the repayment period and will reduce the level of repayments in the 12 months after December 31, 2007 (See Item 18, note 30 to the consolidated financial statements). At December 31, 2007, the total amount outstanding under the facility amounted to US\$39,808,000. The debt is stated net of unamortised funding costs of US\$264,000.

## **Table of Contents**

The additional US\$5 million loan facility was used to fund the Group's acquisitions during 2007. 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. 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 of US\$1,489,000, consisting of cash consideration of US\$1,480,000 and acquisition expenses of US\$9,000.

At December 31, 2007, the balance outstanding on the convertible notes, resulting from the private placement of US\$20,00,000 in July 2003 and a further US\$5,000,000 in January 2004, was US\$nil (2006: US\$1,836,000), including accrued interest at year end of US\$nil (2006: US\$14,000). The final principal repayment was made on January 2, 2007 by way of shares.

In April 2006, Trinity Biotech completed the private placement of 11,593,840 of Class A Ordinary Shares of the Group. Net proceeds from this placement after costs associated with the deal amounted to US\$24,010,000.

### ***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, 2007. These obligations include the repayment of the remaining bank loans, deferred consideration and finance leases. The timing of these repayment obligations and the expected maturity dates are set out in more detail in Item 11.

In the event that the Group makes any further acquisitions, we believe that the Group may be required to obtain additional debt and/or equity funding. The exact timing and amount of such funding will depend on the Group's ability to identify and secure acquisition targets which fit with the Group's growth strategy and core competencies.

### ***Cash management***

As at December 31, 2007, Trinity Biotech's consolidated cash and cash equivalents were US\$8,700,000. This compares to cash and cash equivalents, excluding restricted cash, of US\$2,821,000 at December 31, 2006. At December 31, 2006, the Group also had US\$15,500,000 which was required to be held on interest-bearing deposit. As a result, this cash of US\$15,500,000 was shown as a financial asset at December 31, 2006. This requirement to hold a certain amount of cash on interest bearing deposit was removed by the Group's banks in March 2007.

## **Table of Contents**

Cash generated from operations for the year ended December 31, 2007 amounted to US\$18,178,000 (2006: US\$8,317,000), an increase of US\$9,861,000. The increase in cash generated from operations of US\$9,861,000 is attributable to an increase in operating cash flows before changes in working capital of US\$2,415,000 and favourable working capital movements of US\$7,446,000. The increase in operating cash flows before changes in working capital of US\$2,415,000 is primarily due to higher net profits arising from additional revenue in 2007. The favourable working capital movements are primarily due to an improvement in cash flows from trade and other receivables of US\$15,188,000 which was partially offset by increased cash outflows with respect to inventories (US\$1,667,000) and reduced cash flows from trade and other payables (US\$6,075,000). The cash generated from operations were attributable to a loss before interest and taxation of US\$29,372,000 (2006: profit before interest and taxation of US\$1,941,000), as adjusted for non cash items of US\$47,459,000 (2006: US\$13,731,000) plus cash inflows due to changes in working capital of US\$91,000 (2006: cash outflows of US\$7,355,000).

The increase in other non cash charges from US\$13,731,000 for the year ended December 31, 2006 to US\$47,459,000 for the year ended December 31, 2007 is mainly attributable to the restructuring activity in 2007 (see Item 18, note 3 to the consolidated financial statements). As part of this restructuring it was decided to discontinue various existing products and this resulted in an inventory write off of US\$11,772,000 in 2007. The Group recognised an inventory provision of US\$5,800,000 during 2006. The Group also decided to suspend development of a number of on-going projects, resulting in a write-off of capitalised development and license costs for the year ended December 31, 2007 of US\$6,667,000. An impairment loss of US\$19,156,000 was also recognised against the intangible assets of the Group during 2007. The remaining increase in non cash charges is attributable to increased depreciation, amortisation and share based expenses of US\$605,000, US\$731,000 and US\$262,000 respectively in 2007.

The net cash inflows in 2007 due to changes in working capital of US\$91,000 are due to the following:

A decrease in accounts receivable by US\$5,226,000 due to better collections of outstanding debtor receipts;

An increase in trade and other payables by US\$1,966,000 due to the combination of increased activity in the Group, including the impact of the acquisitions undertaken during the year;

An increase in inventory by US\$7,101,000 due to a combination of increased activity in the Group and the building up safety stock levels on key finished products.

Net interest paid amounted to US\$2,373,000 (2006: US\$803,000). This consisted of interest paid of US\$2,802,000 (2006: US\$1,642,000) on the Group's interest bearing debt including bank loans, convertible notes and finance leases and was partially offset by interest received of US\$429,000 (2006: US\$839,000) on the Group's cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2007 amounted to US\$8,415,000 (2006: US\$63,267,000) which were principally made up as follows:

Payments for acquisitions in 2007 (US\$4,414,000) consisting of payments for the acquisition of the immuno-technology business of Cortex of US\$2,925,000 (including acquisition expenses) and payments for the acquisition of certain components of the distribution business of Sterilab of US\$1,489,000 (including acquisition expenses). In addition, payments were made during 2007 relating to acquisitions in 2006 totalling US\$3,472,000. Deferred consideration of US\$3,208,000 and US\$239,000 was paid to bioMerieux and Nephrotek respectively during 2007. A further amount of US\$25,000 was paid during 2007 relating to accrued acquisition expenses at December 31, 2006;

Payments to acquire intangible assets of US\$7,851,000 (2006: US\$6,085,000), 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\$8,262,000 (2006: US\$4,751,000) incurred as part of the Group's investment programme for its manufacturing and distribution activities;

Movements in financial fixed assets, which resulted in a cash inflow of US\$15,500,000 in 2007 (2006: a cash outflow of US\$6,500,000), was due to the requirement to maintain a certain level of cash deposits



(restricted cash) with the Group's lending banks being removed during 2007. At December 31, 2006 the Group was required to keep US\$15,500,000 on deposit as restricted cash with its lending banks. This restriction was removed during 2007, resulting in a cash outflow from investing activities of US\$15,500,000 in 2007.

Net cashflows used in financing activities for the year ended December 31, 2007 amounted to US\$1,108,000 (2006: cash inflow of US\$48,621,000). The Group received US\$5,000,000 from its revolver loan facility to fund the acquisition of Cortex and Sterilab in 2007 and raised US\$454,000 (2006: US\$25,265,000) from issuing share capital. The Group also received net cash inflows from finance lease obligations of US\$1,793,000 (2006: net cash outflow of US\$198,000). These inflows were offset by the repayment of debt and other liabilities of US\$8,285,000 (2006: US\$1,276,000) and expenses paid in connection with share issues and debt financing of US\$70,000 (2006: US\$1,526,000).

**Table of Contents**

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's euro denominated expenses as a result of the movement in the exchange rate between the US Dollar and the euro. Trinity Biotech continuously monitors its exposure to foreign currency movements and based on expectations on future exchange rate exposure implements a hedging policy which may include covering a portion of this exposure through the use of forward contracts. When used, these forward contracts are cashflow hedging instruments whose objective is to cover a portion of these euro forecasted transactions.

As at December 31, 2007, total year end borrowings were US\$42,133,000 (2006: US\$45,294,000) and cash and cash equivalents were US\$8,700,000 (2006: US\$2,821,000 (US\$18,321,000 inclusive of restricted cash)). For a more comprehensive discussion of the Group's level of borrowings at the end of 2007, 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, 2007:

	Total	Payments due by Period			
		less than 1 year	1-3 Years	3-5 Years	more than 5 years
<b>Contractual Obligations</b>	US\$ '000	US\$ '000	US\$ '000	US\$ '000	US\$ '000
Bank loans	44,330	17,497	18,430	8,403	
Capital (finance) lease obligations	2,616	779	1,048	789	
Other financial liabilities	2,725	2,725			
Operating lease obligations	62,551	4,943	8,050	6,436	43,122
<b>Total</b>	<b>112,222</b>	<b>25,944</b>	<b>27,528</b>	<b>15,628</b>	<b>43,122</b>

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, if the Group's increased investment in its US direct sales force was not to generate comparable margins in sales 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. Since December 31, 2007 the Group has agreed amendments to its bank facility, for more information see Item 18, note 30.

***Impact of Inflation***

Although Trinity Biotech's operations are influenced by general economic trends, Trinity Biotech does not believe that inflation had a material effect on its operations for the periods presented. Management believes, however, that continuing national wage inflation in Ireland and the impact of inflation on costs generally will result in a sizeable increase in the Irish facility's operating costs in 2008.

***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 increase the size of the euro revenue base 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.

## **Table of Contents**

### ***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 29 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.

### ***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 haemostasis 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 microtitre plate based tests, rapid tests, western blot products, clinical chemistry products, haemostasis and immunofluorescent assays. 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.

#### ***Microtitre Plate Development Group***

##### ***Development of microtitre plate assay for the detection of EU Lyme IgG and IgM***

Trinity Biotech is already a leading supplier of diagnostic tests for the detection of Lyme disease. Development was recently completed of two new tests to specifically detect for strains of Lyme disease prevalent in Europe. Development and transfer to production was completed by December 2006 including some clinical trial data. Final clinical data was completed in early 2007 which will allow the product to be CE marked and launched in early 2008.

