TRINITY BIOTECH PLC
Form 20-F/A
December 10, 2003

FORM 20-F /A

(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
RESTATEMENT OF PREVIOUSLY FILED 20-F

For the fiscal year ended: December 31, 2002

Commission file number: 0-22320

Trinity Biotech plc

(Exact name of Registrant as specified in its charter)

Ireland

(Jurisdiction of incorporation or organization)

IDA Business Park, Bray, Co. Wicklow, Ireland

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12 (b)
of the Act:

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: 39,629,169 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 required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No

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

Item 17. Item 18 X

Explanatory Note

Trinity Biotech plc ("Trinity" and / or "the Company") has restated its consolidated financial statements as reported under generally accepted accounting principles in the Republic of Ireland ("Irish GAAP") and in the United States ("US GAAP") at December 31, 2002 and 2001, and for each of the three years in the period ended December 31, 2002. Trinity has also restated its consolidated statement of movements in shareholders' equity as reported under Irish and US GAAP as at January 1, 2000 and December 31, 2002, 2001 and 2000.

Trinity has restated the financial statements for errors in accounting for certain items. The Company has assessed the errors in respect of each of the years presented for the Irish GAAP financial statements and the US GAAP reconciliation. Criteria set out in SEC Staff Accounting Bulletin No. 99 - Materiality ("SAB 99") have been applied to the Irish GAAP financial statements and US GAAP reconciliation. The Company has analysed the errors for each of the years presented, and those applicable to prior periods in aggregate, and has accordingly restated its Irish GAAP financial statements and US GAAP reconciliation.

The Form 20-F/A amends financial information in Items 3, 5 and 18 of the Form 20-F filed by Trinity on July 2, 2003 (the "Form 20-F") in the following manner:

Item 3 "Selected Consolidated Financial Data". The Consolidated Profit and Loss Account Data and Consolidated Balance Sheet Data tables amend in their entirety the corresponding tables in the Form 20-F to provide information regarding the effect of the restatement as of and for all periods presented.

Item 5 "Operating and Financial Review and Prospects" sections "Results of Operations" and "Liquidity and Capital Resources" have been amended to reflect the impact of the restatement of the consolidated financial statements under Irish GAAP.

The consolidated financial statements filed pursuant to Item 18 have been amended to reflect the restatement of the consolidated financial statements under generally accepted accounting principles in the Republic of Ireland ("Irish GAAP") and in the United States ("US GAAP") for each of the three years in the period ended December 31, 2002.

Trinity has also updated certain information in Items 4, 6,7, 9, 10 11 and 15.

Other than as set forth above this form 20-F/A does not amend, update or restate any other items or sections of the Form 20-F.

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 as at December 31, 2002 and 2001 and for each of the years ended December 31, 2002, December 31, 2001 and December 31, 2000, have been derived from, and should be read in conjunction with, the audited Consolidated Financial Statements and Notes (as restated) thereto set forth in Item 18 of this Annual Report. The selected consolidated financial data as at December 31, 2000, December 31, 1999 and December 31, 1998 and for each of the years ended December 31, 1999 and 1998 are derived from the audited Consolidated Financial Statements (as restated) 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, 2002	Year Ended Dec 31, 2001	Year Ended Dec 31,2000	Year Ended Dec 31,1999
	Restated US$	Restated US$	Restated US$	Restated US$
Revenues	51,978,422	37,075,573	29,742,942	25,719,623
Cost of sales	(25,689,879)	(18,049,765)	(15,410,257)	(14,562,619)
Administrative expenses	(12,849,416)	(11,195,884)	(6,013,064)	(2,955,078)
R & D expenses	(4,470,745)	(2,779,729)	(2,681,220)	(2,448,372)
Amortization	(2,385,521)	(2,002,135)	(1,191,290)	(896,913)
Operating profit				
- Continuing Operations	6,523,834	5,816,912	3,201,040	4,856,641

- Acquisitions	59,027	(2,768,852)	1,246,071	--
- Disposals -	--	--	--	--
	6,582,861	3,048,060	4,447,111	4,856,641
Interest expense	(704,460)	(538,401)	(757,852)	(761,501)
Interest income	103,133	142,364	466,151	69,284
Share of operating loss in associate	(317,113)	(268,870)	(30,000)	--
Profit/(loss) on assets	--	--	--	404,328
Net profit before tax	5,664,421	2,383,153	4,125,410	4,568,752
Tax on profit on ordinary activities	(767,510)	(15,876)	(1,000)	10,000
Net profit after tax	4,896,911	2,367,277	4,124,410	4,578,752
Profit from operations per ordinary share (US cents)	16.23	7.54	11.98	17.25
Profit from continuing operations per ordinary share (US cents)	16.09	14.40	8.62	17.25
Basic earnings per ordinary share (US cents)	12.08	5.86	11.11	16.26
Diluted earnings per ordinary share (US cents)	11.73	5.76	10.47	15.80
Weighted average number of shares used in computing basic EPS	40,550,367	40,408,978	37,131,692	28,158,184
Weighted average number of shares used in computing diluted EPS	42,486,227	41,120,060	40,540,494	28,990,725

Consolidated Balance Sheet Data	As at Dec 31, 2002	As at Dec 31, 2001	As at Dec 31, 2000	As at Dec 31,
	Restated US$	Restated US$	Restated US$	Restat US$
Working Capital	20,423,522	17,117,172	15,755,495	5,439
Long-term Liabilities	7,745,442	7,805,237	2,266,425	8,086
Total Assets	89,798,458	77,072,043	66,900,229	44,433
Capital Stock	610,095	603,420	602,807	460
Shareholders' Equity	62,537,284	56,411,625	53,891,729	22,372

Amounts Adjusted for US GAAP

Consolidated Statement of Income	Year Ended Dec 31, 2002	Year Ended Dec 31, 2001	Year Ended Dec 31,2000	Year Dec

	Restated US$	Restated US$	Restated US$	Res U
Net profit	5,042,943	710,151	1,108,114	6
Basic earnings per ordinary share (US cents)	12.44	1.76	2.98	
Diluted earnings per ordinary share (US cents)	12.07	1.73	2.98	

Consolidated Balance Sheet Data	As at Dec 31, 2002	As at Dec 31, 2001	As at Dec 31,2000	As Dec 31
	Restated US$	Restated US$	Restated US$	Resta US
Total Assets	99,067,410	83,239,531	75,858,813	55,696,
Shareholders' Equity	70,944,268	63,463,291	62,899,307	33,121,

No dividends were declared in any of the periods from December 31, 1998 to December 31, 2002.

