TRINITY BIOTECH PLC
Form 20-F
April 01, 2005

FORM 20-F

(MARK ONE)

[ ] 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

[X] FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2004

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
(REPRESENTING '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: 54,904,318 CLASS 'A' ORDINARY SHARES AND 700,000 CLASS 'B' ORDINARY SHARES.

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 REQUIED 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 WHICH FINANCIAL STATEMENT ITEM THE REGISTRANT HAS ELECTED TO FOLLOW:

ITEM 17 [ ] ITEM 18 [X]

This annual report on Form 20-F was not prepared for filing in Ireland in compliance with Irish law or the listing rules of the Irish Stock Exchange. Unless otherwise provided herein or required by the context, references to "we", "us", "Trinity Biotech" or the "Company" in this annual report shall mean Trinity Biotech plc and its world-wide subsidiaries, collectively.

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 accounting principles generally accepted in the Republic of Ireland which differ in certain respects from US generally accepted accounting principles (see note 25) to the consolidated financial statements. All references in this annual report to "Dollars" and "$" are to US Dollars, and all references to "Euro" or "(euro)" are to European Union Euro. Except as otherwise stated herein, all monetary amounts in this annual report have BEEN presented in US Dollars. For presentation purposes all financial information including comparative figures from prior periods have been stated in round thousands.

ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable

ITEM 2 OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable

ITEM 3 SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data of Trinity Biotech as at December 31, 2004 and 2003, and for each of the years ended December 31, 2004, December 31, 2003 and December 31, 2002, 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, 2002, December 31, 2001 and December 31, 2000, and for each of the years ended December 31, 2001 and 2000 are derived from the audited consolidated financial statements not appearing in this annual report. The 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 Dec 31, 2004	Year Ended Dec 31, 2003	Year Ended Dec 31, 2002	Year En Dec 31,

	US$'000	US$'000	US$'000	US$
Revenues	79,944	65,675	51,978	37
Cost of sales	(39,688)	(32,877)	(25,689)	(18
Administrative expenses	(27,304)	(17,063)	(12,849)	(11
Research & development expenses	(4,641)	(5,210)	(4,471)	(2
Amortisation	(2,570)	(856)	(2,386)	(2
Operating profit				
- Continuing operations	4,632	9,669	6,524	5
- Acquisitions	1,109	-	59	(2
- Disposals	-	-	-	
	5,741	9,669	6,583	3
Interest income	302	173	103	
Interest expense	(824)	(792)	(704)	
Net profit before tax and share of operating loss in associate & impairment	5,219	9,050	5,982	2
Share of operating loss in associate & impairment	-	(1,067)	(317)	
Net profit before tax	5,219	7,983	5,665	2
Tax on profit on ordinary activities	(53)	(2,186)	(768)	
Net profit after tax	5,166	5,797	4,897	2
Profit from operations per ordinary share (US Dollars)	0.10	0.22	0.16	
Profit from continuing operations per ordinary share (US Dollars)	0.08	0.22	0.16	
Basic earnings per ordinary share (US Dollars)	0.09	0.13	0.12	
Diluted earnings per ordinary share (US Dollars)	0.09	0.12	0.12	
Weighted average number of shares used in computing basic EPS	55,132,024	43,093,146	40,550,367	40,408
Weighted average number of shares used in computing diluted EPS	63,935,138	50,583,247	42,486,227	41,120

Consolidated Balance Sheet Data

	As at Dec 31, 2004	As at Dec 31, 2003	As at Dec 31, 2002	As a Dec 31,
	US$'000	US$'000	US$'000	US$
Working capital	55,426	45,630	20,424	17
Long-term liabilities	13,119	17,517	7,745	7
Total assets	150,828	118,091	89,798	77
Capital stock	776	670	610	
Shareholders' equity	116,138	80,262	62,537	56

Amounts Adjusted for US GAAP

Consolidated Statement of Income Data

	Year Ended Dec 31, 2004	Year Ended Dec 31, 2003	Year Ended Dec 31, 2002	Year En Dec 31,
	US$'000	US$'000	US$'000	US$
Net profit	4,048	5,146	5,043	
Basic earnings per ordinary share (US Dollars)	0.07	0.12	0.12	
Diluted earnings per ordinary share (US Dollars)	0.07	0.11	0.12	

Consolidated Balance Sheet Data

	As at Dec 31, 2004	As at Dec 31, 2003	As at Dec 31, 2002	As a Dec 31,
	US$'000	US$'000	US$'000	US$
Total assets	158,869	128,650	99,067	83
Shareholders' equity	122,033	87,234	70,944	63

No dividends were declared in any of the periods from December 31, 2000 to December 31, 2004.

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 our 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 size and timing of orders and general economic conditions.

TRINITY BIOTECH'S REVENUES DEPEND TO A HIGH DEGREE ON ITS RELATIONSHIP WITH WAMPOLE LABORATORIES, A FORMER AFFILIATE OF CARTER WALLACE, INC.

- During the financial years ended December 31, 2004, December 31, 2003 and December 31, 2002, approximately 7%, 12% and 20% respectively of Trinity Biotech's revenues were derived from a distribution agreement by and among our subsidiary, Trinity Biotech (USA) Corp. (trading name of Clark

Laboratories, Inc) and Carter-Wallace, Inc ("Carter-Wallace") and its affiliate Wampole Laboratories ("Wampole"). In 2001, Wampole was acquired by Medpointe, Inc and was subsequently acquired by Inverness Medical Innovations, Inc ("Inverness Medical") in 2002. In 2002, the Company negotiated an amendment to the distribution agreement whereby the exclusivity of Inverness Medical's right to sell our products in the US would be removed in stages throughout 2004. During 2003, the Company experienced declining sales revenues under the distribution agreement which it believes is due to Inverness Medical attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, the Company filed legal action against Inverness Medical and Wampole for declaratory judgment and breach of contract. In January 2004, Inverness Medical and Wampole countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. In April of 2004, Trinity amended its complaint to add additional claims alleging breaches of the distribution agreement by the Defendants. In May of 2004, the Defendants amended their counterclaims to add claims alleging, among other things, that Trinity was selling certain products without a licence. Following the expiration of the Defendants' exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity moved to amend its complaint to eliminate the declaratory judgement claims and add additional claims for breach of the distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. The Defendants filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. The case is currently in the discovery phase. For further information relating to this matter please refer to Item 8 "Legal Proceedings". The Company has decided to sell its products directly in the US and has increased its direct sales force. Any inability to recapture lost sales from Inverness Medical may have a material adverse effect on the Company.

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, revenues from operations and bank borrowings. Trinity Biotech expects that the proceeds of recent equity financings, bank borrowings, current working capital and sales revenues will fund its existing operations and payment obligations for the future. 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.

THE DIAGNOSTICS INDUSTRY IS HIGHLY COMPETITIVE, AND TRINITY BIOTECH'S RESEARCH AND DEVELOPMENT COULD BE RENDERED OBSOLETE BY TECHNOLOGICAL ADVANCES OF COMPETITORS.

- 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 significantly 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) are Dade-Behring (Sysmex(R) CA, D-Dimer plus, Enzygnost(R)), bioMerieux (MDA(R), VIDAS(TM)), Zeus Scientific Inc. (Zeus EIA, IFA), Diasorin Inc. (ETI(TM)), Abbott Diagnostics (AxSYM(TM), IMx(TM)), Diagnostic Products Corp. - DPC (Immulite(TM)), Bio-Rad (ELISA & WB), Roche Diagnostics (COBAS AMPLICOR(TM), Ampliscreen(TM), Accutrend(TM)) and OraSure Technologies, Inc (OraQuick(R)).

TRINITY BIOTECH IS HIGHLY DEPENDENT ON SUITABLE DISTRIBUTORS WORLDWIDE.

- Revenue and earnings stability and growth are directly dependent on the effectiveness of advertising, marketing and promotional programmes. Trinity Biotech currently distributes its product portfolio through distributors in over 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 healthcare 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 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.

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 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. 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 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.

- The following table sets forth the US patents Trinity Biotech currently owns. The table provides the relevant patent number, a brief description and the remaining life time for each patent:

PATENT NUMBER	DESCRIPTION	PATENT LIFE REMAINING FROM FEBRUARY 28, 2005
5,006,474	Bi-Directional Lateral Chromatography Test Device	3 years 2 months
5,114,845	Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin	2 years 5 months
5,175,087	Method of Performing Tissue Plasminogen Activator Assay	2 years 5 months
5,985,582	Thrombin-Based Assay for Antithrombin - III	12 years 10 months
6,194,394	Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays	13 years 5 months
6,528,273	Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls	13 years 9 months
6,391,609	Thromboplastin Reagents and Methods for Preparing and Using Such Reagents	14 years 8 months

6,653,066	Device and method for detecting polyvalent substances	18 years and 9 months

In addition to these US patents, Trinity Biotech owns a total of 24 non-US patents.

- 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.

- 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 diagnostic test kits are subject to government regulation in the United States of America by the Food and Drug Administration ("FDA"), and by comparable regulatory authorities in other jurisdictions. The approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive. Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting approval from these regulatory authorities. There is no

certainty that such approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process.

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

TRINITY BIOTECH'S SUCCESS IS DEPENDENT ON CERTAIN KEY MANAGEMENT PERSONNEL.

- Trinity Biotech's success is dependent on certain key management personnel. Our key employees 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 (euro)533,000. 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 US, Germany and Sweden we were able to attract and retain qualified staff. 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 specificity and sensitivity 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 product liability insurance in place for its US manufacturing subsidiaries up to a maximum of US$4,000,000 for any one accident, limited to a maximum of US$4,000,000 in any one year period of insurance. A separate policy is in place for non-US subsidiaries, which are also covered up to a maximum of (euro)4,000,000 (US$5,456,000) for any one accident, limited to a maximum of (euro)4,000,000 (US$5,456,000) in any one year period of insurance. A deductible of US$25,000 is applicable to each insurance event. 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 Euro, US Dollars 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, we are affected by fluctuations in currency exchange rates, especially the exchange rate between the US dollar and the Euro. Fluctuations between these and other exchange rates may adversely affect our earnings and assets. The percentage of 2004 consolidated revenue denominated in US Dollars was approximately 67%. Of the remaining 33% revenue, the breakdown was as follows: Euro (27%), Sterling (5%) and Yen and Swedish Kroner (1%). Thus, a 10% decrease in the value of each of the Euro, Yen, Sterling and Swedish Kroner 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 was 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. As part of a managed hedging policy, Trinity Biotech has identified the extent of this Euro mismatch and implemented a forward currency hedging policy which aims to cover a portion of this mismatch through the use of forward contracts. Trinity Biotech entered into a series of forward contracts to sell US Dollars forward for Euro. These contracts remain in place until late 2005. Trinity Biotech continues to monitor its exposure

to foreign currency movements. 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.

PENNY STOCK REGULATIONS IMPOSE SALES PRACTICE LIMITATIONS ON BROKER-DEALERS WHO SELL OUR SHARES.

- SEC regulations concerning "penny stock" apply to Trinity Biotech's shares. These regulations impose sales practice requirements on broker-dealers who sell our shares to persons other than established customers and "accredited investors" as defined in SEC regulations. For transactions covered by the regulations, broker-dealers must make a suitability determination and receive a written agreement from the purchaser prior to the sale. These regulations may affect the ability of broker-dealers to sell our shares in the secondary market and thus adversely affect our share price.

THE CONVERSION OF OUR OUTSTANDING CONVERTIBLE NOTES AND WARRANTS WOULD DILUTE THE OWNERSHIP INTEREST OF EXISTING SHAREHOLDERS.

- The convertible notes described in Item 18, Note 9 (e), and the warrants described in Item 18, Note 10, issued in 2004, are convertible into ADRs representing our Class "A" Ordinary Shares. Conversion of the remainder of the notes and exercise of the warrants will likely occur only when the conversion price is below the trading price of our ADRs and will dilute the ownership interests of existing shareholders. For instance, should the holders of the Series A Convertible Notes decide to convert the balance of the US$20,000,000 total principal amount of US$11,896,000 and the holders of the Series B Convertible Notes decide to convert the balance of the US$5,000,000 total principal amount of US$4,500,000 into ADRs at conversion prices of US$3.55 and US$4 respectively, and should the 1,317,324 warrants be exercised, Trinity Biotech would have to issue 5,793,239 additional ADRs. On the basis of 55,588,050 outstanding shares at February 28, 2005, this would effectively dilute the ownership interest of the existing shareholders by approximately 9.4%. Management also has the option of repaying these debentures in ordinary shares. Any such repayment would effectively dilute the ownership interest of the existing shareholders. In addition, any sales in the public market of the ADRs issuable upon conversion of the notes could adversely affect prevailing market prices of our ADRs.

IT COULD BE DIFFICULT FOR US HOLDERS OF ADRS 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 Court 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 Company evaluates and reports on the internal controls over financial reporting and have an auditor attest to such evaluation. The Company has prepared an internal plan for compliance and is in the process of documenting and testing the system of internal controls to provide the basis for this report for the year ended December 31, 2006. Due to ongoing evaluation and testing of the Company's internal controls and the uncertainties of the interpretation of these new requirements, the Company 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 could cause a decline in the market price of our stock.

  The Company is spending 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. The process of documenting and testing the internal control systems and procedures and considering improvements has required the Company 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 plc ("Trinity Biotech" or "the Company") 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 coagulation disorders and autoimmune disorders. The Company is also a significant provider of raw materials to the life sciences industry. The Company markets over 500 different diagnostic products in approximately 80 countries.

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 Company has expanded its product base through internal development and acquisitions into product categories that primarily test for infectious, sexually transmitted and autoimmune diseases. In addition, arising from the acquisition of the Biopool haemostasis business in December 2001 and the haemostasis division of Sigma Diagnostics, part of Sigma Aldrich, in August 2002, Trinity Biotech has expanded its product range to include test kits that diagnose blood coagulation and related disorders, and a haemostasis instrumentation portfolio. The acquisition of the speciality clinical chemistry business of Sigma Diagnostics in November 2002 means that Trinity Biotech now participates in this important market segment. In 2004, Trinity Biotech further expanded its product range through the acquisition of the assets of Fitzgerald Industries International Inc (Fitzgerald) a distributor of immunodiagnostic products and the acquisition of the assets of Adaltis US, Inc through which Trinity has obtained distribution rights to Adaltis's open-ended mircoplate analytical instrumentation. Trinity Biotech markets its products in the US and in approximately 80 countries worldwide through a combination of direct selling and a network of national and international distributors. Trinity Biotech has manufacturing facilities in Bray, Ireland, Umea, Sweden and Lemgo, Germany, in Europe, and in Jamestown, New York, and Carlsbad, California in the US.

In the period 2000 to 2003, Trinity Biotech made six acquisitions of diagnostic

businesses. Three of these acquisitions were of Enzyme Immunoassay ("EIA") businesses, two were haemostasis businesses, and the sixth was a speciality clinical chemistry business. Two further acquisitions, a distributor of immunodiagnostic products and a distributor of infectious diseases instrumentation and reagents, were undertaken in 2004. A further acquisition, a provider of immunodiagnostic products, was completed in March 2005. Details of all of these acquisitions are set out below. In July 2001, Trinity Biotech established a direct sales operation in Germany which commenced trading in October 2001, and in 2002 the Company established a small direct sales operation in the United Kingdom. Through these acquisitions and new products added through in-house research and development, Trinity Biotech now has a comprehensive portfolio of over 500 products, including 5 rapid tests.

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 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 also completed the acquisition of the assets of Fitzgerald Industries International Inc for US$16 million. Fitzgerald provides a comprehensive range of immunodiagnostic products to pharmaceutical companies, reference laboratories, diagnostic manufacturers and research facilities worldwide.

ACQUISITION OF THE SPECIALITY CLINICAL CHEMISTRY PRODUCT LINE OF SIGMA DIAGNOSTICS
In November 2002, Trinity Biotech acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4.4 million satisfied in cash and deferred consideration. The deferred consideration of US$1.8 million was paid in 2003. The speciality clinical chemistry business consists of several specialised products that are clearly differentiated in the marketplace, including ACE, Bile Acids, Lactate, Oxalate and G6PDH.

ACQUISITION OF THE HAEMOSTASIS DIVISION OF SIGMA DIAGNOSTICS
In August 2002, Trinity Biotech purchased the haemostasis division of Sigma Diagnostics for a total consideration of US$1.4 million. The consideration was satisfied in cash. The Sigma diagnostics business comprises a comprehensive portfolio of reagents manufactured in St. Louis, Missouri and the Amelung range of automated and semi-automated instruments manufactured in Lemgo, Germany. The Sigma Diagnostics haemostasis reagents comprise more than 50 tests covering both routine and speciality assays. The Amelung range of instruments comprises the smaller KC1 and KC4

products, the mid-size AMAX 200 and the large throughput AMAX 400. Since acquisition Trinity Biotech also received FDA clearance for a new haemostasis analyser the AMAX Destiny(TM).

ACQUISITION OF THE ASSETS OF THE BIOPOOL HAEMOSTASIS BUSINESS
In December 2001, Trinity Biotech acquired the assets of the Biopool haemostasis business for a consideration of US$6.4 million before costs comprising US$3.8

million in cash and US$2.6 million in deferred consideration. The deferred consideration was payable in three instalments of US$0.9 million, US$1.2 million and US$0.5 million on December 21, 2002, 2003 and 2004 respectively. The outstanding deferred consideration has been fully settled as part of a settlement agreement with Xtrana Inc. Biopool develops, manufactures and markets a comprehensive range of test kits which assess and diagnose disorders of blood coagulation, thrombotic risk factors, fibrinolysis, platelet function and the vascular system. These products are sold to hospitals, clinical laboratories, commercial reference laboratories and research institutions on a worldwide basis. Sales in the US are made through a direct sales force and OEM partners, while international sales are handled through a direct sales force in Germany and a network of national distributors elsewhere.

ACQUISITION OF THE AMERLEX HORMONE BUSINESS OF ORTHO CLINICAL DIAGNOSTICS
On October 19, 2001 Trinity Biotech acquired the assets of the Amerlex hormone business of Ortho Clinical Diagnostics for a consideration of US$0.9 million. The consideration was satisfied in cash. The Amerlex hormone business manufactures and sells a range of tests which diagnose hormone disorders. This business has been fully integrated into the Bray manufacturing facility.

ACQUISITION OF BARTELS INC
In December 2000, Trinity Biotech acquired the assets of Bartels Inc ("Bartels"), for a consideration of US$9.5 million comprising US$3.2 million in stock, US$0.4 million in the form of a promissory note and the balance of US$5.9 million in cash. Bartels is a leading manufacturer of cell dependent organism diagnostics and its product range includes antigen detection kits for Herpes Simplex Virus, and respiratory viruses such as Influenza A and B, Parainfluenza Viruses 1, 2 and 3 and Respiratory Syncital Virus.

ACQUISITION OF MARDX DIAGNOSTICS INC
In March 2000, Trinity Biotech acquired all the outstanding share capital of MarDx Diagnostics Inc (MarDx) of Carlsbad, California for a consideration of US$4.2 million. MarDx is a world leader in the development and manufacture of diagnostic products, known as Western Blots, which confirm the primary diagnosis of certain infectious diseases. Their principal product is a Western Blot test for Lyme disease, which is an infection carried by deer ticks. The disease manifests itself as a multi-system inflammatory disease that affects the skin, joints and nervous system. If diagnosed and treated early with antibiotics, Lyme disease is readily cured.

The MarDx test was the first Lyme Western Blot assay to receive FDA clearance and remains the leading selling test for Lyme disease in the US. The acquisition of MarDx gave Trinity Biotech a strong position in the Western Blot segment of the infectious disease market. Western Blot confirmatory testing is a natural extension to Trinity Biotech's EIA products and the Company intends to extend the MarDx Western Blot technology and manufacturing capability to other confirmatory tests.

INVESTMENT IN HIBERGEN LIMITED
On October 2, 2000, the Company acquired 33% of the ordinary share capital of HiberGen for a total consideration of US$1.4 million. On July 2, 2001 the Company increased its shareholding in HiberGen to 40% at a cost of US$0.3 million. On April 3, 2002 the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. In November 2003, the Company announced that a fundraising process undertaken by HiberGen had not been successful and that HiberGen had ceased trading. The Company wrote-off its remaining investment in quarter four of the 2003 financial year.

ESTABLISHMENT OF UK SUBSIDIARY, TRINITY BIOTECH (UK SALES) LTD
In 2002 Trinity Biotech opened a sales and marketing office in Oxfordshire, UK

employing five sales professionals who market the haemostasis and clinical chemistry products from Trinity Biotech.

ESTABLISHMENT OF GERMAN SUBSIDIARY, TRINITY BIOTECH GMBH
In October 2001, Trinity Biotech established a direct sales operation in Germany. After the US and Japan, Germany, with a population of 83 million, is the third largest market in the world for in-vitro diagnostics, accounting for 7% ((euro)1.6 billion) of the total world market of (euro)22.5 billion. In the past Trinity Biotech had serviced the market through five independent distributors who handled a small proportion of the Company's product portfolio whereas the new German

direct sales force markets all of Trinity Biotech's current products. In 2002 Trinity Biotech purchased the haemostasis business of Sigma Diagnostics. The German part of this business was taken over by Trinity Biotech GmbH.

PRE MARKET APPLICATION ("PMA") AND CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS OF 1988 "CLIA" WAIVER APPROVALS FOR UNIGOLD HIV TEST
In March 2001, the US Food and Drug Administration's Centre for Biologics Evaluation and Research (CBER) approved an Investigational Device Exemption (IDE) for treatment use for Trinity Biotech's UniGold HIV test. This IDE allows Trinity Biotech's UniGold HIV test to be used in a limited number of hospitals throughout the US, to provide patients with the results of tests, conducted during ongoing clinical trials.

The product is used to provide diagnostic test results in ten minutes, in situations involving needle stick injuries and pregnant women at high risk of HIV presenting themselves for delivery. In these circumstances, the ability to diagnose HIV status rapidly provides the opportunity to make potentially crucial medical decisions and to administer appropriate medication.

The granting of the IDE application acknowledged that the clinical protocol for the IDE was appropriate and that Trinity Biotech's proposed clinical trials under the treatment IDE met FDA standards for human safety and confidentiality.

During 2001, representatives from Trinity Biotech were informed by the FDA that the FDA required that additional clinical trials be conducted to ensure that the results which have been obtained to date are statistically significant. This means that the results which have been presented to the FDA in the PMA filing must be reproduced on a larger population of samples. The resulting product clinical trials have now been conducted at sites in Houston, Texas and Baltimore, Maryland. Approximately 9,000 samples were collected and tested on Trinity Biotech's UniGold HIV test. This data along with extensive information on the manufacturing process for Trinity Biotech's UniGold HIV test were presented to the FDA. The FDA completed a plant inspection of the Irish manufacturing facility in mid September 2003. On December 23, 2003, the FDA issued approval for the sale of the UniGold HIV test for use with venipuncture blood (whole blood, serum and plasma). In early 2004, an IDE submission was made to the FDA to define data requirements to expand the use of the product to test fingerstick (blood taken directly from finger) samples. Clinical trials were completed by the end of May 2004 and the application in the form of a PMA supplement made to the FDA on June 10, 2004. Three months later on September 21, 2004, the FDA issued approval for the sale of the Unigold HIV test for use with fingerstick samples. This allows for the use of the Unigold HIV test in further settings where venipuncture samples may not be taken.

In the US, laboratories are classed under The Clinical Laboratory Improvements Amendments of 1988 ("CLIA") regulations in to one of three categories: Waived, Moderate and High. Accreditation by CLIA is required by laboratories to use

moderate and high complexity classified tests. No laboratory accreditation is required for use of CLIA waived tests (see 'other FDA regulations' below). Throughout 2004, trials were completed to support a CLIA waiver for the UniGold HIV test. The application for CLIA waiver for use in venipuncture whole blood was made in April 2004. A CLIA waiver approval was granted for venipuncture whole blood in June 2004 and approval for finger stick whole blood was granted in November 2004. This allows for the sale of the Unigold HIV test into clinical laboratories throughout the United States testing the following blood samples; serum, plasma, fingerstick and venipuncture whole blood.

PRINCIPAL MARKETS

The primary market for Trinity Biotech's tests remains the US. During fiscal 2004, the Company sold 52% (US$41.4 million) (2003: 55% or US$36.3 million; 2002: 64% or US$33.5 million) of product in the US. Sales to non-US (principally European and Asian) countries represented 48% (US$38.6 million) during fiscal 2004 (2003: 45% or US$29.4 million; 2002: 36% or US$18.5 million).

For a more comprehensive segmental analysis please refer to Item 5, "Results of Operations" and Note 12 "Analysis of Revenue, Operating Income, Major Customers and Assets" of the Notes to the Consolidated Financial Statements contained in Item 18 "Financial Statements".

PRINCIPAL PRODUCTS

The Company develops, acquires, manufactures and markets a wide range of diagnostic products based on the technology of immunoassay. Immunoassays harness the body's own natural defence mechanisms. Faced with invasion by a foreign agent, known as an antigen, the body defends itself by producing antibodies. Each type of antibody produced is a highly specific response to the invading antigen. The antibodies bind and neutralise the antigen. It is this highly specific binding of antigen to antibody, which forms the basis for all immunoassay tests.

Trinity Biotech's products can test for foreign agents such as viruses, bacteria and parasites, and for naturally occurring conditions such as cancer cells and hormones. The Company's manufacturing processes utilise biotechnology techniques involving the in-house production of recombinant proteins, synthetic peptides and monoclonal antibodies.

Trinity Biotech's product areas can be broken down under the headings of the six key technologies which are sold under the following brand names:

Enzyme Immunoassays (EIA)
- Bartels(R)
- CAPTIA(TM)
- MarDx(R)
- MicroTrak(TM)
- Recombigen(R)

Fluorescence Assays (IFA/DFA)
- Bartels(R)
- MarDx(R)
- MicroTrak(TM)

Western Blot (WB)
- MarDx(R)

Rapid Assays
- Capillus(TM)
- SeroCard(TM)

UniGold(TM)

Haemostasis
Biopool(R)
Amax

Clinical Chemistry
EZ HDL
EZ LDL

ENZYME IMMUNOASSAYS
The Company's wide range of Enzyme Immunoassay (EIA) products includes over 90 assays utilising different formats to accommodate the most demanding of laboratories to the most basic. This type of test is the mainstay of standard clinical laboratories around the world and forms the backbone of the Trinity Biotech product list of over 500 products. Trinity Biotech currently sells over 100 EIA tests of various configurations in many countries around the world. Of these, over 70 are cleared by the FDA for distribution within the US.

These tests are performed on plates that allow for up to 96 simultaneous samples and can be performed manually or more typically on automated equipment. Trinity Biotech also offers a range of equipment for these types of assays as well as validating the Trinity Biotech range for use on the most popular types of analysers, used by most medical laboratories.

In essence, each well is coated with antigen or antibody depending upon the analyte being tested for. When the test is run, the first step would be to add the sample and a reaction will bind any antibodies or antigens (if present) to the well wall. After removal of interfering substances through washing steps, a colour-forming reagent is added and the intensity of colour is read on an instrument indicating the result. EIA's can aid in providing the clinician with accurate information to assist in the diagnosis of a variety of disorders such as autoimmune diseases, hormonal imbalances, sexually transmitted diseases, enteric infections, respiratory infections, cardiovascular diseases, and a wide range of other diseases.

HAEMOSTASIS
The second largest range of assays in Trinity Biotech's portfolio is the haemostasis assays. Arising from the acquisition of the Biopool and Sigma haemostasis businesses, Trinity Biotech now has an extensive range of haemostasis diagnostic kits, offering laboratories the ability to maximise testing. Biopool is a well-known leader and innovator in the worldwide market for haemostasis and fibrinolysis reagents. Strengthening the Biopool reagent portfolio is the addition of the former Sigma Amelung instrumentation and reagents. This strategic combination enables Trinity Biotech to provide the market

with a complete line of haemostasis products that permit customised testing. With the increasing demand to elucidate a wide range of coagulapathies in the aging population, haemostasis testing is quickly advancing to the requirements of today's complexities.

