

**Trinity**

biotech



Annual Report and Financial Statements **2003**

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## Chairman's Statement

Trinity Biotech plc Annual Report 2003

Dear Shareholder

Since I wrote to you one year ago, your Company, Trinity Biotech plc, has had a very successful year with a number of significant achievements as follows:

- FDA approval for our Uni-Gold Recombigen HIV test
- The successful transfer of manufacturing of Sigma Haemostasis and Clinical Chemistry products to Bray, Ireland
- Fundraisings of \$42.5 million through the issuance of convertible notes and equity
- An increase in revenues of 26% \*
- Profit before tax - \$8.0 million \*
- Further significant expansion of our direct sales operations in the U.S., Germany and the U.K.

The Company has three major business segments which are Rapids, Haemostasis and Infectious Disease products for the hospital, laboratory and point of care markets.

On December 29, 2003, Trinity Biotech received approval from the U.S. Food & Drug Administration ("FDA") to market its Rapid Uni-Gold Recombigen HIV test in the United States. The product is approved by the FDA for the detection of antibodies to HIV in human serum, plasma and whole-blood and is the first and only device to be approved for use with all three sample types. Uni-Gold Recombigen HIV is simple to use, requiring only one step and produces a result within ten minutes, whereas, with conventional laboratory tests for HIV, results may not be available for hours, or even days. Uni-Gold Recombigen HIV was approved by the FDA on the basis of clinical trial results on over 9,000 patient specimens where the product demonstrated test sensitivity of 100% and a specificity over 99.7%. This approval provides us with a significant market opportunity in the United States and we will sell the product through our expanded direct salesforce in that market.

In addition to the significant market for Rapid HIV in the United States, we are also seeing a considerable expansion of the Rapid HIV market in sub-Saharan Africa, Eastern Europe and Latin America. In January 2003, President Bush pledged to release \$15 billion of funds to fight the scourge of HIV/AIDS in Africa and the Caribbean. Furthermore, the Three by Five programme which is coordinated by the World Health Organisation, has as its goal, to have 3 million people in sub-Saharan Africa on Anti-Retroviral therapy before the end of 2005. To achieve this goal there will have to be a significant increase in the use of rapid tests for HIV. Trinity's Uni-Gold HIV product is already widely used in this territory and we stand to benefit considerably from the increase in diagnostic testing in this market.

During 2003, Trinity Biotech continued to build its strong position in the field of haemostasis and has now completely integrated the acquisitions of Biopool and the Sigma product lines into our Bray manufacturing facility. Haemostasis is one of the three strategic business units for Trinity Biotech and we feel that we have the best product offering available in the world, incorporating routine and speciality reagents, and a range of instruments of the highest quality. Armed with this product offering the Company is well positioned to experience strong organic growth and to become a leading player in the world haemostasis market.

Our Infectious Disease product range continues to expand and we are currently developing new tests for the detection of EBV-IgA and a Western Blot HIV test. This product range includes leading brands such as MarDx, Capita, Bartels and Microtrak. With effect from April 2004 we have moved to distribute the Microtrak product range through our direct salesforce in the United States.

In the latter half of 2003, we further strengthened our direct sales and marketing capability in the United States with the hiring of senior industry experienced executives from our competitors. We now have over 30 specialized sales professionals in the United States and these are supported by over 40 technical support, field service representatives and support personnel.

During 2002, the Company agreed with our main U.S. distributor, Wampole Laboratories, that their Distribution Agreement would change status from Exclusive to Co-Exclusive with effect from October 1, 2004. We subsequently initiated legal action against Wampole Laboratories to prevent them from converting the existing customer base to a range of products from another supplier prior to that date. This case is still pending, but we are confident that we will prevail and that we now have the sales and marketing capability in the U.S. market to protect our position.

In financial terms, Trinity Biotech produced strong trading performance with revenues up 26% to US\$65.7 million and profit before tax of US\$8.0 million \*. The Company is in a strong financial position, with bank debt of US\$10 million and current cash balances in excess of US\$44 million. This strong position together with our operating cashflows gives us the ability to supplement our organic growth with acquisitions.

On behalf of the Board I would like to express our appreciation to our Shareholders, Customers and 660 employees for their continuing loyalty, support and commitment to Trinity Biotech.

Ronan O'Caomh  
Chairman/C.E.O.

March 31, 2004

\* Under Irish generally accepted accounting principles.

## Business Overview

Trinity Biotech plc Annual Report 2003

### Introduction

Trinity Biotech develops, manufactures and markets diagnostic reagents and instrumentation. The Company was founded in 1992 and shortly after its formation listed on Nasdaq under the symbol: TRIB. Currently Trinity has 51.8 million shares outstanding giving a market capitalization of approximately US\$200 million. The Company is headquartered in Bray, Ireland and currently employs over 660 people worldwide. Trinity has a broad portfolio of more than 500 products and these products are sold to customers in more than 78 countries worldwide.

### Manufacturing

Trinity Biotech has five manufacturing sites as follows:

#### • Bray, Ireland

This is the Company's main manufacturing site and is the location for the production of the Company's Rapid, RIA, Haemostasis, Clinical Chemistry and Immunofluorescence products. There are over 320 people employed in this manufacturing facility.

#### • Jamestown, New York

With a staff of 80, Jamestown specializes in the production of Microtitre Plate EIA products mainly for infectious disease and autoimmunity.

#### • Carlsbad, California

There are more than 40 people in Trinity's facility in Carlsbad which specializes in the manufacture of products using Western Blot technology for Lyme and other infectious diseases.

#### • Lemgo, Germany

Employing 70 people this facility manufactures Haemostasis instrumentation and plastic consumables for use with Haemostasis instruments.

#### • Umea, Sweden

With a staff of 10 this facility produces Haemostasis Reagents.



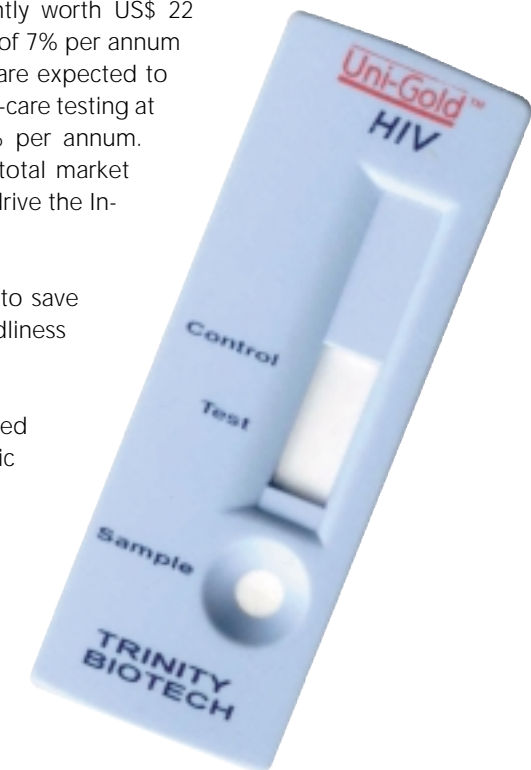
### Sales & Marketing

Trinity Biotech markets its products through more than 300 distributors in 78 countries worldwide. Trinity has established direct sales operations in three major diagnostic markets, namely the U.S.A., Germany and the U.K. The U.S.A. has a team of more than 30 direct sales professionals, backed up by over 40 technical support, field service representatives and support personnel. In Germany, the Company employs more than 20 marketing and sales professionals and in the U.K. there is a sales and marketing staff of 6 people. The Company is currently examining opportunities to set up direct sales forces in other significant markets.

### Diagnostics Industry

The global In-Vitro diagnostics industry is currently worth US\$ 22 billion and is expected to grow at an average rate of 7% per annum over the next three to five years. Certain sectors are expected to grow at significantly higher rates, including point-of-care testing at 14% per annum and nucleic acid testing at 20% per annum. Geographically the U.S. accounts for 45% of the total market and Europe for 25%. The major factors which will drive the In-Vitro diagnostics industry are as follows:

- Increasing trend towards point-of-care testing to save costs and increase service level and user friendliness for patients.
- Higher life expectancy and associated age related illnesses will drive the demand for diagnostic products.
- Increasing wealth is leading to an increased willingness to pay for diagnostic testing.
- Innovative methods of treatment and diagnosis will improve therapeutic opportunities and lead to further growth in the industry.



### Business Units

Trinity Biotech operates three major business units as follows:

- **Infectious Diseases**

The Infectious disease market was worth over US\$4 billion in 2003 and Trinity had revenues of approximately US\$35 million in this segment, US\$4 million of which is in rapid products (see below). Trinity has a very wide product portfolio in this area based on ELISA and Immunofluorescent technologies. Products available range from tests for Measles, Mumps and Varicella through to tests for sexually transmitted diseases like Chlamydia and Herpes, tests for Lyme, Legionella disease, influenza and H.Pylori and a range of products to test for various types of Epstein Barr Virus.

In the area of infectious diseases Trinity has active R&D programmes to develop tests for EU Lyme, EBV-IgA and HIV Western Blot.

- **Rapid Tests**

Trinity's flagship rapid product is our Uni-Gold HIV test which received FDA approval in December 2003. Sales of HIV tests in 2003 amounted to US\$4 million and the main market for Trinity's products was in sub-Saharan Africa. This market is predicted to expand rapidly in 2004 as certain governmental initiatives are put in place. These initiatives include the pledge by President, George Bush to provide US\$15 billion over 5 years to fight HIV/AIDS in Africa and the programme coordinated by the World Health Organisation, called the Three by Five, which is designed to provide anti retroviral therapy for three million people by the end of 2005. The Three by Five programme will require a significant increase in the diagnosis of people to determine their HIV status.

The FDA approval of Trinity's Uni-Gold test will open up an exciting market for this product in the United States. We estimate this market opportunity to be currently in excess of four million tests annually, with an annual market value of US\$40 million.

- **Haemostasis**

The Haemostasis market worldwide is valued at approximately US\$700m. Trinity had revenues of approximately US\$24 million in this business segment in 2003. The Company has a wide range of routine and specialty reagents, as well as a portfolio of instrumentation. R&D programmes are in place to develop products for Protein S and Von-Willebrands disease.

Trinity also has a small specialty clinical chemistry product range which delivered approximately US\$6 million in revenues in 2003.

## Notice of the Annual General Meeting

Trinity Biotech plc Annual Report 2003

Notice is hereby given that the Annual General Meeting of Trinity Biotech plc ("the Company") will be held at the IDA Business Park, Bray, Co. Wicklow on May 17, 2004 at 12 noon to consider and, if thought fit, pass the following resolutions of which resolutions 1 to 3 will be proposed as ordinary resolutions and resolutions 4 and 5 will be proposed as special resolutions.

### Ordinary Business

1. To receive and consider the financial statements for the year ended December 31, 2003 together with the reports of the directors and auditors therein.
2. To re-elect Mr. Denis Burger as a director who retires by rotation and being eligible offers himself for re-election.
3. To authorise the board of directors to fix the auditors' remuneration.

### Special Business

4. "That the Company and/or subsidiary (as such expression is defined by Section 155, Companies Act, 1963) of the Company be generally authorised to make one or more market purchases (within the meaning of Section 212 of the Companies Act, 1990) on the National Association of Securities Dealers Automated Quotation Market (NASDAQ) or the Irish Stock Exchange of 'A' Ordinary Shares of US\$0.0109 each ("Shares") on such terms and conditions and in such manner as the directors may from time to time determine but subject, however, to the provisions of the Companies Act, 1990, the Articles of Association of the Company and to the following provisions:

- (a) the aggregate nominal value of the Shares authorised to be acquired shall not exceed 10% of the aggregate nominal value of the issued share capital of the Company at the close of business on the date of the passing of the resolution;
- (b) the minimum price (exclusive of taxes and expenses) which may be paid for a Share shall be the nominal value of that Share;
- (c) the maximum price (exclusive of taxes and expenses) which may be paid for a Share shall not be more than the average of the closing bid price on NASDAQ in respect of the ten business days immediately preceding the day on which the Share is purchased.

The authority hereby conferred shall expire at the close of business eighteen months from the date upon which the resolution is passed unless previously revoked, varied or renewed in accordance with the provisions of Section 215 of the Companies Act 1990, but the Company, or any subsidiary, may enter into a contract to purchase Shares under the authority hereby conferred prior to the expiry of such authority which would or might be executed wholly or partly after the expiry of such authority and may make a purchase of Shares in pursuance of such contract or contracts notwithstanding that this authority has otherwise expired.

This replaces the authority given by resolution 5 at the Annual General Meeting of the Company held on May 23, 2003 which authority shall, to the extent that it has not been utilised, be deemed to have been withdrawn".

## Notice of the Annual General Meeting continued

5. "That subject to the passing of resolution 4 above and to the provisions of the Companies Act, 1990 for the purposes of Section 209 of the Companies Act, 1990, the re-issue price range at which a treasury share (as defined by the said Section 209) for the time being held by the Company may be re-issued off-market shall be as follows:

- (a) the maximum price at which a treasury share may be re-issued off-market shall be 115% of the Relevant Price;
- (b) the minimum price at which a treasury share may be re-issued off-market shall be 85% of the Relevant Price.

For the purposes of this resolution "the Relevant Price" shall mean the average of the closing bid price of the Shares on NASDAQ in respect of each of ten business days immediately preceding the day on which the treasury share is re-issued.

This replaces the re-issue price range fixed by resolution 6 at the Annual General Meeting of the Company held on May 23, 2003.

The power hereby conferred shall expire at the close of business on the earlier of the day of the next Annual General Meeting of the Company after the passing of this resolution or at the close of business eighteen months from the date upon which the resolution is passed unless such power shall be renewed in accordance with and subject to the provision of the said Section 209"

### Notes

1. Any member entitled to attend and vote at this meeting may appoint a proxy who need not be a member of the Company to attend and vote in his/her place. Completion of a form of proxy will not affect the right of a member to attend and vote at this meeting in person.
2. To be valid, forms of proxy duly signed together with the power of attorney or such other authority under which they are signed (or certified copy of such power or authority), must be lodged with the Company Secretary not later than 12 noon on May 14, 2004.

IDA Business Park,  
Southern Cross Road,  
Bray,  
Co. Wicklow.  
Ireland.

By order of the board  
Rory Nealon  
Secretary

March 31, 2004

**FORM 20-F**

**(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**

**For the fiscal year ended: December 31, 2003**

**Commission file number: 0-22320**

**Trinity Biotech plc**

.....  
**(Exact name of Registrant as specified in its charter)**

**Ireland**

.....  
**(Jurisdiction of incorporation or organization)**

**IDA Business Park, Bray, Co. Wicklow, Ireland**

.....  
**(Address of principal executive offices)**

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

**None**

.....  
**(Title of Class)**

**Name of each exchange on which registered:**

**None**

.....  
**(Title of Class)**

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

**American Depository Shares  
(representing 'A' Ordinary Shares, par value US\$0.0109)**

.....  
**(Title of each class)**

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

**None**

.....  
**(Title of each class)**

**Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 45,160,640 Class 'A' Ordinary Shares and 700,000 Class 'B' Ordinary Shares.**

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

**Yes.....X..... No.....**

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

**Item 17..... Item 18.....X.....**

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

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

Our financial statements are presented in U.S. dollars and are prepared in accordance with accounting principles generally accepted in the Republic of Ireland which differ in certain respects from accounting principles generally accepted in the United States of America (see note 28 to the consolidated financial statements. All references in this annual report to “dollars” and “\$” are to U.S. dollars, and all references to “euro” or “€” are to European Union euro. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in dollars.

## **Item 1** *Identity of Directors, Senior Management and Advisers*

Not Applicable

## **Item 2** *Offer Statistics and Expected Timetable*

Not Applicable

## **Item 3** *Selected Consolidated Financial Data*

The following selected consolidated financial data of Trinity Biotech as at December 31, 2003 and 2002, and for each of the years ended December 31, 2003, December 31, 2002 and December 31, 2001, have been derived from, and should be read in conjunction with, the audited Consolidated Financial Statements and Notes thereto set forth in Item 18 of this Annual Report. The selected consolidated financial data as at December 31, 2001, December 31, 2000 and December 31, 1999, and for each of the years ended December 31, 2000 and 1999 are derived from the audited Consolidated Financial Statements not appearing in this Annual Report. The data should be read in conjunction with the financial statements, related notes, and other financial information included elsewhere herein.

### Consolidated Statement of

<u>Income Data</u>	<u>Year Ended Dec 31, 2003</u>	<u>Year Ended Dec 31, 2002</u>	<u>Year Ended Dec 31, 2001</u>	<u>Year Ended Dec 31, 2000</u>	<u>Year Ended Dec 31, 1999</u>
	US\$	US\$	US\$	US\$	US\$
Revenues	65,675,398	51,978,422	37,075,573	29,742,942	25,719,623
Cost of sales	(32,876,951)	(25,689,879)	(18,049,765)	(15,410,257)	(14,562,619)
Administrative expenses	(17,063,451)	(12,849,416)	(11,195,884)	(6,013,064)	(2,955,078)
Research & Development expenses	(5,210,039)	(4,470,745)	(2,779,729)	(2,681,220)	(2,448,372)
Amortization	(856,355)	(2,385,521)	(2,002,135)	(1,191,290)	(896,913)
Operating profit					
- Continuing Operations	9,668,602	6,523,834	5,816,912	3,201,040	4,856,641
- Acquisitions	-	59,027	(2,768,852)	1,246,071	-
- Disposals	-	-	-	-	-
	<u>9,668,602</u>	<u>6,582,861</u>	<u>3,048,060</u>	<u>4,447,111</u>	<u>4,856,641</u>
Interest income	174,117	103,133	142,364	466,151	69,284
Interest expense	(792,353)	(704,460)	(538,401)	(757,852)	(761,501)
Profit on assets	-	-	-	-	<u>404,328</u>
Net profit before tax and share of operating loss in associate & impairment	9,050,366	5,981,534	2,652,023	4,155,410	4,568,752



Share of operating loss in associate & impairment	(1,067,262)	(317,113)	(268,870)	(30,000)	-
Net profit before tax	7,983,104	5,664,421	2,383,153	4,125,410	4,568,752
Tax on profit on ordinary activities	(2,185,630)	(767,510)	(15,876)	(1,000)	10,000
Net profit after tax	5,797,474	4,896,911	2,367,277	4,124,410	4,578,752
Profit from operations per ordinary share (US dollars)	0.22	0.16	0.08	0.12	0.17
Profit from continuing operations per ordinary share (US dollars)	0.22	0.16	0.14	0.09	0.17
Basic earnings per ordinary share (US dollars)	0.13	0.12	0.06	0.11	0.16
Diluted earnings per ordinary share (US dollars)	0.12	0.12	0.06	0.10	0.16
Weighted average number of shares used in computing basic EPS	43,093,146	40,550,367	40,408,978	37,131,692	28,158,184
Weighted average number of shares used in computing diluted EPS	50,583,247	42,486,227	41,120,060	40,540,494	28,990,725

<u>Consolidated Balance Sheet Data</u>	As at <u>Dec 31, 2003</u>	As at <u>Dec 31, 2002</u>	As at <u>Dec 31, 2001</u>	As at <u>Dec 31, 2000</u>	As at <u>Dec 31, 1999</u>
	US\$	US\$	US\$	US\$	US\$
Working Capital	45,629,978	20,423,522	17,117,172	15,755,495	5,439,566
Long-term Liabilities	17,517,713	7,745,442	7,805,237	2,266,425	8,086,232
Total Assets	118,091,489	89,798,458	77,072,043	66,900,229	44,433,295
Capital Stock	670,388	610,095	603,420	602,807	460,229
Shareholders' Equity	80,261,927	62,537,284	56,411,625	53,891,729	22,372,976

#### Amounts Adjusted for US GAAP

<u>Consolidated Statement of Income Data</u>	Year Ended <u>Dec 31, 2003</u>	Year Ended <u>Dec 31, 2002</u>	Year Ended <u>Dec 31, 2001</u>	Year Ended <u>Dec 31, 2000</u>	Year Ended <u>Dec 31, 1999</u>
	US\$	US\$	US\$	US\$	US\$
Net profit	5,145,594	5,042,943	710,151	1,108,114	651,847
Basic earnings per ordinary share (US dollars)	0.12	0.12	0.02	0.03	0.02
Diluted earnings per ordinary share (US dollars)	0.11	0.12	0.02	0.03	0.02

<u>Consolidated Balance Sheet Data</u>	As at <u>Dec 31, 2003</u>	As at <u>Dec 31, 2002</u>	As at <u>Dec 31, 2001</u>	As at <u>Dec 31, 2000</u>	As at <u>Dec 31, 1999</u>
	US\$	US\$	US\$	US\$	US\$
Total Assets	128,649,751	99,067,410	83,239,531	75,858,813	55,696,411
Shareholders' Equity	87,233,925	70,944,268	63,463,291	62,899,307	33,121,515

No dividends were declared in any of the periods from December 31, 1999 to December 31, 2003.

### ***Risk Factors***

Before you invest in our shares, you should be aware that there are various risks, which are described below. You should consider carefully these risks together with all of the other information included in this annual report before you decide to purchase our shares.

#### ***Trinity Biotech's operating results may be subject to fluctuations.***

- Trinity Biotech's operating results may fluctuate as a result of many factors related to our business, including the competitive conditions in the industry, loss of significant customers, delays in the development of new products and currency fluctuations, as described in more detail below, and general factors such as size and timing of orders and general economic conditions.

#### ***Trinity Biotech's revenues depend to a high degree on its relationship with Wampole Laboratories, a former affiliate of Carter Wallace, Inc.***

- During the financial years ended December 31, 2003, December 31, 2002 and December 31, 2001, approximately 12%, 20% and 27% respectively of Trinity Biotech's revenues were derived from a distribution agreement by and among our subsidiary, Trinity Biotech (USA) Corp. (trading name of Clark Laboratories, Inc.) and Carter-Wallace, Inc. ("Carter-Wallace") and its affiliate Wampole Laboratories ("Wampole"). In 2001, Wampole was acquired by Medpointe, Inc. and was subsequently acquired by Inverness Medical Innovations, Inc. ("Inverness Medical") in 2002. In 2002, the Company negotiated an amendment to the distribution agreement whereby the exclusivity of Inverness Medical's right to sell our products in the US would be removed in stages throughout 2004. During 2003, the Company experienced declining sales revenues under the distribution agreement which it believes is due to Inverness Medical attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, the Company filed legal action against Inverness Medical and Wampole for declaratory judgment and breach of contract. In January 2004, Inverness Medical and Wampole countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. For further information relating to this matter please refer to Item 8 "Legal Proceedings". The Company has decided to sell its products directly in the US and has increased its direct sales force. Any inability to recapture lost sales from Inverness Medical may have a material adverse effect on the Company.

#### ***A need for capital might arise in the future if Trinity Biotech's capital requirements increase or revenues decrease.***

- Up to now Trinity Biotech has funded its operations through the sale of its shares and securities convertible into shares, revenues from operations and bank borrowings. Trinity Biotech expects that the proceeds of recent equity financings, bank borrowings, current working capital and sales revenues will fund its operations and payment obligations for the future. However, if our capital requirements are greater than expected, or if our revenues are not sufficient to fund our operations, we may need to find additional financing which may not be available on attractive terms or at all. Any future financing could have an adverse effect on our current shareholders or the price of our shares in general.

#### ***The diagnostics industry is highly competitive, and Trinity Biotech's research and development could be rendered obsolete by technological advances of competitors.***

- The diagnostics industry is extremely competitive. Trinity Biotech is competing directly with companies which have greater capital resources and larger marketing and business 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® CA, D-Dimer plus, Enzygnost®), bioMérieux (MDA®, VIDAS™), Zeus Scientific Inc. (Zeus EIA, IFA), Diasorin Inc. (ETI™), Abbott Diagnostics (AxSYM™, IMx™), Diagnostic Products Corp. - DPC (Immulite™), Bio-Rad (ELISA & WB), Roche Diagnostics (COBAS AMPLICOR™, Ampliscreen™, Accutrend™) and OraSure Technologies, Inc. (OraQuick®).

***Trinity Biotech is highly dependent on suitable distributors worldwide.***

- Revenue and earnings stability and growth are directly dependent on the effectiveness of advertising, marketing and promotional programmes. Trinity Biotech currently distributes its product portfolio through distributors in over 80 countries worldwide. Our continuing economic success and financial security is dependent on our ability to secure effective channels of distribution on favourable trading terms with suitable distributors.