#### ***HIV Incidence Assay***

In late 2005, Trinity entered a Biological Materials License Agreement with the Centre for Disease Control (CDC) in Atlanta, Georgia, for the rights to produce and sell the CDC devised HIV Incidence assay. The technology was transferred to Trinity during 2006 and the product was developed by the Group during 2007 with the design and development of key raw materials. Final development is planned to take place in early 2008 followed by the launch of the product worldwide.

#### ***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***

For many years, Trinity Biotech's US Domestic Lyme Western Blot has been a market leader. During 2006, a project was undertaken to further develop the product by adding additional process controls to the test, increasing the effectiveness of the product in the end-users hands. This work was successfully completed and Group launched the

enhanced product in late 2007.

## **Table of Contents**

### *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. The Group intends to extend the range of products which can be used on the TrinBlot. In addition to the automated blotter, work is also completed on adapting an automated scanner to aid in the interpretation of the western blots. This system was validated and launched in late 2007.

### ***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's submission for CLIA waiver is currently being considered by the FDA and approval is expected in early 2008 which will allow a full launch of the product during 2008.

#### *Haemoglobin assay development*

In 2007 the Group initiated a project to develop a variant haemoglobin assay for neo-natal screening and a sub one minute HbA1c test. Development will continue into 2008 and both of these tests are expected to launch in 2009.

#### *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 2007 and is expected to continue through 2008.

### ***Haemostasis Development Group***

#### *Destiny Max Development Project*

The Group is in the process of developing a new high throughput haemostasis instrument called the Destiny Max. 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. In so doing, Trinity Biotech will be able to compete effectively in an overall system approach whereby placement of the Destiny Max instruments will drive increased sales of the associated Trinity Biotech reagents, controls and accessories. Development of the instrument continued in 2007. Trinity Biotech is currently finalising the final design and software aspects of the instrument. Completion of the development and validation phase of the project is scheduled for late 2008. Launch of the instrument onto the various worldwide markets is expected to take place in late 2008, with launch in the USA following thereafter post FDA approval.

### ***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.

**Table of Contents****Item 6 Directors and Senior Management**  
**Directors**

<i>Name</i>	<i>Age</i>	<i>Title</i>
Ronan O Caoimh	52	Executive Chairman
Brendan K. Farrell	60	Chief Executive Officer
Rory Nealon	40	Director, Chief Operations Officer
Jim Walsh, PhD	49	Non Executive Director
Denis R. Burger, PhD	64	Non Executive Director
Peter Coyne	48	Non Executive Director
<b>Executive Officers</b>		
Kevin Tansley	37	Chief Financial Officer & Company Secretary

**Board of Directors & Executive Officers**

**Ronan O Caoimh, Executive Chairman**, 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. 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.

**Brendan Farrell, Chief Executive Officer**, joined Trinity Biotech in July 1994 and acted as President until November 2007 when he was appointed Chief Executive Officer. He was previously Marketing Director of B.M. Browne Limited, a company involved in the marketing and distribution of medical and diagnostic products. Prior to that he was Chief Executive of Noctech Limited, an Irish based diagnostics company, following six years with Baxter Healthcare where he was Director of European Business Development. Mr Farrell has a Masters degree in Biochemistry from University College Cork.

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

**Jim Walsh, PhD, 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. Prior to joining the 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 has a degree in Chemistry and a PhD in Microbiology from University College Galway. Dr Walsh remains on the Board as a non executive director of the Company.

**Table of Contents**

**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 a non-executive director of the Company and serves as an independent director on the boards of two other NASDAQ-listed companies. Until March 2007, Dr Burger was the Chairman and Chief Executive Officer of AVI Biopharma Inc, an Oregon based bio-technology 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 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.

**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.

**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 and Mr Ronan O' Caoimh. 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, 2007 amounted to US\$2,370,000. The pension charge for the year amounted to US\$147,000. 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:

	<i>Salary/ Benefits</i>	<i>Performance related bonus</i>	<i>Defined contribution pension</i>	<i>Total 2007</i>	<i>Total 2006</i>
<i>Director</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>
Ronan O' Caoimh	656	207	64	927	854
Brendan Farrell	509	125	47	681	602
Rory Nealon	365	124	20	509	377
Jim Walsh	169	85	16	270	399
	1,699	541	147	2,387	2,232
<i>Non-executive director</i>			<i>Fees</i>	<i>Total 2007</i>	<i>Total 2006</i>
			<i>US\$ '000</i>	<i>US\$ '000</i>	<i>US\$ '000</i>



Denis R. Burger	65	65	50
Peter Coyne	65	65	50
	130	130	100

**Table of Contents**

<i>Chief Financial Officer &amp; Company Secretary</i>	<i>Salary/ Benefits US\$ 000</i>	<i>Performance related bonus US\$ 000</i>	<i>Defined contribution pension US\$ 000</i>	<i>Total 2007 US\$ 000</i>	<i>Total 2006 US\$ 000</i>
Kevin Tansley *	53		2	55	
	53		2	55	

\* appointed November 1, 2007

As at December 31, 2007 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 2007 in respect of options granted to both executive and non executive directors amounted to US\$920,000. See Item 18, note 6 to the consolidated financial statements.

No options were granted to the directors during 2007. The directors were granted 860,000 share options during 2006.

In addition, see Item 7 Major Shareholders and Related Party Transactions for further information on the compensation of Directors and Officers.

#### ***Board Practices***

The Articles of Association of Trinity Biotech provide that one third of the directors in office (other than the Managing Director or a director holding an executive office with Trinity Biotech) or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at every annual general meeting. If at any annual general meeting the number of directors who are subject to retirement by rotation is two, one of such directors shall retire and if the number of such directors is one that director shall retire. Retiring directors may offer themselves for re-election. The directors to retire at each annual general meeting shall be the directors who have been longest in office since their last appointment. As between directors of equal seniority the directors to retire shall, in the absence of agreement, be selected from among them by lot.

In accordance with the Articles of Association of the Company, Mr. Denis Burger will retire by rotation and, being eligible, offer himself for re-election at the Annual General Meeting of the Company.

The board has established audit, remuneration and compensation committees. The functions and membership of the Remuneration Committee are described above. The Audit Committee reviews the Group's annual and interim financial statements and reviews reports on the effectiveness of the Group's internal controls. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The Audit Committee comprises the two independent non-executive directors of the Group, Mr Peter Coyne (committee chairman) and Dr Denis Burger. The Compensation Committee comprises Mr Ronan O' Caoimh (Committee Chairman), Mr Brendan Farrell and Mr Rory Nealon. The Compensation Committee administers the Employee Share Option Plan. The Committee determines the exercise price and the term of the options. Options granted to the members of the Committee are approved by the Remuneration Committee and individual option grants in excess of 30,000 shares are approved by the full board of directors. Share options granted to non-executive directors are decided by the other members of the board.

Because Trinity Biotech is a foreign private issuer, it is not required to comply with all of the corporate governance requirements set forth in NASDAQ Rule 4350 as they apply to U.S. domestic companies. The Group's corporate governance measures differ in the following significant ways. First, the Audit Committee of the Group currently consists of two members while U.S. domestic companies listed on NASDAQ are required to have three members on their audit committee. Second, the board of directors of the Group has only two independent, non-executive directors, while U.S. domestic companies are required to have a majority of independent directors on their board. In addition, the Group has not appointed an independent nominations committee or adopted a board resolution addressing the nominations process. Finally, the Group's Executive Chairman serves on the Group's Remuneration Committee with two non-executive independent directors, while U.S. domestic companies are required to have executive officer

compensation determined by a remuneration committee comprised solely of independent directors or a majority of the independent directors.

**Table of Contents*****Employees***

As of December 31, 2007, Trinity Biotech had 762 employees (2006: 826) consisting of 48 research scientists and technicians, 450 manufacturing and quality assurance employees, and 264 finance, administration and marketing staff (2006: a research director and 44 research scientists and technicians, 520 manufacturing and quality assurance employees, and 261 finance, administration and marketing staff). Trinity Biotech's future hiring levels will depend on the growth of revenues.

The geographic spread of the Group's employees was as follows: 312 in Bray, Co. Wicklow, Ireland, 317 in its US operations, 97 in Germany, 12 in the United Kingdom, 18 in France and 6 in Sweden.

***Stock Option Plan***

The board of directors has adopted the Employee Share Option Plan, as most recently updated in 2006, (the Plan), the purpose of which is to provide Trinity Biotech's employees, consultants, officers and directors with additional incentives to improve Trinity Biotech's ability to attract, retain and motivate individuals upon whom Trinity Biotech's sustained growth and financial success depends. The Plan is administered by a Compensation Committee designated by the board of directors. Options under the Plan may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

The exercise price of options is determined by the Compensation Committee. The term of an option will be determined by the Compensation Committee, provided that the term may not exceed seven years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity Biotech (or one year after such termination because of death or disability) except where a longer period is approved by the board of directors. Under certain circumstances involving a change in control of Trinity Biotech, the Committee may accelerate the exercisability and termination of options. As of February 29, 2008, 4,977,083 of the options outstanding were held by directors and officers of Trinity Biotech.