Trinity Biotech's full range of test kits assess and diagnose disorders of blood coagulation, thrombotic risk factors, fibrinolysis, platelet function and the vascular system. Included in the product range is the range of D-dimer assays. Employing latex technology, Trinity Biotech can offer superior sensitivity and NPV (Negative Predictive Value) for D-dimer testing. Alongside D-dimer are Trinity Biotech's comprehensive routine and speciality assays.

This extensive haemostasis product line is sold to hospitals, clinical laboratories, commercial reference laboratories and research institutions on a worldwide basis.

FLUORESCENCE ASSAYS

Another large range of diagnostic assays in Trinity Biotech's portfolio are the fluorescence assays that are also typically performed in medium to large sized hospital laboratories around the world. Trinity Biotech offers 33 fluorescence assays, of which 25 are cleared by the FDA for distribution within the US, with many variations in kit presentation to suit the customer's needs.

There are two distinct technologies employed, namely Direct Fluorescence Assays (DFA) and Immunofluorescence Assays (IFA). Trinity Biotech offers 24 IFA's with the vast majority forming the comprehensive range of tests to diagnose autoimmune disorders. The remainder of the assays are used to assist in the diagnosis of infectious diseases such as Legionnaires disease, Lyme disease and many others. Of the nine DFA's Trinity Biotech offers, the largest range are FDA cleared for detecting causative agents of sexually transmitted diseases (STD's), principally Chlamydia and Herpes, and forms one of Trinity Biotech's most popular selling product groups.

The principle of the IFA test can be summarised as the introduction of patient's serum to a specially prepared slide containing the specific antigen to which the antibody is directed. The antibody, if present, binds to the antigen and after a series of washing steps and addition of a conjugate, will emit fluorescence when viewed through a microscope equipped with an ultra-violet light source.

The principle of DFA, however, can best be described as the fixation of a patient sample to a microscope slide, which is then introduced to an antibody conjugated to a fluorescent dye, to stain and thereby identify the antigen to which the antibody is directed.

RAPID ASSAYS

Trinity Biotech has developed a range of membrane and latex based rapid assays to cater for point of care ('POC') and over-the-counter ('OTC') markets. This range of five tests facilitates fast and often very important treatment for the patient and can avoid further costly testing. The UniGold(TM) range of tests does not require refrigeration which is very important for the OTC and POC markets, and in less developed countries.

Tests for HIV are available in the UniGold(TM), SeroCard(TM) and Capillus(TM) formats. SeroCard(TM) is a self-encased, flow-through rapid EIA device where results are obtained by visual interpretation of a colour change, whereas Capillus(TM) utilises latex agglutination enhanced by capillary slide technology.

These types of rapid tests give a definitive qualitative answer, indicating the presence or absence of antigens or antibodies (test dependent) as an aid in the diagnosis of infection or other clinical conditions. Rapid diagnostic tests provide information that is essential in allowing key decisions to be made regarding cost effective treatment options.

WESTERN BLOT ASSAYS

Trinity Biotech's extensive range of 18 Western Blot test systems includes the first Lyme Western Blot assay to receive FDA clearance for distribution within the US. Other Western Blot kits in the range include assays to aid in the diagnosis of autoimmune disorders and more typically infectious diseases such as Syphilis, Epstein Barr Virus (EBV), H. pylori and others.

Western Blot assays are typically used in reference or speciality laboratories for confirming the presence, or absence, of antibodies. This can be an essential

part of routine practice for some laboratory investigations for conditions such as Lyme disease, whereby the confirmation of antibody status is the only means to obtain an accurate diagnosis. The principle of these types of tests is that a membrane containing electrophoretically separated proteins of a particular organism are incubated with a patient's serum sample. If specific antibodies to individual proteins are present, they will bind to the corresponding antigen bands. After various washing steps and conjugation, the strip is finally reacted with a precipitating

colour developing solution which deposits a visible precipitate on antibody reacted antigen bands. Bands can then be visualised, scored for intensity, relative to a band of a weakly reactive control, and recorded.

CLINICAL CHEMISTRY
Trinity Biotech acquired the Speciality Clinical Chemistry business of Sigma Diagnostics. This business consists of several specialised products that are clearly differentiated in the marketplace, including ACE, Bile Acids, Lactate, Oxalate and G6PDH.

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. EZ HDL and EZ LDL cholesterol assays broke new ground when they were introduced by Sigma as the first homogenous, non-precipitating liquid reagents for determining HDL and LDL.

DISTRIBUTION AGREEMENT BETWEEN TRINITY BIOTECH USA AND CARTER WALLACE Clark Laboratories, Inc ("Clark") entered into a distribution agreement with Carter-Wallace Inc ("Carter-Wallace") on December 18, 1995 for an initial period of five years and, thereafter, for an indefinite period subject to termination provisions outlined in the distribution agreement. Under the original terms of the agreement, Carter-Wallace had the exclusive right to sell and distribute Clark's ELISA products in the US and Puerto Rico (the "Territory") through its affiliate Wampole Laboratories ("Wampole"). As part of the agreement, Clark obtained from Carter-Wallace the exclusive right to manufacture for Carter-Wallace certain products that Carter-Wallace was obtaining from Bio-Whittaker (the "BW Products"). In 1997, Trinity Biotech, plc ("Trinity" or the "Company") acquired Clark, and succeeded to Clark's rights and obligations under the distribution agreement. In 2002, the Company negotiated an amendment to the distribution agreement with Inverness Medical Innovations, Inc ("Inverness Medical"), the successor to Carter-Wallace's rights under the distribution agreement, whereby the Inverness Medical's exclusive distribution rights would be subject to certain limitations, and would expire in their entirety on October 1, 2004. In 2002, the Company also entered into a letter agreement with Inverness Medical whereby, among other things, Inverness Medical agreed to grant to Trinity a licence to all the granted patents relating to Lateral Flow devices that it owned and to which it had the right to grant licences in exchange for certain royalty payments.

In December 2003, the Company initiated legal proceedings in the Superior Court of Middlesex County, Massachusetts against Inverness Medical and its affiliate Wampole (collectively, Defendants) for declaratory judgment, breach of contract and unfair and deceptive business practices in connection with the Defendants' performance under the distribution agreement. Among other things, the suit requested a judgement declaring that Trinity was entitled to sell certain products directly in the Territory before October 1, 2004 under the terms of the 2002 amendment to the distribution agreement and due to breaches of the distribution agreement by the Defendants. The suit also alleged that the Defendants were attempting to convert customers from Trinity's products to

products manufactured by a competitor (which were modified to look like the Trinity products) by misrepresenting to the customers that the Trinity product was unavailable and was being discontinued. In January 2004, the Defendants countersued alleging, among other things, various breaches of the distribution agreement and the letter agreement (which they alleged was repudiated and rescinded, if ever valid), and sought a preliminary injunction to prevent Trinity from selling directly in the Territory any of its products which are competitive with products sold by the Defendants and sourced from other suppliers. The Superior Court of Middlesex County, Massachusetts, denied this motion for a preliminary injunction on January 28, 2004. In April of 2004, Trinity amended its complaint to add additional claims alleging breaches of the distribution agreement by Defendants. In May of 2004, the Defendants amended their counterclaims to add claims alleging, among other things, that Trinity was selling the BW Products directly without a licence. Following the expiration of the Defendants' exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity moved to amend its complaint to eliminate the declaratory judgment claims and add additional claims for breach of the distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. The Defendants filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. The case is currently in the discovery phase. Please see also Item 8 "Legal Proceedings".

The Company is currently selling its products directly in the US and has increased its direct sales force to approximately one hundred staff. The inability to recapture lost sales from the Defendants may have a material adverse effect on the Company. In addition, an adverse ruling by the court or adverse jury verdict with respect to Trinity's direct sales and/or the validity of the letter agreement and Trinity's licence to the Lateral Flow devices may have a material adverse effect on the Company.

SALES AND MARKETING

Trinity Biotech sells its product through its own direct sales-force in three countries: the United States, Germany and the United Kingdom. In the United States there are approximately 100 sales and marketing professionals responsible for the

sale of haemostasis reagents and instrumentation, clinical chemistry and infectious disease products. The sales force of 20 people in Germany is responsible for selling the full range of Trinity Biotech products including haemostasis, infectious disease, clinical chemistry and radioimmunoassay. In 2002, Trinity Biotech opened a sales and marketing office in Oxfordshire, UK which now employs 5 sales professionals who market the haemostasis and clinical chemistry products from Trinity Biotech. In addition to our direct sales operations, Trinity Biotech also operates in 78 countries, through over 300 independent distributors and strategic partners.

MANUFACTURING AND 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 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. Many of these companies have substantially greater capital resources and have marketing and business organisations of substantially greater size than Trinity Biotech. Many companies have been working on immunodiagnostic reagents and products, including some products believed to be similar to those currently marketed or under development by the Company, for a longer period of time than has the Company. The Company's competition includes several large companies such as Roche, Abbott, Johnson & Johnson, Bayer and Dade-Behring.

PATENTS AND LICENCES

Patents

Trinity Biotech's SeroCardTM diagnostic tests are based on Trinity Biotech Inc's patent for its "Bi-Directional Lateral Chromatography Test Device". On April 9, 1991, a patent was issued to Trinity Biotech Inc (formerly Disease Detection International Inc) by the US Patent and Trademark Office covering this device. The patent expires in 2008. This patented technology allows Trinity Biotech to concentrate and detect antibodies or antigens using a whole blood specimen in addition to serum, urine, saliva and other fluid samples.

In February 1993, Trinity Biotech filed a patent application with the Irish Patents Office under the title "Device for the Processing of Saliva for use in an Immunoassay". The patent describes a saliva collection system for collecting and analysing immunoglobulins extracted from the oral cavity. This patent was granted in May 1993. The Company was granted a second patent covering the mechanics of its Saliva Collection Device in June 1994. Management believes that these two patents, which expire in 2010, will help protect Trinity Biotech's SalivaCardTM test from being copied by a competitor.

In January 1999, Trinity Biotech filed a patent application with the Irish Patents Office describing a device used in the detection of Strep A in Trinity Biotech's Rapid Strep A test. This patent was granted in February 2000.

In December 2002, Trinity Biotech filed a patent application with the Irish Patents Office under the title "A test for detection of antibodies to HIV". The patent describes a method relating to the preparation of a test to detect anti-HIV antibodies in serum, plasma or whole blood. This patent was subsequently granted in October 2003. In April 2002, Trinity Biotech filed a patent application with the Irish Patents Office under the title "A method and apparatus for drying a coated microtitre plate after rinsing" which was also granted in 2003. In December 2002, the Company also filed a patent application with the Irish Patents Office under the title "A cyanide-free reagent for measuring haemoglobin in blood, and a method for measuring haemoglobin" which has been granted.

Many of the Company's tests are not protected by specific patents, due to the significant cost of putting patents in place for the Company's wide range of products. However, the Company 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 licence 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
In 2002, the Company obtained the Unipath and Carter Wallace lateral flow licences under agreement with Inverness Medical Innovations.

On December 20, 1999 the Company 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.

The Company 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 the Company's products are subject to extensive and rigorous government regulation in the United States and in other countries in which the Company'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" or the "agency") in the US, the Irish Medicines Board (as the authority over Trinity Biotech in Europe) and Health Canada. Recently, a European Directive has been implemented allowing one approval system to be applicable throughout Europe, CE marking. Canada has also amended its regulations where it is now mandatory to hold an externally accredited quality system to a very exacting standard.

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 52% of Trinity Biotech's 2004 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 the Company may wish to commercially distribute in the US will likely require either 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). Devices deemed to pose relatively less risk are placed in either class I or II, which requires the

manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a "preamendment" class III device (i.e., in commercial distribution since prior to May 28, 1976) for which PMA applications have not been called, are placed in class III requiring PMA approval. Recently, the FDA have introduced fees for the review of 510(k) and PMA applications. The fee for a PMA application is in excess of US$250,000.

510(k) Clearance Pathway. To obtain 510(k) clearance, the Company 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 4 to 12 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 labelling. 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. 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, it's 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 CBER regulated products intended for use in a blood bank environment, where the blood screening using these products may be administered to an individual following processing. This approval pathway involves even more stringent review of the product, its supporting clinical data and site inspection, than that of a PMA application. The BLA application pathway is more costly, lengthy and uncertain than the PMA clearance process.

Clinical Studies. A clinical study is generally required to support a PMA application and is sometimes 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. In vitro diagnostic devices ("IVD's"), however, are generally exempt from IDE requirements, provided that the testing (i) does not require an invasive sampling procedure that presents a significant risk; (ii) does not by design or intention introduce energy into a subject; and (iii) is not used for a diagnostic determination without confirmation of the diagnosis by another, medically established diagnostic device or procedure.

IVD manufacturers also must establish distribution controls to assure that IVD's distributed for the purpose of conducting research or clinical investigations are used only for that purpose and are not commercialised. Pursuant to current FDA policy, manufacturers of IVD's labelled for research use only ("RUO") or investigational use only ("IUO") are strongly encouraged by the FDA to establish a certification program under which investigational IVD's are distributed to or utilised only by individuals, laboratories, or health care facilities that have provided the manufacturer with a written certification of compliance indicating that the RUO or IUO product will be restricted in use and will, among other things, meet Institutional Review Board approval and informed consent requirements.

FDA Approval for Unigold HIV Test. The Company's complete PMA application for the UniGold HIV Test was filed on March 27, 2003. The PMA application was supported by clinical data involving 9,000 samples. The FDA issued PMA approval for the device on December 23, 2003. This approval allows for the use of serum, plasma and venipuncture whole blood in clinical settings. Early in 2004, an IDE submission was made to the FDA to define the data requirements to expand the use of the product to test fingerstick (blood taken directly from the finger) samples. Clinical tests were completed by the end of May 2004 and the application in the form of a PMA supplement made to the FDA on June 10, 2004. Three months later, on September 21, 2004, the FDA issued approval for the sale of the Unigold HIV test for use with fingerstick samples. This allows for the use of the Unigold HIV test in further settings where venipuncture samples may not be taken.

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 elaborate testing, control, documentation and other quality assurance procedures during the manufacturing process; labelling 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.

The Company 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 Company. Any failure to comply with applicable QSR or other regulatory requirements could have a material adverse effect on the Company's revenues, earnings and financial standing. There can be no assurances that the Company 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 Company's revenues, earnings and financial standing.

Other FDA Regulation

Purchasers of the Company'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. CLIA requirements may prevent some clinical laboratories from using any or all of the Company's diagnostic products. There can be no assurance that the CLIA regulations and future administrative interpretations of CLIA will not have a material adverse impact on the Company by limiting the potential market for the Company's products. Regarding the company's Unigold HIV test, CLIA waiver was granted for venipuncture whole blood in June 2004 and approval for fingerstick whole blood was granted in November 2004. This allows for the sale of the Unigold HIV test into clinical laboratories throughout the United States testing the following blood samples; serum, plasma, fingerstick and venipuncture whole blood.

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 the Company 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 the Company'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 the Company'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 the Company 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 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 GmbH, based in Lemgo, Germany, and at Trinity Biotech (USA), MarDx Diagnostics Inc and Biopool US Inc based in Jamestown, New York State, Carlsbad, California and St. Louis, Missouri respectively. The Group's newly acquired distributor of immunodiagnostic products, Fitzgerald is in Boston, Massachusetts and Bray, Co.Wicklow, Ireland.

For a more comprehensive schedule of the subsidiary and associated undertakings

of the Company please refer to Note 26 of the Notes to the Consolidated Financial Statements "Group Undertakings" contained in Item 18 "Financial Statements" of this Form 20-F.

PROPERTY, PLANT AND EQUIPMENT

Trinity Biotech has five manufacturing sites worldwide, two in the US (Jamestown, NY 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, EN and ISO approved facilities. As part of its ongoing commitment to quality, Trinity Biotech was granted the latest ISO 9001: 2000 and ISO 13485: 1996 certification in February 2003. This certificate was granted by the Underwriters Laboratory, an internationally recognised notified body. It serves as external verification that Trinity Biotech has an established and 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 requirements of the ISO 9001: 2000.

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 Company sold the facility for net proceeds of US$5.2 million and leased it back from the purchaser for 20 years. The current annual rent which is reviewed every five years is set at (euro)392,000 (US$535,000). In July 2000, the Company entered into a 20 year lease for a 25,000 square foot warehouse adjacent to the existing facility at an annual rent of (euro)191,000 (US$261,000). The Company also envisaging that further premises may potentially be required by it entered into a four years eleven month lease at (euro)13,000 (US$18,000) per annum over adjacent lands. On November 20, 2002 the Company entered into an agreement for lease with the lessor for 16,700 square feet of offices at an annual rent of (euro)381,000 (US$520,000), payable from 2004. (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$55,000.

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 July 2001, at an annual rental cost of US$240,000. The second adjacent facility comprises 14,500 square feet and is the subject of a five year lease, renewed in July 2001, at an annual rental cost of US$142,000.

Arising from the acquisition of the Biopool haemostasis business, Trinity Biotech currently operates from an additional facility located in Umea, Sweden. The Umea facility is 8,712 square feet and the annual rental is US$127,000. The lease, renewed in December 2003, expires in December 2006.

Arising from the acquisition of the Sigma haemostasis division in 2002, Trinity Biotech acquired a manufacturing/office facility of 55,000 square feet in Lemgo, Germany. This facility is owned by Trinity Biotech GmbH.

Arising from the acquisition of Adaltis the Company leases a 9,600 square foot

premises in Allentown, Pennsylvania with an annual rental of US$120,000. This lease is due to be expire in August 2005 and is not expected to be renewed.

Additional office space is leased by the Company in Ireland, Darmstadt, St, Louis, Missouri, Boston Massachusetts and New Jersey at an annual cost of US$125,000, US$75,000, US$87,000, US$64,000 and US$120,000 respectively.

ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

OPERATING RESULTS

Trinity Biotech's consolidated financial statements include the attributable results of eight trading entities: - Trinity Biotech Manufacturing Limited (Ireland), Clark Laboratories Inc (trading as Trinity Biotech (USA)), Biopool US Inc, MarDx Diagnostics Inc, Biopool AB, Trinity Biotech (UK Sales) Limited, Trinity Biotech GmbH (Germany) and Benen Trading Limited (trading as Fitzgerald Industries International). These entities are engaged in the manufacture and sale of diagnostic test kits and related instrumentation. The consolidated financial statements for 2003 and 2002 also include a share of the loss of the associate undertaking, HiberGen. This discussion covers the years ended December 31, 2004, December 31, 2003 and December 31, 2002 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 Irish GAAP which differs from US GAAP as indicated in Note 25 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 coagulation disorders and autoimmune disorders. The Company is also a significant provider of raw materials to the life sciences industry. The Company markets over 500 different diagnostic products in approximately 80 countries. In addition, the Company manufactures its own and distributes third party haemostasis and infectious diseases diagnostic instrumentation.

Trinity Biotech was incorporated in Ireland in January 1992. The Company was organised to acquire, develop and market technologies for rapid in-vitro blood and saliva diagnostics for HIV and other infectious diseases. In October 1992, Trinity Biotech completed an initial public offering in the United States in which it raised net proceeds in excess of US$5 million. In October 1993, Trinity Biotech took a controlling interest in DDI and in October 1994, merged Trinity Biotech's wholly-owned US subsidiary into DDI so that DDI became a wholly-owned subsidiary of Trinity Biotech. DDI was the surviving legal entity in the merger and was subsequently renamed Trinity Biotech Inc ("TBI"). In December 1994, Trinity Biotech acquired the remaining 50% of FHC which its subsidiary TBI did not own. During 1995, Trinity Biotech raised net proceeds in excess of US$6 million as a result of a private placement of the Company's shares. In February 1997, the Company purchased the entire share capital of Clark Laboratories Inc ("Clark"), which now trades as Trinity Biotech USA, and in June 1997, the Company purchased the entire share capital of Centocor UK Holdings Ltd ("Centocor"). In 1998, the Company made four product line acquisitions: the acquisition of the Microzyme and Macra Lp(a) product lines in June 1998 and the acquisition of the MicroTrak and Cambridge Diagnostics HIV product lines in September 1998. The manufacture of these product lines has been transferred to the Company's Jamestown, NY and Bray, Co. Wicklow, Ireland manufacturing facilities. In March 2000, the Company purchased 100% of the share capital of MarDx Diagnostics Inc ("MarDx") and in December 2000, the assets of Bartels Inc were acquired. The Bartels plant in Seattle closed in June 2001 and production

has been transferred to the Californian, New York and Irish factories. In October 2001, the Company purchased the Amerlex hormone business of Ortho Clinical Diagnostics and in December 2001 the Company acquired the assets of the Biopool haemostasis business. In October 2001, Trinity Biotech established a direct sales operation in Germany, Trinity Biotech GmbH. In August 2002, Trinity Biotech acquired the haemostasis division of Sigma Diagnostics, part of Sigma-Aldrich. The Sigma diagnostics haemostasis business comprised a comprehensive portfolio of reagents manufactured in St Louis, Missouri and the Amelung range of automated and semi-automated instruments manufactured in Lemgo, Germany. During 2003, Trinity Biotech completed the transfer of the Sigma haemostasis test manufacturing from St. Louis to the Irish facility. On September 30, 2002, Trinity Biotech closed the haemostasis manufacturing facility in Ventura, California which it had acquired from Xtrana, (Biopool), and has integrated these operations into the Wicklow manufacturing facility in Ireland. Trinity Biotech also acquired the speciality clinical chemistry business from Sigma Diagnostics in December 2002. This business consists of several specialised products that are clearly differentiated in the marketplace, including ACE, Bile Acids, Lactate, Oxalate and G6PDH. During 2002, Trinity Biotech established a small direct sales operation in the United Kingdom to handle the Sigma haemostasis and clinical chemistry product lines. In April 2004, Trinity Biotech acquired the assets of Fitzgerald Industries International Inc, a provider of immunodiagnostic products to pharmaceutical companies, reference laboratories, diagnostic manufacturers and research facilities worldwide. Also in April 2004, Trinity acquired the assets of Adaltis US, Inc, the US distribution arm for Adaltis, Inc thus obtaining exclusive distribution rights to Adaltis's open-end microplate analytical instrumentation in the US and non-exclusive distribution rights in the rest of the world, except China. For further information about the company's principal products and principal markets please refer to Item 4, "Information on the Company".

In October 2000, Trinity Biotech subscribed for a 33% shareholding in HiberGen Limited ("HiberGen"). In July 2001 the Company subscribed for a further 300,000 Ordinary Shares in HiberGen, increasing its shareholding to 40%. On April 3, 2002, the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. During 2003, HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading.

In May 1999 Trinity Biotech obtained a secondary listing on the Irish Stock Exchange and in April 2000 raised US$13.4 million by the issue of 4 million Class 'A' Ordinary Shares to institutional investors.

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 company'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 accounting principles generally accepted in Ireland ("Irish GAAP"). 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 Irish GAAP, 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,15 years.

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.

Under US GAAP, we write off all research and development costs as incurred.

Impairment of intangible assets

We assess the impairment of identifiable intangibles and related goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable.

Factors considered important, which could trigger 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 whose development costs we have capitalised;
- 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, long-lived 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.

Under US GAAP, following our adoption of SFAS 142 on January 1, 2002, we have ceased to amortise goodwill. In lieu of amortisation, we were required to perform an annual impairment review of the carrying value of our goodwill and indefinite-lived intangible assets. On January 1, 2002 the Group performed the required impairment review of goodwill and indefinite-lived intangible assets and determined that there was no impairment. On December 31, 2002, December 31, 2003 and December 31, 2004 the Group performed further impairment tests of goodwill and indefinite-lived intangible assets and concluded that there was no impairment in the carrying value of these assets at those dates.

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 reserve based on our estimates of expected losses. We write-off any inventory that is approaching its "use-by" date and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realisable value of inventory is likely to be less than its carrying value.

Allowance for doubtful debts
We make judgements as to our ability to collect outstanding receivables and provide allowances for the portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding receivables. In determining the provision, we analyse our historical collection experience and current economic trends. If the historical data we use to calculate the allowance provided for doubtful debts does not reflect the future ability to collect outstanding receivables, additional provisions for doubtful accounts may be needed and the future results of operations could be materially affected.

Accounting for income taxes
Significant judgement is required in determining our worldwide income tax expense provision. In the ordinary course of a global business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Some of these uncertainties arise as a consequence of revenue sharing and cost reimbursement arrangements among related entities, the process of identifying items of revenue and expense that qualify for preferential tax treatment and segregation of foreign and domestic income and expense to avoid double taxation. 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 net income in the period in which such determination is made. Deferred tax assets and liabilities are determined using enacted tax rates for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realised. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, there is no assurance that the valuation allowance would not need to be increased to cover additional deferred tax assets that may not be realisable. Any increase in the valuation allowance 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.

IMPACT OF RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Share-Based Payment
In December 2004, the FASB issued SFAS No. 123 (revised 2004) "Share-Based Payment" ("SFAS 123R"). This Statement replaces FASB Statement No. 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees", and its related implementation guidance.

This Statement establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This Statement does not change the accounting guidance for share-based payment transactions with parties other than employees provided in Statement 123 as originally issued and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services". This Statement does not address the accounting for employee share ownership plans, which are subject to AICPA Statement of Position 93-6, "Employers' Accounting for Employee Stock Ownership Plans".

This Statement requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exceptions). That cost will be recognised over the period during which an employee is required to provide service in exchange for the award--the requisite service period (usually the vesting period). No compensation cost is recognised for equity instruments for which employees do not render the requisite service. Employee share purchase plans will not result in recognition of compensation cost if certain conditions are met; those conditions are much the same as the related conditions in Statement 123. A public entity will initially measure the cost of employee services received in exchange for an award of liability instruments based on its current fair value; the fair value of that award will be remeasured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognised as compensation cost over that

period. If an equity award is modified after the grant date, incremental compensation cost will be recognised in an amount equal to the excess of the fair value of the modified award over the fair value of the original award immediately before the modification. The proforma disclosures previously permitted under Statement 123 no longer will be an alternative to financial statement recognition

This Statement eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. This Statement is effective for public entities that do not file as small business issuers as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortisation method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock option and restricted stock at the beginning of the first quarter of adoption of SFAS 123R,

while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R and expects that the adoption of SFAS 123R will have a material impact on the Company's consolidated results of operations and earnings per share. The Company has not determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current proforma disclosures under Statement 123.

The adoption or future adoption of the following recent accounting pronouncements have not or are not expected to have a material impact on the Company's results of operations and financial condition.

Consolidation of Variable Interest Entities
The Financial Accounting Standards Board issued FASB Interpretations No. 46, "Consolidation of Variable Interest Entities", ("FIN 46") in January 2003. This interpretation clarifies the application of Accounting Research Bulletin No.51, "Consolidated Financial Statements", to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The provisions of FIN 46 were revised in December 2003 through the issue of FASB Interpretation No. 46(R) ("FIN46R"), "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" to be effective for financial statement periods ended after March 15, 2004. The adoption of FIN 46R is not expected to have a material impact on the consolidated financial statements of the Company as the company has a controlling interest in all of its subsidiaries.

Inventory Costs
The Financial Accounting Standards Board ("FASB") issued SFAS No. 151 "Inventory Costs - an amendment of ARB No. 43, Chapter 4" in November 2004. This standard amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing", to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges..." The amendment removes the ambiguity and requires that all abnormal amounts of idle facility expense, freight, rehandling costs, and wasted material (spoilage) be treated as current period costs. In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005.

Exchanges of Nonmonetary Assets--an amendment of APB Opinion No. 29
The FASB issued Financial Accounting Statement No. 153 "Exchanges of Nonmonetary Assets - an amendment of APB Opinion No. 29" in December 2004. The guidance in APB Opinion No. 29, "Accounting for Nonmonetary Transactions", is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement shall be effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005.

RESULTS OF OPERATIONS

Year ended December 31, 2004 compared to the year ended December 31, 2003.