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

- The healthcare industry is in transition with a number of changes that affect the market for diagnostic test products. Changes in the healthcare industry delivery system have resulted in major consolidation among reference laboratories and in the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. There can be no assurance that we will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers.

***Trinity Biotech's acquisition strategy may be less successful than expected, and therefore, growth may be limited.***

- Trinity Biotech has historically grown organically and through the acquisition of, and investment in, other companies, product lines and technologies. There can be no guarantees that recent or future acquisitions can be successfully assimilated or that projected growth in revenues or synergies in operating costs can be achieved. Our ability to integrate future acquisitions may also be adversely affected by inexperience in dealing with new technologies, and changes in regulatory or competitive environments. Additionally, even during a successful integration, the investment of management's time and resources in the new enterprise may be detrimental to the consolidation and growth of our existing business.

***Trinity Biotech's long-term success depends on its ability to develop new products subject to stringent regulatory control. Even if new products are successfully developed, Trinity Biotech's patents have a limited life time and are thereafter subject to competition with generic products. Also, competitors might claim an exclusive patent for products Trinity Biotech plans to develop.***

- We are committed to significant expenditure on research and development. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. Our organic growth and long-term success is dependent on our ability to develop and market new products but this work is subject to very stringent regulatory control and very significant costs in research, development and marketing. Failure to introduce new products could significantly slow our growth and adversely affect our market share.
- Even when products are successfully developed and marketed, Trinity Biotech's ownership of the technology behind these products has a finite life. In general, generic competition, which can arise after the expiration of a patent, can have a detrimental effect on a product's revenue, profitability and market share. There can be no guarantee that the net income and financial position of Trinity Biotech will not be adversely affected by competition from generic products. Conversely, on occasion, certain companies have claimed exclusive patent, copyright and other intellectual property rights to technologies in the diagnostics industry. If these technologies relate to Trinity Biotech's planned products, Trinity Biotech would be obliged to seek licenses to use this technology and, in the event of being unable to obtain such licenses or it being obtainable on grounds that would be materially disadvantageous to Trinity Biotech, we would be precluded from marketing such products, which could adversely impact our revenues, sales and financial position.

***Trinity Biotech's patent applications could be rejected or the existing patents could be challenged; our technologies could be subject to patent infringement claims; and trade secrets and confidential know-how could be obtained by competitors.***

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

<b>Patent Number</b>	<b>Description</b>	<b>Patent life remaining from February 29, 2004</b>
5,006,474	Bi-Directional Lateral Chromatography Test Device	4 years 2 months
5,114,845	Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin	3 years 5 months
5,175,087	Method of Performing Tissue Plasminogen Activator Assay	3 years 5 months
5,985,582	Thrombin-Based Assay for Antithrombin - III	13 years 10 months
6,194,394	Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays	14 years 5 months
6,528,273	Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls	14 years 9 months
6,391,609	Thromboplastin Reagents and Methods for Preparing and Using Such Reagents	15 years 8 months
6,653,066	Device and method for detecting polyvalent substances	19 years and 9 months

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

- We can provide no assurance that the patents Trinity Biotech may apply for will be obtained or that existing patents will not be challenged. The patents owned by Trinity Biotech and its subsidiaries may be challenged by third parties through litigation and could adversely affect the value of our patents. We can provide no assurance that our patents will continue to be commercially valuable.
- Also, our technologies could be subject to claims of infringement of patents or proprietary technology owned by others. The cost of enforcing our patent and technology rights against infringers or defending our patents and technologies against infringement charges by others may be high and could adversely affect our business.
- Trade secrets and confidential know-how are important to our scientific and commercial success. Although we seek to protect our proprietary information through confidentiality agreements and other contracts, we can provide no assurance that others will not independently develop the same or similar information or gain access to our proprietary information.

***Trinity Biotech's business is heavily regulated, and compliance with applicable regulations could reduce revenues and profitability.***

- Our manufacturing and marketing diagnostic test kits are subject to government regulation in the United States of America by the Food and Drug Administration ("FDA"), and by comparable regulatory authorities in other jurisdictions. The approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive. Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting approval from these regulatory authorities. There is no certainty that such approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process.

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

***Trinity Biotech's success is dependent on certain key management personnel.***

- Trinity Biotech's success is dependent on certain key management personnel. Our key employees are Ronan O'Caomh, our CEO and Chairman, Brendan Farrell, our President, Dr. Jim Walsh, our COO, and Rory Nealon, our CFO and Secretary, with all of which we have entered into employment contracts. We carry a life assurance policy for Mr O'Caomh in the amount of €533,289. Competition for qualified employees among biotechnology companies is intense, and the loss of such personnel or the inability to attract and retain the additional highly skilled employees required for the expansion of our activities, could adversely affect its business. In the USA, Germany and Sweden we were able to attract and retain qualified staff. In Ireland, we have experienced some difficulties in attracting and retaining staff due to competition from other employers in our industry and due to the strength of the Irish economy. We are not aware of any plans by qualified staff to retire or leave Trinity Biotech in the near future.

***Trinity Biotech is dependent on its suppliers for the primary raw materials required for its test kits.***

- The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. Although Trinity Biotech does not expect to be dependent upon any one source for these raw materials, alternative sources of antibodies with the specificity and sensitivity desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

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

- Trinity Biotech may be subject to claims for personal injuries or other damages resulting from its products or services. Trinity Biotech has product liability insurance in place for its US manufacturing subsidiaries up to a maximum of US\$2,000,000 for any one accident, limited to a maximum of US\$2,000,000 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 €4,000,000 (US\$5,020,710) for any one accident, limited to a maximum of €4,000,000 (US\$5,020,710) in any one year period of insurance. A deductible of US\$25,000 is applicable to each insurance event. There can be no assurance that our product liability insurance is sufficient to protect us against liability that could have a material adverse effect on our business.

***Currency fluctuations may adversely affect our earnings and assets.***

- Trinity Biotech records its transactions in Euro and US dollars and prepares its financial statements in US dollars. A substantial portion of our expenses is denominated in Euro. However, Trinity Biotech's revenues are primarily denominated in US dollars. As a result, we are affected by fluctuations in currency exchange rates, especially the exchange rate between the US dollar and the Euro. Fluctuations between these and other exchange rates may adversely affect our earnings and assets. The percentage of 2003 consolidated revenue denominated in US\$ was approximately 67%. Of the remaining 33% revenue, the breakdown was as follows: Euro (29%), Yen (1%) and Sterling and Swedish Kroner (3%). Thus, a 10% decrease in the value of each of the Euro, Yen, Sterling and Swedish Kroner would have approximately a 3% adverse impact on consolidated revenues. As part of the process of mitigating foreign exchange risk, the principal exchange risk identified by Trinity Biotech was with respect to fluctuations in the Euro. This is attributable to the level of Euro denominated expenses exceeding the level of Euro denominated revenues thus creating a Euro deficit. As part of a managed hedging policy, Trinity Biotech has identified the extent of this Euro mismatch and implemented a forward currency hedging policy which aims to cover a portion of this mismatch through the use of forward contracts. Trinity Biotech entered into a series of forward contracts to sell US\$ forward for Euro. These contracts remain in place until late 2005. Trinity Biotech continues to monitor its exposure to foreign currency movements. In the medium term, our objective is to increase the level of non-US\$ denominated revenue, thus creating a natural hedge of the non-US\$ expenditure.

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

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

***The conversion of our outstanding convertible notes and warrants would dilute the ownership interest of existing shareholders.***

- The convertible notes described in Item 18, Note 10 (e), and the warrants described in Item 18, Note 11, issued since year end, are convertible into ADRs representing our Class "A" Ordinary Shares. Conversion of the remainder of the notes and exercise of the warrants will likely occur only when the conversion price is below the trading price of our ADRs and will dilute the ownership interests of existing shareholders. For instance, should the holders of the Series A Convertible Notes decide to convert the balance of the US\$20,000,000 total principal amount of US\$13,217,500 and the holders of the Series B Convertible Notes decide to convert the total principal amount of US\$5,000,000 into ADRs at conversion prices of US\$3.55 and US\$4 respectively, and should the 1,258,824 warrants be exercised, Trinity Biotech would have to issue 6,232,063 additional ADRs. On the basis of 51,766,449 outstanding shares at February 29, 2004, this would effectively dilute the ownership interest of the existing shareholders by approximately 11%. In addition, any sales in the public market of the ADRs issuable upon conversion of the notes could adversely affect prevailing market prices of our ADRs.

***It could be difficult for US holders of ADRs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.***

- At present, no treaty exists between the United States and Ireland for the reciprocal enforcement of foreign judgments. The laws of Ireland do however, as a general rule, provide that the judgments of the courts of the United States have in Ireland the same validity as if rendered by Irish Courts. Certain important requirements must be satisfied before the Irish Court will recognize the United States judgment. The originating court must have been a court of competent jurisdiction, the judgment may not be recognized if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgment obtained in contravention of the rules of natural justice will not be enforced in Ireland.

## **Item 4**

### ***Information on the Company***

#### ***History and Development of the Company***

Trinity Biotech Plc ("Trinity Biotech" or "the Company") develops, manufactures and markets diagnostic test kits used for the clinical laboratory and point-of-care ("POC") segments of the diagnostic market. These test kits are used to detect infectious diseases, sexually transmitted diseases, blood coagulation disorders and autoimmune disorders. The Company markets over 500 different diagnostic products in approximately 80 countries.

Trinity Biotech was incorporated as a public limited company (plc) registered in Ireland in 1992. The Company commenced operations in 1992 and, in October 1992, completed an initial public offering of its securities in the 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 haemostasis business in December 2001 and the haemostasis division of Sigma Diagnostics, part of Sigma Aldrich, in August 2002, Trinity Biotech has expanded its product range to include test kits that diagnose blood coagulation and related disorders, and a haemostasis instrumentation portfolio. The acquisition of the speciality clinical chemistry business of Sigma Diagnostics in November 2002 means that Trinity Biotech now participates in this important market segment. Trinity Biotech 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 Biotech has manufacturing facilities in Bray, Ireland, Umea, Sweden and Lemgo, Germany, in Europe, and in Jamestown, New York, and Carlsbad, California in the USA.

Over the past four years, Trinity Biotech 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 haemostasis businesses and the sixth was a speciality clinical chemistry business. In July 2001, Trinity Biotech established a direct sales operation in

Germany which commenced trading in October 2001, and in 2002 the Company established a small direct sales operation in the United Kingdom. Through these acquisitions and new products added through in-house research and development, Trinity Biotech now has a comprehensive portfolio of over 500 products, including 7 rapid tests.

***Acquisition of the speciality clinical chemistry product line of Sigma Diagnostics***

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

***Acquisition of the haemostasis division of Sigma Diagnostics***

In August 2002, Trinity Biotech purchased the haemostasis division of Sigma Diagnostics for a total consideration of US\$1.4m. 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 haemostasis 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 Biotech also received FDA clearance recently for its new haemostasis analyser the AMAX Destiny™.

***Acquisition of the assets of the Biopool haemostasis business***

In December 2001, Trinity Biotech acquired the assets of the Biopool haemostasis business for a consideration of US\$6.4m 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 Biotech acquired the assets 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.

***Acquisition of Bartels Inc***

In December 2000, Trinity Biotech acquired the assets 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.

***Acquisition of MarDx Diagnostics Inc***

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

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

***Investment in HiberGen Limited***

On October 2, 2000, the Company acquired 33% of the ordinary share capital of HiberGen for a total consideration of US\$1.4m. On July 2, 2001 the Company increased its shareholding in HiberGen to 40% at a cost of US\$0.3m. On April 3, 2002 the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 ‘A’ Ordinary Shares in Trinity Biotech plc. In

November 2003, the Company announced that the recent fundraising process undertaken by HiberGen had not been successful and that HiberGen had ceased trading. The Company wrote-off its remaining investment in quarter four of the 2003 financial year.

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

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

***Establishment of German subsidiary, Trinity Biotech GmbH***

In October 2001, Trinity Biotech established a direct sales operation in Germany. After the USA and Japan, Germany, with a population of 83m, is the third largest market in the world for in-vitro diagnostics, accounting for 7% (€1.6bn) of the total world market of €22.5bn. In the past Trinity Biotech had serviced the market through five independent distributors who handled a small proportion of the Company's product portfolio whereas the new German direct sales force markets all of Trinity Biotech's current products. In 2002 Trinity Biotech purchased the haemostasis business of Sigma Diagnostics. The German part of this business was taken over by Trinity Biotech GmbH.

***Pre Market Application ("PMA") 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 Biotech's UniGold HIV test. This IDE allows Trinity Biotech's UniGold HIV test to be used in a limited number of hospitals throughout the 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 Biotech's proposed clinical trials under the treatment IDE met FDA standards for human safety and confidentiality.

During 2001, representatives from Trinity Biotech were informed by the FDA that the FDA required that additional clinical trials be conducted to ensure that the results which have been obtained to date are statistically significant. This means that the results which have been presented to the FDA in the PMA filing must be reproduced on a larger population of samples. The resulting product clinical trials have now been conducted at sites in Houston, Texas and Baltimore, Maryland. Approximately 9,000 samples were collected and tested on Trinity Biotech's UniGold HIV test. This data along with extensive information on the manufacturing process for Trinity Biotech's UniGold HIV test were presented to the FDA. The FDA completed a plant inspection of the Irish manufacturing facility in mid September. On December 29, 2003, the FDA issued approval for the sale of the UniGold HIV test. This allows for sale of the UniGold HIV test into clinical laboratories throughout the United States testing the following blood sample types: serum, plasma and venipuncture whole blood.

In the US laboratories are classed under The Clinical Laboratory Improvements Amendments of 1988 ("CLIA") regulations in to one of three categories: Waived, Moderate and High. Accreditation by CLIA is required by laboratories to use moderate and high complexity classified tests. No laboratory accreditation is required for use of CLIA waived tests (see 'other FDA regulations' below). Trials are currently underway to support a CLIA waiver for the UniGold HIV test. Should CLIA waiver be granted; the use of the UniGold HIV test will be expanded to Point of Care settings. Early in 2004, an IDE submission was made to the FDA to define the data requirements to expand the use of the product to test finger stick (blood taken directly from the finger) samples.

***Principal Markets***

The primary market for Trinity Biotech's tests remains the USA. During fiscal 2003, the Company sold 55% (US\$36.3) (2002: 64% or US\$33.5m; 2001: 68% or US\$25.0m) of product in the USA. Sales to non-USA (principally European and Asian) countries represented 45% (US\$29.4m) during fiscal 2003 and 36% (US\$18.5m) during fiscal 2002. The comparable figure in 2001 was 32% (US\$12.1m).

For a more comprehensive segmental analysis please refer to Item 5, "Results of Operations" and 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 Biotech's products can test for foreign agents such as viruses, bacteria and parasites, and for naturally occurring conditions such as cancer cells and hormones. The Company's manufacturing processes utilize biotechnology techniques involving the in-house production of recombinant proteins, synthetic peptides and monoclonal antibodies.

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

#### *Enzyme Immunoassays (EIA)*

*Bartels®*  
*CAPTIA™*  
*MarDx®*  
*MicroTrak™*  
*Recombigen®*

#### *Fluorescence Assays (IFA/DFA)*

*Bartels®*  
*MarDx®*  
*MicroTrak™*

#### *Western Blot (WB)*

*MarDx®*

#### *Rapid Assays*

*Capillus™*  
*SeroCard™*  
*UniGold™*

#### *Haemostasis*

*Biopool®*  
*Amax*

#### *Clinical Chemistry*

*EZ HDL*  
*EZ LDL*

### ***Enzyme Immunoassays***

The Company's wide range of Enzyme Immunoassay (EIA) products includes over 90 assays utilising different formats to accommodate the most demanding of laboratories to the most basic. This type of test is the mainstay of standard clinical laboratories around the world and forms the backbone of the Trinity Biotech product list of over 500 products. Trinity Biotech currently sells 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 samples and can be performed manually or more typically on automated equipment. Trinity Biotech also offers a modest range of equipment for these types of assays as well as validating the Trinity Biotech range for use on the most popular types of analysers, used by most medical laboratories.

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

### ***Haemostasis***

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

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

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

### ***Fluorescence Assays***

Another large range of diagnostic assays in Trinity Biotech's portfolio are the fluorescence assays that are also typically performed in medium to large sized hospital laboratories around the world. Trinity Biotech offers 33 fluorescence assays, of which 25 are cleared by the FDA for distribution within the 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 Biotech offers 24 IFA's with the vast majority forming the comprehensive range of tests to diagnose autoimmune disorders. The remainder of the assays are used to assist in the diagnosis of infectious diseases such as Legionnaires disease, Lyme disease and many others. Of the 9 DFA's Trinity Biotech offers, the largest range are FDA cleared for detecting causative agents of sexually transmitted diseases (STD's), principally Chlamydia and Herpes, and forms one of Trinity Biotech's most popular selling product groups.

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

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

### ***Rapid Assays***

Trinity Biotech has developed a range of membrane and latex based rapid assays to cater for point of care ('POC') and over-the-counter ('OTC') markets. This range of 7 tests facilitates fast and often very important treatment for the patient and can avoid further costly testing. The UniGold™ 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™, SeroCard™ and Capillus™ formats. SeroCard™ is a self-encased, flow-through rapid EIA device where results are obtained by visual interpretation of a colour change, whereas Capillus™ utilises latex agglutination enhanced by capillary slide technology.

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

### ***Western Blot Assays***

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

Western Blot assays are typically used in reference or speciality laboratories for confirming the presence, or absence, of antibodies. This can be an essential part of routine practice for some laboratory investigations for conditions such as Lyme disease, whereby the confirmation of antibody status is the only means to obtain an accurate diagnosis. The principle of these types of tests is that a membrane containing electrophoretically separated proteins of a particular organism are incubated with a patient's serum sample. If specific antibodies to individual proteins are present, they will bind to the corresponding antigen bands. After various washing steps and conjugation, the strip is finally reacted with a precipitating colour developing solution which deposits a visible precipitate on antibody reacted antigen bands. Bands can then be visualised, scored for intensity, relative to a band of a weakly reactive control, and recorded.

### ***Clinical Chemistry***

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

These products are suitable for both manual and automated testing and have proven performance in the diagnosis of many disease states from liver and kidney disease to G6PDH deficiency which is an indicator of haemolytic anaemia. EZ HDL and EZ LDL cholesterol assays broke new ground when they were introduced by Sigma as the first homogenous, non-precipitating liquid reagents for determining HDL and LDL.

### ***Distribution Agreement between Trinity Biotech USA and Carter Wallace***

Trinity Biotech USA ("Trinity USA") entered into a distribution agreement with Carter-Wallace Inc. ("Carter-Wallace") on December 18, 1995 for an initial period of five years and, thereafter, for an indefinite period subject to termination provisions outlined in the distribution agreement. Under the terms of the agreement, Carter-Wallace has the exclusive right to sell and distribute Trinity USA's products in the USA and Puerto Rico through its affiliate Wampole Laboratories ("Wampole"). Under the distribution agreement, the Company retained the right to market certain Trinity USA products in the USA and Puerto Rico, which Carter-Wallace has chosen not to market in those territories. In addition, the Company 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 with Inverness Medical Innovations, Inc. ("Inverness Medical"), the successor to Carter-Wallace's rights under the distribution agreement, whereby the exclusivity would be removed in stages throughout 2004. In December 2003, the Company initiated legal proceedings against Inverness Medical for declaratory judgment and breach of contract. The suit alleges that Inverness Medical is attempting to convert customers from the Trinity Biotech product to a product manufactured by a competitor by claiming that the Trinity Biotech product is unavailable and is being discontinued. In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent Trinity Biotech from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied this motion for a preliminary injunction on January 28, 2004. For further information relating to this matter please refer to Item 8 "Legal Proceedings". The Company has decided to sell its products directly in the US and has increased its direct sales force to approximately seventy staff. Any inability to recapture lost sales from Wampole may have a material adverse effect on the Company.

### ***Sales and Marketing***

Trinity Biotech sells its product through its own direct sales-force in three countries: the United States, Germany and the United Kingdom. In the United States there are approximately seventy sales and marketing professionals responsible for the sale of haemostasis reagents and instrumentation, clinical chemistry and infectious disease products. The sales force of twenty people in Germany is responsible for selling the full range of Trinity Biotech products including haemostasis, infectious disease, clinical chemistry and radioimmunoassay. In 2002, Trinity Biotech opened a sales and marketing office in Oxfordshire, UK employing three sales professionals who market the haemostasis and clinical chemistry products from Trinity Biotech. In addition to our direct sales operations, Trinity Biotech also operates in seventy-eight countries, through over three hundred independent distributors and strategic partners.

### ***Manufacturing and Raw Materials***

The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens, human plasma, latex beads, rabbit brain phospholipids, bovine source material, other reagents, glass fibre and packaging materials. The reagents used as raw materials have been acquired for the most part from third parties. Although Trinity Biotech is not dependent upon any one source for such raw materials, alternative sources of antibodies and antigens with the specificity and sensitivity desired by Trinity Biotech may not be available. Such unavailability could affect the quality of its products and its ability to meet orders for specific products, if such orders are obtained. Trinity Biotech's growth may be limited by its ability to obtain or develop the necessary quantity of antibodies or antigens required for specific products. Thus, Trinity Biotech's strategy is, whenever possible, to establish alternative sources of supply of antibodies.

### ***Competition***

The diagnostic industry is very competitive. There are many companies, both public and private, engaged in diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. Many of these companies have substantially greater capital resources and have marketing and business organizations of substantially greater size than Trinity Biotech. Many companies have been working on immunodiagnostic reagents and products, including some products believed to be similar to those currently marketed or under development by the Company, for a longer period of time than has the Company. The Company's competition includes several large companies such as Roche, Abbott, Johnson & Johnson, Bayer, Chiron and Dade-Behring.

### ***Patents and Licences***

#### ***Patents***

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

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

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

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

Many of the Company's tests are not protected by specific patents, due to the significant cost of putting patents in place for the Company's wide range of products. However, the Company believes that substantially all of its tests are protected by proprietary know-how, manufacturing techniques and trade secrets.

From time-to-time, certain companies have asserted exclusive patent, copyright and other intellectual property rights to technologies that are important to the industry in which Trinity Biotech operates. In the event that any of such claims relate to its planned products, Trinity Biotech intends to evaluate such claims and, if appropriate, seek a licence to use the protected technology. There can be no assurance that Trinity Biotech would, firstly, be able to obtain licences to use such technology or, secondly, obtain such licences on satisfactory commercial terms. If Trinity Biotech or its suppliers are unable to licence any such protected technology that might be used in Trinity Biotech's products, Trinity Biotech could be prohibited from marketing such products. It could also incur substantial costs to redesign its products or to defend any legal action taken against it. If Trinity Biotech's products should be found to infringe protected technology, Trinity Biotech could also be required to pay damages to the infringing party.

### *Licences*

In 2002, the Company obtained the Unipath and Carter Wallace lateral flow licences under agreement with Inverness Medical Innovations.

On December 20, 1999 the Company obtained a non-exclusive commercial licence from the National Institute of Health (“NIH”) in the USA for NIH patents relating to the general method of producing HIV-1 in cell culture and methods of serological detection of antibodies to HIV-1.

The Company has also entered into a number of licence/supply agreements for key raw materials used in the manufacture of its products.

### ***Government Regulation***

The preclinical and clinical testing, manufacture, labelling, distribution, and promotion of the Company’s products are subject to extensive and rigorous government regulation in the United States and in other countries in which the Company’s products are sought to be marketed. The process of obtaining regulatory clearance varies, depending on the product categorization and the country, from merely notifying the authorities of intent to sell, to lengthy formal approval procedures which often require detailed laboratory and clinical testing and other costly and time-consuming processes. The main regulatory bodies which require extensive clinical testing are the Food and Drug Administration (“FDA” or the “agency”) in the USA, the Irish Medicines Board (as the authority over Trinity Biotech in Europe) and Health Canada. Recently, a European Directive has been implemented allowing one approval system to be applicable throughout Europe, CE marking. Canada has also recently amended their regulations where it is now mandatory to hold an externally accredited quality system to a very exacting standard.