The Irish and US GAAP selected financial data as of and for all periods presented have been restated for errors in accounting for certain items. The necessary adjustments to the relevant periods are set out in the tables below. More detailed information on the restatement is contained in Note 1(a) and Note 28 of Notes to the Consolidated Financial Statements contained in Item 18 of this Annual Report on Form 20-F / A in respect of Irish GAAP and US GAAP consolidated financial statements, respectively.

AMOUNTS IN ACCORDANCE WITH IRISH GAAP	Year Ended Dec 31, 2002	Year Ended Dec 31, 2001	Year Ended Dec 31, 2000	Year Ended Dec 31, 199
	US$	US$	US$	US$
Net profit after tax:				
Before effect of restatement	5,010,317	1,449,348	4,823,465	4,915,697
Effect of restatement for the period	(113,406)	917,929	(699,055)	(336,945)
As restated	4,896,911	2,367,277	4,124,410	4,578,752
Per Ordinary Share:				
Basic earnings per ordinary share (US cents)				
Before effect of restatement	12.36	3.59	12.99	17.46
Effect of restatement for the period	(0.28)	2.27	(1.88)	(1.20)

As restated	12.08	5.86	11.11	16.26
Diluted earnings per ordinary share (US cents)				
Before effect of restatement	11.99	3.52	12.20	16.96
Effect of restatement for the period	(0.26)	2.24	(1.73)	(1.16)
As restated	11.73	5.76	10.47	15.80

	Year Ended Dec 31, 2002	Year Ended Dec 31, 2001	Year Ended Dec 31, 2000	Year Ended Dec 31, 199
AMOUNTS IN ACCORDANCE WITH US GAAP	US$	US$	US$	US$
Net profit after tax:				
Before effect of restatement	5,225,804	293,816	1,667,958	988,792
Effect of restatement for the period	(182,861)	416,335	(559,844)	(336,945
As restated	5,042,943	710,151	1,108,114	651,847
Per Ordinary Share:				
Basic earnings per ordinary share (US cents)				
Before effect of restatement	12.89	0.73	4.49	3.51
Effect of restatement for the period	(0.45)	1.03	(1.51)	(1.20
As restated	12.44	1.76	2.98	2.31
Diluted earnings per ordinary share (US cents)				
Before effect of restatement	12.50	0.71	4.49	3.41
Effect of restatement for the period	(0.43)	1.02	(1.51)	(1.16
As restated	12.07	1.73	2.98	2.25

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 prospectus 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.

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 operations and payment obligations for the future including a future purchase price payment for a business acquisition described below under "Recent Developments - Acquisitions" in the amount of $800,000 payable on November 27, 2003. 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 organizations 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) and Roche Diagnostics (COBAS AMPLICOR(TM), Ampliscreen(TM), Accutrend(TM)).

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 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, 2002, December 31, 2001 and December 31, 2000, approximately 20%, 27% and 30% respectively of Trinity Biotech's revenues were derived from a distribution agreement between our subsidiary, Trinity Biotech (USA) Corp. (trading name of Clark Laboratories, Inc.) and Wampole. In 2001, Wampole was acquired by Medpointe, Inc. and was subsequently acquired by Inverness Medical in 2002. In 2002 we negotiated an amendment to the distribution agreement whereby the exclusivity of Wampole's right to sell our products in the US will be removed in stages throughout 2004. During 2003 Trinity has experienced declining sales revenues under the Wampole distribution agreement which it believes is due to Wampole attempting to convert customers from the Trinity product to an alternative product. Accordingly in December 2003 the Company filed an action against Inverness Medical for breach of contract. For further information relating to this matter please refer to Note 31 of the Notes to the Consolidated Financial Statements "Events Subsequent to Date of Auditors' Report - Unaudited" in Item 18 "Financial Statements" of this Form 20F/A. Any material ongoing reduction in sales arising from this matter will have a material adverse effect on Trinity Biotech.

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 licenses to use this technology and, in the event of being unable to obtain such licenses 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 October 31, 2003
5,006,474	Bi-Directional Lateral Chromatography Test Device	4 years 6 months
5,114,845	Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin	3 years 9 month
5,175,087	Method of Performing Tissue Plasminogen Activator Assay	3 years 9 month
5,985,582	Thrombin-Based Assay for Antithrombin - III	14 years 2 months
6,194,394	Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays	14 years 9 month

6,528,273	Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls	15 years 1 months
6,391,609	Thromboplastin Reagents and Methods for Preparing and Using Such Reagents	16 years

In addition to these US patents, Trinity Biotech owns a total of 21 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.

A premarket application or PMA for the UniGold HIV Test is currently undergoing FDA review. No assurance can be given that the FDA will grant PMA approval to the UniGold HIV Test on a timely basis or at all. A delay or failure to receive such approval could have a material adverse effect on our revenues, earnings and financial standing.

- We are required to comply with extensive postmarket 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 insurance policy for Mr O'Caoimh in the amount of (euro)533,289. 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 its business. In the USA, 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. We are not aware of any plans by qualified staff to retire or leave Trinity Biotech in the near future.

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 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$4,327,200) for any one accident, limited to a maximum of (euro)4,000,000 (US$4,327,200) 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 and U.S. dollars and prepares its financial statements in U.S. dollars. A substantial portion of our expenses is denominated in Euro. However, Trinity Biotech's revenues are primarily denominated in U.S. dollars. As a result, we are affected by fluctuations in currency exchange rates, especially the exchange rate between the U.S. dollar and the Euro.

Fluctuations between these and other exchange rates may adversely affect our earnings and assets. The percentage of 2002 consolidated revenue denominated in US$ was approximately 80%. Of the remaining 20% revenue, the breakdown was as follows: Euro (17%), Yen (2%) and Sterling 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 2% 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 this mismatch through the use of forward contracts. Trinity Biotech entered into a series of forward contracts to sell US$ and Japanese Yen forward for Euro. These contracts remain in place until early 2004. 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$ denominated revenue, thus creating a natural hedge of the non-US$ 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 would dilute the ownership interest of existing shareholders.