The following compares our results in the year ended December 31, 2004 to those of the year ended December 31, 2003. 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 22% through a combination of increased sales of existing products (11%) and sales from acquisitions (11%). Geographically, 52% of sales were generated in the USA, 28% in Europe and 20% in the rest of the world.

The gross margin for the year ended December 31, 2004 was 50.4% compared to 49.9% for the year ended December 31, 2003. The increase in gross margin is primarily explained by higher margins from the sale of Fitzgerald products since its acquisition in April 2004.

Operating profit fell by 41%, primarily due to the cost impact of the increased sales force in the USA and increasing costs in the Irish operations. The impact of these factors was partially offset by the operating profit earned from new acquisitions. The combination of the above factors caused the operating margin to fall from 14.7% in 2003 to 7.2% in 2004.

Retained profit for the period decreased by 11% (compared to 41% for operating profit). The lower decrease in retained profit is due to the impact of the share of operating losses and impairment of an investment in an associated company in 2003 and a lower effective rate of taxation in 2004.

2. REVENUES

The Company's revenues consist primarily 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 is predominantly recognised on the basis of shipment to customers. The only exception to this is for bill and hold transactions, whereby revenue is recognised once all of the company's obligations have been fulfilled. There were no instances of bill and hold transactions at December 31, 2003 and 2004. The Company ships its products on a variety of freight terms, including ex-works and CIF (carriage including freight), depending on the specific terms agreed with customers.

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

A small number of sales transactions are made on extended credit terms. This revenue is recognised in the financial statements at the date of shipment. However, under US GAAP alternative treatment is required (see note 25 to the financial statements for treatment under US GAAP).

The Company also derives a portion of its revenues from leasing haemostasis diagnostic instrumentation to customers. In cases where the risks and rewards of

ownership pass to the customer the non-financing portion of the revenue is recognised at the time of sale. In the case of operating leases, revenue is recognised over the term of the lease. In certain markets, the company also earns revenue from servicing the haemostasis diagnostic 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,		
	2004	2003	% CHANGE
	(US$ '000)	(US$ '000)	
REVENUES			
Infectious diseases	31,638	30,678	3
Rapids	9,807	4,449	120
Haemostasis	26,772	24,435	10
Other	11,727	6,113	92
TOTAL	79,944	65,675	22

Trinity Biotech's consolidated revenues for the year ended December 31, 2004 were US$79,944,000 compared to consolidated revenues of US$65,675,000 for the year ended December 31, 2003.

Infectious diseases
Sales of infectious diseases products have increased by US$960,000 primarily due to increased sales of Lyme kits (US$1,366,000), EIA instruments (US$510,000) and MMV products (US$203,000) as offset by reductions in the sales of Respiratory Laboratory (US$729,000) and Hormone products (US$507,000).

The above increases and decreases are stated after the impact of a US$2,625,000 decrease in revenues resulting from declining sales under the distribution agreement with Carter-Wallace, Inc ("Carter-Wallace") and its affiliate Wampole Laboratories ("Wampole"), now owned by Inverness Medical Innovations, Inc ("Inverness Medical"). The Company believes this is due to Inverness Medical and Wampole attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, the Company filed legal action against Inverness Medical and Wampole for declaratory judgment and breach of contract. In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. In April of 2004, Trinity amended its complaint to add additional claims alleging breaches of the distribution agreement by the Defendants. In May of 2004, the Defendants amended their counterclaims to add claims alleging, among other things, that Trinity was selling certain products without a licence. Following the expiration of the Defendants' exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity moved to amend its complaint to eliminate the declaratory judgment claims and add additional claims for breach of the distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. The Defendants filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. The case is currently in the discovery phase.

For further information relating to this matter please refer to Item 8 "Legal Proceedings". The Company decided to sell its products directly in the US and has increased its direct sales force in 2004 in the US to approximately 100 staff.

Rapids
Sales of Rapids have increased by US$5,358,000 which is primarily attributable to increased sales of rapid HIV products to Africa.

Haemostasis Revenues
The increase in haemostasis revenues of US$2,337,000 is attributable to increased sales of the Company's Biopool/Amax range of products. This increase in sales occurred predominantly in the Company's European market.

Other Revenues
Additional other revenues of US$5,614,000 were earned in 2004 due to a combination of sales of immunodiagnostic products by Fitzgerald (US$4,765,000) and increased sales of the Amax speciality clinical chemistry product line, originally acquired from Sigma in 2002 (US$849,000).

Revenues by Geographical Region
The following table sets forth selected sales data, analysed by geographic region:

	YEAR ENDED DECEMBER 31,		
	2004	2003	% CHANGE
	(US$ '000)	(US$ '000)	
REVENUES			
USA	41,380	36,299	14
Europe	22,654	19,983	13
Middle East /Africa	11,550	6,248	85
Other overseas	4,360	3,145	39
TOTAL	79,944	65,675	22

The US$5,081,000 increase in the US is primarily attributable to the inclusion of sales from Fitzgerald (US$2,751,000) and Adaltis (US$2,283,000) since their acquisition in April 2004. Sales of existing product ranges (excluding sales to Wampole) have increased by US$2,672,000. This is partially offset by the US$2,625,000 reduction in sales to Wampole discussed above.

The US$2,671,000 increase in Europe is primarily due to higher sales of the Company's Biopool/Amax range of products (US$1,833,000) and sales of Fitzgerald products (US$876,000).

The US$5,302,000 increases in Middle East/Africa is primarily attributable to increased sales of rapid HIV products to Africa (US$4,863,000) and Haemostasis products (US$283,000).

The US$1,215,000 increase in sales to other overseas countries is principally due to the inclusion of sales of Fitzgerald products to the Far East since its acquisition in April 2004 (US$1,138,000).

For further information about the company'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 company's operating expenses.

	YEAR ENDED DECEMBER 31,		
	2004	2003	% CHANGE
	(US$ '000)	(US$ '000)	
Revenues	79,944	65,675	22
Cost of sales	(39,688)	(32,877)	21
Research & development	(4,641)	(5,210)	(11)
Administrative expenses	(29,874)	(17,919)	67
Operating profit	5,741	9,669	(41)

Cost of sales
Trinity Biotech's consolidated cost of sales increased 21% or by US$6,811,000 from US$32,877,000 for the year ended December 31, 2003 to US$39,688,000 for the year ended December 31, 2004. The increase in cost of sales is primarily attributable to incremental cost of sales associated with the newly acquired Fitzgerald and Adaltis product ranges (US$4,064,000). The remaining US$2,747,000 is attributable to the increased cost of sales associated with higher sales levels of the company's existing product ranges. See Revenues section above for details on movements in revenues during 2004.

Research and development
Research and development ("R&D") expenditure decreased to US$4,641,000 in 2004. This represents 5.8% of consolidated revenues compared to expenditure of US$5,210,000 or 7.9% of consolidated revenues in 2003. For a consideration of the various R&D projects see "Research and Products under Development" in Item 5.

Administrative expenses
Overall normal administrative expenses account for 37% of consolidated revenues in 2004 which compares with 27% in 2003. The following table outlines the breakdown of administrative expenses compared to a similar breakdown for 2003.

	YEAR ENDED DECEMBER 31,			
	2004	2003	INCREASE	% CHANGE
	US$'000	US$'000	US$'000	
SG&A	27,304	17,063	10,241	60
Amortisation	2,570	856	1,714	200
TOTAL	29,874	17,919	11,955	67

SG&A
Administrative expenses increased 60% or by US$10,240,000 from US$17,063,000 to US$27,304,000, which compares to revenue growth of 22% during the same period. The higher growth is primarily attributable to the strengthening of the company's sales force in the US during the year, increased costs in the Irish operations and the inclusion of additional SG&A expenditure associated with the Fitzgerald and Adaltis acquisitions.

A detailed analysis of this increase in SG&A expenses of US$10,241,000 in 2004 is as follows:

- An increase of US$3,735,000 in the company's US direct sales operation, principally attributable to expansion of the Group's sales and marketing capability within the US in order to reflect the Group's expanding product range. This includes the impact of increasing the sales force in the US to approximately 100 people. The key objectives of the expanded

sales force in the US are to grow sales of the Unigold rapid HIV test, to significantly increase our market share in the coagulation market, to recover business from our US distributor and to expand our presence in the infectious disease market.

- Increased SG&A costs in the Irish operations of US$2,845,000. This is due to a combination of
  - (i) foreign exchange caused by the strengthening of the Euro versus the US Dollar.
  - (ii) increased royalties and commissions principally associated with the significant increase in the sales of rapid HIV products.
  - (iii) increased central administration costs in Bray, Ireland reflecting the first full year of the significantly increased level of activity now being undertaken at Bray following the transfer of the Sigma and Biopool lines to Bray during 2003.
- Increased SG&A expenditure in relation to the Fitzgerald acquisition (US$936,000) and Adaltis acquisition (US$320,000).
- An increase of US$172,000 in the UK principally due an increased sales force. The UK direct sales operation which was established in 2002 was further expanded during 2004.
- A reduction in foreign exchange gains in 2004 compared to 2003 (US$1,565,000).
- The remaining increase of US$667,000 which represents 3.9% of the prior year SG&A costs is principally due to general inflation across the Group.

Amortisation

The increase in amortisation of US$1,714,000 from US$856,000 to US$2,570,000 is largely attributable to the release of a lower level of negative goodwill of US$620,000 (2003: US$1,572,000) arising from the Sigma haemostasis acquisition in 2002. The remaining increase of US$762,000 is mainly attributable to goodwill amortisation in relation to the acquisitions for Fitzgerald and Adaltis during 2004 (US$575,000) and increased amortisation of other non-current intangible assets (US$279,000).

4. RETAINED PROFIT

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

	YEAR ENDED DECEMBER 31,		
	2004	2003	% CHANGE
	(US$ '000)	(US$ '000)	
OPERATING INCOME	5,741	9,669	(41)
Net interest charge	(522)	(619)	(16)
PROFIT BEFORE TAX AND SHARE OF OPERATING LOSS IN ASSOCIATED COMPANY AND IMPAIRMENT	5,219	9,050	(42)
Share of operating loss in associated company and impairment	-	(1,067)	(100)
PROFIT BEFORE TAX	5,219	7,983	(35)
Tax	(53)	(2,186)	(98)

RETAINED PROFIT	5,166	5,797	(11)

Net interest charge
Net interest decreased to US$522,000 in 2004 compared to US$619,000 in 2003. The decreased level of interest reflects the Company's lower level of net debt during the year, mainly attributable to higher level of deposit interest being earned on cash deposits following the Company's fund raising activities during 2004. Please refer to "Liquidity and Capital Resources" later in this section for information on Trinity Biotech's use of debt.

Share of loss in associated company and impairment
On October 2, 2000, the Company acquired 33% of the share capital of HiberGen Limited for a total consideration of US$1,372,000. On July 2, 2001 the Company subscribed for a further 300,000 Ordinary Shares of (euro)0.0127 each in HiberGen Limited, increasing its shareholding to 40%, at a cost of US$309,000. On April 3, 2002 the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. During 2003 HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading. The company wrote off its investment in HiberGen in 2003, thus there is no impact on the results for 2004.

Taxation
A tax charge of US$53,000 was incurred in the year ended December 31, 2004. The comparable charge for 2003 was US$2,186,000. This represented a decrease in current tax in absolute terms of US$1,091,000 and a decrease in deferred tax of US$1,042,000. The decrease in current tax is primarily attributable to a reduction in overseas taxation as a result of the current year losses in the US. This also had the impact of increasing the deferred tax asset thus decreasing the deferred tax charge. For further details on the Group's tax charge please refer to Note 8 "Deferred Tax" and Note 14 "Income Taxes" of the Notes to the Consolidated Financial Statements contained in Item 18 "Financial Statements".

Retained Profit
Retained profit for the period decreased by US$631,000, from US$5,797,000 to US$5,166,000. As a percentage of consolidated revenues this represents a decrease to 6.5% from 8.8%. This decrease is principally due to the higher costs associated with strengthening the sales force in the US more than offsetting the increased gross margins earned from higher sales levels, the impact of reduced taxation charge in 2004 and the share of losses and the impairment of the investment in an associated company in 2003.

RESULTS OF OPERATIONS
Year ended December 31, 2003 compared to the year ended December 31, 2002. The following compares our results in the year ended December 31, 2003 to those of the year ended December 31, 2002. Our analysis is divided as follows:

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

1. OVERVIEW

In US Dollars, our consolidated revenues increased by 26%; operating income grew by 47%; retained profit increased by 18% and cash flow from operating activities increased by 17%.

Geographically, 55% of our sales were generated in the USA, 30% in Europe and 15% in the rest of the world.

The gross margin for the year ended December 31, 2003 was 49.9% compared to 50.6% for the year ended December 31, 2002. The decrease in gross margin is partly explained by the weakening of the US Dollar, causing the margin to drop by 0.7%.

Our operating margin in 2003 was 14.7% of sales, an increase of 2% over the 12.7% of sales of the previous year. This is due to the increase in turnover, primarily attributable to a full year's revenues of the Sigma haemostasis and Sigma speciality clinical chemistry product lines in 2003. This is partially offset by (i) the increase in cost of sales arising from

these product lines of US$8,710,000 and (ii) the increase in administration expenses due to the expansion of sales and marketing activities.

As a result of these factors, operating income increased by US$3,086,000 to US$9,669,000.

2. REVENUES

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

	YEAR ENDED DECEMBER 31,		
	2003	2002	% CHANGE
	(US$ '000)	(US$ '000)	
REVENUES			
Infectious diseases			
- infectious disease (excl rapids)	30,678	33,939	(10)
- rapids	4,449	3,890	14
Haemostasis	24,435	13,780	77
Clinical Chemistry	6,113	369	1,557
TOTAL	65,675	51,978	26

Trinity Biotech's consolidated revenues for the year ended December 31, 2003 were US$65,675,000 compared to consolidated revenues of US$51,978,000 for the year ended December 31, 2002.

US$2,200,000 of the decrease of US$2,702,000 in infectious diseases revenues resulted from declining sales under the distribution agreement with Carter-Wallace, Inc ("Carter-Wallace") and its affiliate Wampole Laboratories ("Wampole"), now owned by Inverness Medical Innovations, Inc ("Inverness Medical"). The Company believes this is due to Inverness Medical and Wampole attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, the Company filed legal action against Inverness Medical and Wampole for declaratory judgement and breach of contract. In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. For further information relating to this matter please refer to Item 8 "Legal Proceedings.

Additional revenues of US$5,744,000 were earned on clinical chemistry products in 2003 due to the contribution of a full year's sales of the Sigma speciality clinical chemistry product line in 2003. This compares to one month's revenues from the same product line in 2002.

The increase in haemostasis revenues of US$10,655,000 is principally attributable to a full year's revenues of the Sigma haemostasis product line in 2003 as compared to five month's revenues, from August to December, in 2002.

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

The following table sets forth selected sales data, analysed by geographic region:

	YEAR ENDED DECEMBER 31,		
	2003	2002	% CHANGE
	(US$ '000)	(US$ '000)	
REVENUES			
USA	36,299	33,512	8
Europe	19,982	11,899	68
Middle East /Africa	6,249	4,396	42
Other overseas	3,145	2,171	45
TOTAL	65,675	51,978	26

The US$2,787,000 increase in the US is attributable to the increase in haemostasis and clinical chemistry sales of US$5,300,000 due to the inclusion of a full year's revenues of the Sigma haemostasis and Sigma speciality clinical chemistry product lines. This is partially offset by the US$2,200,000 reduction in sales from Wampole discussed above.

The US$8,083,000, US$1,853,000 and US$974,000 increases in the Europe, Middle East/Africa and other overseas segments, respectively, are primarily driven by the inclusion of a full year's revenues of the Sigma haemostasis and Sigma speciality clinical chemistry product lines.

3. OPERATING EXPENSES

The following table sets forth our operating expenses.

	YEAR ENDED DECEMBER 31,		
	2003	2002	% CHANGE
	(US$ '000)	(US$ '000)	
Revenues	65,675	51,978	26
Cost of sales	(32,877)	(25,690)	28
Research & development	(5,210)	(4,471)	17
Administrative expenses	(17,919)	(15,234)	18
Operating profit	9,669	6,583	47

Cost of sales
Trinity Biotech's consolidated cost of sales increased 28% or by US$7,187,000 from US$25,690,000 for the year ended December 31, 2002 to US$32,877,000 for the year ended December 31, 2003. The increase in cost of sales is primarily attributable to (i) the Sigma haemostasis and speciality clinical chemistry product lines which contributed an additional US$8,710,000 to cost of sales, and

(ii) the decrease in cost of sales associated with the decrease in revenues for infectious diseases sales categories of US$1,523,000.

Research and development
Research and development ("R&D") expenditure increased to US$5,210,000 in 2003. This represents 7.9% of consolidated revenues and is comparable to R&D spend in 2002 of US$4,471,000 or 8.6% of consolidated revenues. For a consideration of the various R&D projects see "Research and Products under Development" in Item 5 of the 20-F.

Administrative expenses
Overall normal administrative expenses account for 27% of consolidated revenues in 2003 which compares with 29% in 2002. The following table outlines the breakdown of administrative expenses compared to a similar breakdown for 2002.

	YEAR ENDED DECEMBER 31,			
	2003	2002	INCREASE/ (DECREASE)	% CHANGE
	US$'000	US$'000	US$'000	
SG&A	17,063	12,849	4,214	33
Amortisation	856	2,386	(1,530)	(64)
TOTAL	17,919	15,235	2,684	18

SG&A
Administrative expenses increased 33% or by US$4,214,000 from US$12,849,000 to US$17,063,000, this compares to revenue growth of 26% during the same period. The higher growth is attributable to the strengthening of the Group's sales and marketing and administrative functions following the acquisitions of the Sigma haemostasis product line in August 2002 and the Sigma clinical chemistry product line in November 2002. In April 2002 Sigma Aldrich announced plans to sell the assets of its diagnostics business. When the Group took on these businesses in August and November 2002 a significant selling effort was required to retain the customer base.

Specifically the Group (i) opened a new sales and marketing facility in St. Louis, Missouri in October 2002, (ii) opened a direct sales and marketing operation in the UK in October 2002, and (iii) expanded its sales and marketing operations in Germany and Ireland to cater for the new product lines acquired in these acquisitions. This expansion occurred in Quarter 4,

2002 and 2003 represented the first full year's operation of these expanded sales and marketing and administrative functions.

The effect of these acquisitions was to significantly expand the haemostasis product line into instruments, consumables and a wider range of reagents, and to introduce a new product line in clinical chemistry. Accordingly the focus of the sales and marketing effort changed from infectious disease and the Biopool haemostasis reagents to encompass a broader haemostasis range and clinical chemistry. This expansion in the volume and complexity of our product range necessitated a substantial increase in the level of sales and marketing effort and a redirection and retraining of our existing salesforce and distributors.

A detailed analysis of this increase in SG&A expenses of US$4,214,000 in 2003 is as follows:

- An increase of US$1,691,000 in the Group's US operations, principally attributable to expansion of the Group's sales and marketing capability within the US in order to reflect the Group's expanding product range as noted above. 2003 represented the first full year of the Group's central

sales and marketing facility in St. Louis which was established in October 2002.

- An increase in SG&A expenses of US$1,613,000 in the Group's operations in Germany. This is principally attributable to the inclusion of a full year's SG&A expenses incurred at the Group's haemostasis instrument manufacturing facility in Lemgo versus four months of such costs in 2002. This plant was acquired as part of the acquisition of the haemostasis business line from Sigma in August 2002.
- An increase of US$458,000 due to the inclusion of a full year of SG&A costs in the UK, compared to three months in 2002 following the establishment of a UK sales office in Oxfordshire in October 2002.
- The remaining increase of US$452,000 is principally attributable to;
  - (i) a strengthening of the Group's central sales and marketing function, located in Bray, Ireland, in line with the broadening of the Group's product range (US$1,392,000);
  - (ii) increased central administrative costs (US$895,000) in Bray, Ireland reflecting the significant increase in level of activity now being undertaken at Bray following the transfer of the manufacture of the Sigma and Biopool product lines to Bray during 2003 and increase in head office administrative functions reflective of the increasing size of the Group and the level of fundraising and acquisition activities; and,
  - (iii) an offset by foreign exchange gains of US$1,835,000 incurred by the Group which arose during the year.

Amortisation

The decrease in amortisation of US$1,530,000 from US$2,386,000 to US$856,000 is largely attributable to the release of negative goodwill of US$1,572,000 arising from the Sigma haemostasis acquisition in 2002. Following the completion of the fair value exercises in 2003 in respect of the Sigma Haemostasis and Sigma Clinical Chemistry acquisitions made during 2002, amendments have been made to the fair values reported in the 2002 financial statements. The amendments relate to the identification of additional obligations of US$929,000 assumed on the acquisition of the Sigma Haemostasis business, the completion of the fair value exercise on inventory acquired in both acquisitions resulting in the recognition of additional value of US$3,031,000 and the recognition of additional costs of US$68,000 relating to the Sigma Hemostasis acquisition and US$97,000 relating to the Clinical Chemistry acquisition. In accordance with Irish GAAP, negative goodwill has been released to the profit and loss account as the related assets are utilised. Please refer to Note 19 "Acquisition of Businesses" in Item 18, "Financial Statements", for full disclosure of these acquisitions and fair value adjustments.

4. RETAINED PROFIT

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

	YEAR ENDED DECEMBER 31,		
	2003	2002	% CHANGE
	(US$ '000)	(US$ '000)	
OPERATING INCOME	9,669	6,583	47
Net interest charge	(619)	(601)	3
PROFIT BEFORE TAX AND SHARE OF OPERATING LOSS IN ASSOCIATED COMPANY AND IMPAIRMENT	9,050	5,982	51

Share of operating loss in associated company and impairment	(1,067)	(317)	237
PROFIT BEFORE TAX	7,983	5,665	41
Tax	(2,186)	(768)	185
RETAINED PROFIT	5,797	4,897	18

Net interest charge
Net interest increased to US$619,000 in 2003 compared to US$601,000 in 2002. The increased level of interest reflects the Company's higher level of net debt during the year, mainly attributable to the completion of the US$10 million club banking facility with Allied Irish Banks plc and Bank of Scotland (Ireland) Ltd in June 2003 and the private placement of US$20 million of 3% convertible notes in July 2003. Please refer to "Liquidity and Capital Resources" later in this section for information on Trinity Biotech's use of debt.

Share of loss in associated company and impairment
From 2000 to 2002, the Company acquired 42.9% of the share capital of Hibergen Limited. During 2003, Hibergen Limited was unsuccessful in raising additional funds and on November 14, 2003, the board of Hibergen Limited decided to cease trading. The carrying value of the Company's investment in Hibergen was written off in 2003.

Taxation
A tax charge of US$2,186,000 was incurred in the year ended December 31, 2003. The comparable charge for 2002 was US$767,000. This represented an increase in current tax in absolute terms of US$1,279,000 and an increase in deferred tax of US$140,000. The increase in current tax is primarily attributable to a higher corporation tax charge in Ireland in 2003 as the level of relief for losses carried forward enjoyed by the Company in previous years is no longer available. The utilisation of losses carried forward also helped to increase the Group net deferred tax charge. For further details on the Group's tax charge please refer to Note 8 "Deferred Taxation" and Note 14 "Income Taxes" of the notes to the consolidated financial statements contained in Item 18 "Financial Statements" of this Form 20-F.

Retained Profit
Retained profit increased by US$900,000, from US$4,897,000 to US$5,797,000. As a percentage of consolidated revenues this represents a decrease from 9.4% to 8.8%, principally due to the write-off of the investment in HiberGen.

LIQUIDITY AND CAPITAL RESOURCES

FINANCING
During 2003, US$1,000,000 principal amount of 6% convertible debentures was converted into 666,667 Class 'A' Ordinary Shares of the Company.

On April 3, 2002, the Company increased its shareholding in Hibergen Limited, an associate company, from 40% to 42.9% by the acquisition of 165,000 Ordinary Shares in HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.

In December 2001, the Company acquired the assets of the Biopool haemostasis business for a total consideration of US$6,409,000, after costs, satisfied in cash and deferred consideration. The deferred consideration of US$2,591,000 was payable in three instalments of US$855,000, US$1,166,000 and US$570,000 on December 21, 2002, 2003 and 2004 respectively. The deferred consideration was

not conditional on any future event and has been fully settled.

On August 27, 2002, Trinity Biotech purchased the haemostasis division of Sigma Diagnostics for a total consideration of US$1,428,000. The consideration was satisfied in cash. On November 27, 2002, the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4,412,000 satisfied in cash and deferred consideration. The cash consideration was partly financed by the issue of US$2.5 million of convertible debentures. The deferred consideration of US$1,810,000 was paid during 2003.

In November 2002, the Company completed a private placement of (i) US$2,500,000 principal amount of 5.25% convertible debentures and (ii) 50,000 warrants (the "Second Warrants") to purchase 'A' Ordinary Shares of the

Company. The debentures bore interest at a rate of 5.25% per annum and were convertible into Class 'A' Ordinary Shares of the Company at a price of US$1.50. During 2003, the debenture was fully converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

In December 1999, the Company completed a private placement of (i) US$3,500,000 principal amount of 7.5% Convertible Debentures and (ii) 483,701 warrants to purchase 'A' Ordinary shares of the Company (the "First Warrants"), which resulted in aggregate gross proceeds to the Company of US$3,500,000. In relation to the First Warrants, 333,701 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.74 per share and the remaining 150,000 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.80 per share. 100,000 of these warrants were exercised to purchase 'A' Ordinary Shares in the Company in 2000. The balance of these 150,000 warrants expired unexercised on June 25, 2002. During 2003, 133,701 of the remaining First Warrants were exercised and the final 200,000 were exercised in 2004. The Second Warrants are each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.50 and will expire in November 2007. None of the Second Warrants have been exercised.

In June 2003, Trinity Biotech completed a new US$10,000,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Ltd. The new facility consists of a five year term loan of US$6,000,000 and a one year revolver of US$4,000,000. This facility was partly used to repay existing loans and the loan notes payable to Xtrana, Inc. During 2004 the Company repaid US$1,200,000 of the term loan. At December 31, 2004, the term loan outstanding was US$4,800,000. During 2004 US$1,000,000 of the revolver was repaid leaving US$2,000,000 outstanding at December 31, 2004.

In July 2003, the Company completed a private placement of US$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum, convertible into Class 'A' Ordinary Shares of the Company at a price of US$3.55. In December 2003, US$6,355,000 of the US$20,000,000 principal amount of the debentures was converted into 1,790,141 Class 'A' Ordinary Shares of the Company, a further US$44,500 of accrued interest was settled by the issue of 12,535 Class 'A' Ordinary Shares of the Company at US$3.55 per share. In 2004, a further US$427,500 of the principal amount of the debenture was converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July 2003 placement, convertible notes in the aggregate principal amount of up to US$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a

rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$4. All of above debentures are unsecured and are repayable in ten equal instalments on a quarterly basis commencing October 2004. Under the terms of the agreement, the Company has the right to satisfy each repayment either in cash or in shares. In October 2004, the first principal repayment of $1,822,000 was made to the debenture holders in cash. At 31 December 2004, the total amount of debentures outstanding amounted to US$15,819,000. The debt is stated net of unamortised issue costs of US$576,000.

In January 2004, the Company has completed a private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US$5.25 per share. Under the terms of the placement, investors were also granted the right to purchase an additional 2,647,059 Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share for a period of up to 30 days after the closing of the transaction. An additional 431,617 Class 'A' Ordinary Shares of the Company were issued within the 30 day period following the closing of the transaction to investors who exercised this option.

CASH MANAGEMENT
As at December 31, 2004, Trinity Biotech's consolidated cash and cash equivalents were US$22,287,000. This compares to cash and cash equivalents of US$20,563,000 at December 31, 2003. The increase is due to cash inflow of US$2,348,000 from operations, the issue of share capital, and the issue of convertible debentures, offset by the repayment of bank borrowings and cash payments for the purchase of businesses and fixed assets. This resulted in an increase in cash and liquid resources of US$1,723,000 during the year.