The process in each country varies considerably depending on the nature of the test, the perceived risk to the user and patient, the facility at which the test is to be used and other factors. As 55% of Trinity Biotech’s 2003 revenues were generated in the USA and the USA represents approximately 43% of the worldwide diagnostics market, an overview of FDA regulation has been included below.

### *FDA Regulation*

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. The FDA’s regulations govern, among other things, the following activities: product development; testing; labelling; storage; premarket clearance or approval; advertising and promotion; and sales and distribution.

*Access to U.S. Market.* Each medical device that the Company may wish to commercially distribute in the U.S. will likely require either 510(k) clearance or premarket application (“PMA”) approval prior to commercial distribution. Devices deemed to pose relatively less risk are placed in either class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a “preamendment” class III device (i.e., in commercial distribution since prior to May 28, 1976) for which PMA applications have not been called, are placed in class III requiring PMA approval.

*510(k) Clearance Pathway.* To obtain 510(k) clearance, the Company must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a “predicate device” – either a previously cleared class I or II device or a class III preamendment device, for which the FDA has not called for PMA applications. The FDA’s 510(k) clearance pathway usually takes from four to 12 months, but it can last longer. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could even require a PMA approval.

*PMA Approval Pathway.* A device that does not qualify for 510(k) clearance generally will be placed in class III and required to obtain PMA approval, which requires proof of the safety and effectiveness of the device to the FDA’s satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. In addition, an advisory committee made up of clinicians and/or other appropriate experts is typically convened to evaluate the application and make recommendations to the FDA as to whether the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel’s recommendation is important to the FDA’s overall decision making process. The PMA approval pathway is more costly, lengthy and uncertain than the 510(k) clearance process. It generally takes from one to three years or even longer. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its

manufacturing process. The FDA has recently implemented substantial fees for the submission and review of PMA applications.

*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.

*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 issued PMA approval for the device on December 29, 2003. This approval allows for the use of serum, plasma and venipuncture whole blood in clinical settings. The company is actively pursuing the expansion of the product use to point of care setting and the use of blood taken directly from the finger.

#### *Postmarket Regulation*

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply, including: the Quality System Regulation (“QSR”), which requires manufacturers to follow elaborate testing, control, documentation and other quality assurance procedures during the manufacturing process; 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 by the FDA to determine compliance with regulatory requirements. If the FDA finds any failure to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions, and civil penalties; recall or seizure of products; the issuance of public notices or warnings; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

Unanticipated changes in existing regulatory requirements or adoption of new requirements could have a material adverse effect on the Company. Any failure to comply with applicable QSR or other regulatory requirements could have a material adverse effect on the Company’s revenues, earnings and financial standing. There can be no assurances that the Company will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not have a material adverse effect upon the Company’s revenues, earnings and financial standing.

#### *Other FDA Regulation*

Purchasers of the Company’s clinical diagnostic products in the United States may be regulated under The Clinical Laboratory Improvements Amendments of 1988 (“CLIA”) and related federal and state regulations. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA established three levels of diagnostic tests (“waived”, “moderately complex” and “highly complex”) and the standards applicable to a clinical laboratory depend on the level of the tests it performs. CLIA requirements may prevent some clinical laboratories from using any or all of the Company’s diagnostic products. There can be no assurance that the CLIA regulations and future administrative interpretations of CLIA will not have a material adverse impact on the Company by limiting the potential market for the Company’s products.

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 Biotech’s executive offices are located at Bray, Co. Wicklow, Ireland while its research and development, manufacturing and marketing activities are principally conducted at Trinity Biotech Manufacturing Limited, based in Bray, Co. Wicklow, Ireland, Trinity Biotech GmbH, based in Lemgo, Germany, and at Trinity Biotech (USA), MarDx Diagnostics Inc and Biopool US Inc based in Jamestown, New York State, Carlsbad, California and St. Louis, Missouri respectively.

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.

#### **Property, Plant and Equipment**

Trinity Biotech has five manufacturing sites worldwide, two in the USA (Jamestown, NY and Carlsbad, CA), one in Bray, Co. Wicklow, Ireland, one in Umea, Sweden and one in Lemgo, Germany. The US and Irish facilities are each FDA, EN and ISO approved facilities. As part of its ongoing commitment to quality, Trinity Biotech was granted the latest ISO 9001: 2000 and ISO 13485: 1996 certification in February 2003. This certificate was granted by the Underwriters Laboratory, an internationally recognised notified body. It serves as external verification that Trinity Biotech has an established and effective quality system in accordance with an internationally recognised standard. By having an established quality system there is a presumption that Trinity Biotech will consistently manufacture products in a controlled manner. To achieve this certification Trinity Biotech performed an extensive review of the existing quality system and implemented any additional requirements of the ISO 9001: 2000.

Trinity Biotech's manufacturing and research and development facilities consisting of approximately 45,000 square feet are located at IDA Business Park, Bray, Co. Wicklow, Ireland. This facility is ISO 9001 approved and was purchased in December 1997. The facilities include offices, research and development laboratories, production laboratories, cold storage and drying rooms and warehouse space. Trinity Biotech spent US\$4.2m 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 €392,349 (US\$492,468). 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 €190,500 (US\$239,111). 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 €12,860 (US\$16,142) per annum over adjacent lands. On November 20, 2002 the Company entered into an agreement for lease with the lessor for 16,000 square foot of offices that have recently been constructed on part of these lands. The annual rent of €365,760 (US\$459,094) is payable from January 1, 2004. (See Item 7 – Major Shareholders and Related Party Transactions).

Trinity Biotech USA operates from a 24,000 square foot FDA and ISO 9001 approved facility in Jamestown, New York. The facility was purchased by Trinity Biotech USA in 1994. Additional warehousing space is also leased in upstate New York at an annual rental charge of US\$48,144.

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\$213,600. 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\$134,985.

Arising from the acquisition of the Biopool haemostasis business, Trinity Biotech currently operates from an additional facility located in Umea, Sweden. The Umea facility is 8,712 square feet and the annual rental is US\$116,054. The lease, renewed in December 2003, expires in December 2006.

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

Additional office space is leased by the Company in Ireland, Darmstadt and St. Louis, Missouri at an annual cost of US\$114,773, US\$53,497 and US\$78,089 respectively. The Company is currently negotiating the lease of additional office space in New Jersey.

## **Item 5**

### ***Operating and Financial Review and Prospects***

#### ***Operating Results***

Trinity Biotech's consolidated financial statements include the attributable results of seven trading entities: - Trinity Biotech Manufacturing Limited (Ireland), Clark Laboratories Inc. (trading as Trinity Biotech (USA)), Biopool US Inc., MarDx Diagnostics Inc, Biopool AB, Trinity Biotech (UK Sales) Limited and Trinity Biotech GmbH (Germany). These entities are engaged in the manufacture and sale of diagnostic test kits. The consolidated financial statements also include a share of the loss of the associate undertaking, HiberGen. This discussion covers the years ended December 31, 2003, December 31, 2002 and December 31, 2001 and should be read in conjunction with the Consolidated Financial Statements and notes thereto appearing elsewhere in this Form 20-F. The financial statements have been prepared in accordance with Irish GAAP which differs from US GAAP as indicated in Note 28 to the Consolidated Financial Statements.

#### ***Overview***

Trinity Biotech develops, manufactures and markets diagnostic test kits used for the clinical laboratory and point-of-care ("POC") segments of the diagnostic market. These test kits are used to detect infectious diseases, sexually transmitted diseases, blood coagulation disorders and autoimmune disorders. The Company markets over 500 different diagnostic products in approximately 80 countries.

Trinity Biotech was incorporated in Ireland in January 1992. The Company was organised to acquire, develop and market technologies for rapid *in-vitro* blood and saliva diagnostics for HIV and other infectious diseases. In October 1992, Trinity Biotech completed an initial public offering in the United States in which it raised net proceeds in excess of US\$5 million. In October 1993, Trinity Biotech took a controlling interest in DDI and in October 1994, merged Trinity Biotech's wholly-owned US subsidiary into DDI so that DDI became a wholly-owned subsidiary of Trinity Biotech. DDI was the surviving legal entity in the merger and was subsequently renamed Trinity Biotech Inc ("TBI"). In December 1994, Trinity Biotech acquired the remaining 50% of FHC which its subsidiary TBI did not own. During 1995, Trinity Biotech raised net proceeds in excess of US\$6 million as a result of a private placement of the Company's shares. In February 1997, the Company purchased the entire share capital of Clark Laboratories Inc ("Clark"), which now trades as Trinity Biotech USA, and in June 1997, the Company purchased the entire share capital of Centocor UK Holdings Ltd ("Centocor"). In 1998, the Company made four product line acquisitions: the acquisition of the Microzyme and Macra Lp(a) product lines in June 1998 and the acquisition of the MicroTrak and Cambridge Diagnostics HIV product lines in September 1998. The manufacture of these product lines has been transferred to the Company's Jamestown, NY and Bray, Co. Wicklow, Ireland manufacturing facilities. In March 2000, the Company purchased 100% of the share capital of MarDx Diagnostics Inc ("MarDx") and in December 2000, the assets of Bartels Inc were acquired. The Bartels plant in Seattle closed in June 2001 and production has been transferred to the Californian, New York and Irish factories. In October 2001, the Company purchased the Amerlex hormone business of Ortho Clinical Diagnostics and in December 2001 the Company acquired the assets of the Biopool haemostasis business. In October 2001, Trinity Biotech established a direct sales operation in Germany, Trinity Biotech GmbH. In August 2002, Trinity Biotech acquired the haemostasis division of Sigma Diagnostics, part of Sigma-Aldrich. The Sigma diagnostics haemostasis business comprised a comprehensive portfolio of reagents manufactured in St Louis, Missouri and the Amelung range of automated and semi-automated instruments manufactured in Lemgo, Germany. During 2003, Trinity Biotech completed the transfer of the Sigma haemostasis test manufacturing from St. Louis to the Irish facility. On September 30, 2002, Trinity Biotech closed the haemostasis manufacturing facility in Ventura, California which it had acquired from Xtrana, (Biopool), and has integrated these operations into the Wicklow manufacturing facility in Ireland. Trinity Biotech also acquired the speciality clinical chemistry business from Sigma Diagnostics in December 2002. This business consists of several specialised products that are clearly differentiated in the marketplace, including ACE, Bile Acids, Lactate, Oxalate and G6PDH. During 2002, Trinity Biotech



established a small direct sales operation in the United Kingdom to handle the Sigma haemostasis and clinical chemistry product lines. For further information about the company's principal products and principal markets please refer to Item 4, "Information on the Company".

In October 2000, Trinity Biotech subscribed for a 33% shareholding in HiberGen Limited ("HiberGen"). In July 2001 the Company subscribed for a further 300,000 Ordinary Shares in HiberGen, increasing its shareholding to 40%. On April 3, 2002, the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. During 2003, HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading.

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

#### ***Factors affecting our results***

The global diagnostics market is growing rapidly due to, among other reasons, the ageing population and the increasing demand for rapid tests in a clinical environment.

Our revenues are directly related to our ability to identify high potential products while they are still in development and to bring them to market quickly and effectively. Efficient and productive research and development is crucial in this environment as we, like our competitors, search for effective and cost-efficient solutions to diagnostic problems. The growth in new technology will almost certainly have a fundamental effect on the diagnostics industry as a whole and upon our future development. For further information about the company's principal products, principal markets and competition please refer to Item 4, "Information on the Company".

#### ***Critical Accounting Policies and Estimates***

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in Ireland ("Irish GAAP"). The preparation of these financial statements requires us to make estimates and judgements that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities.

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

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

#### ***Research and development expenditure***

Under Irish GAAP, we write-off research and development expenditure as incurred, with the exception of expenditure on projects whose outcome has been assessed with reasonable certainty as to technical feasibility, commercial viability and recovery of costs through future revenues. Such expenditure is capitalized at cost within intangible assets and amortized over 10 years.

Factors which impact our judgement to capitalize certain research and development expenditure include the degree of regulatory approval for products and the results of any market research to determine the likely future commercial success of products being developed. We review these factors each year to determine whether our previous estimates as to feasibility, viability and recovery should be changed.

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

#### ***Impairment of intangible assets***

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

Factors considered important, which could trigger an impairment review, include the following:

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

When we determine that the carrying value of intangibles, long-lived assets and related goodwill may not be recoverable based upon the existence of one or more of the above indicators of impairment, any impairment is measured based on our estimates of projected net discounted cash flows expected to result from that asset, including eventual disposition. Our estimated impairment could prove insufficient if our analysis overestimated the cash flows or conditions change in the future.

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

#### *Allowance for slow-moving and obsolete inventory*

We evaluate the 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 and for which no further re-processing can be performed. We also consider recent trends in revenues for various inventory items and instances where the realizable value of inventory is likely to be less than its carrying value.

#### *Allowance for doubtful debts*

We make judgments 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 judgment is required in determining our worldwide income tax expense provision. In the ordinary course of a global business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Some of these uncertainties arise as a consequence of revenue sharing and cost reimbursement arrangements among related entities, the process of identifying items of revenue and expense that qualify for preferential tax treatment and segregation of foreign and domestic income and expense to avoid double taxation. Although we believe that our estimates are reasonable, no assurance can be given that the final tax outcome of these matters will not be different than that which is reflected in our historical income tax provisions and accruals. Such differences could have a material effect on our income tax provision and net income in the period in which such determination is made. Deferred tax assets and liabilities are determined using enacted tax rates for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, there is no assurance that the valuation allowance would not need to be increased to cover additional deferred tax assets that may not be realizable. Any increase in the valuation allowance could have a material adverse impact on our income tax provision and net income in the period in which such determination is made. In addition, we operate within multiple taxing jurisdictions and are subject to audits in these jurisdictions. These audits can involve complex issues that may require an extended period of time for resolution. In management's opinion, adequate provisions for income taxes have been made.

#### *Asset Retirement Obligations*

The Company is responsible for certain costs of restoring leased premises to their original condition. The terms of such obligations vary. Generally, a maximum obligation is not explicitly stated. Because the obligated amounts of these types of agreements often are not explicitly stated, the overall maximum amount of the obligations cannot be reasonably estimated. Historically, the Company has not been obligated to make significant payments for these obligations, and no liabilities have been recorded for these obligations on its balance sheet as of December 31, 2003 and 2002.

## ***Recent 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 was effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. The Company adopted SFAS 144 as of January 1, 2002. Such adoption had no material impact on the results of the Company.

### *Costs Associated with Exit or Disposal Activities*

The Financial Accounting Standards Board issued Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") in June 2002. SFAS 146 provides guidance on the recognition and measurement of liabilities associated with exit or disposal activities and requires that such liabilities be recognized when incurred. In many cases, those costs will be recognized as liabilities in periods following a commitment to a plan, not at the date of commitment. SFAS 146 also changes the recognition of one-time termination benefits, such as severance pay or other termination indemnities, whenever the benefit arrangement requires employees to render future service beyond a minimum retention period. SFAS 146 also addresses the accounting for other costs associated with an exit or disposal activity, such as costs to consolidate or close facilities and relocate employees. A liability for such costs has to be recognized and measured at its fair value in the period in which it is incurred. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Application of SFAS 146 had no material impact on the consolidated financial statements of the Company as it had no exit costs in 2003.

### *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*

The Financial Accounting Standards Board issued FASB Interpretation No. 45 "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others", ("FIN 45") in November 2002. FIN 45 requires a guarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by it in issuing the guarantee. It also expands the disclosure requirements in the financial statements of the guarantor with respect to its obligations under certain guarantees that it has issued. The Company is required to adopt the initial recognition and initial measurement accounting provisions of this interpretation on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are required to have been adopted as of December 31, 2002. Application of FIN 45 had no material impact on the consolidated financial statements of the Company, as in the normal course of business, the Company does not issue guarantees to third parties and the Company had no guarantees in 2003.

### *Consolidation of Variable Interest Entities*

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

### *Derivative Instruments and Hedging Activities*

The Financial Accounting Standards Board issued Statement No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities", ("SFAS 149") in April 2003. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as "derivatives") and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". This statement requires contracts with comparable characteristics be accounted for similarly. In particular, this Statement (a) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative as discussed in SFAS No. 133, (b) clarifies when a derivative contains a financing component and (c) amends the definition of an "underlying" to conform it to language used in FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". This Statement is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of the new rules had no material impact on the consolidated financial statements of the Company.

### *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*

The Financial Accounting Standards Board issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", ("SFAS 150") in May 2003. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer

classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003. Application of SFAS 150 had no material impact on the consolidated financial statements of the Company as it had no such financial instruments in 2003.

### **Results of Operations**

Year ended December 31, 2003 compared to the Year Ended December 31, 2002

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

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

#### **1. Overview**

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

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

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

Our operating margin in 2003 was 14.7% of sales, an increase of 2% over the 12.7% of sales of the previous year. This is due to the increase in turnover, primarily attributable to a full year's revenues of the Sigma haemostasis and Sigma speciality clinical chemistry product lines in 2003. This is partially offset by (i) the increase in cost of sales arising from these product lines of US\$8,710,000 and (ii) the increase in administration expenses due to the expansion of sales and marketing activities.

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

#### **2. Revenues**

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

	Year ended December 31,		% Change
	2003	2002	
	(US\$ '000)	(US\$ '000)	
<b>Revenues</b>			
Infectious diseases	35,127	37,829	(7)
Haemostasis	24,435	13,780	77
Clinical Chemistry	6,113	369	1,557
<b>Total</b>	<b>65,675</b>	<b>51,978</b>	<b>26</b>

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

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

2004. For further information relating to this matter please refer to Item 8 “Legal Proceedings”. The Company has decided to sell its products directly in the US and has increased its direct sales force in 2004 in the US to approximately 70 staff.

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

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

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

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

	Year ended December 31,		% Change
	2003	2002	
	(US\$ ‘000)	(US\$ ‘000)	
<b>Revenues</b>			
USA	36,299	33,512	8
Europe	19,982	11,899	68
Middle East /Africa	6,249	4,396	42
Other overseas	3,145	2,171	45
<b>Total</b>	<b>65,675</b>	<b>51,978</b>	<b>26</b>

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

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

### 3. Operating Expenses

The following table sets forth our operating expenses.

	Year ended December 31,		% Change
	2003	2002	
	(US\$ ‘000)	(US\$ ‘000)	
Revenues	65,675	51,978	26
Cost of sales	(32,877)	(25,690)	28
Research & development	(5,210)	(4,471)	17
Administrative expenses	(17,919)	(15,234)	18
Operating profit	<b>9,669</b>	<b>6,583</b>	<b>47</b>

#### Cost of sales

Trinity Biotech’s consolidated cost of sales increased 28% or by US\$7,187,000 from US\$25,690,000 for the year ended December 31, 2002 to US\$32,877,000 for the year ended December 31, 2003. The increase in cost of sales is primarily attributable to (i) the Sigma haemostasis and speciality clinical chemistry product lines which contributed an additional US\$8,710,000 to cost of sales, and (ii) the decrease in cost of sales associated with the decrease in revenues for infectious diseases sales categories of US\$1,523,000.

### Research and development

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

### Administrative expenses

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

	Year ended December 31,		Increase/(decrease) US\$'000	% Change
	2003 US\$'000	2002 US\$'000		
SG&A	17,063	12,848	4,215	33
Amortization	856	2,386	(1,530)	(64 )
<b>Total</b>	<b>17,919</b>	<b>15,234</b>	<b>2,685</b>	<b>18</b>

### SG&A

Administrative expenses increased 33% or by US\$4,215,000 from US\$12,848,000 to US\$17,063,000, this compares to revenue growth of 26% during the same period. The higher growth is attributable to the strengthening of the Group’s sales and marketing and administrative functions following the acquisitions of the Sigma haemostasis product line in August 2002 and the Sigma clinical chemistry product line in November 2002. In April 2002 Sigma Aldrich announced plans to sell the assets of its diagnostics business. When the Group took on these businesses in August and November 2002 a significant selling effort was required to retain the customer base.

Specifically the Group (i) opened a new sales and marketing facility in St. Louis, Missouri in October 2002, (ii) opened a direct sales and marketing operation in the UK in October 2002, and (iii) expanded its sales and marketing operations in Germany and Ireland to cater for the new product lines acquired in these acquisitions. This expansion occurred in Quarter 4, 2002 and 2003 represented the first full year’s operation of these expanded sales and marketing and administrative functions.

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

A detailed analysis of this increase in SG&A expenses of \$4,215,000 in 2003 is as follows:

- An increase of \$1,691,000 in the Group’s US operations, principally attributable to expansion of the Group’s sales and marketing capability within the US in order to reflect the Group’s expanding product range as noted above. 2003 represented the first full year of the Group’s central sales and marketing facility in St. Louis which was established in October 2002.
- An increase in SG&A expenses of \$1,613,000 in the Group’s operations in Germany. This is principally attributable to the inclusion of a full year’s SG&A expenses incurred at the Group’s haemostasis instrument manufacturing facility in Lemgo versus four months of such costs in 2002. This plant was acquired as part of the acquisition of the haemostasis business line from Sigma in August 2002.
- An increase of \$459,000 due to the inclusion of a full year of SG&A costs in the UK, compared to three months in 2002 following the establishment of a UK sales office in Oxfordshire in October 2002.
- The remaining increase of \$452,000 is principally attributable to;
  - (i) a strengthening of the Group’s central sales and marketing function, located in Bray, Ireland, in line with the broadening of the Group’s product range (\$1,392,000);
  - (ii) increased central administrative costs (\$895,000) in Bray, Ireland reflecting the significant increase in level of activity now being undertaken at Bray following the transfer of the manufacture of the Sigma and Biopool product lines to Bray during 2003 and increase in head office administrative functions reflective of the increasing size of the Group and the level of fundraising and acquisition activities; and,
  - (iii) As offset by foreign exchange gains of US\$1,835,000 incurred by the Group which arose during the year.

## **Amortization**

The decrease in amortisation of US\$1,530,000 from US\$2,386,000 to US\$856,000 is largely attributable to the release of negative goodwill of US\$1,572,000 arising from the Sigma haemostasis acquisition in 2002. Following the completion of the fair value exercises in 2003 in respect of the Sigma Haemostasis and Sigma Clinical Chemistry acquisitions made during 2002, amendments have been made to the fair values reported in the 2002 financial statements. The amendments relate to the identification of additional obligations of US\$928,881 assumed on the acquisition of the Sigma Haemostasis business, the completion of the fair value exercise on inventory acquired in both acquisitions resulting in the recognition of additional value of US\$3,031,420 and the recognition of additional costs of US\$67,595 relating to the Sigma Hemostasis acquisition and US\$97,479 relating to the Clinical Chemistry acquisition. In accordance with Irish GAAP, negative goodwill has been released to the profit and loss account as the related assets are utilised. Please refer to Note 22 “Acquisition of Businesses” in Item 18, “Financial Statements”, for full disclosure of these acquisitions and fair value adjustments.

## **4. Retained Profit**

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

	Year ended December 31,		
	2003	2002	
	(US\$ '000)	(US\$ '000)	% Change
<b>Operating Income</b>	<b>9,669</b>	<b>6,583</b>	<b>47</b>
Net interest charge	(619)	(601)	3
<b>Profit before tax and Share of operating loss in associated company and impairment</b>	<b>9,050</b>	<b>5,982</b>	<b>51</b>
Share of operating loss in associated company and impairment	(1,067)	(317)	237
<b>Profit before tax</b>	<b>7,983</b>	<b>5,665</b>	<b>41</b>
Tax	(2,186)	(768)	185
<b>Retained profit</b>	<b>5,797</b>	<b>4,897</b>	<b>18</b>

### *Net interest charge*

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

### *Share of loss in associated company and impairment*

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 €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. During 2003 HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading.

### *Taxation*

A tax charge of US\$2,186,000 was incurred in the year ended December 31, 2003. The comparable charge for 2002 was US\$768,000. This represented an increase in current tax in absolute terms of US\$1,278,000 and an increase in deferred tax of US\$140,000. The increase in current tax is primarily attributable to a higher corporation tax charge in Ireland in 2003 as the level of relief for losses carried forward enjoyed by the Company in previous years is no longer available. The utilization of losses carried forward also helped to increase the Group net deferred tax charge. For further details on the Group's tax charge please refer to Note 9 “Deferred Taxation” and Note 17 “Income Taxes” of the Notes to the Consolidated Financial Statements contained in Item 18 “Financial Statements” of this Form 20-F.

