TRINITY BIOTECH PLC
Form 20-F
May 08, 2007

FORM 20-F
(MARK ONE)
o REGISTRATION STATEMENT PURSUANT TO SECTION 12(B) OR (G) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
ýFor the fiscal year ended: December 31, 2006
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIE EXCHANGE ACT OF 1934
For the transition period from _____ to __
OR
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)

Ireland

(Jurisdiction of incorporation or organisation)

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:
None

(Title of Class)

Name of each exchange on which registered:
None

(Title of Class)

Securities registered or to be registered pursuant to Section 12 (g) of the Act:
American Depository Shares
(each representing 4 'A' Ordinary Shares, par value US$0.0109)

(Title of each class)

Securities for which there is a reporting obligation pursuant to Section 15 (d) of the Act:
None

(Title of each class)

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: 73,601,497 Class 'A' Ordinary Shares and 700,000 Class 'B' Ordinary Shares.

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

Yes __ No X

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

Yes __ No X

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

Yes X No __

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

Large accelerated filer o Accelerated filer x Non -accelerated filer o

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

Item 17 __ Item 18 X

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

This Report on Form 20-F is incorporated by reference into our Registration Statement on Form F-3 File No. 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.

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

We have a secondary listing on the Irish Stock Exchange. For this reason, we are not subject to the same ongoing regulatory requirements as those which would apply to an Irish company with a primary listing on the Irish Stock Exchange, including the requirement that certain transactions require the approval of shareholders. For further information, shareholders should consult their own financial advisor.

Our financial statements are presented in US Dollars and are prepared in accordance with International Financial Reporting Standards ("IFRS"), as adopted by the European Union ("EU"), which differ in certain respects from US generally accepted accounting principles (See Item 18, note 33 to the consolidated financial statements). IFRS as adopted by the EU differ in certain respects from IFRS issued by the International Accounting Standards Board ("IASB"). However, as none of these differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented would be no different had IFRS as issued by the IASB been applied. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "euro" or "€" are to European Unio 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.

The provisions of IAS 32 and IAS 39 have been applied from January 1, 2005. An explanation of how the transition to compliance with IAS 32 and IAS 39, as adopted by the EU, from the previous basis of accounting, Irish GAAP ("Previous GAAP'') has affected the reported financial position of the Group as at January 1, 2005 is provided in Item 18, note 31 to the consolidated financial statements.

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, 2006 and 2005, and for each of the years ended December 31, 2006, 2005 and 2004 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, 2004, December 31, 2003 and December 31, 2002 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

Consolidated Statement of Income Data	*Year ended December 31 2006*	*Year ended December 31 2005*	*Year ended December 31 2004*
	(US$'000 except for share and per share data)		
Revenues	118,674	98,560	80,008
Cost of sales - including share based payments of US$89,000 (2005: US$110,000) (2004: US$81,000)	(62,090)	(51,378)	(40,047)
Cost of sales - inventory provision	(5,800)	-	-
Gross profit	50,784	47,182	39,961
Other operating income	275	161	302
Research and development expenses - including share based payments of US$36,000 (2005: US$210,000) (2004: US$96,000)	(6,696)	(6,070)	(4,744)
Selling, general and administrative - including share based payments of US$1,016,000 (2005: US$1,048,000) (2004: US$581,000)	(42,422)	(34,651)	(29,332)
Operating profit	1,941	6,622	6,187
Financial income	1,164	389	302
Financial expenses	(2,653)	(1,058)	(824)
Profit before tax	452	5,953	5,665
Income tax credit / (expense)	2,824	(673)	49
Profit for the year	3,276	5,280	5,714
Basic earnings per 'A' ordinary share (US Dollars)	0.05	0.09	0.10
Basic earnings per 'B' ordinary share (US Dollars)	0.10	0.18	0.20
Diluted earnings per 'A' ordinary share (US Dollars)	0.05	0.09	0.09
Diluted earnings per 'B' ordinary share (US Dollars)	0.10	0.18	0.18
Basic earnings per ADS (US Dollars)	0.19	0.36	0.41

Diluted earnings per ADS (US Dollars)	0.19	0.35	0.37
Weighted average number of shares used in computing basic EPS	70,693,753	58,890,084	55,132,024
Weighted average number of shares used in computing diluted EPS	72,125,740	67,032,382	65,527,802

Consolidated Balance Sheet Data	*December 31, 2006 US$'000*	*December 31, 2005 US$'000*	*December 31, 2004 US$'000*
Net current assets (current assets less current liabilities)	61,435	44,964	53,448
Non current liabilities	(45,928)	(19,083)	(16,636)
Total assets	249,131	184,602	156,040
Capital stock	978	830	776
Shareholders' equity	167,262	133,618	118,894

Amounts Adjusted for US GAAP

	Year ended December 31,				
Consolidated Statement of Income data	*2006 US$'000*	*2005 US$'000*	*2004 US$'000*	*2003 US$'000*	*2002 US$'000*
Revenues	118,674	98,560	80,008	65,531	51,978
Net (loss) / profit	(1,946)	2,582	4,048	5,146	5,043
Basic (loss) / earnings per 'A' ordinary share (US Dollar)	(0.03)	0.04	0.07	0.12	0.12
Basic (loss) / earnings per 'B' ordinary share (US Dollar)	(0.06)	0.08	0.14	0.24	0.24
Diluted (loss) / earnings per 'A' ordinary share	(0.03)	0.04	0.07	0.11	0.12
Diluted (loss) / earnings per 'B' ordinary share	(0.06)	0.08	0.14	0.22	0.24

	As at December 31,				
Consolidated Balance Sheet Data	*2006 US$'000*	*2005 US$'000*	*2004 US$'000*	*2003 US$'000*	*2002 US$'000*
Total assets	239,426	181,699	158,869	128,650	99,067
Shareholders' equity	161,303	132,769	122,033	87,234	70,944

No dividends were declared in any of the periods from December 31, 2002 to December 31, 2006.