As of February 29, 2008 the following options were outstanding:

	Number of A Ordinary Shares Subject to Option	Range of Exercise Price per Ordinary Share	Range of Exercise Price per ADS
Total options outstanding	7,788,878	US\$0.98-US\$4.00	US\$ 3.92-US\$16.00
In addition, in January 2004, the Group completed a private placement and as part of this the investors were granted five year warrants to purchase an aggregate of 1,058,824 A Ordinary Shares of Trinity Biotech at an exercise price of US\$5.25 per ordinary share and the agent received 200,000 warrants to purchase 200,000 A Ordinary Shares of Trinity Biotech at an exercise price of US\$5.25 per ordinary share. As of February 29, 2008 there were warrants to purchase 1,258,824 A Ordinary Shares in the Group outstanding.			

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

As of February 29, 2008 Trinity Biotech has outstanding 74,756,765 A Ordinary shares and 700,000 B Ordinary shares. Such totals exclude 9,047,702 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 29, 2008, the Trinity Biotech A Ordinary Shares and B Ordinary Shares beneficially held by (i) each person believed by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and officer of Trinity Biotech, and (iii) all officers and directors as a group.

Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Group is not controlled by another corporation or government.

**Table of Contents**

	Number of A Ordinary Shares  Beneficially Owned	Percentage  Outstanding A Ordinary Shares	Number of B Ordinary Shares  Beneficially Owned	Percentage  Outstanding B Ordinary Shares	Percentage  Total  Voting Power
Ronan O Caoimh	4,837,287(1)	6.4%			6.3%
Brendan Farrell	1,934,135(2)	2.5%			2.5%
Rory Nealon	531,250(3)	0.7%			0.7%
Jim Walsh	1,889,240(4)	2.5%			2.5%
Denis R. Burger	182,833(5)	0.2%			0.2%
Peter Coyne	155,833(6)	0.2%			0.2%
Kevin Tansley	39,999(7)	0.05%			0.05%
Potenza Investments Inc, ( Potenza ) Statenhof Building, Reaal 2A 23 50AA Leiderdorp Netherlands			500,000(8)	71.4%	1.3%
Officers and Directors as a group (7 persons)	9,570,577(1)(2)(3)(4)(5)(6)(7)	12.55%			12.0%
(1) Includes 1,145,832 shares issuable upon exercise of options.					
(2) Includes 1,345,000 shares issuable upon exercise of options.					
(3) Includes 331,250 shares issuable upon exercise of options.					
(4) Includes 535,625 shares issuable upon exercise of options.					

- (5) Includes  
135,833 shares  
issuable upon  
exercise of  
options.
- (6) Includes  
155,833 shares  
issuable upon  
exercise of  
options.
- (7) Includes 39,999  
shares issuable  
upon exercise of  
options.
- (8) These B shares  
have two votes  
per share.

***Related Party Transactions***

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

In July 2000, Trinity Biotech entered into an agreement with JRJ pursuant to which the Group took a lease of a 25,000 square foot premises adjacent to the existing facility for a term of 20 years at a rent of 7.62 per square foot for an annual rent of 190,000 (US\$260,000). During 2006, the rent on this property was reviewed and increased to 11.00 per square foot, resulting in an annual rent of 275,000 (US\$377,000).

In November 2002, the Group entered into an agreement for a 25 year lease with JRJ for offices that have been constructed adjacent to its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. The annual rent of 381,000 (US\$522,000) is payable from January 1, 2004.

## **Table of Contents**

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\$1,158,000).

Independent valuers have advised the Group that the rent in respect of each of the leases represents a fair market rent. Trinity Biotech and its directors (excepting Mr O Caoimh and Dr Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Group can meet its ongoing requirements for premises.

Rayville Limited, an Irish registered company, which is wholly owned by the four executive directors and certain other executives of the Group, owns all of the B non-voting Ordinary Shares in Trinity Research Limited, one of the Group's subsidiaries. The B shares do not entitle the holders thereof to receive any assets of the company on a winding up. All of the A voting ordinary shares in Trinity Research Limited are held by the Group. Trinity Research Limited may, from time to time, declare dividends to Rayville Limited and Rayville Limited may declare dividends to its shareholders out of those amounts. Any such dividends paid by Trinity Research Limited are ordinarily treated as a compensation expense by the Group in the consolidated financial statements prepared in accordance with IFRS, notwithstanding their legal form of dividends to minority interests, as this best represents the substance of the transactions.

In December 2006, the Remuneration Committee of the Board approved the payment of a dividend of US\$5,331,000 by Trinity Research Limited to Rayville Limited on the B shares held by it. This amount was then lent back by Rayville to Trinity Research Limited. This loan was partially used to fund executive compensation in 2007 and will fund future executive compensation over the next number of years under the arrangement described above, with the amount of such funding being reflected in compensation expense over the corresponding period. As the dividend is matched by a loan from Rayville Limited to Trinity Research Limited which is repayable solely at the discretion of the Remuneration Committee of the Board and is unsecured and interest free, the Group netted the dividend paid to Rayville Limited against the corresponding loan from Rayville Limited in the 2007 and 2006 consolidated financial statements.

The amount of payments to Rayville included in compensation expense was US\$1,410,000, US\$1,911,000 and US\$2,061,000 for 2005, 2006 and 2007 respectively, of which US\$1,333,000, US\$1,779,000 and US\$1,867,000 respectively related to the key management personnel of the Group. There were no dividends payable to Rayville Limited as of December 31, 2005, 2006 or 2007. Of the US\$2,061,000 of payments made to Rayville Limited in 2007, US\$955,000 represented repayments of the loan to Trinity Research Limited referred to above.

### ***Item 8 Financial Information***

#### ***Legal Proceedings***

Trinity Biotech was not involved in any significant legal proceedings during 2007. A legal dispute regarding the distribution agreements with Inverness Medical Innovations Inc. was settled in August 2006.

### ***Item 9 The Offer and Listing***

Trinity Biotech's American Depositary Shares (ADSs) are listed on the NASDAQ National Cap Market under the symbol TRIB. In 2005, the Trinity Biotech adjusted the ratio of American Depositary Receipts (ADSs) to Ordinary Shares and changed its NASDAQ Listing from the NASDAQ Small Capital listing to a NASDAQ National Market Listing. The ratio of ADSs to underlying Ordinary Shares has changed from 1 ADS : 1 Ordinary Share to 1 ADS : 4 Ordinary Shares and all historical data has been restated as a result.

**Table of Contents**

The Group's A Ordinary Shares were also listed and traded on the Irish Stock Exchange until November 2007, whereby the Company de-listed from the Irish Stock Exchange. The Group's depository bank for ADSs is The Bank of New York. On February 29, 2008, the reported closing sale price of the ADSs was US\$4.58 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech's ADSs for (a) the years ended December 31, 2003, 2004, 2005, 2006 and 2007; (b) the quarters ended March 31, June 30, September 30 and December 31, 2006; March 31, June 30, September 30 and December 31, 2007; and (c) the months of March, April, May, June, July, August, September, October, November and December 2007 and January and February 2008 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	ADSs	
	High	Low
<b>Year Ended December 31</b>		
2003	\$ 26.88	\$ 5.00
2004	\$ 23.96	\$ 9.40
2005	\$ 11.72	\$ 6.28
2006	\$ 9.54	\$ 7.09
2007	\$ 11.75	\$ 5.72
<b>2006</b>		
Quarter ended March 31	\$ 9.31	\$ 8.20
Quarter ended June 30	\$ 9.51	\$ 7.45
Quarter ended September 30	\$ 9.30	\$ 7.09
Quarter ended December 31	\$ 9.54	\$ 8.34
<b>2007</b>		
Quarter ended March 31	\$ 10.45	\$ 8.68
Quarter ended June 30	\$ 11.74	\$ 9.13
Quarter ended September 30	\$ 11.75	\$ 10.05
Quarter ended December 31	\$ 11.40	\$ 5.72
<b>Month Ended</b>		
March 31, 2007	\$ 10.05	\$ 8.81
April 30, 2007	\$ 10.82	\$ 9.13
May 31, 2007	\$ 11.28	\$ 10.51
June 30, 2007	\$ 11.74	\$ 11.11
July 31, 2007	\$ 11.75	\$ 10.33
August 31, 2007	\$ 11.45	\$ 10.05
September 30, 2007	\$ 11.41	\$ 10.25
October 31, 2007	\$ 11.40	\$ 8.76
November 30, 2007	\$ 9.28	\$ 8.10
December 31, 2007	\$ 8.45	\$ 5.72
January 31, 2008	\$ 6.95	\$ 6.20
February 29, 2008	\$ 6.55	\$ 4.52

The number of record holders of Trinity Biotech's ADSs as at February 29, 2008 amounts to 431, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clientele (with each such brokerage house and/or clearing house being considered as one holder).





## **Table of Contents**

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

#### ***Objects***

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

#### ***Powers and Duties of Directors***

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

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

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

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

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

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

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

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

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



## **Table of Contents**

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

The Company may, subject to the provisions of the Companies Acts, 1963 to 2007 of Ireland, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution. Before recommending a dividend, the directors may reserve out of the profits of the Company such sums as they think proper which shall be applicable for any purpose to which the profits of the Company may properly be applied and, pending such application, may be either employed in the business of the Company or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

Subject to any conditions of allotment, the directors may from time to time make calls on members in respect of monies unpaid on their shares. At least 14 days notice must be given of each call. A call shall be deemed to have been made at the time when the directors resolve to authorise such call.

