

Edgar Filing: TRINITY BIOTECH PLC - Form 20-F/A

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

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

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(Title of Class)

Name of each exchange on which registered:

None

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(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)

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(Title of each class)

Securities for which there is a reporting obligation pursuant to Section 15 (d)  
of the Act:

None



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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.

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### 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

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- 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	As at	As at	As at
	Dec 31, 2002	Dec 31, 2001	Dec 31, 2000	Dec 31,
	-----	-----	-----	-----
	Restated	Restated	Restated	Restat
	US\$	US\$	US\$	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

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Amounts Adjusted for US GAAP

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

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	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 ----- Restated US\$	As at Dec 31, 2001 ----- Restated US\$	As at Dec 31, 2000 ----- Restated US\$	As Dec 31 ----- 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.

	Year Ended Dec 31, 2002 ----- US\$	Year Ended Dec 31, 2001 ----- US\$	Year Ended Dec 31, 2000 ----- US\$	Year Ended Dec 31, 199 ----- US\$
AMOUNTS IN ACCORDANCE WITH IRISH GAAP				
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)

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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
	-----	-----	-----	-----

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	Year Ended Dec 31, 2002	Year Ended Dec 31, 2001	Year Ended Dec 31, 2000	Year Ended Dec 31, 1999
	-----	-----	-----	-----
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.

- o Trinity Biotech's operating results may fluctuate as a result of many factors related to our business, including the competitive conditions

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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.

- o 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.

- o 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)).

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Trinity Biotech is highly dependent on suitable distributors worldwide.

- o 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.

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Trinity Biotech's business could be adversely affected by changing market conditions resulting in the reduction of the number of institutional customers.

- o 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.

- o 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.

- o 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.

- o 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



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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.

- o 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.

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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

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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
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6,391,609	Thromboplastin Reagents and Methods for Preparing and Using Such Reagents	16 years
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In addition to these US patents, Trinity Biotech owns a total of 21 non-US patents.

- o 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.
- o 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.
- o 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.

- o 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.

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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.

- o 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.

- o 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.

- o 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.

- o 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.

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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.

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Penny Stock Regulations impose sales practice limitations on broker-dealers who sell our shares.

- o 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.

- o 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.

- o At present, no treaty exists between the United States and Ireland for the reciprocal enforcement of foreign judgments. The laws of Ireland do

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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.

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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

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### 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

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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 Syncytial Virus.

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### 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

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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

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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 coagulopathies in the aging population, hemostasis testing is quickly advancing to the requirements of today's complexities.

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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.

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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.

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### 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

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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

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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.

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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.

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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 Ehrlich 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.

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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

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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.

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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.



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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.

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### 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

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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

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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

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("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

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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.

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#### 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:

- o significant underperformance relative to expected historical or projected future operating results;
- o significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- o obsolescence of products whose development costs we have capitalized;
- o significant decline in our stock price for a sustained period; and

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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

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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.

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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

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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.

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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

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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



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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.

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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

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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.

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### 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

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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

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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.

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### 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

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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

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##### 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.

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

Director US\$	Salary/ Benefits -----	Performance related bonus -----	Defined contribution pension -----	Total 2002 ----	Total 2001 ----
Ronan O'Caoimh	303,675	70,175	48,092	421,942	356,555
Brendan Farrell	224,068	50,125	23,699	297,892	251,794
Maurice Hickey	191,110	31,339	13,186	235,635	140,088
Jim Walsh	224,554 -----	50,125 -----	9,729 -----	284,408 -----	252,684 -----
	943,407 -----	201,764 -----	94,706 -----	1,239,877 -----	1,001,121 -----
Non-executive director US\$	Fees -----			Total 2002 ----	Total 2001 ----
Denis R. Burger	10,000			10,000	10,000
Peter Coyne	10,000 -----			10,000 -----	1,877 -----
	20,000 -----			20,000 -----	11,877 -----

#### Board Practices

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

In accordance with the Articles of Association of the Company, Mr. Peter Coyne retired by rotation and, being eligible, offered himself for re-election and was re-elected as a director at the Annual General Meeting of the Company held on May 23, 2003. Furthermore, Mr. Rory Nealon, who was co-opted to the board during the year following the resignation of Mr. Maurice Hickey, and who retired in

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accordance with the Articles of Association, was also re-elected.

The board has established audit and remuneration committees. The functions and membership of the remuneration committee is described above. The audit committee is responsible to the board for the review of the quarterly and annual reports and ensuring that an effective system of internal controls is maintained. It also appoints the external auditors, reviews the scope and results of the external audit and monitors the relationship with the auditors. The audit committee comprises the two independent non-executive directors of the Company, Mr. Peter Coyne (committee chairman) and Dr. Denis Burger, and Mr. Rory Nealon, Chief Financial Officer.

### Employees

As of December 31, 2002, Trinity had 580 employees consisting of a research director and 40 research scientists and technicians, 389 manufacturing and quality assurance employees, and 150 finance, administration and marketing staff. Trinity's future hiring levels will depend on the growth of revenues.

The geographic spread of the Company's employees was as follows: 263 in Bray, Co. Wicklow, Ireland, 96 in Germany, 22 in Sweden, 3 in the United Kingdom and 196 in its US operations.

### Stock Option Plan

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

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The exercise price of options is determined by the compensation committee. The term of an option will be determined by the compensation committee, provided that the term may not exceed seven years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity (or one year after such termination because of death or disability). Under certain circumstances involving a change in control of Trinity, the committee may accelerate the exercisability and termination of the options. As of September 30, 2003, 5,141,875 of the options outstanding were held by directors and officers of Trinity.

As of September 30, 2003 the following options were outstanding:

	Number of 'A' Ordinary Shares Subject to Option	Range of Exercise Price per Share
Total Options Outstanding	8,677,498	US\$0.81-US\$5.00

In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary



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Shares at prices ranging from \$1.50 to \$2.75 to agents who were involved in the Company's Private Placements in 1994, 1995 and 1999 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was granted to a consultant of the Company. As of September 30, 2003 there were warrants to purchase 258,500 Class 'A' Ordinary Shares in the Company outstanding.

Item 7

### Major Shareholders and Related Party Transactions

As of September 30, 2003 Trinity has outstanding 42,740,944 'A' Ordinary shares and 700,000 'B' Ordinary shares. Such totals exclude 8,935,998 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of September 30, 2003, the Trinity 'A' Ordinary Shares and 'B' Ordinary Shares beneficially held by (i) each person known by Trinity to beneficially hold 5% or more of such shares, (ii) each director and officer of Trinity, and (iii) all officers and directors as a group. Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Company is not controlled by another corporation or government.

	Number of 'A' Ordinary Shares Beneficially Owned -----	Percentage Outstanding 'A' Ordinary Shares -----	Number of 'B' Ordinary Shares Beneficially Owned -----
Ronan O'Caoimh	2,196,432 (1)	5.0%	0
Brendan Farrell	1,452,043 (2)	3.3%	0
Rory Nealon	100,000 (3)	0.2%	0
Jim Walsh	1,332,948 (4)	3.1%	0
Denis R. Burger	695,000 (5)	1.6%	0
Peter Coyne	13,333 (6)	0.03%	0
Potenza Investments, Inc ("Potenza") Statenhof Building, Reaal 2A 23 50AA Leiderdorp, Netherlands	0	0	500,000 (7)
The Tailwind Fund Limited	2,373,701 (8)	5.6%	0
Smithfield Fiduciary LLC	4,130,282 (9)	8.8%	0
Officers and Directors as a group (6 persons)	5,676,423 (1) (2) (3) (4) (5) (6)	12.7%	0

- (1) Includes 825,777 shares issuable upon exercise of options.
- (2) Includes 945,208 shares issuable upon exercise of options.
- (3) Includes 100,000 shares issuable upon exercise of options.
- (4) Includes 613,333 shares issuable upon exercise of options.
- (5) Includes 50,000 of 100,000 owned by Sovereign Ventures, a general partnership owned 50% by Dr. Denis Burger which are included in the shares deemed owned by Dr. Denis Burger, and 304,000 shares issuable upon exercise of options.
- (6) Includes 13,333 shares issuable upon exercise of options.
- (7) Includes shares beneficially owned by SRL (350,000 'B') and Brindisi Investments Inc. (150,000 'B'). SRL has advised Trinity that Potenza owns a majority of SRL's common stock. These 'B' shares have two votes per share.
- (8) Based on Schedule 13G filed by The Tail Wind Fund Ltd. on January 8, 2003.
- (9) Based on Schedule 13G filed by Smithfield Fiduciary LLC on September 16, 2003. The filing discloses voting and dispositive power over US\$12 million of 3% convertible notes convertible into 3,380,282 "A" Ordinary Shares and the right to acquire up to an additional US\$3 million of 3% convertible notes convertible into 750,000 "A" Ordinary Shares.

#### Related Party Transactions

The Company has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr. O'Caomh and Dr. Walsh, directors of the Company, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. It has entered into an agreement with JRJ pursuant to which the Company has taken a lease of premises adjacent to the existing facility for a term of 20 years at a rent of (euro)7.62 per square foot ("the Current Extension"). The lease commenced on the newly completed 25,000 square foot building in July 2000. The Company also envisages that a further premises may potentially be required by it and, for that purpose, has entered into a four years eleven month lease at (euro)28,568 per annum over adjacent lands with JRJ. On November 20, 2002, the Company signed an agreement for lease with JRJ for offices that are currently being constructed on part of these lands. The lease is expected to commence in quarter four on terms similar to that for the Current Extension. Independent valuers have advised the Company that the rent fixed in respect of the Current Extension, the agreement for lease and the adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr. O'Caomh and Dr. Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and

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reasonable basis on which the Company can meet its ongoing requirements for premises.

Item 8

### Financial Statements

#### Legal Proceedings

##### Dispute Regarding the Acquisition from Xtrana Inc.

On December 19, 2002, Trinity filed a lawsuit against Xtrana, Inc. ("Xtrana") in the United States District Court for the Southern District of New York in connection with an Asset Purchase Agreement entered into between Trinity and Xtrana as of November 9, 2001. After the Asset Purchase Agreement was finalised, Xtrana entered into a consent judgement with Instrumentation Laboratories ("IL") in which it admitted that one of the products listed in the Asset Purchase Agreement (identified as "Bioclot") infringed on patents held by IL. Trinity asserted claims against Xtrana for breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, common law fraud, negligent misrepresentation and violation of the Delaware Consumer Fraud Act as a result of misrepresentations made by Xtrana regarding the IL lawsuit and for entering into the consent judgement. The Company sought damages of not less than US\$1,200,000 from Xtrana and punitive damages of not less than US\$3,000,000.

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On or about January 17, 2003 Xtrana filed an answer to the complaint filed by the Company and counterclaims against the Company for tortuous interference with prospective economic advantage, breach of contract for failure to pay promissory notes in connection with the Asset Purchase Agreement, breach of covenant of good faith and fair dealing and seeking a declaratory judgement that the Company is obligated to make payments under the promissory notes. Xtrana sought not less than US\$27,000,000 for each of its claims and punitive damages of not less than US\$30,000,000 on its claims for tortuous interference and breach of covenant of good faith and fair dealing.

On June 16, 2003 Trinity and Xtrana settled this litigation. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity agreed to pay Xtrana the amounts due on two promissory notes of US\$1,166,200 and US\$570,100, together with interest thereon as provided in the notes, less US\$225,000, and less US\$24,148, which represented the amount due and owing by Xtrana to Trinity as of May 31, 2003 pursuant to a Letter Agreement, dated December 20, 2001, between Trinity and Xtrana, relating to a third party. The total amount of the settlement payment made by Trinity to Xtrana was US\$1,505,942.

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

Item 9

#### The Offer and Listing

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Trinity's American Depository Shares ("ADS's") are listed on the NASDAQ Small Cap Market under the symbol "TRIB". The Company's Class B Warrant (symbol "TRIZF"), expired on February 28, 1999. Each ADS represents one 'A' Ordinary Share of the Company. The Company's 'A' Ordinary Shares are also listed and trade on the Irish Stock Exchange. The Company's depository bank for the ADS's is The Bank of New York. On September 30, 2003, the reported closing sale price of the ADS's was US\$3.69 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity's ADS, and Class B Warrants for (a) the years ended December 31, 1998, 1999, 2000, 2001 and 2002; (b) the quarters ended March 31, June 30, September 30 and December 31, 2001; March 31, June 30, September 30 and December 31, 2002, and the quarters ended March 31, June 30 and September 30 2003; and (c) the months of December 2002, and January, February, March, April, May, June, July, August and September 2003 as reported on NASDAQ. These quotes reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	ADS's Low	High	Class B Low
Year Ended December 31				
1998	\$2.56	\$0.47	\$0.63	\$0.28
1999	\$2.47	\$1.16	\$0.12	\$0.03
2000	\$7.59	\$1.69		
2001	\$3.22	\$0.97		
2002	\$1.86	\$0.89		
	High	ADS's Low		
2001				
Quarter ended March 31	\$3.22	\$2.00		
Quarter ended June 30	\$2.50	\$1.67		
Quarter ended September 30	\$1.91	\$0.97		
Quarter ended December 31	\$1.84	\$1.20		
2002				
Quarter ended March 31	\$1.86	\$1.41		
Quarter ended June 30	\$1.64	\$1.24		
Quarter ended September 30	\$1.49	\$0.89		
Quarter ended December 31	\$1.67	\$0.93		
2003				
Quarter ended March 31	\$2.44	\$1.25		

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Quarter ended June 30	\$3.50	\$2.09
Quarter ended September 30	\$4.01	\$2.26
Month Ended		
December 31, 2002	\$1.38	\$1.28
January 31, 2003	\$1.65	\$1.25
February 28, 2003	\$1.97	\$1.52
March 31, 2003	\$2.44	\$1.77
April 30, 2003	\$2.83	\$2.09
May 31, 2003	\$2.73	\$2.20
June 30, 2003	\$3.50	\$2.36
July 31, 2003	\$3.45	\$2.31
August 31, 2003	\$3.65	\$2.26
September 30, 2003	\$4.01	\$3.11

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The number of record holders of Trinity's ADS's as at September 30, 2003 amounts to 1,707, inclusive of those brokerage firms and/or clearing houses holding Trinity's securities for their clientele (with each such brokerage house and/or clearing house being considered as one holder).

Item 10

### Memorandum and Articles of Association

Objects

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

Powers and Duties of Directors

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

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

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

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

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

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

### Rights, Preferences and Restrictions Attaching to Shares

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

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

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

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

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

The Company may, subject to the provisions of the Companies Acts, 1963 to 2001 of Ireland, issue any share on the terms that it is, or at the option of the Company is to be liable, to be redeemed on such terms and in such manner as the Company may determine by special resolution. Before recommending a dividend, the directors may reserve out of the profits of the Company such sums as they think proper which shall be applicable for any purpose to which the profits of the Company may properly be applied and, pending such application, may be either employed in the business of the Company or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

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

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

### Action Necessary to Change the Rights of Shareholders

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

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

The Company must hold a general meeting as its annual general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in Ireland unless all of the members entitled to attend and vote at it consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding Annual General Meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2001 of Ireland. In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days notice of the meeting is required and in any other case it is 7 clear days notice. Notice must be given in writing to all members and to the auditors and must state the

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details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided in the Companies Acts, 1963 to 2001 of Ireland, extended notice is required. These include removal of a director. No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum. The Company is not obliged to serve notices upon members who have addresses outside Ireland and the USA but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in the Company.