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, 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.

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 recent 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 are not sufficient 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's principal business is the supply of medical diagnostic test kits and related diagnostic instrumentation. The diagnostics industry is extremely competitive. Trinity Biotech is competing directly with companies which have greater capital resources and larger marketing and business organisations than Trinity Biotech. Trinity Biotech's ability to grow revenue and earnings may be adversely impacted by competitive product and pricing pressures and by its inability to gain or retain market share as a result of the action of competitors. We have invested in research and development ("R&D") but there can be no guarantees that our R&D programmes will not be rendered technologically obsolete or financially non-viable by the technological advances of our competitors, which would also adversely affect our existing product lines and inventory. The main competitors of Trinity Biotech (and their principal products with which Trinity Biotech competes) include 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.

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 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.

As a foreign private issuer whose shares are listed on the NASDAQ National Market, we are allowed to follow certain home country corporate governance practices instead of certain NASDAQ requirements.

- As a foreign private issuer whose shares are listed on the NASDAQ National Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the NASDAQ Marketplace Rules. We have elected to follow home country corporate legislation with respect to the number of persons on our audit committee, the number of independent directors on our Board of Directors, director nomination procedures, and the composition of our compensation committee, as described in more detail under Item 6 of this annual report.

- In addition, we may follow Irish law instead of the NASDAQ Marketplace Rules that require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of Trinity Biotech, certain transactions other

than a public offering involving issuances of a 20% or more interest in Trinity Biotech and certain acquisitions of the stock or assets of another company.

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 are Ronan O'Caoimh, our CEO and Chairman, Brendan Farrell, our President, Dr Jim Walsh, our COO, and Rory Nealon, our CFO and Secretary, with all of which we have entered into employment contracts. We carry a life assurance policy for Mr O'Caoimh in the amount of €533,000 (US$706,000). 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.

Trinity Biotech may be subject to liability resulting from its products or services.

- Trinity Biotech may be subject to claims for personal injuries or other damages resulting from its products or services. Trinity Biotech has global product liability insurance in place for its manufacturing subsidiaries up to a maximum of €6,500,000 (US$8,609,000) for any one accident, limited to a maximum of €6,500,000 (US$8,609,000) 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 2006 consolidated revenue denominated in US Dollars was approximately 67%. Of the remaining 33% revenue, 26% relates to revenue denominated in Euro and 7% 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 2006, as described in Item 18, note 19 to the consolidated financial statements, are convertible into American Depository Shares (ADSs), 1 ADS representing 4 Class “A” Ordinary Shares. The exercise of the share options exercisable and of the warrants will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders.

For instance, should the options and warrant holders of the 5,605,469 'A' Ordinary shares (1,401,367 ADSs) exercisable at December 31, 2006 be exercised, Trinity Biotech would have to issue 5,605,469 additional 'A' ordinary shares (1,401,367 ADSs). On the basis of 73,601,497 'A' ordinary shares outstanding at December 31, 2006, this would effectively dilute the ownership interest of the existing shareholders by approximately 7%.

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.

Trinity Biotech is exposed to potential risks and increased costs from the requirements of Section 404 of the Sarbanes Oxley Act of 2002 to evaluate internal controls over financial reporting.

- Section 404 of the Sarbanes Oxley Act of 2002 requires that the Group evaluates and reports on the effectiveness of internal controls in providing reasonable assurance regarding the reliability of Financial Reporting. The initial compliance date for management to evaluate and report on internal control over financial reporting under Section 404 of the Sarbanes Oxley Act of 2002 for Foreign Accelerated Filers is for the financial year ending on or after July 15, 2006. The Group has prepared and implemented an internal plan for compliance and has completed the process of documenting and testing the system of internal controls over financial reporting to provide the basis for this report for the year ending December 31, 2006, which is set out in Item 15. The requirement to provide an auditors' report on internal controls over financial reporting of the Group will apply for the financial year ending December 31, 2007.

Due to ongoing evaluation and testing of the Group's internal controls and the uncertainties of the interpretation of these new requirements, the Group cannot assure that there may not be significant deficiencies or material weaknesses that would be required to be reported. In the event that significant deficiencies or material weaknesses are reported, investor perceptions may be adversely affected and may cause a decline in the market price of our stock.

The Group has incurred increased costs and an increased amount of management time and external resources in order to comply with the above legislation by the end of 2006 and may continue to do so in years to come. The process of documenting and testing the Group's internal controls over financial reporting and considering improvements has required the Group to hire additional personnel and outside advisory services, resulting in additional accounting and consultancy expenses.