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

### ***Action Necessary to Change the Rights of Shareholders***

In order to change the rights attaching to any class of shares, a special resolution passed at a class meeting of the holders of such shares is required. The provisions in relation to general meetings apply to such class meetings except the quorum shall be two persons holding or representing by proxy at least one third in nominal amount of the issued shares of that class. In addition, in order to amend any provisions of the Articles of Association in relation to rights attaching to shares, a special resolution of the shareholders as a whole is required.

### ***Calling of AGM s and EGM s of Shareholders***

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in Ireland unless all of the members entitled to attend and vote at it consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2007 of Ireland.

In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days notice of the meeting is required and in any other case it is seven clear days notice. Notice must be given in writing to all members and to the auditors and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided in the Companies Acts, 1963 to 2007 of Ireland, extended notice is required. These include removal of a director. No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum. The Company is not obliged to serve notices upon members who have addresses outside Ireland and the US but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in the Company.

However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in

Exchange Controls below. In addition, Irish competition law may restrict the acquisition by a party of shares in the

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

**Table of Contents**

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

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

which would have an effect of delaying, deferring or preventing a change in control of the Company and  
which would operate only with respect to a merger, acquisition or corporate restructuring involving the  
Company (or any of its subsidiaries); or

governing the ownership threshold above which a shareholder ownership must be disclosed; or

imposing conditions governing changes in the capital which are more stringent than is required by Irish law.

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

***Irish Law***

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

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

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

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

***Material Contracts***

See Item 4 History and Development of the Company regarding acquisitions made by the Group.



**Table of Contents**

***Exchange Controls and Other Limitations  
Affecting Security Holders***

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of the Republic of Ireland dealing in domestic securities which includes shares or depository receipts of Irish companies such as Trinity Biotech, and dividends and redemption proceeds, subject to the withholding where appropriate of withholding tax as described under Item 10, are freely transferable to non-resident holders of such securities.

The Financial Transfers Act, 1992 was enacted in December 1992. This Act gives power to the Minister of Finance of the Republic of Ireland to make provision for the restriction of financial transfers between the Republic of Ireland and other countries. Financial transfers are broadly defined and include all transfers, which would be movements of funds within the meaning of the treaties governing the European Communities. The acquisition or disposal of ADSs representing shares issued by an Irish incorporated company and associated payments may fall within this definition. In addition, dividends or payments on redemption or purchase of shares, interest payments, debentures or other securities in an Irish incorporated company and payments on a liquidation of an Irish incorporated company would fall within this definition. Currently, orders under this Act prohibit any financial transfer to or by the order of or on behalf of residents of the Federal Republic of Yugoslavia, Federal Republic of Serbia, Angola and Iraq, any financial transfer in respect of funds and financial resources belonging to the Taliban of Afghanistan (or related terrorist organisations), financial transfers to the senior members of the Zimbabwean government and financial transfers to any persons, groups or entities listed in EU Council Decision 2002/400/EC of June 17, 2002 unless permission for the transfer has been given by the Central Bank of Ireland. Trinity Biotech does not anticipate that Irish exchange controls or orders under the Financial Transfers Act, 1992 will have a material effect on its business.

For the purposes of the orders relating to Iraq and the Federal Republic of Yugoslavia, reconstituted in 1991 as Serbia and Montenegro, a resident of those countries is a person living in these countries, a body corporate or entity operating in these countries and any person acting on behalf of any of these persons.

Any transfer of, or payment for, an ordinary share or ADS involving the government of any country which is currently the subject of United Nations sanctions, any person or body controlled by any government or country under United Nations sanctions or any persons or body controlled acting on behalf of these governments of countries, may be subject to restrictions required under these sanctions as implemented into Irish law.

***Taxation***

The following discussion is based on US and Republic of Ireland tax law, statutes, treaties, regulations, rulings and decisions all as of the date of this annual report. Taxation laws are subject to change, from time to time, and no representation is or can be made as to whether such laws will change, or what impact, if any, such changes will have on the statements contained in this summary. No assurance can be given that proposed amendments will be enacted as proposed, or that legislative or judicial changes, or changes in administrative practice, will not modify or change the statements expressed herein.

This summary is of a general nature only. It does not constitute legal or tax advice nor does it discuss all aspects of Irish taxation that may be relevant to any particular Irish Holder or US Holder of ordinary shares or ADSs.

This summary does not discuss all aspects of Irish and US federal income taxation that may be relevant to a particular holder of Trinity Biotech ADSs in light of the holder's own circumstances or to certain types of investors subject to special treatment under applicable tax laws (for example, financial institutions, life insurance companies, tax-exempt organisations, and non-US taxpayers) and it does not discuss any tax consequences arising under the laws of taxing jurisdictions other than the Republic of Ireland and the US federal government. The tax treatment of holders of Trinity Biotech ADSs may vary depending upon each holder's own particular situation.

Prospective purchasers of Trinity Biotech ADSs are advised to consult their own tax advisors as to the US, Irish or other tax consequences of the purchase, ownership and disposition of such ADSs.



**Table of Contents**

***US Federal Income Tax Consequences to US Holders***

The following is a summary of the material US federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADSs, in the case of a purchaser of such ADSs who is a US Holder (as defined below) and who holds the ADSs as capital assets. This summary is based on the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. For the purposes of this summary, a US Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organized in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to US federal income tax regardless of its source; or a trust that (a) is subject to the primary supervision of a court within the United States and the control of one or more US persons or (b) has a valid election in effect under applicable US Treasury regulations to be treated as a US person.

This summary does not address all tax considerations that may be relevant with respect to an investment in ADSs. This summary does not discuss all the tax consequences that may be relevant to a US holder in light of such holder's particular circumstances or to US holders subject to special rules, including persons that are non-US holders, broker dealers, financial institutions, certain insurance companies, investors liable for alternative minimum tax, tax exempt organisations, regulated investment companies, non-resident aliens of the US or taxpayers whose functional currency is not the dollar, persons who hold ADSs through partnerships or other pass-through entities, persons who acquired their ADSs through the exercise or cancellation of employee stock options or otherwise as compensation for services, investors that actually or constructively own 10% or more of Trinity Biotech's voting shares, and investors holding ADSs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction.

If a partnership or an entity treated as a partnership for US federal income tax purposes owns ADSs, the US federal income tax treatment of a partner in such a partnership will generally depend upon the status of the partner and the activities of the partnership. A partnership that owns ADSs, the partners in such partnership should consult their tax advisors about the US federal income tax consequences of holding and disposing of ADSs.

This summary does not address the effect of any US federal taxation other than US federal income taxation. In addition, this summary does not include any discussion of state, local or foreign taxation. You are urged to consult your tax advisors regarding the foreign and US federal, state and local tax considerations of an investment in ADSs.

For US federal income tax purposes, US Holders of Trinity Biotech ADSs will be treated as owning the underlying Class A Ordinary Shares, represented by the ADSs held by them. The gross amount of any distribution made by Trinity Biotech to US Holders with respect to the underlying shares represented by the ADSs held by them, including the amount of any Irish taxes withheld from such distribution, will be treated for US federal income tax purposes as a dividend to the extent of Trinity Biotech's current and accumulated earnings and profits, as determined for US federal income tax purposes. The amount of any such distribution that exceeds Trinity Biotech's current and accumulated earnings and profits will be applied against and reduce a US Holder's tax basis in the holder's ADSs, and any amount of the distribution remaining after the holder's tax basis has been reduced to zero will constitute capital gain. The capital gain will be treated as a long-term, or short-term, capital gain depending on whether or not the holder's ADSs have been held for more than one year as of the date of the distribution.

Dividends paid by Trinity Biotech generally will not qualify for the dividends received deduction otherwise available to US corporate shareholders.

Subject to complex limitations, any Irish withholding tax imposed on such dividends will be a foreign income tax eligible for credit against a US Holder's US federal income tax liability (or, alternatively, for deduction against income in determining such tax liability). The limitations set out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the US federal income taxes otherwise payable with respect to each such class of income. Dividends generally will be treated as foreign-source passive category income or, in the case of certain US Holders, general category income for US foreign tax credit purposes. Further, there are special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to a reduced tax, see discussion below.



**Table of Contents**

A US Holder will be denied a foreign tax credit with respect to Irish income tax withheld from dividends received on the ordinary shares to the extent such US Holder has not held the ordinary shares for at least 16 days of the 31-day period beginning on the date which is 15 days before the ex-dividend date or to the extent such US Holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a US Holder has substantially diminished its risk of loss on the ordinary shares are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex, and you should consult with your personal tax advisors to determine whether and to what extent you would be entitled to this credit.

Subject to certain limitations, qualified dividend income received by a noncorporate US Holder in tax years beginning on or before December 31, 2010 will be subject to tax at a reduced maximum tax rate of 15%. Distributions taxable as dividends paid on the ordinary shares should qualify for the 15% rate provided that either: (i) we are entitled to benefits under the income tax treaty between the United States and Ireland (the Treaty) or (ii) the ADSs are readily tradable on an established securities market in the US and certain other requirements are met. We believe that we are entitled to benefits under the Treaty and that the ADSs currently are readily tradable on an established securities market in the US. However, no assurance can be given that the ordinary shares will remain readily tradable. The rate reduction does not apply unless certain holding period requirements are satisfied. With respect to the ADSs, the US Holder must have held such ADSs for at least 61 days during the 121-day period beginning 60 days before the ex-dividend date. The rate reduction also does not apply to dividends received from passive foreign investment companies, see discussion below, or in respect of certain hedged positions or in certain other situations. The legislation enacting the reduced tax rate contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the reduced tax rate. US Holders of Trinity Biotech ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

Upon a sale or exchange of ADSs, a US Holder will recognise a gain or loss for US federal income tax purposes in an amount equal to the difference between the amount realised on the sale or exchange and the holder's adjusted tax basis in the ADSs sold or exchanged. Such gain or loss generally will be capital gain or loss and will be long-term or short-term capital gain or loss depending on whether the US Holder has held the ADSs sold or exchanged for more than one year at the time of the sale or exchange.