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

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

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

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

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

### Irish Law

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



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permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the company. Any shareholder who complains that the affairs of the company are being conducted or that the powers of the directors of the company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the company.

Ordinarily, our directors owe their duties only to Trinity Biotech and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to Trinity Biotech. Those duties include duties to act in good faith towards Trinity Biotech in any transaction, not to make use of any money or other property of Trinity Biotech, not to gain directly or indirectly any improper advantage for himself at the expense of Trinity Biotech, to act bona fide in the interests of Trinity Biotech and exercise powers for the proper purpose. A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. When directors, as agents in transactions, make contracts on behalf of the company, they generally incur no personal liability under these contracts. It is Trinity Biotech, as principal, which will be liable under them, as long as the directors have acted within Trinity Biotech's objects and within their own authority. A director who commits a breach of his fiduciary duties shall be liable to Trinity Biotech for any profit made by him or for any damage suffered by Trinity Biotech as a result of the breach. In addition to the above, a breach by a director of his duties may lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to Trinity Biotech for profit made and restriction of the director from acting as a director in the future.

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### Material Contracts

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

### Exchange Controls and Other Limitations Affecting Security Holders

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

The Financial Transfers Act, 1992 was enacted in December 1992. This Act gives power to the Minister of Finance of the Republic of Ireland to make provision for the restriction of financial transfers between the Republic of Ireland and other countries. Financial transfers are broadly defined and include all transfers, which would be movements of funds within the meaning of the treaties governing the European Communities. The acquisition or disposal of ADS's representing shares issued by an Irish incorporated company and associated payments may fall within this definition. In addition, dividends or payments on redemption or purchase of shares, interest payments, debentures or other securities in an Irish incorporated company and payments on a liquidation of an

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Irish incorporated company would fall within this definition. Currently, orders under this Act prohibit any financial transfer to or by the order of or on behalf of residents of the Federal Republic of Yugoslavia, Federal Republic of Serbia, Angola and Iraq, any financial transfer in respect of funds and financial resources belonging to the Taliban of Afghanistan (or related terrorist organisations), financial transfers to the senior members of the Zimbabwean government and financial transfers to any persons, groups or entities listed in EU Council Decision 2002/400/EC of June 17, 2002 unless permission for the transfer has been given by the Central Bank of Ireland.

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

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

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

### Taxation

The following discussion is based on US and Republic of Ireland tax law, statutes, treaties, regulations, rulings and decisions now in effect, all of which are subject to change. No representation is or can be made as to whether such laws, statutes, treaties, regulations, rulings and decisions will change, or as to the impact any such change might have on the statements contained in this summary. This summary does not discuss all aspects of Irish and US federal income taxation that may be relevant to a particular holder of Trinity Biotech ADRs in light of the holder's own circumstances or to certain types of investors subject to special treatment under applicable tax laws (for example, financial institutions, life insurance companies, tax-exempt organizations, and non-US taxpayers) and it does not discuss any tax consequences arising under the laws of taxing jurisdictions other than the Republic of Ireland and the US federal government. The tax treatment of holders of Trinity Biotech ADRs may vary depending upon each holder's own particular situation. Prospective purchasers of Trinity Biotech ADRs are advised to consult their own tax advisors as to the U.S., Irish or other tax consequences of the purchase, ownership and disposition of such ADRs.

### US Federal Income Tax Consequences to US Holders

The following is a summary of the material US federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADRs, in the case of a purchaser of such ADRs who is a US Holder (as defined below) and who holds the ADRs as capital assets. This summary is based on the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and

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administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. Unless otherwise indicated, all statements describing US federal income tax consequences that are contained in this summary represent the opinion of Carter Ledyard & Milburn LLP, United States counsel for Trinity Biotech. For purposes of this summary, a US Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organized in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to US federal income tax regardless of its source; or a trust that (a) is subject to the primary supervision of a court within the United States and the control of one or more US persons or (b) has a valid election in effect under applicable US Treasury regulations to be treated as a US person.

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

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

Irish withholding tax imposed on any dividends paid by Trinity Biotech will constitute a foreign income tax eligible for credit against a US Holder's US federal income tax liability, subject to certain limitations set out in the Code. Alternatively, the Irish withholding tax may be claimed by the US Holder as a deduction against income in determining such tax liability. The rules relating to the determination of the allowable foreign tax credit are complex, and US Holders should consult with their own tax advisors to determine whether and to what extent they may be entitled to this credit.

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

Under recently enacted amendments to the Code, dividends received by individuals from domestic and certain foreign corporations, and long-term capital gains realized by individuals, generally are subject to US federal income tax at a reduced maximum tax rate of 15 percent. Dividends received by a US Holder with respect to the underlying shares represented by the holder's ADRs should qualify for the 15 percent rate. The reduced tax rate on capital gains applies to sales and exchanges occurring on or after May 6, 2003 and before January 1, 2009. The reduced tax rate on dividend income applies to dividends received after December 31, 2002 and before January 1, 2009. The reduced tax rate will not apply to dividends received in respect of certain short-term or hedged positions in common stock or in certain other situations. The legislation enacting the reduced tax rate contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the

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reduced tax rate. US Holders of Trinity Biotech ADRs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

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

If Trinity Biotech were to become a PFIC, a US Holder of Trinity Biotech ADRs would be required to allocate to each day in the holding period for such holder's ADRs a pro rata portion of any distribution received (or deemed to be received) by the holder from Trinity Biotech, to the extent the distribution so received constitutes an "excess distribution," as defined under US federal income tax law. Generally, a distribution received during a taxable year by a US Holder with respect to the underlying shares represented by any of the holder's ADRs would be treated as an "excess distribution" to the extent that the distribution so received, plus all other distributions received (or deemed to be received) by the holder during the taxable year with respect to such underlying shares, is greater than 125% of the average annual distributions received by the holder with respect to such underlying shares during the three preceding years (or during such shorter period as the US Holder may have held the ADRs). Any portion of an excess distribution that is treated as allocable to one or more taxable years prior to the year of distribution would be subject to US federal income tax in the year in which the excess distribution is made, but it would be subject to tax at the highest tax rate applicable to the holder in the prior tax year or years. The holder also would be subject to an interest charge, in the year in which the excess distribution is made, on the amount of taxes deemed to have been deferred with respect to the excess distribution. In addition, any gain recognized on a sale or other disposition of a US Holder's ADRs, including any gain recognized on a liquidation of Trinity Biotech, would be treated in the same manner as an excess distribution. Any such gain would be treated as ordinary income rather than as capital gain. Finally, the 15% reduced US federal income tax rate otherwise applicable to dividend income as discussed above, will not apply to any distribution made by Trinity Biotech in any taxable year in which it is a PFIC (or made in the taxable year following any such year), whether or not the distribution is an "excess distribution".

For US federal income tax purposes, a foreign corporation is treated as a "foreign personal holding company" (or FPHC) in any taxable year in which (i) five or fewer individuals who are citizens or residents of the United States own directly or by attribution more than 50%, by vote or value, of the shares of the corporation and (ii) at least 60 percent of the corporation's gross income consists of foreign personal holding company income. Based on the composition of its share ownership and the nature of its business operations and gross income at the present time, Trinity Biotech believes that it is not currently subject to treatment as an FPHC. However, no assurance can be given that there will not occur changes in the composition of its share ownership and in the nature of its

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business operations and gross income that might cause Trinity Biotech to be treated as a FPHC at some future time.

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

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

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

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

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

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

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

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

### Republic of Ireland Taxation

Unless otherwise noted, the statements contained in the following discussion of Republic of Ireland tax consequences represent the opinion of Ernst & Young, Trinity Biotech's independent auditor.

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

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

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

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

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

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

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from the intermediary that the beneficial shareholder's address in the intermediary's records is in the US.

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

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

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- o a corporation that is not resident in Ireland and which is ultimately controlled by persons resident in the US (or certain other countries); or
- o a corporation that is not resident in Ireland and whose principal class of shares (or its 75 per cent. parent's principal class of shares) are substantially or regularly traded on a recognized stock exchange; or
- o is otherwise entitled to an exemption from DWT.

A person who is not an Irish holder will not be subject to Irish capital gains tax on the disposal of ordinary shares or ADRs provided that the ordinary shares or ADRs are quoted on a recognized stock exchange. Nasdaq and the ISEQ are recognized stock exchanges.

A gift or inheritance of ordinary shares or ADRs will be within the charge to capital acquisitions tax, regardless of where the disponent or the donee/successor in relation to the gift/inheritance is domiciled, resident or ordinarily resident. The capital acquisitions tax is charged at a rate of 20 per cent. on the taxable value of the gift or inheritance above a tax-free threshold. This tax-free threshold is determined by the amount of the current benefit and of previous benefits, received since December 5, 1991, within the charge to the capital acquisitions tax and the relationship between the former holder and the successor. Gifts and inheritances between spouses are not subject to the capital acquisitions tax. Gifts of up to (euro)3,000 can be received each year from any given individual without triggering a charge to capital acquisitions tax. Where a charge to Irish capital gains tax and capital acquisitions tax arises on the same event, capital acquisitions tax payable on the event can be reduced by the amount of the capital gains tax payable.

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

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

Dividend Policy

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

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

Item 11

### Qualitative and Quantitative Disclosures About Market Risk

#### Qualitative information about Market Risk

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

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

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

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

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The Group borrows in appropriate currencies at fixed and floating rates of interest. Year-end borrowings, net of cash, totalled US\$8,644,320 (2001: US\$4,290,293) at interest rates ranging from 2.30% to 7.41% and including US\$3,964,683 of fixed rate debt at interest rates ranging from 5% to 7.50% (2001: US\$1,309,607 at 7.50%). In broad terms, a one-percentage point increase in interest rates would increase the net interest charge by US\$46,796 (2001: US\$29,807).

Long-term borrowing requirements are met by funding in the USA and Ireland. Short-term borrowing requirements are primarily drawn under committed bank facilities. At the year-end, 50% of gross debt fell due for repayment within one year. The Company continues to comply with all of its borrowing covenants, none of which represents a restriction on funding or investment policy in the foreseeable future.

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



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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. Given the recent weakening of the US Dollar, the Company's objective is to mitigate this exposure by increasing the level of Euro denominated sales and the Company anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Group had foreign currency denominated cash balances equivalent to US\$2,089,940 at December 31, 2002.

### Quantitative information about Market Risk

#### Interest rate sensitivity

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

The Company estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Company is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be a reduction in profit before tax for 2002 of less than two per cent.

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

Maturity before December 31	2003	2004	2005	2006	2007	After 2007
-----						
US\$000 (except percentages)						
Long-term debt						
Variable rate - US\$000	4,259					
Average interest rate	2.9%					
Fixed rate - US\$000	2,814	26	15	16	16	22
Average interest rate	5.4%	5.0%	5.0%	5.0%	5.0%	5.0%

\* Represents the maturity profile as at June 17, 2003 of the Company's long-term debt as at December 31, 2002.

\*\*Represents the net present value of the expected cash flows discounted at current market rates of interest.

#### Exchange rate sensitivity

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At year-end 2002, less than 1% of the Company's US\$62,847,230 net worth (shareholders' equity and minority interest) was denominated in currencies other than the US Dollar, principally the Euro.

A strengthening of the US Dollar by 10% against all the other currencies in which the Company operates would not materially reduce the Company's 2002 year-end net worth.

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Item 12

### Description of Securities Other than Equity Securities

Not applicable.

Part II

Item 13

### Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14

### Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15

### Control Procedures

Trinity has restated the financial statements for errors in accounting for certain items. Details of the restatement to the Irish GAAP and US GAAP amounts are set out in Notes 1 and Note 28, respectively of the restated consolidated financial statements. Some of these differences resulted from a lack of resources within the finance department of Trinity. In early 2003 the Company has augmented the finance team with the addition of two qualified accountants to the head office finance team and has also replaced two other accountants within the team. The Company believes that sufficient resources are now in place.

Within the 90 days prior to the date of the filing of this annual report, we carried out an evaluation, under the supervision and with the participation of our senior management, including Chief Executive Officer, Ronan O'Caoimh, and Chief Financial Officer, Rory Nealon, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13(a)-14(c) of the Securities Exchange Act of 1934. Disclosure controls and procedures are designed to ensure that the material financial and non-financial information required to be disclosed in this Form 20-F/ A filed with the SEC is recorded, processed, summarized and reported timely. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable, rather than absolute, assurance of achieving the desired control

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objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures, as supplemented by the addition of accounting personnel described above, are effective in timely alerting them to material information relating to us required to be included in the our periodic SEC filings.

There have been no significant changes in our internal controls or other factors, which could significantly affect internal controls subsequent to the date of the evaluation. Therefore, no corrective actions were taken.

Item 16

Reserved

Part III

Item 17

Financial Statements

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

Item 18

Financial Statements

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Item 19

Exhibits

Exhibit No.	Description of Exhibit
1.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
1.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
1.3	Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
1.4	Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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CERTIFICATION PURSUANT TO

SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Ronan O'Caoimh, certify that:

1. I have reviewed this annual report on Form 20-F / A of Trinity Biotech plc;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 25, 2003

RONAN O'CAOIMH \*

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Ronan O'Caoimh  
Chief Executive Officer

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\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

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Exhibit 1.2

### CERTIFICATION PURSUANT TO

#### SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Rory Nealon, certify that:

1. I have reviewed this annual report on Form 20-F / A of Trinity Biotech plc;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent

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to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 25, 2003

RORY NEALON \*  
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Rory Nealon  
Chief Financial Officer

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

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Exhibit 1.3

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F / A for the period ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronan O'Caoimh, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

RONAN O'CAOIMH \*  
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Ronan O'Caoimh  
Chief Executive Officer  
November 25, 2003

\*The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

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Exhibit 1.4

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

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AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trinity Biotech plc (the "Company") on Form 20-F / A for the period ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Rory Nealon, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

RORY NEALON\*

-----

Rory Nealon  
Chief Financial Officer

November 25, 2003

\*The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

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## REPORT OF INDEPENDENT AUDITORS

To: The Board of Directors of Trinity Biotech plc

We have audited the consolidated balance sheets of Trinity Biotech plc as of December 31, 2002 and 2001 and the related consolidated statements of income, total recognised gains and losses, movement in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the financial statement schedule listed in the Index at Item 18. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Trinity Biotech plc at December 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended

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December 31, 2002, in conformity with accounting principles generally accepted in the Republic of Ireland, which differ in certain respects from those followed in the United States (see note 28 of Notes to Consolidated Financial Statements). Also in our opinion the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 and Note 28, the Consolidated Financial Statements at December 31, 2002 and 2001 and for each of the three years in the period ended December 31, 2002 have been restated for the matters set forth therein.