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 test kits 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 800 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 US.

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

Acquisition of Haemostasis line of bioMerieux Inc
In June 2006, Trinity Biotech acquired the haemostasis product line 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 the year end, Trinity Biotech has accrued US$5,688,000 for the deferred consideration which will be paid in June 2007 and June 2008, (see Item 18, note 23 to the consolidated financial statements). A further US$5.5 million of consideration was contingent on the performance of the product line during 2006. However, the Group has determined that this contingent element is not payable as certain milestones concerning the performance of the business line were not met during 2006. The bioMerieux portfolio comprises a range of haemostasis test kits in addition to a range of automated instruments which are comparable to various test kits and instruments within Trinity Biotech's product range.

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, of which US$239,000 remained payable at December, 31 2006 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.

Acquisition of the assets of Adaltis US, Inc
In April 2004, Trinity acquired the assets of Adaltis US, Inc for US$2,852,000 in cash. Adaltis US, Inc. is the US distribution arm for Adaltis, Inc. As part of the transaction, Trinity Biotech has obtained exclusive distribution rights to Adaltis' open-end microplate analytical instrumentation in the US and non-exclusive distribution rights in the rest of the world, except China.

Acquisition of the assets of Fitzgerald Industries International Inc
In April 2004, Trinity Biotech also completed the acquisition of the assets of Fitzgerald Industries International Inc. for US$16 million. Under the terms of the purchase agreement, contingent consideration would be payable depending on the financial performance of that business during the first two years of operation post acquisition relative to its pre-acquisition performance. At December 31, 2005 it was determined, based on the performance of Fitzgerald in 2005, that an amount of US$1,002,000 would be payable to the shareholders of Fitzgerald. This was paid by the Group in 2006. Fitzgerald provides a comprehensive range of raw materials to pharmaceutical companies, reference

laboratories, diagnostic manufacturers and research facilities worldwide.

Principal Markets
The primary market for Trinity Biotech's tests remains the US. During fiscal 2006, the Group sold 51% (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 49% (US$57.9 million) for fiscal year 2006 (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:

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

Haemostasis
The haemostasis product line comprises of test kits and instrumentation used for the detection of blood disorders. Trinity 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 line in 2006, the haemostasis product line has become the largest 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 has recognised and also demonstrated a flexibility to adapt to these demands.

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.

Point of Care (POC)
Point of Care refers to diagnostic tests which are carried 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.

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.

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.

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.

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 127 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 29 in Germany and 12 in the UK. In October 2006, Trinity Biotech established a direct selling operation in France, Trinity Biotech France SARL, which currently employs 10 sales professionals. 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.

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.

In 2002, Trinity Biotech obtained the Unipath and Carter Wallace lateral flow licences under agreement with Inverness Medical Innovations. 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 51% of Trinity Biotech's 2006 revenues were generated in the US and the US represents approximately 43% of the worldwide diagnostics market, an overview of FDA regulation has been included below.

FDA Regulation
Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. The FDA's regulations govern, among other things, the following activities: product development, testing; 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 know 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 last 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.

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 Boston, 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.

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 manufacturing and research and development facilities consisting of approximately 45,000 square feet are located at IDA Business Park, Bray, Co. Wicklow, Ireland. 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 proceed 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$634,000).

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, 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$364,000). 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$504,000), payable from 2004. In December 2006, Trinity Biotech has agreed to enter into a further 25 year lease for an additional 43,000 square foot manufacturing facility adjacent to the existing facilities at an annual rent of €484,000 (US$641,000). (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$115,000.

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$244,000. 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$160,000.

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.

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$178,000). In 2006, Trinity Biotech entered into a lease for a 5,750 square foot premises in France, at an annual rent of €46,000 (US$61,000).

Additional office space is leased by the Group in Ireland, Kansas City, Missouri, Concord, Massachusetts and New Jersey at an annual cost of US$121,000, US$100,000, US$109,000 and US$154,000, respectively.

Capital expenditures and divestitures

Following the acquisition of the haemostasis product line of bioMerieux, the Group is currently expanding its operations in Ireland. Significant capital expenditure will be undertaken as part of the integration of the manufacture of this product line with the existing manufacturing operations being carried out in Ireland. Most of the expenditure on this integration will be carried out during 2007.

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

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, 2006, December 31, 2005 and December 31, 2004, 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 as adopted by the EU which differs from US GAAP as indicated in Note 33 to the consolidated financial statements.

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. 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 International Financial Reporting Standards (IFRS), as adopted by the EU. The preparation of these financial statements requires us to make estimates and judgements that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities.

On an on-going basis, we evaluate our estimates, including those related to intangible assets, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the critical accounting policies described below reflect our more significant judgements and estimates used in the preparation of our consolidated financial statements.

Research and development expenditure

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

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. During 2006 and 2005 there were no changes in the assumptions regarding the degree of regulatory approval for any of the projects being undertaken. The Group did make changes to the estimates used to determine the future commercial success of the projects in the normal course of business by including updated revenue estimates. However, these changes in revenue estimates did not result in changes in the carrying value of any of the development costs capitalised during or prior to 2006. At December 31,

2006 the carrying value of capitalised development costs was US$17,290,000 (2005: US$11,853,000) (note 11). The increase in 2006 was attributable to development costs of US$5,862,000 being capitalised during 2006, foreign exchange movements of US$43,000 and partially offset by amortisation of US$468,000. Given the 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 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$3,304,000.