For US federal income tax purposes, a foreign corporation is treated as a passive foreign investment company (or PFIC) in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable look through rules, either (1) at least 75% of the corporation's gross income is passive income or (2) at least 50% of the average value of the corporation's assets is attributable to assets that produce passive income or are held for the production of passive income. Based on the nature of its present business operations, assets and income, Trinity Biotech believes that it is not currently subject to treatment as a PFIC. However, no assurance can be given that changes will not occur in Trinity Biotech's business operations, assets and income that might cause it to be treated as a PFIC at some future time.

If Trinity Biotech were to become a PFIC, a US Holder of Trinity Biotech ADSs would be required to allocate to each day in the holding period for such holder's ADSs a pro rata portion of any distribution received (or deemed to be received) by the holder from Trinity Biotech, to the extent the distribution so received constitutes an excess distribution, as defined under US federal income tax law. Generally, a distribution received during a taxable year by a US Holder with respect to the underlying shares represented by any of the holder's ADSs would be treated as an excess distribution to the extent that the distribution so received, plus all other distributions received (or deemed to be received) by the holder during the taxable year with respect to such underlying shares, is greater than 125% of the average annual distributions received by the holder with respect to such underlying shares during the three preceding years (or during such shorter period as the US Holder may have held the ADSs). Any portion of an excess distribution that is treated as allocable to one or more taxable years prior to the year of distribution during which Trinity Biotech was classified as a PFIC would be subject to US federal income tax in the year in which the excess distribution is made, but it would be subject to tax at the highest tax rate applicable to the holder in the prior tax year or years. The holder also would be subject to an interest charge, in the year in which the excess distribution is made, on the amount of taxes deemed to have been deferred with respect to the excess distribution. In addition, any gain recognised on a

sale or other disposition of a US Holder's ADSs, including any gain recognised on a liquidation of Trinity Biotech, would be treated in the same manner as an excess distribution. Any such gain would be treated as ordinary income rather than as capital gain. Finally, the 15% reduced US federal income tax rate otherwise applicable to dividend income as discussed above, will not apply to any distribution made by Trinity Biotech in any taxable year in which it is a PFIC (or made in the taxable year following any such year), whether or not the distribution is an excess distribution.

**Table of Contents**

If Trinity Biotech became a PFIC, a US Holder may make a qualifying electing fund election in the year Trinity Biotech first becomes a PFIC or in the year the holder acquires the shares, whichever is later. This election provides for a current inclusion of Trinity Biotech's ordinary income and capital gain income in the US Holder's US taxable income. In return, any gain on sale or other disposition of a US Holder's ADSs in Trinity Biotech, if it were classified as a PFIC, will be treated as capital, and the interest penalty will not be imposed. This election is not made by Trinity Biotech, but by each US Holder.

Alternatively, if the ADSs are considered marketable stock a US Holder may elect to mark-to-market its ADSs, and such US Holder would not be subject to the rules described above. Instead, such US Holder would generally include in income any excess of the fair market value of the ADSs at the close of each tax year over its adjusted basis in the ADSs. If the fair market value of the ADSs had depreciated below the US Holders adjusted basis at the close of the tax year, the US Holder may generally deduct the excess of the adjusted basis of the ADSs over its fair market value at that time. However, such deductions generally would be limited to the net mark-to-market gains, if any, that the US Holder included in income with respect to such ADSs in prior years. Income recognized and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of ADSs with respect to which the mark-to-market election is made, is treated as ordinary income or loss (except that loss is treated as capital loss to the extent the loss exceeds the net mark-to-market gains, if any, that a US Holder included in income with respect to such ordinary shares in prior years). However, gain or loss from the disposition of ordinary shares (as to which a mark-to-market election was made) in a year in which Trinity Biotech is no longer a PFIC, will be capital gain or loss. The ADSs should be considered marketable stock if they traded at least 15 days during each calendar quarter of the relevant calendar year in more than de minimis quantities.

If Trinity Biotech were to become a CFC, each US Holder treated as a US Ten-percent Shareholder would be required to include in income each year such US Ten-percent Shareholder's pro rata share of Trinity Biotech's undistributed Subpart F income. For this purpose, Subpart F income generally would include interest, original issue discount, dividends, net gains from the disposition of stocks or securities, net gains on forward and option contracts, receipts with respect to securities loans and net payments received with respect to equity swaps and similar derivatives.

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

Distributions made with respect to underlying shares represented by ADSs may be subject to information reporting to the US Internal Revenue Service and to US backup withholding tax at a rate equal to the fourth lowest income tax rate applicable to individuals (which, under current law, is 28%). Backup withholding will not apply, however, if the holder (i) is a corporation or comes within certain exempt categories, and demonstrates its eligibility for exemption when so required, or (ii) furnishes a correct taxpayer identification number and makes any other required certification. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a US Holder's US tax liability, and a US Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service.

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

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

## **Table of Contents**

### ***Republic of Ireland Taxation***

For the purposes of this summary, an **Irish Holder** means a holder of ordinary shares or ADSs evidenced by ADSs that (i) beneficially owns the ordinary shares or ADSs registered in their name; (ii) in the case of individual holders, are resident, ordinarily resident and domiciled in Ireland under Irish taxation laws; (iii) in the case of holders that are companies, are resident in Ireland under Irish taxation laws; and (iv) are not also resident in any other country under any double taxation agreement entered into by Ireland. For Irish taxation purposes, Irish Holders of ADSs will be treated as the owners of the underlying ordinary shares represented by such ADSs.

Solely for the purposes of this summary of Irish Tax Considerations, a **US Holder** means a holder of ordinary shares or ADSs evidenced by ADSs that (i) beneficially owns the ordinary shares or ADSs registered in their name; (ii) is resident in the United States for the purposes of the Republic of Ireland/United States Double Taxation Convention (the Treaty); (iii) in the case of an individual holder, is not also resident or ordinarily resident in Ireland for Irish tax purposes; (iv) in the case of a corporate holder, is not a resident in Ireland for Irish tax purposes and is not ultimately controlled by persons resident in Ireland; and (v) is not engaged in any trade or business in Ireland and does not perform independent personal services through a permanent establishment or fixed base in Ireland.

The Board of Directors does not expect to pay dividends for the foreseeable future. Should Trinity Biotech begin paying dividends, such dividends will generally be subject to dividend withholding tax (DWT) at the standard rate of income tax in force at the time the dividend is paid, currently 20%. Under current legislation, where DWT applies, Trinity Biotech will be responsible for withholding it at source. DWT will not be withheld where an exemption applies and where Trinity Biotech has received all necessary documentation from the recipient prior to payment of the dividend.

Corporate Irish Holders will generally be entitled to claim an exemption from DWT by delivering a declaration, which confirms that the company is resident in Ireland for tax purposes, to Trinity Biotech in the form prescribed by the Irish Revenue Commissioners. Such corporate Irish Holders will generally not otherwise be subject to Irish tax in respect of dividends received.

Individual Irish Holders will be subject to income tax on the gross amount of any dividend (that is the amount of the dividend received plus any DWT withheld), at their marginal rate of tax (currently either 20% or 41% depending on the individual's circumstances). Individual Irish Holders will be able to claim a credit against their resulting income tax liability in respect of DWT withheld. Individual Irish Holders may, depending on their circumstances, also be subject to the Irish health levy of up to 2.5% and pay related social insurance contribution of up to 3% in respect of their dividend income.

Shareholders who are individuals resident in the US (and certain other countries) and who are not resident or ordinarily resident in Ireland may receive dividends free of DWT where the shareholder has provided Trinity Biotech with the relevant declaration and residency certificate required by legislation.

Corporate shareholders that are not resident in Ireland and who are ultimately controlled by persons resident in the US (or certain other countries) or corporate holders of ordinary shares resident in a relevant territory (being a country with which Ireland has a double tax treaty, which includes the United States) or resident in a member state of the European Union other than Ireland which are not controlled by Irish residents or whose principal class of shares or its 75% parent's principal class of shares are substantially or regularly traded on a recognised stock exchange in a country with which Ireland has a tax treaty, may receive dividends free of DWT where they provide Trinity Biotech with the relevant declaration, auditors' certificate and Irish Revenue Commissioners' certificate or a certificate from the tax authority in the relevant territory as required by Irish law.

US resident holders of ordinary shares (as opposed to ADSs) should note that these documentation requirements may be burdensome. As described below, these documentation requirements do not apply in the case of holders of ADSs. US resident holders who do not comply with the documentation requirements or otherwise do not qualify for an exemption may be able to claim treaty benefits under the treaty. US resident holders who are entitled to benefits under the treaty will be able to claim a partial refund of DWT from the Irish Revenue Commissioners.