Dublin, Ireland  
November 25, 2003

Ernst & Young  
Registered Auditors

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### CONSOLIDATED BALANCE SHEETS

	Notes	As at December 31 2002 Restated US\$
<b>ASSETS</b>		
Inventories	2	20,851,459
Accounts receivable and prepayments	3	12,676,756
Cash and cash equivalents		5,807,514
		-----
		39,335,729
Intangible assets, net	4	39,511,786
Property, plant & equipment, net	5	9,883,681
Financial assets	6	1,067,262
		-----
<b>TOTAL ASSETS</b>		<b>89,798,458</b>
		-----
 <b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
Accounts payable and accrued expenses	7	18,912,207
Provisions for liabilities and charges (Deferred tax)	9	293,579
Long term liabilities	8	7,745,442
<b>SHAREHOLDERS' EQUITY</b>		
Called up share capital		
Class 'A' Ordinary shares	10	597,840



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Class 'B' Ordinary shares	10	12,255
Share premium account		75,987,779
Currency adjustment		(4,266,173)
Profit and loss reserve	12 (a)	(9,966,417)
Other reserves		172,000
		-----
Shareholders' equity - (all equity interests)		62,537,284
Minority interest - (all equity interests)	12 (b)	309,946
		-----
		62,847,230
		-----
Total Liabilities and Shareholders' Equity		89,798,458
		-----

See Notes to the Consolidated Financial Statements

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### CONSOLIDATED STATEMENTS OF INCOME

	Notes	2002 Restated US\$
Revenues		
- Continuing operations		47,447,422
- Acquisitions	15	4,531,000
		-----
	13	51,978,422
Cost of sales		(25,689,879)
		-----
Gross profit		26,288,543
Research & development expenses		(4,470,745)
Administrative expenses - normal		(15,234,937)
Administrative expenses - exceptional	16	-
		-----
Operating profit		
- Continuing operations		6,523,834
- Acquisitions		59,027
		-----
	13	6,582,861
Share of operating loss in associate		(317,113)

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Interest receivable and similar income		103,133
Interest payable and similar charges		(704,460)
		-----
Profit on ordinary activities before taxation	14	5,664,421
Tax on profit on ordinary activities	17	(767,510)
		-----
Retained profit for the financial period		4,896,911
		-----
Basic earnings per ordinary share (US cents)	18	12.08
Diluted earnings per ordinary share (US cents)	18	11.73

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

CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES

		December 31 2002 Restated US\$
Profit for the financial period attributable to group shareholders excluding share of loss in associate		5,214,024
Share of operating loss in associate		(317,113)
Currency adjustment		355,782
		-----
Total recognised gains and losses for the period		5,252,693
		-----

See Notes to the Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF MOVEMENT IN SHAREHOLDERS' EQUITY (AS RESTATED)

	Class 'A' Ordinary Shares	Class
	-----	-----
	Number of shares	Share capital US\$0.0109 each US\$
	-----	-----
Authorised	75,000,000	817,500
	-----	-----
Issued:		
Balance as at December 31, 1999, as previously reported	28,905,832	447,974

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Restatement	--	--	
	-----	-----	
Balance as at December 31, 1999, as restated	28,905,832	447,974	
Class `A' shares issued for cash	4,239,198	59,755	
Class `A' shares issued on conversion of debenture	1,041,667	14,839	
Class `A' shares issued on exercise of warrant	100,000	1,425	
Options exercised	2,784,496	39,667	
Class `A' shares issued as consideration in business acquisition	1,834,431	26,131	
Class `A' shares issued for financial asset	67,872	761	
Share issue expenses	--	--	
Currency adjustment	--	--	
Retained profit	--	--	
Stock compensation	--	--	
	-----	-----	
Balance as at December 31, 2000	38,973,496	590,552	
	-----	-----	
Options exercised	43,250	613	
Share issue expenses	--	--	
Currency adjustment	--	--	
Retained profit	--	--	
Stock compensation	--	--	
	-----	-----	
Balance as at December 31, 2001	39,016,746	591,165	
	-----	-----	
Shares issued for cash	443,900	4,839	
Options exercised	12,334	134	
Class `A' shares issued for financial asset	156,189	1,702	
Share issue expenses	--	--	
Currency adjustment	--	--	
Retained profit	--	--	
Stock compensation	--	--	
	-----	-----	
Balance as at December 31, 2002	39,629,169	597,840	
	-----	-----	
		Retained profit	Currency adjustment
		US\$	US\$
		-----	-----
Authorized			
Issued:			
Balance as at December 31, 1999, as previously reported	1,044,143	(4,637,484)	(2)
Restatement	(622,475)	20,231	
	-----	-----	-----
Balance as at December 31, 1999, as restated	421,668	(4,617,253)	(2)
Class `A' shares issued for cash	--	--	
Class `A' shares issued on conversion of debenture	--	--	
Class `A' shares issued on exercise of warrant	--	--	
Options exercised	--	--	
Class `A' shares issued as consideration in business acquisition	--	--	
Class `A' shares issued for financial asset	--	--	
Share issue expenses	--	--	
Currency adjustment	--	(53,653)	
Retained profit	4,124,410	--	

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Stock compensation	--	--	--
Balance as at December 31, 2000	4,546,078	(4,670,906)	(2,124,828)
Options exercised	--	--	--
Share issue expenses	--	--	--
Currency adjustment	--	48,951	--
Retained profit	2,367,277	--	--
Stock compensation	--	--	--
Balance as at December 31, 2001	6,913,355	(4,621,955)	(2,708,600)
Shares issued for cash	--	--	--
Options exercised	--	--	--
Class `A' shares issued for financial asset	--	--	--
Share issue expenses	--	--	--
Currency adjustment	--	355,782	--
Retained profit	4,896,911	--	--
Stock compensation	--	--	--
Balance as at December 31, 2002	11,810,266	(4,266,173)	(7,544,093)

See Notes to Consolidated Financial Statements

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended December 31, 2002 Restated US\$	Year ended December 31, 2001 Restated
Net cash inflow from operating activities	20	3,580,752	5,722,142
Returns on investments and servicing of finance			
Interest received		57,133	142,142
Interest paid		(695,489)	(369,142)
Finance interest paid		(9,037)	(23,142)
Net cash outflow from returns on investments and servicing of finance		(647,393)	(250,142)
Taxation			
Taxation (paid)/refund		(403,935)	(319,142)
Capital expenditure and financial investment			
Purchase of tangible fixed assets	19	(2,516,982)	(1,343,142)

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Purchase of intangible fixed assets		(468,941)	(986)
Net cash outflow from investing activities		(2,985,923)	(2,329)
Acquisitions and disposals			
Acquisition of subsidiary undertakings		-	(4,777)
Payments to acquire trades or businesses		(4,408,692)	
Purchase of associate undertaking		-	(309)
Deferred consideration paid		-	
Net cash outflow for acquisitions and disposals		(4,408,692)	(5,086)
Net cash outflow before use of liquid resources and financing		(4,865,191)	(2,263)
Management of liquid resources	19	553,310	(2,373)
Financing			
Loan from unconnected third party		(163,213)	(73)
Issue of shares		558,698	74
Expenses paid in respect of share issues		-	(183)
Movement in finance leases		3,955	(310)
(Decrease)/increase in long term debt		(1,803,466)	4,829
(Decrease) in promissory note		-	(350)
Increase in other financial liabilities		4,107,755	
Increase/(decrease) in convertible debentures		2,500,000	(625)
Net cash inflow from financing		5,203,729	3,362
Increase/(decrease) in cash		891,848	(1,274)
Reconciliation of net cash flow to movement in net debt			
Increase/(decrease) in cash in the year		891,848	(1,274)
Decrease/(increase) in long term debt		1,803,466	(4,829)
Increase in other financial liabilities		(4,041,506)	
(Issue)/redemption of convertible debentures		(2,500,000)	625
Long term debt acquired		-	
(Decrease)/increase in liquid resources		(553,310)	2,373
Decrease in finance leases		17,350	310
Change in net debt resulting from cash flows		(4,382,152)	(2,796)
New finance leases		-	
Conversion of debentures		-	
Promissory notes paid/(issued)		-	350
Exchange movements on net debt		(87,554)	
Non cash exchange movement		95,000	
Debt issue costs		20,679	
		28,125	350
Movement in net debt in the year		(4,354,027)	(2,446)
Net debt at January 1		(4,290,293)	(1,843)
Net debt at December 31	21	(8,644,320)	(4,290)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

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

(a) Restatement

The financial statements have been restated for 2002, 2001 and 2000. Detailed below are comparisons of the original reported numbers with the restated numbers, together with a summary of the adjustments made.

Trinity's consolidated financial statements for each of the years in the three year period ended 31 December 2002, set forth herein differ from its previously reported financial statements. These differences increase net income for the periods presented by US\$105,468 and reduce shareholders' equity at January 1, 2000 by US\$622,475.

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 SAB 99 have been applied to the Irish GAAP financial statements and US GAAP reconciliation. The Company has analysed the errors for each year presented, and those applicable to prior periods in the aggregate, and has accordingly restated its Irish GAAP financial statements and US GAAP reconciliation.

	2002 US\$'000	2001 US\$'000
Retained profit for the financial period, as previously stated	5,010	1,449
Impact of restatements		
Translation adjustment	134	100
Lease provision	-	-
Amortisation	6	(201)
Receivables	-	555
Stock-based compensation	(120)	(45)
Inventory	435	78
Restructuring expense	(380)	-
Foreign exchange differences	40	268
Current taxation	(145)	292
Other	40	(27)
Deferred taxation	(123)	(102)
	-----	-----
Total impact of restatements	(113)	918
Retained profit for the financial period, as restated	4,897	2,367

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### Translation adjustment

The Company previously charged foreign exchange amounts arising on non-US\$ denominated transactions entered into by the Company to currency translation adjustment in Shareholders' Equity rather than to the profit and loss account.

### Lease provision

In 2000 the Company credited the release of a provision in relation to an onerous lease obligation to the profit and loss account. The Company was released from the obligations under the lease in 1999 and accordingly this release is now recorded in the appropriate year.

### Amortisation

Amortisation was incorrectly charged in 2000 in respect of goodwill arising before 1998 which under Irish GAAP had been previously written off on completion of the acquisition against Shareholders' Equity. This charge for amortisation in 2000 has now been reversed, as has the Company's original correcting entry in 2001. The Company has also included an impairment charge for two intangible assets which the Company deemed to be impaired at December 31, 2001 amounting to US\$61,000.

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## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

### 1. ACCOUNTING POLICIES (Continued)

#### Receivables

US\$170,000 of revenue was recognized in 1998, and US\$385,000 was recognized in 1999 in respect of milestones under a licensing agreement. Although the Company had delivered the products to the customer, customer acceptance was not completed and consequent FDA approval and sale by the customer of licensed product did not occur. Consequently this revenue has now been reversed in the original periods recognised and the subsequent write-off in 2001 of the amount originally recorded as a receivable has been reversed.

#### Stock-based compensation

The Company issued options with exercise prices which were less than the market value of the underlying shares at the date of grant and has now recorded the compensation charge representing the intrinsic value of this price differential over the vesting period of the options.

#### Inventory

The Company has amended the value of inventory principally relating to book to physical and overhead allocation adjustments. The Company periodically compares physical records of inventory on hand to its book accounts. As part of the restatement process the Company has posted such differences to the financial statements and this has resulted in an increase in inventory and retained profit in 2002 and 2001. In addition the level of overhead allocated to inventory was understated in 2002 thereby resulting in an increase in retained profit for that year.

#### Restructuring expense

The Company has recorded a charge in respect of the termination of employees at one of its manufacturing facilities. The Company originally

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intended to make certain employees redundant in 2002, however these employees were subsequently made redundant in 2003 and the Company previously deferred recognition of the termination expense until 2003. As the Company had communicated their intention to terminate to the effected employees before the end of 2002 the criteria for provision recognition existed at 31 December 2002.

### Foreign exchange differences

The Company has recognised the impact on the income statements of restating certain monetary assets and liabilities by amending exchange rates used for the translation of these amounts to the correct closing rates of exchange pertaining to the periods presented. In 2002 the difference arose principally due to a difference between the Company's standard US\$ / Euro rate (used to retranslate monetary assets and liabilities denominated in Euro) and the official US\$ / Euro exchange rate. In 2001, the difference arose due to the application of an incorrect exchange rate to a specific non-US\$ denominated monetary liability.

### Current taxation

At the time of approval of the Company's 2001 financial statements the Company had overestimated its consolidated liability for taxation. The Company has reallocated the overprovision in respect of 2001 taxation that was previously released to the profit and loss account in 2002, to 2001 in respect of estimates that were not impacted by events subsequent to the completion of the financial statements.

### Deferred taxation

Deferred taxation has been adjusted for the taxation impact of the various adjustments for all periods presented.

### CONSOLIDATED BALANCE SHEETS

	DECEMBER 31, 2002	
	As Originally Reported US\$	Resta
<b>ASSETS</b>		
Inventories	20,362,389	20,851,
Accounts receivable and prepayments	12,494,467	12,676,
Cash and cash equivalents	5,768,401	5,807,
	-----	-----
Intangible assets, net	38,625,257	39,335,
Property, plant & equipment, net	39,605,251	39,511,
Financial assets	9,878,818	9,883,
	1,158,245	1,067,
	-----	-----
<b>TOTAL ASSETS</b>	<b>89,267,571</b>	<b>89,798,</b>
	-----	-----



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LIABILITIES & SHAREHOLDERS' EQUITY		
Accounts payable and accrued expenses	18,350,165	18,912,
Provisions for liabilities and charges (Deferred tax)	263,722	293,
Long term liabilities	7,745,442	7,745,
SHAREHOLDERS' EQUITY		
Called up share capital		
Class 'A' Ordinary shares	597,840	597,
Class 'B' Ordinary shares	12,255	12,
Share premium account	75,886,015	75,987,
Currency adjustment	(4,448,404)	(4,266,
Other reserves	-	172,
Profit and loss reserve	(9,449,410)	(9,966,
	-----	-----
Shareholders' equity - (all equity interests)	62,598,296	62,537,
Minority interest - (all equity interests)	309,946	309,
	-----	-----
	62,908,242	62,847,
	-----	-----
Total Liabilities and Shareholders' Equity	89,267,571	89,798,
	-----	-----

CONSOLIDATED BALANCE SHEETS

	DECEMBER 31, 2001	
	As Originally Reported US\$	Resta
ASSETS		
Inventories	16,342,308	16,389,
Accounts receivable and prepayments	7,684,575	7,756,
Cash and cash equivalents	5,281,976	5,373,
	-----	-----
	29,308,859	29,519,
Intangible assets, net	40,402,394	40,308,
Property, plant & equipment, net	5,967,443	5,967,
Financial assets	1,350,517	1,276,
	-----	-----
TOTAL ASSETS	77,029,213	77,072,
	-----	-----
LIABILITIES & SHAREHOLDERS' EQUITY		
Accounts payable and accrued expenses	12,570,405	12,402,
Provisions for liabilities and charges (Deferred tax)	122,000	143,
Long term liabilities	7,805,237	7,805,
SHAREHOLDERS' EQUITY		
Called up share capital		

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Class 'A' Ordinary shares	591,165	591,
Class 'B' Ordinary shares	12,255	12,
Share premium account	75,132,118	75,241,
Currency adjustment	(5,054,186)	(4,621,
Other reserves	-	52,
Profit and loss reserve	(14,459,727)	(14,863,
	-----	-----
Shareholders' equity - (all equity interests)	56,221,625	56,411,
Minority interest - (all equity interests)	309,946	309,
	-----	-----
	56,531,571	56,721,
	-----	-----
Total Liabilities and Shareholders' Equity	77,029,213	77,072,
	-----	-----

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2002

#### ACCOUNTING POLICIES

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

(b) Basis of Consolidation

The consolidated financial statements include the financial statements of Trinity Biotech plc ("Trinity" and/or "the Company") and its subsidiary undertakings in Ireland, the United States, the United Kingdom, Sweden and Germany made up to the end of the financial year. Where a subsidiary undertaking is acquired during the financial year the Group financial statements include the attributable results from the date of acquisition up to the end of the financial year. All inter-company transactions and balances have been eliminated in the preparation of these consolidated financial statements.