### *Retained Profit*

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

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

*The following compares our results in the year ended December 31, 2002 to those of the year ended December 31, 2001. Our analysis is divided as follows:*

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

#### **1. Overview**

In US dollars, our consolidated revenues increased by 40%; operating income grew by 116%; retained profit increased by 107% and cash flow from operating activities decreased by 37%.

Geographically, 64% of our sales were generated in the USA, 23% in Europe and 13% in the rest of the world.

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.

Our operating margin in 2002 was 12.7% of sales, an increase of 4.5% over the 8.2% of sales of the previous year. This is due to the increase in turnover, primarily attributable to the full integration of the Biopool acquisition and the additional contributions from the Sigma haemostasis and Sigma speciality clinical chemistry product lines, of US\$14,149,000. This is partially offset by (i) the increase in cost of sales arising from these product lines of US\$7,093,000; (ii) the increase in research and development of US\$1,691,000 mainly arising from the acquisitions made in 2001 and 2002 and (iii) the increase in administration costs due to the increase in the direct sales force in the US, Germany and the UK.

As a result of these factors, operating income increased by US\$3,535,000 to US\$6,583,000.

#### **2. Revenues**

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

	<b>Year ended December 31,</b>		<b>% Change</b>
	<b>2002</b>	<b>2001</b>	
	<b>(US\$ '000)</b>	<b>(US\$ '000)</b>	
<b>Revenues</b>			
Infectious diseases	37,829	37,076	2
Haemostasis	13,780	-	-
Clinical Chemistry	369	-	-
<b>Total</b>	<b>51,978</b>	<b>37,076</b>	<b>40</b>

Trinity Biotech's consolidated revenues for the year ended December 31, 2002 were US\$51,978,000 compared to consolidated revenues of US\$37,076,000 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\$753,000 from the organic growth of existing product lines, US\$9,618,000 from the full integration of the Biopool acquisition which was acquired in December 2001, the added contribution of US\$4,162,000 from the Sigma haemostasis product line from August 2002 and US\$369,000 from the introduction of the Sigma speciality clinical chemistry product line with effect from December 2002.



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

	Year ended December 31,		% Change
	2002	2001	
	(US\$ '000)	(US\$ '000)	
<b>Revenues</b>			
USA	33,512	25,058	34
Europe	11,899	6,880	73
Middle East /Africa	4,396	3,900	13
Other overseas	2,171	1,238	75
<b>Total</b>	<b>51,978</b>	<b>37,076</b>	<b>40</b>

The major segmental changes occurred in the US and Europe regions, with increases of US\$8,454,000 and US\$5,019,000 respectively. These increases are largely attributable to the increase in haemostasis revenues following the inclusion of a full year's revenues from the Biopool product line and five months of revenue from the Sigma haemostasis product line, acquired in August 2002.

### 3. Operating Expenses

The following table sets forth our operating expenses.

	Year ended December 31,		% Change
	2002	2001	
	(US\$ '000)	(US\$ '000)	
Revenues	51,978	37,076	40
Cost of sales	(25,690)	(18,050)	42
Research & development	(4,471)	(2,780)	61
Administrative expenses – normal	(15,234)	(9,563)	59
Administrative expenses – exceptional	-	(3,635)	(100)
Operating profit	<b>6,583</b>	<b>3,048</b>	<b>116</b>

#### Cost of Sales

Trinity Biotech's consolidated cost of sales increased by US\$7,640,000 from US\$18,050,000 for the year ended December 31, 2001 to US\$25,690,000 for the year ended December 31, 2002. The increase in cost of sales is primarily attributable to (i) the Biopool acquisition which added US\$4,832,000 to cost of sales, (ii) the Sigma haemostasis and speciality clinical chemistry product lines which contributed an additional US\$2,261,000 to cost of sales, and (iii) the increased cost of sales from organic sales growth which contributed an additional US\$516,000 to cost of sales in 2002. The balance of the increase of US\$31,000 is attributable to increased overhead costs and is principally driven by inflation.

#### Research and Development

Research and development ("R&D") expenditure increased to US\$4,471,000 in 2002. This represents 8.6% of consolidated revenues and is comparable to the R&D spend in 2001 of US\$2,780,000 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.

#### Administrative Expenses

Normal administrative expenses for the year ended December 31, 2002 amounted to US\$15,234,000 compared to US\$9,563,000 for the year ended December 31, 2001. The following table outlines the breakdown of administrative expenses compared to a similar breakdown for 2001.

	Year ended December 31,		Increase/(decrease ) US\$'000	% Change
	2002 US\$'000	2001 US\$'000		
SG&A – normal	12,848	7,561	5,287	70
Amortization	2,386	2,002	384	19
Administrative expenses - exceptional	-	3,635	(3,635)	(100)
<b>Total</b>	<b>15,234</b>	<b>13,198</b>	<b>2,036</b>	<b>15</b>

#### **SG&A**

SG&A costs in normal administrative expenses amount to US\$12,848,000 in 2002, an increase from US\$7,561,000 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 and an expansion of our sales and marketing effort in Ireland. As described above this was necessitated by the acquisitions of the Sigma product lines completed in August 2002 and November 2002.

#### **Amortization**

Amortization increased to US\$2,386,000 in 2002 compared to US\$2,002,000 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.

#### **Administrative Expenses - Exceptional**

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 of the Biopool haemostasis 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. The restructuring programme at Bartels was implemented during the first two quarters of 2001 and the Seattle facility was closed on June 8, 2001.

#### **4. Retained Profit**

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

	Year ended December 31,		% Change
	2002 (US\$ '000)	2001 (US\$ '000)	
<b>Operating Income</b>	<b>6,583</b>	<b>3,048</b>	<b>116</b>
Net interest charge	(601)	(396)	52
<b>Profit before tax and share of operating loss in associated company</b>	<b>5,982</b>	<b>2,652</b>	<b>126</b>
Share of operating loss in associated company	(317)	(269)	18
<b>Profit before tax</b>	<b>5,665</b>	<b>2,383</b>	<b>138</b>
Tax	(768)	(16)	4,700
<b>Retained profit</b>	<b>4,897</b>	<b>2,367</b>	<b>107</b>

#### **Net Interest Charge**

Net interest increased to US\$601,000 in 2002 compared to US\$396,000 in 2001. The increased level of interest reflects the Company's higher level of net debt during the year.

#### **Taxation**

A tax charge of US\$768,000 was incurred in the year ended December 31, 2002. The comparable charge for 2001 was US\$16,000. The tax charge in previous years has been low due to the effect of net operating losses forward. In 2002 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. For further details on the Group's tax charge please refer to Note 9 "Deferred Taxation" and Note 17 "Income Taxes" of the Notes to the Consolidated Financial Statements contained in Item 18 "Financial Statements" of this Form 20-F.

#### *Retained profit*

Retained profit as a percentage of consolidated revenues increased from 6.4% to 9.4%, principally due to the acquisition of the Sigma haemostasis and Sigma speciality clinical chemistry product lines and the full integration of the Biopool haemostasis product lines.

#### ***Liquidity and Capital Resources***

##### ***Financing***

In December 1999, the Company completed a private placement of (i) US\$3,500,000 principal amount of 7.5% Convertible Debentures and (ii) 483,701 warrants (the "First Warrants") to purchase 'A' Ordinary Shares of the Company, which resulted in aggregate gross proceeds to the Company of US\$3,500,000. The debentures were convertible into 'A' Ordinary Shares of the Company at a price of US\$1.80. During 2000, US\$1,875,000 of the US\$3,500,000 principal amount of the debenture was converted into 1,041,667 Class 'A' Ordinary Shares of the Company. During 2001, US\$625,000 of the remaining balance of the debenture was redeemed. The remaining balance of the principal amount was rolled over in November 2002 at an annual interest rate of 6% and a conversion price of US\$1.50. During 2003 these debentures were fully converted into 666,667 Class 'A' Ordinary Shares of the Company.

In March 2000, Trinity Biotech 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. 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 December 2000, the assets 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 Biotech 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 of the Biopool haemostasis 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 haemostasis division of Sigma Diagnostics for a total consideration of US\$1,428,001. The consideration was satisfied in cash. On November 27, 2002, the Company also acquired the speciality clinical chemistry product line from Sigma Diagnostics for a total consideration of US\$4,412,372 satisfied in cash and deferred consideration. The cash consideration was partly financed by the issue of US\$2.5m of convertible debentures. The deferred consideration of US\$1,810,000 was paid during 2003.

In November 2002, the Company completed a private placement of (i) US\$2,500,000 principal amount of 5.25% convertible debentures and (ii) 50,000 warrants (the "Second Warrants") to purchase 'A' Ordinary Shares of the Company (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. During 2003, the debenture was fully converted into 1,666,667 Class 'A' Ordinary Shares of the Company.

In relation to the First Warrants, 333,701 were each exercisable to purchase one 'A' Ordinary Share of the Company at US\$1.74 per share and the remaining 150,000 were each exercisable to purchase one 'A' Ordinary Share of the Company at US\$1.80 per share. 100,000 of these warrants were exercised to purchase 'A' Ordinary Shares in the Company in 2000. The balance of these 150,000 warrants expired unexercised on June 25, 2002. During 2003 133,701 of the remaining First Warrants were exercised and since year end a further 100,000 of these warrants have been exercised, the balance of these warrants expire in December 2004. The Second Warrants are each exercisable to purchase one 'A' Ordinary Share of the Company at US\$1.50 and will expire in November 2007.

In June 2003, Trinity Biotech completed a new US\$10,000,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Ltd. The new facility consists of a five year term loan of US\$6,000,000 and a one year revolver of US\$4,000,000. This facility was partly used to repay existing loans and the loan notes payable to Xtrana, Inc. At December 31, 2003, the term loan was fully drawn and US\$3,000,000 of the revolver had been drawn down.

In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$3.55. In December 2003, US\$6,355,000 of the US\$20,000,000 principal amount of the debenture was converted into 1,790,141 Class 'A' Ordinary Shares of the Company. Since the year end, a further US\$427,500 of the principal amount of the debenture has been converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July placement, convertible notes in the aggregate principal amount of up to US\$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US\$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$4.

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

#### **Cash management**

As at December 31, 2003, Trinity Biotech's consolidated cash and cash equivalents were US\$20,563,000. This compares to cash and cash equivalents of US\$5,808,000 at December 31, 2002. The increase is due to cash inflow of US\$4,176,000 from operations, the issue of share capital, the drawdown of financial facilities and the issue of US\$20 million convertible debentures, offset by the repayment of bank borrowings and cash payments for the purchase of businesses and fixed assets. This resulted in an increase in cash and liquid resources of US\$14,755,000 during the year.

A significant portion of the Company's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Company's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Company pursues a treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. The Company's current hedging policy is to cover a portion of its expenses forward for a minimum of three months. The Company expects that its forward contracts as at December 31, 2003 will have a positive impact on the cashflows of the business. At December 31, 2003 forward contracts with a carrying value of US\$Nil had a fair value of US\$3,121,000 (asset) and US\$2,775,000 (liability) respectively.

As at December 31, 2003, year end borrowings were US\$26,271,000 and cash in hand was US\$20,563,000. For a more comprehensive discussion of the Company's level of borrowings at the end of 2003, the maturity profile of the borrowings, the company's use of financial instruments, its currency and interest rate structure and its funding and treasury policies please refer to Item 11 "Qualitative and Quantitative Disclosures about Market Risk".

#### **Contractual obligations**

The following table summarizes our minimum contractual obligations and commercial commitments, as of December 31, 2003:

<b>Contractual Obligations</b>	<b>Payments due by Period</b>				
	Total US\$'000	less than 1 year	1-3 Years	3-5 Years	more than 5 years
		US\$'000	US\$'000	US\$'000	US\$'000
Long-term debt obligations	8,911	4,177	2,355	2,379	-
Capital (finance) lease obligations	1,014	264	425	325	-
Operating lease obligations	26,906	2,182	3,798	2,688	18,238
Other long-term liabilities reflected on the company's balance sheet under Irish GAAP	13,225	1,191	10,587	1,439	8
<b>Total</b>	<b>50,056</b>	<b>7,814</b>	<b>17,165</b>	<b>6,831</b>	<b>18,246</b>

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

#### ***Impact of Inflation***

Although Trinity Biotech's operations are influenced by general economic trends, Trinity Biotech does not believe that inflation had a material effect on its operations for the periods presented. Management believes, however, that continuing national wage inflation in Ireland and the impact of inflation on costs generally will result in a sizeable increase in the Irish facility's operating costs in 2004.

#### ***Impact of Currency Fluctuation***

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

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

#### ***Exchange Rates***

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

#### ***Off-Balance Sheet Arrangements***

Not applicable

#### ***Research and Products under Development***

##### **History**

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

Hepatitis B

HIV (recombinant protein format)

H. pylori

Malaria

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

##### **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 has developed HSV-1 and HSV-2 specific tests to complement its HSV-1/2 tests. HSV-2 causes more serious complications to pregnant women and HSV-2 positive patients are more susceptible to contracting HIV. These type specific tests utilize recombinant proteins rather than the less specific viral lysates in the older generations of these products. This work was completed in the latter half of 2003 and the Company is now seeking approval for these tests from the FDA.

###### ***Development of microtitre plate assay for the detection of Lyme IgG and IgM***

Prompted by the company's successful Western Blots, development has commenced on two new elisas to specifically detect Lyme IgG and IgM.

#### *Adaptation of assays to Microtrak XL units*

During 1998, Trinity Biotech acquired the Microtrak Chlamydia business from Dade Behring Inc. As a result of the acquisition, Trinity Biotech acquired instruments to run Microtitre plate tests. These instruments only ran Chlamydia EIA tests and Trinity Biotech 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 Biotech's ability to sell these tests.

#### *Redevelopment of the Captia Products*

The re-development of the Captia Syphilis IgM product commenced in 2002. This re-optimization includes the provision of a stable freeze-dried conjugate and the introduction of a stable one component, ready-to-use substrate.

#### *Rapid Development Group*

##### *Development of UniGold™ Recombigen HIV (2000-2003)*

This represents a modification of Trinity Biotech's original UniGold HIV Test using recombinant protein antigens rather than peptides in the test. It is a single use rapid test for the detection of antibodies to HIV-1 in plasma, serum and whole blood. The test is intended for use as an aid in diagnosis, in settings where the rapid diagnosis of HIV infection can ensure early initiation of antiretroviral therapy. The test can be performed in 10 minutes, enabling health care providers to supply preliminary results to patients at the time of testing, potentially increasing the overall effectiveness of counselling and testing programs.

The recombinant proteins are manufactured by Trinity Biotech and allow the UniGold™ HIV Test to be produced in a more cost-effective manner. Development of this product has been completed. All clinical and non-clinical trials have been concluded with a sensitivity of 100% and a specificity of 99.7%. On December 29, 2003 the company announced that it had received approval from the U.S. Food and Drug Administration (FDA) to market its Uni-Gold Recombigen™ HIV test in the United States.

##### *Development of UniGold™ Influenza A and B test.*

A project to develop a rapid test for Influenza A and B using UniGold™ technology commenced in 2002. This test will allow for the rapid qualitative detection of influenza A and B directly from nasal swab, nasal wash and/or nasal aspirate specimens. It is an immunochromatographic test using UniGold™ lateral flow technology and is intended for use as an aid in the rapid diagnosis of acute influenza virus infection. The UniGold™ Influenza A and B test employs highly sensitive monoclonal antibodies that are specific for influenza antigens.

#### *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 were launched in the first quarter of 2003.

##### *HIV Western Blot*

Trinity Biotech has developed a western blot test for detecting antibodies to HIV. This product is expected to be ready for commencement of trials in the USA in 2004 which will run for approximately 6 months. This product is available for evaluation use outside of the USA.

#### *Immunofluorescent Assay Development Group*

The development department in Trinity Biotech 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.

##### *Influenza A/B DFA kit.*

This is a test for the detection of Influenza A and B in both patient specimens and culture samples. It employs a one step method with a total test time of 15 minutes, allowing the differentiation of Influenza A from Influenza B.

##### *Influenza/RSV DFA kit.*

This is combined screening test for Influenza A, Influenza B and RSV (Respiratory syncytial virus) in both direct patient specimens and cultured samples. The test employs a one step method with a total test time of 15 minutes. Such a product will complement the Influenza A/B DFA kit and the existing RSV DFA kit.

For the 12 months ended December 31, 2003, the Company spent US\$5,210,039 on research and development. This expenditure is broken down into salary costs, reagents, consultancy fees and other related costs. The comparable net expenditure in 2002 and 2001 was US\$4,470,745 and US\$2,779,729 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**

<i>Name</i>	<i>Age</i>	<i>Title</i>
Ronan O’Caoimh	48	Chairman of the Board of Directors Chief Executive Officer
Brendan K. Farrell	56	Director, President
Jim Walsh Ph.D.	45	Director, Chief Operating Officer
Rory Nealon	36	Director, Chief Financial Officer, Company Secretary
Denis R. Burger, Ph.D.	60	Non Executive Director
Peter Coyne	44	Non Executive Director

#### ***Board of Directors***

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

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

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

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

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

### *Compensation of Directors and Officers*

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

<i>Director</i>	Salary/ <u>Benefits</u>	Performance related <u>bonus</u>	Defined contribution <u>pension</u>	Total <u>2003</u>	Total <u>2002</u>
US\$					
Ronan O'Caoimh	314,667	60,190	48,092	422,949	421,942
Brendan Farrell	232,122	40,127	21,327	293,576	297,892
Rory Nealon	131,541	-	13,350	144,891	-
Jim Walsh	<u>232,695</u>	<u>40,127</u>	<u>21,327</u>	<u>294,149</u>	<u>284,408</u>
	<u>911,025</u>	<u>140,444</u>	<u>104,096</u>	<u>1,155,565</u>	<u>1,004,242</u>
<i>Non-executive director</i>	<u>Fees</u>			Total <u>2003</u>	Total <u>2002</u>
US\$					
Denis R. Burger	20,000			20,000	10,000
Peter Coyne	<u>20,000</u>			<u>20,000</u>	<u>10,000</u>
	<u>40,000</u>			<u>40,000</u>	<u>20,000</u>



### ***Board Practices***

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

In accordance with the Articles of Association of the Company, Mr. Denis Burger will retire by rotation and, being eligible, offer himself for re-election at the Annual General Meeting of the Company, which will be held on May 17, 2004.

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, 2003, Trinity Biotech had 624 employees (2002: 580) consisting of a research director and 40 research scientists and technicians, 430 manufacturing and quality assurance employees, and 153 finance, administration and marketing staff (2002: a research director and 40 research scientists and technicians, 389 manufacturing and quality assurance employees, and 150 finance, administration and marketing staff). Trinity Biotech's future hiring levels will depend on the growth of revenues.

The geographic spread of the Company's employees was as follows: 318 in Bray, Co. Wicklow, Ireland, 93 in Germany, 9 in Sweden, 3 in the United Kingdom and 201 in its US operations.

### ***Stock Option Plan***

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

The exercise price of options is determined by the compensation committee. The term of an option will be determined by the compensation committee, provided that the term may not exceed seven years from the date of grant. All options will terminate 90 days after termination of the option holder's employment, service or consultancy with Trinity Biotech (or one year after such termination because of death or disability). Under certain circumstances involving a change in control of Trinity Biotech, the committee may accelerate the exercisability and termination of the options. As of February 29, 2004, 4,838,541 of the options outstanding were held by directors and officers of Trinity Biotech.

As of February 29, 2004 the following options were outstanding:

	Number of 'A' Ordinary Shares Subject to Option	Range of Exercise Price per Share
Total Options Outstanding	7,409,241	US\$0.81-US\$5.00

In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary Shares at prices ranging from \$1.50 to \$2.75 to agents who were involved in the Company's Private Placements in 1994, 1995 and 1999 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was granted to a consultant of the Company. Since the year end, the Company has completed a private placement, as part of this the investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US\$5.25 per share and the agent received 200,000 warrants to purchase 200,000 Class 'A' Ordinary Shares of the Company at an exercise price of US\$5.25. As of February 29, 2004 there were warrants to purchase 1,417,324 Class 'A' Ordinary Shares in the Company outstanding.

## Item 7

### *Major Shareholders and Related Party Transactions*

As of February 29, 2004 Trinity Biotech has outstanding 51,766,449 'A' Ordinary shares and 700,000 'B' Ordinary shares. Such totals exclude 8,826,565 shares issuable upon the exercise of outstanding options and warrants.

The following table sets forth, as of February 29, 2004, the Trinity Biotech 'A' Ordinary Shares and 'B' Ordinary Shares beneficially held by (i) each person known by Trinity Biotech to beneficially hold 5% or more of such shares, (ii) each director and officer of Trinity Biotech, and (iii) all officers and directors as a group. Except as otherwise noted, all of the persons and groups shown below have sole voting and investment power with respect to the shares indicated. The Company is not controlled by another corporation or government.

	Number of 'A' Ordinary Shares Beneficially <u>Owned</u>	Percentage Outstanding 'A' Ordinary <u>Shares</u>	Number of 'B' Ordinary Shares Beneficially <u>Owned</u>	Percentage Outstanding 'B' Ordinary <u>Shares</u>	Percentage Total Voting <u>Power</u>
Ronan O'Caoimh	1,785,321 (1)	3.4%	0	0	3.3%
Brendan Farrell	1,064,135 (2)	2.0%	0	0	2.0%
Rory Nealon	100,000 (3)	0.2%	0	0	0.2%
Jim Walsh	1,099,615 (4)	2.1%	0	0	2.0 %
Denis R. Burger	391,000 (5)	0.8%	0	0	0.7%
Peter Coyne	13,333 (6)	0.03%	0	0	0.03%
Potenza Investments, Inc ("Potenza") Statenhof Building, Reaal 2A 23 50AA Leiderdorp, Netherlands	0	0	500,000 (7)	71.4%	1.9%
Smithfield Fiduciary LLC	3,381,316 (8)	6.24%	0	0	6.24%
Officers and Directors as a group (6 persons)	4,453,404(1)(2)(3)(4)(5)(6)	8.2%	0	0	8.0%

- (1) Includes 914,666 shares issuable upon exercise of options.
- (2) Includes 1,011,875 shares issuable upon exercise of options.
- (3) Includes 100,000 shares issuable upon exercise of options.
- (4) Includes 680,000 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.
- (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 Biotech 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 Smithfield Fiduciary LLC on March 8, 2004. The filing discloses voting and dispositive power over 941,176 "A" Ordinary Shares and US\$9 million of 3% convertible notes convertible into 2,440,140 "A" Ordinary Shares. The filing excludes dispositive power over 188,235 warrants; the percentage total voting power including these warrants would be 6.56%.

#### ***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 €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 €12,860 per annum over adjacent lands with JRJ. On November 20, 2002, the Company entered into an agreement for lease with JRJ for offices that have been constructed on part of these lands. The annual rent of €365,760 (US\$459,054) is payable from January 1, 2004. Independent valuers have advised the Company that the rent fixed in respect of the Current Extension, the agreement for lease and the lease of adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr. O'Caomh and Dr. Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Company can meet its ongoing requirements for premises.

## **Item 8**

#### ***Financial Statements***

#### ***Legal Proceedings***

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

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

On June 16, 2003 Trinity Biotech and Xtrana settled this litigation. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the amounts due on two promissory notes of US\$1,166,200 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 Biotech as of May 31, 2003 pursuant to a Letter Agreement, dated December 20, 2001, between Trinity Biotech and Xtrana, relating to a third party. The total amount of the settlement payment made by Trinity Biotech to Xtrana was US\$1,505,942.

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 Biotech to Xtrana, the litigation, the security agreements entered into between the parties, the Asset Purchase Agreement made as of November 9, 2001 and any other matter whatsoever, except for the parties executory obligations as set forth in the settlement agreement.

### ***Dispute Regarding the Distribution Agreement with Inverness Medical Innovations Inc.***

In December 2003, the Company filed an action against Inverness Medical for declaratory judgment and breach of contract. Inverness Medical, through its affiliate, Wampole Laboratories, has acted as exclusive distributor for certain of Trinity Biotech's infectious disease products in the US. This exclusivity is due to end on September 30, 2004, at which time it had been agreed that both Trinity Biotech and Inverness Medical would sell the products under their respective labels. The suit alleges that Inverness Medical is attempting to convert customers from the Trinity Biotech product to a product manufactured by a competitor by claiming that the Trinity Biotech product is unavailable and being discontinued. The suit alleges that, under the terms of the contract, the Company is entitled to sell direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. With immediate effect, the Company has exercised this right.