- The convertible notes described below under "Recent Developments - Sale of Convertible Notes" are convertible into ADRs representing our Class "A" Ordinary Shares. Conversion of the notes 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 total principal amount of US$20,000,000 million into ADRs at a conversion price of US$3.55, Trinity Biotech would have to issue 5,633,803 additional ADRs. On the basis of 42,423,294 outstanding shares, this would effectively dilute the ownership interest of the existing shareholders by approximately 12%. 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 judgments. The laws of Ireland do

however, as a general rule, provide that the judgments 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 recognize the United States judgment. The originating court must have been a court of competent jurisdiction, the judgment may not be recognized if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgment obtained in contravention of the rules of natural justice will not be enforced in Ireland.

Item 4

Information on the Company

History and Development of the Company

Trinity 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 markets over 500 different diagnostic products in approximately 80 countries.

Trinity 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 USA. 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 hemostasis business in December 2001 and the hemostasis division of Sigma Diagnostics, part of Sigma Aldrich, in August 2002, Trinity has expanded its product range to include test kits that diagnose blood coagulation and related disorders, and a hemostasis instrumentation portfolio. The acquisition of the speciality clinical chemistry business of Sigma Diagnostics in November 2002 means that Trinity now participates in this important market segment. Trinity markets its products in the USA and in approximately 80 countries worldwide through a combination of direct selling and a network of national and international distributors. Trinity has manufacturing facilities in Bray, Ireland, and Lemgo, Germany, in Europe, and in Jamestown, New York, and Carlsbad, California in the USA.

Over the past four years, Trinity has made six acquisitions of diagnostic businesses the details of which are set out below. Three of these acquisitions have been of Enzyme Immunoassay ("EIA") businesses, two were hemostasis businesses and the sixth was a speciality clinical chemistry business. In October 2000, the Company also subscribed for 33% of the share capital of HiberGen Limited ("HiberGen"), an Irish-based genomics company. In July 2001, the Company further increased its shareholding in HiberGen to 40% and in April 2002 increased it further to 42.9%. In July 2001, Trinity 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 now has a comprehensive portfolio of over 500 products, including 14 rapid tests.

Acquisition of the speciality clinical chemistry product line of Sigma

Diagnostics

In November 2002, Trinity acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4.4m satisfied in cash and deferred consideration. The deferred consideration is payable in two instalments. The first instalment of US$1m was paid on May 27, 2003. The second instalment of US$0.8m is payable on November 27, 2003. The deferred consideration is not conditional on any future event. 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 hemostasis division of Sigma Diagnostics

In August 2002, Trinity Biotech purchased the hemostasis division of Sigma Diagnostics for a total consideration of US$1.4m. 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 hemostasis reagents comprise more than fifty 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. Trinity also received FDA clearance recently for its new hemostasis analyser the AMAX Destiny(TM).

Acquisition of the assets and goodwill of the Biopool hemostasis business

In December 2001, Trinity acquired the assets and goodwill of the Biopool hemostasis business for a consideration of US$6.4m before costs comprising US$3.8m in cash and US$2.6m in deferred consideration. The deferred consideration was payable in three instalments of US$0.9m, US$1.2m and US$0.6m 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 USA 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 acquired the assets and goodwill of the Amerlex hormone business of Ortho Clinical Diagnostics for a consideration of US$0.9m. 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.

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$1.4m. On July 2, 2001 the Company increased its shareholding in HiberGen to 40% at a cost of US$0.3m. 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$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. In November 2003, the Company announced that the recent fundraising

process undertaken by HiberGen had not been successful and that HiberGen had ceased trading. The Company has a 42.9% interest in HiberGen and treats the investment in its financial statements as an investment in an associated company. The Company intends to write off its remaining investment of US$968,000 in quarter four of the 2003 financial year.

Acquisition of Bartels Inc

In December 2000, Trinity acquired the assets and goodwill of Bartels Inc ("Bartels"), for a consideration of US$9.5m comprising US$3.2m in stock, US$0.4m in the form of a promissory note and the balance of US$5.9m 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 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 USA. The acquisition of MarDx gave Trinity a strong position in the Western Blot segment of the infectious disease market. Western Blot confirmatory testing is a natural extension to Trinity's EIA products and the Company intends to extend the MarDx Western Blot technology and manufacturing capability to other confirmatory tests.

Establishment of UK subsidiary, Trinity Biotech (UK Sales) Ltd

In 2002 Trinity opened a sales and marketing office in Oxfordshire, UK employing three sales professionals who market the hemostasis and clinical chemistry products from Trinity Biotech.

Establishment of German subsidiary, Trinity Biotech GmbH

In October 2001, Trinity established a direct sales operation in Germany which commenced trading in October. After the USA and Japan, Germany, with a population of 83m, is the third largest market in the world for in-vitro diagnostics, accounting for 7% ((euro)1.6bn) of the total world market of (euro)22.5bn. In the past Trinity 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's current products. In 2002 Trinity purchased the hemostasis business of Sigma

Diagnostics. This business was taken over by Trinity Biotech GmbH.

Pre Market Application ("PMA") Application 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's UniGold HIV test. This IDE allows Trinity's UniGold HIV test to be used in a limited number of hospitals throughout the USA, to provide patients with the results of tests, conducted during ongoing clinical trials.

The product is used to provide diagnostic test results in less than fifteen 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's proposed clinical trials under the treatment IDE met FDA standards for human safety and confidentiality.

During 2001, representatives from Trinity 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's UniGold HIV test. This data along with extensive information on the manufacturing process for Trinity's UniGold HIV test have been presented to the FDA. The FDA recently completed a plant inspection of the Irish manufacturing facility in mid September. The company is currently awaiting notification from the FDA of the results of its PMA filing.

Principal Markets

The primary market for Trinity's tests remains the USA. During fiscal 2002, the Company sold 64% (US$33.5m) (2001: 68% or US$25.0m; 2000: 58% or US$17.3m) of product in the USA. Sales to non-USA (principally European and Asian) countries represented 36% (US$18.5m) during fiscal 2002 and 32% (US$12m) during fiscal 2001. The comparable figure in 2000 was 42% (US$12.5m).

For a more comprehensive segmental analysis please refer to Note 13 "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 neutralize the antigen. It is this highly specific binding of antigen to antibody which forms the basis for all immunoassay tests.

Trinity'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 utilize biotechnology techniques involving the in-house production of recombinant proteins, synthetic peptides and monoclonal antibodies.