(c) Goodwill

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

(d) Tangible Fixed Assets

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

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

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

### (e) Intangible Assets

Patents and licences are stated at cost and are amortised over the lesser of their expected useful lives or their statutory lives which range between 3 and 20 years. The carrying value of intangibles is reviewed annually by the directors to determine whether there should be a reduction to reflect any permanent diminution in value.

Research and development expenditure is written off as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalised at cost within intangible assets and amortised over 10 years. With effect from January 1, 1998, goodwill on acquisition of businesses and product lines is capitalised in the balance sheet and is amortised over a period of 20 years and 15 years respectively. Negative goodwill is to be released over the period of release of the related non-monetary assets. This is also subject to an annual impairment review by the directors and any diminution in value is immediately taken to the profit and loss account.

### (f) Inventories

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

### (g) Taxation

Taxation, which is based on the results for the year, is reduced where appropriate by manufacturing companies' relief. Deferred taxation, the estimated future tax consequences of transactions and events recognised in the financial statements of the current and previous years, is provided on all material timing differences using the tax rates substantively enacted at the balance sheet date which are expected to apply in the periods in which the timing differences are expected to reverse. Timing differences between the Group's taxable profits and its results as stated in the financial statements arise from the inclusion of gains and losses in tax assessments in periods different from those in which they are recognised in the financial statements. Deferred tax liabilities are not discounted.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 2. ACCOUNTING POLICIES (Continued)

##### (h) Sales and Revenue Recognition

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

##### (i) Pension Costs

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

##### (j) Leases

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

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

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

##### (k) Government Grants

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

##### (l) Foreign Currency

The functional currency of the Company is the United States Dollar. As of January 1 1998, the Company changed its functional currency from the Irish Pound to the United States Dollar.

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

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

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included in the income statement.

- (m) **Liquid Resources**  
Liquid resources are current asset investments, which are held as readily disposable stores of value. Liquid resources include investments in equity investments and short term deposits.
- (n) **Use of Estimates**  
The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from these estimates.
- (o) **Companies Acts, 1963 to 2001**  
The financial information relating to the Company and its subsidiary undertakings included in this document does not comprise statutory financial statements as referred to in Section 19 of the Companies (Amendment) Act, 1986, copies of which are required by that Act to be annexed to the Company's annual return lodged with the Registrar of Companies. Copies of statutory financial statements of Trinity Biotech plc are annexed to the Company's annual returns.
- (p) **Cost of Sales**

Cost of sales comprises the product cost including shipping, handling and packaging costs.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 1. ACCOUNTING POLICIES (Continued)

- (q) **Provision for Bad Debts**  
The Group sells its products to companies in various markets throughout the world. The Group maintains reserves for potential credit losses. To date such losses have been within management's expectations. The Group had an allowance for doubtful accounts of approximately US\$496,412, US\$30,000 and US\$31,850 as at December 31, 2002, 2001 and 2000 respectively.
- (r) **Financial Instruments**  
Financial instruments include (i) borrowings, (ii) cash deposits and liquid resources and (iii) interest and forward contracts. Derivatives, principally forward foreign exchange contracts, are used to manage the working capital requirements of the Group in a cost effective, low-risk manner. Working capital management is a key element in the effective management of overall liquidity. Where derivatives are used to hedge cross-currency cash flows arising from trading activities, the underlying transaction is ultimately recorded at the contract rate upon settlement.
- (s) **Employee Stock Compensation**  
Options may be issued to employees to purchase ordinary shares with exercise prices which are less than the market value of the ordinary shares at the date of grant. In such cases the excess of the market value over the

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exercise price for the total number of options so issued is treated as compensation expense and recorded in the profit and loss account over the vesting period, with an appropriate credit to other reserves.

### 2. INVENTORIES

	December 31	December 31
(As restated)	2002	2001
	US\$	US\$
Raw materials	5,995,894	5,145,345
Work in progress	6,499,224	7,044,487
Finished goods	8,356,341	4,199,476
	20,851,459	16,389,308

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

### 3. ACCOUNTS RECEIVABLE AND PREPAYMENTS

	December 31	December 31
(Amounts falling due within one year)	2002	2001
(As restated)	US\$	US\$
Accounts receivable	9,798,967	5,166,014
Prepayments	1,015,795	930,892
Value Added Tax	159,736	155,858
Called up share capital not paid	260,203	291,211
Grants receivable	532,665	290,389
Other receivables	490,482	312,959
Deferred tax asset (see note 9)	418,908	608,800
	12,676,756	7,756,123

### 4. INTANGIBLE ASSET

	December 31	December 31
(As restated)	2002	2001
	US\$	US\$
Cost		
Patents and licenses	4,889,791	4,420,850
Goodwill (see note 22)	41,580,827	40,555,153
	46,470,618	44,976,003
Less accumulated amortisation	(6,958,832)	(4,667,457)
	39,511,786	40,308,546

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

### 5. PROPERTY, PLANT AND EQUIPMENT

	December 31	December 31
--	-------------	-------------

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(As restated)	2002	2001
Cost	US\$	US\$
Land & buildings	4,229,485	1,636,350
Leasehold improvements	1,213,153	677,234
Computer & office equipment	2,758,023	1,825,634
Plant and equipment	8,194,774	7,221,485
	-----	-----
	16,395,435	11,360,703
Less accumulated depreciation	(6,511,754)	(5,393,260)
	-----	-----
	9,883,681	5,967,443
	-----	-----

A mortgage amounting to US\$167,406 is secured by a charge over the plant in Jamestown, New York.

Included in the net book value of tangible fixed assets is an amount for capitalised leased assets of US\$944,352 (2001: US\$826,127). The depreciation charge in respect of capitalised leased assets for the year ended December 31, 2002 was US\$110,345 (2001: US\$111,512).

### 6. FINANCIAL ASSETS

(As restated)	December 31 2002 US\$	December 31 2001 US\$
Investment in associate (see below)	1,067,262	1,276,647
	-----	-----

On October 2, 2000, the Company acquired 33% of the share capital of HiberGen Limited for a total consideration of US\$1,371,642. On July 2, 2001 the Company subscribed for a further 300,000 Ordinary Shares of (euro)0.0127 each in HiberGen Limited, increasing its shareholding to 40%, at a cost of US\$309,399. 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.

The carrying amount of the investment in the associate is split as follows:

	December 31 2002 US\$	December 31 2001 US\$
Share of net assets of associate on acquisition	118,220	71,883
Goodwill arising on acquisition	1,764,695	1,609,158
Accumulated amortisation	(199,670)	(105,524)
Share of operating loss in associate	(615,983)	(298,870)
	-----	-----
	1,067,262	1,276,647
	-----	-----

See Note 30 for details of events subsequent to the balance sheet date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

7. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31, 2002
(Amounts falling due within one year)	2002
(As restated)	US\$
Accounts payable	3,080,450
Income tax deducted under PAYE	90,950
Employee related social insurance	81,960
Corporate income taxes	184,390
Accrued liabilities	3,854,470
Accrued exceptional charges	
Accrued royalties	532,620
Obligations under finance leases	218,160
Financial liabilities from unconnected third party - current portion	4,107,750
Long term debt - current portion	1,978,150
Deferred consideration - current portion	3,803,950
6.0/7.5% convertible debenture (see note 8)	979,320
	-----
	18,912,200
	-----

In December 2001, the Company acquired the assets and goodwill of the Biopool hemostasis business. Under the terms of the purchase agreement US\$2,591,500 of the total consideration of US\$6,409,329 has been deferred. The deferred consideration of US\$2,591,500 is payable in three instalments of US\$855,200, US\$1,166,200 and US\$570,100 on December 21, 2002, 2003 and 2004 respectively. At December 31, 2002, US\$2,021,400 of the deferred consideration for the Biopool hemostasis business is included in current liabilities under deferred consideration. See Note 30 for details of events subsequent to the balance sheet date.

In November 2002, the Company 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. This deferred consideration of US\$1,810,000 is payable in two instalments of US\$1,010,000 and US\$800,000 on May 27 and November 27, 2003 respectively. The present value of these amounts of US\$1,782,553 is included in current liabilities under deferred consideration at December 31, 2002.

As at December 31, 2002 the undrawn portion of existing banking facilities amounted to US\$2,170,242.

8. LONG TERM LIABILITIES



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(As restated) (Amounts falling due after more than one year)	December 31 2002 US\$	December 31 2001 US\$
5.25% convertible debenture	2,500,000	-
Bank loans (secured, see note 23(h))	4,655,785	6,027,649
Deferred consideration	570,100	1,736,300
Lease creditors	12,655	41,288
Other creditors	6,902	-
	-----	-----
	7,745,442	7,805,237
	-----	-----

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

	December 31 2002 US\$	December 31 2001 US\$
In more than one year, but not more than two	2,065,750	2,919,734
In more than two years, but not more than three	1,466,965	2,019,898
In more than three years, but not more than four	1,055,071	1,422,726
In more than four years, but not more than five	3,073,491	1,254,776
In more than five years	71,510	146,815
	-----	-----
	7,732,787	7,763,949
	-----	-----

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 8. LONG TERM LIABILITIES (Continued)

In December 1999, the Company completed a private placement of US\$3,500,000 principal amount of 7.5% convertible debentures. The debentures bore interest at a rate of 7.5% per annum which was payable semi-annually. The debentures were convertible, at the option of the holder, into Class '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. The remaining US\$1,000,000 principal amount of the debenture has been converted into 666,667 Class 'A' Ordinary Shares of the Company since year

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end.

In November 2002, the Company completed a private placement of US\$2,500,000 principal amount of 5.25% convertible debentures (see Note 22). The debentures bear interest at a rate of 5.25% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$1.50. Since the year end, these debentures have been converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

As at December 31, 2002 payments falling due under finance leases of less than one year's duration amounted to US\$218,163 (2001: US\$185,575). As at December 31, 2002 obligations under finance leases of between two and five years' duration amounted to US\$12,655 (2001: US\$41,288). There were no payments falling due extending beyond five years.

### 9. DEFERRED TAXATION

	December 31 2002 US\$	December 31 2001 US\$
(As restated)		
Movement in Deferred Tax Asset		
At beginning of year	608,800	390,800
Charge to profit and loss account (see note 17)	(189,892)	-
Credit to profit and loss account (see note 17)	-	218,000
	-----	-----
At end of year	418,908	608,800
	-----	-----
Movement in Deferred Tax Liability		
At beginning of year	143,000	-
Charge to profit and loss account (see note 17)	150,579	143,000
	-----	-----
At end of year	293,579	143,000
	-----	-----

The deferred tax asset is due to the tax effect of net operating loss carryforwards. During 2002 the Company used some of these loss carryforwards which resulted in a reduction in the deferred tax asset. During 2001 the deferred tax asset increased due to a reduction in the valuation allowance associated with the loss carryforwards.

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Net operating loss carryforwards	488,513	707,659	1,167,690
Other timing differences	61,812	174,800	160,800
	-----	-----	-----
Total deferred tax assets	550,325	882,459	1,328,490
Valuation allowance	(131,417)	(273,659)	(937,690)
	-----	-----	-----
Net deferred tax assets	418,908	608,800	390,800
	-----	-----	-----

At 31 December 2002, the Company had Irish, German and US net operating loss carryforwards of US\$399,013, US\$345,835 and US\$774,174 respectively. The utilisation of these net operating loss carryforwards is limited to the future profitable operations of the Group in the related tax jurisdictions in which such carryforwards arose. The Irish

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

9. DEFERRED TAXATION (Continued)

and German losses carryforward indefinitely. The US loss carryforwards will expire by 2008, if not previously utilised. Valuation allowances have been provided against the net operating loss carryforwards for uncertainties regarding future full utilisation of operating losses in the related tax jurisdictions in future periods.

The deferred tax liability is caused by the net book value of fixed assets being greater than the tax written down value of fixed assets. During 2002 and 2001 the excess of the book value of fixed assets over the tax value increased thereby resulting in an increase in the deferred tax liability.

10. CALLED UP SHARE CAPITAL

(a) In December 1999, the Company completed a private placement of US\$3,500,000 principal amount of 7.5% convertible debentures. During 2000, US\$1,875,000 of the US\$3,500,000 principal amount of the debentures 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. The remaining US\$1,000,000 principal amount of the debenture has been converted into 666,667 Class 'A' Ordinary Shares of the Company since year end.

(b) In November 2002, the Company completed a private placement of US\$2,500,000 principal amount of 5.25% convertible debentures. The debentures bear interest at a rate of 5.25% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$1.50. Since the year end, these debentures have been converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

(c) On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its associate HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.

(d) In December 2002, Enterprise Ireland subscribed for 443,900 'A' Ordinary Shares in the Company (see note 23(e)).

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

(f) The AGM held on May 28, 2001, approved a resolution for the renominatisation of the Company's share capital from IR(pound)0.01 each to US\$0.0109 each.

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

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

### 11. SHARE OPTIONS AND WARRANTS

Under the terms of the Company's Employee Share Option Plan options to purchase 8,781,174 Class 'A' Ordinary Shares were outstanding at December 31, 2002. Under the plan, options are granted to officers, employees and consultants of the Group at the discretion of the remuneration committee of the board. In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary Shares in the Company to agents of the Company who were involved in the Company's private placements in 1994 and 1995 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was also granted to a consultant of the Company. At December 31, 2002 there were warrants to purchase 553,525 Class 'A' Ordinary Shares in the Company outstanding.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 11. SHARE OPTIONS AND WARRANTS (continued)

The share options and warrants outstanding at December 31, 2002 were as follows:

	Options & Warrants Shares	Range
Outstanding		US\$
January 1, 2000	4,884,472	0.81-5.00
Granted	4,112,194	1.75-4.00
Exercised	(2,884,496)	0.81-4.00
Cancelled	(243,467)	1.00-4.00
	-----	-----
December 31, 2000	5,868,703	0.81-5.00
Granted	2,039,500	0.98-1.20
Exercised	(43,250)	1.00-2.00
	-----	-----
December 31, 2001	7,864,953	0.81-5.00
Granted	2,223,500	0.98-1.50
Exercised	(12,334)	1.13
Cancelled	(741,420)	0.98-2.78

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December 31, 2002	----- 9,334,699 -----	----- 0.81-5.00 -----
-------------------	-----------------------------	-----------------------------

12. PROFIT AND LOSS RESERVE/MINORITY INTEREST  
(As restated)

(a) Profit and loss reserve

	December 31 2002 US\$	December 31 2001 US\$
Accumulated surplus	11,810,266	6,913,355
Goodwill reserve	(21,776,683)	(21,776,683)
	-----	-----
	(9,966,417)	(14,863,328)
	-----	-----

Due to the adoption of Financial Reporting Standard No. 10 by the Company, the goodwill reserve is disclosed as part of the profit and loss reserve on the face of the balance sheet. This adoption does not affect the potential distributable reserves of the Company.