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

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

When we determine that the carrying value of intangibles, non-current assets and related goodwill may not be recoverable based upon the existence of one or more of the above indicators of impairment, any impairment is measured based on our estimates of projected net discounted cash flows expected to result from that asset, including eventual disposition. Our estimated impairment could prove insufficient if our analysis overestimated the cash flows or conditions change in the future. As part of the impairment review for 2006 and 2005, updated estimates of cash flows from sales were employed based on the latest sales and forecast information available. These revised estimates did not result in any impairment of intangible assets, non-current assets or related goodwill. In the event that there was a 10% variation in the assumed level of future growth in cashflows from sales, which would represent a reasonably likely range of outcomes, no impairment of assets would occur in any of the Group's cash generating units at December 31, 2006 and December 31, 2005. Similarly if there was a 10% variation in the discount rate used to calculate the potential impairment of the carrying values, which would represent a reasonably likely range of outcomes, no impairment of assets would occur at December 31, 2006 and December 31, 2005. See Item 18, note 11 to the consolidated financial statements.

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 or 2006 which would have an impact on the carrying values of inventory during those periods.

At December 31, 2006 our allowance for slow moving and obsolete inventory was US$7,284,000 which represents approximately 13.8% of gross inventory value. This compares with US$3,654,000, or approximately 9.1% of gross inventory value, at December 31, 2005 (see Item 18, note 14 to the consolidated financial statements). The change in the estimated allowance for slow moving and obsolete inventory as a percentage of gross inventory 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 product line 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$1,057,000 at December 31, 2006 (2005: US$802,000) would result.

Allowance for impairment of receivables
We make judgements as to our ability to collect outstanding receivables and where necessary make allowances for impairment. Such impairments are made based upon a specific review of all significant outstanding receivables. In determining the allowance, we analyse our historical collection experience and current economic trends. If the

historical data we use to calculate the allowance for impairment of receivables does not reflect the future ability to collect outstanding receivables, additional allowances for impairment of receivables may be needed and the future results of operations could be materially affected. Given the specific manner in which the allowance is calculated, there were no material changes in estimates made during 2006 or 2005 which would have an impact on the carrying values of receivables in these periods. At December 31, 2006, the allowance was US$1,074,000 which represents approximately 0.9% of Group revenues. This compares with US$587,000 at December 31, 2005 which represents approximately 0.6% of Group revenues (see Item 18, note 15 to the consolidated financial statements). 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$475,000 at December 31, 2006 (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. 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 which are recognised 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 12 to the consolidated financial statements outlines the basis for the deferred tax assets and liabilities and Schedule II includes a movement on the valuation allowances for income taxes during the period. There was no material changes in estimates used to calculate the income tax expense provision during 2006 or 2005.

Impact of Recently Issued Accounting Pronouncements
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRS”) as adopted by the EU. IFRS as adopted by the EU differ in certain respects from IFRS as issued by the International Accounting Standards Board (“IASB”). However, the consolidated financial statements for the periods presented would be no different had we applied IFRS as issued by the IASB as all standards issued by the IASB with effective dates up to December 31, 2006 have been adopted by the EU. During 2006, 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 and which have not yet been adopted by the EU. 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 *Financial Statements,* note 1(z).

Recently Issued US GAAP Accounting Pronouncements
The Group has considered the impact of recently issued accounting pronouncements under US GAAP. The Group’s consideration is outlined in Item 18 *Financial Statements*, note 33.

Results of Operations
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 as adopted by the EU. 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 product line of bioMerieux, 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.

Revenues by Product Line

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

	Year ended December 31,		
	2006	2005	
	US$'000	US$'000	% Change
Revenues			
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%
Total	**118,674**	**98,560**	**20%**

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. For further information relating to this matter please refer to Item 8 "Legal Proceedings". 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 net increase in haemostasis revenues of US$16,710,000 is principally attributable to the impact of the acquisition of the haemostasis product line 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:

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

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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 as discussed above.

The US$9,151,000 increase in Europe is primarily due to the impact of the acquisition of the haemostasis product line 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 product line 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.

	Year ended December 31,		
	2006	**2005**	
	US$'000	**US$'000**	**% Change**
Revenues	118,674	98,560	20%
Cost of sales (including share-based payments)	(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	**1,941**	**6,622**	**(71%)**

Cost of sales
Cost of sales (excluding the impact of the once-off 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 product line 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 product line 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.

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.

	Year ended December 31,			
	2006 US$'000	**2005 US$'000**	**Increase/ (decrease) US$'000**	**% Change**
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%
Total	**42,422**	**34,651**	**7,771**	**23%**

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 product line 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 product line of bioMerieux.

Share-based payments
The Group recorded a total charge to the income statement 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 income statement 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. For further details refer to Item 18, note 19 to the consolidated financial statements.

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 product line 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.