A significant portion of the Company's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Company's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Company pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. The Company's current hedging policy is to cover a portion of its expenses forward. The Company expects that its forward contracts as at December 31, 2004 will have a positive impact on the cashflows of the business. At December 31, 2004 forward contracts with a carrying value of US$Nil had a fair value of US$418,000.

As at December 31, 2004, year end borrowings were US$24,011,000 and cash in hand was US$22,287,000. For a more comprehensive discussion of the Company's level of borrowings at the end of 2004, the maturity profile of the borrowings, the company's use of financial instruments, its currency and interest rate structure and its funding and treasury policies please refer to Item 11 "Qualitative and Quantitative Disclosures about Market Risk".

CONTRACTUAL OBLIGATIONS

The following table summarises our minimum contractual obligations and commercial commitments, as of December 31, 2004:

CONTRACTUAL OBLIGATIONS	PAYMENTS DUE BY PERIOD			
	Total	less than 1 year	1-3 Years	3-5 Years

	US$'000	US$'000	US$'000	US$'000
Bank loans	6,731	3,150	3,581	-
Financial liabilities from unconnected third party	669	669	-	-
Capital (finance) lease obligations	792	238	554	-
Operating lease obligations	28,753	2,648	3,977	3,216
Other long-term liabilities reflected on the company's balance sheet under Irish GAAP	15,819	7,031	7,321	1,467
Total	52,764	13,736	15,433	4,683

Trinity Biotech incurs debt to pursue its policy of growth through acquisition. Trinity Biotech believes that, with further funds generated from operations, it will have sufficient funds to meet its capital commitments and continue existing operations for the foreseeable future. If operating margins on sales were to decline substantially, if the Company's increased investment in its US direct sales force was not to generate comparable margins in sales or if the Company was to make a large and unanticipated cash outlay, the Company would have further funding requirements. If this were the case, there can be no assurance that financing will be available at attractive terms, or at all. The Company believes that success in raising additional capital or obtaining profitability will be dependent on the viability of its products and their success in the market place.

IMPACT OF INFLATION

Although Trinity Biotech's operations are influenced by general economic trends, Trinity Biotech does not believe that inflation had a material effect on its operations for the periods presented. Management believes, however, that continuing national wage inflation in Ireland and the impact of inflation on costs generally will result in a sizeable increase in the Irish facility's operating costs in 2005.

IMPACT OF CURRENCY FLUCTUATION

Trinity Biotech's revenue and expenses are affected by fluctuations in currency exchange rates especially the exchange rate between the US Dollar and the Euro. Trinity Biotech's revenues are primarily denominated in US Dollars, its expenses are incurred principally in Euro and US Dollars. The recent weakening of the US Dollar could have an adverse impact on future profitability. Management are actively seeking to increase the size of the Euro revenue base to mitigate this risk. The revenues and costs incurred by US subsidiaries are denominated in US Dollars.

Trinity Biotech holds most of its cash assets in US Dollars. As Trinity Biotech reports in US Dollars, fluctuations in exchange rates do not result in exchange differences on these cash assets.

EXCHANGE RATES

Fluctuations in the exchange rate between the Euro and the US Dollar may impact on the Company's Euro monetary assets and liabilities and on Euro expenses and consequently the Company's earnings.

OFF-BALANCE SHEET ARRANGEMENTS

Not applicable.

RESEARCH AND PRODUCTS UNDER DEVELOPMENT

HISTORY

Trinity Biotech has invested considerable funds in research and development over the past number of years. It has developed a platform technology for its rapid UniGold tests and, arising from this, the Company has focused on

developing rapid tests for certain infectious diseases utilising this platform. The Company continues to expand and improve its product offerings in other areas including EIAs, immunofluorescent assays and Western Blots.

DEVELOPMENT GROUPS

The Company has research and development groups focusing separately on microtitre based tests, rapid tests, western blot products and immunofluorescent assays. These groups are located in Dublin and the US. The Company sub-contracts some research and development to independent researchers based in the US and from time to time sponsors various projects in universities. Each of these research and development groups is currently involved in the following projects:

Microtitre Plate Development Group

Development of type specific microtitre plate assay for the detection of HSV-1 and HSV-2 The Company has developed HSV-1 and HSV-2 specific tests to complement its HSV-1/2 tests. HSV-2 causes more serious complications to pregnant women and HSV-2 positive patients are more susceptible to contracting HIV. These type specific tests utilise recombinant proteins rather than the less specific viral lysates in the older generations of these products. This work was completed in the latter half of 2003 and the Company received FDA approval for these tests from the FDA on July 13, 2004.

Development of microtitre plate assay for the detection of EU Lyme IgG and IgM Prompted by the company's successful Lyme Western Blots and the company's successful domestic (US) Lyme IgG and IgM EIAs, development has commenced on two new elisas to specifically detect EU Lyme IgG and IgM. It is anticipated that development should be completed and the products launched on the market by mid 2005.

One Plate IgMs

The Company has a repertoire of IgM EIA products against various infectious agents. These were originally in a two plate format but a program was initiated to convert these to a one plate format. Work on converting Rubella IgM, Toxo IgM, VZV IgM, Measles IgM and Mumps IgM was completed in 2003. The conversion of HSV 1 IgM, HSV 2 IgM and CMV IgM assays to a one plate format commenced in 2004 and is expected to be completed in 2005.

Rapid Development Group

Development of UniGold Recombigen HIV (2000-2003)

This represents a modification of Trinity Biotech's original UniGold HIV Test using recombinant protein antigens rather than peptides in the test. It is a single use rapid test for the detection of antibodies to HIV-1 in plasma, serum and whole blood. The test is intended for use as an aid in diagnosis, in settings where the rapid diagnosis of HIV infection can ensure early initiation of antiretroviral therapy. The test can be performed in ten minutes, enabling health care providers to supply preliminary results to patients at the time of testing, potentially increasing the overall effectiveness of counselling and testing programs.

The recombinant proteins are manufactured by Trinity Biotech and allow the UniGold HIV Test to be produced in a more cost-effective manner. Clinical and non-clinical trials demonstrated that the test has a sensitivity of 100% and a specificity of 99.7%.

On December 23, 2003, the FDA issued approval for the sale of the UniGold HIV test for use with vennipuncture blood (whole blood, serum and plasma). Early in 2004, an IDE submission was made to the FDA to define the data requirements to expand the use of the product to test fingerstick (blood taken directly from the

finger) samples. Clinical trials were completed by the end of May 2004 and the application in the form of a PMA supplement made to the FDA on June 10, 2004. Three months later on September 21, 2004 the FDA issued approval for the sale of the UniGold HIV test for use with fingerstick samples. This allows for the use of the UniGold HIV test in further settings where vennipuncture samples may not be taken.

Throughout 2004 trials were completed to support CLIA waiver applications for the UniGold HIV test. The application for CLIA waiver for use with vennipuncture whole blood was made in April 2004. CLIA waiver approval was granted for whole blood on June 23, 2004. An additional waiver approval was submitted for fingerstick blood in September 2004 and approval granted in November 2004. This allows for sale of the UniGold HIV test into clinical laboratories throughout the United States testing the following blood sample types: serum, plasma, fingerstick and venipuncture whole blood.

Western Blot Development Group

HIV Western Blot
Trinity Biotech has developed a western blot test for detecting antibodies to HIV for use as a diagnostic and confirmatory product in blood banks. The products had been designed and developed at the Trinity Biotech plc facility in Carlsbad California where the company has established a long history in Western Blot products. The development work on the Recombigen(R) HIV-1 Western Blot was completed during the first half of 2004. An Investigational New Drug (IND) application was completed and submitted to the CBER division of the FDA on July 20, 2004. Approval for this application was granted by the FDA on September 24, 2004. This application outlined the manufacturing processes for the product and defined the clinical trials to be performed on the product to support a BLA application. Clinical trials and product validation are planned for 2005. Once all trials are complete a BLA application will be made. This product is available for evaluation use outside of the US.

Immunofluorescent Assay Development Group

Research is also ongoing on redesigning various immunofluorescent assays from indirect assays to direct assays. This redevelopment will make the products more user friendly and reduce assay time.

VRK DFA kit
This is a test for the detection of Influenza A and B, RSV (Respiratory syncytial virus), Para and Adenovirus in both patient specimens and culture samples. It employs a one step method with a total test time of 15 minutes, allowing the differentiation of various viruses responsible for respiratory system infections. Such a product will complement the existing RSV DFA kit. This product is due to be completed and launched (ROW) in 2005 and submitted for 510(k) approval in 2006.

For the 12 months ended December 31, 2004, the Company spent US$4,641,000 on research and development. This expenditure is broken down into salary costs, reagents, consultancy fees and other related costs. This is broadly comparable with the net expenditure in previous two years (2003: US$5,210,000, 2002 US$4,471,000).

TREND INFORMATION
For information on trends in future operating expenses and capital resources, see "Results of Operations", "Liquidity and Capital Resources" and "Impact of Inflation" under Item 5.

ITEM 6

DIRECTORS AND SENIOR MANAGEMENT

DIRECTORS AND EXECUTIVE OFFICERS

Name	Age	Title
Ronan O'Caoimh	49	Chairman of the Board of Directors Chief Executive Officer
Brendan K. Farrell	57	Director, President
Jim Walsh Ph.D.	46	Director, Chief Operating Officer
Rory Nealon	37	Director, Chief Financial Officer, Company
Denis R. Burger, Ph.D.	61	Non Executive Director
Peter Coyne	45	Non Executive Director

BOARD OF DIRECTORS

RONAN O'CAOIMH, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, co-founded Trinity Biotech in June 1992 and acted as Chief Financial Officer until March 1994 when he became Chief Executive Officer. He has been Chairman since May 1995. Prior to joining Trinity Biotech, Mr O'Caoimh was Managing Director of Noctech Limited, an Irish diagnostics company. Mr O'Caoimh was Finance Director of Noctech Limited from 1988 until January 1991 when he became Managing Director. Mr O'Caoimh holds a Bachelor of Commerce degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

BRENDAN FARRELL, PRESIDENT, joined Trinity Biotech in July 1994. He was previously Marketing Director of B.M. Browne Limited, a company involved in the marketing and distribution of medical and diagnostic products. Prior to that

he was Chief Executive of Noctech Limited, an Irish based diagnostics company, following six years with Baxter Healthcare where he was Director of European Business Development. Mr Farrell has a Masters degree in Biochemistry from University College Cork.

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

JIM WALSH, PHD, CHIEF OPERATING OFFICER, joined Trinity Biotech in October 1995. Prior to joining the Company, Dr Walsh was Managing Director of Cambridge Diagnostics Ireland Limited (CDIL). He was employed with CDIL since 1987. Before joining CDIL he worked with Fleming GmbH as Research & Development Manager. Dr

Walsh has a degree in Chemistry and a PhD in Microbiology from University College Galway.

DENIS R. BURGER, PHD, NON-EXECUTIVE DIRECTOR, co-founded Trinity Biotech in June 1992 and acted as Chairman from June 1992 to May 1995. He is currently a non-executive director of the Company. Dr Burger is Chairman, Chief Executive Officer and a director of AVI Biopharma Inc, an Oregon based biotechnology company. Dr Burger is also a 50% partner in Sovereign Ventures, a healthcare consulting and funding firm based in Portland, Oregon. He was a co-founder and, from 1981 to 1990, Chairman of Epitope Inc. In addition, Dr Burger has held a professorship in the Department of Microbiology and Immunology and Surgery (Surgical Oncology) at the Oregon Health Sciences University in Portland. Dr Burger received his degree in Bacteriology and Immunology from the University of California in Berkeley in 1965 and his Master of Science and PhD in 1969 in Microbiology and Immunology from the University of Arizona.

PETER COYNE, NON-EXECUTIVE DIRECTOR, joined the board of Trinity Biotech in November 2001 as a non-executive director. Mr Coyne is a director of AIB Corporate Finance, a subsidiary of AIB Group plc, the Irish banking group. He has extensive experience in advising public and private groups on all aspects of corporate strategy. Prior to joining AIB, Mr Coyne trained as a chartered accountant and was a senior manager in Arthur Andersen's Corporate Financial Services practice. Mr Coyne holds a Bachelor of Engineering degree from University College Dublin and is a Fellow of the Institute of Chartered Accountants in Ireland.

COMPENSATION OF DIRECTORS AND OFFICERS

The remuneration committee is responsible for determining the remuneration of the executive directors. The basis for the executive directors' remuneration and level of annual bonuses is determined by the remuneration committee of the board. In all cases, performance bonuses and the granting of share options are subject to stringent performance criteria. The remuneration committee consists of Dr Denis Burger (committee chairman and senior independent director), Mr Peter Coyne and Mr Ronan O'Caoimh. Directors' remuneration shown below comprises salaries, pension contributions and other benefits and emoluments in respect of executive directors. Non-executive directors are remunerated by fees and the granting of share options. Non-executive directors who perform additional services outside the normal duties of a director receive additional fees. The fees payable to non-executive directors are determined by the Board. Each director is reimbursed for expenses incurred in attending meetings of the board of directors.

Director	Salary/ Benefits	Performance related bonus	Defined contribution pension	Total 2004
	US$,000	US$'000	US$'000	US$'000
Ronan O'Caoimh	325	120	63	508
Brendan Farrell	240	73	28	341
Rory Nealon	196	23	18	237
Jim Walsh	240	48	63	351
	1,001	264	172	1,437

Non-executive director	Fees	Total 2004
	US$,000	US$'000
Denis R. Burger	28	28
Peter Coyne	28	28
	56	56

BOARD PRACTICES

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

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

The board has established audit and remuneration committees. The functions and membership of the remuneration committee is described above. The audit committee is responsible to the board for the review of the quarterly and annual reports and ensuring that an effective system of internal controls is maintained. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The audit committee comprises the two independent non-executive directors of the Company, Mr Peter Coyne (committee chairman) and Dr Denis Burger. Nasdaq Rule 4350(d)(2)(A) requires each Nasdaq-listed company to have an independent audit committee of three members. Foreign private issuers are required to comply with Nasdaq Rule 4350(d) by July 31, 2005. The audit committee of Trinity Biotech plc currently consists of only two members.

EMPLOYEES

As of December 31, 2004, Trinity Biotech had 675 employees (2003: 624) consisting of a research director and 40 research scientists and technicians, 411 manufacturing and quality assurance employees, and 223 finance, administration and marketing staff (2003: a research director and 40 research scientists and technicians, 430 manufacturing and quality assurance employees, and 153 finance, administration and marketing staff). Trinity Biotech's future hiring levels will depend on the growth of revenues.

The geographic spread of the Company's employees was as follows: 319 in Bray, Co. Wicklow, Ireland, 93 in Germany, 10 in Sweden, 5 in the United Kingdom and 248 in its US operations.

STOCK OPTION PLAN

The board of directors has adopted the Employee Share Option Plan 2003 (the "Plan"), the purpose of which is to provide Trinity Biotech's employees, consultants, officers and directors with additional incentives to improve Trinity Biotech's ability to attract, retain and motivate individuals upon whom Trinity Biotech's sustained growth and financial success depends. The Plan is administered by a compensation committee designated by the board of directors. The aggregate maximum number of 'A' Ordinary shares of Trinity Biotech available for awards under the Plan is 3,000,000 subject to adjustments to reflect changes in Trinity Biotech's capitalisation. Options under the Plan may be awarded only to employees, officers, directors and consultants of Trinity Biotech.

The exercise price of options is determined by the compensation committee. The term of an option will be determined by the compensation committee, provided that the term may not exceed seven years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity Biotech (or one year after such termination because of death or disability) except where a longer period is approved by the Board of Directors. Under certain circumstances involving a change in control of Trinity Biotech, the committee may accelerate the exercisability and termination of the options. As of February 28, 2005, 6,108,541 of the options outstanding were held by directors and officers of Trinity Biotech.

As of February 28, 2005 the following options were outstanding:

	Number of 'A' Ordinary Shares Subject to Option	Range of Exercise Price per Share
Total options outstanding	8,617,517	US$0.81-US$5.00

In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary Shares at prices ranging from $1.50 to $2.75 to agents who were involved in the Company's private placements in 1994, 1995 and 1999 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was granted to a consultant of the Company. In January 2004, the Company has completed a private placement, as part of this the investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US$5.25 per share and the agent received 200,000 warrants to purchase 200,000 Class 'A' Ordinary Shares of the Company at an exercise price of US$5.25. As of February 28, 2005 there were warrants to purchase 1,317,324 Class 'A' Ordinary Shares in the Company outstanding.

ITEM 7

MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

As of February 28, 2005 Trinity Biotech has outstanding 55,588,050 'A' Ordinary shares and 700,000 'B' Ordinary shares. Such totals exclude 9,934,841 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 28, 2005, the Trinity Biotech 'A' Ordinary Shares and 'B' Ordinary Shares beneficially held by (i) each person believed by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and officer of Trinity Biotech, and (iii) all officers and directors as a group. Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Company is not controlled by another corporation or government.

	Number of 'A' Ordinary Shares Beneficially Owned	Percentage Outstanding 'A' Ordinary Shares	Number of 'B' Ordinary Shares Beneficially Owned	Percen Outstan 'B' Ordi Sh
Ronan O'Caoimh	2,087,988(1)	3.7%	0	
Brendan Farrell	1,264,135(2)	2.2%	0	
Rory Nealon	200,000(3)	0.4%	0	
Jim Walsh	1,299,615(4)	2.3%	0	
Denis R. Burger	67,000(5)	0.1%	0	
Peter Coyne	43,333(6)	0.1%	0	
Potenza Investments, Inc ("Potenza") Statenhof Building, Reaal 2A 23 50AA Leiderdorp, Netherlands	0	0	500,000(7)	
Officers and Directors as a group (6 persons)	4,925,071(1)(2)(3)(4)(5)(6)	8.4%	0	

(1) Includes 1,217,333 shares issuable upon exercise of options.

(2) Includes 1,211,875 shares issuable upon exercise of options.

(3) Includes 200,000 shares issuable upon exercise of options.

(4) Includes 880,000 shares issuable upon exercise of options.

(5) Includes 30,000 shares issuable upon exercise of options.

(6) Includes 43,333 shares issuable upon exercise of options.

(7) Includes shares beneficially owned by SRL (350,000 'B') and Brindisi Investments Inc (150,000 'B'). SRL has previously advised Trinity Biotech that Potenza owns a majority of SRL's common stock. These 'B' shares have two votes per share.

RELATED PARTY TRANSACTIONS

The Company has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of the Company, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. It has entered into an agreement with JRJ pursuant to which the Company has taken a lease of premises adjacent to the existing facility for a term of 20 years at a rent of (euro)7.62 per square foot ("the Current Extension"). The lease commenced on the newly completed 25,000 square foot building in July 2000. The Company also envisages that a further premises may potentially be required by it and, for that purpose, has entered into a four years eleven month lease at (euro)13,000 per annum over adjacent lands with JRJ. On November 20, 2002, the Company entered into an agreement for a 25 year lease with JRJ for offices that have been constructed on part of these lands. The annual rent of (euro)381,000 (US$520,000) is payable from 2004.

Independent valuers have advised the Company that the rent fixed in respect of the Current Extension, the agreement for the lease and the lease of adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr O'Caoimh and Dr Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Company can meet its ongoing requirements for premises.

ITEM 8

FINANCIAL STATEMENTS

LEGAL PROCEEDINGS

DISPUTE REGARDING THE ACQUISITION FROM XTRANA INC
In December 2002, the Company filed an action against Xtrana Inc relating to the purchase of the Biopool business from Xtrana in 2001. The Company was seeking US$1,200,000 in damages and US$3,000,000 in punitive damages alleging breach of contract and other damages regarding the sale of an individual product line. On January 17, 2003 Xtrana countersued seeking US$57,000,000 in damages.

On June 16, 2003 Trinity Biotech and Xtrana settled this litigation. Pursuant to the terms of the settlement agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the amounts due on two promissory notes of US$1,166,000 and US$570,000, together with interest thereon as provided in the notes, less US$225,000, and less US$24,000, which represented the amount due and owing by Xtrana to Trinity Biotech as of May 31, 2003 pursuant to a letter agreement, dated December 20, 2001, between Trinity Biotech and Xtrana, relating to a third party. The total amount of the settlement payment made by Trinity Biotech to Xtrana was US$1,506,000.

The parties also agreed that, following Xtrana's receipt of the settlement payment, they would cause the litigation to be dismissed with prejudice and without costs to any party. The parties also released each other from any claims arising from or in connection with the notes due from Trinity Biotech to Xtrana, the litigation, the security agreements entered into between the parties, the asset purchase agreement made as of November 9, 2001 and any other matter whatsoever, except for the parties executory obligations as set forth in the settlement agreement.

DISPUTE REGARDING THE DISTRIBUTION AGREEMENT WITH INVERNESS MEDICAL INNOVATIONS INC
In December 2003, the Company initiated legal proceedings in the Superior Court of Middlesex County, Massachusetts against Inverness Medical and its affiliate Wampole (collectively, Defendants) for declaratory judgment, breach of contract and unfair and deceptive business practices in connection with the Defendants' performance under a distribution agreement initially entered into in 1995 by Clark Laboratories Inc (now part of the Trinity Biotech Group) and subsequently amended in 2002. Inverness Medical, through its affiliate, Wampole Laboratories, has acted as exclusive distributor for certain of Trinity Biotech's infectious disease products in the US. This exclusivity ended on September 30, 2004, at which time it had been agreed that both Trinity Biotech and Inverness Medical would sell the products under

their respective labels. Among other things, the suit requested a judgement declaring that Trinity was entitled to sell certain products directly in the US and Puerto Rico before October 1, 2004 under the terms of the 2002 amendment to the distribution agreement and due to breaches of the distribution agreement by

the Defendants. The suit also alleged that the Defendants were attempting to convert customers from Trinity's products to products manufactured by a competitor (which were modified to look like the Trinity products) by misrepresenting to the customers that the Trinity product was unavailable and was being discontinued. In January 2004, the Defendants countersued alleging, among other things, various breaches of the distribution agreement and subsequent amendments, and sought a preliminary injunction to prevent Trinity from selling directly in the Territory any of its products which are competitive with products sold by the Defendants and sourced from other suppliers. The Superior Court of Middlesex County, Massachusetts, denied this motion for a preliminary injunction on January 28, 2004. In April of 2004, Trinity amended its complaint to add additional claims alleging breaches of the distribution agreement by the Defendants. In May of 2004, the Defendants amended their counterclaims to add claims alleging, among other things, that Trinity was selling certain products without a license. Following the expiration of the Defendants' exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity moved to amend its complaint to eliminate the declaratory judgment claims and add additional claims for breach of the distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. The Defendants filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. The case is currently in the discovery phase. Please see also Item 4, "Distribution Agreement between Trinity Biotech USA and Carter Wallace".

ITEM 9 THE OFFER AND LISTING

Trinity Biotech's American Depository Shares ("ADS's") are listed on the NASDAQ Small Cap Market under the symbol "TRIB". The Company's Class B Warrant (symbol "TRIZF"), expired on February 28, 1999. Each ADS represents one 'A' Ordinary Share of the Company. The Company's 'A' Ordinary Shares are also listed and trade on the Irish Stock Exchange. The Company's depository bank for the ADS's is The Bank of New York. On February 28, 2005, the reported closing sale price of the ADS's was US$2.56 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech's ADS, and Class B Warrants for (a) the years ended December 31, 2000, 2001, 2002, 2003 and 2004; (b) the quarters ended March 31, June 30, September 30 and December 31, 2003; March 31, June 30, September 30 and December 31, 2004; and (c) the months of March, April, May, June, July, August, September, October, November and December 2004 and January and February 2005 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	ADS's	
	High	Low
YEAR ENDED DECEMBER 31		
2000	$ 7.59	$ 1.69
2001	$ 3.22	$ 0.97
2002	$ 1.86	$ 0.89
2003	$ 6.72	$ 1.25
2004	$ 5.99	$ 2.36
2003		
Quarter ended March 31	$ 2.44	$ 1.25
Quarter ended June 30	$ 3.50	$ 2.09
Quarter ended September 30	$ 4.01	$ 2.26

Quarter ended December 31	$ 6.72	$ 2.61
2004		
Quarter ended March 31	$ 5.99	$ 3.52
Quarter ended June 30	$ 3.81	$ 2.70
Quarter ended September 30	$ 3.42	$ 2.36
Quarter ended December 31	$ 3.18	$ 2.60
MONTH ENDED		
March 31, 2004	$ 4.47	$ 3.52
April 30, 2004	$ 3.81	$ 2.81
May 31, 2004	$ 3.15	$ 2.70
June 30, 2004	$ 3.62	$ 2.80
July 31, 2004	$ 3.42	$ 2.36
August 31, 2004	$ 3.10	$ 2.51
September 30, 2004	$ 3.23	$ 2.69
October 31, 2004	$ 3.18	$ 2.60
November 30, 2004	$ 3.15	$ 2.66
December 31, 2004	$ 2.99	$ 2.61
January 31, 2005	$ 3.02	$ 2.65
February 28, 2005	$ 2.83	$ 2.50

The number of record holders of Trinity Biotech's ADS's as at February 28, 2005 amounts to 1,681, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clientele (with each such brokerage house and/or clearing house being considered as one holder).

ITEM 10

MEMORANDUM AND
ARTICLES OF ASSOCIATION

OBJECTS

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

POWERS AND DUTIES OF DIRECTORS

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

A director is entitled to vote and be counted in the quorum in respect of certain arrangements in which he is interested (in the absence of some other material interest). These include the giving of a security or indemnity to him

in respect of money lent or obligations incurred by him for the Company, the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company for which he has assumed responsibility, any proposal concerning an offer of shares or other securities in which he may be interested as a participant in the underwriting or sub-underwriting and any proposal concerning any other company in which he is interested provided he is not the holder of or beneficially interested in 1% or more of the issued shares of any class of share capital of such company or of voting rights.

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

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

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

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

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

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

One third of the directors other than an executive director or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at each annual general meeting. If, however, the number of directors subject to retirement by rotation is two, one of such directors shall retire. If the number is one, that director shall

retire. The directors to retire at each annual general meeting shall be the ones who have been longest in office since their last appointment. Where directors are of equal seniority, the directors to retire shall, in the absence of agreement, be selected by lot. A retiring director shall be eligible for re-appointment and shall act as director throughout the meeting at which he retires. A separate motion must be put to a meeting in respect of each director to be appointed unless the meeting itself has first agreed that a single resolution is acceptable without any vote being given against it.

The Company may, subject to the provisions of the Companies Acts, 1963 to 2003 of Ireland, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution. Before recommending a dividend, the directors may reserve out of the profits of the Company such sums as they think proper which shall be applicable for any purpose to which the profits of the Company may properly be applied and, pending such application, may be either employed in the business of the Company or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

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

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

ACTION NECESSARY TO CHANGE THE RIGHTS OF SHAREHOLDERS

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

CALLING OF AGM'S AND EGM'S OF SHAREHOLDERS

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in Ireland unless all of the members entitled to attend and vote at it consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time

call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2003 of Ireland. In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days notice of the meeting is required and in any other case it is seven clear days notice. Notice must be given in writing to all members and to the auditors and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain

circumstances provided in the Companies Acts, 1963 to 2003 of Ireland, extended notice is required. These include removal of a director. No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum. The Company is not obliged to serve notices upon members who have addresses outside Ireland and the US but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in the Company.

However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in "Exchange Controls" below. In addition, Irish competition law may restrict the acquisition by a party of shares in the Company but this does not apply on the basis of nationality or residence.

OTHER PROVISIONS OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION
The Memorandum and Articles of Association do not contain any provisions:

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

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

IRISH LAW

Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept at the registered office of the company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper books of account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the company (new share capital issues, changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office (the "CRO") in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the company carrying the right of voting at general meetings of the company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the company. Any shareholder who complains that the affairs of the company are being conducted or that the powers of the directors of the company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as

shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the company.