Trinity'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)

Hemostasis
- Biopool(R)
- Amelung

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 product list of over 500 products. Trinity currently sells 95 EIA tests of various configurations in many countries around the world. Of these, 68 are cleared by the FDA for distribution within the USA.

These tests are performed on plates that allow for up to 96 simultaneous tests and can be performed manually or more typically on automated equipment. Trinity also offers a modest range of equipment for these types of assays as well as validating the Trinity 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.

Hemostasis

The second largest range of assays in Trinity's portfolio is the hemostasis assays. Arising from the acquisition of the Biopool and Sigma hemostasis businesses, Trinity now has an extensive range of hemostasis diagnostic kits, offering laboratories the ability to maximize testing. Biopool is a well-known leader and innovator in the worldwide market for hemostasis and fibrinolysis reagents. Strengthening the Biopool reagent portfolio is the addition of the former Sigma Amelung instrumentation and reagents. This strategic combination enables Trinity to provide the market with a complete line of hemostasis products that permit customized testing. With the increasing demand to elucidate a wide range of coagulapathies in the aging population, hemostasis testing is quickly advancing to the requirements of today's complexities.

From routine PTs to the esoteric aPC, Trinity'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 can offer superior sensitivity and NPV (Negative Predictive Value) for D-dimer testing. Alongside D-dimer are Trinity's comprehensive routine and speciality assays.

This extensive hemostasis 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's portfolio are the fluorescence assays that are also typically performed in medium to large sized hospital laboratories around the world. Trinity offers 33 fluorescence assays, of which 25 are cleared by the FDA for distribution within the USA, 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 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 9 DFA's Trinity 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'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. 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 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 14 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, especially in developing countries.

Tests for HIV are also 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's extensive range of 18 Western Blot test systems includes the first Lyme Western Blot assay to receive FDA clearance for distribution within the USA. 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 USA and Carter Wallace

Trinity Biotech USA ("Trinity USA") entered into a distribution agreement with Carter Wallace Inc 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 terms of the agreement, Carter Wallace has exclusive rights to Trinity USA's products in the USA and Puerto Rico. Trinity USA and Trinity may market certain Trinity USA products in the USA and Puerto Rico, which Carter Wallace has chosen not to market in those territories. In addition, Trinity and Trinity USA may market all of Trinity USA's products in all territories outside of the USA and Puerto Rico. As part of the agreement, Carter Wallace paid Trinity USA an amount of US$2.0m for the rights to the Trinity USA products in the territories of the USA and Puerto Rico. In 2002 the Company negotiated an amendment to the distribution agreement whereby the exclusivity will be removed in stages throughout 2004.

Sales and Marketing

Trinity 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 over thirty-five sales and marketing professionals responsible for the sale of hemostasis reagents and instrumentation, clinical chemistry and infectious disease products. The sales force of sixteen people in Germany is responsible for selling the full range of Trinity Biotech products including hemostasis, infectious disease, clinical chemistry and radioimmunoassay. In 2002, Trinity opened a sales and marketing office in Oxfordshire, UK employing three sales professionals who market the hemostasis and clinical chemistry products from Trinity Biotech. In addition to our direct sales operations, Trinity also operates in seventy-eight countries, through over three hundred independent distributors and strategic partners.

Manufacturing and Raw Materials

The primary raw materials required for Trinity'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 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 may not be available. Such unavailability could affect the quality of its products and its ability to meet orders for specific products, if such orders are obtained. Trinity'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'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 organizations of substantially greater size than Trinity. 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 Chiron and Dade Behring. The Company expects competition within the industry to intensify.

Patents and Licences

Patents

Trinity's SeroCard(TM) 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 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 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's SalivaCard(TM) test from being copied by a competitor.

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

Many of the Company's tests are not protected by specific patents. 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 operates. In the event that any of such claims relate to its planned products, Trinity intends to evaluate such claims and, if appropriate, seek a licence to use the protected technology. There can be no assurance that Trinity would, firstly, be able to obtain licences to use such technology or, secondly, obtain such licences on satisfactory commercial terms. If Trinity or its suppliers are unable to licence any such protected technology that might be used in Trinity's products, Trinity 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's products should be found to infringe protected technology, Trinity 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 USA 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 categorization 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 USA, the Paul Erhlich Institute in Germany and the Agence Francaise de Securite Sanitaire des Produits de Sante in France. Recently, a European Directive has been implemented allowing one approval system to be applicable throughout Europe, CE marking.

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 64% of Trinity's 2002 revenues were generated in the USA and the USA 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 U.S. Market. Each medical device that the Company may wish to commercially distribute in the U.S. will likely require either 510(k) clearance or premarket application ("PMA") approval prior to commercial distribution. 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.

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 four 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 labeling. In addition, an advisory committee made up of clinicians and/or other appropriate experts is typically convened to evaluate the application and make recommendations to the FDA as to whether the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. It generally takes from one to three years or even longer. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

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 commercialized. Pursuant to current FDA policy, manufacturers of IVD's labeled 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 utilized 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.

The Company has developed tests, software and instrument systems that it distributes in the United States on an RUO or IUO basis. Failure of the Company or recipients of the Company's RUO and IUO devices to comply with the regulatory limitations on the distribution and use of such devices could result in enforcement action by the FDA that would adversely affect the Company's ability to distribute the tests prior to obtaining FDA clearance or approval. Such restrictions could have a material adverse effect on the Company's revenues, earnings and financial standing.

Product under FDA Review. The Company's complete PMA application for the UniGold HIV Test was filed as of March 27, 2003. The PMA application was supported by clinical data involving 9,000 samples. The FDA is reviewing the PMA application and clinical data. No assurance can be given that the necessary PMA approval for the UniGold HIV Test will be granted on a timely basis, if at all. Delays in the receipt of, or a failure to receive, such PMA approval could have a material adverse effect on the Company's revenues, earnings and financial standing.

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 design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the Medical Device Reporting ("MDR") regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

The Company is subject to inspection and market surveillance 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.

Some clinical laboratories prepare their own finished diagnostic tests using purchased reagents. In the past, the FDA did not generally exercise regulatory authority over these individual reagents or such finished tests. In November 1997, the FDA issued special rules for these reagents, individually termed an analyte specific reagent ("ASR"), that apply a regulatory framework to them, including restrictions on sales or promotional claims that could be made about these products and the restriction of sales to clinical laboratories certified under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") as high complexity testing laboratories. The Company sells individual reagents that fall within the ASR regulatory framework and is therefore subject to the labelling and restriction of sales requirements set forth therein.