In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent the Company from selling direct in the US of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. Please see also Item 4, Distribution Agreement between Trinity Biotech USA and Carter Wallace.

## **Item 9**

### ***The Offer and Listing***

Trinity Biotech's American Depository Shares ("ADS's") are listed on the NASDAQ Small Cap Market under the symbol "TRIB". The Company's Class B Warrant (symbol "TRIZF"), expired on February 28, 1999. Each ADS represents one 'A' Ordinary Share of the Company. The Company's 'A' Ordinary Shares are also listed and trade on the Irish Stock Exchange. The Company's depository bank for the ADS's is The Bank of New York. On February 27, 2004, the reported closing sale price of the ADS's was US\$4.03 per ADS. The following tables set forth the range of quoted high and low sale prices of Trinity Biotech's ADS, and Class B Warrants for (a) the years ended December 31, 1999, 2000, 2001, 2002 and 2003; (b) the quarters ended March 31, June 30, September 30 and December 31, 2002; March 31, June 30, September 30 and December 31, 2003; and (c) the months of March, April, May, June, July, August, September, October, November and December 2003 and January and February 2004 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.

<b>Year Ended December 31</b>	<b>ADS's</b>		<b>Class B</b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
1999	\$2.47	\$1.16	\$0.12	\$0.03
2000	\$7.59	\$1.69		
2001	\$3.22	\$0.97		
2002	\$1.86	\$0.89		
2003	\$6.72	\$1.25		
<b>2002</b>				
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		
<b>2003</b>				
Quarter ended March 31	\$2.44	\$1.25		
Quarter ended June 30	\$3.50	\$2.09		
Quarter ended September 30	\$4.01	\$2.26		
Quarter ended December 31	\$6.72	\$2.61		

<b>Month Ended</b>		
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
October 31, 2003	\$4.41	\$3.55
November 30, 2003	\$3.79	\$3.10
December 31, 2003	\$6.72	\$2.61
January 31, 2004	\$5.99	\$4.25
February 29, 2004	\$4.75	\$3.75

The number of record holders of Trinity Biotech's ADS's as at February 29, 2004 amounts to 1,690, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clientele (with each such brokerage house and/or clearing house being considered as one holder).

## **Item 10**

### *Memorandum and Articles of Association*

#### *Objects*

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

#### *Powers and Duties of Directors*

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

A director is entitled to vote and be counted in the quorum in respect of certain arrangements in which he is interested (in the absence of some other material interest). These include the giving of a security or indemnity to him in respect of money lent or obligations incurred by him for the Company, the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company for which he has assumed responsibility, any proposal concerning an offer of shares or other securities in which he may be interested as a participant in the underwriting or sub-underwriting and any proposal concerning any other company in which he is interested provided he is not the holder of or beneficially interested in 1% or more of the issued shares of any class of share capital of such company or of voting rights.

The Board may exercise all the powers of the Company to borrow money but it is obliged to restrict these borrowings to ensure that the aggregate amount outstanding of all monies borrowed by the Company does not, without the previous sanction of an ordinary resolution of the Company, exceed an amount equal to 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.

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. 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.

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

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

#### ***Material Contracts***

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

#### ***Exchange Controls and Other Limitations Affecting Security Holders***

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

The Financial Transfers Act, 1992 was enacted in December 1992. This Act gives power to the Minister of Finance of the Republic of Ireland to make provision for the restriction of financial transfers between the Republic of Ireland and other countries. Financial transfers are broadly defined and include all transfers, which would be movements of funds within the meaning of the treaties governing the European Communities. The acquisition or disposal of ADS's representing shares issued by an Irish incorporated company and associated payments may fall within this definition. In addition, dividends or payments on redemption or purchase of shares, interest payments, debentures or other securities in an Irish incorporated company and payments on a liquidation of an Irish incorporated company would fall within this definition. Currently, orders under this Act prohibit any financial transfer to or by the order of or on behalf of residents of the Federal Republic of Yugoslavia, Federal Republic of Serbia, Angola and Iraq, any financial transfer in respect of funds and financial resources belonging to the Taliban of Afghanistan (or related terrorist organisations), financial transfers to the senior members of the Zimbabwean government and financial transfers to any persons, groups or entities listed in EU Council Decision 2002/400/EC of June 17, 2002 unless permission for the transfer has been given by the Central Bank of Ireland.

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

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

Any transfer of, or payment for, an ordinary share or ADS involving the government of any country which is currently the subject of United Nations sanctions, any person or body controlled by any government or country under United Nations sanctions or any persons or body controlled acting on behalf of these governments of countries, may be subject to restrictions required under these sanctions as implemented into Irish law. 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 all as of the date of this annual report. Taxation laws are subject to change, from time to time, and no representation is or can be made as to whether such laws will change, or what impact, if any, such changes will have on the statements contained in this summary. No assurance can be given that proposed amendments will be enacted as proposed, or that legislative or judicial changes, or changes in administrative practice, will not modify or change the statements expressed herein.

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

This summary does not discuss all aspects of Irish and US federal income taxation that may be relevant to a particular holder of Trinity Biotech ADRs in light of the holder's own circumstances or to certain types of investors subject to special treatment under applicable tax laws (for example, financial institutions, life insurance companies, tax-exempt 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 administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. 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%. Dividends received by a US Holder with respect to the underlying shares represented by the holder's ADRs should qualify for the 15% 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 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.

For US federal income tax purposes, a foreign corporation is treated as a "passive foreign investment company" (or PFIC) in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable "look through" rules, either (1) at least 75% of the corporation's gross income is passive income or (2) at least 50% of the average value of the corporation's assets is attributable to assets that produce passive income or are held for the production of passive income. Based on the nature of its present business operations, assets and income, Trinity Biotech believes that it is not currently subject to treatment as a PFIC. However, no assurance can be given that 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% 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 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 Biotech is a FPHC would have to include in the holder's gross income for that year the holder's *pro rata* share of Trinity Biotech's "undistributed foreign personal holding company income." The amount so included would not qualify for taxation at the 15% reduced tax rate applicable to dividend income, and thus would be subject to US federal income tax at regular ordinary income rates. If Trinity Biotech were to distribute in a subsequent tax year any undistributed foreign person holding company income so taxed, the amount so distributed would not be counted as part of an "excess distribution" under the PFIC rules discussed above.

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

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

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

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

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

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

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

### ***Republic of Ireland Taxation***

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

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

Solely for the purposes of this summary of Irish Tax Considerations, a "U.S. Holder" means a holder of ordinary shares or ADSs evidenced by ADRs that (i) beneficially owns the ordinary shares or ADSs registered in their name; (ii) is resident in the United

States for the purposes of the Republic of Ireland/United States Double Taxation Convention (the Treaty); (iii) in the case of an individual holder, is not also resident or ordinarily resident in Ireland for Irish tax purposes; (iv) in the case of a corporate holder, is not a resident in Ireland for Irish tax purposes and is not ultimately controlled by persons resident in Ireland; and (v) is not engaged in any trade or business and does not perform independent personal services through a permanent establishment or fixed base in Ireland.

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

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

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

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

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

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

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

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

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

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

The DWT rate applicable to U.S. Holders is reduced to 5% under the terms of the Treaty for corporate U.S. Holders holding 10% or more of our voting shares, and to 15% for other U.S. Holders. While this will, subject to the application of Article 23 of the Treaty, generally entitle U.S. Holders to claim a partial refund of DWT from the Irish Revenue Commissioners, U.S. Holders will, in most circumstances, likely prefer to seek a full refund of DWT under Irish domestic legislation.

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

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

#### *Disposals of Ordinary Shares or ADRs*

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

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

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

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

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

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

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

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

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

A gift or inheritance of ordinary shares or ADRs will be within the charge to capital acquisitions tax, regardless of where the 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% on the taxable value of the gift or inheritance above a tax-free threshold. This tax-free threshold is determined by the amount of the current benefit and of previous benefits, received within the group threshold since December 5, 1991, which are within the charge to the capital acquisitions tax and the relationship between the former holder and the successor. Gifts and inheritances between spouses are not subject to the capital acquisitions tax. Gifts of up to €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.

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

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

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

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.

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

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

### **Dividend Policy**

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

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

## **Item 11**

### **Qualitative and Quantitative Disclosures About Market Risk**

#### **Qualitative information about Market Risk**

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

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

The main risks arising from the 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.

The Group borrows in appropriate currencies at fixed and floating rates of interest. Year-end borrowings, net of cash, totalled US\$5,707,384 (2002: US\$8,644,320) at interest rates ranging from 2.15% to 7.42% and including US\$14,134,621 of fixed rate debt at interest rates ranging from 3% to 5.50% (2002: US\$3,964,683 at interest rates ranging from 5% to 7.50%). In broad terms, a one-percentage point increase in interest rates would decrease the net interest charge by US\$82,544 (2002: increase by US\$46,796).

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, 34% of gross debt fell due for repayment within one year.

A significant portion of the Company's activities are conducted in US Dollars. The primary foreign exchange risk arises from the fluctuating value of the Company's Euro expenses as a result of the movement in the exchange rate between the US Dollar and the Euro. Arising from this, the Company pursues a treasury policy which aims to sell US Dollars forward to match a portion of the uncovered Euro expenses at exchange rates lower than budgeted exchange rates. The Company's current hedging policy is to cover forward a portion of its exposure for a minimum of three months. Under US GAAP, US\$67,682 was recognised in the income statement in respect of gains on the fair value of derivative instruments (2002: US\$161,975). 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\$585,758 at December 31, 2003.

## Quantitative information about Market Risk

### Interest rate sensitivity

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

The Company estimates that the maximum effect of a rise of one percentage point in one of the principal interest rates to which the Company is exposed, without making any allowance for the potential impact of such a rise on exchange rates, would be an increase in profit before tax for 2003 of less than two per cent.

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

<i>Maturity before December 31</i>	<i>2005</i>	<i>2006</i>	<i>2007</i>	<i>2008</i>	<i>After 2008</i>	<i>Total</i>	<i>Fair Value*</i>
US\$000 (except percentages)							
<b>Long-term debt</b>							
Variable rate – US\$000	4,666					4,666	4,666
Average interest rate	2.41%					2.41%	
Fixed rate – US\$000	5,493	5,474	1,542	184	-	12,693	12,693
Average interest rate	3.08%	3.08%	3.21%	4.78%	-	3.12%	

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

### Exchange rate sensitivity

At year-end 2003, less than 6% of the Company's US\$80,261,927 net worth (shareholders' equity) was denominated in currencies other than the US Dollar, principally the Euro.

A strengthening or weakening of the US Dollar by 10% against all the other currencies in which the Company operates would not materially reduce the Company's 2003 year-end net worth.

## Item 12

### *Description of Securities Other than Equity Securities*

Not applicable.



## Part II

### Item 13

#### *Defaults, Dividend Arrearages and Delinquencies*

Not applicable.

### Item 14

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

Not applicable.

### Item 15

#### *Control Procedures*

In the fourth quarter of this annual report period, we carried out an evaluation, under the supervision and with the participation of our senior management, including Chief Executive Officer, Ronan O’Caoimh, and Chief Financial Officer, Rory Nealon, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13(a)-14(c) of the Securities Exchange Act of 1934. Disclosure controls and procedures are designed to ensure that the material financial and non-financial information required to be disclosed in this Form 20-F filed with the SEC is recorded, processed, 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 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, 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

#### *Audit Committee Financial Expert*

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

#### *Code of Ethics*

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

#### *Principal Accounting fees and services*

##### *Fees Paid to Independent Public Accountants*

The following table sets forth, for each of the years indicated, the fees paid to our independent public accountants and the percentage of each of the fees out of the total amount paid to the accountants.

Services Rendered	Year Ended December 31,			
	2002		2003	
	Fees (US\$)	Percentages	Fees (US\$)	Percentages
Audit	190,000	90%	421,207	66%
Audit-related	-	-	*208,557	33%
Tax	-	-	4,986	1%
Other	<u>20,000</u>	10%	=	
Total	<u>210,000</u>		<u>634,750</u>	

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

### ***Pre-Approval Policies and Procedures***

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

### ***Exemptions from the Listing Requirements and Standards for Audit Committee***

Not applicable.

### ***Purchase of equity securities by the issuer and affiliates and purchasers***

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

<b>Period in 2003</b>	<b>Total Number of shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
January	-	-	-	3,925,322
February	-	-	-	3,925,322
March	-	-	-	3,925,322
April	-	-	-	3,925,322
May	-	-	-	3,925,322
June	-	-	-	4,183,462
July	-	-	-	4,183,462
August	-	-	-	4,183,462
September	-	-	-	4,183,462
October	-	-	-	4,183,462
November	-	-	-	4,183,462
December	-	-	-	4,183,462

## **Part III**

### **Item 17**

#### *Financial Statements*

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

### **Item 18**

## REPORT OF INDEPENDENT AUDITORS

To: The Board of Directors of Trinity Biotech plc

We have audited the accompanying consolidated balance sheets of Trinity Biotech plc as of December 31, 2003 and 2002, 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, 2003. Our audits also included the financial statement schedule included at Item 18. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with Irish Auditing Standards issued by the Auditing Practices Board and auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Trinity Biotech plc at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the Republic of Ireland, which differ in certain respects from accounting principles generally accepted in the United States of America (see note 28 of Notes to the Consolidated Financial Statements). Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Dublin, Ireland  
March 31, 2004

Ernst & Young  
Registered Auditors

## CONSOLIDATED BALANCE SHEETS

	<i>Notes</i>	<i>As at December 31 2003 US\$</i>	<i>As at December 31 2002 US\$</i>
<b>ASSETS</b>			
Inventories	2	30,554,618	20,851,459
Accounts receivable, net and prepayments	3	13,912,889	12,676,756
Cash and cash equivalents		20,563,418	5,807,514
		<hr/>	<hr/>
		65,030,925	39,335,729
Intangible assets, net	4	38,850,780	39,511,786
Property, plant and equipment, net	5	13,659,680	9,883,681
Financial assets	6	-	1,067,262
Other assets	3	550,104	-
TOTAL ASSETS		<hr/>	<hr/>
		118,091,489	89,798,458
		<hr/>	<hr/>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>			
Accounts payable and accrued expenses	7	19,400,947	18,912,207
Provisions for liabilities and charges (deferred tax)	9	910,902	293,579
Long-term liabilities	8	17,517,713	7,745,442
<b>SHAREHOLDERS' EQUITY</b>			
Called up share capital			
Class 'A' Ordinary shares	10	658,133	597,840
Class 'B' Ordinary shares	10	12,255	12,255
Share premium account		87,596,132	75,987,779
Currency adjustment		(4,091,568)	(4,266,173)
Profit and loss reserve	12(a)	(4,168,943)	(9,966,417)
Other reserves		<u>255,918</u>	<u>172,000</u>
Shareholders' equity – (all equity interests)		80,261,927	62,537,284
Minority interest – (all equity interests)	12(b)	-	309,946
		<hr/>	<hr/>
		80,261,927	62,847,230
		<hr/>	<hr/>
Total Liabilities and Shareholders' Equity		<hr/>	<hr/>
		118,091,489	89,798,458
		<hr/>	<hr/>

See Notes to the Consolidated Financial Statements

## CONSOLIDATED STATEMENTS OF INCOME

	Notes	Year ended December 31		
		2003 US\$	2002 US\$	2001 US\$
Revenues				
- Continuing operations		65,675,398	47,447,422	36,627,278
- Acquisitions	15	-	4,531,000	448,295
	13	<u>65,675,398</u>	<u>51,978,422</u>	<u>37,075,573</u>
Cost of sales		(32,876,951)	(25,689,879)	(18,049,765)
Gross profit		<u>32,798,447</u>	<u>26,288,543</u>	<u>19,025,808</u>
Research and development expenses		(5,210,039)	(4,470,745)	(2,779,729)
Administrative expenses - normal		(17,919,806)	(15,234,937)	(9,563,019)
Administrative expenses - exceptional	16	-	-	(3,635,000)
Operating profit		<u>9,668,602</u>	<u>6,523,834</u>	<u>5,816,912</u>
- Continuing operations		-	59,027	(2,768,852)
- Acquisitions	13	<u>9,668,602</u>	<u>6,582,861</u>	<u>3,048,060</u>
Interest receivable and similar income		174,117	103,133	142,364
Interest payable and similar charges	13	<u>(792,353)</u>	<u>(704,460)</u>	<u>(538,401)</u>
Profit on ordinary activities before taxation and share of operating loss in associate company and impairment		9,050,366	5,981,534	2,652,023
Share of operating loss in associate company and impairment		<u>(1,067,262)</u>	<u>(317,113)</u>	<u>(268,870)</u>
Profit on ordinary activities before taxation	14	7,983,104	5,664,421	2,383,153
Tax on profit on ordinary activities	17	(2,185,630)	(767,510)	(15,876)
Retained profit for the financial period		<u>5,797,474</u>	<u>4,896,911</u>	<u>2,367,277</u>
Basic earnings per ordinary share (US dollars)	18	<u>0.13</u>	<u>0.12</u>	<u>0.06</u>
Diluted earnings per ordinary share (US dollars)	18	0.12	0.12	0.06

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

## CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES

	December 31 2003 US\$	December 31 2002 US\$	December 31 2001 US\$
Profit for the financial period attributable to group shareholders excluding share of operating loss in associate company and impairment	6,864,736	5,214,024	2,636,147
Share of operating loss in associate company and impairment	(1,067,262)	(317,113)	(268,870)
Currency adjustment	<u>174,605</u>	<u>355,782</u>	<u>48,951</u>
Total recognised gains and losses for the period	<u>5,972,079</u>	<u>5,252,693</u>	<u>2,416,228</u>

See Notes to the Consolidated Financial Statements

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## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended December 31		
		2003 US\$	2002 US\$	2001 US\$
<i>Net cash inflow from operating activities</i>	20	<u>4,176,227</u>	<u>3,580,752</u>	<u>5,722,748</u>
<i>Returns on investments and servicing of finance</i>				
Interest received		174,117	57,133	142,364
Interest paid		(566,077)	(695,489)	(369,312)
Finance interest paid		<u>(23,120)</u>	<u>(9,037)</u>	<u>(23,424)</u>
<i>Net cash outflow from returns on investments and servicing of finance</i>		<u>(415,080)</u>	<u>(647,393)</u>	<u>(250,372)</u>
<i>Taxation</i>				
Taxation (paid)		<u>(156,625)</u>	<u>(403,935)</u>	<u>(319,510)</u>
<i>Capital expenditure and financial investment</i>				
Purchase of tangible fixed assets	19	(3,856,069)	(2,516,982)	(1,343,370)
Purchase of intangible fixed assets		<u>(1,846,109)</u>	<u>(468,941)</u>	<u>(986,502)</u>
<i>Net cash outflow from investing activities</i>		<u>(5,702,178)</u>	<u>(2,985,923)</u>	<u>(2,329,872)</u>
<i>Acquisitions and disposals</i>				
Acquisition of subsidiary undertakings		-	-	(4,777,388)
Payments to acquire trades or businesses		(762,518)	(4,408,692)	-
Purchase of associate undertaking		-	-	(309,399)
Deferred consideration paid		<u>(4,374,053)</u>	<u>-</u>	<u>-</u>
<i>Net cash outflow for acquisitions and disposals</i>		<u>(5,136,571)</u>	<u>(4,408,692)</u>	<u>(5,086,787)</u>
<i>Net cash outflow before use of liquid resources and financing</i>		<u>(7,234,227)</u>	<u>(4,865,191)</u>	<u>(2,263,793)</u>
<i>Management of liquid resources</i>	19	<u>(15,296,181)</u>	<u>553,310</u>	<u>(2,373,316)</u>
<i>Financing</i>				
Repayment of loan from unconnected third party		(57,198)	(163,213)	(73,336)
Repayment of minority interest		(309,946)	-	-
Issue of shares		2,251,844	558,698	74,144
Expenses paid in respect of share issues and debt financing		(1,123,058)	-	(183,521)
Movement in finance leases		(129,889)	3,955	(310,076)
Increase / (decrease) in long term debt		2,449,653	(1,803,466)	4,829,963
(Decrease) in promissory note		-	-	(350,000)
(Decrease) / increase in other financial liabilities		(1,092,516)	4,107,755	-
Issue / (settlement) of convertible debentures		<u>20,000,000</u>	<u>2,500,000</u>	<u>(625,000)</u>
<i>Net cash inflow from financing</i>		<u>21,988,890</u>	<u>5,203,729</u>	<u>3,362,174</u>
(Decrease)/increase in cash		<u>(541,518)</u>	<u>891,848</u>	<u>(1,274,935)</u>
<i>Reconciliation of net cash flow to movement in net debt</i>				
(Decrease)/increase in cash in the year		(541,518)	891,848	(1,274,935)
(Increase)/ decrease in long term debt		(2,449,653)	1,803,466	(4,829,963)
Decrease / (increase) in other financial liabilities		1,149,714	(4,041,506)	-
(Issue)/settlement of convertible debentures		(20,000,000)	(2,500,000)	625,000
Increase/ (decrease) in liquid resources		15,296,181	(553,310)	2,373,316
Decrease in finance leases		129,889	17,350	310,076
Expenses paid in respect of debt financing		<u>650,287</u>	<u>-</u>	<u>-</u>
<i>Change in net debt resulting from cash flows</i>		<u>(5,765,100)</u>	<u>(4,382,152)</u>	<u>(2,796,506)</u>
New finance leases		(670,620)	-	-
Finance leases acquired		(201,926)	-	-
Conversion of debentures		9,834,321	-	-
Promissory notes paid		-	-	350,000
Exchange movements on net debt		(391,936)	(87,554)	-
Non cash exchange movement		1,241	95,000	-
Debt issue costs		<u>130,956</u>	<u>20,679</u>	<u>-</u>
		<u>8,702,036</u>	<u>28,125</u>	<u>350,000</u>
Movement in net debt in the year		2,936,936	(4,354,027)	(2,446,506)
Net debt at January 1		<u>(8,644,320)</u>	<u>(4,290,293)</u>	<u>(1,843,787)</u>
Net debt at December 31	21	<u>(5,707,384)</u>	<u>(8,644,320)</u>	<u>(4,290,293)</u>



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

**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 accounting principles generally accepted in Ireland.

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

*(a) Basis of Consolidation*

The consolidated financial statements include the financial statements of Trinity Biotech plc (“Trinity Biotech” and/or “the Company”) and its subsidiary 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.

*(b) Goodwill*

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

*(c) Tangible Fixed Assets*

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

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

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

*(d) Intangible Assets*

Patents and licences are stated at cost and are amortised over the lesser of their expected useful lives or their statutory lives which range between 10 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 included in intangible assets and is to be released over the period of release of the related non-monetary assets. This is also subject to an annual impairment review by the directors and any diminution in value is immediately taken to the profit and loss account.

*(e) Inventories*

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

*(f) Taxation*

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

1. ACCOUNTING POLICIES (Continued)

(g) *Sales and Revenue Recognition*

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

(h) *Pension Costs*

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

(i) *Leases*

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

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

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

(j) *Government Grants*

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

(k) *Foreign Currency*

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 included in the income statement.

(l) *Liquid Resources*

Liquid resources are current asset investments, which are held as readily disposable stores of value. Liquid resources include investments in equity investments and short term deposits.

(m) *Use of Estimates*

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

(n) *Companies Acts, 1963 to 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.