Ordinarily, our directors owe their duties only to Trinity Biotech and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to Trinity Biotech. Those duties include duties to act in good faith towards Trinity Biotech in any transaction, not to make use of any money or other property of Trinity Biotech, not to gain directly or indirectly any improper advantage for himself at the expense of Trinity Biotech, to act bona fide in the interests of Trinity Biotech and exercise powers for the proper purpose. A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. When directors, as agents in transactions, make contracts on

behalf of the company, they generally incur no personal liability under these contracts. It is Trinity Biotech, as principal, which will be liable under them, as long as the directors have acted within Trinity Biotech's objects and within their own authority. A director who commits a breach of his fiduciary duties shall be liable to Trinity Biotech for any profit made by him or for any damage suffered by Trinity Biotech as a result of the breach. In addition to the above, a breach by a director of his duties may lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to Trinity Biotech for profit made and restriction of the director from acting as a director in the future.

MATERIAL CONTRACTS

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

EXCHANGE CONTROLS AND OTHER LIMITATIONS AFFECTING SECURITY HOLDERS

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

The Financial Transfers Act, 1992 was enacted in December 1992. This Act gives power to the Minister of Finance of the Republic of Ireland to make provision for the restriction of financial transfers between the Republic of Ireland and other countries. Financial transfers are broadly defined and include all transfers, which would be movements of funds within the meaning of the treaties governing the European Communities. The acquisition or disposal of ADS's representing shares issued by an Irish incorporated company and associated payments may fall within this definition. In addition, dividends or payments on redemption or purchase of shares, interest payments, debentures or other securities in an Irish incorporated company and payments on a liquidation of an Irish incorporated company would fall within this definition. Currently, orders under this Act prohibit any financial transfer to or by the order of or on behalf of residents of the Federal Republic of Yugoslavia, Federal Republic of Serbia, Angola and Iraq, any financial transfer in respect of funds and financial resources belonging to the Taliban of Afghanistan (or related terrorist organisations), financial transfers to the senior members of the Zimbabwean government and financial transfers to any persons, groups or entities

listed in EU Council Decision 2002/400/EC of June 17, 2002 unless permission for the transfer has been given by the Central Bank of Ireland.

Trinity Biotech does not anticipate that Irish exchange controls or orders under the Financial Transfers Act, 1992 will have a material effect on its business.

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

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

TAXATION

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

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

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

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

US FEDERAL INCOME TAX CONSEQUENCES TO US HOLDERS

The following is a summary of the material US federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADRs, in the case of a purchaser of such ADRs who is a US Holder (as defined below) and who holds the ADRs as capital assets. This summary is based on the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. For the purposes of

this summary, a US Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organised in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to US federal income tax regardless of its source; or a trust that (a) is subject to the primary supervision of a court within the United States and the control of one or more US persons or (b) has a valid election in effect under applicable US Treasury regulations to be treated as a US person.

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

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

Subject to complex limitations, any Irish withholding tax imposed on such dividends will be a foreign income tax eligible for credit against a US Holder's US federal income tax liability (or, alternatively, for deduction against income in determining such tax liability). The limitations set out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the US federal income taxes otherwise payable with respect to each such class of income. Dividends generally will be treated as foreign-source passive income or, in the case of certain US Holders, financial services income for US foreign tax credit purposes. US Holders should note that recently enacted legislation eliminates the "financial services income" category with respect to taxable years beginning after December 31, 2006. Under this legislation, the foreign tax credit limitation categories will be limited to "passive category income" and "general category income." Further, there are special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to a reduced tax, see discussion below. A US Holder will be denied a foreign tax credit with respect to Irish income tax withheld from dividends received on the ordinary shares to the extent such US Holder has not held the ordinary shares for at least 16 days of the 30-day period beginning on the date which is 15 days before the ex-dividend date or to the extent such US Holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a US Holder has substantially diminished its risk of loss on the ordinary shares are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex, and you should consult with your personal tax advisors to determine whether and to what extent you would be entitled to this credit.

Subject to certain limitations, "qualified dividend income" received by a noncorporate US Holder in tax years beginning on or before December 31, 2008 will be subject to tax at a reduced maximum tax rate of 15%. Distributions taxable as dividends paid on the ordinary shares should qualify for the 15% rate provided that either: (i) we are entitled to benefits

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

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

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

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

ordinary income rather than as capital gain. Finally, the 15% reduced US federal income tax rate otherwise applicable to dividend income as discussed above, will not apply to any distribution made by Trinity Biotech in any taxable year in which it is a PFIC (or made in the taxable year following any such year), whether or not the distribution is an "excess distribution".

For US federal income tax purposes, a foreign corporation is treated as a "foreign personal holding company" (or FPHC) in any taxable year in which (i) five or fewer individuals who are citizens or residents of the United States own directly or by attribution more than 50%, by vote or value, of the shares of the corporation and (ii) at least 60% of the corporation's gross income consists of foreign personal holding company income. Based on the composition of its share ownership and the nature of its business operations and gross income at the present time, Trinity Biotech believes that it was not subject to treatment as an FPHC for 2004.

If Trinity Biotech were classified as a FPHC, each US Holder of Trinity Biotech ADRs on the last day of any taxable year in which Trinity Biotech is a FPHC would have to include in the holder's gross income for that year the holder's pro rata share of Trinity Biotech's "undistributed foreign personal holding company income." The amount so included would not qualify for taxation at the 15% reduced tax rate applicable to dividend income, and thus would be subject to US federal income tax at regular ordinary income rates. If Trinity Biotech were to distribute in a subsequent tax year any

undistributed foreign person holding company income so taxed, the amount so distributed would not be counted as part of an "excess distribution" under the PFIC rules discussed above.

The FPHC rules are repealed for tax years beginning after December 31, 2004.

For US federal income tax purposes, a foreign corporation is treated as a "controlled foreign corporation" (or CFC) in any taxable year in which one or more US Shareholders, each of whom owns (directly or by attribution) at least 10% of the voting power of all classes of the corporation's stock (a "US Ten-Percent Shareholder"), own, in the aggregate, more than 50% of the corporation's stock, by vote or value.

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

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

Distributions made with respect to underlying shares represented by ADRs may be

subject to information reporting to the US Internal Revenue Service and to US backup withholding tax at a rate equal to the fourth lowest income tax rate applicable to individuals (which, under current law, is 28%). Backup withholding will not apply, however, if the holder (i) is a corporation or comes within certain exempt categories, and demonstrates its eligibility for exemption when so required, or (ii) furnishes a correct taxpayer identification number and makes any other required certification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a US Holder's US tax liability, and a US Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service.

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

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

REPUBLIC OF IRELAND TAXATION

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

For Irish taxation purposes, Irish Holders of ADSs will be treated as the owners of the underlying ordinary shares represented by such ADSs.

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

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

Corporate Irish Holders will generally be entitled to claim an exemption from DWT by delivering a declaration to us in the form prescribed by the Irish Revenue Commissioners. Such corporate Irish Holders will generally not otherwise be subject to Irish tax in respect of dividends received.

Individual Irish Holders will be subject to income tax on the gross amount of any dividend (that is the amount of the dividend received plus any DWT withheld), at their marginal rate of tax (currently either 20% or 42% depending on the individual's circumstances). Individual Irish Holders will be able to claim a credit against their resulting income tax liability in respect of DWT withheld.

Individual Irish Holders may, depending on their circumstances, also be subject to the Irish health levy of 2% and pay related social insurance contribution of up to 3% in respect of their dividend income.

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

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

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

Special DWT arrangements are available in the case of shares held by US resident holders in Irish companies through American depository banks using ADRs who enter into intermediary agreements with the Irish Revenue Commissioners. Under such agreements, American depository banks who receive dividends from Irish companies and pay the dividends on to the US resident ADR holders are allowed to receive and pass on a dividend from the Irish company on a gross basis (without any withholding) if:

- the depository bank's ADR register shows that the direct beneficial owner has a US address on the register, or
- there is an intermediary between the depository bank and the beneficial shareholder and the depository bank receives confirmation from the intermediary that the beneficial shareholder's address in the intermediary's records is in the US.

Where the above procedures have not been complied with and DWT is withheld from dividend payments to US Holders of ordinary shares or ADSs evidenced by ADRs, such US Holders can apply to the Irish Revenue Commissioners claiming a full refund of DWT paid by filing a declaration, a certificate of residency and, in the case of US Holders that are corporations, an auditor's certificate, each in the form prescribed by the Irish Revenue Commissioners.

The DWT rate applicable to US Holders is reduced to 5% under the terms of the Treaty for corporate US Holders holding 10% or more of our voting shares, and to

15% for other US Holders. While this will, subject to the application of Article 23 of the Treaty, generally entitle US Holders to claim a partial refund of DWT from the Irish Revenue Commissioners, US Holders will, in most circumstances, likely prefer to seek a full refund of DWT under Irish domestic legislation.

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

- an individual resident in the US (or certain other countries with which Ireland has a double taxation treaty) and who is neither resident nor ordinarily resident in Ireland; or
- a corporation that is not resident in Ireland and which is ultimately controlled by persons resident in the US (or certain other countries); or
- a corporation that is not resident in Ireland and whose principal class of shares (or its 75% parent's principal class of shares) are substantially or regularly traded on a recognised stock exchange; or
- is otherwise entitled to an exemption from DWT.

Disposals of Ordinary Shares or ADRs

Irish Holders that acquire ordinary shares or ADRs will generally be considered, for Irish tax purposes, to have acquired their ordinary shares or ADRs at a base cost equal to the amount paid for the ordinary shares or ADRs. On subsequent dispositions, ordinary shares or ADRs acquired at an earlier time will generally be deemed, for Irish tax purposes, to be disposed of on a "first in first out" basis before ordinary shares or ADRs acquired at a later time.

Irish Holders that dispose of their ordinary shares or ADRs will be subject to Irish capital gains tax (CGT) to the extent that the proceeds realised from such disposition exceed the indexed base cost of the ordinary shares or ADRs disposed of and any incidental expenses. The current rate of CGT is 20%. Indexation of the base cost of the ordinary shares or ADRs will only be available up to December 31, 2002, and only in respect of ordinary shares or ADRs held for more than 12 months prior to their disposal.

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

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

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

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

future years.

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

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

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

A gift or inheritance of ordinary shares or ADRs will be within the charge to capital acquisitions tax, regardless of where the disponer or the donee/successor in relation to the gift/inheritance is domiciled, resident or ordinarily resident. The capital acquisitions tax is charged at a rate of 20% on the taxable value of the gift or inheritance above a tax-free threshold. This tax-free threshold is determined by the amount of the current benefit and of previous benefits, received

within the group threshold since December 5, 1991, which are within the charge to the capital acquisitions tax and the relationship between the former holder and the successor. Gifts and inheritances between spouses are not subject to the capital acquisitions tax. Gifts of up to (euro)3,000 can be received each year from any given individual without triggering a charge to capital acquisitions tax. Where a charge to Irish CGT and capital acquisitions tax arises on the same event, capital acquisitions tax payable on the event can be reduced by the amount of the CGT payable.

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

Irish stamp duty, which is a tax imposed on certain documents, is payable on all transfers of ordinary shares (other than transfers made between spouses, transfers made between 90% associated companies, or certain other exempt transfers) regardless of where the document of transfer is executed. Irish stamp duty is also payable on electronic transfers of ordinary shares.

A transfer of ordinary shares made as part of a sale or gift will generally be stampable at the ad valorem rate of 1% of the value of the consideration received for the transfer, or, if higher, the market value of the shares transferred. A minimum stamp duty of (euro)1.00 will apply to a transfer of ordinary shares. Where the consideration for a sale is expressed in a currency other than Euro, the duty will be charged on the Euro equivalent calculated at the rate of exchange prevailing at the date of the transfer.

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

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

Transfers of ordinary shares from the Depositary or the Depositary's custodian upon surrender of ADRs for the purposes of withdrawing the underlying ordinary shares from the ADS/ADR system, and transfers of ordinary shares to the Depositary or the Depositary's custodian for the purposes of transferring ordinary shares onto the ADS/ADR system, will be stampable at the ad valorem rate of 1% of the value of the shares transferred if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of ordinary shares. Such transfers will be exempt from Irish stamp duty if the transfer does not relate to or involve any change in the beneficial ownership in the underlying ordinary shares and the transfer form contains the appropriate certification. In the absence of an appropriate certification, stamp duty will be applied at the nominal rate of (euro)12.50.

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

DIVIDEND POLICY

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

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

ITEM 11
QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

QUALITATIVE INFORMATION ABOUT MARKET RISK

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

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

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

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

The Company borrows in appropriate currencies at fixed and floating rates of interest. Year-end borrowings, net of cash, totalled US$1,723,000 (2003: US$5,707,000) at interest rates ranging from 3% to 5.5% and including US$16,680,000 of fixed rate debt at interest rates ranging from 3% to 5.50% (2003: US$14,135,000 at interest rates ranging from 5% to 7.50%). In broad terms, a one-percentage point increase in interest rates would decrease the net interest charge by US$150,000 (2003: decrease by US$83,000).

Long-term borrowing requirements are met by funding in the US and Ireland. Short-term borrowing requirements are primarily drawn under committed bank facilities. At the year-end, 46% of gross debt fell due for repayment within one year.

A significant portion of the Company's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Company's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Company pursues a treasury policy which aims to sell US Dollars forward to match a portion of the uncovered Euro expenses at exchange rates lower than budgeted exchange rates. The Company's current hedging policy is to cover forward a portion of its exposure for a minimum of three months. Under US GAAP, US$126,000 was recognised in the income statement in respect of gains on the fair value of derivative instruments (2003: US$68,000). Given the recent weakening of the US Dollar, the Company's objective is to mitigate this exposure by increasing the level of Euro denominated sales and the Company anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Company had foreign currency denominated cash balances equivalent to US$874,000 at December 31, 2004.

QUANTITATIVE INFORMATION ABOUT MARKET RISK

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

The Company estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Company is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be an increase in profit before tax for 2004 of less than 3%.

The table below provides information about the Company's long term debt obligations that are sensitive to changes in interest rates. The table presents principal cash flows and related weighted average interest rates by expected maturity dates. Weighted average variable rates are based on rates set at the balance sheet date. The information is presented in US Dollars, which is the Company's reporting currency. The actual currencies of the instruments are as indicated.

MATURITY AFTER FAIR

BEFORE DECEMBER 31	2006	2007	2008	2009	2010	TOTAL	VALUE*
LONG-TERM DEBT							
Variable rate - US$000	1,176	1,176	1,175	-	-	3,527	3,527
Average interest rate	3.37%	3.37%	3.37%	3.37%		3.37%	
Fixed rate - US$000	7,558	1,660	177	2	-	9,396	9,396
Average interest rate	3.06%	3.21%	4.79%	5.0%	-	3.12%	

*Represents the net present value of the expected cash flows discounted at current market rates of interest which approximate the total average interest rates.

EXCHANGE RATE SENSITIVITY

At year-end 2004, approximately 11% of the Company's US$116,138,000 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the Euro.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Company operates would not materially reduce the Company's 2004 year-end net worth.

ITEM 12

DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

PART II

ITEM 13

DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14

MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15

CONTROL AND PROCEDURES

During the annual report period, we carried out an evaluation, under the supervision and with the participation of our senior management, including Chief Executive Officer, Ronan O'Caoimh, and Chief Financial Officer, Rory Nealon, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13(a)-14(c) of the Securities Exchange Act of 1934. Disclosure controls and procedures are designed to ensure that the material financial and non-financial information required to be disclosed in this Form 20-F filed with the SEC is recorded, processed, summarised and reported timely. In designing and evaluating the disclosure controls and procedures, management recognised that any controls and procedures, no matter how well designed and operated, can provide only reasonable, rather than absolute, assurance of achieving the desired control objectives, and management necessarily was required to apply its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures, are effective in timely alerting them to material information relating to us required to be included in the our periodic SEC filings, except as indicated below.

During the audit of the 2004 financial statements the Company's auditors identified a material weakness relating to the Company's interpretation and

appropriate application of generally accepted accounting principles. Two of the more significant examples of which are described below.

- The inappropriate recognition of revenue on a bill and hold arrangement with a customer who was arranging their own courier to collect the goods. While the Company followed its own internal procedures in this regard these procedures did not address all of the criteria necessary to permit the recognition of revenue in this instance as outlined in SAB 104. These procedures are being amended to include requirements to ensure that in such cases fixed delivery schedules are provided by customers and to consider further the basis for bill and hold customer requests.

- In response to market forces existing in some jurisdictions the Company in certain circumstances sells instruments to customers at a price which is less than manufacturing cost with a view to recouping those initial discounts from the future sale of reagents and consumables which can only be utilised on those instruments. The Company's original interpretation of Irish GAAP determined that it was appropriate to defer these initial discounts with a plan to amortise over a three year period being reflective of the period over which the Company anticipates the sale of such reagents and consumables. The auditors concluded that the discounts deferred did not meet the definition of an asset.

As part of the process to design its program for complying with Section 404 of the Sarbanes Oxley Act of 2002 the Company will evaluate and enhance its procedures where the interpretation of GAAP is involved and will expand its external consultative process in advance of implementing new accounting procedures. The interpretation issues have been accounted for correctly in the preparation of the financial statements set out in Item 18.

Except for the matters referred to above, there have been no significant changes in our internal controls over financial reporting or other factors, which could significantly affect internal controls over financial reporting subsequent to the date of the evaluation.

ITEM 16

AUDIT COMMITTEE FINANCIAL EXPERT

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

CODE OF ETHICS

We have adopted a code of ethics for executive and financial officers, a code of ethics that applies to our chief executive officer, chief financial officer, corporate controller and other finance organisation employees. Written copies of the code of ethics are available free of charge upon request. If we make any substantive amendments to the code of ethics or grant any waivers, including any implicit waiver, from a provision of these codes to our chief executive officer, chief financial officer or corporate controller, we will disclose the nature of such amendment or waiver on our website.

PRINCIPAL ACCOUNTING FEES AND SERVICES

Fees Paid to Independent Public Accountants
The following table sets forth, for each of the years indicated, the fees paid

to our independent public accountants and the percentage of each of the fees out of the total amount paid to the accountants.

	YEAR ENDED DECEMBER 31,			
	2003		2004	
SERVICES RENDERED	FEES	PERCENTAGES	FEES	PERCENTAGES
	(US$'000)		(US$'000)	
Audit	421	66%	419	91%
Audit-related	*209	33%	25	5%
Tax	5	1%	17	4%
Other	-		-	
Total	635		461	

* includes capitalised costs of acquisition and costs of finance relating to fundraising activities.

PRE-APPROVAL POLICIES AND PROCEDURES

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

EXEMPTIONS FROM THE LISTING REQUIREMENTS AND STANDARDS FOR AUDIT COMMITTEE

Not applicable.

PURCHASE OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATES AND PURCHASERS

The following table sets forth, for each of the months indicated, the total number of shares purchased by us or on our behalf or any affiliated purchaser, the average price paid per share, the number of shares purchased as part of a publicly announced repurchase plan or program, the maximum number of shares or approximate US Dollar value that may yet be purchased under the plans or programs.

TOTAL NUMBER OF

PERIOD IN 2004	TOTAL NUMBER OF SHARES PURCHASED	AVERAGE PRICE PAID PER SHARE	SHARES PURCHASED AS PART OF PUBLICLY ANNOUNCED PLANS OR PROGRAMS	MAXIMUM SHARES T BE PURCH THE PLANS
January	-	-	-	
February	-	-	-	
March	-	-	-	
April	-	-	-	
May	-	-	-	
June	-	-	-	
July	-	-	-	
August	-	-	-	
September	-	-	-	
October	-	-	-	
November	-	-	-	
December	-	-	-	

PART III

ITEM 17

FINANCIAL STATEMENTS

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

ITEM 18

FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To: The Board of Directors of Trinity Biotech plc

We have audited the accompanying consolidated balance sheets of Trinity Biotech plc ("the Company") as of December 31, 2004 and 2003, and the related consolidated statements of income, total recognised gains and losses, movement in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule included at Item 18. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with Auditing Standards issued by the Auditing Practices Board for use in Ireland and standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Trinity Biotech plc at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the Republic of Ireland, which differ in certain respects from U.S. generally accepted accounting principles (see note 25 of Notes to the Consolidated Financial Statements). Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Dublin, Ireland
March 30, 2005

Ernst & Young

CONSOLIDATED BALANCE SHEETS

	Notes	As at December 31 2004	As at December 31 2003
		US$'000	US$'000
ASSETS			
Inventories	2	37,519	30,555
Accounts receivable, net and prepayments	3	15,880	13,913
Cash and cash equivalents		22,287	20,562
		75,686	65,030
Intangible assets, net	4	57,870	38,851
Property, plant and equipment, net	5	15,942	13,660
Other assets	3	1,330	550
TOTAL ASSETS		150,828	118,091
LIABILITIES & SHAREHOLDERS' EQUITY			
Accounts payable and accrued expenses	6	20,260	19,401
Provisions for liabilities and charges (deferred tax)	8	1,311	911
Long-term liabilities	7	13,119	17,517
SHAREHOLDERS' EQUITY			
Called up share capital			
Class 'A' Ordinary shares	9	764	658
Class 'B' Ordinary shares	9	12	12
Share premium account		120,444	87,596
Currency adjustment		(3,975)	(4,091)
Profit and loss reserve	11	997	(4,169)
Other reserves		(2,104)	256
SHAREHOLDERS' EQUITY - (all equity interests)		116,138	80,262
Total Liabilities and Shareholders' Equity		150,828	118,091

See Notes to the Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF INCOME

	Notes	Year ended December 31 2004	2003	
		US$'000	US$'000	U
Revenues				
- Continuing operations		72,896	65,675	
- Acquisitions	19	7,048	-	
	12	79,944	65,675	
Cost of sales		(39,688)	(32,877)	
Gross profit		40,256	32,798	
Research and development expenses		(4,641)	(5,210)	
Administrative expenses		(29,874)	(17,919)	
Operating profit				
- Continuing operations		4,632	9,669	
- Acquisitions		1,109	-	
	12	5,741	9,669	
Interest receivable and similar income		302	173	
Interest payable and similar charges	12	(824)	(792)	
Profit on ordinary activities before taxation and share of operating loss in associate company and impairment		5,219	9,050	
Share of operating loss in associate company and impairment	13	-	(1,067)	
Profit on ordinary activities before taxation	13	5,219	7,983	
Tax on profit on ordinary activities	14	(53)	(2,186)	
Retained profit for the financial period		5,166	5,797	
Basic earnings per ordinary share (US Dollars)	15	0.09	0.13	
Diluted earnings per ordinary share (US Dollars)	15	0.09	0.12	

Movements on reserves are shown in the "Consolidated Statements of Movement in Shareholders' Equity".

CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES

	Year ended December
2004	2003

	US$'000	US$'000	U
Profit for the financial period attributable to company shareholders excluding share of operating loss in associate company and impairment	5,166	6,864	
Share of operating loss in associate company and impairment	-	(1,067)	
Currency adjustment	116	175	
Total recognised gains and losses for the period	5,282	5,972	

See Notes to the Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF MOVEMENT IN SHAREHOLDERS' EQUITY

	Class 'A' Ordinary Shares		Class 'B' Ord
	Number of shares	Share capital US$0.0109 each	Number of shares
		US$'000	
Authorised	75,000,000	817	700,000
Issued:			
Balance as at December 31, 2001	39,016,746	591	700,000
Shares issued for cash	443,900	5	-
Options exercised	12,334	- (*)	-
Class 'A' shares issued for financial asset	156,189	2	-
Share issue expenses	-	-	-
Currency adjustment	-	-	-
Retained profit	-	-	-
Stock compensation	-	-	-
Balance as at December 31, 2002	39,629,169	598	700,000
Shares issued for cash	10,279	- (*)	-
Options and warrants exercised	1,397,717	15	-
Class 'A' shares issued on conversion of debentures	4,123,475	45	-
Share issue expenses	-	-	-
Currency adjustment	-	-	-
Retained profit	-	-	-
Stock compensation	-	-	-
Balance as at December 31, 2003	45,160,640	658	700,000

Options and warrants exercised	1,113,538	12	-
Class 'A' shares issued on conversion of debenture	120,423	1	-
Class 'A' shares issued in private placing	5,725,733	63	-
Class 'A' shares issued to fund acquisition	2,783,984	30	-
Share issue expenses	-	-	-
Currency adjustment	-	-	-
Retained profit	-	-	-
Stock compensation	-	-	-
Issued share capital unpaid (note 9(g))	-	-	-
Balance as at December 31, 2004	54,904,318	764	700,000

	Retained profit	Currency adjustment	Goodwill reserve	r
	US$'000	US$'000	US$'000	U
Authorised				
Issued:				
Balance as at December 31, 2001	6,913	(4,622)	(21,777)	
Shares issued for cash	-	-	-	
Options exercised	-	-	-	
Class 'A' shares issued for financial asset	-	-	-	
Share issue expenses	-	-	-	
Currency adjustment	-	356	-	
Retained profit	4,897	-	-	
Stock compensation	-	-	-	
Balance as at December 31, 2002	11,810	(4,266)	(21,777)	
Shares issued for cash	-	-	-	
Options and warrants exercised	-	-	-	
Class 'A' shares issued on conversion of debentures	-	-	-	
Share issue expenses	-	-	-	
Currency adjustment	-	175	-	
Retained profit	5,798	-	-	
Stock compensation	-	-	-	
Balance as at December 31, 2003	17,608	(4,091)	(21,777)	
Options and warrants exercised	-	-	-	
Class 'A' shares issued on conversion of debenture	-	-	-	
Class 'A' shares issued in private placing	-	-	-	
Class 'A' shares issued to fund acquisition	-	-	-	
Share issue expenses	-	-	-	
Currency adjustment	-	116	-	
Retained profit	5,166	-	-	
Stock compensation	-	-	-	
Issued share capital unpaid (note 9(g))	-	-	-	

Balance as at December 31, 2004	22,774	(3,975)	(21,777)	

(*) Amount less than US$1,000

See Notes to Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year 2004
		US$'000
Net cash inflow from operating activities	17	2,348
Returns on investments and servicing of finance		
Interest received		291
Interest paid		(884)
Finance interest paid		(47)
Net cash outflow from returns on investments and servicing of finance		(640)
Taxation		
Taxation (paid)		(1,666)
Capital expenditure and financial investment		
Purchase of tangible fixed assets	16	(3,689)
Disposal/ retirement of fixed assets		31
Purchase of intangible fixed assets		(3,295)
Net cash outflow from investing activities		(6,953)
Acquisitions and disposals		
Payments to acquire trades or businesses		(19,090)
Deferred consideration paid		-
Net cash outflow from acquisitions and disposals		(19,090)
Net cash outflow before use of liquid resources and financing		(26,001)
Management of liquid resources	16	2,158
Financing		
Repayment of loan from unconnected third party		-
Repayment of minority interest		-

Issue of shares		31,708
Expenses paid in respect of share issues and debt financing		(2,238)
Movement in finance leases		(267)
(Decrease)/ increase in long term debt		(2,214)
(Decrease)/ increase in other financial liabilities		(2,675)
Issue of convertible debentures, net		3,178
Net cash inflow from financing		27,492
Increase/ (decrease) in cash		3,649
Reconciliation of net cash flow to movement in net debt		
Increase/ (decrease) in cash in the year		3,649
Decrease/ (increase) in long term debt		2,214
Decrease/ (increase) in other financial liabilities		2,675
Issue of convertible debentures, net		(3,178)
(Decrease)/ increase in liquid resources		(2,158)
Decrease in finance leases		267
Expenses paid in respect of debt financing		251
Change in net debt resulting from cash flows		3,720
New finance leases		-
Finance leases acquired		-
Conversion of debentures		427
Exchange movements on net debt		(79)
Non cash exchange movement		233
(Release)/ deferral of debt issue costs		(317)
		264
Movement in net debt in the year		3,984
Net debt at January 1		(5,707)
Net debt at December 31	18	(1,723)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2004

1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

The consolidated financial statements have been prepared in United States Dollars under the historical cost convention and are in accordance with accounting principles generally accepted in Ireland.