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 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, 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.

Export of products subject to 510(k) notification requirements, but not yet cleared to market, are permitted without FDA export approval, if statutory requirements are met. Unapproved products subject to PMA requirements can be exported to any country without prior FDA approval provided, among other things, they are not contrary to the laws of the destination country, they are manufactured in substantial compliance with the QSR, and have been granted valid marketing authorization in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or member countries of the European Union or of the European Economic Area ("EEA"). FDA approval must be obtained for exports of unapproved products subject to PMA requirements if these export conditions are not met. There can be no assurance that 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.

Organizational Structure

Trinity Biotech plc and its subsidiaries ("the Group") is a manufacturer of diagnostic test kits for sale and distribution worldwide. Trinity'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.

For a more comprehensive schedule of the subsidiary and associated undertakings of the Company please refer to Note 29 of the Notes to the Consolidated Financial Statements "Group Undertakings" contained in Item 18 "Financial Statements" of this Form 20-F / A.

Property, Plant and Equipment

Trinity has four manufacturing sites worldwide, two in the USA (Jamestown, NY and Carlsbad, CA), one in Bray, Co. Wicklow, Ireland and one in Lemgo, Germany. The US and Irish facilities are each an FDA, EN and ISO approved facility. As part of its ongoing commitment to quality, Trinity was granted the latest ISO/9001/2000 certification in August 2003. This certificate was granted by the International Organisation for Standardisation, an internationally recognised body. It serves as external verification that Trinity 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 will consistently manufacture products in a controlled manner. To achieve this certification Trinity performed an extensive review of the existing quality system and implemented any additional requirements of the ISO/9001/2000.

Trinity's executive offices and 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 spent US$4.2m buying and fitting out the facility. In December 1999, the Company sold the facility for net proceeds of US$5.2m and leased it back from the purchaser for 20 years. The current annual rent which is reviewed every 5 years is set at (euro)392,337 (US$411,208). 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)190,455 (US$199,616). The Company also envisages that further premises may potentially be required by it and, for that purpose, has entered into a four years eleven month lease at (euro)28,568 (US$29,942) per annum over adjacent lands. On November 20, 2002 the Company signed an agreement for lease with the lessor for offices that are currently being constructed on part of these lands. The lease is expected to commence in quarter four 2003 on terms similar to that for the warehouse. (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 USA in 1994. Additional warehousing space is also leased in upstate New York at an annual rental charge of US$34,642.

MarDx operates from two facilities in Carlsbad, California. The first facility comprises 21,500 sq feet and is the subject of a 5 year lease, renewed in July 2001, at an annual rental cost of US$212,640. The second adjacent facility comprises 14,500 square feet and is the subject of a 5 year lease, renewed in July 2001, at an annual rental cost of US$130,200.

Arising from the acquisition of the Biopool hemostasis business, Trinity currently operates from an additional facility located in Umea, Sweden. The Umea facility is 12,500 square feet and the annual rental is US$170,000. The lease expires in December 2004.

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

Additional office space is leased by the Company in Ireland and St, Louis, Missouri at an annual cost of US$114,249 and US$78,089 respectively.

Item 5 Operating and Financial Review and Prospects

General

Trinity 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 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 took a controlling interest in DDI and in October 1994, merged Trinity's wholly-owned US subsidiary into DDI so that DDI became a wholly-owned subsidiary of Trinity. DDI was the surviving legal entity in the merger and was subsequently renamed Trinity Biotech Inc ("TBI"). In December 1994, Trinity acquired the remaining 50% of FHC

which its subsidiary TBI did not own. During 1995, Trinity 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 and goodwill 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 and goodwill of the Biopool hemostasis business. In October 2001, Trinity established a direct sales operation in Germany, Trinity Biotech GmbH. In August 2002, Trinity acquired the hemostasis division of Sigma Diagnostics, part of Sigma-Aldrich. The Sigma diagnostics hemostasis 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. Trinity is currently transferring the Sigma hemostasis test manufacturing from St. Louis to the Irish facility, with the transfer scheduled for completion in Q4 2003. On September 30, 2002, Trinity closed the hemostasis 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 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 established a small direct sales operation in the United Kingdom to handle the Sigma hemostasis and clinical chemistry product lines.

In October 2000, Trinity 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$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.

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

Trinity's financial statements include the attributable results of seven trading entities - Trinity Biotech Manufacturing Limited, Trinity Biotech (USA), Biopool US Inc, MarDx Diagnostics Inc, Biopool AB, Trinity Biotech (UK Sales) Limited and Trinity Biotech GmbH which are engaged in the manufacture and sale of diagnostic test kits, and a share of the loss of the associate undertaking, HiberGen. This discussion covers the years ended December 31, 2002, December 31, 2001 and December 31, 2000 and should be read in conjunction with the Consolidated Financial Statements and notes thereto appearing elsewhere in this Form 20-F / A. The financial statements have been prepared in accordance with Irish GAAP which differs from US GAAP as indicated in Note 28 to the

Consolidated Financial Statements.

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 judgments 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 judgments 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 capitalized at cost within intangible assets and amortized over 10 years.

Factors which impact our judgement to capitalize 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 capitalized;
- significant decline in our stock price for a sustained period; and

our market capitalization 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 and SFAS 144 on January 1, 2002, we have ceased to amortize goodwill. In lieu of amortization, we are required to perform an initial impairment review of our goodwill. 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 the Group performed a further impairment test of goodwill and indefinite-lived intangible assets and concluded that there was no impairment in the carrying value of these assets at this date.

Allowance for slow-moving and obsolete inventory

We evaluate the realizability 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. We also consider recent trends in revenues for various inventory items and instances where the realizable 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 analyze 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 income sharing and cost reimbursement arrangements among related entities, the process of identifying items of income 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 that period in which such determination is made.

Impairment or disposal of long-lived assets

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for

Long-Lived Assets to be Disposed Of, and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations for a disposal of a Segment of a Business. SFAS 144 is effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. The Company has adopted SFAS 144 as of January 1, 2002. It has had no material impact on the results of the Company.