(b) Minority interest

	December 31 2002 US\$	December 31 2001 US\$
Minority interest	309,946	309,946
	-----	-----

In March 1998 Benen Trading Limited ("Benen") received an injection of funds under the Business Expansion Scheme. In order to present a true and fair view of the consolidated financial statements, the substance of this transaction, as distinct from its strict legal form, is considered in determining its true nature and the appropriate accounting treatment. In particular, the option which is incorporated within the transaction, and the most likely exercise of it, determined the substance of the transaction. Since the year end this option has been exercised.

In these circumstances it is considered that the injection of these funds is in the nature of quasi equity. The Group does have obligations to transfer economic benefits at the end of the investment period. This obligation is limited to a maximum of (euro)330,200 being (euro)1.32 per share. Accordingly, the Group has continued to consolidate Benen as a 100% subsidiary undertaking and the proceeds (after deducting share issue costs and expenses) of the investment have been credited to minority interest.

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(As restated)

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

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

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Rest of World	23,968,227	13,548,075	14,410,284
United States	28,010,195	23,527,498	15,332,658
	-----	-----	-----
	51,978,422	37,075,573	29,742,942
	-----	-----	-----

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

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

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
U.S.A.	33,511,564	25,057,609	17,282,005
Europe	11,899,290	6,879,597	7,197,185
Middle East/Africa	4,396,270	3,900,154	4,047,205
Other overseas	2,171,298	1,238,213	1,216,547
	-----	-----	-----
	51,978,422	37,075,573	29,742,942
	-----	-----	-----

d) It is not deemed practical to present an analysis of revenue by major product group.

e) The distribution of intersegmental sales was as follows:

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	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Rest of World	21,448,012	12,208,904	11,918,545
Rest of World - intersegmental sales	18,365,780	13,732,096	12,224,323
United States	28,010,195	23,527,498	15,332,658
Less intercompany sales	(15,845,565)	(12,392,925)	(9,732,584)
	-----	-----	-----
	51,978,422	37,075,573	29,742,942
	-----	-----	-----

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

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

13. ANALYSIS OF REVENUE, OPERATING INCOME, MAJOR CUSTOMERS AND ASSETS  
(Continued)

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

	December 31 2002 US\$	December 31 2001 US\$
Rest of World	3,754,912	679,891
United States	2,827,949	2,368,169
	-----	-----
Total operating income	6,582,861	3,048,060
	-----	-----

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

	December 31 2002 US\$	December 31 2001 US\$
Ireland	56,314,112	54,536,663
Rest of Europe	5,759,724	206,900
United States	27,724,622	22,328,480
	-----	-----

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Total assets	89,798,458	77,072,043
	-----	-----

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

	December 31 2002 US\$	December 31 2001 US\$
Ireland	35,989,233	35,899,242
Rest of Europe	2,752,661	55,665
United States	11,720,835	11,597,729
	-----	-----
Total long-lived assets	50,462,729	47,552,636
	-----	-----

- i) The concentrations of revenues to customers representing 10% or more of total revenues was as follows:

	December 31 2002	December 31 2001
Customer A	20%	27%

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

	December 31 2002 US\$	December 31 2001 US\$
Ireland	2,386,761	2,109,221
Rest of Europe	19,220	2,655
United States	1,098,034	763,445
	-----	-----
Total depreciation and amortisation	3,504,015	2,875,321
	-----	-----



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(Continued)

k) The distribution of unusual items by geographical area was as follows:

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
United States	-	(3,635,000)	(1,222,203)
	-----	-----	-----
Total unusual items	-	(3,635,000)	(1,222,203)
	-----	-----	-----

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

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Rest of World	(607,750)	(310,877)	(358,574)
United States	(96,710)	(227,524)	(399,278)
	-----	-----	-----
Total interest	(704,460)	(538,401)	(757,852)
	-----	-----	-----

14. PROFIT ON ORDINARY ACTIVITIES BEFORE TAXATION  
(As restated)

	December 31 2002 US\$	December 31 2001 US\$
The profit on ordinary activities before taxation is stated after charging/(crediting)		
Directors' emoluments:		
Remuneration	1,165,171	953,84
Pension	94,706	59,15
Auditors' remuneration:		
Audit fees	190,000	170,00
Non audit fees	20,000	25,37
Depreciation	1,118,494	873,18
Amortisation	2,385,521	2,002,13
Operating lease rentals:		
Plant and machinery	26,048	
Other	1,444,623	942,49
Research and development grants	-	
Employment grants	(214,091)	
Settlement of litigation (see note below)	-	(1,360,97)
Other non-recurring charges	-	357,44
	-----	-----

Trinity and Selfcare entered into a settlement in 2001 whereby Selfcare paid Trinity US\$1,500,000 and Trinity (i) conveyed to Selfcare its rights in an HIV I/II RTD product licence and (ii) agreed to supply certain antigens at cost for a ten-year period, pursuant to an Antigen Supply

Agreement.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

15. ACQUISITIONS

On August 27, 2002 Trinity Biotech purchased the Hemostasis division of Sigma Diagnostics and on November 27, 2002 the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics. The results of these acquisitions for 2002 are incorporated from the date of acquisition in the profit and loss account for the year ended December 31, 2002.

On October 19, 2001 Trinity Biotech purchased the Amerlex hormone business of Ortho Clinical Diagnostics and on December 21, 2001 the Company acquired the assets and goodwill of the Biopool Hemostasis business. The results of these acquisitions for 2001 are incorporated from the date of acquisition in the profit and loss account for the year ended December 31, 2001.

On December 8, 2000, the Group purchased the assets and goodwill of Bartels Inc, based in Seattle, Washington. As no audited financial statements were available for the acquired business in the period prior to the acquisition, the directors used the fair values established at the time of the acquisition to derive the following approximate results of the entity from the date of acquisition to December 31, 2000. The results of Bartels are incorporated into continuing operations in the years ended December 31, 2001 and 2002.

	December 31 2000 US\$
Sales	465,871
Cost of sales	(82,000)
	-----
	383,871
	-----

16. ADMINISTRATIVE EXPENSES - EXCEPTIONAL ITEMS  
(As restated)

An exceptional charge of US\$2,835,000 was incurred during 2001 relating to the acquisition of the assets and goodwill of the Biopool hemostasis business on December 21, 2001. The principal components of this charge were commitments on the acquisition of the assets and goodwill of the Biopool hemostasis business to make payments to employees.

An exceptional charge of US\$800,000 was also incurred during 2001 relating 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 Dublin. A similar exceptional charge of US\$1,222,203 arose in 2000 relating to commitments on acquisition to make payments to employees. There were no exceptional charges recognised in 2002.

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	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Administrative expenses			
-Exceptional	-	3,635,000	1,222,203
	-----	-----	-----

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

17. INCOME TAXES  
(As restated)

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

	December 31 2002 US\$	December 31 2001 US\$
Current tax		
Corporation tax at 16% (2001: 20%, 2000: 24%)	9,299	107,876
Manufacturing relief	-	(64,000)
	-----	-----
	9,299	43,876
Overseas tax	481,862	47,000
Relief in respect of prior year	(64,122)	-
	-----	-----
Total current tax	427,039	90,876
Deferred tax charge/(credit)		
Movement in deferred tax asset (see note 9)	189,892	(218,000)
Movement in deferred tax liability (see note 9)	150,579	143,000
	-----	-----
Total taxation on profit on ordinary activities	767,510	15,876
	-----	-----
Effective tax rate		
Profit on ordinary activities before taxation	5,664,421	2,383,153
As a percentage of profit before tax		
Current tax	7.5%	3.8%
Total tax (current and deferred)	13.5%	0.7%

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

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	2002 % of profit before taxation	2001 % of profit before taxation
Irish corporation tax	16.0	20.0
Manufacturing relief	(0.0)	(2.7)
Tax rates on overseas earnings	4.0	0.7
Relief in respect of prior year	(1.1)	-
Other including benefit of loss carryforwards	(11.4)	(14.2)
	-----	-----
Current tax	7.5	3.8
Deferred tax	6.0	(3.1)
	-----	-----
Total tax (current and deferred)	13.5	0.7
	=====	=====

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

	December 31 2002 US\$	December 31 2001 US\$	December 31 2000 US\$
Rest of World	2,920,204	174,491	1,264,969
United States	2,744,217	2,208,662	2,860,441
	-----	-----	-----
Total profits before taxation	5,664,421	2,383,153	4,125,410
	-----	-----	-----

- (c) The tax effects of temporary differences that give rise to significant portions of deferred tax assets relate principally to net operating losses. The valuation allowance for deferred tax assets at December 31, 2002, 2001 and 2000 was US\$131,417, US\$240,245 and US\$937,690 respectively.
- (d) At December 31, 2002, the Group had Irish net operating losses of approximately US\$399,013 (2001: approximately US\$478,854). The utilisation of these net operating loss carryforwards is limited to offset

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

17. INCOME TAXES (Continued)

against the future profits earned by the Group arising from the same trade and in the tax jurisdiction in which they arose.

At December 31, 2002, the Group had U.S. net operating loss carryforwards of approximately US\$774,174 (2001 : US\$1,894,049) for US federal income tax

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purposes, which will expire in 2008 if not previously utilised. Utilisation of the U.S. net operating loss carryforward may be subject to an annual limitation due to the change in ownership rules provided by the Internal Revenue Code of 1986. This limitation and other restrictions provided by the Internal Revenue Code of 1986 may reduce the net operating loss carryforward such that it would not be available to offset future taxable income of the US subsidiaries.

### 18. EARNINGS PER ORDINARY SHARE (As restated)

#### (a) Basic earnings per ordinary share

Earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US\$4,896,911 (December 31, 2001, US\$2,367,277 and December 31, 2000, US\$4,124,410) for the financial year by the weighted average number of ordinary shares in issue of 40,550,367 (December 31, 2001 - 40,408,978 and December 31, 2000 - 37,131,692).

#### (b) Diluted earnings per ordinary share

Diluted earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US\$4,896,911 (December 31, 2001, US\$2,367,277 and December 31, 2000, US\$4,124,410) for the financial year, adjusted for debenture interest saving of US\$85,829 (December 31, 2001, US\$nil and December 31, 2000 US\$121,875) by the diluted weighted average number of ordinary shares in issue of 42,486,227 (December 31, 2001, 41,120,060 and December 31, 2000, 40,540,494). The basic weighted average number of shares may be reconciled to the number used in the diluted earnings per ordinary share calculation as follows:

	December 31 2002	December 31 2001	Dec
Basic earnings per share denominator	40,550,367	40,408,978	37
Issuable on exercise of options	1,214,703	711,082	2
Issuable on conversion of debentures	721,157	-	
	-----	-----	
Diluted earnings per share denominator	42,486,227	41,120,060	40
	-----	-----	

No adjustment is included for debenture conversion for 2001 as the impact would have been anti-dilutive.

### 19. SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION (As restated)

	December 31 2002 US\$	December 31 2001 US\$	Dece
(a) Purchase of tangible fixed assets			
Additions to tangible fixed assets	2,516,982	1,343,370	1,3
Less new finance leases	-	-	(1
	-----	-----	
	2,516,982	1,343,370	1,1
	-----	-----	

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- (b) Management of liquid resources  
Cash flows from the use of liquid resources in 2002 arose from the movement of cash from fixed deposit accounts.

Cash flows from the use of liquid resources in 2001 arose from the movement of cash to fixed deposit accounts. Cash flows from the use of liquid resources in 2000 arose from the sale of equity investments of US\$127,500, less the purchase of equity investments of US\$49,685.

- (c) Impact of acquisitions on cash flow headings  
As the working capital of the acquired businesses was fully integrated within the Group at year end, post acquisition operating cash flows are not readily obtainable. The operating results of the hemostasis division and the speciality clinical chemistry product line of Sigma Diagnostics acquired on August 27 and November 27, 2002 respectively contributed US\$59,027 to the operating profit of the Group.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 19. SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION (Continued)

The cash outflow of US\$4,408,692 from the acquisition of businesses and product lines in 2002 was partly funded by the issue of US\$2,500,000 of convertible debentures in November 2002 (see note 10).

The operating results of the Amerlex hormone business of Ortho Clinical Diagnostics acquired on October 19, 2001 contributed US\$41,148 to the net cash inflow from operating activities of the Group.

#### 20. RECONCILIATION OF OPERATING PROFIT TO NET CASH INFLOW FROM OPERATING ACTIVITIES (As restated)

	December 31 2002 US\$	December 31 2001 US\$
Operating profit	6,582,861	3,048,060
Depreciation and amortisation	3,504,015	2,875,321
Disposal of investments	-	-
Exceptional administrative expenses	(2,835,000)	2,835,000
(Increase)/decrease in receivables and prepayments	(4,250,982)	990,800
Increase/(decrease) in accounts payable	2,874,740	(2,044,110)
Increase in inventory	(2,414,882)	(2,027,323)
Non cash compensation expense	120,000	45,000
	-----	-----
Net cash inflow from operating activities	3,580,752	5,722,748

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21. ANALYSIS OF NET DEBT  
(As restated)

	December 31 2001 US\$	Cash flow US\$	Acquisitions/ disposals US\$	Non-cash changes US\$
Cash	2,106,844	891,848	-	-
Liquid resources	3,267,132	(553,310)	-	-
	5,373,976	338,538	-	-
Long term debt				
- current portion	(2,409,757)	431,602	-	-
Long term debt	(6,027,649)	1,371,864	-	-
Other financial liabilities	-	(4,041,506)	-	-
Finance leases	(226,863)	17,350	-	-
Convertible debentures	(1,000,000)	(2,500,000)	-	20,679
Net debt	(4,290,293)	(4,382,152)	-	20,679

	December 31 2000 US\$	Cash flow US\$	Acquisitions/ disposals US\$	Non-c chang U
Cash	3,381,779	(1,274,935)	-	
Liquid resources	893,816	2,373,316	-	
	4,275,595	1,098,381	-	
Long term debt				
- current portion	(2,574,185)	164,428	-	
Long term debt	(1,033,258)	(4,994,391)	-	
Finance leases	(536,939)	310,076	-	
Convertible debentures	(1,625,000)	625,000	-	
Promissory note	(350,000)	350,000	-	
Net debt	(1,843,787)	(2,446,506)	-	

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	December 31 1999 US\$	Cash flow US\$	Acquisitions/ disposals US\$	Non-cash changes US\$
Cash	2,092,812	1,288,967	-	-
Liquid resources	971,631	(77,815)	-	-
	-----	-----	-----	-----
	3,064,443	1,211,152	-	
Long term debt				
- current portion	(2,967,595)	737,160	(343,750)	-
Long term debt	(4,255,857)	4,178,849	(956,250)	-
Finance leases	(653,118)	291,838	-	(175,659)
Convertible debentures	(3,500,000)	-	-	1,875,000
Promissory note	-	-	-	(350,000)
	-----	-----	-----	-----
Net debt	(8,312,127)	6,418,999	(1,300,000)	1,349,341
	-----	-----	-----	-----

22. ACQUISITION OF BUSINESSES  
(As restated)

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. Acquisition expenses amounted to US\$78,698. The division comprises a portfolio of reagents manufactured in St. Louis, Missouri and the Amelung range of instruments manufactured in Lemgo, Germany. The Company recently completed training its workforce in the manufacture of the reagent product line in the Sigma St Louis operations and is currently in the process of transferring the production of these reagents to Bray, Ireland. This acquisition together with the acquisition of Biopool in 2001 position the Company with a significant market position in the hemostasis diagnostic market.