4. Profit for the year

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

	Year ended December 31,		
	2006	**2005**	
	US$'000	**US$'000**	**% Change**
Operating Profit	1,941	6,622	(71%)
Net financing costs	**(1,489)**	**(669)**	**123%**
Profit before tax	452	5,953	(92%)
Income tax credit/(expense)	**2,824**	**(673)**	**(520%)**
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 line 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 income statement. For further details on the Group's tax charge please refer to Item 18, note 8, Income Tax Expense/ (Credit), and note 12, Deferred Tax Assets and Liabilities, to the consolidated financial statements.

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 once-off 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.

Results of Operations
Year ended December 31, 2005 compared to year ended December 31, 2004
The following compares our results in the year ended December 31, 2005 to those of the year ended December 31, 2004 under IFRS as adopted by the EU.
Our analysis is divided as follows:

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

1. Overview

In US Dollars, consolidated revenues increased by 23% through a combination of increased sales of existing products (11%) and sales from acquisitions (12%). Geographically, 51% of sales were generated in the USA, 26% in Europe and 23% in the rest of the world.

The gross margin for the year ended December 31, 2005 was 48% compared to 50% for the year ended December 31, 2004. The decrease in gross margin is primarily explained by a high level of sales of infectious diseases and haemostasis instrumentation. Sales of instrumentation traditionally have lower margins than the accompanying reagents and consumables.

Operating profit increased by 7%, primarily due to the impact of increased sales. However, the impact of sales, which grew by 23%, was partially offset by lower gross margins, increased selling, general & administrative (SG&A) costs, the impact of share based payments and increased amortisation charges. The combination of the above factors caused the operating margin to fall from 8% in 2004 to 7% in 2005.

Following the introduction of IFRS as adopted by the EU, the Group recorded a charge to the income statement of US$1,368,000 in 2005 for share-based payments. This compared to US$758,000 in 2004.

Retained profit for the period decreased by 8% (compared to an increase of 7% for operating profit). The decrease in retained profit compared to the increase in operating profit is due to the impact of increased financing costs primarily attributable to a higher effective rate of interest being applied to convertible debt and a higher effective rate of taxation compared to 2004.

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. Very occasionally, sales transactions are made on extended credit terms. In these instances, in accordance with IFRS as adopted by the EU and US GAAP, this revenue is recognised when the amounts fall due rather than at the date of shipment.

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.

Revenues by Product Line

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

	Year ended December 31,		
	2005	**2004**	
	US$'000	**US$'000**	**% Change**
Revenues			
Infectious diseases	44,078	36,402	21
Haemostasis	29,766	26,836	11
Clinical Chemistry	11,880	6,963	71
Point of Care	12,836	9,807	31
Total	**98,560**	**80,008**	**23**

Trinity Biotech's consolidated revenues for the year ended December 31, 2005 were US$98,560,000 compared to consolidated revenues of US$80,008,000 for the year ended December 31, 2004.

Infectious Diseases
Sales of infectious diseases products have increased by US$7,676,000. Of this US$8,983,000 is due to increased sales arising from the full year impact of the acquisition of Fitzgerald made in April 2004 together with the acquisition of RDI during 2005. This increase was partially offset by a reduction in sales of US$1,559,000 to Wampole. For further information relating to this matter please refer to Item 8 “Legal Proceedings”. The remaining increase of US$252,000 is attributable to the net increase in non-Wampole sales over a wide range of products.

Haemostasis Revenues
The increase in haemostasis revenues of US$2,930,000 is attributable to increased sales of the Company’s Biopool/Amax range of products. In particular the increase was attributable to an increase in the sales of the Company’s Amax range of haemostasis instruments (US$2,017,000). The remaining increase of US$913,000 is due to an increase in non-instrumentation products, namely reagents, consumables and service revenues.

Clinical Chemistry Revenues
The increase in clinical chemistry revenues of US$4,917,000 is primarily attributable to the acquisition of Primus in July 2005. Primus specialises in the field of in vitro diagnostic testing for haemoglobin A1c and haemoglobin variants.

Point of Care
Sales of Point of Care have increased by US$3,029,000 which is primarily attributable to increased sales of rapid HIV products to Africa and sales of Trinity’s Unigold rapid HIV test in the USA.

Revenues by Geographical Region

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

	Year ended December 31,		
	2005	**2004**	
	US$’000	**US$’000**	**% Change**
Revenues			
USA	50,627	41,380	22
Europe	25,301	22,718	11
Asia/Africa	22,632	15,910	42
Total	**98,560**	**80,008**	**23**

The US$9,247,000 increase in the US is primarily attributable to the following factors:
- The full year impact of Fitzgerald which was acquired in 2004, plus a further increase due to the acquisition of RDI (now part of Fitzgerald) in 2005 resulting in an overall increase in Fitzgerald sales in the USA of US$4,664,000;
- The inclusion of sales of US$2,900,000 of Primus products in the US from the date of acquisition on July 19, 2005;
- An increase of US$1,080,000 in sales of Adaltis products partially attributable to 2005 being the first full year since its acquisition in April 2004 ;
- Sales of existing product ranges in the USA (excluding sales to Wampole) have increased by US$2,162,000. This is partially offset by the US$1,559,000 reduction in sales to Wampole as discussed above.