## **Table of Contents**

Special DWT arrangements are available in the case of shares held by US resident holders in Irish companies through American depository banks using ADSs who enter into intermediary agreements with the Irish Revenue Commissioners and hence such banks are viewed as qualifying intermediaries under Irish Tax legislation.

Under such agreements, American depository banks who receive dividends from Irish companies and pay the dividends on to the US resident ADS holders are allowed to receive and pass on a dividend from the Irish company on a gross basis (without any withholding) if:

the depository bank's ADS register shows that the direct beneficial owner of the dividends has a US address on the register, or

there is an intermediary between the depository bank and the beneficial shareholder and the depository bank receives confirmation from the intermediary that the beneficial shareholder's address in the intermediary's records is in the US.

Where the above procedures have not been complied with and DWT is withheld from dividend payments to US Holders of ordinary shares or ADSs evidenced by ADSs, such US Holders can apply to the Irish Revenue Commissioners claiming a full refund of DWT paid by filing a declaration, a certificate of residency and, in the case of US Holders that are corporations, an auditor's certificate, each in the form prescribed by the Irish Revenue Commissioners. The DWT rate applicable to US Holders is reduced to 5% under the terms of the Treaty for corporate US Holders holding 10% or more of our voting shares, and to 15% for other US Holders. While this will, subject to the application of Article 23 of the Treaty, generally entitle US Holders to claim a partial refund of DWT from the Irish Revenue Commissioners, US Holders will, in most circumstances, likely prefer to seek a full refund of DWT under Irish domestic legislation.

Under the Irish Taxes Consolidation Act 1997, non-Irish shareholders may, unless exempted, be liable to DWT tax on dividends received from Trinity Biotech. Such a shareholder will not suffer DWT on dividends if the shareholder is:

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

a corporation that is not resident in Ireland and which is ultimately controlled by persons resident in the US (or certain other countries with which Ireland has a double taxation treaty); or

a corporation that is not resident in Ireland and whose principal class of shares (or its 75% parent's principal class of shares) are substantially or regularly traded on a recognised stock exchange; or

is otherwise entitled to an exemption from DWT.

### *Disposals of Ordinary Shares or ADSs*

Irish Holders that acquire ordinary shares or ADSs will generally be considered, for Irish tax purposes, to have acquired their ordinary shares or ADSs at a base cost equal to the amount paid for the ordinary shares or ADSs. On subsequent dispositions, ordinary shares or ADSs acquired at an earlier time will generally be deemed, for Irish tax purposes, to be disposed of on a first in first out basis before ordinary shares or ADSs acquired at a later time. Irish Holders that dispose of their ordinary shares or ADSs will be subject to Irish capital gains tax (CGT) to the extent that the proceeds realised from such disposition exceed the indexed base cost of the ordinary shares or ADSs disposed of and any incidental expenses. The current rate of CGT is 20%. Indexation of the base cost of the ordinary shares or ADSs will only be available up to December 31, 2002, and only in respect of ordinary shares or ADSs held for more than 12 months prior to their disposal.

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

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



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

## **Table of Contents**

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

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

US Holders will not be subject to Irish capital gains tax (CGT) on the disposal of ordinary shares or ADSs provided that such ordinary shares or ADSs are quoted on a stock exchange at the time of disposition. The stock exchange for this purpose is the Nasdaq National Market (NASDAQ). While it is our intention to continue the quotation of ADSs on NASDAQ, no assurances can be given in this regard.

If, for any reason, our ADSs cease to be quoted on NASDAQ, US Holders will not be subject to CGT on the disposal of their ordinary shares or ADSs provided that the ordinary shares or ADSs do not, at the time of the disposal, derive the greater part of their value from land, buildings, minerals, or mineral rights or exploration rights in Ireland.

A gift or inheritance of ordinary shares will be or in the case of ADSs may be within the charge to capital acquisitions tax, regardless of where the disponent or the donee/successor in relation to the gift/inheritance is domiciled, resident or ordinarily resident. The capital acquisitions tax is charged at a rate of 20% on the taxable value of the gift or inheritance above a tax-free threshold. This tax-free threshold is determined by the amount of the current benefit and of previous benefits, received within the group threshold since December 5, 1991, which are within the charge to the capital acquisitions tax and the relationship between the former holder and the successor. Gifts and inheritances between spouses are not subject to the capital acquisitions tax. Gifts of up to 3,000 can be received each year from any given individual without triggering a charge to capital acquisitions tax. Where a charge to Irish CGT and capital acquisitions tax arises on the same event, capital acquisitions tax payable on the event can be reduced by the amount of the CGT payable. There should be no clawback of the same event credit of CGT offset against capital acquisitions tax provided the donee/successor does not dispose of the ordinary shares or ADRs within two years from the date of gift/inheritance.

The Estate Tax Convention between Ireland and the United States generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited, in whole or in part, against tax payable in the United States, in the case where an inheritance of ordinary shares or ADSs is subject to both Irish capital acquisitions tax and US federal estate tax. The Estate Tax Convention does not apply to Irish capital acquisitions tax paid on gifts.

Irish stamp duty, which is a tax imposed on certain documents, is payable on all transfers of ordinary shares of an Irish registered company (other than transfers made between spouses, transfers made between 90% associated companies, or certain other exempt transfers) regardless of where the document of transfer is executed. Irish stamp duty is also payable on electronic transfers of ordinary shares. A transfer of ordinary shares made as part of a sale or gift will generally be stampable at the ad valorem rate of 1% of the value of the consideration received for the transfer, or, if higher, the market value of the shares transferred. A minimum stamp duty of 1.00 will apply to a transfer of ordinary shares. Where the consideration for a sale is expressed in a currency other than euro, the duty will be charged on the euro equivalent calculated at the rate of exchange prevailing at the date of the transfer.

Transfers of ordinary shares where no beneficial interest passes (e.g. a transfer of shares from a beneficial owner to a nominee), will generally be exempt from stamp duty if the transfer form contains an appropriate certification, otherwise a nominal stamp duty rate of 12.50 will apply.

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

Transfers of ordinary shares from the Depositary or the Depositary's custodian upon surrender of ADSs for the purposes of withdrawing the underlying ordinary shares from the ADS system, and transfers of ordinary shares to the Depositary or the Depositary's custodian for the purposes of transferring ordinary shares onto the ADS system, will be stampable at the ad valorem rate of 1% of the value of the shares transferred if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of ordinary shares. Such transfers will be exempt from Irish stamp duty if the transfer does not relate to or involve any change in the beneficial ownership in the underlying ordinary shares and the transfer form contains the appropriate certification. In the absence of an

appropriate certification, stamp duty will be applied at the nominal rate of 12.50.

## **Table of Contents**

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

### **Dividend Policy**

Since its inception Trinity Biotech has not declared or paid dividends on its A Ordinary Shares. Trinity Biotech anticipates, for the foreseeable future, that it will retain any future earnings in order to fund the business operations of the Group. Trinity Biotech does not, therefore, anticipate paying any cash or share dividends on its A Ordinary Shares in the foreseeable future.

Any cash dividends or other distributions, if made, are expected to be made in US Dollars, as provided for by the Articles of Association.

### **Documents on Display**

This annual report and the exhibits thereto and any other document that we have to file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549; and on the Securities and Exchange Commission Internet site (<http://www.sec.gov>). You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the Securities and Exchange Commission at 1-800-SEC-0330 or by visiting the Securities and Exchange Commission's website at <http://www.sec.gov>, and may obtain copies of our filings from the public reference room by calling (202) 551-8090. The Exchange Act file number for our Securities and Exchange Commission filings is 000-22320.

## ***Item 11 Qualitative and Quantitative Disclosures about Market Risk***

### **Qualitative information about Market Risk**

Trinity Biotech's treasury policy is to manage financial risks arising in relation to or as a result of underlying business needs. The activities of the treasury function, which does not operate as a profit centre, are carried out in accordance with board approved policies and are subject to regular internal review. These activities include the Group making use of spot and forward foreign exchange markets.

Trinity Biotech uses a range of financial instruments (including cash, bank borrowings, convertible notes, forward contracts, promissory notes and finance leases) to fund its operations. These instruments are used to manage the liquidity of the Group in a cost effective, low-risk manner. Working capital management is a key additional element in the effective management of overall liquidity. Trinity Biotech does not trade in financial instruments or derivatives.

The main risks arising from the utilisation of these financial instruments are interest rate risk, liquidity risk and foreign exchange risk.

Trinity Biotech's reported net income, net assets and gearing (net debt expressed as a percentage of shareholders equity) are all affected by movements in foreign exchange rates.

The Group borrows in US dollars at floating and fixed rates of interest. At December 31, 2007 borrowings totalled US\$42,133,000 (2006: US\$45,294,000), (net of cash: US\$33,433,000 (2006: net of cash and restricted cash: US\$26,973,000)), at interest rates ranging from 5% to 6.99% (2006: 3.0% to 6.87%).