(o) *Cost of Sales*

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

(p) *Provision for Bad Debts*

The Group sells its products to companies in various markets throughout the world. The Group maintains reserves for potential credit losses. To date such losses have been within management's expectations. The Group had an allowance for doubtful accounts of approximately US\$478,062, US\$496,412 and US\$30,000 as at December 31, 2003, 2002 and 2001, respectively.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

1. ACCOUNTING POLICIES (Continued)

(q) *Financial Instruments*

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

(r) *Employee Stock Compensation*

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

2. INVENTORIES	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
Raw materials	11,712,402	5,995,894
Work-in-progress	9,206,838	6,499,224
Finished goods	<u>9,635,378</u>	<u>8,356,341</u>
	<u>30,554,618</u>	<u>20,851,459</u>

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

3. ACCOUNTS RECEIVABLE AND PREPAYMENTS

Amounts falling due within one year	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
Accounts receivable, net	11,602,955	9,798,967
Prepayments	825,030	1,015,795
Value added tax	73,914	159,736
Called up share capital not paid	252,580	260,203
Grants receivable	181,687	532,665
Other receivables	282,597	490,482
Deferred costs	138,897	-
Deferred tax asset (see note 9)	555,229	418,908
	<u>13,912,889</u>	<u>12,676,756</u>
Other Assets, falling due after more than one year	<u>550,104</u>	<u>-</u>

4. INTANGIBLE ASSETS	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
Cost		
Patents and licenses	7,068,390	4,889,791
Goodwill (see note 22)	<u>39,643,377</u>	<u>41,580,827</u>
	46,711,767	46,470,618
Less accumulated amortisation	<u>(7,860,987)</u>	<u>(6,958,832)</u>
	<u>38,850,780</u>	<u>39,511,786</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

5. PROPERTY, PLANT AND EQUIPMENT	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>
Cost		
Land and buildings	5,133,246	4,229,485
Leasehold improvements	2,444,469	1,213,153
Computer and office equipment	3,838,985	2,758,023
Plant and equipment	9,163,810	8,194,774
	<u>20,580,510</u>	<u>16,395,435</u>
Less accumulated depreciation and amortisation	(6,920,830)	(6,511,754)
	<u>13,659,680</u>	<u>9,883,681</u>

Included in the net book value of tangible fixed assets is an amount for capitalised leased assets of US\$1,538,042 (2002: US\$944,352). The amortisation charge in respect of capitalised leased assets for the year ended December 31, 2003 was US\$117,506 (2002: US\$110,345, 2001: US\$111,512).

6. FINANCIAL ASSETS	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>
Investment in associate (see below)	-	1,067,262

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 €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. During 2003 HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading.

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

	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>
Share of net assets of associate on acquisition	118,220	118,220
Goodwill arising on acquisition	1,764,695	1,764,695
Accumulated amortisation	(270,455)	(199,670)
Share of operating loss in associate	(869,625)	(615,983)
Write-off of investment	(742,835)	-
	<u>-</u>	<u>1,067,262</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

7. ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Amounts falling due within one year)	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
Accounts payable	3,518,470	3,080,455
Income tax deducted under PAYE	137,442	90,953
Employee related social insurance	140,172	81,960
Corporate income taxes	1,573,913	184,394
Accrued liabilities	4,895,142	3,854,477
Accrued royalties	224,235	532,621
Obligations under finance leases	264,442	218,163
Financial liabilities from unconnected third party	3,309,027	4,107,755
Long-term debt - current portion (see note 8)	4,176,403	1,978,155
Deferred consideration - current portion	-	3,803,953
3% convertible debenture (see note 8)	1,161,701	-
6.0/7.5% convertible debenture (see note 8)	-	979,321
	<u>19,400,947</u>	<u>18,912,207</u>

In December 2001, the Company acquired the assets of the Biopool haemostasis business. Under the terms of the purchase agreement US\$2,591,500 of the total consideration of US\$6,409,329 had been deferred. The deferred consideration was payable in three instalments, commencing on December 21, 2002. At December 31, 2002, US\$2,021,400 of the deferred consideration for the Biopool haemostasis business was included in current liabilities under deferred consideration. In December 2002, the Company filed an action against Xtrana Inc relating to the purchase of the Biopool business from Xtrana in 2001. On June 16, 2003 Trinity Biotech and Xtrana settled this litigation. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the remaining amounts due on the deferred consideration.

In November 2002, the Company acquired the speciality clinical chemistry product line from Sigma Diagnostics. Under the terms of the purchase agreement US\$1,810,000 of the total consideration of US\$4,412,372 was deferred and payable in two instalments commencing on May 27, 2003. Included in the line "Deferred consideration – current portion" at December 31, 2002 is an amount of US\$1,782,553, representing the present value of the deferred consideration. This debt was settled in full during 2003.

As at December 31, 2003, the undrawn portion of existing banking facilities amounted to US\$1,000,000.

8. LONG-TERM LIABILITIES (Amounts falling due after more than one year)	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
5.25% convertible debenture	-	2,500,000
3% convertible debenture	11,874,903	-
Bank loans (secured, see note 23(h))	4,734,343	4,655,785
Deferred consideration	-	570,100
Lease creditors	749,983	12,655
Corporate income taxes	158,484	6,902
	<u>17,517,713</u>	<u>7,745,442</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
In more than one year, but not more than two	6,461,675	2,065,750
In more than two years, but not more than three	6,480,394	1,466,965
In more than three years, but not more than four	2,562,538	1,055,071
In more than four years, but not more than five	1,255,077	3,073,491
In more than five years	8,046	71,510
	<u>16,767,730</u>	<u>7,732,787</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

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. During 2003 the remaining US\$1,000,000 principal amount of the debenture was converted into 666,667 Class 'A' Ordinary Shares of the Company.

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

In June 2003, Trinity Biotech completed a new US\$10,000,000 club banking facility with Allied Irish Bank plc and Bank of Scotland (Ireland) Ltd. The new facility consists of a five year term loan of US\$6,000,000 and a one year revolver of US\$4,000,000. This facility is secured by the assets of the Group; the term loan is repayable in ten equal instalments commencing on January 2, 2004. The debt is stated net of unamortized issue costs of US\$172,846.

In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$3.55. The debentures are unsecured, and are repayable in ten equal instalments commencing on October 1, 2004. In December 2003, US\$6,355,000 of the US\$20,000,000 principal amount of the debenture and US\$44,500 of the related accrued interest was converted into 1,802,676 Class 'A' Ordinary Shares of the Company. Since the year end, a further US\$427,500 of the principal amount of the debenture has been converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July placement, convertible notes in the aggregate principal amount of up to US\$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US\$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$4. The debt is stated net of unamortized issue costs of US\$608,397.

As at December 31, 2003 payments falling due under finance leases of less than one year's duration amounted to US\$264,442 (2002: US\$218,163). As at December 31, 2003 obligations under finance leases of between two and five years' duration amounted to US\$749,983 (2002: US\$12,655). There were no payments falling due extending beyond five years.

9. DEFERRED TAXATION	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
<i>Movement in Deferred Tax Asset</i>		
At beginning of year	418,908	608,800
Charge to profit and loss account (see note 17)	(306,585)	(189,892)
Credit to profit and loss account (see note 17)	442,906	-
At end of year	<u>555,229</u>	<u>418,908</u>
<i>Movement in Deferred Tax Liability</i>		
At beginning of year	293,579	143,000
Charge to profit and loss account (see note 17)	632,587	150,579
Credit to profit and loss account (see note 17)	(15,264)	-
At end of year	<u>910,902</u>	<u>293,579</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

9. DEFERRED TAXATION (Continued)

The deferred tax asset is due to timing differences created by net operating losses and state credit carryforwards, the tax written-down value of fixed assets being greater than the related net book value and the elimination of unrealised intercompany profit. The deferred tax asset increased in 2003 as the tax effect of the excess of the tax written-down value of fixed assets over the net book value and the elimination of unrealised intercompany profit exceeded the tax consequences of the utilisation of net operating loss carryforwards. In 2002 the deferred tax asset decreased as the Company utilised some of its loss carryforwards.

	December 31 2003 US\$	December 31 2002 US\$	December 31 2001 US\$
Net operating loss carryforwards	41,511	488,513	707,659
Other timing differences	<u>692,583</u>	<u>61,812</u>	<u>174,800</u>
Total deferred tax assets	<u>734,094</u>	550,325	882,459
Valuation allowance	<u>(178,865)</u>	<u>(131,417)</u>	<u>(273,659)</u>
Net deferred tax assets	<u>555,229</u>	<u>418,908</u>	<u>608,800</u>

At December 31, 2003, the Company had Irish net operating loss carryforwards of US\$332,087. The utilisation of these net operating loss carryforwards is limited to the future profitable operations of the parent company in Ireland. These losses carry forward indefinitely. Valuation allowances have been provided against state credit carryforwards for uncertainties regarding future full utilisation of these credits in the related tax jurisdiction in future periods.

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

During 2002 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. During 2003 the remaining US\$1,000,000 principal amount of the debenture was converted into 666,667 Class 'A' Ordinary Shares of the Company.
- (b) On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its then associate HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc.
- (c) In November 2002, the Company completed a private placement of US\$2,500,000 principal amount of 5.25% convertible debentures. The debentures bore interest at a rate of 5.25% per annum and were convertible into Class 'A' Ordinary Shares of the Company at a price of US\$1.50. During 2003 these debentures were converted into 1,666,667 Class 'A' Ordinary Shares of the Company.
- (d) In December 2002, Enterprise Ireland subscribed for 443,900 'A' Ordinary Shares in the Company (see note 23(d)).
- (e) In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$3.55. In December 2003, US\$6,355,000 of the US\$20,000,000 principal amount of the debenture was converted into 1,790,141 Class 'A' Ordinary Shares of the Company, a further US\$44,500 of accrued interest was settled by the issue of 12,535 Class 'A' Ordinary Shares of the Company at US\$3.55 per share. Since the year end, a further US\$427,500 of the principal amount of the debenture has been converted into 120,423

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

**10. CALLED UP SHARE CAPITAL (Continued)**

Class 'A' Ordinary Shares of the Company. As part of the July placement, convertible notes in the aggregate principal amount of up to US\$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US\$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$4.

- (f) Since the year end, the Company has completed a US\$22.5m private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US\$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US\$5.25 per share. Under the terms of the placement, investors were also granted the right to purchase an additional 2,647,059 Class 'A' Ordinary Shares of the Company at a price of US\$4.25 per share for a period of up to 30 days after the closing of the transaction. An additional 431,617 Class 'A' Ordinary Shares of the Company, amounting to US\$1,834,372, were issued within the 30 day period following the closing of the transaction to investors who exercised this option.
- (g) 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.
- (h) The AGM held on May 28, 2001, approved a resolution for the renominialisation of the Company's share capital from IR£0.01 each to US\$0.0109 each.
- (i) Since its incorporation the Company has not declared or paid dividends on its 'A' Ordinary Shares. The Company anticipates, for the foreseeable future, that it will retain any future earnings in order to fund its business operations. The Company does not, therefore, anticipate paying any cash or share dividends on its 'A' Ordinary Shares in the foreseeable future.

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

**11. SHARE OPTIONS AND WARRANTS**

Under the terms of the Company's Employee Share Option Plan options to purchase 8,068,894 Class 'A' Ordinary Shares were outstanding at December 31, 2003. Under the plan, options are granted to officers, employees and consultants of the Group at the discretion of the board. In addition, the Company granted warrants to purchase 940,405 Class 'A' Ordinary Shares in the Company to agents of the Company who were involved in the Company's private placements in 1994 and 1995 and the debenture issues in 1997, 1999 and 2002. A further warrant to purchase 100,000 Class 'A' Ordinary Shares was also granted to a consultant of the Company. At December 31, 2003 there were warrants to purchase 258,500 Class 'A' Ordinary Shares in the Company outstanding. Since the year end, the Company has completed a private placement of 5,294,118 of Class 'A' Ordinary Shares of the Company at a price of US\$4.25 per share. The investors were granted five year warrants to purchase an aggregate of 1,058,824 Class 'A' Ordinary Shares of the Company at an exercise price of US\$5.25 per share. The Company further granted warrants to purchase 200,000 Class 'A' Ordinary Shares in the Company to agents of the Company who were involved in this private placement.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

11. SHARE OPTIONS AND WARRANTS (Continued)

The share options and warrants outstanding at December 31, 2003 were as follows:

	<i>Options &amp; Warrants</i>	
	<i>Shares</i>	<i>Range</i>
		<i>US\$</i>
Outstanding		
January 1, 2001	5,939,453*	0.81-5.00
Granted	665,000*	1.20 -1.75
Granted under value	1,414,500*	0.98
Exercised	(43,250)	1.00-2.00
December 31, 2001	<u>7,975,703</u>	<u>0.81-5.00</u>
Granted	2,243,500*	0.98-1.50
Exercised	(12,334)	1.13
Cancelled	(741,420)	0.98-2.78
December 31, 2002	<u>9,465,449</u>	<u>0.81-5.00</u>
Granted	1,340,500	0.98- 3.11
Granted over value	155,000	1.80
Exercised	(1,397,717)	0.81- 2.75
Cancelled	(1,235,838)	0.98- 2.60
December 31, 2003	<u>8,327,394</u>	<u>0.81-5.00</u>

\* Amounts adjusted for previously issued stock options

12. PROFIT AND LOSS RESERVE/MINORITY INTEREST

	<i>December 31</i>	<i>December 31</i>
(a)	<i>2003</i>	<i>2002</i>
	<i>US\$</i>	<i>US\$</i>
Profit and loss reserve		
Accumulated surplus	17,607,740	11,810,266
Goodwill reserve	<u>(21,776,683)</u>	<u>(21,776,683)</u>
	<u>(4,168,943)</u>	<u>(9,966,417)</u>

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)	<i>December 31</i>	<i>December 31</i>
	<i>2003</i>	<i>2002</i>
	<i>US\$</i>	<i>US\$</i>
Minority interest		
Minority interest	<u>-</u>	<u>309,946</u>

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. On April 4, 2003 this option was exercised and the shares of Benen were purchased by Trinity Biotech Plc.

In 2001 it was considered that the injection of these funds was in the nature of quasi equity. The Group had obligations to transfer economic benefits at the end of the investment period. This obligation was limited to a maximum of €330,200 being €1.32 per share. Accordingly, the Group had consolidated Benen as a 100% subsidiary undertaking and the proceeds (after deducting share issue costs and expenses) of the investment had been credited to minority interest.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
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13. ANALYSIS OF REVENUE, OPERATING INCOME, MAJOR CUSTOMERS AND ASSETS

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	46,526,957	23,968,227	13,548,075
United States	19,148,441	28,010,195	23,527,498
	<u>65,675,398</u>	<u>51,978,422</u>	<u>37,075,573</u>

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:

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
United States	36,299,136	33,511,564	25,057,609
Europe	19,982,761	11,899,290	6,879,597
Middle East/Africa	6,248,603	4,396,270	3,900,154
Other overseas	3,144,898	2,171,298	1,238,213
	<u>65,675,398</u>	<u>51,978,422</u>	<u>37,075,573</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Infectious diseases	35,127,128	37,829,479	37,075,573
Haemostasis	24,435,581	13,779,611	-
Clinical chemistry	6,112,689	369,332	-
	<u>65,675,398</u>	<u>51,978,422</u>	<u>37,075,573</u>

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

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

e) The distribution of intersegmental sales was as follows:

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	25,480,477	21,448,012	12,208,904
Rest of World – intersegmental sales	15,964,429	18,365,780	13,732,096
United States	37,120,136	28,010,195	23,527,498
Less intercompany sales	(12,889,644)	(15,845,565)	(12,392,925)
	<u>65,675,398</u>	<u>51,978,422</u>	<u>37,075,573</u>

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

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	7,947,134	3,754,912	679,891
United States	1,721,468	2,827,949	2,368,169
Total operating income	<u>9,668,602</u>	<u>6,582,861</u>	<u>3,048,060</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	85,178,683	62,073,836	54,743,563
United States	32,912,806	27,724,622	22,328,480
Total assets	<u>118,091,489</u>	<u>89,798,458</u>	<u>77,072,043</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	42,893,866	38,741,894	35,954,907
United States	10,166,698	11,720,835	11,597,729
Total long-lived assets	<u>53,060,564</u>	<u>50,462,729</u>	<u>47,552,636</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
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13. ANALYSIS OF REVENUE, OPERATING INCOME, MAJOR CUSTOMERS AND ASSETS (Continued)

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

	<i>December 31</i> 2003	<i>December 31</i> 2002	<i>December 31</i> 2001
Customer A	12%	20%	27%

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	1,268,222	2,405,981	2,111,876
United States	955,445	1,098,034	763,445
Total depreciation and amortisation	<u>2,223,667</u>	<u>3,504,015</u>	<u>2,875,321</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
United States	-	-	(3,635,000)
Total unusual items	<u>-</u>	<u>-</u>	<u>(3,635,000)</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	(728,220)	(607,750)	(310,877)
United States	(64,133)	(96,710)	(227,524)
Total interest	<u>(792,353)</u>	<u>(704,460)</u>	<u>(538,401)</u>

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Rest of World	1,408,407	230,557	6,876
United States	<u>777,223</u>	<u>536,953</u>	<u>9,000</u>
	<u>2,185,630</u>	<u>767,510</u>	<u>15,876</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
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14.	PROFIT ON ORDINARY ACTIVITIES BEFORE TAXATION	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
	The profit on ordinary activities before taxation is stated after charging/(crediting):			
	Directors' emoluments:			
	Remuneration	1,091,469	1,165,171	953,841
	Pension	104,096	94,706	59,157
	Auditors' remuneration:			
	Audit fees	455,335	190,000	170,000
	Non audit fees	18,255	20,000	25,377
	Depreciation	1,367,312	1,118,494	873,186
	Amortisation	856,355	2,385,521	2,002,135
	Operating lease rentals:			
	Plant and machinery	-	26,048	-
	Other	1,686,713	1,444,623	942,495
	Employment grants	(306,799)	(214,091)	-
	Settlement of litigation (see note below)	(225,000)	-	(1,360,971)
	Other non-recurring charges	-	-	357,447
		_____	_____	_____

Trinity Biotech and Selfcare entered into a settlement in 2001 whereby Selfcare paid Trinity Biotech US\$1,500,000 and Trinity Biotech (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.

On June 16, 2003 Trinity Biotech and Xtrana entered into a settlement agreement. Pursuant to the terms of the Settlement Agreement entered into between the parties, Trinity Biotech agreed to pay Xtrana the amounts due on two promissory notes of US\$1,166,200 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 Biotech.

15. ACQUISITIONS

On August 27, 2002 Trinity Biotech purchased the Haemostasis 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 of the Biopool Haemostasis 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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
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16. ADMINISTRATIVE EXPENSES - EXCEPTIONAL ITEMS

An exceptional charge of US\$2,835,000 was incurred during 2001 relating to the acquisition of the assets of the Biopool haemostasis business on December 21, 2001. The principal components of this charge were commitments on the acquisition of the assets of the Biopool haemostasis 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. There were no exceptional charges recognised in 2002 or 2003.

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Administrative expenses			
-Exceptional	-	-	3,635,000

17. INCOME TAXES

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
<i>Current tax</i>			
Corporation tax at 12.5% (2002: 16%, 2001: 20%)	1,531,692	9,299	107,876
Manufacturing relief	<u>(194,890)</u>	-	<u>(64,000)</u>
	1,336,802	9,299	43,876
Overseas tax	367,826	481,862	47,000
Relief in respect of prior year	-	<u>(64,122)</u>	-
Total current tax	1,704,628	427,039	90,876
<i>Deferred tax charge/(credit)</i>			
Movement in deferred tax asset (see note 9)	(136,321)	189,892	(218,000)
Movement in deferred tax liability (see note 9)	<u>617,323</u>	<u>150,579</u>	<u>143,000</u>
Total taxation on profit on ordinary activities	<u>2,185,630</u>	<u>767,510</u>	<u>15,876</u>
<i>Effective tax rate</i>			
Profit on ordinary activities before taxation	7,983,104	5,664,421	2,383,153
As a percentage of profit before tax			
Current tax	21.4%	7.5%	3.8%
Total tax (current and deferred)	27.4%	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:

	<i>2003</i> <i>% of profit</i> <i>before taxation</i>	<i>2002</i> <i>% of profit</i> <i>before taxation</i>	<i>2001</i> <i>% of profit</i> <i>before taxation</i>
Irish corporation tax	12.5	16.0	20.0
Manufacturing relief	(2.4)	(0.0)	(2.7)
Tax rates on overseas earnings	1.2	4.0	0.7
Relief in respect of prior year	-	(1.1)	-
Effect of non-taxable costs in PBT	6.2	-	-
Other including benefit of loss carryforwards	<u>3.9</u>	<u>(11.4)</u>	<u>(14.2)</u>
Current tax	21.4	7.5	3.8
Deferred tax	<u>6.0</u>	<u>6.0</u>	<u>(3.1)</u>
Total tax (current and deferred)	<u>27.4</u>	<u>13.5</u>	<u>0.7</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

17. INCOME TAXES (Continued)

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Ireland	5,771,847	2,933,528	389,193
Overseas	<u>2,211,257</u>	<u>2,730,893</u>	<u>1,993,960</u>
Total profits before taxation	<u>7,983,104</u>	<u>5,664,421</u>	<u>2,383,153</u>

(c) The tax effects of temporary differences that give rise to significant portions of deferred tax assets relate principally to the elimination of unrealised intercompany profit and net operating losses and state credit carryforwards. The valuation allowance for deferred tax assets at December 31, 2003, 2002 and 2001 was US\$178,865, US\$131,417 and US\$273,659 respectively.

(d) At December 31, 2003, the Group had Irish net operating losses of approximately US\$332,087 (2002: approximately US\$399,013). The utilisation of these net operating loss carryforwards is limited to offset against the future profits earned by the Group arising from the same trade and in the company in which they arose.

At December 31, 2003, the Group had fully utilised its U.S. net operating loss carryforwards.

18. EARNINGS PER ORDINARY SHARE

(a) *Basic earnings per ordinary share*

Earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US\$5,797,474 (December 31, 2002, US\$4,896,911 and December 31, 2001, US\$2,367,277) for the financial year by the weighted average number of ordinary shares in issue of 43,093,146 (December 31, 2002: 40,550,367 and December 31, 2001: 40,408,978).

(b) *Diluted earnings per ordinary share*

Diluted earnings per ordinary share is computed by dividing the profit on ordinary activities after taxation of US\$5,797,474 (December 31, 2002, US\$4,896,911 and December 31, 2001, US\$2,367,277) for the financial year, adjusted for debenture interest saving of US\$343,910 (December 31, 2002, US\$85,829 and December 31, 2001 US\$nil) by the diluted weighted average number of ordinary shares in issue of 50,583,247 (December 31, 2002, 42,486,227 and December 31, 2001, 41,120,060). The basic weighted average number of shares may be reconciled to the number used in the diluted earnings per ordinary share calculation as follows:

	<i>December 31</i> 2003	<i>December 31</i> 2002	<i>December 31</i> 2001
Basic earnings per share denominator	43,093,146	40,550,367	40,408,978
Issuable on exercise of options	4,106,791	1,214,703	711,082
Issuable on conversion of debentures	<u>3,383,310</u>	<u>721,157</u>	-
Diluted earnings per share denominator	<u>50,583,247</u>	<u>42,486,227</u>	<u>41,120,060</u>

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

If the 5,294,118 and the 431,617 of Class 'A' Ordinary Shares issued in the private placement completed since the year end (see note 10 (f)) had been included in the calculation of the weighted average number of shares; the basic earnings per share denominator would have been 43,108,833 and the diluted earnings per share denominator would have been 50,598,934.

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19. SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

	<i>December 31</i>	<i>December 31</i>	<i>December 31</i>
	<i>2003</i>	<i>2002</i>	<i>2001</i>
	<i>US\$</i>	<i>US\$</i>	<i>US\$</i>
(a) Purchase of tangible fixed assets			
Additions to tangible fixed assets	4,526,689	2,516,982	1,343,370
Less new finance leases	<u>(670,620)</u>	<u>-</u>	<u>-</u>
	<u>3,856,069</u>	<u>2,516,982</u>	<u>1,343,370</u>

(b) Management of liquid resources

Cash flows of US\$15,296,181 from the use of liquid resources in 2003 arose from the movement of cash to fixed deposit accounts.

Cash flows of US\$553,310 from the use of liquid resources in 2002 arose from the movement of cash from fixed deposit accounts.

Cash flows of US\$2,373,316 from the use of liquid resources in 2001 arose from the movement of cash to fixed deposit accounts.

(c) Impact of acquisitions on cash flow headings

There were no acquisitions in 2003. Additional costs incurred and obligations assumed from the acquisitions completed in 2002 resulted in cash outflows to the Group of US\$762,518 during 2003. Deferred consideration of US\$1,810,000 relating to the purchase of the speciality clinical chemistry product line from Sigma Diagnostics was paid during 2003.

