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,