The total year-end borrowings consists of fixed rate debt of US\$2,325,000 (2006: US\$2,377,000) at interest rates ranging from 5% to 6.32% (2006: 3% to 5%) and floating rate debt of US\$39,808,000 (2006: US\$42,917,000) at interest rates ranging from 6.49% to 6.99% (2006: 6.62% to 6.87%). In broad terms, a one-percentage point increase in interest rates would increase interest income by US\$87,000 (2006: US\$183,000) and increase the interest expense by US\$401,000 (2006: US\$433,000) resulting in an increase in the net interest charge of US\$314,000 (2006: increase by US\$246,000).

Long-term borrowing requirements are met by funding in the US and Ireland. Short-term borrowing requirements are primarily drawn under committed bank facilities. At the year-end, 39% of total long term borrowings fell due for repayment within one year.



**Table of Contents**

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's euro denominated expenses as a result of the movement in the exchange rate between the US Dollar and the euro. Arising from this, where considered necessary, the Group pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered euro expenses at exchange rates lower than budgeted exchange rates. These forward contracts are primarily cashflow hedging instruments whose objective is to cover a portion of these euro forecasted transactions. These forward contracts normally have maturities of less than one year after the balance sheet date. The forward contracts in place at December 31, 2007 have maturity dates of less than one year after the balance sheet date. Where necessary, the forward contracts are rolled over at maturity. There were no forward contracts in place at December 31, 2006.

With an increasing level of euro denominated sales, the Group anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Group had foreign currency denominated cash balances equivalent to US\$1,659,000 at December 31, 2007 (2006: US\$952,000).

**Quantitative information about Market Risk****Interest rate sensitivity**

Trinity Biotech monitors its exposure to changes in interest and exchange rates by estimating the impact of possible changes on reported profit before tax and net worth. The Group accepts interest rate and currency risk as part of the overall risks of operating in different economies and seeks to manage these risks by following the policies set above.

Trinity Biotech estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Group is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be an increase in the loss before tax for 2007 by approximately 1%.

The table below provides information about the Group's long term debt obligations, including variable rate debt obligation which are sensitive to changes in interest rates. The table presents principal cash flows and related weighted average interest rates by expected maturity dates. Weighted average variable rates are based on rates set at the balance sheet date. The information is presented in US Dollars, which is Trinity Biotech's reporting currency.

**Group****Maturity**

<b>Before December 31</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>After 2013</b>	<b>Total</b>	<b>Fair value</b>
<b>Long-term debt</b>								
Variable rate US\$000	15,146	8,183	8,221	8,258			39,808	39,808
Average interest rate	6.74%	6.74%	6.74%	6.74%			6.74%	
Fixed rate US\$000	674	464	438	460	289		2,325	2,318
Average interest rate	5.88%	6.28%	6.14%	6.12%	6.12%		6.09%	

**Exchange rate sensitivity**

At year-end 2007, approximately 6% of the Group's US\$136,845,000 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the euro.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Group operates would not materially reduce the Group's 2007 year-end net worth.

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

Not applicable.

**Table of Contents**

**Part II**

**Item 13 *Defaults, Dividend Arrearages and Delinquencies***

Not applicable.

**Item 14 *Material Modifications to the Rights of Security Holders and Use of Proceeds***

Not applicable.

**Item 15 *Control and Procedures***

***Evaluation of Disclosure Controls and Procedures***

The Group's disclosure and control procedures are designed so that information required to be disclosed in reports filed or submitted under the Securities Exchange Act 1934 is prepared and reported on a timely basis and communicated to management, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(d) of the Securities Exchange Act of 1934 as of the end of the period covered by this Form 20-F. The Chief Executive Officer and Chief Financial Officer have concluded that disclosure controls and procedures were effective as of December 31, 2007.

In designing and evaluating our disclosure controls and procedures, our management, with the participation of the Chief Executive Officer and Chief Financial Officer, recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Group have been detected.

***Management's Annual Report on Internal Control over Financial Reporting***

The management of Trinity Biotech are responsible for establishing and maintaining adequate internal control over financial reporting. Trinity Biotech's internal control over financial reporting is a process designed under the supervision and with the participation of the principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and preparation of Trinity Biotech's financial statements for external reporting purposes in accordance with IFRS both as issued by the IASB and as subsequently adopted by the EU.

Trinity Biotech's internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of the financial statements in accordance with IFRS and that receipts and expenditures are being made only in accordance with the authorization of management and the directors of Trinity Biotech; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Trinity Biotech's assets that could have a material effect on our financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, and that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of internal control over financial reporting based on criteria established in the Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that the Group's internal control over financial reporting was effective as of December 31, 2007.

Our independent auditor, KPMG, a registered public accounting firm, has issued an attestation report on the Group's internal control over financial reporting as of December 31, 2007 (see Item 18).

**Table of Contents*****Changes in Internal Controls over Financial Reporting***

During the 2006 year end financial statement close process, a material weakness was identified in relation to controls concerning revenue recognition from a cut off perspective. As a result of this material weakness the Group reviewed internal controls, particularly over the area of revenue cut off and remediated control weaknesses. Regarding the item specifically mentioned in the Form 20-F for 2006 the Group implemented controls to ensure that instructions provided to third party logistics providers to ensure that all goods had been collected prior to raising an invoice are followed and accordingly comply with Group policy.

Except for the matters referred to above, there were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 16*****16A Audit Committee Financial Expert***

Mr Peter Coyne is an independent director and a member of the Audit Committee.

Our board of directors has determined that Mr Peter Coyne meets the definition of an audit committee financial expert, as defined in Item 401 of Regulation S-K.

This determination is made on the basis that Mr Coyne is a Fellow of the Institute of Chartered Accountants in Ireland and was formerly a senior manager in Arthur Andersen's Corporate Financial Services practice. Mr Coyne is currently a director of AIB Corporate Finance, a subsidiary of AIB Group plc, the Irish banking group and has extensive experience in advising public and private groups on all aspects of corporate strategy.

***16B Code of Ethics***

Trinity Biotech has adopted a code of ethics that applies to the Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and all organisation employees. Written copies of the code of ethics are available free of charge upon request. If we make any substantive amendments to the code of ethics or grant any waivers, including any implicit waiver, from a provision of these codes to our Chief Executive Officer, Chief Financial Officer or Chief Accounting Officer, we will disclose the nature of such amendment or waiver on our website.

***16C Principal Accounting fees and services***

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

	<i>Year ended December 31,</i>		<i>Year ended December 31,</i>	
	<i>2007</i>		<i>2006</i>	
	<i>US\$ '000</i>	<i>%</i>	<i>US\$ '000</i>	<i>%</i>
Audit	997	93%	683	75%
Audit-related			206	23%
Tax	71	7%	20	2%
Total	1,068		909	

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



**Table of Contents**

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

Our Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent public accountants, KPMG. The policy generally pre-approves certain specific services in the categories of audit services, audit-related services, and tax services up to specified amounts, and sets requirements for specific case-by-case pre-approval of discrete projects, those which may have a material effect on our operations or services over certain amounts. Pre-approval may be given as part of the Audit Committee's approval of the scope of the engagement of our independent auditor or on an individual basis. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be presented to the full Audit Committee at its next scheduled meeting. The policy prohibits retention of the independent public accountants to perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the SEC, and also considers whether proposed services are compatible with the independence of the public accountants.

***Exemptions from the Listing Requirements and Standards for Audit Committee***

Not applicable.

***Purchase of equity securities by the issuer and affiliates and purchasers***

The maximum number of shares that may yet be purchased under the Group share option plan by Trinity Biotech or on the Group's behalf at December 31, 2007 was 7,465,330 (2006: 7,168,320). No shares were purchased by Trinity Biotech or on our behalf or by any affiliated purchaser in 2007 and 2006. No shares were purchased as part of a publicly announced repurchase plan or program in 2007 and 2006.

**Part III**

***Item 17 Financial Statements***

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

***Item 18 Financial Statements***

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited Trinity Biotech plc's internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Trinity Biotech's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, appearing under Item 15 in this Annual Report on Form 20-F. Our responsibility is to express an opinion on Trinity Biotech plc's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Trinity Biotech maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control – Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Trinity Biotech plc and subsidiaries, as of December 31, 2007 and 2006, and the related consolidated statements of operations, recognised income and expense and cash flows for each of the years in the three-year period ended December 31, 2007 and our report dated April 2, 2008 expressed an unqualified opinion on those consolidated financial statements.

KPMG

Dublin, Ireland  
April 2, 2008

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Trinity Biotech plc

We have audited the accompanying consolidated balance sheets of Trinity Biotech plc and subsidiaries (the Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, recognised income and expense, and cash flows for each of the years in the three-year period ended December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Trinity Biotech plc and subsidiaries as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and as adopted by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Trinity Biotech plc's internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated April 2, 2008 expressed an unqualified opinion on the effective operation of internal control over financial reporting.