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

(a) Basis of Consolidation

The consolidated financial statements include the financial statements of Trinity Biotech plc ("Trinity Biotech" and/or "the Company") and its subsidiary and associated undertakings in Ireland, the United States, the United Kingdom, Sweden and Germany made up to the end of the

financial year. Where a subsidiary undertaking or interest in an associated undertaking is acquired during the financial year the Group financial statements include the attributable results from the date of acquisition up to the end of the financial year. All inter-company transactions and balances have been eliminated in the preparation of these consolidated financial statements. Associated undertakings are consolidated using the equity method of accounting.

(b) Goodwill

With effect from January 1, 1998, goodwill arising on consolidation (representing the excess of the fair value of consideration over the fair value of the separable net assets acquired), at the date of acquisition of subsidiary and associated undertakings, is capitalised in the balance sheet and amortised over an appropriate period. Goodwill arising prior to that date was written-off against reserves and has not been reinstated in the Group balance sheet.

(c) Tangible Fixed Assets

Tangible fixed assets are stated at cost less accumulated depreciation. Depreciation is provided on a straight line basis to write off the cost of the assets over their expected useful lives as follows:

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

The carrying value of tangible assets is reviewed for impairment if events or changes in circumstances indicate that the carrying value may not be recoverable. Impairment is assessed by comparing the carrying value of an asset with its recoverable amount (being the higher of net realisable value and value in use). Net realisable value is defined as the amount at which an asset could be disposed of net of any direct selling costs. Value in use is defined as the present value of the future cash flows obtainable through continued use of an asset including those anticipated to be realised on its eventual disposal.

(d) Intangible Assets

Patents and licences are stated at cost and are amortised over the lesser of their expected useful lives or their statutory lives which range between 6 and 15 years. Certain trade names acquired are deemed to have an indefinite useful life. The carrying value of intangibles is reviewed annually by the directors to determine whether there should be a reduction to reflect any impairment in value.

Research and development expenditure is written-off 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, 15 years. With effect from January 1, 1998, goodwill on acquisition of businesses and product lines is capitalised in the balance sheet and is amortised over a period of 20 years. Negative goodwill is included in intangible assets and is to be released over the period of release of the related non-monetary assets. This is also subject to an annual impairment review by the directors and any diminution in value is immediately taken to the profit and loss account.

(e) Inventories

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

(f) Taxation

Taxation, which is based on the results for the year, is reduced where appropriate by manufacturing companies' relief. Deferred taxation, the estimated future tax consequences of transactions and events recognised in the financial statements of the current and previous years, is provided on all material timing differences using the tax rates substantively enacted at the balance sheet date which are expected to apply in the periods in which the

timing differences are expected to reverse. Timing differences between the Group's taxable profits and its results as stated in the financial statements arise from the inclusion of gains and losses in tax assessments in periods different from those in which they are recognised in the financial statements. Deferred tax is measured on a non-discounted basis. Deferred tax assets are recognised to the extent that the directors consider that it is more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

(g) Sales and Revenue Recognition

Sales of products are recorded as of the date of shipment. Sales represent the value of goods supplied to external customers and exclude sales taxes and discounts.

(h) Pension Costs

The Group operates a defined contribution pension scheme. Contributions to the scheme are expensed as incurred.

(i) Leases

Where tangible assets are financed by leasing agreements which give rights approximating to ownership ("finance leases"), they are treated as if they had been purchased outright at the present values of the minimum lease payments; the corresponding obligations are shown in the balance sheet as obligations under finance leases. The present value of the minimum payments under a lease is derived by discounting those payments at the interest rate implicit in the lease, and is normally the price at which the asset could be acquired in an arm's length transaction.

Amortisation is calculated in order to write-off the amounts capitalised over the estimated useful lives of the assets by equal annual instalments. The excess of the total rentals under a lease over the amount capitalised is treated as interest, which is charged to the income statement in proportion to the amount outstanding under the lease.

Leases other than finance leases are classified as "operating leases", and the rentals thereunder are charged to the income statement on a straight line basis over the periods of the leases.

(j) Government Grants
Research and development, employment and training grants are credited to the income statement against related expenditure in the period in which the expenditure is incurred.

(k) Foreign Currency
A majority of the revenue of the Company and its subsidiaries is generated in US Dollars. The Company's management believes that the US dollar is the primary currency of the economic environment in which the Company and its subsidiaries (with the exception of the Company's subsidiaries in Germany and Sweden) principally operate. Thus the functional currency of the Company and its subsidiaries (other than those in Germany and Sweden) is the US Dollar. The functional currency of the German and Swedish subsidiaries is the Euro and the Swedish Kroner respectively. The reporting currency of the Company is the US Dollar.

Results and cash flows of subsidiary undertakings, which have a functional currency other than the US Dollar, are translated into US Dollars at average exchange rates for the year, and the related balance sheets have been translated at the rates of exchange ruling on the balance sheet date. Adjustments arising on translation of the results of these subsidiary undertakings and on restatement of the opening net assets at closing rates, are dealt with in reserves.

Foreign currency transactions are translated at the rates of exchange ruling at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the rates of exchange ruling at the balance sheet date. The resulting gains and losses are included in the income statement.

(l) Liquid Resources
Liquid resources are current asset investments, which are held as readily disposable stores of value. Liquid resources comprise short term deposits.

(m) Use of Estimates
The preparation of financial statements in conformity with accounting principles generally accepted in the Republic of Ireland requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from these estimates.

(n) Companies Acts, 1963 to 2003
The financial information relating to the Company and its subsidiaries included in this document does not comprise full group accounts as referred to in Regulation 40 of the European Communities (Companies: Group Accounts) Regulations 1992, copies of which are required by that Act to be annexed to the Company's annual return. The auditors have made reports without qualification under Section 193 of the Companies Act,

1990 in respect of the group financial statements for the years ended December 31, 2003 and 2002. Copies of full group accounts for each of the years ended December 31, 2003 and 2002 have been annexed together to the relevant annual returns, and a copy of the full group accounts for the year ended December 31, 2004 together with the report of the auditors thereon will in due course be annexed to the relevant annual return, which will be filed after the annual general meeting of the

Company in 2005.

(o) Cost of Sales
Cost of sales comprises the product cost including shipping, handling and packaging costs.

(p) Provision for Bad Debts
The Group sells its products to companies in various markets throughout the world. The Group maintains reserves for potential credit losses. To date such losses have been within management's expectations. The Group had an allowance for doubtful accounts of approximately US$462,000, US$478,000, and US$496,000 as at December 31, 2004, 2003 and 2002, respectively.

(q) Financial Instruments
Financial instruments include (i) borrowings; (ii) cash deposits and liquid resources; and, (iii) interest and forward contracts. Derivatives, principally forward foreign exchange contracts, are used to manage the working capital requirements of the Group in a cost effective, low-risk manner. Working capital management is a key element in the effective management of overall liquidity. Where derivatives are used to hedge cross-currency cash flows arising from trading activities, the underlying transaction is ultimately recorded at the contract rate upon settlement.

(r) Employee Stock Compensation
Options may be issued to employees to purchase ordinary shares with exercise prices which are less than the market value of the ordinary shares at the date of grant. In such cases the excess of the market value over the exercise price for the total number of options so issued is treated as compensation expense and recorded in the consolidated statements of income over the vesting period, with an appropriate credit to other reserves.

2. INVENTORIES

	December 31 2004	December 31 2003
	US$'000	US$'000
Raw materials	9,239	11,713
Work-in-progress	10,520	9,207
Finished goods	17,760	9,635
	37,519	30,555

The replacement cost of inventory is not materially different from the cost stated above.

3. ACCOUNTS RECEIVABLE AND PREPAYMENTS (Amounts falling due within one year)

	December 31 2004	December 31 2003
	US$'000	US$'000
Accounts receivable, net	10,879	11,603
Prepayments	1,908	825
Value added tax	70	74
Called up share capital not paid	158	253
Grants receivable	-	182
Other receivables	902	282
Deferred costs	447	139
Deferred tax asset (see note 8)	1,516	555
	15,880	13,913

OTHER ASSETS (Amounts falling due after more than one year)	December 31 2004	December 31 2003
	US$'000	US$'000
Deferred costs	875	410
Other assets	455	140
	1,330	550

4. INTANGIBLE ASSETS

	December 31 2004	December 31 2003
	US$'000	US$'000
Cost		
Product licence and development costs	11,327	7,069
Goodwill (see note 19)	56,889	39,643
	68,216	46,712
Less accumulated amortisation	(10,346)	(7,861)
	57,870	38,851

5. PROPERTY, PLANT AND EQUIPMENT

	December 31 2004	December 31 2003
	US$'000	US$'000
Cost		
Land and buildings	5,504	5,133
Leasehold improvements	2,699	2,444
Computer and office equipment	4,642	3,839
Plant and equipment	12,014	9,164
	24,859	20,580
Less accumulated depreciation	(8,917)	(6,920)
	15,942	13,660

Included in the net book value of tangible fixed assets is an amount for capitalised leased assets of US$1,354,000 (2003: US$1,538,000). The amortisation charge in respect of capitalised leased assets for the year ended December 31, 2004 was US$184,000 (2003: US$118,000 and 2002: US$110,000).

6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Amounts falling due within one year)

	December 31 2004	December 31 2003
	US$'000	US$'000
Accounts payable	3,328	3,519
Income tax deducted under PAYE	244	138
Employee related social insurance	366	140
Corporate income taxes	542	1,574
Accrued liabilities	3,995	4,895

Accrued royalties	697	224
Obligations under finance leases	238	264
Financial liabilities from unconnected third party	669	3,309
Bank loans - current portion (see note 7)	3,150	4,176
3% convertible debentures (see note 7)	7,031	1,162
	20,260	19,401

As at December 31, 2004, the undrawn portion of existing banking facilities amounted to US$2,000,000.

7. LONG-TERM LIABILITIES

(Amounts falling due after more than one year)	December 31 2004	December 31 2003
	US$'000	US$'000
3% convertible debentures	8,788	11,875
Bank loans (secured, see note 20(e))	3,581	4,734
Lease creditors	554	750
Corporate income taxes	161	158
Other creditors	35	-
	13,119	17,517

The age profile of the Group's long-term liabilities, excluding obligations under finance leases, is as follows:

	December 31 2004	December 31 2003
	US$'000	US$'000
In more than one year, but not more than two	8,578	6,462
In more than two years, but not more than three	2,706	6,480
In more than three years, but not more than four	1,256	2,562
In more than four years, but not more than five	13	1,255
In more than five years	12	8
	12,565	16,767

In June 2003, Trinity Biotech completed a new US$10,000,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Ltd. The facility consists of a five year term loan of US$6,000,000 and a one year revolver of US$4,000,000. This facility is secured by the assets of the Group. The term loan is repayable in ten equal biannual instalments which commenced on January 2, 2004. At December 31, 2004, the total amount outstanding on the term loan amounted to US$4,800,000 and the drawn portion of the revolver loan amounted to US$2,000,000. The debt is stated net of unamortised issue costs of US$138,000.

In July 2003, the Company completed a private placement of US$20,000,000 principal amount of 3% convertible debentures. The debentures bear

interest at a rate of 3% per annum, convertible into Class 'A' Ordinary Shares of the Company at a price of US$3.55. In December 2003, US$6,355,000 of the US$20,000,000 principal amount of the debentures and US$44,000 of the related accrued interest was converted into 1,802,676 Class 'A' Ordinary Shares of the Company. In January 2004, a further US$427,000 of the principal amount of the debenture was converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July 2003 placement, convertible notes in the aggregate principal amount of up to US$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$4. All of the above debentures are unsecured and are repayable in ten equal instalments on a quarterly basis. Under the terms of the agreement, the Company has the right to satisfy each repayment either in cash or in shares. In October 2004, the first principal repayment of US$1,822,000 was made to the debenture holders in cash. At December 31, 2004, the total debentures cost outstanding was US$15,819,000. The debt is stated net of unamortised issue costs of US$576,000.

As at December 31, 2004 payments falling due under finance leases of less than one year's duration amounted to US$238,000 (2003: US$264,000). As at December 31, 2004 obligations under finance leases of between two and five years' duration amounted to US$554,000 (2003: US$750,000). There were no payments falling due extending beyond five years.

8. DEFERRED TAX

	December 31 2004	December 31 2003
	US$'000	US$'000
Movement in Deferred Tax Asset		
At beginning of year	555	419
Charge to profit and loss account (see note 14)	(455)	(307)
Credit to profit and loss account (see note 14)	1,416	443
At end of year	1,516	555

Movement in Deferred Tax Liability		
At beginning of year	911	294
Charge to profit and loss account (see note 14)	683	632
Credit to profit and loss account (see note 14)	(283)	(15)
At end of year	1,311	911

The deferred tax asset is due to timing differences created by net operating losses and state credit carryforwards, the tax written-down value of fixed assets being greater than the related net book value and the elimination of unrealised intercompany profit. The deferred tax asset increased in 2004 due to the tax effect of the excess of the tax written-down value of fixed assets over the net book value, the

elimination of unrealised intercompany profit and the availability of net operating losses for offset against future profits. The higher level of increase in 2004 compared to 2003 is due principally to the availability of higher net operating losses carrying forward in the Company's US entities. In 2003, the deferred tax asset increased as the tax effect of the excess of tax written-down value of fixed assets over the net book value and the elimination of unrealised profit exceeded the tax consequences of the utilisation of net operating loss carryforwards.

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Net operating loss carryforwards	845	41	488
Other timing differences	973	693	62
Total deferred tax assets	1,818	734	550
Valuation allowance	(302)	(179)	(131)
Net deferred tax assets	1,516	555	419

At December 31, 2004, the Company recognised a deferred tax asset of US$845,000 in respect of net operating loss carryforwards in the US and the UK. The utilisation of these net operating loss carryforwards is limited to the future profitable operations of these entities. These losses carry forward indefinitely. Valuation allowances have been provided against state credit carryforwards for uncertainties regarding future full utilisation of these credits in the related tax jurisdiction in future periods.

The deferred tax liability is caused by the net book value of fixed assets being greater than the tax written down value of fixed assets and timing differences due to the acceleration of the recognition of certain charges in calculating taxable income permitted in Ireland. The deferred tax liability increased in 2004 and 2003 as the excess of the net book value of fixed assets over the tax written down value increased and the Company was able to recognise an upfront charge in the calculation of its taxable income in Ireland.

9. CALLED UP SHARE CAPITAL

(a) During 2003 US$1,000,000 principal amount of 6% convertible debentures was converted into 666,667 Class 'A' Ordinary Shares of the Company.

(b) On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its then associate HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.

(c) In November 2002, the Company completed a private placement of US$2,500,000 principal amount of 5.25% convertible debentures. The debentures bore interest at a rate of 5.25% per annum and were convertible into Class 'A' Ordinary Shares of the Company at a price of US$1.50. During 2003 these debentures were converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

(d) In December 2002, Enterprise Ireland subscribed for 443,900 'A' Ordinary

Shares in the Company.

(e) In July 2003, the Company completed a private placement of US$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum, convertible into Class 'A'

Ordinary Shares of the Company at a price of US$3.55. In December 2003, US$6,355,000 of the US$20,000,000 principal amount of the debentures was converted into 1,790,141 Class 'A' Ordinary Shares of the Company, a further US$44,000 of accrued interest was settled by the issue of 12,535 Class 'A' Ordinary Shares of the Company at US$3.55 per share. In 2004, a further US$427,000 of the principal amount of the debenture was converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July 2003 placement, convertible notes in the aggregate principal amount of up to US$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$4. All of above debentures are unsecured and are repayable in ten equal instalments on a quarterly basis commencing in October 2004. Under the terms of the agreement, the Company has the right to satisfy each repayment either in cash or in shares. In October 2004, the first principal repayment of US$1,822,000 was made to the debenture holders in cash. At December 31, 2004, the total amount of debentures outstanding amounted to US$15,819,000. The debt is stated net of unamortised issue costs of US$576,000.

(f) In January 2004, the Company completed a US$22.5m private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US$5.25 per share. Under the terms of the placement, investors were also granted the right to purchase an additional 2,647,059 Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share for a period of up to 30 days after the closing of the transaction. An additional 431,617 Class 'A' Ordinary Shares of the Company, amounting to US$1,834,000, were issued within the 30 day period following the closing of the transaction to investors who exercised this option.

(g) In April 2004, Trinity completed the acquisition of the assets of Fitzgerald Industries International Inc (Fitzgerald) for US$16,000,000 in cash. The acquisition was partly funded by the issue of 2,783,984 'A' Ordinary Shares of the Company. As at December 31, 2004, 817,470 shares with a value of US$2,373,000 remain unpaid (see the consolidated statements of movement in shareholders' equity).

(h) The Class `B' Ordinary Shares have two votes per share and the rights to participate in any liquidation or sale of the Company and to receive dividends as if each Class `B' Ordinary Share were two Class 'A' Ordinary Shares.

(i) Since its incorporation the Company has not declared or paid dividends on its 'A' Ordinary Shares. The Company anticipates, for the foreseeable future, that it will retain any future earnings in order to fund its business operations. The Company does not, therefore, anticipate paying

any cash or share dividends on its 'A' Ordinary Shares in the foreseeable future.

As provided in the Articles of Association of the Company, dividends or other distributions will be declared and paid in US Dollars.

(j) In March 1998 Benen Trading Limited ("Benen") received an injection of funds under the Business Expansion Scheme. In order to present a true and fair view of the consolidated financial statements, the substance of this transaction, as distinct from its strict legal form, was considered in determining its true nature and the appropriate accounting treatment. In particular, the option which is incorporated within the transaction, and the most likely exercise of it, determined the substance of the transaction. It was considered that the injection of funds was in the nature of quasi equity. The Company had obligations to transfer economic benefits at the end of the investment period limited to a maximum of (euro)330,200 and accordingly consolidated Benen as a 100% subsidiary undertaking and the proceeds of the investment were credited to minority interest. On April 4, 2003 this option was exercised and the shares of Benen were purchased by Trinity Biotech plc.

10. SHARE OPTIONS AND WARRANTS

Under the terms of the Company's Employee Share Option Plan options to purchase 8,629,017 Class 'A' Ordinary Shares were outstanding at December 31, 2004. Under the plan, options are granted to officers, employees and consultants of the Group at the discretion of the board. In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary Shares in the Company to agents of the Company who were involved in the Company's private placements in 1994 and 1995 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was also granted to a consultant of the Company. In January 2004, the Company completed a private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares in the Company at an exercise price of US$5.25 per share. The Company further granted warrants to purchase 200,000 Class 'A' Ordinary Shares in the Company

to agents of the Company who were involved in this private placement at an exercise price of US$5.25. At December 31, 2004 there were warrants to purchase 1,317,324 Class 'A' Ordinary shares in the Company outstanding.

The share options and warrants outstanding at December 31, 2004 were as follows:

	Options & Warrants	
Outstanding	Shares	Range US$
January 1, 2002	7,975,703	0.81-5.00
Granted	2,243,500*	0.98-1.50
Exercised	(12,334)	1.13
Cancelled	(741,420)	0.98-2.78

December 31, 2002	9,465,449	0.81-5.00
Granted	1,340,500	0.98- 3.11
Granted over value	155,000	1.80
Exercised	(1,397,717)	0.81- 2.75
Cancelled	(1,235,838)	0.98- 2.60
December 31, 2003	8,327,394	0.81-5.00
Granted	3,162,824*	2.33 - 5.25*
Exercised	(1,113,538)	0.98 - 2.75
Cancelled	(430,339)	0.98 - 4.00
December 31, 2004	9,946,341	0.81 - 5.25

* Amounts adjusted for previously issued stock options

11. PROFIT AND LOSS RESERVE

Profit and loss reserve	December 31 2004	December 31 2003
	US$'000	US$'000
Accumulated surplus	22,774	17,608
Goodwill reserve	(21,777)	(21,777)
	997	(4,169)

12. ANALYSIS OF REVENUE, OPERATING INCOME, MAJOR CUSTOMERS AND ASSETS

a) The Group operates in one business segment, the market for diagnostic tests for a range of diseases and other medical conditions, and in two reportable segments, the United States and the Rest of World, which are based on a geographical split. Information on assets is maintained by location analysed between the United States and the Rest of World. The information presented below relates to these operating segments and is presented in a manner consistent with information presented to the Group's chief operating decision maker. The basis of accounting for each segment is the same basis as used in the preparation of the consolidated financial statements.

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

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	51,007	46,527	23,968
United States	28,937	19,148	28,010
	79,944	65,675	51,978

Revenue is attributed to geographical area based on where customer orders are satisfied from.

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

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
United States	41,380	36,299	33,512
Europe	22,654	19,983	11,899
Asia/Africa	11,550	6,248	4,396
Other overseas	4,360	3,145	2,171
	79,944	65,675	51,978

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

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Infectious diseases	31,638	30,678	33,939
Haemostasis	26,772	24,435	13,780
Rapids	9,807	4,449	3,890
Other	11,727	6,113	369
	79,944	65,675	51,978

This analysis of revenue is provided for information purposes but does not form the basis of information provided to or used by the Group's chief operating decision maker in making strategic or operational decisions.

e) The distribution of intersegmental sales was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	20,502	25,481	21,448
Rest of World - intersegmental sales	9,773	15,964	18,366
United States	56,427	37,120	28,010
Less intercompany sales	(6,758)	(12,890)	(15,846)
	79,944	65,675	51,978

Sales of product between companies in the Group are made on commercial terms (cost plus a mark-up) which reflect the nature of the relationship between the relevant companies.

f) The distribution of operating income by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	11,111	7,947	3,755
United States	(5,370)	1,722	2,828
Total operating income	5,741	9,669	6,583

g) The distribution of consolidated total assets by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	117,069	85,178	62,074
United States	33,759	32,913	27,724
Total assets	150,828	118,091	89,798

h) The distribution of consolidated long-lived assets by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	66,951	42,894	38,742
United States	8,191	10,167	11,721
Total long-lived assets	75,142	53,061	50,463

i) In 2004 there were no customers with 10% or more of total revenues. However, in prior periods one customer did exceed 10% of total revenue as shown below:

	December 31 2004	December 31 2003	December 31 2002
Customer A	n/a	12%	20%

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

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	3,405	1,267	2,406
United States	984	956	1,098
Total depreciation and amortisation	4,389	2,223	3,504

k) The analysis of interest expense by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	(812)	(728)	(608)
United States	(12)	(64)	(96)
Total interest	(824)	(792)	(704)

l) The analysis of taxation charge by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Rest of World	1,153	1,409	231
United States	(1,100)	777	537
	53	2,186	768

13. PROFIT ON ORDINARY ACTIVITIES BEFORE TAXATION

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
The profit on ordinary activities before taxation is stated after charging/(crediting):			
Directors' emoluments:			
Remuneration	1,321	1,092	1,165
Pension	172	104	95
Auditors' remuneration:			
Audit fees	419	455	190
Non audit fees	17	18	20
Depreciation	1,819	1,367	1,118
Amortisation	2,570	856	2,386
Operating lease rentals:			
Plant and machinery	19	-	26
Other	1,975	1,687	1,445
Employment grants	(135)	(307)	(214)
Settlement of litigation (see note below)	-	(225)	-

On June 16, 2003 Trinity Biotech and Xtrana entered into a settlement agreement. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the amounts due on two promissory notes of US$1,166,000 and US$5,700,000, together with interest thereon as provided in the notes, less US$225,000, and less US$24,000, which represented the amount due and owing by Xtrana to Trinity Biotech.

From 2000 to 2002, the Company acquired 42.9% of the share capital of Hibergen Limited. During 2003, Hibergen Limited was unsuccessful in raising additional funds and on November 14, 2003, the board of Hibergen Limited decided to cease trading. The carrying value of the Company's investment in Hibergen was written off in 2003.

14. INCOME TAXES

(a) The charge for taxation based on the profit on ordinary activities, comprises:

	December 31 2004	December 31 2003	December 31 2002
	US$'000	US$'000	US$'000
Current tax			
Corporation tax at 12.5% (2003: 12.5%, 2002: 16%)	1,111	1,532	9
Manufacturing relief	(144)	(195)	-

	967	1,337	9
Overseas tax*	(139)	368	482
Relief in respect of prior year	(214)	-	(64)
Total current tax	614	1,705	427
Deferred tax charge/(credit)			
Movement in deferred tax asset (see note 8)	(961)	(136)	190
Movement in deferred tax liability (see note 8)	400	617	151
Total taxation on profit on ordinary activities	53	2,186	768
Effective tax rate			
Profit on ordinary activities before taxation	5,219	7,983	5,665
As a percentage of profit before tax			
Current tax	11.8%	21.4%	7.5%
Total tax (current and deferred)	1.0%	27.4%	13.5%

* The credit in 2004 of US$139,000 primarily arises as a result of expected refunds relating to a loss carry-back claim in respect of the current year US loss.

The following table relates the applicable Republic of Ireland statutory tax rate to the effective current tax rate of the Group:

	2004 % of profit before taxation	2003 % of profit before taxation	200 % of profi before taxatio
Irish corporation tax	12.5	12.5	16.
Manufacturing relief	(2.8)	(2.4)	(0.
Tax rates on overseas (losses)/earnings	(13.4)	1.2	4.
Relief in respect of prior year	(4.1)	-	(1.
Effect of non-taxable costs in PBT	20.0	6.2	
Other including benefit of loss carryforwards	(0.4)	3.9	(11.
Current tax	11.8	21.4	7.
Deferred tax	(10.8)	6.0	6.
Total tax (current and deferred)	1.0	27.4	13.

(b) The distribution of profit on ordinary activities before taxes by geographical area was as follows:

	December 31 2004	December 31 2003	December 31 2002

	US$'000	US$'000	US$'000
Ireland	10,599	5,772	2,934
Overseas	(5,380)	2,211	2,731
Total profits before taxation	5,219	7,983	5,665

(c) The tax effects of temporary differences that give rise to significant portions of deferred tax assets relate principally to the elimination of unrealised intercompany profit and net operating losses and state credit carryforwards. The valuation allowance for deferred tax assets at December 31, 2004, 2003 and 2002 was US$302,000, US$179,000 and US$131,000 respectively.

(d) At December 31, 2004, the Group had net operating losses of approximately US$2,517,000 (2003: approximately US$332,000). The utilisation of these net operating loss carryforwards is limited to offset against the future profits earned by the Group arising from the same trade and in the company in which they arose.

15. EARNINGS PER ORDINARY SHARE

Basic earnings per ordinary share Earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US$5,166,000 (December 31, 2003, US$5,797,000 and December 31, 2002, US$4,897,000) for the financial year by the weighted average number of ordinary shares in issue of 55,132,024 (December 31, 2003: 43,093,146 and December 31, 2002: 40,550,367).

Diluted earnings per ordinary share Diluted earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US$5,166,000 (December 31, 2003, US$5,797,000 and December 31, 2002, US$4,897,000) for the financial year, adjusted for debenture interest saving of US$514,000 (December 31, 2003, US$344,000 and December 31, 2002, US$86,000) by the diluted weighted average number of ordinary shares in issue of 63,935,138 (December 31, 2003, 50,583,247 and December 31, 2002, 42,486,227). The basic weighted average number of shares may be reconciled to the number used in the diluted earnings per ordinary share calculation as follows:

	December 31 2004	December 31 2003	December 31 2002
Basic earnings per share denominator	55,132,024	43,093,146	40,550,367
Issuable on exercise of options	4,158,159	4,106,791	1,214,703
Issuable on conversion of debentures	4,644,955	3,383,310	721,157
Diluted earnings per share denominator	63,935,138	50,583,247	42,486,227

16. SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

		December 31 2004	December 31 2003	December 31 2002
		US$'000	US$'000	US$'000
(a)	Additions to tangible fixed assets	3,689	4,527	2,517
	Less new finance leases	-	(671)	-
		3,689	3,856	2,517

(b) Management of liquid resources

Cash flows of US$2,158,000 from the use of liquid resources in 2004 arose from the movement of fixed deposit accounts to cash. Cash flows of US$15,296,000 from the use of liquid resources in 2003 arose from the movement of cash to fixed deposit accounts. Cash flows of US$553,000 from the use of liquid resources in 2002 arose from the movement of cash from fixed deposit accounts.