On November 27, 2002 the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US\$4,443,852 satisfied in cash and deferred consideration with a fair value of US\$4,412,372. The cash consideration was partly financed by the issue of US\$2.5m of convertible debentures (see note 10). The deferred consideration of US\$1,810,000 is payable in two instalments of US\$1,010,000 and US\$800,000 on May 27 and November 27, 2003 respectively. The fair value of deferred consideration at November 27, 2002 was US\$1,778,520. The deferred consideration is not conditional on any future event. Total acquisition expenses amounted to US\$93,852. The Company recently completed training its workforce in the manufacture of this product line in the Sigma St Louis operations and is in the process of transferring production of the product line from St Louis, Missouri to Bray, Ireland. Goodwill arising on acquisition of US\$3.8 million represents the value of the expected synergies created by combining production within Trinity's existing manufacturing operations.

The Company does not allocate any value to trademarks of acquired entities as part of the purchase price allocation as the Company re-brands any products acquired, under a Trinity Biotech label. The Company does not allocate any value to customer relationships or customer lists obtained as part of these acquisitions as these are not considered proprietary to the acquired entities and the Company is already in possession of such customer lists and has existing relationships with customers of acquired entities given its existing position in the diagnostics industry.



NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

22. ACQUISITION OF BUSINESSES (Continued)

	Sigma Hemostasis
	US\$
Tangible fixed assets	2,500,000
Working capital	206,462
	-----
Net assets at fair value	2,706,462
Goodwill	(1,278,461)
	-----
Consideration	1,428,001
	-----
Satisfied by:	
Cash payments including costs	1,428,001
	-----
Net cashflow	1,428,001
Deferred consideration	--
	-----
Consideration	1,428,001
	-----

Goodwill capitalised during the year in respect of acquired businesses amounted to US\$2,508,642 and comprises:

	Book Values US\$	Fair Value Adjustment US\$	Fair Value US\$
Sigma Hemostasis			
Tangible fixed assets	1,321,652	1,178,348 *	2,500,000
Working capital	8,457,883	(8,251,421) *	206,462
	-----	-----	-----
	9,779,535	(7,073,073)	2,706,462

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Sigma Clinical Chemistry			
Working capital	1,490,593	(865,324) *	625,269
	1,490,593	(865,324)	625,269
Total	11,270,128	(7,938,397)	3,331,731

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

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

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

On October 19, 2001 the Group purchased the Amerlex hormone business of Ortho Clinical Diagnostics for a total consideration of US\$877,797. The consideration was satisfied in cash. Acquisition expenses amounted to US\$94,860. This business added a range of tests which diagnose hormone disorders to the Company's portfolio of products. The manufacture of these products was transferred to the Bray, Ireland manufacturing facility. Goodwill arising on acquisition of US\$877,797 represents the value of expected synergies created by combining production within the Company's existing manufacturing operations.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

22. ACQUISITION OF BUSINESSES (Continued)  
(As restated)

On December 21, 2001 the Group acquired the assets and goodwill of the Biopool hemostasis business for a total consideration of US\$6,409,329 satisfied in cash and deferred consideration. The deferred consideration of US\$2,591,500 is 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 is not conditional on any future event. Since year end all amounts due have been paid. Total acquisition expenses amounted to US\$159,329. This business comprises a range of test kits which assess and diagnose disorders of blood coagulation, thrombotic risk factors, fibrinolysis, platelet function and the vascular system. As part of the acquisition the Company assumed the workforce in Ventura, California and Umea, Sweden. In the ten

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months after acquisition the Company learnt the production techniques associated with this product range and transferred the Ventura production facility together with a number of key employees to the Bray, Ireland facility. The Company has maintained the Umea operation and will continue to benefit from the expertise associated with this assumed workforce. Goodwill arising on acquisition of US\$5.1 million after fair value adjustments represents the value of the expected synergies created by combining production within the Company's existing manufacturing operations in Ireland together with the specialist product knowledge acquired with the assumed workforce in Ventura and Umea.

The Company does not allocate any value to any trademarks of acquired entities as part of the purchase price allocation as the Company re-brands any products acquired, under a Trinity Biotech label. The Company does not allocate any value to customer relationships or customer lists obtained as part of these acquisitions as these are not considered proprietary to the acquired entities and the Company is already in possession of such customer lists and has existing relationships with customers of acquired entities given its existing position in the diagnostics industry.

		Ortho US\$
Working capital	--	-----
Net liabilities at fair value	--	-----
Goodwill	877,797	-----
Consideration	877,797	-----
Satisfied by:		
Cash payments including costs	877,797	-----
Net cash outflow	877,797	-----
Deferred consideration	--	-----
Consideration	877,797	-----

Goodwill capitalised during 2001 in respect of acquired businesses amounted to US\$7,423,126 and comprises:

	Book Values	Fair Value Adjustment	Fair Value
--	----------------	-----------------------------	---------------

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	US\$	US\$	US\$
Ortho	--	--	--
	-----	-----	-----
Biopool			
Working capital	3,022,000	(3,158,000) *	(136,000)
	-----	-----	-----
	3,022,000	(3,158,000)	(136,000)
	-----	-----	-----
Total	3,022,000	(3,158,000)	(136,000)
	-----	-----	-----

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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22. ACQUISITION OF BUSINESSES (Continued)  
(As restated)

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

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

\* Write-down of inventories and receivables following an assessment of the realisable value of inventories and the collectability of receivables.

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

	Provisional fair value 2001 US\$	Adjustments to net assets 2002 US\$
Ortho		
Consideration and costs	877,797	--
	-----	-----

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Biopool		
Working capital	(136,000)	1,551,132
	-----	-----
Consideration and costs	(6,409,329)	--
	-----	-----

On February 29, 2000 the Group purchased MarDx Diagnostics Inc for a total consideration of US\$4,208,279. The consideration was satisfied by cash and the issue of 'A' Ordinary Shares. Acquisition expenses amounted to US\$244,992. On December 8, 2000 the Group acquired the assets and goodwill of Bartels Inc for a total consideration of US\$9,463,974 satisfied by cash, the issue of 'A' Ordinary Shares and a promissory note. Total acquisition expenses amounted to US\$158,874.

	Mardx US\$
Tangible fixed assets	72,306
Working capital	660,458
Long-term debt	(956,250)
	-----
Net assets/(liabilities) at fair value	(223,486)
Goodwill	4,431,765
	-----
Consideration	4,208,279
	-----
Satisfied by:	
Cash payments including costs	2,044,992
	-----
Net cash outflow	2,044,992
Promissory Note	--
Issue of 'A' Ordinary Shares	2,163,287
	-----
Consideration	4,208,279

Goodwill capitalised during 2000 in respect of acquired businesses amounted to US\$13,145,739 and comprised:

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### 22. ACQUISITION OF BUSINESSES (Continued) (As restated)

	Book Values US\$	Fair Value Adjustment US\$	Fair Value US\$
<b>Mardx</b>			
Tangible fixed assets	572,306	(500,000) *	72,306
Working capital	910,458	(250,000) *	660,458
Long-term debt	(956,250)	--	(956,250)
	-----	-----	-----
	526,514	(750,000)	(223,486)
	-----	-----	-----
<b>Bartels</b>			
Working capital	959,478	(209,478) *	750,000
	-----	-----	-----
	959,478	(209,478)	750,000
	-----	-----	-----
<b>Total</b>	<b>1,485,992</b>	<b>(959,478)</b>	<b>526,514</b>
	-----	-----	-----

The book value of the assets and liabilities shown above have been taken from management accounts and other information of the acquired businesses at the date of acquisition.

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

Write-down of fixed assets, inventories and receivables following an assessment of the continuing economic contribution of fixed assets, the realisable value of inventories and the collectability of accounts receivable.

Following the completion of the fair value exercises in 2001 in respect of the acquisitions made during 2000, amendments have been made to the fair values reported in the 2000 financial statements. The difference has been taken as an adjustment to goodwill on acquisition. Provisional and final values of net assets acquired and consideration paid are as follows:

	Provisional fair value 2000 US\$	Adjustments to net assets 2001 US\$
<b>Mardx</b>		
Tangible fixed assets	72,306	--
Working Capital	660,458	--
Long-term debt	(956,250)	--
	-----	-----

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Net assets	(223,486)	--
	-----	-----
Consideration and costs	(4,208,279)	--
	-----	-----
Bartels Working capital	750,000	127,090
	-----	-----
Consideration and costs	(9,463,974)	--
	-----	-----

23. COMMITMENTS AND CONTINGENCIES

(a) Capital Commitments

The capital commitments of the Group were as follows:

	31 December 2002 US\$
Contracted for	--
Authorised, not contracted for	--
	-----
	-----

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

23. COMMITMENTS AND CONTINGENCIES (Continued)

(b) Operating lease commitments payable during the next twelve months amount to US\$1,529,849 (2001: US\$936,101) payable on leases of buildings at Dublin and Bray, Ireland, Umea, Sweden, St. Louis, Missouri, upstate New York and Carlsbad, California and plant and machinery in Lemgo, Germany. US\$30,452 of the operating lease commitments total relates to leases whose remaining term will expire within one year, US\$149,845 relates to leases whose remaining term expires between one and two years, US\$711,425 between two and five years and the balance of US\$638,127 relates to leases which expire after more than five years.

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

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	Operating Leases US\$ Restated	Finance Leases US\$ Restated
2003	1,660,230	218,163
2004	1,517,174	12,655
2005	1,266,200	--
2006	1,020,814	--
2007	784,751	--
Later years	8,268,281	--
	----- 14,517,450 -----	----- 230,818 -----

- (c) Under agreements between the Group and Enterprise Ireland, grants amounting to US\$532,665 (2001: US\$290,389) are receivable which may be revoked, cancelled or abated in certain circumstances.
- (d) Under agreements between the Group and Enterprise Ireland, a loan amounting to US\$57,198 (2001: US\$220,411) is payable which may be required to be repaid immediately in certain circumstances.
- (e) Under an agreement reached in November 2000, between the Group and Enterprise Ireland, grants of US\$605,680 are payable in the event of predefined employment targets being achieved. As part of this agreement, Enterprise Ireland could subscribe for 'A' Ordinary Shares of the Company up to a value of (euro)1,097,054 at a share price 10% below the market price of the Company's shares. In December 2000 Enterprise Ireland subscribed (euro)548,527 of this amount for 239,198 'A' Ordinary Shares of the Company. In December 2002 Enterprise Ireland subscribed the remaining (euro)548,527 for 443,900 'A' Ordinary Shares of the Company.
- (f) At December 31, 2002 the Company has guaranteed the borrowings of subsidiary undertakings to the amount of US\$2,776,343.
- (g) Pursuant to the provisions of Section 17, Companies (Amendment) Act, 1986, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited, a subsidiary undertaking in the Republic of Ireland, for the financial year to December 31, 2002 and, as a result, this subsidiary undertaking has been exempted from the filing provisions of Section 7, Companies (Amendment) Act, 1986.
- (h) The Company's bank borrowings are secured by a fixed and floating charge over the assets of the Company. The Company had also given security over certain US assets, subordinate to other banking arrangements, to Xtrana Inc relating to the deferred consideration due as part of the acquisition of the Biopool hemostasis business. See Note 30 for further details.
- (i) In December 2002 the Company filed an action against Xtrana Inc relating to the purchase of the Biopool business from Xtrana in 2001. The Company was seeking US\$1.2m in damages and US\$3m in punitive damages alleging breach of contract and other damages regarding the sale of an individual product line. On January 17, 2003 Xtrana countersued seeking US\$57m in damages. On June 16, 2003 Trinity and Xtrana settled this litigation. See Note 30 for further details.



NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

24. SIGNIFICANT CONCENTRATIONS AND BUSINESS RISKS

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

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

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

25. PENSION SCHEME

The Group operates a defined contribution pension scheme for its full-time employees. The benefits under this scheme are financed by both Group and employee contributions. Total contributions made by the Group in the financial year and charged against income amounted to US\$522,797 (December 31, 2001, US\$583,065 and December 31, 2000, US\$547,475). This represents the total cost to the Group of the pension scheme for the financial year and as such it was not necessary to accrue or prepay pension contributions at the year end.

26. RELATED PARTY TRANSACTIONS

The Company has entered into various arrangements with JRJ Investments ("JRJ"), a partnership owned by Mr. O'Caoimh and Dr. Walsh, directors of the Company, to provide for current and potential future needs to extend its premises at IDA Business Park, Bray, Co. Wicklow, Ireland. It has entered into an agreement with JRJ pursuant to which the Company has taken a lease of premises adjacent to the existing facility for a term of 20 years at a rent of (euro)7.62 per square foot ("the Current Extension"). The lease commenced on the newly completed 25,000 square foot building in July 2000. The Company also envisages that further premises may potentially be required by it and, for that purpose, has entered into a four years eleven month lease at (euro)28,568 per annum over adjacent lands with JRJ. On November 20, 2002 the Company signed an agreement for lease with JRJ 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 current extension. Independent Valuers have advised the Company that the rent fixed in respect of the Current Extension, the agreement for lease and the adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr. O'Caoimh and Dr. Walsh who express no opinion on this point) believe that the arrangements entered

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into represent a fair and reasonable basis on which the Company can meet its ongoing requirements for premises.

### 27. DERIVATIVES AND FINANCIAL INSTRUMENTS (As restated)

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

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

#### Interest Rate Risk

The Group borrows in appropriate currencies at floating and fixed rates of interest. Year-end borrowings, net of cash, totalled US\$8,644,320 (2001: US\$4,290,293) at interest rates ranging from 2.30% to 7.41% and including US\$3,985,988 of fixed rate debt at interest rates ranging from 5% to 7.50% (2001: US\$1,309,607 at interest rates ranging from 5% to 7.50%). In broad terms, a one-percentage point increase in interest rates would increase the net interest charge by US\$46,796 (2001: US\$29,807).

#### Liquidity Risk

The Group's operations are cash generating. Short term flexibility is achieved with overdraft facilities.

#### Foreign Exchange Risk

The vast bulk of the Group's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Group's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Group pursues a formalised treasury policy which aims to sell US Dollars forward to match uncovered Euro expenses at exchange rates lower than budgeted exchange rates. With an increasing

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 27. DERIVATIVES AND FINANCIAL INSTRUMENTS (Continued)

level of Euro denominated sales, the Group anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Group had foreign currency denominated cash balances equivalent to US\$2,089,940 at December 31, 2002.

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The disclosures below exclude short term accounts receivable and payable

### Interest Rate Profile of Financial Liabilities

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

Financial liabilities on which no interest is paid  
Floating rate financial liabilities  
Fixed rate financial liabilities

Financial liabilities, on which no interest is paid, comprise loans from unconnected third parties and have a weighted average period until maturity of 1 year.

Floating rate financial liabilities comprise overdrafts and other borrowings that bear interest at rates of between 2.30% and 7.41%. These overdrafts and borrowings are provided by financial institutions at margins ranging from 1% to 3.50% over interbank rates.