The cash outflow of US\$4,408,692 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). As the working capital of the acquired businesses was fully integrated within the Group by December 31, 2002 post acquisition operating cash flows were not readily obtainable. The operating results of the haemostasis division and the speciality clinical chemistry product line of Sigma Diagnostics acquired on August 27 and November 27, 2002 respectively contributed US\$59,027 to the operating profit of the Group.

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

	<i>December 31</i>	<i>December 31</i>	<i>December 31</i>
	<i>2003</i>	<i>2002</i>	<i>2001</i>
	<i>US\$</i>	<i>US\$</i>	<i>US\$</i>
PROFIT TO NET CASH INFLOW			
FROM OPERATING ACTIVITIES			
Operating profit	9,668,602	6,582,861	3,048,060
Depreciation and amortisation	2,223,667	3,504,015	2,875,321
Exceptional administrative expenses	-	(2,835,000)	2,835,000
(Increase)/decrease in receivables and prepayments	(64,500)	(4,250,982)	990,800
(Decrease) / increase in accounts payable	(2,560,673)	2,874,740	(2,044,110)
Increase in inventory	(6,005,103)	(2,414,882)	(2,027,323)
Non cash compensation expense	83,918	120,000	45,000
Foreign exchange losses on non-operating cashflows	484,822	-	-
Loss on retirement of fixed assets	185,987	-	-
Other non-cash items	159,507	-	-
	<u>4,176,227</u>	<u>3,580,752</u>	<u>5,722,748</u>
Net cash inflow from operating activities			



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21. ANALYSIS OF NET DEBT

	<i>December 31 2002 US\$</i>	<i>Cash flow US\$</i>	<i>Acquisitions/ disposals US\$</i>	<i>Non-cash changes US\$</i>	<i>Exchange movements US\$</i>	<i>December 31 2003 US\$</i>
Cash	3,093,692	(541,518)	-	-	1,241	2,553,415
Liquid resources	<u>2,713,822</u>	<u>15,296,181</u>	-	-	-	<u>18,010,003</u>
Long-term debt	5,807,514	14,754,663	-	-	1,241	20,563,418
- current portion	(1,978,155)	(2,198,248)	-	-	-	(4,176,403)
Long-term debt	(4,655,785)	(78,558)	-	-	-	(4,734,343)
Other financial liabilities	(4,107,755)	1,149,714	-	-	(350,986)	(3,309,027)
Finance leases	(230,818)	129,889	(201,926)	(670,620)	(40,950)	(1,014,425)
Convertible debentures	(3,479,321)	(19,522,560)	-	9,965,277	-	(13,036,604)
Net debt	<u>(8,644,320)</u>	<u>(5,765,100)</u>	<u>(201,926)</u>	<u>9,294,657</u>	<u>(390,695)</u>	<u>(5,707,384)</u>
	<i>December 31 2001 US\$</i>	<i>Cash flow US\$</i>	<i>Acquisitions/ disposals US\$</i>	<i>Non-cash changes US\$</i>	<i>Exchange movements US\$</i>	<i>December 31 2002 US\$</i>
Cash	2,106,844	891,848	-	-	95,000	3,093,692
Liquid resources	<u>3,267,132</u>	<u>(553,310)</u>	-	-	-	<u>2,713,822</u>
Long-term debt	5,373,976	338,538	-	-	95,000	5,807,514
- current portion	(2,409,757)	431,602	-	-	-	(1,978,155)
Long-term debt	(6,027,649)	1,371,864	-	-	-	(4,655,785)
Other financial liabilities	-	(4,041,506)	-	-	(66,249)	(4,107,755)
Finance leases	(226,863)	17,350	-	-	(21,305)	(230,818)
Convertible debentures	(1,000,000)	(2,500,000)	-	20,679	-	(3,479,321)
Net debt	<u>(4,290,293)</u>	<u>(4,382,152)</u>	<u>-</u>	<u>20,679</u>	<u>7,446</u>	<u>(8,644,320)</u>
	<i>December 31 2000 US\$</i>	<i>Cash flow US\$</i>	<i>Acquisitions/ disposals US\$</i>	<i>Non-cash changes US\$</i>	<i>Exchange movements US\$</i>	<i>December 31 2001 US\$</i>
Cash	3,381,779	(1,274,935)	-	-	-	2,106,844
Liquid resources	<u>893,816</u>	<u>2,373,316</u>	-	-	-	<u>3,267,132</u>
Long-term debt	4,275,595	1,098,381	-	-	-	5,373,976
- current portion	(2,574,185)	164,428	-	-	-	(2,409,757)
Long-term debt	(1,033,258)	(4,994,391)	-	-	-	(6,027,649)
Finance leases	(536,939)	310,076	-	-	-	(226,863)
Convertible debentures	(1,625,000)	625,000	-	-	-	(1,000,000)
Promissory note	(350,000)	350,000	-	-	-	-
Net debt	<u>(1,843,787)</u>	<u>(2,446,506)</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(4,290,293)</u>

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**22. ACQUISITION OF BUSINESSES**

On August 27, 2002 Trinity Biotech purchased the haemostasis 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 has recently transferred 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 haemostasis 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. During 2003 the deferred consideration was paid in full. 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 has recently transferred production of the product line from St. Louis, Missouri to Bray, Ireland. Goodwill arising on acquisition of US\$4 million after fair value adjustments represents the value of the expected synergies created by combining production within Trinity Biotech's existing manufacturing operations.

The 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.

	Sigma Haemostasis	Sigma Clinical Chemistry	Total
	US\$	US\$	US\$
Tangible fixed assets	2,500,000	-	2,500,000
Working capital	<u>206,462</u>	<u>625,269</u>	<u>831,731</u>
Net assets at fair value	2,706,462	625,269	3,331,731
Goodwill	<u>(1,278,461)</u>	<u>3,787,103</u>	<u>2,508,642</u>
Consideration	<u>1,428,001</u>	<u>4,412,372</u>	<u>5,840,373</u>
Satisfied by:			
Cash payments including costs	<u>1,428,001</u>	<u>2,633,852</u>	<u>4,061,853</u>
Net cashflow	1,428,001	2,633,852	4,061,853
Deferred consideration	-	<u>1,778,520</u>	<u>1,778,520</u>
Consideration	<u>1,428,001</u>	<u>4,412,372</u>	<u>5,840,373</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

22. ACQUISITION OF BUSINESSES (Continued)

Goodwill capitalised during 2002 in respect of acquired businesses amounted to US\$2,508,642 and comprises:

	Book Values US\$	Fair Value Adjustment US\$	Fair Value US\$	Consideration US\$	Goodwill US\$
<b>Sigma Haemostasis</b>					
Tangible fixed assets	1,321,652	1,178,348 *	2,500,000		
Working capital	8,457,883	(8,251,421)*	206,462		
	<u>9,779,535</u>	<u>(7,073,073)</u>	<u>2,706,462</u>	<u>(1,428,001)</u>	<u>1,278,461</u>
<b>Sigma Clinical Chemistry</b>					
Working capital	<u>1,490,593</u>	<u>(865,324)*</u>	<u>625,269</u>		
	<u>1,490,593</u>	<u>(865,324)</u>	<u>625,269</u>	<u>(4,412,372)</u>	<u>(3,787,103)</u>
Total	<u>11,270,128</u>	<u>(7,938,397)</u>	<u>3,331,731</u>	<u>(5,840,373)</u>	<u>(2,508,642)</u>

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

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

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

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

	Provisional fair value 2002 US\$	Adjustments to net assets 2003 US\$	Adjustments to costs 2003 US\$	Final fair value 2003 US\$
<b>Sigma Haemostasis</b>				
Tangible fixed assets	2,500,000	-	-	2,500,000
Working capital	<u>206,462</u>	<u>2,239,693</u>	<u>-</u>	<u>2,446,155</u>
Net Assets	<u>2,706,462</u>	<u>2,239,693</u>	<u>-</u>	<u>4,946,155</u>
Consideration and costs	<u>(1,428,001)</u>	<u>-</u>	<u>(67,595)</u>	<u>(1,495,596)</u>
<b>Sigma Clinical Chemistry</b>				
Working capital	<u>625,269</u>	<u>(137,154)</u>	<u>-</u>	<u>488,115</u>
Consideration and costs	<u>(4,412,372)</u>	<u>-</u>	<u>(97,479)</u>	<u>(4,509,851)</u>

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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

22. ACQUISITION OF BUSINESSES (Continued)

On December 21, 2001 the Group acquired the assets of the Biopool haemostasis business for a total consideration of US\$6,409,329 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. 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 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\$	Biopool US\$	Total US\$
Working capital	-	(136,000)	(136,000)
Net liabilities at fair value	-	(136,000)	(136,000)
Goodwill	<u>877,797</u>	<u>6,545,329</u>	<u>7,423,126</u>
Consideration	<u>877,797</u>	<u>6,409,329</u>	<u>7,287,126</u>
Satisfied by:			
Cash payments including costs	<u>877,797</u>	<u>3,817,829</u>	<u>4,695,626</u>
Net cash outflow	877,797	3,817,829	4,695,626
Deferred consideration	-	<u>2,591,500</u>	<u>2,591,500</u>
Consideration	<u>877,797</u>	<u>6,409,329</u>	<u>7,287,126</u>

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

	Book Values US\$	Fair Value Adjustment US\$	Fair Value US\$	Consideration US\$	Goodwill US\$
<b>Ortho</b>	-	-	-	<u>(877,797)</u>	<u>(877,797)</u>
<b>Biopool</b>					
Working capital	<u>3,022,000</u>	<u>(3,158,000)*</u>	<u>(136,000)</u>	-	-
	<u>3,022,000</u>	<u>(3,158,000)</u>	<u>(136,000)</u>	<u>(6,409,329)</u>	<u>(6,545,329)</u>
Total	<u>3,022,000</u>	<u>(3,158,000)</u>	<u>(136,000)</u>	<u>(7,287,126)</u>	<u>(7,423,126)</u>

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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

22. ACQUISITION OF BUSINESSES (Continued)

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\$	Adjustments to costs 2002 US\$	Final fair value 2002 US\$
<b>Ortho</b>				
Consideration and costs	<u>877,797</u>	<u>-</u>	<u>-</u>	<u>877,797</u>
<b>Biopool</b>				
Working capital	<u>(136,000)</u>	<u>1,551,132</u>	<u>-</u>	<u>1,415,132</u>
Consideration and costs	<u>(6,409,329)</u>	<u>-</u>	<u>(68,164)</u>	<u>(6,477,493)</u>

23. COMMITMENTS AND CONTINGENCIES

(a) Capital Commitments

The capital commitments of the Group were as follows:

	31 December 2003 US\$	31 December 2002 US\$	31 December 2001 US\$
Contracted for	-	-	-
Authorised, not contracted for	-	-	-
	<u>-</u>	<u>-</u>	<u>-</u>

- (b) Operating lease commitments payable during the next twelve months amount to US\$2,182,494 (2002: US\$1,529,849) payable on leases of buildings at Dublin and Bray, Ireland, Darmstadt, Germany, Umea, Sweden, St. Louis, Missouri, upstate New York and Carlsbad, California and cars and equipment in the UK and Lemgo, Germany. US\$53,458 of the operating lease commitments total relates to leases whose remaining term will expire within one year, US\$169,094 relates to leases whose remaining term expires between one and two years, US\$654,496 between two and five years and the balance of US\$1,305,446 relates to leases which expire after more than five years.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

23. COMMITMENTS AND CONTINGENCIES (Continued)

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

	Operating Leases US\$	Finance Leases US\$
2004	2,182,494	307,408
2005	2,072,879	252,774
2006	1,725,041	223,791
2007	1,380,804	173,144
2008	1,306,562	168,786
Later years	18,238,295	-
Total minimum payments	<u>26,906,075</u>	<u>1,125,903</u>
Less amounts representing interest	-	<u>(111,478)</u>
Total lease obligations	<u>26,906,075</u>	<u>1,014,425</u>

- (c) Under agreements between the Group and Enterprise Ireland, grants amounting to US\$181,687 (2002: US\$532,665) are receivable which may be revoked, cancelled or abated in certain circumstances.
- (d) 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 €1,097,054 at a share price 10% below the market price of the Company's shares. In December 2000 Enterprise Ireland subscribed €548,527 of this amount for 239,198 'A' Ordinary Shares of the Company. In December 2002 Enterprise Ireland subscribed the remaining €548,527 for 443,900 'A' Ordinary Shares of the Company.
- (e) At December 31, 2002 the Company had guaranteed the borrowings of subsidiary undertakings to the amount of US\$2,776,343. These borrowings were paid in full during 2003.
- (f) In June 2003, Trinity Biotech completed a new US\$10,000,000 club banking facility with Allied Irish Banks plc and Bank of Scotland (Ireland) Ltd, this facility is guaranteed by the subsidiaries of the company.
- (g) Pursuant to the provisions of Section 17, Companies (Amendment) Act, 1986, the Company has guaranteed the liabilities of Trinity Biotech Manufacturing Limited and Trinity Research Limited, subsidiary undertakings in the Republic of Ireland, for the financial year to December 31, 2003 and, as a result, these subsidiary undertakings have 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.
- (i) In December 2003, the Company filed an action against Inverness Medical for declaratory judgment and breach of contract. The suit alleges that Inverness Medical is attempting to convert customers from the Trinity Biotech product to a product manufactured by a competitor by claiming that the Trinity Biotech product is unavailable and being discontinued.

In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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\$400,411 (December 31, 2002, US\$522,797 and December 31, 2001, US\$583,065). 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'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 €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 €12,860 per annum over adjacent lands with JRJ. On November 20, 2002, the Company entered into an agreement for lease with JRJ for offices that have been constructed on part of these lands. The annual rent of €365,760 (US\$459,094) is payable from January 1, 2004. Independent Valuers have advised the Company that the rent fixed in respect of the Current Extension, the agreement for lease and the adjacent lands represents a fair market rent. The rent for any future property constructed will be set at the then open market value. The Company and its directors (excepting Mr. O'Caomh and Dr. Walsh who express no opinion on this point) believe that the arrangements entered into represent a fair and reasonable basis on which the Company can meet its ongoing requirements for premises.

27. DERIVATIVES AND FINANCIAL INSTRUMENTS

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

The main risks arising from the 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\$5,707,384 (2002: US\$8,644,320) at interest rates ranging from 2.15% to 7.42% and including US\$14,134,621 of fixed rate debt at interest rates ranging from 3% to 5.50% (2002: US\$3,985,988 at interest rates ranging from 5% to 7.50%). In broad terms, a one-percentage point increase in interest rates would reduce the net interest charge by US\$82,544 (2002: increase by US\$46,796).

***Liquidity Risk***

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

27. DERIVATIVES AND FINANCIAL INSTRUMENTS (Continued)

***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 treasury policy which aims to sell US Dollars forward to match a portion of its uncovered Euro expenses at exchange rates lower than budgeted exchange rates. With an increasing level of Euro denominated sales, the Group anticipates that, over the next three years, a higher proportion of its non-US Dollar expenses will be matched by non-US Dollar revenues. The Group had foreign currency denominated cash balances equivalent to US\$585,758 at December 31, 2003.

*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:

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
Financial liabilities on which no interest is paid	-	57,198
Floating rate financial liabilities	12,136,181	10,429,953
Fixed rate financial liabilities	<u>14,134,621</u>	<u>3,964,683</u>
	<u>26,270,802</u>	<u>14,451,834</u>

Financial liabilities at December 31, 2002, on which no interest is paid, comprise loans from unconnected third parties.

Floating rate financial liabilities comprise overdrafts and other borrowings that bear interest at rates of between 2.15% and 7.42%. These overdrafts and borrowings are provided by financial institutions at margins ranging from 1% to 3.25% over interbank rates.

	<i>December 31</i> 2003	<i>December 31</i> 2002
Fixed rate financial liabilities		
- weighted-average interest rate	3.28%	5.50%
- weighted-average period for which rate is fixed	3.24 years	3.78 years

***Maturity of Financial Liabilities***

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

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$
In one year or less, or on demand	8,911,573	7,296,049
In more than one year, but not more than two	6,654,177	1,488,748
In more than two years, but not more than five	10,705,052	5,595,527
In more than five years	<u>-</u>	<u>71,510</u>
	<u>26,270,802</u>	<u>14,451,834</u>

***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, 2003. At December 31, 2003 forward contracts with a carrying value of US\$Nil had a fair value of US\$3,120,691 (asset) and US\$2,775,000 (liability) respectively (2002: US\$1,068,738 (asset) and US\$271,515 (liability) respectively).



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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

The Consolidated Financial Statements are prepared in accordance with accounting principles generally accepted in the Republic of Ireland ("Irish GAAP"), which differ in certain significant respects from 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 Statement of Income on a systematic basis over its useful economic life. From 1998, goodwill must be capitalised and amortised over the period of its expected useful life, however, historic goodwill continues to remain an offset against shareholders' equity. Under US GAAP, accounting for goodwill as an offset against shareholders' equity is not permitted. Prior to January 1, 2002 goodwill was amortised, except for goodwill arising on acquisitions after June 30, 2001, over the period of its expected useful life, subject to a maximum write off period of 40 years, through the income statement. A useful life of 10 years was adopted for the purposes of the reconciliation.

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

There has not been a disposal of all or a portion of a reporting unit in the three years to December 31, 2003. 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:

	2003 US\$	2002 US\$	2001 US\$
Rest of World	(1,937,465)	1,181,211	7,553,576
United States	-	-	-
Total	<u>(1,937,465)</u>	<u>1,181,211</u>	<u>7,553,576</u>

In 2003, the Group's investment in its associate, including unamortized goodwill of US\$1,659,171, was written off.

Negative goodwill arises when the net amounts assigned to assets acquired and liabilities assumed exceed the cost of an acquired entity. Under Irish GAAP, negative goodwill arising on acquisitions is recognised as a negative asset, within intangible fixed assets, and recognised in the profit and loss account in the periods in which the non-monetary assets acquired are depreciated or sold. Any negative goodwill in excess of the fair values of the non-monetary assets acquired is recognised in the profit and loss account in the periods expected to benefit. Under US GAAP, negative goodwill would be allocated to reduce proportionately the values assigned to the acquired non-current assets. Any excess remaining negative goodwill is recognised in US GAAP income as an extraordinary gain for the periods beginning after December 15, 2001. At December 31, 2003, gross negative goodwill of US\$2,500,000 within intangible fixed assets under Irish GAAP would be disclosed as a reduction from property, plant and equipment under US GAAP and the balance of US\$950,559 would be recognised as an extraordinary gain in 2003. 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. Depreciation of US\$76,634 in 2003, under Irish GAAP, on property, plant and equipment acquired would not be recognised under US GAAP as the value of the acquired building has been fully offset by the negative goodwill arising on the acquisition.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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

Following the completion of the fair value exercises in 2003 in respect of the Sigma Haemostasis and Sigma Clinical Chemistry acquisitions made during 2002, amendments have been made to the fair values reported in the 2002 financial statements. The amendments relate to the identification of additional obligations of US\$928,881 assumed on the acquisition of the Sigma Haemostasis business, the completion of the fair value exercise on inventory acquired in both acquisitions resulting in the recognition of additional value of US\$3,031,420 and the recognition of additional costs of US\$67,595 relating to the Sigma Hemostasis acquisition and US\$97,479 relating to the Clinical Chemistry acquisition. The difference has been taken as an adjustment to goodwill on acquisition.

Net income and earnings per share for the years ended December 31, 2003, 2002 and 2001, adjusted to exclude amortization of goodwill, is as follows:

	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>	<i>December 31</i> <i>2001</i> <i>US\$</i>
Reported net income under US GAAP	5,145,594	5,042,943	710,151
Excluded goodwill amortisation under Irish GAAP	-	-	1,825,960
Excluded additional goodwill amortisation under US GAAP	-	-	2,166,700
Adjusted net income	<u>5,145,594</u>	<u>5,042,943</u>	<u>4,702,811</u>
Reported basic earnings per share (US dollars)	0.12	0.12	0.02
Excluded goodwill amortisation	-	-	0.10
Adjusted basic earnings per share (US dollars)	<u>0.12</u>	<u>0.12</u>	<u>0.12</u>
Reported diluted earnings per share (US dollars)	0.11	0.12	0.02
Excluded goodwill amortisation	-	-	0.10
Adjusted diluted earnings per share (US dollars)	<u>0.11</u>	<u>0.12</u>	<u>0.12</u>

Identifiable intangible assets comprise goodwill, which is not amortizable and certain other non-current intangible assets, which are amortizable. Other non-current asset amortization under US GAAP for the years ended December 31, 2003, 2002 and 2001 was US\$154,052, US\$138,886 and US\$115,175 respectively. Other non-current amortization of identifiable intangible assets under US GAAP is estimated to be approximately US\$184,363 in 2004, US\$182,804 in 2005, US\$180,940 in 2006, US\$180,941 in 2007, US\$180,944 in 2008 and US\$806,529 thereafter.

The net book value of goodwill at December 31, 2003 was US\$48,397,474.

*(b) Cash Flow Statements:*

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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

*(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, 2003, is US\$252,580 (2002: US\$260,203).

*(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 2003 the Company made certain sales on extended credit terms. Under US GAAP, SAB 104 "Revenue Recognition in Financial Statements", such sales on extended credit terms would not be recognisable as revenue until 2004, when the cash is actually received. No similar provisions exist under Irish GAAP to preclude revenue recognition. Sales were not made on extended credit terms in 2002 or 2001. Revenue of US\$35,000 was recognised in 2001, relating to sales made on extended credit terms in 2000.

*(g) Restructuring Costs:*

Under Irish GAAP, certain provisions made for restructuring costs incurred upon and related to acquisitions of acquired companies (principally payments to employees and certain facilities costs) and expensed immediately would not be recognisable under US GAAP, because EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination", requires costs that meet certain criteria be treated as part of the purchase price allocation. Certain termination costs not determined on the basis of length of service or other exit costs which are not incremental to the acquired company, even if they provide a reduced economic benefit, are considered period costs which are expensed when incurred. Certain facilities costs amounting to US\$270,000 representing post-closure lease commitments for a facility acquired in 2001 were originally capitalised. These costs were subsequently excluded as a fair value adjustment in 2002 as the facility was not closed within a year of the acquisition. A decision to maintain the facility for certain operations was subsequently taken in 2003.

*(h) 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) Derivatives and Financial Instruments:*

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

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

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28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY  
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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 Biotech began documenting its hedging transactions in accordance with the requirements of SFAS 133. In 2003 an unrealized loss of US\$790,729 (2002: gain of US\$1,178,278) was taken to comprehensive income in respect of such contracts in accordance with the standard.

During the year ended December 31, 2003 US\$2,374,055 of foreign exchange gains were recognised in the Income Statement. This included realised foreign exchange gains of US\$67,682 (2002: US\$161,975) on the exercise of forward contracts under US GAAP, relating to contracts entered into in 2003 which had not been designated as hedging instruments as the level of cover provided was not deemed significant. At December 31, 2003 contracts with a fair value of US\$101,449 are recorded in other comprehensive income which the Company anticipates will be reclassified into earnings on the exercise of forward contracts in the year ending December 31, 2004. The last of the Company's forward contracts expires in December 2005.

(j) *Deferred Tax:*

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

CUMULATIVE EFFECT ON SHAREHOLDERS' EQUITY	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>	<i>December 31</i> <i>2001</i> <i>US\$</i>
Total shareholders' equity before minority interests under Irish GAAP	80,261,927	62,537,284	56,411,625
<i>US GAAP adjustments:</i>			
Goodwill			
- Gross (a)	21,776,683	21,776,683	21,776,683
(b)	-	-	270,000
- Aggregate amortisation	(9,853,550)	(11,412,266)	(13,677,901)
Property, plant and equipment	76,634	-	-
Share capital not paid	(252,580)	(260,203)	(291,211)
Adjustment for sale and leaseback	(811,264)	(861,968)	(912,672)
Adjustment for sales on extended credit	(144,345)	-	-
Adjustment for restructuring costs	-	-	2,565,000
Adjustment for research and development costs	(4,667,646)	(2,327,444)	(1,910,083)
Adjustment for fair value of derivative instruments	345,691	1,068,738	(271,515)
Deferred tax	502,375	423,444	(496,635)
Shareholders' equity under US GAAP	<u>87,233,925</u>	<u>70,944,268</u>	<u>63,463,291</u>

(a) Pre-1998 goodwill written-off against shareholders' equity under Irish GAAP.