(c) Impact of acquisitions on cash flow headings

There were two acquisitions in 2004. The cash outflow of US$19,090,000 in 2004 was partly funded by the issue of 2,783,983 'A' Ordinary Shares. As at December 31, 2004, 817,470 shares with a value of US$2,373,000 remained unpaid. The operating results of Adaltis and Fitzgerald acquired on April 7 and April 15 respectively contributed US$1,109,000 to the operating profit of the group. The net cash inflow from operating activities for Fitzgerald for the period from April 15, 2004 (the date of acquisition) to December 31, 2004 was US$1,212,000. The acquisition of Fitzgerald did not have a material impact on any other headings of the consolidated statement of cashflows. As the working capital of Adaltis was fully integrated into the Group's existing US operations by December 31, 2004 post operating cashflows were not obtainable.

There were no acquisitions in 2003. Additional costs incurred and obligations assumed from the acquisitions completed in 2002 resulted in cash outflows to the Group of US$763,000 during 2003. Deferred consideration of US$1,810,000 relating to the purchase of the speciality clinical chemistry product line from Sigma Diagnostics was paid during 2003.

The cash outflow of US$4,409,000 from the acquisition of businesses and product lines in 2002 was partly funded by the issue of US$2,500,000 of convertible debentures in November 2002 (see note 9(c)). As the working capital of the acquired businesses was fully integrated within the Group by December 31, 2002 post acquisition operating cash flows were not readily obtainable. The operating results of the haemostasis division and the speciality clinical chemistry product line of Sigma Diagnostics acquired on August 27 and November 27, 2002 respectively contributed US$59,000 to the operating profit of the Group.

17.	RECONCILIATION OF OPERATING PROFIT TO NET CASH INFLOW FROM OPERATING ACTIVITIES	December 31 2004	December 31 2003	December 31 2002
		US$'000	US$'000	US$'000

Operating profit	5,741	9,669	6,583
Depreciation and amortisation	4,389	2,224	3,504
Exceptional administrative expenses	-	-	(2,835)
Decrease/ (increase) in receivables and prepayments	484	(65)	(4,251)
(Decrease)/ increase in accounts payable	(2,419)	(2,561)	2,875
Increase in inventory	(5,883)	(6,005)	(2,415)
Non cash compensation expense	13	84	120
Foreign exchange (gains)/ losses on non-operating cashflows	(131)	485	-
Loss on disposal/ retirement of fixed assets	14	186	-
Other non-cash items	140	159	-
Net cash inflow from operating activities	2,348	4,176	3,581

18. ANALYSIS OF NET DEBT

	December 31 2003	Cash flow	Acquisitions/ disposals	Non-cas change
	US$'000	US$'000	US$'000	US$'00
Cash	2,553	3,649	-	
Liquid resources	18,010	(2,158)	-	
	20,563	1,491	-	
Long-term debt - current portion	(4,176)	1,067	-	(4
Long-term debt	(4,734)	1,153	-	
Other financial liabilities	(3,309)	2,675	-	
Finance leases	(1,014)	267	-	
Convertible debentures	(13,037)	(2,933)	-	15
Net debt	(5,707)	3,720	-	11

	December 31 2002	Cash flow	Acquisitions/ disposals	Non-ca chang
	US$'000	US$'000	US$'000	US$'0
Cash	3,094	(542)	-	
Liquid resources	2,714	15,296	-	
	5,808	14,754	-	
Long-term debt - current portion	(1,978)	(2,198)	-	
Long-term debt	(4,656)	(79)	-	
Other financial liabilities	(4,108)	1,150	-	

Finance leases	(231)	131	(201)	(6
Convertible debentures	(3,479)	(19,523)	-	9,9
Net debt	(8,644)	(5,765)	(201)	9,2

	December 31 2001	Cash flow	Acquisitions/ disposals	Non-cas change
	US$'000	US$'000	US$'000	US$'00
Cash	2,107	892	-	
Liquid resources	3,267	(553)	-	
	5,374	339	-	
Long-term debt				
- current portion	(2,410)	432	-	
Long-term debt	(6,028)	1,372	-	
Other financial liabilities	-	(4,042)	-	
Finance leases	(227)	17	-	
Convertible debentures	(1,000)	(2,500)	-	2
Net debt	(4,291)	(4,382)	-	2

19. ACQUISITION OF BUSINESSES

2004 Acquisitions
In April, 2004, the Company acquired the business of Fitzgerald Industries International, Inc ("Fitzgerald") for US$16 million in cash. Acquisition expenses amounted to US$152,000. Fitzgerald provides a comprehensive range of immunodiagnostic products to pharmaceutical companies, reference laboratories, diagnostic manufacturers and research facilities worldwide. The acquisition of Fitzgerald places the Company in the life sciences market with significant potential for future growth. In April 2004, the Company also acquired the assets of Adaltis US, Inc for US$2,852,000 in cash. Adaltis US, Inc is the distribution arm for Adaltis Inc. Acquisition costs amounted to US$112,000. As part of the transaction, Trinity 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, excluding China. This acquisition gives Trinity access to the existing installed base of instruments in the US and provides an opportunity for Trinity to place its own reagents on this installed base of instruments. The results of these acquisitions for 2004 are incorporated from the date of acquisition in the consolidated statement of income for the year ended December 31, 2004.

	Fitzgerald	Adaltis	Total
	US$'000	US$'000	US$'000
Tangible fixed assets	35	237	272
Working capital	193	332	525
Intangible fixed assets	1,073	-	1,073

Net assets at fair value	1,301	569	1,870
Goodwill	14,851	2,395	17,246
Consideration	16,152	2,964	19,116
Satisfied by:			
Cash payments including costs	16,152	2,964	19,116

Goodwill capitalised during 2004 in respect of acquired businesses amounted to US$17,246,000 and comprises:

	Book Values	Fair Value Adjustment	Fair Value	Consideration	Goodw
	US$'000	US$'000	US$'000	US$'000	US$'
FITZGERALD					
Tangible fixed assets	35	-	35		
Working capital	210	(17)	193		
Intangible fixed assets	33	1,040	1,073		
	278	1,023	1,301	(16,152)	14,
ADALTIS					
Tangible fixed assets	237	-	237		
Working capital	327	5	332		
	564	5	569	(2,964)	2,
Total	842	1,028	1,870	(19,116)	17,

During the period, following the acquisitions, initial fair value adjustments were made to the acquired working capital of Fitzgerald (US$17,000 decrease) and Adaltis (US$5,000 increase). In addition a fair value adjustment was made to recognise an indefinite lived intangible asset representing the trade name acquired of US$970,000 and other intangibles of US$70,000. These fair value adjustments were made following an assessment of the carrying value of the assets acquired.

Due to the material size of the acquisition, the following unaudited financial information for Fitzgerald for the period during 2004 prior to its acquisition by the Company (i.e. from January 1, 2004 to April 14, 2004) is provided:

Fitzgerald

	US$'000
Turnover	1,471
Operating Profit	646
Profit before tax	649
Tax	-
Profit after tax	649

There were no gains or loss during the period from January 1, 2004 to the April 14, 2004 other than those recognised through the statement of income.

The profit after tax for Fitzgerald for the year ended December 31, 2003 was US$3,153,000.

2002 Acquisitions
On August 27, 2002 Trinity Biotech purchased the haemostasis division of Sigma Diagnostics for a total consideration of US$1,428,000. The consideration was satisfied in cash. Acquisition expenses amounted to US$79,000. The division comprises a portfolio of reagents manufactured in St. Louis, Missouri and the Amelung range of instruments manufactured in Lemgo, Germany. During 2003 and 2004 Trinity transferred the production of these reagents to Bray, Ireland.

On November 27, 2002 the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4,444,000 satisfied in cash and deferred consideration with a fair value of US$4,412,000. The cash consideration was partly financed by the issue of US$2.5 million of convertible debentures (see note 9(c)). The deferred consideration of US$1,810,000 was paid in two instalments of US$1,010,000 and US$800,000 on May 27 and November 27, 2003, respectively. The fair value of deferred consideration at November 27, 2002 was US$1,778,000. Total acquisition expenses amounted to US$94,000. During 2003 and 2004 Trinity Biotech transferred production of the product line from St. Louis, Missouri to Bray, Ireland. Goodwill arising on acquisition of US$4 million after fair value adjustments represents the value of the expected synergies created by combining production within Trinity Biotech's existing manufacturing operations. (The results of these acquisitions for 2002 are incorporated from the date of acquisition in the consolidated statement of income for the year ended December 31, 2002.)

The Company did not allocate any value to trademarks of the Sigma acquired entities as part of the purchase price allocation as the Company re-branded the products acquired under a Trinity Biotech label. The Company

did not allocate any value to customer relationships or customer lists obtained as part of these acquisitions as these are not considered proprietary to the acquired entities and the Company is already in possession of such customer lists and has existing relationships with

customers of acquired entities given its existing position in the diagnostics industry.

	Sigma Haemostasis	Sigma Clinical Chemistry	Total
	US$'000	US$'000	US$'000
Tangible fixed assets	2,500	-	2,500
Working capital	206	625	831
Net assets at fair value	2,706	625	3,331
Goodwill	(1,278)	3,787	2,509
Consideration	1,428	4,412	5,840
Satisfied by:			
Cash payments including costs	1,428	2,634	4,062
Net cashflow	1,428	2,634	4,062
Deferred consideration	-	1,778	1,778
Consideration	1,428	4,412	5,840

Goodwill capitalised during 2002 in respect of acquired businesses amounted to US$2,509,000 and comprises:

	Book Values	Fair Value Adjustment	Fair Value	Consideration	Go
	US$'000	US$'000	US$'000	US$'000	U
SIGMA HAEMOSTASIS					
Tangible fixed assets	1,322	1,178*	2,500		
Working capital	8,458	(8,252)*	206		
	9,780	(7,074)	2,706	(1,428)	
SIGMA CLINICAL CHEMISTRY					
Working capital	1,490	(865)*	625		
	1,490	(865)	625	(4,412)	
Total	11,270	(7,939)	3,331	(5,840)	

The book values of the assets shown above have been taken from management accounts and other information of the acquired businesses at

the dates of acquisitions.

The fair value adjustments above principally arise for the following reasons:

* Revaluation of fixed assets and inventories following an assessment of the continuing economic contribution of fixed assets and the realisable value of inventories.

Following the completion of the fair value exercises in 2003 in respect of the acquisitions made during 2002, amendments have been made to the fair values reported in the 2002 financial statements. The amendments relate to the identification of additional obligations assumed on the acquisition of the Sigma Haemostasis business, the fair valuation of inventory acquired and the recognition of additional costs in both the Sigma Haemostasis and Clinical Chemistry acquisitions. The difference has been taken as an adjustment to goodwill on acquisition. Provisional and final values of net assets acquired and consideration paid are as follows:

	Provisional fair value 2002	Adjustments to net assets 2003	Adjustments to costs 2003	Final fair value 2003
	US$'000	US$'000	US$'000	US$'000
SIGMA HAEMOSTASIS				
Tangible fixed assets	2,500	-	-	2,500
Working capital	206	2,240	-	2,446
Net assets	2,706	2,240	-	4,946
Consideration and costs	(1,428)	-	(68)	(1,496)
SIGMA CLINICAL CHEMISTRY				
Working capital	625	(137)	-	488
Consideration and costs	(4,412)	-	(98)	(4,510)

2001 Acquisitions

On December 21, 2001 the Group acquired the assets of the Biopool haemostasis business for a total consideration of US$6,409,000 satisfied in cash and deferred consideration. The deferred consideration of US$2,591,000 was payable in three instalments of US$855,000, US$1,166,000 and US$570,000 on December 21, 2002, 2003 and 2004 respectively. At December 31, 2002, US$2,021,000 of the deferred consideration was included in current liabilities under deferred consideration. In December 2002, the Company filed an action against Xtrana Inc relating to the purchase of the Biopool business from Xtrana in 2001. On June 16, 2003 Trinity Biotech and Xtrana settled this litigation. Pursuant to the terms of the settlement agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the

remaining amount due on the deferred consideration. This debt was settled in full in 2003. Total acquisition expenses amounted to US$159,000. This business comprises a range of test kits which assess and diagnose disorders of blood coagulation, thrombotic risk factors, fibrinolysis, platelet function and the vascular system. As part of the acquisition the Company assumed the workforce in Ventura, California and Umea, Sweden. In the ten months after acquisition the Company learnt the production techniques associated with this product range and transferred the Ventura production facility together with a number of key employees to the Bray, Ireland facility. The Company has maintained the Umea operation and will continue to benefit from the expertise associated with this assumed workforce. Goodwill arising on acquisition of US$5.1 million after fair value adjustments represents the value of the expected synergies created by combining production within the Company's existing manufacturing operations in Ireland together with the specialist product knowledge acquired with the assumed workforce in Ventura and Umea.

Following the completion of the fair value exercise in 2002 in respect of the Biopool acquisition made during 2001, amendments have been made to the fair values reported in the 2001 financial statements. The difference has been taken as an adjustment to goodwill on acquisition. Provisional and final values of net assets acquired and consideration paid are as follows:

	Provisional fair value 2001	Adjustments to net assets 2002	Adjustments to costs 2002	Final fair value 2002
	US$'000	US$'000	US$'000	US$'000
Working capital	(136)	1,551	-	1,415
Consideration and costs	(6,409)	-	(68)	(6,477)

20. COMMITMENTS AND CONTINGENCIES

(a) Capital Commitments
There were no capital commitments contracted for or authorised at December 31, 2004, 2003 or 2002

(b) Operating lease commitments payable during the next 12 months amount to US$2,648,000 (2003: US$2,182,000) payable on leases of buildings at Dublin and Bray, Ireland, Darmstadt, Germany, Umea, Sweden, St. Louis, Missouri, upstate New York and Carlsbad, California and cars and equipment in the UK and Lemgo,

Germany. US$206,000 of the operating lease commitments total relates to leases whose remaining term will expire within one year, US$630,000 relates to leases whose remaining term expires between one and two years, US$253,000 between two and five years and the balance of US$1,559,000 relates to leases which expire after more than five years.

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

	Operating Leases	Finance Leases
	US$'000	US$'000
2005	2,648	268
2006	2,200	241
2007	1,777	188
2008	1,632	163
2009	1,584	-
Later years	18,912	-
Total minimum payments	28,753	860
Less amounts representing interest	-	(68)
Total lease obligations	28,753	792

(c) In June 2003, Trinity Biotech completed a new US$10,000,000 club banking facility with Allied Irish Banks plc and Bank of Scotland (Ireland) Ltd, this facility is guaranteed by the subsidiaries of the company. At December 2004, US$6,800,000 of this balance was drawn down by the company.

(d) Pursuant to the provisions of Section 17, Companies (Amendment) Act, 1986, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, Trinity Research Limited, Benen Trading Limited, Trinity Biotech Sales Limited, Flambelle Limited and Reddinview Limited, subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2004 and, as a result, these subsidiary undertakings have been exempted from the filing provisions of Section 7, Companies (Amendment) Act, 1986.

(e) The Company's bank borrowings are secured by a fixed and floating charge over the assets of the Company.

(f) In December 2003, the Company initiated legal proceedings in the Superior Court of Middlesex County, Massachusetts against Inverness Medical and its affiliate Wampole (collectively, Defendants) for declaratory judgment, breach of contract and unfair and deceptive business practices in connection with the Defendants' performance under a distribution agreement initially entered into in 1995 by Clark Laboratories Inc (now part of the Trinity Biotech Group) and subsequently amended in 2002. Inverness Medical, through its affiliate, Wampole Laboratories, has acted as exclusive distributor for certain of Trinity Biotech's infectious disease products in the US. This exclusivity ended on September 30, 2004, at which time it had been agreed that both Trinity Biotech and Inverness Medical would sell the products under their respective labels. Among other things, the suit requested a judgement declaring that Trinity was entitled to sell certain products directly in the US and Puerto Rico before October 1, 2004 under the terms of the 2002 amendment to the distribution agreement and due to breaches of the distribution agreement by the Defendants. The suit also alleged that the Defendants were attempting to convert customers from Trinity's products to products manufactured by a competitor (which were modified to look like the Trinity products) by misrepresenting to the customers that the Trinity product was unavailable and was being discontinued. In January 2004, the Defendants countersued alleging, among other things, various breaches of the distribution agreement and subsequent amendments, and sought a preliminary injunction to prevent Trinity from selling directly in the

Territory any of its products which are competitive with products sold by the Defendants and sourced from other suppliers. The Superior Court of Middlesex County, Massachusetts, denied this motion for a preliminary injunction on January 28, 2004. In April of 2004, Trinity amended its complaint to add additional claims alleging breaches of the distribution agreement by the Defendants. In May of 2004, the Defendants amended their counterclaims to add claims alleging, among other things, that Trinity was selling certain products directly without a license. Following the expiration of the Defendants' exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity moved to amend its complaint to eliminate the declaratory judgment claims and add additional claims for breach of the

distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. The Defendants filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. It is possible that the Company will incur a loss arising out of this legal case. However, it is currently not possible to quantify the amount of this potential loss.

21. SIGNIFICANT CONCENTRATIONS AND BUSINESS RISKS

The Group maintains cash and cash equivalents with various financial institutions. These financial institutions are located in a number of countries and Group policy is designed to limit exposure to any one institution. The Company performs periodic evaluations of the relative credit standing of those financial institutions.

The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Due to the large numbers of customers and the geographical dispersion of these customers, the Group has no significant concentrations of accounts receivable.

22. PENSION SCHEME

The Group operates a defined contribution pension scheme for its full-time employees. The benefits under this scheme are financed by both Group and employee contributions. Total contributions made by the Group in the financial year and charged against income amounted to US$450,000 (December 31, 2003, US$400,000 and December 31, 2002, US$523,000). This represents the total cost to the Group of the pension scheme for the financial year and as such it was not necessary to accrue or prepay pension contributions at the year end.

23. RELATED PARTY TRANSACTIONS

The Company has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr O'Caoimh and Dr Walsh, directors of the Company, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. It has entered into an agreement with JRJ pursuant to which the Company has taken a lease of premises adjacent to the existing facility for a term of 20 years at a rent of (euro)7.62 per square foot ("the Current Extension"). The lease commenced on the newly completed 25,000 square foot building in July 2000. The Company also envisages that further premises may potentially be required by it and, for that purpose, has entered into a four years eleven month lease at (euro)13,000 per annum over adjacent lands with JRJ. On November 20, 2002, the Company entered into an agreement for a 25 year lease with JRJ for offices that have

been constructed on part of these lands. The annual rent of (euro)381,000 (US$520,000) is payable from January 1, 2004. Independent valuers have advised the Company that the rent fixed in respect of the current extension, the agreement for lease and the adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr O'Caoimh and Dr Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Company can meet its ongoing requirements for premises.

24. DERIVATIVES AND FINANCIAL INSTRUMENTS

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

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

INTEREST RATE RISK

The Group borrows in appropriate currencies at floating and fixed rates of interest. Year-end borrowings, net of cash, totalled US$1,723,000 (2003: US$5,707,000) at interest rates ranging from 3.0% to 5.5% and including US$16,680,000 of fixed rate debt at interest rates ranging from 3% to 5.50% (2003: US$14,135,000 at interest rates ranging from 3% to 5.50%). In broad terms, a one-percentage point increase in interest rates would reduce the net interest charge by US$150,000 (2003: decrease by US$83,000).

LIQUIDITY RISK

The Group's operations are cash generating. Short-term flexibility is achieved through the management of the group's short-term deposits and through the use of its revolver facility.

FOREIGN EXCHANGE RISK

The majority of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Group pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. With an increasing level of Euro denominated sales, the Group anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Group had foreign currency denominated cash balances equivalent to US$874,000 at December 31, 2004.

The disclosures below exclude short term accounts receivable and payable

INTEREST RATE PROFILE OF FINANCIAL LIABILITIES

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

	December 31 2004	December 31 2003
	US$'000	US$'000
Floating rate financial liabilities	7,331	12,135
Fixed rate financial liabilities	16,680	14,135
	24,011	26,270

Floating rate financial liabilities comprise other borrowings that bear interest at rates of between 3.33% and 4.86%. These borrowings are provided by financial institutions at margins ranging from 1% to 2.25% over interbank rates.

Fixed rate financial liabilities	December 31 2004	December 31 2003
- weighted-average interest rate	3.20%	3.28%
- weighted-average period for which rate is fixed	2.15 years	3.24 years

MATURITY OF FINANCIAL LIABILITIES

The maturity profile of the Group's financial liabilities was as follows:

	December 31 2004	December 31 2003
	US$'000	US$'000
In one year or less, or on demand	11,088	8,912
In more than one year, but not more than two	8,733	6,654
In more than two years, but not more than five	4,190	10,705
In more than five years	-	-
	24,011	26,271

FAIR VALUES OF FINANCIAL ASSETS AND LIABILITIES

There is no significant difference between the fair value and the carrying value of the Group's financial assets and liabilities as at December 31, 2004. At December 31, 2004 forward contracts with a carrying value of US$Nil had a fair value of US$418,000.

25. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES

The Consolidated Financial Statements are prepared in accordance with accounting principles generally accepted in the Republic of Ireland ("Irish GAAP"), which differ in certain significant respects from US generally accepted accounting principles ("US GAAP"). These differences relate principally to the following items and the necessary adjustments are shown in the table set out below:

(a) Goodwill:

In prior years under Irish GAAP, goodwill was either written-off

immediately on completion of the acquisition against shareholders' equity, or capitalised in the balance sheet and amortised through the statement of income on a systematic basis over its useful economic life. From 1998, goodwill must be capitalised and amortised over the period of its expected useful life, however, historic goodwill continues to remain an offset against shareholders' equity. Under US GAAP, accounting for goodwill as an offset against shareholders' equity is not permitted. Prior to January 1, 2002 goodwill was amortised under US GAAP, except for goodwill arising on acquisitions after June 30, 2001, over the period of its expected useful life, subject to a maximum write off period of 40 years, through the income statement. A useful life of 10 years was adopted for the purposes of the reconciliation.

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") 141, "Business Combinations", and SFAS 142, "Goodwill and Other Intangible Assets", both of which are effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill is no longer amortised under US GAAP, but is subject to annual impairment tests in accordance with SFAS 142 and when conditions of impairment are present. On January 1, 2002 the Group performed the required impairment review of goodwill and indefinite-lived intangible assets upon the adoption of SFAS 142 and determined that there was no impairment. On December 31, 2003 and December 31, 2004, the Group performed further impairment tests of goodwill and indefinite-lived intangible assets, and concluded that there was no impairment in the carrying value of these assets at those dates.

There has not been a disposal of all or a portion of a reporting unit in the three years to December 31, 2004. The aggregate amount of goodwill relating to acquisitions during the period for the Group and for each reportable segment for each of the periods presented including goodwill arising on acquisition of interest in associate, net of fair value adjustments, is as follows:

	2004 US$'000	2003 US$'000	2002 US$'000
Rest of World	8,728	(1,937)	1,181
United States	-	-	-
Total	8,728	(1,937)	1,181

Goodwill of US$17,246,000 arises on the 2004 acquisitions of Fitzgerald Industries International Inc, ("Fitzgerald") and Adaltis US, Inc under Irish GAAP. Under US GAAP, US$10,050,000 representing the allocated value of US$8,690,000 for customer relationships and US$700,000 for supplier relationships in respect of the Fitzgerald acquisition and US$660,000 for customer relationships in respect of the Adaltis US, Inc acquisition have been accounted for as intangible assets under US GAAP. Irish GAAP does not permit the separate recognition of such assets. Such goodwill is amortised under Irish GAAP on a straight-line basis over 20 years. The separately identified intangible assets have been amortised on a straight-line basis over 13 years and 11 years for customer relationships and supplier relationships, respectively, in respect of the Fitzgerald acquisition and over 10 years for customer lists in respect of the Adaltis US, Inc acquisition under US GAAP.

In 2003, the Group's investment in its associate, including unamortised goodwill of US$1,659,000, was written-off.

Negative goodwill arises when the net amounts assigned to assets acquired and liabilities assumed exceed the cost of an acquired entity. Under Irish GAAP, negative goodwill arising on acquisitions is recognised as a negative asset, within intangible fixed assets, and recognised in the profit and loss account in the periods in which the non-monetary assets acquired are depreciated or sold. Any negative goodwill in excess of the fair values of the non-monetary assets acquired is recognised in the profit and loss account in the periods expected to benefit. Under US GAAP, negative goodwill would be allocated to reduce proportionately the values assigned to the acquired non-current assets. Any excess remaining negative goodwill is recognised in US GAAP income as an extraordinary gain for periods beginning after December 15, 2001. In 2004 negative goodwill of US$620,000 was released to the statement of income under Irish GAAP as the related non-monetary assets acquired were depreciated and sold. Under US GAAP there is no release of negative goodwill to the statement of income in 2004 as the balance of US$951,000 remaining after the gross negative goodwill of US$2,500,000 was reduced from property, plant and equipment under US GAAP would have been recognised as an extraordinary gain in 2003. Similarly at December 31, 2004 gross negative goodwill of US$2,500,000 within intangible fixed assets under Irish GAAP would be disclosed as a reduction from property, plant and equipment under US GAAP. Depreciation of US$63,000 (2003: US$76,000), under Irish GAAP, on property, plant and equipment acquired would not be recognised under US GAAP as the value of the acquired building has been fully offset by the negative goodwill arising on the acquisition.

Following the completion of the fair value exercises in 2003 in respect of the Sigma Haemostasis and Sigma Clinical Chemistry acquisitions made during 2002, amendments have been made to the fair values reported in the 2002 financial statements. The amendments relate to the identification of additional obligations of US$929,000 assumed on the acquisition of the Sigma Haemostasis business, the completion of the fair value exercise on inventory acquired in both acquisitions resulting in the recognition of additional value of US$3,031,000 and the recognition of additional costs of US$68,000 relating to the Sigma Haemostasis acquisition and US$98,000 relating to the Clinical Chemistry acquisition. The difference has been taken as an adjustment to goodwill on acquisition.

Identifiable intangible assets comprise goodwill, which is not amortisable and certain other non-current intangible assets, which are amortisable. Other non-current asset amortisation under US GAAP for the years ended December 31, 2004, 2003 and 2002 was US$715,000, US$154,000, and US$139,000, respectively. Other non-current amortisation of identifiable intangible assets under US GAAP is estimated to be approximately US$954,000 in 2005, US$947,000 in 2006, US$941,000 in 2007, US$937,000 in 2008, US$924,000 in 2009 and US$4,703,000 thereafter.

The net book value of goodwill at December 31, 2004 was US$57,126,000.

(b) Cash Flow Statements:
The consolidated statement of cash flows prepared under Irish GAAP presents substantially the same information as required under US GAAP by SFAS 95, "Statement of Cash Flows". This standard differs, however, with regard to the classification of items within the statements and as regards the definition of cash equivalents. Under US GAAP, cash

equivalents would not include bank overdrafts. The movements on such bank overdrafts are required to be included in financing activities under SFAS 95. Under US GAAP short term investments with a maturity of three months or less at the date of acquisition are included in cash equivalents. Under Irish GAAP, movements in short-term investments are classified as management of liquid resources. Under Irish GAAP, cash flows are presented separately for operating activities, returns on investments and servicing of finance, dividends received from associated undertakings, taxation, capital expenditure and financial investment, acquisitions and disposals, equity dividends paid, management of liquid resources and financing. US GAAP, however, requires only three categories of cash flow activity to be reported: operating, investing and financing. Cash flows from taxation and returns on investments and servicing of finance shown under Irish GAAP would, with the exception of preference dividends paid, be included as operating activities under US GAAP. The payment of dividends would be included as a financing activity under US GAAP. Under US GAAP, capitalised interest is treated as part of the cost of the asset to which it relates and is thus included as part of investing cash flows; under Irish GAAP all interest is treated as part of returns on investments and servicing of finance.

(c) Share Capital Not Paid:
Under Irish GAAP, unpaid share capital is classified as a receivable under current assets. Under US GAAP, share capital receivable should be reported as a reduction to Shareholders' Equity. Unpaid share capital at December 31, 2004 is US$158,000 (2003: US$253,000).