Fixed rate financial liabilities  
- weighted average interest rate  
- weighted average period for which rate is fixed

### Maturity of Financial Liabilities

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

In one year or less, or on demand  
In more than one year, but not more than two

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In more than two years, but not more than five  
In more than five years

### Fair Values of Financial Assets and Liabilities

There is no significant difference between the fair value and the carrying value of the Group's financial assets and liabilities as at December 31, 2002. At December 31, 2002 and 2001 forward contracts with a carrying value of US\$Nil had a fair value of US\$1,068,738 (asset) and US\$271,515 (liability) respectively.

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES  
(As restated)

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

(a) Goodwill:

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

useful life, subject to a maximum write off period of 40 years, through the income statement. A useful life of 10 years was adopted for the purposes of the reconciliation.

In June 2001, the US Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") 141 "Business Combinations" and SFAS 142 "Goodwill and Other Intangible

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Assets", both of which are effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill is no longer amortised under US GAAP, but is subject to annual impairment tests in accordance with the statements. 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. There were no impairment losses recognised in the three years to December 31, 2002.

There has not been a disposal of all or a portion of a reporting unit in the three years to December 31, 2002. The aggregate amount of goodwill relating to acquisitions during the period for the Group and for each reportable segment for each of the periods presented including goodwill arising on acquisition of interest in associate, net of fair value adjustments, is as follows:

	2002 US\$
Ireland	1,181,211
United States	--
Total	1,181,211

Negative goodwill arises when the net amounts assigned to assets acquired and liabilities assumed exceed the cost of an acquired entity. Under Irish GAAP, negative goodwill arising on acquisitions is recognised as a negative asset, within intangible fixed assets, and recognised in the profit and loss account in the periods in which the non-monetary assets acquired are depreciated or sold. Any negative goodwill in excess of the fair values of the non-monetary assets acquired is recognised in the profit and loss account in the periods expected to benefit. Under US GAAP, negative goodwill would be allocated to reduce proportionately the values assigned to the acquired non-current assets. Any excess remaining negative goodwill is recognised in US GAAP income as an extraordinary gain for the periods beginning after December 15, 2001. At December 31, 2002, gross negative goodwill of US\$1,278,461 within intangible fixed assets under Irish GAAP would be disclosed as a reduction from property, plant and equipment under US GAAP. Amortisation of negative goodwill of US\$21,308 would be disclosed as a reduction from depreciation under US GAAP.

Net income and earnings per share for the years ended December 31, 2002, 2001 and 2000, adjusted to exclude amortization of goodwill is as follows:

December 31  
2002  
US\$  
Restated

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Reported net income under US GAAP	5,042,943
Excluded goodwill amortisation under Irish GAAP	--
Excluded additional goodwill amortisation under US GAAP	--
	-----
Adjusted net income	5,042,943
Reported basic earnings per share (US cents)	12.44
Excluded goodwill amortisation	--
	-----
Adjusted basic earnings per share (US cents)	12.44

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

Reported diluted earnings per share (US cents)	12.07
Impact of anti-dilution	--
Excluded goodwill amortisation	--
	-----
Adjusted diluted earnings per share (US cents)	12.07

Identifiable intangible assets comprise goodwill, which is not amortizable and certain intangible other non-current assets, which are amortizable. Other non-current asset amortization under US GAAP for the years ended December 31, 2002, 2001 and 2000 was US\$138,886, US\$115,175 and US\$27,367 respectively. Other non-current amortization under US GAAP is estimated to be approximately US\$138,022 in 2003, US\$203,978 in 2004, US\$199,358 in 2005, US\$193,358 in 2006, US\$185,714 in 2007 and US\$839,599 thereafter.

#### (b) Cash Flow Statements:

The consolidated statement of cash flows prepared under Irish GAAP presents substantially the same information as required under US GAAP by SFAS 95 "Statement of Cash Flows". This standard differs, however, with regard to the classification of items within the statements and as regards the definition of cash equivalents. Under US GAAP, cash equivalents would not include bank overdrafts. The movements on such bank overdrafts are required to be included in financing activities under SFAS 95. Under US GAAP short term investments with a maturity of three months or less at the date of acquisition are included in cash equivalents. Under Irish GAAP, movements in short term investments are classified as management of liquid resources. Under Irish GAAP, cash flows are presented separately for operating activities, returns on investments and servicing of finance, dividends received from associated undertakings, taxation, capital expenditure and financial investment, acquisitions and disposals, equity dividends paid, management of liquid resources and financing. US GAAP, however, requires only three categories of cash flow activity to be reported: operating, investing and financing. Cash flows from taxation and

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returns on investments and servicing of finance shown under Irish GAAP would, with the exception of preference dividends paid, be included as operating activities under US GAAP. The payment of dividends would be included as a financing activity under US GAAP. Under US GAAP, capitalised interest is treated as part of the cost of the asset to which it relates and is thus included as part of investing cash flows; under Irish GAAP all interest is treated as part of returns on investments and servicing of finance.

(c) Share Capital Not Paid:

Under Irish GAAP, unpaid share capital is classified as a receivable under current assets. Under US GAAP, share capital receivable should be reported as a reduction to Shareholders' Equity. Unpaid share capital at December 31, 2002, is US\$260,203 (2001 : US\$291,211).

(d) Statement of Comprehensive Income:

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

(e) Sale and Leaseback:

Under Irish GAAP, the Company's sale and leaseback transaction which took place in December 1999 was treated as a disposal of assets with the gain on the disposal of US\$1,014,080 being credited to the profit and loss account in the period of the transaction. Under US GAAP, this amount is deferred and released to the profit and loss account over the period of the lease (20 years).

(f) Sales on Extended Credit Terms:

In 2000 the Company made certain sales on extended credit terms. Under US GAAP, SAB 101 "Revenue Recognition in Financial Statements", such sales on extended credit terms would not be recognisable as revenue until 2001. No similar provisions exist under Irish GAAP to preclude revenue recognition. Sales were not made on extended credit terms in 2001 or 2002.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

(g) Restructuring Costs:

Under Irish GAAP, certain provisions made for restructuring costs incurred upon and related to acquisitions of acquired companies (principally payments to employees and certain facilities costs) and expensed immediately would not be recognisable under US GAAP, because EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination", requires costs that meet certain criteria be treated as part of the purchase price allocation. Certain termination costs not determined on the basis of length of service or other exit costs which are not incremental to the acquired company, even if they provide a reduced economic benefit, are considered period costs which

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are expensed when incurred. Certain facilities costs amounting to US\$270,000 representing post-closure lease commitments for a facility acquired in 2001 were originally capitalised. These costs were subsequently excluded as a fair value adjustment in 2002 as the facility was not closed within a year of the acquisition. A decision to maintain the facility for certain operations was subsequently taken in 2003.

(h) Research and Development:

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

(i) Stock-based Compensation Expense:

US GAAP, as set forth in SFAS 123 "Accounting for Stock-Based Compensation" and EITF 96-18 "Accounting for Equity Instruments That Are Issued for Sales of Goods and Services to Other Than Employees" requires stock options issued to non-employees to be valued at fair value and compensation cost to be recognised based on that fair value. Irish GAAP only requires stock options issued to employees at exercise prices which are less than the market values at the date of grant to be treated as compensation cost based on their intrinsic value.

(j) Derivatives and Financial Instruments:

In June 1998, the FASB issued SFAS No 133 "Accounting for Derivative Instruments and Hedging Activities". SFAS 133 requires that all derivatives be recognised on the balance sheet at fair value. Derivatives which are not hedges or where hedge correlation cannot be demonstrated must be adjusted to fair value through income. Under Irish GAAP derivatives are not recognised until settled. Realised gains and losses on transactions where derivatives are used to hedge cross-currency cashflows are ultimately recorded in the income statement on settlement.

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

During 2001 Trinity began documenting its hedging transactions in accordance with the requirements of SFAS 133. In 2002 an unrealized gain of US\$1,178,278 (2001: loss of US\$286,100) was taken to comprehensive income in respect of such contracts in accordance with the standard.

During the year ended December 31, 2002 realised foreign exchange gains of US\$161,975 (2001 : US\$14,585) were credited to normal administrative expenses in the Income Statement on the exercise of forward contracts under US GAAP. At December 31, 2002 contracts with a fair value of US\$874,410 are recorded in other comprehensive income which the Company anticipates will be reclassified into earnings on the exercise of



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forward contracts in the year ending December 31, 2003. The last of the Company's forward contracts expires in March 2004.

- (k) **Deferred Tax:**  
Deferred tax differences arise between Irish GAAP and US GAAP due to the impact of the nature and timing of the reconciling items arising.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

CUMULATIVE EFFECT ON SHAREHOLDERS' EQUITY	December 31 2002 Restated US\$
Total shareholders' equity before minority interests under Irish GAAP	62,537,284
US GAAP adjustments:	
Goodwill	
- Gross (a)	21,776,683
(b)	--
- Aggregate amortisation	(11,412,266)
Property, plant and equipment	
Share capital not paid	(260,203)
Adjustment for sale and leaseback	(861,968)
Adjustment for sales on extended credit	--
Adjustment for restructuring costs	--
Adjustment for research and development costs	(2,327,444)
Adjustment for fair value of derivative instruments	1,068,738
Deferred tax	423,444
	-----
Shareholders' equity under US GAAP	70,944,268
	-----
Shareholders' equity under US GAAP, as previously stated	70,990,056
Impact of restatements from Irish GAAP (i)	(633,007)
Translation adjustments (ii)	298,231
Compensation expense (ii)	172,000
Licence and patent amortisation (iii)	(138,886)
Deferred taxation (iv)	(203,276)
Restatement of restructuring costs (v)	--
Fair value of financial instruments (vi)	357,386
Share premium (vii)	101,764
	-----
Shareholders' equity under US GAAP, as restated	70,944,268

- (a) Pre-1998 goodwill written off against shareholders' equity under Irish GAAP.  
 (b) Liabilities assumed on acquisition capitalised under EITF 95-3.  
 (i) - (vii) See footnotes on page 83.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
 DECEMBER 31, 2002 (Continued)

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

EFFECT ON NET PROFIT	December 31 2002 Restated US\$
Profit on ordinary activities after taxation under Irish GAAP	4,896,911
US GAAP adjustments:	
Goodwill amortisation	2,265,635
Adjustment for sale and leaseback	50,704
Adjustment for sales on extended credit	--
Adjustment for restructuring costs	(2,835,000)
Adjustment for research and development costs	(417,361)
Adjustment for stock based compensation	--
Adjustment for fair value of derivative instruments	161,975
Deferred tax	920,079
	-----
Profit under US GAAP	5,042,943
	-----
Profit under US GAAP, as previously stated	5,225,804
Impact of restatements from Irish GAAP (i)	(113,406)
Restatement adjustment for Biopool restructuring (v)	15,000
Licence and patent amortisation (iii)	(138,886)
Deferred tax (iv)	(122,129)
Fair value of financial instruments (vi)	176,560
	-----
Profit under US GAAP, as restated	5,042,943
	-----
Profit per ordinary share (US cents)	12.44
Diluted profit per ordinary share (US cents)	12.07
Weighted average number of ordinary shares used in computing basic earnings per ordinary share	40,550,367
Diluted weighted average number of ordinary shares used in computing diluted profit per ordinary share	42,486,227

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(i) - (vi) See footnotes on page 83

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	December 31 2002 Restated US\$
Profit under US GAAP	5,042,943
Translation adjustment	355,782
Fair value of derivative instruments	1,178,278
	-----
Total Comprehensive Income	6,577,003
	-----

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN  
IRELAND AND IN THE UNITED STATES (Continued)

	December 31 2002 US\$
Total Comprehensive Income, as previously stated	6,542,938
Impact of restatements from Irish GAAP (i)	(113,406)
Restatement adjustment for Biopool restructuring (v)	15,000
Translation adjustment (ii)	(250,000)
Licence and patent amortisation (iii)	(138,886)
Deferred tax (iv)	(122,129)
Fair value of financial instruments (vi)	643,486
	-----
Total Comprehensive Income, as restated	6,577,003
	-----

CHANGES IN US GAAP EQUITY FOR THE YEARS ENDED DECEMBER 31 2002, DECEMBER 31 2001  
AND DECEMBER 31 2000

December 31  
2002

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	Restated US\$
US GAAP Shareholders' Equity at January 1	63,463,291
Net profit for the period	5,042,943
'A' shares issued for cash without deduction of prepaid offering expenses of US\$226,008	544,823
'A' shares issued for conversion of debenture	--
'A' shares issued on conversion of warrant	--
Options exercised	13,875
Stock based compensation - additional paid in capital	120,000
'A' shares issued as consideration for acquisition	--
'A' shares issued for financial asset	201,874
Share issue expenses	(7,606)
Share capital not paid in previous periods now paid	31,008
Share capital not paid	--
Other comprehensive income:	
Translation adjustment	355,782
Fair value of derivative instruments	1,178,278
	-----
US GAAP Shareholders' Equity at December 31	70,944,268
	-----

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

- (i) For detailed information on the restatements from Irish GAAP, see Note 1(a) of Notes to the Consolidated Financial Statements.
- (ii) The cumulative and annual effects of the restatement for translation adjustment arising on consolidation of non-US\$ functional subsidiaries are excluded from the effect on Shareholders' Equity and Total Comprehensive Income, respectively, as the effect on net income is matched by a corresponding effect on the translation adjustment reserve. Similarly, the cumulative effects of the restatement for compensation expense are excluded from the effect on Shareholders' Equity, as the effect on the cumulative profit and loss account reserve is matched by a corresponding entry to Additional Paid In Capital.
- (iii) The Company has amended the US GAAP adjustment for goodwill amortisation to correctly include amortisation on licence and patent assets in determining net income and Shareholders' Equity under US GAAP.
- (iv) The restatement corrects the deferred taxation effect on net income and Shareholders' Equity and Total Other Comprehensive

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Income to incorporate the appropriate tax rates for the deferred tax impact on reconciling items and the allocation of the restatement items to the appropriate period under US GAAP.

- (v) The Company has made a correction in the calculation of the restructuring amounts accrued under Irish GAAP at 31 December 2001, which has been consequently adjusted to the difference in this regard between Irish GAAP and US GAAP.
- (vi) The Company has corrected its calculation of the fair values of forward contracts at December 31, 2002 to take account of an exchange rate error in the US\$/Euro rate used by the Company at December 31, 2002 to the official rate; and to reclassify the fair value of a forward contract that was entered into prior to formalisation of the Company's hedge documentation to income from shareholders' equity. The Company has corrected its calculation of the fair values of forward contracts at December 31, 2001 to include a loss in shareholders' equity for a forward contract entered into in December 2001 not previously accounted for.
- (vii) The Company has corrected its calculation of share premium by including all potential share issue expenses arising from various fundraisings.