(b) Liabilities assumed on acquisition capitalised under EITF 95-3.

CUMULATIVE TOTAL OF OTHER COMPREHENSIVE INCOME	<i>December 31</i> <i>2003</i> <i>US\$</i>	<i>December 31</i> <i>2002</i> <i>US\$</i>	<i>December 31</i> <i>2001</i> <i>US\$</i>
US GAAP Other Comprehensive Income at January 1	(3,373,995)	(4,908,055)	(4,670,906)
Translation adjustment	174,605	355,782	48,951
Fair value of derivative instruments	<u>(790,729)</u>	<u>1,178,278</u>	<u>(286,100)</u>
US GAAP Other Comprehensive Income at December 31	<u>(3,990,119)</u>	<u>(3,373,995)</u>	<u>(4,908,055)</u>

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

At December 31, 2003 the cumulative total fair value of derivative instruments in Other Comprehensive Income was US\$101,449, (2002: US\$892,178, 2001: (US\$286,100). At December 31, 2003 the total accumulated translation reserve in Other Comprehensive Income was (US\$4,091,568), (2002: (US\$4,266,173), 2001: (US\$4,621,955)).

EFFECT ON NET PROFIT	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Profit on ordinary activities after taxation under Irish GAAP	5,797,474	4,896,911	2,367,277
<i>US GAAP adjustments:</i>			
Goodwill amortisation	1,558,716	2,265,635	(2,166,700)
Adjustment for property, plant and equipment	76,634	-	-
Adjustment for sale and leaseback	50,704	50,704	50,704
Adjustment for sales on extended credit	(144,345)	-	35,000
Adjustment for restructuring costs	-	(2,835,000)	1,612,797
Adjustment for research and development costs	(2,340,202)	(417,361)	(881,710)
Adjustment for fair value of derivative instruments	67,682	161,975	14,585
Deferred tax	78,931	920,079	(321,802)
	<hr/>	<hr/>	<hr/>
Profit under US GAAP	5,145,594	5,042,943	710,151
	<hr/>	<hr/>	<hr/>
Profit per ordinary share (US dollars)	0.12	0.12	0.02
Diluted profit per ordinary share (US dollars)	0.11	0.12	0.02
Weighted average number of ordinary shares used in computing basic earnings per ordinary share	43,093,146	40,550,367	40,408,978
Diluted weighted average number of ordinary shares used in computing diluted profit per ordinary share	50,583,247	42,486,227	41,120,060
 <b>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</b>			
	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
Profit under US GAAP	5,145,594	5,042,943	710,151
Translation adjustment	174,605	355,782	48,951
Fair value of derivative instruments	(790,729)	1,178,278	(286,100)
	<hr/>	<hr/>	<hr/>
Total Comprehensive Income	4,529,470	6,577,003	473,002
	<hr/>	<hr/>	<hr/>

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DECEMBER 31, 2003**

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

CHANGES IN US GAAP EQUITY FOR THE YEARS ENDED DECEMBER 31 2003, DECEMBER 31 2002 AND  
DECEMBER 31 2001

	<i>December 31</i> 2003 US\$	<i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
US GAAP Shareholders' Equity at January 1	70,944,268	63,463,291	62,899,307
Net profit for the period	5,145,594	5,042,943	710,151
'A' shares issued for cash	44,500	544,823	-
'A' shares issued for conversion of debenture	9,855,000	-	-
'A' shares issued on conversion of warrant	232,640	-	-
Options exercised	2,011,579	13,875	74,144
Stock-based compensation - additional paid-in capital	83,918	120,000	45,000
'A' shares issued for financial asset	-	201,874	-
Share issue expenses	(475,073)	(7,606)	(15,476)
Share capital not paid in previous periods now paid	7,623	31,008	-
Share capital not paid	-	-	(12,686)
Other comprehensive income:			
Translation adjustment	174,605	355,782	48,951
Fair value of derivative instruments	<u>(790,729)</u>	<u>1,178,278</u>	<u>(286,100)</u>
US GAAP Shareholders' Equity at December 31	<u>87,233,925</u>	<u>70,944,268</u>	<u>63,463,291</u>

	<i>December 31</i> 2003 US\$	<i>Year ended</i> <i>December 31</i> 2002 US\$	<i>December 31</i> 2001 US\$
<b>CONSOLIDATED STATEMENTS OF CASH FLOWS</b>			
<i>Operating Activities</i>			
Retained profit under Irish GAAP	5,797,474	4,896,911	2,367,277
Adjustments to reconcile net profit to cash provided by operating activities:			
Depreciation	1,367,312	1,118,494	873,186
Amortisation	856,355	2,385,521	2,002,135
Taxation (paid)	(156,625)	(403,935)	(319,510)
Share of operating loss in associate	253,642	317,113	268,870
Write off of investment in associate	813,620	-	-
Provision for corporation tax charge	2,185,630	767,510	15,876
Net interest payable accrual	158,656	(46,066)	145,665
Exceptional administrative expenses	-	(2,835,000)	2,835,000
(Increase)/decrease in accounts receivable and prepayments	(64,500)	(4,250,982)	990,800
(Decrease) /increase in accounts payable and accrued expenses	(2,560,673)	2,874,740	(2,044,110)
Increase in inventory	(6,005,103)	(2,414,882)	(2,027,323)
Non-cash compensation expense	83,918	120,000	45,000
Foreign exchange losses on non-operating cash flows	484,822	-	-
Loss on retirement of fixed assets	185,987	-	-
Non cash settlement of interest	44,500	-	-
Other non-cash items	<u>159,507</u>	<u>-</u>	<u>-</u>
<i>Net cash inflow from operating activities</i>	<u>3,604,522</u>	<u>2,529,424</u>	<u>5,152,866</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY  
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*Investing activities*

Acquisition of subsidiary undertakings	-	-	(4,777,388)
Payments to acquire trades or businesses	(762,518)	(4,408,692)	-
Purchase of associate undertaking	-	-	(309,399)
Deferred consideration paid	(4,374,053)	-	-
Payment for patents and deferred development costs	(1,846,109)	(468,941)	(986,502)
Payment for tangible fixed assets	<u>(3,856,069)</u>	<u>(2,516,982)</u>	<u>(1,343,370)</u>
<i>Net cash outflow from investing activities</i>	<u>(10,838,749)</u>	<u>(7,394,615)</u>	<u>(7,416,659)</u>

*Financing Activities*

Repayment of loan from unconnected third party	(57,198)	(163,213)	(73,336)
Repayment of minority interest	(309,946)	-	-
Issue of ordinary share capital including premium	2,251,844	558,698	74,144
Expenses paid in connection with share issue and debt financing	(1,123,058)	-	(183,521)
Increase / (decrease) in long-term debt	2,449,653	(1,803,466)	4,829,963
Movement in finance leases	(129,889)	3,955	(310,076)
Issue / (redemption) of convertible debentures	20,000,000	2,500,000	(625,000)
Decrease in promissory note	-	-	(350,000)
(Decrease) / increase in other financial liabilities	(1,092,516)	4,107,755	-
<i>Net cash inflow from financing</i>	<u>21,988,890</u>	<u>5,203,729</u>	<u>3,362,174</u>

Increase in cash and cash equivalents	14,754,663	338,538	1,098,381
Effects of exchange rate movements on cash	1,241	95,000	-
Cash and cash equivalents at beginning of year	<u>5,807,514</u>	<u>5,373,976</u>	<u>4,275,595</u>
Cash and cash equivalents at end of year	<u>20,563,418</u>	<u>5,807,514</u>	<u>5,373,976</u>

**Non Cash transactions**

In December 2000, the Group acquired the assets 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 of the Biopool haemostasis 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% convertible debentures. The debentures bear interest at a rate of 5.25% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$1.50. The Company also issued 50,000 warrants (the "Second Warrants") in November 2002. The deferred consideration of US\$1,810,000 was paid in full in 2003. This transaction relates to the Rest of World reportable segment.

On April 3, 2002, the Company acquired a further 165,000 Ordinary Shares in its associate HiberGen Limited. The consideration of US\$201,874 was satisfied by the issue of 156,189 'A' Ordinary Shares in Trinity Biotech plc. During 2003 HiberGen Limited was unsuccessful in raising additional funds and on November 14, 2003, the Board of HiberGen Limited decided to cease trading. The Company wrote off its remaining investment in quarter four of the 2003 financial year. This transaction relates to the Rest of World reportable segment.

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

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. In 2003 the debenture has been fully converted into 666,667 Class "A" Ordinary shares of the Company.

In relation to the First Warrants, 333,701 were each exercisable to purchase one 'A' Ordinary Share of the Company at US\$1.74 per share and the remaining 150,000 were each exercisable to purchase one 'A' Ordinary Share of the Company at US\$1.80 per share. 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 were exercised in 2003 and 100,000 were exercised in the first quarter of 2004. The balance of the First Warrants expires in December 2004.

In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$3.55. In December 2003, US\$6,355,000 of the US\$20,000,000 principal amount of the debenture was converted into 1,790,141 Class 'A' Ordinary Shares of the Company. Since the year end, a further US\$427,500 of the principal amount of the debenture has been converted into 120,423 Class 'A' Ordinary Shares of the Company. As part of the July placement, convertible notes in the aggregate principal amount of up to US\$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US\$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$4.

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

**Share Option Scheme - Additional information required by SFAS 123**

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

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



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28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY  
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	2003	2002	2001
Expected option life (years)	4.0	4.0	3.0
Risk-free weighted-average interest rate	4.25%	2.3%	4.5%
Stock price volatility	0.855	0.411	0.620
Dividend yield	0%	0%	0%

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

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

	December 31 2003 US\$	December 31 2002 US\$	December 31 2001 US\$
Net income as reported	5,145,594	5,042,943	710,151
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	83,918	120,000	45,000
Deduct : Total stock based employee compensation under fair value based method for all awards, net of related tax effects	<u>(1,807,763)</u>	<u>(1,425,348)</u>	<u>(1,249,719)</u>
Proforma net income / (loss)	3,421,749	3,737,595	(494,568)
Earnings per share:			
Basic – as reported (US dollars)	0.12	0.12	0.02
Diluted – as reported (US dollars)	0.11	0.12	0.02
Basic – proforma (US dollars)	0.08	0.09	(0.01)
Diluted – proforma (US dollars)	0.07	0.09	(0.01)

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

	2003 Weighted-Average Options Exercise Price		2002 Weighted-Average Options Exercise Price		2001 Weighted-Average Options Exercise Price	
Outstanding-beginning of year	9,465,449	\$1.44	7,975,703	\$1.57	5,939,453*	\$1.70
Granted	1,495,500	\$1.90	2,243,500*	\$1.10	2,079,500*	\$1.02
Exercised	(1,397,717)	\$1.61	(12,334)	\$1.13	(43,250)	\$1.71
Forfeited	(1,235,838)	\$1.82	(741,420)	\$1.80	-	-
Outstanding at end of year	8,327,394	\$1.44	9,465,449	\$1.44	7,975,703	\$1.57
Exercisable at end of year	3,995,076	\$1.48	3,927,771	\$1.56	2,899,339	\$1.37
Weighted-average fair value of options granted during the year	\$1.09		\$0.58		\$0.56	

\* Amounts adjusted for previously issued stock options

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

The weighted-average remaining contractual life of options outstanding at December 31, 2003 is 3.98 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 2003 follows:

Option price range	Outstanding		Weight.-Av. contractual life remaining	No. of Shares	Exercisable	
	No. of Shares	Weight.-Av. exercise price			Weight.-Av. exercise price	Weight.-Av. contractual life remaining
\$0.81 - \$0.99	3,127,530	\$0.95	1.6 years	1,043,197	\$0.88	0.54 years
\$1.00 - \$1.99	3,892,674	\$1.42	1.78 years	2,302,672	\$1.39	1.62 years
\$2.00 - \$2.99	1,052,690	\$2.45	0.45 years	559,207	\$2.43	0.25 years
\$3.00 - \$5.00	254,500	\$3.70	0.15 years	90,000	\$4.78	0.01 years

**Capital shares reserved for future issuance**

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

	<b>Year ended December 31, 2003</b>
Shares issuable on conversion of debentures	3,843,662
Shares underlying outstanding stock options	8,068,894
Shares available for grant under option plans	2,507,000
Shares issuable upon exercise of warrants	<u>258,500</u>
	<b><u>14,678,056</u></b>

**Investments**

The Company had no trading securities as at December 31, 2003 or December 31, 2002.

The gross realised gains on sales of trading securities during 2003 was US\$Nil (2002: US\$Nil, 2001: US\$Nil).

The Company had no "available for sale" or "held to maturity securities" as at December 31, 2003 or December 31, 2002.

**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.

**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.

The carrying amounts and fair values of the Company's financial instruments at December 31, 2003 and 2002 are as follows:

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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28. DIFFERENCES BETWEEN ACCOUNTING PRINCIPLES GENERALLY  
ACCEPTED IN IRELAND AND IN THE UNITED STATES (Continued)

	<i>December 31, 2003</i>		<i>December 31, 2002</i>	
	Carrying Amount US\$	Fair Value US\$	Carrying Amount US\$	Fair Value US\$
Cash and cash equivalents	20,563,418	20,563,418	5,807,514	5,807,514
Short-term debt	8,911,573	9,152,783	7,283,394	7,283,394
Long-term debt	17,359,229	17,899,262	7,168,440	7,168,440
Forward contracts	-	345,691	-	1,068,738

**Additional Unaudited Proforma Information for Acquisitions made in 2001 and 2002**

The information below presents 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, 2001.

	<i>December 31 2002 US\$</i>	<i>December 31 2001 US\$</i>
Proforma revenues	63,351,166	63,596,202
Proforma net income	6,445,995	2,347,447
Proforma earnings per share (US dollars)	0.16	0.06
Proforma diluted earnings per share (US dollars)	0.15	0.06

The proforma information was compiled using extrapolations of the results for the haemostasis division and speciality clinical chemistry product line acquired from Sigma Diagnostics during 2002. There were no acquisitions in 2003.

**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:

Provision for Restructuring Costs

Bartels	<b>2000 US\$</b>	<b>2001 US\$</b>
Opening Provision	-	1,222,203
<i>Current year provision</i>		
Employee severance	491,000	-
Other employee costs	554,953	-
Idle facilities	<u>176,250</u>	=
	1,222,203	-
Incurred	-	(1,153,322)
Write back of provision	=	<u>(68,881)</u>
Closing provision	<u>1,222,203</u>	=

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2003**

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

Provision for Restructuring costs (Continued)

	<b>2001</b>	<b>2002</b>	<b>2003</b>
Biopool	<b>US\$</b>	<b>US\$</b>	<b>US\$</b>
Opening Provision	-	2,835,000	315,000
<i>Current year provision</i>			
Employee severance	1,059,000	-	-
Other employee costs	1,140,000	-	-
Idle facilities	<u>636,000</u>	-	-
	2,835,000	2,835,000	315,000
Incurred	-	(2,289,930)	(315,000)
Write back of provision	<u>-</u>	<u>(230,070)</u>	-
Closing provision	<u>2,835,000</u>	<u>315,000</u>	<u>-</u>

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.

*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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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

**Accounting Pronouncements**

*Asset Retirement Obligations*

The Company is responsible for certain costs of restoring leased premises to their original condition. The terms of such obligations vary. Generally, a maximum obligation is not explicitly stated. Because the obligated amounts of these types of agreements often are not explicitly stated, the overall maximum amount of the obligations cannot be reasonably estimated. Historically, the Company has not been obligated to make significant payments for these obligations, and no liabilities have been recorded for these obligations on its balance sheet as of December 31, 2003 and 2002.

*Impairment or disposal of long-lived assets*

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 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 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.

*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, 2003, the Company has elected not to change to the fair value based method of accounting for stock-based employee compensation.

*Costs Associated with Exit or Disposal Activities*

The Financial Accounting Standards Board issued Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") in June 2002. SFAS 146 provides guidance on the recognition and measurement of liabilities associated with exit or disposal activities and requires that such liabilities be recognized when incurred. In many cases, those costs will be recognized as liabilities in periods following a commitment to a plan, not at the date of commitment. SFAS 146 also changes the recognition of one-time termination benefits, such as severance pay or other termination indemnities, whenever the benefit arrangement requires employees to render future service beyond a 'minimum retention period.' SFAS 146 also addresses the accounting for other costs associated with an exit or disposal activity, such as costs to consolidate or close facilities and relocate employees. A liability for such costs has to be recognized and measured at its fair value in the period in which it is incurred. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Application of SFAS 146 had no material impact on the consolidated financial statements of the Company as it had no exit costs in 2003.

*Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*

The Financial Accounting Standards Board issued FASB Interpretation No. 45 "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others", ("FIN 45") in November 2002. FIN 45 requires a guarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by it in issuing the guarantee. It also expands the disclosure requirements in the financial statements of the guarantor with respect to its obligations under certain guarantees that it has issued. The Company is required to adopt the initial recognition and initial measurement accounting provisions of this interpretation on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are required to and have been adopted by the Company as of December 31, 2002. Application of FIN 45 had no material impact on the consolidated financial statements of the Company. In the normal course of business, the Company does not issue guarantees to third parties and the Company had no guarantees in 2003.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

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

*Consolidation of Variable Interest Entities*

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

*Derivative Instruments and Hedging Activities*

The Financial Accounting Standards Board issued Statement No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities", ("SFAS 149") in April 2003. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as "derivatives") and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". This statement requires contracts with comparable characteristics be accounted for similarly. In particular, this Statement (a) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative as discussed in SFAS No. 133, (b) clarifies when a derivative contains a financing component and (c) amends the definition of an "underlying" to conform it to language used in FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". This Statement is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of the new rules had no material impact on the consolidated financial statements of the Company.

*Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*

The Financial Accounting Standards Board issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", ("SFAS 150") in May 2003. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003. Application of SFAS 150 had no material impact on the consolidated financial statements of the Company as it had no financial instruments, as defined in SFAS 150, in 2003.

29. GROUP UNDERTAKINGS

<i>Name and registered office Holding Company</i>	<i>Principal activity</i>	<i>Principal Country of incorporation and operation</i>	<i>Group % holding</i>
Trinity Biotech plc IDA Business Park Bray, Co. Wicklow, Ireland	Investment and holding company	Ireland	
Trinity Biotech Inc. (Formerly Disease Detection International Inc.) Girts Road Jamestown NY 14702, USA	Holding Company	U.S.A.	100%
Clark Laboratories Inc. Trading as Trinity Biotech (USA) Girts Road Jamestown NY 14702, USA	Manufacture and sale of diagnostic test kits	U.S.A.	100%

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

29. GROUP UNDERTAKINGS (Continued)

<i>Name and registered office Holding Company</i>	<i>Principal activity</i>	<i>Principal Country of incorporation and operation</i>	<i>Group % holding</i>
FHC Corporation Girts Road Jamestown NY 14702, USA	Non-trading	U.S.A.	100%
Trinity Biotech Manufacturing Limited IDA Business Park Bray Co. Wicklow, Ireland	Manufacture and sale of diagnostic test kits	Ireland	100%
Trinity Research Limited IDA Business Park Bray Co. Wicklow, Ireland	Research and development	Ireland	100%
Trinity Biotech Sales Limited IDA Business Park, Bray Co. Wicklow, Ireland	Non - trading	Ireland	100%
MarDx Diagnostics Inc 5919 Farnsworth Court Carlsbad CA 92008, USA	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Flambelle Limited 16 Fitzwilliam Place Dublin, Ireland	Non-trading	Ireland	100%
Eastcourt Limited Chichester House 278/282, High Holborn London, UK	Non-trading	UK	100%
Trinity Biotech UK Holdings Ltd (Formerly Centocor UK Holdings Ltd) Shalford Guildford, Surrey, UK	Holding company	UK	100%
Trinity Biotech UK Ltd (Formerly Centocor UK Ltd) Shalford Guildford, Surrey, UK	In voluntary liquidation	UK	100%
Trinity Biotech (UK Sales) Limited 54 Queens Road Reading RG1 4A2, England	Sales of diagnostic test kits	UK	100%
Benen Trading Ltd IDA Business Park, Bray Co. Wicklow, Ireland	Non-trading	Ireland	100%
Reddinview Ltd IDA Business Park, Bray Co. Wicklow, Ireland	Dormant company	Ireland	100%
Trinity Biotech GmbH Otto Hesse Str 19 64293 Darmstadt, Germany	Sale of diagnostic test kits	Germany	100%

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2003**

29. GROUP UNDERTAKINGS (Continued)

<i>Name and registered office Holding Company</i>	<i>Principal activity</i>	<i>Principal Country of incorporation and operation</i>	<i>Group % holding</i>
Biopool US Inc Girts Road Jamestown NY 14702, USA	Manufacture and sale of diagnostic test kits	U.S.A.	100%
Biopool AB S-903 47 Umea Sweden	Manufacture and sale of diagnostic test kits	Sweden	100%

30. EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. As part of this placement convertible notes in the aggregate principal amount of up to US\$5,000,000 could be issued at the option of the investors by the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement. In March 2004, the investors exercised this option in full and the Company completed a further placement of US\$5,000,000 principal amount of 3% convertible debentures. The debentures bear interest at a rate of 3% per annum and are convertible into Class 'A' Ordinary Shares of the Company at a price of US\$4.

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

In December 2003, the Company filed an action against Inverness Medical for declaratory judgment and breach of contract. Inverness Medical, through its affiliate, Wampole Laboratories, has acted as exclusive distributor for certain of Trinity Biotech's infectious disease products in the US. This exclusivity is due to end on September 30, 2004, at which time it had been agreed that both Trinity Biotech and Inverness Medical would sell the products under their respective labels. The suit alleges that Inverness Medical is attempting to convert customers from the Trinity Biotech product to a product manufactured by a competitor by claiming that the Trinity Biotech product is unavailable and being discontinued. The lawsuit alleges that, under the terms of the contract, the Company is entitled to sell direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. With immediate effect, the Company has exercised this right.

In January 2004, Inverness Medical countersued and sought a preliminary injunction to prevent the Company from selling direct in the US any of its products which are competitive with products sold by Inverness Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004.



## TRINITY BIOTECH PLC.

## VALUATION AND QUALIFYING ACCOUNTS

<b>Doubtful Debts</b>	Balance at beginning of period US\$	Charged to costs and expenses US\$	Charged to other accounts US\$ (a)	Deductions US\$ (b)	Balance at end of period US\$
2003	496,412	261,562	(38,273)	(241,639)	478,062
2002	30,000	466,412	-	-	496,412
2001	31,850	30,000	-	(31,850)	30,000

(a) Amounts recovered during the year

(b) Amounts written off during the year

<b>Valuation Allowance for Income Taxes</b>	Balance at beginning of period US\$	Provided US\$ (a)	Reductions US\$ (b)	Balance at end of period US\$
2003	131,417	178,865	(131,417)	178,865
2002	273,659	-	(142,242)	131,417
2001	937,690	-	(664,031)	273,659

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

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

## *Signatures*

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

TRINITY BIOTECH PLC

By: RONAN O'CAOIMH  
Mr. Ronan O'Caoimh  
Director/  
Chief Executive Officer

Date: March 31, 2004

By: RORY NEALON  
Mr. Rory Nealon  
Director/  
Chief Financial Officer

Date: March 31, 2004

*Financial Statements*

**Item 19**

*Exhibits*

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
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.

**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 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 15(d)-15(e)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation ; and
  - c) disclosed in this annual report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.
5. The registrant’s other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2004

RONAN O’CAOIMH \*

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Ronan O’Caoimh  
Chief Executive 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.

**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 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 15(d)-15(e)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - c) disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2004

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.

**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 for the period ended December 31, 2003 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. § 1350, as adopted pursuant to § 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 \*

\_\_\_\_\_  
Ronan O’Caoimh  
Chief Executive Officer  
March 31, 2004

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

**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 for the period ended December 31, 2003 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. § 1350, as adopted pursuant to § 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

March 31, 2004

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

Trinity Biotech plc  
IDA Business Park  
Bray, Co. Wicklow  
Ireland.

Tel: + 353 1 276 9800  
Fax: + 353 1 276 9888  
email: [info@trinitybiotech.com](mailto:info@trinitybiotech.com)  
[www.trinitybiotech.com](http://www.trinitybiotech.com)