Results of Operations

Year Ended December 31, 2002 Compared to the Year Ended December 31, 2001

Trinity's consolidated revenues for the year ended December 31, 2002 were US$51,978,422 compared to consolidated revenues of US$37,075,573 for the year ended December 31, 2001. The growth in revenues of 40% was due to a combination of factors including additional revenue of US$753,906 from the organic growth of existing product lines, US$9,617,943 from the full integration of the Biopool acquisition which was acquired in December 2001, the added contribution of US$4,161,668 from the Sigma hemostasis product line from August 2002 and US$369,332 from the introduction of the Sigma speciality clinical chemistry product line with effect from December 2002.

Trinity's consolidated cost of sales increased by US$7,640,114 from US$18,049,765 for the year ended December 31, 2001 to US$25,689,879 for the year ended December 31, 2002. The increase in cost of sales is primarily attributable to (i) the Biopool acquisition which added US$4,831,972 to cost of sales, (ii) the Sigma hemostasis and speciality clinical chemistry product lines which contributed an additional US$2,261,396 to cost of sales, and (iii) the increased cost of sales from organic sales growth which contributed an additional US$516,281 to cost of sales in 2002. The balance of the increase of US$30,465 is attributable to increased overhead costs and is principally driven by inflation.

The gross margin for the year ended December 31, 2002 was 50.6% compared to 51.3% for the year ended December 31, 2001. The decrease in gross margin is partly explained by differing product mixes and the inefficiencies associated with transferring acquisitions.

Net interest increased to US$601,327 in 2002 compared to US$396,037 in 2001. The increased level of interest reflects the Company's higher level of net debt during the year.

Research and development ("R&D") expenditure increased to US$4,470,745 in 2002. This represents 8.6% of consolidated revenues and is comparable to the R&D spend in 2001 of US$2,779,729 or 7.5% of consolidated revenues. The increase in absolute terms is in part explained by the inclusion of a full year's R&D expenditure for the acquisitions made in 2001 and a part year's spend for the 2002 acquisitions. For a consideration of the various R&D projects see "Research and Products under Development" in Item 5 of the 20-F/A.

Normal administrative expenses for the year ended December 31, 2002 amounted to US$15,234,937 compared to US$9,563,019 for the year ended December 31, 2001. SG&A costs in normal administrative expenses amount to US$12,849,416 in 2002, an increase from US$7,560,884 in 2001. This is a 70% increase in the absolute level of these costs and reflects the significant increase in the size of the direct sales force in the USA, Germany and the UK. In relative terms the indirect cost base is 29.3% of consolidated revenues which is comparable with the ratio

attained in 2001. Amortization increased to US$2,385,521 in 2002 compared to US$2,002,135 in 2001 as a result of the inclusion of a full year's amortization charge on the goodwill relating to the Biopool acquisition completed in December 2001 and the commencement of amortization on the Sigma clinical chemistry product line in quarter four 2002. There was no exceptional administrative charge recognised in 2002. An exceptional administrative expense of US$3,635,000 was recognised in 2001. Of this charge US$2,835,000 relates to commitments made on the acquisition of the assets and goodwill of the Biopool hemostasis business on December 21, 2001 primarily to make payments to employees for redundancy, and plant closure costs, including commitments for onerous leasing arrangements. The Biopool facility in Ventura, California was closed in September 2002. The balance of the exceptional charge of US$800,000 relates to the acquisition of Bartels Inc on December 8, 2000. This charge comprised payments to employees so as to ensure the effective transfer of the business from Seattle to other facilities. The restructuring programme at Bartels was implemented during the first two quarters of 2001 and the Seattle facility was closed on June 8, 2001.

A tax charge of US$767,510 was incurred in the year ended December 31, 2002. The comparable charge for 2001 was US$15,876. The tax charge in previous years has been low due to the effect of net operating losses forward. In the current year the effective rate of tax was 13.5%. The Group enjoys the benefit of a 10% tax rate in Ireland and also had some operating losses forward which were utilised during the year. Please refer to Note 17 of the consolidated financial statements for further details of the tax charge.

As a result of the above profit after tax and exceptionals in 2002 amounted to US$4,896,911 compared to US$2,367,277 in 2001. The profit before exceptionals in 2001 was US$6,002,277.

Increase in turnover in the Rest of World reportable segment during 2002 of US$10,420,152 is attributable to additional revenues generated from (i) the inclusion of the first full year of the manufacture of the Bartels product line following its transfer to the Irish manufacturing facility and (ii) the acquisition of the Sigma and Biopool hemostasis businesses in August 2002 and December 2001 respectively. Increased revenues and overhead synergies achieved from the above acquisitions, exceeded the direct costs of transferring the product lines to Ireland, resulting in operating income in this reportable segment of US$3,754,912 for the year ended 31 December 2002 as compared to US$679,891 for the year ended 31 December 2001. Inclusion of a full year's revenues generated from the Biopool and Sigma hemostasis businesses has contributed to the increase in revenues of US$4,482,697 during 2002 in the US reportable segment. The indirect costs associated with the acquired product lines, principally the cost of the direct sales force in the US, has been offset by the benefit of additional revenues generated during the year, resulting in an overall increase in operating income of US$459,780 in the US reportable segment in the financial year ended December 31, 2002.

Year Ended December 31, 2001 Compared to the Year Ended December 31, 2000

Trinity's consolidated revenues for the year ended December 31, 2001 were US$37,075,573 compared to consolidated revenues of US$29,742,942 for the year ended December 31, 2000. The growth in revenues of 25% was primarily attributable to increased revenues generated by the Bartels product line which was acquired in December 2000.

Trinity's consolidated cost of sales increased by US$2,639,508 from

US$15,410,257 for the year ended December 31, 2000 to US$18,049,765 for the year ended December 31, 2001. The principal cause of this increase in cost of sales was the cost of sales attributed to the revenues generated by the Bartels product line which was acquired in December 2000.

The gross margin for the year ended December 31, 2001 was 51% compared to 48% for the year ended December 31, 2000. This improvement was due to both a better mix of sales during the year and the increased level of higher margin sales arising from the US acquisitions completed during 2000.

Net interest increased to US$396,037 in 2001 compared to US$291,701 in 2000. The increased level of interest reflects the Company's higher level of net debt during the year.

Normal administrative expenses for the year ended December 31, 2001 amounted to US$9,563,019 compared to US$5,982,151 for the year ended December 31, 2000. This significant increase reflects the costs incurred in these areas by the companies acquired in 2000 and 2001 plus the direct sales investment in Germany and the USA. Amortization increased to US$2,002,135 compared to US$1,191,291 in 2000 as a result of the commencement of amortization on certain product lines and the new acquisitions. An exceptional administrative expense of US$3,635,000 was recognised in the figures for 2001. This was described in more detail in the preceding paragraphs detailing the Company's performance in 2002.