KPMG

Dublin, Ireland

April 2, 2008

Table of Contents**CONSOLIDATED STATEMENTS OF OPERATIONS**

		<i>Year ended December, 31</i>		
		<i>2007</i>	<i>2006</i>	<i>2005</i>
		<i>Total</i>	<i>Total</i>	<i>Total</i>
	<i>Notes</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b>Revenues</b>	<b>2</b>	<b>143,617</b>	<b>118,674</b>	<b>98,560</b>
Cost of sales		(75,643)	(62,090)	(51,378)
Cost of sales restructuring expenses	3	(953)		
Cost of sales inventory write off/ provision	3, 2	(11,772)	(5,800)	
<b>Total cost of sales</b>		<b>(88,368)</b>	<b>(67,890)</b>	<b>(51,378)</b>
<b>Gross profit</b>		<b>55,249</b>	<b>50,784</b>	<b>47,182</b>
Other operating income	5	413	275	161
Research and development expenses		(6,802)	(6,696)	(6,070)
Research and development restructuring expenses	3	(6,907)		
<b>Total research and development expenses</b>		<b>(13,709)</b>	<b>(6,696)</b>	<b>(6,070)</b>
Selling, general and administrative expenses		(51,010)	(42,422)	(34,651)
Selling, general and administrative restructuring expenses (including goodwill impairment of US\$19,156,000)	3	(20,315)		
<b>Total selling, general and administrative expenses</b>		<b>(71,325)</b>	<b>(42,422)</b>	<b>(34,651)</b>
<b>Operating (loss)/ profit</b>		<b>(29,372)</b>	<b>1,941</b>	<b>6,622</b>
Financial income	4	457	1,164	389
Financial expenses	2, 4	(3,148)	(2,653)	(1,058)
<b>Net financing costs</b>		<b>(2,691)</b>	<b>(1,489)</b>	<b>(669)</b>
<b>(Loss)/ profit before tax</b>	<b>6</b>	<b>(32,063)</b>	<b>452</b>	<b>5,953</b>
Total income tax (expense)/ credit	2, 9	(3,309)	2,824	(673)
	<b>2</b>	<b>(35,372)</b>	<b>3,276</b>	<b>5,280</b>

**(Loss)/ profit for the year (all attributable to equity holders)**

Basic (loss)/ earnings per ordinary share (US Dollars)	10	(0.47)	0.05	0.09
Diluted (loss)/ earnings per ordinary share (US Dollars)	10	(0.47)	0.05	0.09
Basic (loss)/ earnings per ADS (US Dollars)	10	(1.86)	0.19	0.36
Diluted (loss)/ earnings per ADS (US Dollars)	10	(1.86)	0.19	0.35

**Table of Contents****CONSOLIDATED STATEMENTS OF RECOGNISED INCOME AND EXPENSE**

		<i>Year ended December, 31</i>		
		<i>2007</i>	<i>2006</i>	<i>2005</i>
	<i>Notes</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Foreign exchange translation differences	19	1,072	1,347	(1,740)
<i>Cash flow hedges:</i>				
Effective portion of changes in fair value		224	226	(295)
Deferred tax on income and expenses recognised directly in equity		(23)	4	41
 <i>Net income/ (expense) recognised directly in equity</i>		 1,273	 1,577	 (1,994)
Cash flow hedge recycled to the statement of operations			(166)	(183)
(Loss)/ profit for the year	2	(35,372)	3,276	5,280
 <i>Total recognised income and expense (all attributable to equity holders)</i>		 (34,099)	 4,687	 3,103

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

		<i>December 31, 2007 US\$ 000</i>	<i>December 31, 2006 US\$ 000</i>
	<i>Notes</i>		
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	11	26,409	22,255
Goodwill and intangible assets	12	104,928	121,768
Deferred tax assets	13	3,937	7,656
Other assets	14	896	515
<b>Total non-current assets</b>		<b>136,170</b>	<b>152,194</b>
<b>Current assets</b>			
Inventories	15	44,420	45,572
Trade and other receivables	16	25,683	32,676
Income tax receivable		782	368
Derivative financial instruments	30	224	
Financial assets – restricted cash	17		15,500
Cash and cash equivalents	18	8,700	2,821
<b>Total current assets</b>		<b>79,809</b>	<b>96,937</b>
<b>TOTAL ASSETS</b>	<b>2</b>	<b>215,979</b>	<b>249,131</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to the equity holders of the parent</b>			
Share capital	19	991	978
Share premium	19	153,961	151,774
(Accumulated deficit)/ retained earnings	19	(22,908)	10,818
Translation reserve	19	797	(275)
Other reserves	19	4,004	3,967
<b>Total equity</b>		<b>136,845</b>	<b>167,262</b>
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	21	15,821	10,382
Convertible notes-interest bearing	22		1,836
Income tax payable		86	44
Trade and other payables	23	24,779	20,459
Other financial liabilities	24	2,725	3,120
Provisions	25	100	100

<b>Total current liabilities</b>		43,511	35,941
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	21	26,312	33,076
Other financial liabilities	24		2,568
Other payables	26	74	838
Deferred tax liabilities	13	9,237	9,446
<b>Total non-current liabilities</b>		35,623	45,928
<b>TOTAL LIABILITIES</b>	2	79,134	81,869
<b>TOTAL EQUITY AND LIABILITIES</b>		215,979	249,131



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

		<i>Year ended December 31,</i>		
		<i>2007</i>	<i>2006</i>	<i>2005</i>
	<i>Notes</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
<b>Cash flows from operating activities</b>				
(Loss)/ profit for the year		(35,372)	3,276	5,280
<i>Adjustments to reconcile net profit to cash provided by operating activities:</i>				
Depreciation		4,341	3,736	2,434
Amortisation		3,418	2,687	1,803
Income tax expense/ (credit)		3,309	(2,824)	673
Financial income		(457)	(1,164)	(389)
Financial expense		3,148	2,653	1,058
Share-based payments		1,403	1,141	1,368
Foreign exchange losses on operating cash flows		(26)	(100)	(292)
Loss/ (profit) on disposal / retirement of property, plant and equipment		17	(2)	469
Goodwill impairment	3	19,156		
Non- cash restructuring expenses	3	18,573		
Inventory write off			5,800	
Other non-cash items		577	469	232
<b>Operating cash flows before changes in working capital</b>		<b>18,087</b>	<b>15,672</b>	<b>12,636</b>
Decrease/ (increase) in trade and other receivables		5,226	(9,962)	(8,034)
(Increase)/ decrease in inventories		(7,101)	(5,434)	1,311
Increase in trade and other payables		1,966	8,041	4,689
<b>Cash generated from operations</b>		<b>18,178</b>	<b>8,317</b>	<b>10,602</b>
Interest paid		(2,802)	(1,642)	(972)
Interest received		429	839	371
Income taxes paid		(456)	(146)	(792)
<b>Net cash provided by operating activities</b>		<b>15,349</b>	<b>7,368</b>	<b>9,209</b>
<b>Cash flows from investing activities</b>				
Payments to acquire subsidiaries and businesses	27	(4,414)	(39,334)	(13,129)
Deferred consideration to acquire subsidiaries and businesses		(3,472)	(6,802)	
Cash received with subsidiary				127
Payments to acquire intangible assets		(7,851)	(6,085)	(5,509)
Disposal/ (acquisition) of financial assets		15,500	(6,500)	(1,852)
Proceeds from disposal of property, plant and equipment		84	205	4
Acquisition of property, plant and equipment		(8,262)	(4,751)	(4,039)

<b>Net cash used in investing activities</b>		<b>(8,415)</b>	<b>(63,267)</b>	<b>(24,398)</b>
<b>Cash flows from financing activities</b>				
Proceeds from issue of ordinary share capital		454	25,265	4,755
Proceeds from borrowings, short-term debt		5,000	6,000	1,800
Proceeds from borrowings, long-term debt			24,000	7,200
Expenses paid in connection with share issue and debt financing		(70)	(1,526)	(195)
Repayment of long-term debt		(8,285)	(1,276)	(1,217)
Proceeds from new finance leases		2,087	78	154
Payment of finance lease liabilities		(294)	(276)	(348)
Repayment of convertible debt			(3,644)	(1,822)
Repayment of other financial liabilities				(648)
<b>Net cash provided by (used in) financing activities</b>		<b>(1,108)</b>	<b>48,621</b>	<b>9,679</b>
Increase/ (decrease) in cash and cash equivalents		5,826	(7,278)	(5,510)
Effects of exchange rate movements on cash held		53	218	252
Cash and cash equivalents at beginning of year		2,821	9,881	15,139
<b>Cash and cash equivalents at end of year</b>	<b>18</b>	<b>8,700</b>	<b>2,821</b>	<b>9,881</b>

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2007**

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

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

*a) Statement of compliance*

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ( IFRS ) both as issued by the International Accounting Standards Board ( IASB ) and as subsequently adopted by the European Union ( EU ) (together IFRS ). The IFRS applied are those effective for accounting periods beginning on or after 1 January 2007. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU.

*b) Basis of preparation*

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

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

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

Judgements made by management that have a significant effect on the financial statements and estimates with a significant risk of material adjustment in the next year are discussed in note 31.

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

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

Certain prior year amounts have been reclassified to conform to current presentation.

c) *Basis of consolidation*

***Subsidiaries***

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

***Transactions eliminated on consolidation***

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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2007***d) Property, plant and equipment****Owned assets***

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

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

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

Land is not depreciated. The residual values, if not insignificant, useful lives and depreciation methods of property, plant and equipment are reviewed and adjusted if appropriate, at each balance sheet date.

***Leased assets as lessee***

Leases under terms of which the Group assumes substantially all the risks and rewards of ownership are classified as finance leases. Property, plant and equipment acquired by way of finance lease is stated at an amount equal to the lower of its fair value and present value of the minimum lease payments at inception of the lease, less accumulated depreciation and any impairment losses.

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

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

***Leased assets as lessor***

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

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

***Subsequent costs***

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

**Table of Contents**