(d) Statement of Comprehensive Income:
The Company prepares a "Statement of Total Recognised Gains and Losses" which is essentially the same as the "Statement of Comprehensive Income" required under US GAAP, except for the recognition of unrealised gains and losses on qualified derivative hedging transactions, which are recognised in US GAAP Comprehensive Income. SFAS 130 requires disclosure of the cumulative amounts of other comprehensive income.

(e) Sale and Leaseback:
Under Irish GAAP, the Company's sale and leaseback transaction which took place in December 1999 was treated as a disposal of assets with the gain on the disposal of US$1,014,000 being credited to the profit and loss account in the period of the transaction. Under US GAAP, this amount is deferred and released to the profit and loss account over the period of the lease (20 years).

(f) Sales on Extended Credit Terms:
In 2003 and 2004 the Company made certain sales on extended credit terms. Under US GAAP, SAB 104, "Revenue Recognition in Financial Statements", such sales on extended credit terms would not be recognisable as revenue until the subsequent year, when the cash is actually received. No similar provisions exist under Irish GAAP to preclude revenue recognition. Sales were not made on extended credit terms in 2002.

(g) Restructuring Costs:
Under Irish GAAP, certain provisions made for restructuring costs incurred upon and related to acquisitions of acquired companies (principally payments to employees and certain facilities costs) and expensed immediately would not be recognisable under US GAAP, because EITF 95-3, "Recognition of Liabilities in Connection with a Purchase

Business Combination", requires costs that meet certain criteria be treated as part of the purchase price allocation. Certain termination costs not determined on the basis of length of service or other exit costs which are not incremental to the acquired company, even if they provide a reduced economic benefit, are considered period costs which are expensed when incurred. Certain facilities costs amounting to US$270,000 representing post-closure lease commitments for a facility acquired in 2001 were originally capitalised. These costs were subsequently excluded as a fair value adjustment in 2002 as the facility was not closed within a year of the acquisition. A decision to maintain the facility for certain operations was subsequently taken in 2003.

(h) Product Development Costs:
US GAAP, as set forth in SFAS 2, "Accounting for Research and Development Costs", requires development costs to be written-off in the year of expenditure. Under Irish GAAP, development expenditure on projects whose outcome can be assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues, are capitalised at cost within intangible assets.

(i) Derivatives and Financial Instruments:
In June 1998, the FASB issued SFAS 133, "Accounting for Derivative Instruments and Hedging Activities". SFAS 133 requires that all derivatives be recognised on the balance sheet at fair value. Derivatives which are not hedges or where hedge correlation cannot be demonstrated must be adjusted to fair value through income. Under Irish GAAP derivatives are not recognised until settled. Realised gains and losses on transactions where derivatives are used to hedge cross-currency cashflows are ultimately recorded in the income statement on settlement.

As part of a managed hedging policy Trinity Biotech has entered into a series of forward contracts to sell US Dollars forward for Euro. These contracts were entered into by the Company to mitigate its foreign exchange risk. The principal exchange risk identified by Trinity Biotech was with respect to fluctuations in the Euro as a substantial portion of its expenses is denominated in Euro but its revenues are primarily denominated in US Dollars. These forward contracts are cashflow hedging instruments whose objective is to cover a portion of this Euro mismatch. In the medium term, the Company's objective is to increase the level of non-US Dollar denominated revenue, thus creating a natural hedge of its non-US Dollar expenditure.

During 2001 Trinity Biotech began documenting its hedging transactions in accordance with the requirements of SFAS 133. In 2004 an unrealised loss of US$54,000 (2003: loss of US$791,000, 2002 gain of US$1,178,000) was taken to comprehensive income in respect of such contracts in accordance with the standard.

During the year ended December 31, 2004 US$868,000 (2003: US$2,374,000) of foreign exchange gains were recognised in the Income Statement. This included realised foreign exchange gains of US$126,000 (2003: US$68,000, 2002: US$162,000) on the exercise of forward contracts under US GAAP, relating to contracts entered into during the year which had not been designated as hedging instruments. At December 31, 2004 contracts with a fair value of US$47,000 are recorded in other comprehensive income which the Company anticipates will be reclassified into earnings on the exercise of forward contracts in the year ending December 31, 2005. The last of the Company's forward contracts expires in December 2005.

(j) Deferred Tax:

Deferred tax differences arise between Irish GAAP and US GAAP due to the impact of the nature and timing of the reconciling items arising.

CUMULATIVE EFFECT ON SHAREHOLDERS' EQUITY	December 31 2004 US$'000	December 31 2003 US$'000
Total shareholders' equity before minority interests under Irish GAAP	116,138	80,262
US GAAP adjustments:		
Goodwill		
- Gross (a)	11,727	21,777
- Gross (b)	1,532	-
- Aggregate amortisation	(7,717)	(9,854)
Intangible assets		
- Gross (c)	10,050	-
- Aggregate amortisation	(532)	-
Product development costs		
- Gross	(8,441)	(4,668)
- Aggregate amortisation	251	-
Property, plant and equipment	139	77
Share capital not paid	(158)	(253)
Adjustment for sale and leaseback	(760)	(811)
Adjustment for sales on extended credit	(80)	(144)
Adjustment for fair value of derivative instruments	418	346
Deferred tax		
- Fair value intangible assets	(1,455)	-
- Other	921	502
Shareholders' equity under US GAAP	122,033	87,234

(a) Includes pre -1998 goodwill written-off against shareholders' equity under Irish GAAP of US$21,777,000.
(b) Deferred tax liability recognised on identifiable intangible assets from Fitzgerald and Adaltis US, Inc acquisitions.
(c) Intangible assets of US$10,050,000 arising on 2004 acquisitions under US GAAP are accounted for as goodwill under Irish GAAP.

At December 31, 2004 the cumulative total fair value of derivative instruments in other comprehensive income was US$47,000, (2003: US$101,000). At December 31, 2004 the total accumulated translation reserve in other comprehensive income was (US$3,975,000), (2003: (US$4,091,000)).

EFFECT ON NET PROFIT For the year ended	December 31 2004 US$'000	December 31 2003 US$'000
Profit on ordinary activities after taxation under Irish GAAP	5,166	5,797
US GAAP adjustments:		

Goodwill amortisation	2,136	1,559
Intangible amortisation	(532)	-
Adjustment for property, plant and equipment	63	76
Adjustment for sale and leaseback	51	51
Adjustment for sales on extended credit	64	(144)
Adjustment for restructuring costs	-	-
Adjustment for product development costs		
- Cost	(3,773)	(2,340)
- Amortisation	251	-
Adjustment for fair value of derivative instruments	126	68
Deferred tax	496	79
Profit under US GAAP	4,048	5,146
Profit per ordinary share (US Dollars)	0.07	0.12
Diluted profit per ordinary share (US Dollars)	0.07	0.11
Weighted-average number of ordinary shares used in computing basic profit per ordinary share	55,132,024	43,093,146
Diluted weighted-average number of ordinary shares used in computing diluted profit per ordinary share	63,935,138	50,583,247

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

For the year ended	December 31 2004 US$'000	December 31 2003 US$'000
Profit under US GAAP	4,048	5,146
Translation adjustment	116	175
Fair value of derivative instruments	(54)	(791)
Total comprehensive income	4,110	4,530

CHANGES IN US GAAP EQUITY FOR THE YEARS ENDED DECEMBER 31 2004, DECEMBER 31 2003 AND DECEMBER 31 2002

	December 31 2004 US$'000	Decem U
US GAAP Shareholders' Equity at January 1	87,234	
Net profit for the period	4,048	
'A' shares issued for cash	24,335	
'A' shares issued for conversion of debenture	427	
'A' shares issued on conversion of warrant	348	
Options exercised	1,632	
Stock-based compensation - additional paid-in capital	13	
'A' shares issued as consideration for acquisition	7,721	
'A' shares issued for financial asset	-	

Share issue expenses	(1,509)
Share proceeds outstanding	(2,373)
Share capital not paid in previous periods no longer payable	95
Other comprehensive income:	
Translation adjustment	116
Fair value of derivative instruments	(54)
US GAAP Shareholders' Equity at December 31	122,033

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the year	
	December 31 2004 US$'000	December 3 200 US$'00
Operating Activities		
Retained profit under Irish GAAP	5,166	5,79
Adjustments to reconcile net profit to cash provided by operating activities:		
Depreciation	1,819	1,36
Amortisation	2,570	85
Taxation (paid)	(1,666)	(15
Share of operating loss in associate	-	25
Write off of investment in associate	-	81
Provision for corporation tax charge	53	2,18
Net interest payable accrual	(118)	15
Exceptional administrative expenses	-	
Decrease/ (increase) in accounts receivable and prepayments	484	(6
(Decrease) /increase in accounts payable and accrued expenses	(2,419)	(2,56
Increase in inventory	(5,883)	(6,00
Non-cash compensation expense	13	8
Foreign exchange losses on non-operating cash flows	(131)	48
Loss on disposal/retirement of fixed assets	14	18
Non cash settlement of interest	-	4
Other non-cash items	140	16
Net cash inflow from operating activities	42	3,60
Investing activities		
Payments to acquire trades or businesses	(19,090)	(76
Deferred consideration paid	-	(4,37
Payment for intangible fixed assets	(3,295)	(1,84
Disposal of fixed assets	31	
Payment for tangible fixed assets	(3,689)	(3,85
Net cash outflow from investing activities	(26,043)	(10,83
Financing activities		
Repayment of loan from unconnected third party	-	(5
Repayment of minority interest	-	(30
Issue of ordinary share capital including premium	31,708	2,25

Expenses paid in connection with share issue and debt financing	(2,238)	(1,12
Increase / (decrease) in long-term debt	(2,214)	2,45
Movement in finance leases	(267)	(13
Issue /(settlement) of convertible debentures, net	3,178	20,00
(Decrease) / increase in other financial liabilities	(2,675)	(1,09
Net cash inflow from financing	27,492	21,98
Increase in cash and cash equivalents	1,491	14,75
Effects of exchange rate movements on cash	233	
Cash and cash equivalents at beginning of year	20,563	5,80
Cash and cash equivalents at end of year	22,287	20,56

NON CASH TRANSACTIONS

In December 2001, the Group acquired the assets of the Biopool haemostasis business for a total consideration of US$6,409,000 satisfied in cash and deferred consideration. The deferred consideration was payable in three instalments of US$855,000, US$1,166,000 and US$570,000 on December 21, 2002, 2003 and 2004, respectively. The deferred consideration was not conditional on any future event and has been fully settled. This transaction relates to the Rest of World reportable segment.

In November 2002, the Company acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4,412,000 satisfied in cash and deferred consideration. The cash consideration was partly financed by the issue of US$2,500,000 of 5.25% convertible debentures. The debentures bear interest at a rate of 5.25% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$1.50. The Company also issued 50,000 warrants (the "Second Warrants") in November 2002. The deferred consideration of US$1,810,000 was paid in full in 2003. This transaction relates to the Rest of World reportable segment.

On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its associate HiberGen Limited. The consideration of US$202,000 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. During 2003, HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading. The Company wrote off its remaining investment in quarter four of the 2003 financial year. This transaction relates to the Rest of World reportable segment.

In December 1999, the Company completed a private placement of (i) US$3,500,000 principal amount of 7.5% Convertible Debentures and (ii) 483,701 warrants to purchase 'A' Ordinary shares of the Company (the "First Warrants"), which resulted in aggregate gross proceeds to the Company of US$3,500,000.

In relation to the First Warrants, 333,701 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.74 per share and the remaining 150,000 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.80 per share. 100,000 of these warrants were exercised to purchase 'A' Ordinary Shares in the Company in 2000. The balance of these 150,000 warrants expired unexercised on June 25, 2002. During 2003, 133,701 of the remaining First Warrants were exercised and the final 200,000 were exercised in 2004. The Second Warrants are each exercisable to purchase one 'A' Ordinary Share of the

Company at US$1.50 and will expire in November 2007. To date none of the Second Warrants have been exercised.

In July 2003, the Company completed a private placement of US$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$3.55. In December 2003, US$6,355,000 of the US$20,000,000 principal amount of the debenture was converted into 1,790,141 Class 'A' Ordinary Shares of the Company. In January 2004, a further US$427,500 of the principal amount of the debenture has been converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July placement, convertible notes in the aggregate principal amount of up to US$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US$4. The debentures are unsecured and are repayable in ten equal instalments. Under the terms of the agreement, the Company has the right to satisfy each repayment either in cash or in shares. In October 2004, the first principal repayment of US$1,822,000 was made to the debenture holders in cash. At December 31, 2004, total debentures outstanding were US$15,819,000. The debt is stated net of unamortised issue costs of US$576,000.

In January 2004, the Company has completed a private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US$5.25 per share. The Company further granted warrants to purchase 200,000 Class 'A' Ordinary Shares in the Company to agents of the Company who were involved in this private placement at an exercise price of US$5.25. Under the terms of the placement, investors were also granted the right to purchase an additional 2,647,059 Class 'A' Ordinary Shares of the Company at a price of US$4.25 per share for a period of up to 30 days after the closing of the transaction. An additional 431,617 Class 'A' Ordinary Shares of the Company were issued within the 30 day period following the closing of the transaction to investors who exercised this option.

In April 2004, Trinity completed the acquisition of the assets of Fitzgerald Industries International Inc (Fitzgerald) for US$16,000,000 in cash. The acquisition was partly funded by the issue of 2,783,984 'A' Ordinary Shares of the Company. As at December 31, 2004, 817,470 shares with a value of US$2,373,000 remain unpaid (see the consolidated statements of movement in shareholders' equity).

SHARE OPTION SCHEME - ADDITIONAL INFORMATION REQUIRED BY SFAS 123 The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under SFAS 123, "Accounting for Stock-Based Compensation," requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, where the exercise price of the Company's employee stock options is less than the market price of the underlying stock on the grant date, compensation expense is recognised in the income statement over the vesting period.

Proforma information regarding net income and earnings per share is required by

SFAS 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	2004	2003	2002
Expected option (in years)	4.0	4.0	4.0
Risk-free weighted-average interest rate	4.25%	4.25%	2.3%
Stock price volatility	0.398	0.855	0.411
Dividend yield	0%	0%	0%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The information required by SFAS 148, "Accounting for Stock-Based Compensation", is as follows:

	December 31 2004 US$'000	December 31 2003 US$'000	Dece U
Net income as reported	4,048	5,146	
Add: Total stock-based employee compensation expense included in reported net income, net of related tax effects	13	84	
Deduct: Total stock based employee compensation under fair value based method for all awards, net of related tax effects	(1,408)	(1,808)	(
Proforma net income	2,653	3,422	
Earnings per share:			
Basic - as reported (US Dollars)	0.07	0.12	
Diluted - as reported (US Dollars)	0.07	0.11	
Basic - proforma (US Dollars)	0.05	0.08	
Diluted - proforma (US Dollars)	0.05	0.07	

A summary of the Company's stock option activity, and related information, for the years ended December 31 follows:

	2004 Weighted-Average Options	Exercise Price	2003 Weighted-Average Options	Exercise Price
Outstanding-beginning of year	8,327,394	US$1.44	9,465,449	US$1.44
Granted	3,162,824*	US$3.68	1,495,500	US$1.90
Exercised	(1,113,538)	US$1.82	(1,397,717)	US$1.61

Forfeited	(430,339)	US$1.66	(1,235,838)	US$1.82
Outstanding at end of year	9,946,341	US$2.10	8,327,394	US$1.44
Exercisable at end of year	5,693,844	US$2.20	3,995,076	US$1.48
Weighted-average fair value of options granted during the year		US$0.99		US$1.09

* Amounts adjusted for previously issued stock options.

The weighted-average remaining contractual life of options outstanding at December 31, 2004 is 4.39 years. The information above also includes outstanding warrants.

A summary of the range of prices for the Company's stock options for the year ended December 31 2004 follows:

	Outstanding			
Option price range	No. of Shares	Weight.-Av. exercise price	Weight.-Av. contractual life remaining	No. of Shares
US$0.81 - US$0.99	2,947,530	US$0.94	3.92 years	1,756,863
US$1.00 - US$1.99	2,999,677	US$1.35	3.89 years	2,195,344
US$2.00 - US$2.99	2,315,310	US$2.55	5.69 years	386,513
US$3.00 - US$5.25	1,683,824	US$4.84	4.36 years	1,355,124

CAPITAL SHARES RESERVED FOR FUTURE ISSUANCE

The following table sets forth the shares of common stock reserved for future issuance:

	YEAR ENDED DECEMBER 31, 2004
Shares issuable on conversion of debentures	4,475,915
Shares underlying outstanding stock options	8,629,017
Shares available for grant under option plans	1,033,339
Shares issuable upon exercise of warrants	1,317,324
	15,455,595

INVESTMENTS
The Company had no trading securities as at December 31, 2004 or December 31, 2003.

The gross realised gains on sales of trading securities during 2004 was US$Nil (2003: US$Nil, 2002: US$Nil).

The Company had no "available-for-sale" or "held to maturity securities" as at December 31, 2004 or December 31, 2003.

FAIR VALUES OF FINANCIAL INSTRUMENTS
The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments:

Cash and cash equivalents, trade accounts receivable and trade accounts payable: The carrying amount reported in the balance sheet for cash and cash equivalents, trade accounts receivable and trade accounts payable approximates their fair value.

Long and short-term debt: The carrying amounts of the Company's borrowings approximate their fair value as substantially all of the debt bears interest at market rates.

Forward contracts: The Company marks its forward contracts to market in determining fair value.

The carrying amounts and fair values of the Company's financial instruments at December 31, 2004 and 2003 are as follows:

	December 31, 2004		December 31, 20
	Carrying Amount US$'000	Fair Value US$'000	Carrying Amount US$'000
Cash and cash equivalents	22,287	22,287	20,563
Trade accounts receivable	10,799	10,799	11,459
Trade accounts payable	3,328	3,328	3,519
Short-term debt	11,088	11,410	8,911
Long-term debt	12,923	13,316	17,359
Forward contracts	418	418	346

ADDITIONAL UNAUDITED PROFORMA INFORMATION FOR ACQUISITIONS MADE IN 2004
The information below presents the proforma effect of the acquisitions made in 2004 as if they had occurred on January 1, 2004 and January 1, 2003.

	December 31 2004 US$'000	December 20 US$'0
Proforma revenues	82,241	79,2
Proforma income before extraordinary items	4,227	3,6
Proforma net income	4,227	4,6
Proforma earnings per share (US Dollars)	0.08	0.
Proforma diluted earnings per share (US Dollars)	0.07	0.

The proforma information was compiled using a combination of available financial information or where unavailable, extrapolations of the results of Adaltis and Fitzgerald both of which were acquired during 2004. There were no acquisitions in 2003.

ADDITIONAL UNAUDITED PROFORMA INFORMATION FOR ACQUISITIONS MADE IN 2002
The information below presents the proforma effect of the acquisitions in 2002, as if they had occurred on January 1, 2002.

	December 31 2002 US$'000
Proforma revenues	63,351
Proforma net income	6,446
Proforma earnings per share (US Dollars)	0.16
Proforma diluted earnings per share (US Dollars)	0.15

The proforma information was compiled using extrapolations of the results for the haemostasis division and speciality clinical chemistry product line acquired from Sigma Diagnostics during 2002.

RESTRUCTURING COSTS

In December 2001, the Company purchased Biopool and decided to consolidate its operation into the Bray facility.

Restructuring provisions were determined based on estimates prepared at the time the restructuring actions were approved by management. An analysis of the movement on the Company's restructuring plan reserves for 2002 and 2003 is as follows:

Provision for Restructuring Costs (under Irish GAAP)	2002 US$'000	2003 US$'000
Opening provision	2,835	315
Incurred	(2,290)	(315)
Write back of provision	(230)	-
Closing provision	315	-

Date of completion

The anticipated and actual date of closure of the Biopool facility at Ventura, CA was September 30, 2002. The anticipated date of completion of the transfer of operations from the Biopool facility at Umea, Sweden was also September 30, 2002. However, in 2003 the Company made a decision to maintain the operations of the Umea facility at a reduced level with a staff of approximately eight employees and the transfer of certain other operations did not occur until 2003. 15 employees were only terminated in January 2003 and 15 further employees in July, 2003. 54 employees were involuntarily terminated consequent to the Biopool Ventura facility closure.

IMPACT OF RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Share-Based Payment
In December 2004, the FASB issued SFAS No. 123 (revised 2004) "Share-Based Payment" ("SFAS 123R"). This Statement replaces FASB Statement No. 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees", and its related implementation guidance.

This Statement establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. It also addresses transactions in which an entity incurs liabilities in exchange for goods or services that are based on the fair value of the entity's equity instruments or that may be settled by the issuance of those equity instruments. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This Statement does not change the accounting guidance for share-based payment transactions with parties other than employees provided in Statement 123 as originally issued and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services". This Statement does not address the accounting for employee share ownership plans, which are subject to AICPA Statement of Position 93-6, "Employers' Accounting for Employee Stock Ownership Plans".

This Statement requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award (with limited exceptions). That cost will be recognised over the period during which an employee is required to provide service in exchange for the award--the requisite service period (usually the vesting period). No compensation cost is recognized for equity instruments for which employees do not render the requisite service. Employee share purchase plans will not result in recognition of compensation cost if certain conditions are met; those conditions are much the same as the related conditions in Statement 123. A public entity will initially measure the cost of employee services received in exchange for an award of liability instruments based on its current fair value; the fair value of that award will be remeasured subsequently at each reporting date through the settlement date. Changes in fair value during the requisite service period will be recognised as compensation cost over that period. If an equity award is modified after the grant date, incremental compensation cost will be recognized in an amount equal to the excess of the fair value of the modified award over the fair value of the original award immediately before the modification. The proforma disclosures previously permitted under Statement 123 no longer will be an alternative to financial

statement recognition.

This Statement eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. This Statement is effective for public entities that do not file as small business issuers as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortisation method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock option and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R and expects that the adoption of SFAS 123R will have a material impact on the Company's consolidated results of operations and earnings per share. The Company has not determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current proforma disclosures under Statement 123.

The adoption or future adoption of the following recent accounting pronouncements have not or are not expected to have a material impact on the Company's results of operations and financial condition.

Consolidation of Variable Interest Entities
The Financial Accounting Standards Board issued FASB Interpretations No. 46, "Consolidation of Variable Interest Entities", ("FIN 46") in January 2003. This interpretation clarifies the application of Accounting Research Bulletin No.51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The provisions of FIN 46 were revised in December 2003 through the issue of FASB Interpretation No. 46(R) ("FIN46R"), "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" to be effective for financial statement periods ended after March 15, 2004. The adoption of FIN 46R is not expected to have a material impact on the consolidated financial statements of the Company as the Company has a controlling interest in all of its subsidiaries.

Inventory Costs
The Financial Accounting Standards Board ("FASB") issued SFAS 151, "Inventory Costs - an amendment of ARB No. 43, Chapter 4", in November 2004. This standard amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing", to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so

abnormal as to require treatment as current period charges..." The amendment removes the ambiguity and requires that all abnormal amounts of idle facility expense, freight, rehandling costs, and wasted material (spoilage) be treated as current period costs. In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005.

Exchanges of Nonmonetary Assets - an amendment of APB Opinion No. 29
The FASB issued SFAS 153, "Exchanges of Nonmonetary Assets - an amendment of APB Opinion No. 29", in December 2004. The guidance in APB Opinion No. 29, "Accounting for Nonmonetary Transactions", is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions of this statement shall be effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005.

26. GROUP UNDERTAKINGS

Name and registered office	Principal activity	Principal C of incorpo and ope
Trinity Biotech plc IDA Business Park Bray, Co. Wicklow, Ireland	Investment and holding company	Irel
Trinity Biotech Manufacturing Limited IDA Business Park Bray Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Irel
Trinity Research Limited IDA Business Park Bray Co. Wicklow, Ireland	Research and development	Irel
Trinity Biotech Sales Limited IDA Business Park, Bray Co. Wicklow, Ireland	Non - trading	Irel
Flambelle Limited 16 Fitzwilliam Place Dublin, Ireland	Non-trading	Irel
Benen Trading Ltd IDA Business Park, Bray	Trading	Irel

Co. Wicklow, Ireland		
Reddinview Ltd IDA Business Park, Bray Co. Wicklow, Ireland	Dormant company	Irel
Trinity Biotech Inc (Formerly Disease Detection International Inc) Girts Road Jamestown NY 14702, USA	Holding Company	U.S.
Clark Laboratories Inc Trading as Trinity Biotech (USA) Girts Road Jamestown NY 14702, USA	Manufacture and sale of diagnostic test kits	U.S.
FHC Corporation Girts Road Jamestown NY 14702, USA	Non-trading	U.S.
MarDx Diagnostics Inc 5919 Farnsworth Court Carlsbad CA 92008, USA	Manufacture and sale of diagnostic test kits	U.S.
Fitzgerald Industries International, Inc 2711 Centerville Road, Suite 400 Wilmington, New Castle Delaware, 19808	Management services company	U.S.
Biopool US Inc Girts Road Jamestown NY 14702, USA	Manufacture and sale of diagnostic test kits	U.S.
Eastcourt Limited Chichester House 278/282, High Holborn London, UK	Non-trading	UK
Trinity Biotech UK Holdings Ltd (Formerly Centocor UK Holdings Ltd) Shalford Guildford, Surrey, UK	Holding company	UK
Trinity Biotech UK Ltd (Formerly Centocor UK Ltd) Shalford Guildford, Surrey, UK	In voluntary liquidation	UK
Trinity Biotech (UK Sales) Limited 54 Queens Road Reading RG1 4A2, England	Sales of diagnostic test kits	UK
Trinity Biotech GmbH Otto Hesse Str 19 64293 Darmstadt, Germany	Manufacture of diagnostic instrumentation and sale of diagnostic test kits	Germ

Biopool AB S-903 47 Umea Sweden	Manufacture and sale of diagnostic test kits	Swed

27. EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

In January 2005, Trinity made the second repayment on the total convertible debenture principal amount outstanding. Under the terms of the agreement, the Company has the right to satisfy each repayment either in cash or in shares. The amount due to be paid was US$1,822,000 and this repayment was satisfied by the issue of 672,232 shares on January 4, 2005. At February 28, 2005, the total amount of convertible debt outstanding was US$13,997,000.

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 and earned revenues of US$5,054,000 (unaudited) in 2004.

As part of the acquisition of RDI the Company acquired working capital of approximately US$176,000 (unaudited). As a formal valuation of the intangible assets acquired has not been completed it is not practical to provide any further details of the net assets acquired on acquisition.

SCHEDULE II

TRINITY BIOTECH PLC

VALUATION AND QUALIFYING ACCOUNTS

DOUBTFUL DEBTS	Balance at beginning of period US$'000	Charged to costs and expenses US$'000	Charged to other accounts US$'000 (a)	Deductions US$'000 (b)	Balan at en of peri US$'0
2004	478	180	(143)	(53)	4
2003	496	262	(38)	(242)	4
2002	30	466	-	-	4

(a) Amounts recovered during the year
(b) Amounts written-off during the year

VALUATION ALLOWANCE FOR INCOME TAXES	Balance at beginning of period US$'000	Provided US$'000 (a)	Reductions US$'000 (b)
2004	179	302	(179)
2003	131	179	(131)
2002	273	-	(142)

(a) Increase in valuation allowance associated with deferred tax asset.
(b) Reduction in valuation of allowance associated with deferred tax asset.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorised the undersigned to sign this annual report on its behalf.

TRINITY BIOTECH PLC

By: RONAN O'CAOIMH

Mr Ronan O'Caoimh
Director/
Chief Executive Officer

Date: March 31, 2005

By: RORY NEALON

Mr Rory Nealon
Director/
Chief Financial Officer

Date: March 31, 2005

ITEM 19

EXHIBITS

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
12.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-O
12.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-O
13.1	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Ad 906 of the Sarbanes-Oxley Act of 2002.
13.2	Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Ad of the Sarbanes-Oxley Act of 2002.