A tax charge of US$15,876 was incurred in the year. The Company did not pay any significant taxes during 2001 or 2000 due to the availability of net operating losses carried forward.

As a result of the above, profit after tax amounted to US$6,002,277 (before exceptionals) compared to US$5,346,613 (before exceptionals) in 2000. Profit after tax and exceptionals in 2001 amounted to US$2,367,277 compared to US$4,124,410 in 2000.

There was no significant movement in revenues in the Rest of World reportable segment during 2001. The decrease in revenue for the Irish reportable segment for the year ended 2001 compared to 2000 was a result of greater emphasis on the acquired businesses and a small decrease in revenue generated by an older product line. The operating profit for the Rest of World reportable segment in 2001 has decreased due to the inclusion of costs associated with the acquisitions completed in 2000 and the higher level of inflation in Ireland in 2001 as compared to 2000. The significant increase in sales revenues in the US reportable segment in 2001 as compared to 2000 resulted from the successful acquisition and integration of Bartels Inc acquired in December 2000. The benefit of additional revenues from this business was noted above regarding the financial year ended December 2002. Significant costs associated with the reorganization and transfer of this business were incurred during 2001. Transfer costs resulted in a decrease in operating income to US$2,368,169 during 2001 in the US reportable segment as compared to US$3,259,719 in 2000. The Company recognized an exceptional administrative charge of US$2,835,000 in the year ended 2001 relating to the transfer of the Biopool facility, and an additional charge of US$800,000 relating to the transfer of the Bartels business from Seattle, Washington to Bray, Ireland. The comparable charge in 2000 was US$1,222,203 relating to the transfer of the Bartels business.

Liquidity and Capital Resources

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

in aggregate gross proceeds to the Company of US$3,500,000. The debentures were convertible into 'A' Ordinary Shares of the Company at a price of US$1.80. During 2000, US$1,875,000 of the US$3,500,000 principal amount of the debenture was converted into 1,041,667 Class 'A' Ordinary Shares of the Company. During 2001, US$625,000 of the remaining balance of the debenture was redeemed. The remaining balance of the principal amount was rolled over in November 2002 at an annual interest rate of 6% and a conversion price of US$1.50. Since the year end the debenture has been fully converted into 666,667 Class 'A' Ordinary Shares of the Company.

In November 2002, the Company completed a private placement of (i) US$2,500,000 principal amount of 5.25% convertible debentures and (ii) 50,000 warrants to purchase 'A' Ordinary Shares of the Company (see Item 18 "Financial Statements"). The debentures bore interest at a rate of 5.25% per annum and were convertible into Class 'A' Ordinary Shares of the Company at a price of US$1.50. Since the year end, the debenture has been fully converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

In relation to the First Warrants, 333,701 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.74 per share and the remaining 150,000 were each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.80 per share. 100,000 of these warrants were exercised to purchase 'A' Ordinary Shares in the Company in 2000. The balance of these 150,000 warrants expired unexercised on June 25, 2002. The Second Warrants are each exercisable to purchase one 'A' Ordinary Share of the Company at US$1.50. 133,701 of the remaining First Warrants have since been exercised.

In March 2000, Trinity paid US$4,208,279 for 100% of the share capital of MarDx. This acquisition was funded through the issuance of shares to the value of US$2,163,287 and cash of US$2,044,992. In October 2000, the Company acquired 33% of the share capital of HiberGen for a consideration of US$1,371,642 which was satisfied by cash of US$1,185,197 and shares to the value of US$186,445. In July 2001, the Company subscribed for a further 300,000 Ordinary Shares in HiberGen, increasing its shareholding to 40% at a cost of US$309,399. In December 2000, the assets and goodwill of Bartels Inc were acquired for a consideration of US$9,463,974 which was satisfied with shares to the value of US$3,190,000, a promissory note of US$350,000 and cash of US$5,923,974. The promissory note was settled in 2001.

In October 2001, Trinity purchased the Amerlex hormone business of Ortho Clinical Diagnostics for a total consideration of US$877,797. The consideration was satisfied in cash. In December 2001, the Company acquired the assets and goodwill of the Biopool hemostasis business for a total consideration of US$6,409,329, after costs, satisfied in cash and deferred consideration. The deferred consideration of US$2,591,500 was payable in three instalments of US$855,200, US$1,166,200 and US$570,100 on December 21, 2002, 2003 and 2004 respectively. The deferred consideration was not conditional on any future event and has been fully settled.

On August 27, 2002, Trinity Biotech purchased the hemostasis division of Sigma Diagnostics for a total consideration of US$1,428,001. The consideration was satisfied in cash. On November 27, 2002, the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US$4,412,372 satisfied in cash and deferred consideration. The cash consideration was partly financed by the issue of US$2.5m of convertible

debentures. The first instalment of US$1,010,000 of the deferred consideration was paid on May 27, 2003. The second instalment of US$800,000 is payable on November 27, 2003.

As at December 31, 2002, Trinity's consolidated cash and cash equivalents were US$5,807,514. This compares to cash and cash equivalents of US$5,373,976 at December 31, 2001. The increase is due to a cash inflow of US$3,580,752 from operations, the issue of share capital, the drawdown of financial facilities and the issue of convertible debentures, offset by the repayment of bank borrowings and cash payments for the purchase of businesses and fixed assets. This resulted in net cash inflows of US$891,848 during the year.

A significant portion of the Company's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Company's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Company pursues a formalised treasury policy which aims to sell US Dollars forward to match uncovered Euro expenses at exchange rates lower than budgeted exchange rates. The Company's current hedging policy is to cover forward for a minimum of three months. The Company expects that its forward contracts as at December 31, 2002 will have a positive impact on the cashflows of the business. At December 31, 2002 forward contracts with a carrying value of US$Nil had a fair value of US$1,068,738.