The US$2,583,000 increase in Europe is due the full year impact of the acquisition of Fitzgerald and the impact of the RDI acquisition in 2005 (US$824,000), sales of Primus products of US$1,386,000 with the remaining increase of US$373,000 arising principally in relation to direct sales in the United Kingdom.

The US$6,722,000 increase in Asia/Africa is primarily due to increased revenues in Fitzgerald of US$3,495,000 due to the full year impact of the business acquired during 2004, the impact of RDI and particularly strong sales of flu product in the Japanese market, sales of Primus products of US$1,594,000 with the remaining increase of

US$1,633,000 being primarily attributable to increased sales of HIV products to 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.

	Year ended December 31,		
	2005	**2004**	
	US$'000	**US$'000**	**% Change**
Revenues	98,560	80,008	23
Cost of sales (including share-based payments)	(51,378)	(40,047)	28
Other operating income	161	302	(47)
Research & development	(6,070)	(4,744)	28
SG&A expenses	(34,651)	(29,332)	18
Operating profit	**6,622**	**6,187**	**7**

Cost of sales
Trinity Biotech's consolidated cost of sales increased 28% or by US$11,331,000 from US$40,047,000 for the year ended December 31, 2004 to US$51,378,000 for the year ended December 31, 2005. The increase in cost of sales is attributable to the incremental cost of sales associated with the 2005 acquisitions of RDI and Primus US$4,873,000 with the balance of US$6,458,000 attributable to the increased cost of sales associated with higher sales levels of the Group's existing product ranges. See Revenues section above for details on movements in revenues during 2005.

Research and development
Research and development ("R&D") expenditure increased to US$6,070,000 in 2005. This represents 6.2% of consolidated revenues compared to expenditure of US$4,744,000 or 5.9% of consolidated revenues in 2004. For a consideration of the Group's various R&D projects see "Research and Products under Development" in Item 5.

Selling, General & Administrative expenses
The following table outlines the breakdown of SG&A expenses in 2005 compared to a similar breakdown for 2004.

	Year ended December 31,			
	2005	**2004**	**Increase**	**% Change**
	US$'000	**US$'000**	**US$'000**	
SG&A (excl. share-based payments and amortisation)	31,800	27,640	4,160	15
Share-based payments	1,048	581	467	80
Amortisation	1,803	1,111	692	62
Total	**34,651**	**29,332**	**5,319**	**18**

Selling General & Administrative Expenditure (SG&A) (excluding share-based payments and amortisation)
SG&A (excluding share-based payments and amortisation) increased 15% or by US$4,160,000 from US$27,640,000 to US$31,800,000, which compares to revenue growth of 23% during the same period. The lower growth in SG&A expenditure compared with revenue growth is attributable to economies of scale, particularly in relation to the Group's selling activities and central administration costs. The increase in SG&A costs in 2005 are primarily due to the impact of the acquisitions of Primus and RDI in 2005 and the full year impact of Fitzgerald and Adaltis both of which were acquired in 2004.

A detailed analysis of this increase in SG&A expenses of US$4,160,000 in 2005 is as follows:

- Increased SG&A expenditure in relation to Fitzgerald (US$1,391,000). 2005 represented the first full year for Fitzgerald compared to 2004 when the results were included from April 2004 (the date of acquisition). The increase in costs was also attributable to the acquisition of RDI, whose activities were absorbed into the Fitzgerald organisation from March 2005.
- Increased SG&A costs of US$1,164,000 in the USA. This was mainly attributable to costs in relation to Primus whose results have been incorporated from the date of acquisition on July 19, 2005. The impact of Primus has partially been offset by cost savings in the existing US distribution and manufacturing entities.

- Increased SG&A costs in the Head Office/European operations (excluding Fitzgerald and the UK) of US$896,000. This is mainly due to a combination of

(i) increased marketing costs in conjunction with the growth in the business;
(ii) increased costs associated with the first time implementation of International Financial Reporting Standards, as adopted by the EU;
(iii) increased stock exchange costs associated with Trinity Biotech's listing on the Nasdaq National Market;
(iv) increased costs associated with the Group's preparation for compliance with Section 404 of the Sarbanes-Oxley Act 2002; as partially offset by
(v) lower costs associated with implementing the CE marking process as required under the In Vitro Diagnostic Directive when compared with 2004.

- An increase of US$263,000 in the UK. The UK direct sales operation, which was established in 2002, was expanded during 2004. 2005 represents the first full year impact of increasing the sales force in late 2004.
- A reduction in foreign exchange gains in 2005 compared to 2004 (US$446,000).

Amortisation
The increase in amortisation of US$692,000 from US$1,111,000 to US$1,803,000 is largely attributable to the amortisation of intangible assets acquired as part of the Group's acquisitions in 2004 and 2005. The impact of the full year of the acquisition of Fitzgerald and Adaltis, both of whom were acquired in 2004 was US$154,000 whilst a further US$255,000 was amortised in relation to intangibles assets valued on the acquisition of Primus and RDI in 2005.

The remaining increase of US$283,000 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.