Consolidated Statements of Cash Flows	December 31 2002 Restated
Operating Activities	US\$
Retained profit under Irish GAAP	4,896,911
Adjustments to reconcile net profit to cash provided by operating activities:	
Depreciation and amortisation	3,504,015
Taxation (paid)/refund	(403,935)
Share of operating loss in associate	317,113
Provision for corporation tax charge	767,510
Net interest payable accrual	(46,066)
Disposal of investments	--
Exceptional administrative expenses	(2,835,000)
(Increase)/decrease in accounts receivable and prepayments	(4,250,982)
Increase/(decrease) in accounts payable & accrued expenses	2,874,740
Increase in inventory	(2,414,882)
Non cash compensation expense	120,000
Net cash inflow from operating activities	2,529,424
Investing activities	
Acquisition of subsidiary undertakings	--
Payments to acquire trades or businesses	(4,408,692)
Purchase of associate undertaking	--
Deferred consideration paid	--
Payment for patents and deferred development costs	(468,941)
Payment for tangible fixed assets	(2,516,982)
Net cash outflow from investing activities	(7,394,615)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 200228. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND  
AND IN THE UNITED STATES (Continued)

## Financing Activities

Loan from unconnected third party	(163,213)
Issue of ordinary share capital including premium	558,698
Expenses paid in connection with share issue	--
(Decrease)/increase in long term debt	(1,803,466)
Movement in finance leases	3,955
Increase/(decrease) in convertible debentures	2,500,000
Decrease in promissory note	--
Increase in other financial liabilities	4,107,755
	-----
Net cash inflow from financing	5,203,729
	-----
Increase in cash and cash equivalents	338,538
Effects of exchange rate movements on cash	95,000
Cash and cash equivalents at beginning of year	5,373,976
	-----
Cash and cash equivalents at end of year	5,807,514
	-----

## Non cash transactions

In December 2000, the Group acquired the assets and goodwill of Bartels Inc, for a consideration of US\$9,463,974 comprising US\$3,190,000 in stock, US\$5,923,974 in cash and the balance of US\$350,000 in the form of a promissory note. This promissory note was settled in full during the second quarter of 2001. This transaction relates to the Rest of World reportable segment.

In December 2001, the Group acquired the assets and goodwill of the Biopool hemostasis business for a total consideration of US\$6,409,329 satisfied in cash and deferred consideration. The deferred consideration 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. This transaction relates to the Rest of World reportable segment.

In November 2002, the Company acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US\$4,412,372 satisfied in cash and deferred consideration. The cash consideration was partly financed by the issue of US\$2,500,000 of 5.25%

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convertible debentures. The debentures bear interest at a rate of 5.25% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$1.50. The Company also issued 50,000 warrants (the "Second Warrants") in November 2002.

On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its associate HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.

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

The debentures bear interest at the rate of 7.5% per annum, payable quarterly. US\$2,500,000 of the principal amount originally matured on December 18, 2001 with the remaining US\$1,000,000 maturing on December 18, 2002. The debentures are 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 debentures was converted into 1,041,667 Class 'A' Ordinary Shares of the Company. During 2001, US\$625,000 of the remaining balance of the debentures 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.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

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. 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 in the Company at US\$1.50 per share. The Second Warrants expire in November 2007. 133,701 of the remaining First Warrants have since been exercised.

Share Option Scheme - Additional information required by SFAS 123  
The Company has elected to follow Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, "Accounting for Stock-Based Compensation," requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, where the exercise price of the Company's employee stock options is

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less than the market price of the underlying stock on the grant date, compensation expense is recognised in the US GAAP reconciliation over the vesting period.

Proforma information regarding net income and earnings per share is required by Statement 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions:

	2002	2
Expected option life (years)	4.0	3
Risk-free weighted average interest rate	2.3%	4
Stock price volatility	0.411	0
Dividend yield	0%	0

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

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

	December 31 2002 US\$
Net income as reported	5,042,943
Add: Stock based employee compensation expense included in reported net income, net of related tax effects	120,000
Deduct : Total stock based employee compensation under fair value based method for all awards, net of related tax effects	(1,425,348)
	-----
Proforma net income / (loss)	3,737,595



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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND  
AND IN THE UNITED STATES (Continued)

Earnings per share:	
Basic - as reported (US cents)	12.44
Diluted - as reported (US cents)	12.07
Basic - proforma (US cents)	9.22
Diluted - proforma (US cents)	9.00

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

	2002 Weighted-Average Options Exercise Price		2001 Weighted-Average Options Exercise Price	
Outstanding-beginning of year	7,864,953	\$1.57	5,868,703	\$1.78
Granted	2,223,500	\$1.10	2,039,500	\$1.02
Exercised	(12,334)	\$1.13	(43,250)	\$1.71
Forfeited	(741,420)	\$1.80	--	--
Outstanding at end of year	9,334,699	\$1.44	7,864,953	\$1.57
Exercisable at end of year	3,927,771	\$1.56	2,899,339	\$1.37
Weighted average fair value of options granted during the year		\$0.58		\$0.56

The weighted average remaining contractual life of options outstanding at December 31, 2002 is 4.6 years. The information above also includes outstanding warrants.

A summary of the range of prices for the Company's stock options for the year ended December 31 2002 follows:

Option price range	No. of Shares	Outstanding Weight. Av. exercise price	Weight. Av. contractual life remaining	No. of Shares	ex
\$0.81 - \$0.99	3,942,530	\$0.94	5.3 years	825,030	
\$1.00 - \$1.99	3,646,534	\$1.40	4.3 years	1,986,368	
\$2.00 - \$2.99	1,150,567	\$2.35	2.8 years	808,017	
\$3.00 - \$5.00	595,068	\$3.25	3.7 years	308,356	

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### Investments

The Company had no trading securities as at December 31, 2002 or December 31, 2001.

The gross realised gains on sales of trading securities during 2002 was US\$Nil (2001: US\$Nil, 2000: US\$37,465).

The Company had no "available for sale" or "held to maturity securities" as at December 31, 2002 or December 31, 2001.

### Fair Values of Financial Instruments

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

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

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

Long and short-term debt: The carrying amounts of the Company's borrowings approximate their fair value as substantially all of the debt bears interest at market rates. In addition, debt originally due for repayment over an average period of 3.78 years, has been predominantly settled in 2003.

The carrying amounts and fair values of the Company's financial instruments at December 31, 2002 and 2001 are as follows:

	December 31, 2002	
	Carrying Amount US\$	Fair Value US\$
Cash and cash equivalents	5,807,514	5,807,514
Short term debt	7,283,394	7,283,394
Long term debt	7,168,440	7,168,440
Forward contracts	--	1,068,738

Additional Unaudited Proforma Information for Acquisitions made in 2000, 2001 and 2002  
(As restated)

The information below presents the proforma effect of the acquisitions

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made in 2000 as if they had occurred on January 1, 2000, the proforma effect of the acquisitions made in 2001, as if they had occurred on January 1, 2001 and the proforma effect of the acquisitions made in 2002, as if they had occurred on January 1, 2002.

	December 31 2002 US\$
Proforma revenues	63,351,166
Proforma net income	6,445,995
Proforma earnings per share (US cents)	15.90
Proforma diluted earnings per share (US cents)	15.37

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

### Restructuring Costs

In December 2000 the Company purchased Bartels and decided to consolidate the Seattle operation into its existing facilities in Bray, Ireland. Similarly in December 2001 the Company purchased Biopool and decided to consolidate its operation into the Bray facility.

Restructuring provisions were determined based on estimates prepared at the time the restructuring actions were approved by management. These exit plans were submitted to the Board on December 22, 2000 in the case of Bartels and on December 7, 2001 in the case of Biopool. An analysis of the Company's restructuring plan reserves is as follows:

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

##### Provision for Restructuring Costs

##### Bartels

Opening Provision  
Current year provision

Employee severance

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Other employee costs  
Idle facilities

Incurred  
Write back of provision

Closing provision

Biopool

Opening Provision  
Current year provision

Employee severance  
Other employee costs  
Idle facilities

Incurred  
Write back of provision

Closing provision

The above costs are broken down as follows:

### Idle facilities

In December 2001 the Company recorded restructuring provisions relating to idle facilities and related costs of approximately US\$636,000 in connection with the consolidation of the Biopool facilities at Ventura, CA and Umea, Sweden into the Company's existing operations in Bray, Ireland and Jamestown, New York. Idle facilities costs represented management's allocation of the lease rental costs for the portion of the facilities not engaged in productive activities from consummation to the expected date of cessation of site operations and amounted to US\$393,000. A commensurate allocation of associated maintenance, utilities, insurance and other site costs were also provided for and amounted to US\$243,000. In December 2000, a similar provision of US\$176,250 was made in relation to the Bartels facility.

### Employee severance and termination benefits

The accruals for employee severance and termination benefits comprised the expected future payments relating to the termination of contracts including severance payments and payroll taxes. Bartels and Biopool employees were notified of the intention to terminate in December 2000 and December 2001, respectively. Termination benefits not based on length of service were subsequently communicated to employees. In fiscal year 2000 the Company recorded restructuring provisions relating to such costs of US\$491,000 associated with the Bartels acquisition and the related consolidation of the Seattle facility to Bray, Ireland. In fiscal year 2001 the Company also recorded restructuring costs of US\$1,059,000 relating to employee severance and termination benefits associated with the Biopool consolidation from Ventura and Umea to Bray.

Other employee costs

Employees not involved in the manufacturing, product support, customer service, sales and marketing, distribution and warehousing functions and certain key employees in quality control, product development and finance and administration functions were deemed excess to requirements in the period from consummation of the acquisitions to the envisaged date of closure. However these employees were not given an earlier date for involuntary termination. Costs for such resources which were providing no significant economic benefit were included in the restructuring provisions at December 31, 2000 and December 31, 2001, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

Date of completion

The anticipated date of completion of the transfer of operations from Bartels to the Company's facilities in Bray, Ireland was June 30, 2001 and the transfer was completed in June 2001. The anticipated and actual date of closure of the Biopool facility at Ventura, CA was September 30, 2002. The anticipated date of completion of the transfer of operations from the Biopool facility at Umea, Sweden was also September 30, 2002. However, in 2003 the Company made a decision to maintain the operations of the Umea facility at a reduced level with a staff of approximately eight employees and the transfer of certain other operations did not occur until 2003. Fifteen employees were only terminated in January 2003 and fifteen further employees in July, 2003. Sixty three employees were involuntarily terminated consequent to the Bartels facility closure. Fifty four employees were involuntarily terminated consequent to the Biopool Ventura facility closure.

Accounting Pronouncements

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. There was no material impact to the company from the adoption of this standard.

Business combinations/Goodwill and Other Intangible Assets

The impact of adoption of these pronouncements is discussed at Note 28(a).

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### Stock Compensation

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, "Accounting for Stock-Based Compensation", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and of the effect of the method used on reported results. The provisions of SFAS 148 are effective in fiscal years ending after December 15, 2002 and interim periods beginning after December 15, 2002. As of December 31, 2002, the Company has elected not to change to the fair value based method of accounting for stock-based employee compensation.

### 29. GROUP UNDERTAKINGS

Name and registered office Holding Company	Principal activity	Principal Coun of incorporat and operat
Trinity Biotech plc IDA Business Park Bray, Co. Wicklow, Ireland	Investment and holding company	Ireland
Trinity Biotech Inc. (Formerly Disease Detection International Inc.) Girls Road Jamestown NY 14702, USA	Holding Company	U.S.A.

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### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 29. GROUP UNDERTAKINGS (Continued)

Name and registered office	Principal activity	Principal Coun of incorporat and operat
Subsidiary and Associate Undertakings (continued)		
Clark Laboratories Inc. Trading as Trinity Biotech (USA)	Manufacture and sale of diagnostic test kits	U.S.A.

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Girts Road Jamestown NY 14702, USA		
FHC Corporation Girts Road Jamestown NY 14702, USA	Non-trading	U.S.A.
Trinity Biotech Manufacturing Limited IDA Business Park Bray Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland
Trinity Research Limited IDA Business Park Bray Co. Wicklow, Ireland	Research and development	Ireland
Trinity Biotech Sales Limited IDA Business Park, Bray Co. Wicklow, Ireland	Non - trading	Ireland
MarDx Diagnostics Inc 5919 Farnsworth Court Carlsbad CA 92008, USA	Manufacture and sale of diagnostic test kits	U.S.A.
Flambelle Limited 16 Fitzwilliam Place Dublin, Ireland	Non-trading	Ireland
Eastcourt Limited Chichester House 278/282, High Holborn London, UK	Non-trading	UK
Trinity Biotech UK Holdings Ltd (Formerly Centocor UK Holdings Ltd) Shalford Guildford, Surrey, UK	Holding company	UK
Trinity Biotech UK Ltd (Formerly Centocor UK Ltd) Shalford Guildford, Surrey, UK	In voluntary liquidation	UK
Trinity Biotech (UK Sales) Limited 54 Queens Road Reading RG1 4A2, England	Sales of diagnostic test kits	UK
Benen Trading Ltd IDA Business Park, Bray Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland
Reddinview Ltd IDA Business Park, Bray Co. Wicklow, Ireland	Dormant company	Ireland

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2002

29. GROUP UNDERTAKINGS (Continued)

Name and registered office	Principal activity	Principal Country of incorporation and operation
Subsidiary and Associate Undertakings (continued)		
HiberGen Limited IDA Business Park, Bray Co. Wicklow, Ireland	Genetic Variation Detection	Ireland
Trinity Biotech GmbH Otto Hesse Str 19 64293 Darmstadt, Germany	Sale of diagnostic test kits	Germany
Biopool US Inc Girts Road Jamestown NY 14702, USA	Manufacture and sale of diagnostic test kits	U.S.A.
Biopool AB S-903 47 Umea Sweden	Manufacture and sale of diagnostic test kits	Sweden

30. EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE  
(As restated)

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

On June 16, 2003 Trinity and Xtrana settled this litigation. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity agreed to pay Xtrana the amounts due on two promissory notes of US\$1,166,200 and US\$570,100, together with interest thereon as provided in the notes, less US\$225,000, and less US\$24,148, which represented the amount due and owing by Xtrana to Trinity as of May 31, 2003 pursuant to a Letter Agreement, dated December 20, 2001, between Trinity and Xtrana, relating to a third party. The total amount of the settlement payment made by Trinity to Xtrana was US\$1,505,942.

The parties also agreed that, following Xtrana's receipt of the



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

In June 2003, Trinity completed a new US\$10,000,000 club banking facility with Allied Irish Banks 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, the Company 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 the Company's common stock at a fixed conversion price of US\$3.55.

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.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002

#### 31 EVENTS SUBSEQUENT TO DATE OF AUDITORS' REPORT - UNAUDITED

In December 2003 the Company filed an action against Inverness Medical for breach of contract. Inverness acts as exclusive distributor for certain of Trinity's infectious disease products in the US. This exclusivity is due to end on September 30, 2004, at which time it had been agreed that both Trinity and Inverness would sell the products under their respective labels. The suit alleges that Inverness are attempting to convert customers from the Trinity product to a product manufactured by Zeus Scientific by claiming that the Trinity product is unavailable and being discontinued. The lawsuit alleges that under the terms of the contract Trinity is entitled to sell direct in the US any product which Inverness sells in competition with Trinity. With immediate effect Trinity is exercising this right.

TRINITY BIOTECH PLC.

VALUATION AND QUALIFYING ACCOUNTS  
(As Restated)

	Balance at beginning of period US\$	Charged to costs and expenses US\$	Charged to other accounts US\$ (a)
2002			
Doubtful debts	30,000	466,412	--
2001			
Doubtful debts	31,850	30,000	--
2000			
Doubtful debts	88,822	31,850	--

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

Signatures

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

TRINITY BIOTECH PLC

By: RONAN O'CAOIMH

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Mr. Ronan O'Caoimh  
Director/  
Chief Executive Officer

Date: November 25 2003

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By: RORY NEALON

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Mr. Rory Nealon  
Director/  
Chief Financial Officer

Date: November 25, 2003