As at December 31, 2002, year end borrowings were US$14,451,834 and cash in hand was US$5,807,514. For a more comprehensive discussion of the Company's level of borrowings at the end of 2002, the maturity profile of the borrowings, the company's use of financial instruments, its currency and interest rate structure and its funding and treasury policies please refer to Item 11 "Qualitative and Quantitative Disclosures about Market Risk". In June 2003, Trinity completed a new US$10,000,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Ltd. The new facility consists of a five year term loan of US$6,000,000 and a one year revolver of US$4,000,000. This facility was partly used to repay existing loans and the loan notes payable to Xtrana, Inc. In July 2003, Trinity completed a private placement of US$20 million of convertible notes to a group of private investors. The notes have a final maturity date of January 1, 2007, bear interest at a rate of 3% per annum, and are convertible at the investor's option at any time into Trinity's common stock at a fixed conversion price of US$3.55. Trinity believes that, with further funds generated from operations, it will have sufficient funds to meet its capital commitments and continue operations for the foreseeable future. If operating margins on sales were to decline substantially or the Company was to make a large and unanticipated cash outlay, the Company would have further funding requirements. If this were the case, there can be no assurance that financing will be available at attractive terms, or at all. The Company believes that success in raising additional capital or obtaining profitability will be dependent on the viability of its products and their success in the market place.

Impact of Inflation

Although Trinity's operations are influenced by general economic trends, Trinity does not believe that inflation had a material effect on its operations for the periods presented. Management believes, however, that continuing national wage inflation in Ireland and the impact of inflation on costs generally will result in a sizeable increase in the Irish facility's operating costs in 2003.

Impact of Currency Fluctuation

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

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

Exchange Rates

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

Research and Products under Development

History

Trinity has invested considerable funds in research and development over the past number of years. It has developed a platform technology for its rapid UniGold(TM) tests and, arising from this, the Company has focused on developing rapid tests for certain infectious diseases utilizing this platform. The following tests have already been successfully developed:

Hepatitis B
HIV (recombinant protein format)
H. pylori
Malaria
Strep A (CLIA Waivable)

A research project is presently underway to develop a rapid test for influenza A and B using the UniGold(TM) technology.

The Company has also developed numerous tests utilising the microtitre well format platform technology for its laboratory-based business. For example, the Company has developed EIA plate tests for Adenovirus, Rotavirus, C. difficile, Cryptosporidium and Mycoplasma. Many of Trinity's EIA plate products are undergoing re-optimisation in order to make them compatible with automated assay processing systems.

Development Groups

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

Microtitre Plate Development Group

Development of microtitre plate assay for the detection of HSV-1 and HSV-2

The Company is developing HSV-1 and HSV-2 specific tests to complement its HSV-1/2 tests. HSV-2 causes more serious complications to pregnant women and HSV-2 positive patients are more susceptible to contracting HIV. These type specific tests will utilize recombinant proteins rather than the less specific

viral lysates in the older generations of these products.

Adaptation of assays to Microtrak XL units

During 1998, Trinity acquired the Microtrak Chlamydia business from Dade Behring Inc. As a result of the acquisition, Trinity acquired instruments to run Microtitre plate tests. These instruments only ran Chlamydia EIA tests and Trinity is now adapting its other Microtitre plate assays so that they can be run on this instrument. The Microtrak XL instruments are placed in a number of laboratories in the USA and around the rest of the world. The development of more tests using these instruments will enhance Trinity's ability to sell these tests.

Redevelopment of the Captia Products

The Syphilis IgG product has been re-developed making these kits more user friendly and compatible with automated assay systems. These re-optimizations include the introduction of a one step tracer, the addition of a stop solution and including a stable one component, ready to use substrate.

Rapid Development Group

Development of Recombinant HIV UniGold(TM) Test

This represents a modification of Trinity's UniGold HIV Test using recombinant proteins as opposed to peptides for the test. These recombinant proteins are manufactured by Trinity and allow the UniGold(TM) HIV Test to be produced in a more cost-effective manner. Development of this product has been completed. All clinical and non-clinical trials have been concluded and Trinity's PMA (pre-market application) modules have been submitted to the FDA.

CLIA Waived Strep A test

Trinity has already developed a rapid Strep A test for the doctor's office market. However, smaller doctors' practices are not entitled to use the test as it is considered to be moderately complex under the CLIA regulations. Trinity has developed a simpler form of the test, which will enable it to be sold to doctors' offices in the USA. The worldwide market for this Strep A test was 90 million tests in 1998, of which 40 million tests were in the USA. This product has been 510(k) approved and the objective is to achieve the CLIA waiver.

Western Blot Development Group

European Lyme IgG and IgM Western Blots

Development has been completed on two new western blots that have been designed specifically for the detection of European Lyme. Both products are in pilot production and on completion of this phase of the project extensive trials will be performed in order to ensure compliance with CE requirements.

HIV 1 / 2 Western Blot

Trinity has developed a western blot test for detecting antibodies to HIV 1 and HIV 2 that is presently undergoing clinical trials in Africa and the USA. The product is now available for sale outside the USA.

Immunofluorescent Assay Development Group

The development department in Trinity has recently been expanded to include a group that will work exclusively on redesigning various immunofluorescent assays from indirect assays to direct assays. This redevelopment will make the products more user friendly and reduce assay time.

For the 12 months ended December 31, 2002, the Company spent US$4,470,745 on research and development. This expenditure is broken down into salary costs, reagents, consultancy fees and other related costs. The comparable net expenditure in 2001 and 2000 was US$2,779,729 and US$2,681,220 respectively.

Trend Information

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

Item 6

Directors and Senior Management

Directors and Executive Officers

Name	Age	Title
Ronan O'Caoimh	47	Chairman of the Board of Directors Chief Executive Officer
Brendan K. Farrell	55	Director, President
Jim Walsh Ph.D.	44	Director, Chief Operating Officer
Rory Nealon	35	Director, Chief Financial Officer, Company Secretary
Denis R. Burger, Ph.D.	59	Non Executive Director
Peter Coyne	44	Non Executive Director

Board of Directors

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

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

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

Mr. Nealon replaces Mr. Maurice Hickey who resigned from the board in December 2002.

Jim Walsh, Ph.D., Chief Operating Officer, joined Trinity in October 1995. Prior to joining the Company, Dr. Walsh was Managing Director of Cambridge Diagnostics Ireland Limited (CDIL). He was employed with CDIL since 1987. Before joining CDIL he worked with Fleming GmbH as Research & Development Manager. Dr. Walsh has a degree in Chemistry and a Ph.D. in Microbiology from University College, Galway.

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

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

Compensation of Directors and Officers

The remuneration committee is responsible for determining the remu