Share-based payments
Following the introduction of IFRS as adopted by the EU, the Group recorded a total charge to the income statement in 2005 of US$1,368,000 (2004: US$758,000) for share-based payments. Of the 2005 charge US$110,000 (2004: US$81,000) was charged against cost of sales. Of the remaining US$1,258,000, US$210,000 (2004: US$96,000) was charged against research and development expenses and US$1,048,000 (2004: US$581,000) 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 income statement 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 increase in the expense for 2005 compared to 2004 is due to the full year impact of the 3,162,824 options issued during 2004 plus the impact of a further 1,670,000 options issued during the course of 2005. For further details refer to Item 18, note 19 to the Consolidated Financial Statements.

4. Retained Profit

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

	Year ended December 31,		
	2005	**2004**	
	US$'000	**US$'000**	**% Change**
Operating Profit	6,622	6,187	7
Net financing costs	**(669)**	**(522)**	**28**
Profit before tax	5,953	5,665	
	(673)	**49**	

Income tax (expense)/credit		
Retained profit	5,280	5,714

Net Financing Costs
Net financing costs increased to US$669,000 compared to US$522,000 in 2004. This increase is primarily due to the impact of IAS 32 *Financial Instruments: Disclosure and Presentation* on the interest charge attributable to convertible debentures, which was implemented for the first time in 2005. Under IAS 32, interest on convertible debentures is charged based on an effective interest rate. This effective interest rate includes the nominal interest rate of 3%, a cost ascribed to the equity element of the instrument and the transaction costs incurred at the time the debt was raised. This compares to the charge for 2004 which was based entirely on the nominal interest rate of 3%, as the provisions of IAS 32 did not apply in 2004. The impact of the above increase was partially offset by the lower average level of convertible debt outstanding during 2005 compared with 2004 due to scheduled repayments of the debt. Please refer to "Liquidity and Capital Resources" later in this section for information on Trinity Biotech's use of debt.

Taxation
A tax charge of US$673,000 was incurred in the year ended December 31, 2005. This compares to a tax credit of US$49,000 for 2004. This represented a decrease in current tax in absolute terms of US$439,000 which is more than offset by an increase in deferred tax of US$1,161,000. The decrease in current tax is 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 income statement, and to current year losses in the US, Germany and Sweden. The upfront deductions had the impact of decreasing the current tax charge, primarily in Ireland, and of increasing the Group's deferred tax liability. This increase in the net deferred tax position was partially offset by the increase in the deferred tax asset caused by the current year losses in the US and Germany. The Group was able to offset the current year loss in Sweden against its deferred corporation tax liabilities from previous years. For further details on the Group's tax charge please refer to Note 8 "Income Tax Expense/(Credit)" and Note 12 "Deferred Tax Assets and Liabilities" of the Notes to the Consolidated Financial Statements contained in Item 18 "Financial Statements".

Profit for the year
Profit for the period decreased by US$434,000, from US$5,714,000 to US$5,280,000. As a percentage of consolidated revenues this represents a decrease to 5.3% from 7.1%. This decrease is principally due to the combination of higher SG&A costs (including the impact of share-based payments under IFRS as adopted by the EU), financing costs (mainly due to a change in the basis in calculating interest on convertible debt under IFRS as adopted by the EU) and an increased tax charge more than offsetting the increased gross margins earned from higher sales levels.

Liquidity and Capital Resources

Financing
Trinity Biotech has a US$43,340,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Limited. The facility consists of a five year term loan of US$41,340,000 and a one year revolver of US$2,000,000. The 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 term loan is repayable in ten equal biannual instalments commencing in January 2007. This facility is secured by the assets of the Group (see Item 18, note 27 (c) to the consolidated financial statements).Various covenants apply to the Group's bank borrowings. As at December 31, 2006, the Group was in breach of a number of these covenants which had been waived by the banks. The bank also agreed to amend those covenants for subsequent periods. At December 31, 2006, the total amount outstanding under the facility amounted to US$42,917,000. The debt is stated net of unamortised funding costs of US$423,000.

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.

The additional US$30 million loan facility and the proceeds of the US$24 million private placement were principally used to fund the Group's acquisitions during 2006. In June 2006 the Group acquired the haemostasis product line of 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$755,000. The cash consideration of US$38.2 million and the acquisition expenses of US$755,000 were paid in 2006. Of the deferred consideration of US$5.5 million (US$6.0 million before the impact of discounting), US$3.0 million is payable is June 2007 and US$2.5 million in June 2008. In October 2006 the Group acquired the French distribution business of Laboratoires Nephrotek SARL for US$1,204,000, consisting of cash consideration of US$1,089,000 and acquisition expenses of US$115,000, of which US$239,000 remained payable at December 31, 2006. The remaining proceeds from the abovementioned funding will be used to fund the future growth of the Group.

At December 31, 2006, 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$1,836,000 (2005: US$9,039,000), including accrued interest at year end of US$14,000 (2005: US$70,000). The Group made four principal repayments of US$1,822,000 each during 2006. Two repayments were made by way of cash and two repayments were made by the issue of shares. The final principal repayment was made on January 2, 2007 by way of shares.

Working capital

In the Group's opinion the Group's existing cash position and cash generated from operations will be sufficient to support its existing operations for at least the next 12 months. The amount of cash generated from operations will depend on a number of factors which include the following:

- The ability of the Group to continue to generate revenue growth from its existing product lines;
- The ability of the Group to generate revenues from new products following the successful completion of its development projects;
- The extent to which capital expenditure is incurred on additional property plant and equipment;
- The level of investment required to undertake both new and existing development projects;
- Successful working capital management in the context of a growing Group.

The Group expects that the cashflows that the business will generate will be sufficient to repay the debt obligations which were outstanding at December 31, 2006. These obligations include the repayment of the remaining convertible notes, 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. However, if the assumptions underlying such expectations change, the Group may be required to raise additional capital to meet its cash requirements.

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. It is anticipated that some or all of the costs of such acquisitions may be met from debt funding. The cost of such funding will depend on prevailing interest rates at the time and the size and nature of the funding being provided. The extent of future equity requirements will depend on the size of any acquisitions and the availability and/or the cost of debt funding.

Cash management

As at December 31, 2006, Trinity Biotech's consolidated cash and cash equivalents, excluding restricted cash, were US$2,821,000. This compares to cash and cash equivalents, excluding restricted cash of US$9,881,000 at December 31, 2005.

Cash generated from operations for the year ended December 31, 2006 amounted to US$8,317,000 (2005: US$10,602,000). These cash flows were generated by profit before interest and taxation of US$1,941,000 (2005: US$6,622,000), as adjusted for non cash items of US$13,731,000 (2005: US$6,014,000) less cash outflows due to changes in working capital of US$7,355,000 (2005: US$2,034,000).

The increase in other non cash charges from US$6,014,000 for the year ended December 31, 2005 to US$13,731,000 for the year ended December 31, 2006 is mainly attributable to an inventory provision of US$5.8 million during 2006. Following the acquisition of the haemostasis product line of bioMerieux, 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 inventory. The remaining increase in non cash charges is attributable to increased depreciation and amortisation expenses of US$1,302,000 and US$884,000 respectively in 2006, marginally offset by a decrease in share based expenses of US$227,000.

The net cash outflows in 2006 due to changes in working capital of US$7,355,000 are due to the following:

- An increase in accounts receivable by US$9,962,000 due to increased Group revenues arising from both continuing activities and acquisitions in 2006;
- An increase in trade and other payables by US$8,041,000 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$5,434,000 due to a combination of inventory purchased as part of the acquisition of the haemostasis product line of bioMerieux during 2006 (see Item 18, note 26 of the consolidated financial statements) and the building up safety stock levels on key finished products.

Net interest paid amounted to US$803,000 (2005: US$601,000). This consisted of interest paid of US$1,642,000 (2005: US$972,000) on the Group's interest bearing debt including bank loans, convertible notes and finance leases and was partially offset by interest received of US$839,000 (2005: US$371,000) on the Group's cash deposits.

Net cash outflows from investing activities for the year ended December 31, 2006 amounted to US$63,267,000 (2005: US$24,398,000) which were principally made up as follows:

- Payments for acquisitions in 2006 (US$46,136,000) principally consisting of payments for the acquisition of the haemostasis product line of bioMerieux of US$38,397,000 (including acquisition expenses) and payments for the acquisition of the assets of Nephrotek of US$936,000 (including acquisition expenses). In addition, payments were made during 2006 relating to acquisitions in 2005 and 2004 totalling US$6,803,000. A one year promissory note of US$3,000,000, issued as part of the acquisition of Primus in 2005, was paid to the shareholders of Primus on the first anniversary of the acquisition in 2006. As part of the acquisition of Primus in 2005 and Fitzgerald in 2004, additional consideration was due to the shareholders depending on the growth of the respective businesses during 2005. As a result, US$2,705,000 was paid to the shareholders of Primus and US$1,098,000 was paid to the shareholders of Fitzgerald in 2006;
- Payments to acquire intangible assets of US$6,085,000 (2005: US$5,509,000), 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$4,751,000 (2005: US$4,039,000) 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 outflow of US$6,500,000 in 2006 (2005: US$1,852,000), was due to an increase in the level of cash deposits (restricted cash) which the Group agreed to keep with its lending banks in accordance with the terms of its bank facility. At December 31, 2005 the Group was required to keep US$9,000,000 on deposit as restricted cash with its lending banks. This restriction was increased to US$15,500,000 at December 31, 2006, resulting in a cash outflow from investing activities of US$6,500,000 in 2006.

Net cash provided by financing activities for the year ended December 31, 2006 amounted to US$48,621,000 (2005: US$9,679,000). The Group received US$30,000,000 as part of an amendment to it current loan facilities to fund the acquisition of the haemostasis product line of bioMerieux and raised US$25,265,000 (2005: US$4,755,000) from issuing share capital. These inflows were offset by the repayment of convertible notes by cash in 2006 of US$3,644,000 (2005: US$1,822,000), repayments of debt and other liabilities of US$1,276,000 (2005: US$1,865,000), expenses paid in connection with share issues and debt financing of US$1,526,000 (2005: US$195,000) and net repayments on finance lease obligations of US$198,000 (2005: US$194,000).

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

As at December 31, 2006, year end borrowings were US$45,294,000 (2005: US$27,128,000) and cash and cash equivalents were US$2,821,000 (US$18,321,000 inclusive of restricted cash) (2005: US$9,881,000 (US$18,881,000 inclusive of restricted cash)). For a more comprehensive discussion of the Group's level of borrowings at the end of 2006, 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".