TRINITY BIOTECH PLC
Form 6-K
December 10, 2003

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER

Pursuant to Rule 13a-16 or 15d-16 of
The Securities Exchange Act of 1934

For the month of December, 2003

TRINITY BIOTECH PLC
(Translation of registrant's name into English)

IDA BUSINESS PARK,

BRAY,

CO. WICKLOW, IRELAND

(Address of Principal Executive Officers)

Management's Discussion and Analysis of
Financial Condition and Results of
Operations

Trinity Biotech plc ("Trinity" or the "Company") develops, acquires, manufactures and markets diagnostic test kits for the clinical laboratory and point-of-care ("POC") segments of the diagnostic market. The broad line of test kits is primarily used to detect infectious diseases, sexually transmitted diseases, blood coagulation disorders and autoimmune disorders. Through its own sales force as well as a network of international distributors, the Company markets over 500 different diagnostic products in approximately 80 countries.

Trinity was incorporated as a public limited company (plc) registered in Ireland in 1992. The Company was organised to acquire, develop and market technologies for rapid in-vitro blood and saliva diagnostics for HIV and other infectious diseases. The Company commenced operations in 1992 and, in October 1992, completed an initial public offering of its securities in the USA in which it raised net proceeds in excess of US$5 million. In October 1993, Trinity took a

controlling interest in Disease Detection International Inc ("DDI") and, in October 1994, merged Trinity's wholly owned US subsidiary into DDI so that DDI became a wholly owned subsidiary of Trinity. DDI was the surviving entity in the merger and was subsequently renamed Trinity Biotech Inc ("TBI"). In December 1994, Trinity acquired the remaining 50% of FHC Corporation ("FHC"), which its subsidiary TBI did not own. In 1995, Trinity raised net proceeds of US$6 million as a result of a private placement of the Company's shares. In February 1997, Trinity purchased the entire share capital of Clark Laboratories Inc., ("Clark"), which now trades as Trinity Biotech USA. In June 1997, Trinity acquired Centocor UK Holdings Limited ("Centocor"), a company based in Guildford in the U.K. Centocor was a 100% subsidiary of Centocor, Inc., a U.S. biotechnology company. 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. Also, in September 1998, Trinity disposed of its interest in its pregnancy sales contract with Warner Lambert to Applied Biotech Inc, a subsidiary of Sybron International Corporation. In March 2000 the Company purchased 100% of the share capital of Mardx Diagnostics Inc ("Mardx") and in December 2000 the assets and goodwill of Bartels Inc were acquired. The Bartels plant in Seattle closed in June 2001 and production has been transferred to the Californian, New York and Irish factories. In October 2001, the Company purchased the Amerlex hormone business of Ortho Clinical Diagnostics and, in December 2001, the Company acquired the assets and goodwill of the Biopool hemostasis business. The manufacture of the Biopool product line has since been transferred to the Bray, Ireland facility. In October 2001, Trinity established a direct sales operation in Germany, Trinity Biotech GmbH. In August 2002, Trinity acquired the hemostasis division of Sigma Diagnostics, part of Sigma-Aldrich. The Sigma diagnostics hemostasis business comprised a comprehensive portfolio of reagents manufactured in St Louis, Missouri and the Amelung range of automated and semi-automated instruments manufactured in Lemgo, Germany. Trinity also acquired the specialty clinical chemistry product line from Sigma Diagnostics in November 2002. This business consists of several niche products that are clearly differentiated in the marketplace. Trinity is currently in the process of transferring the manufacture of the Sigma hemostasis reagent product line and the Sigma clinical chemistry product line from St Louis to the Bray, Ireland facility.

In October 2000, Trinity subscribed for a 33.3% shareholding in HiberGen Limited ("HiberGen"). In July 2001 the Company subscribed for a further 300,000 Ordinary Shares in HiberGen, thereby increasing its shareholding to 40%. In April 2002 the Company increased its shareholding to 42.9% by the acquisition of a further 165,000 Ordinary Shares in HiberGen. 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 intends to write off the carrying amount of the investment in quarter four of the 2003 financial year.

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

In June 2003, Trinity raised US$10 million through a club banking facility which was provided by Bank of Scotland and Allied Irish Banks.

In July 2003, Trinity completed a private placement of US$20m of convertible debenture notes.

Trinity's financial statements include the attributable results of seven trading entities - Trinity Biotech Manufacturing Limited, Biopool US Inc, Trinity Biotech (USA), MarDx Diagnostics Inc, Trinity Biotech GmbH, Trinity Biotech (UK Sales) Limited and Biopool AB. These entities are engaged in the manufacture and sale of diagnostic test kits. A share of the loss of the associate undertaking, HiberGen, is also included in the financial statements. The following discussion should be read in conjunction with the unaudited condensed interim financial statements and notes thereto. The financial statements have been prepared in accordance with Irish generally accepted accounting principles (except for the classification of cashflows set out in the unaudited condensed consolidated statement of cashflows), which conform in all material respects to US GAAP except as indicated in the notes to the condensed financial statements.

Restatement of Form 20-F

In December 2003, Trinity filed a restated Form 20-F/A restating its financial statements for 2000, 2001 and 2002. These financial statements were restated to make corrections in the accounting for certain items. This resulted in a reduction of profit of US$699,055 for financial year 2000, an increase in profit of US$917,929 for the financial year 2001, a reduction in profit of US$113,406 for the financial year 2002, and a reduction in shareholders' equity at January 1, 2000 of US$622,475. For the three years in question the cumulative profit increased by US$105,468. Where comparative figures are used for 2002 in this document the restated figures have been used.

Results of Operations

Six Months Ended June 30, 2003 Compared to Six Months Ended June 30, 2002
Trinity's consolidated revenues for the six month period ended June 30, 2003 were US$33,293,870, an increase of US$10,104,310 compared to consolidated revenues of US$23,189,560 for the six months ended June 30, 2002. This increase in revenues is primarily due to sales on the product lines acquired from Sigma in the second half of 2002.

The gross margin from product sales for the six month period ended June 30, 2003 was 48.9% compared to 49.7% for the same period in 2002. This decrease is attributable to a slightly lower gross margin (c. 48%) being earned on sales on the product lines acquired from Sigma in the second half of 2002.

The increase in selling, general and administrative costs of US$3,000,546 to US$8,213,453 between the 6 month period ended June 30, 2002 and the six month period ended June 30, 2003 has been caused by (i) additional incremental costs of US$711,014 relating to a direct sales force established in St. Louis, Missouri, following the acquisition of the hemostasis division of Sigma Diagnostics in August 2002, (ii) increased costs of US$1,063,048 in Trinity Biotech Germany following the acquisition of the hemostasis instrument manufacturing facility in Lemgo, Germany, again as part of the acquisition of the hemostasis division of Sigma Diagnostics in August 2002, (iii) employee number and activity growth in Trinity's principal Irish based subsidiary, Trinity Biotech Manufacturing Limited, due to an increase in the range of products being manufactured and sold from the facility resulting in an increase of US$1,105,096, (iv) the establishment of a UK based sales office in Oxfordshire in October 2002 which contributed US$251,625 to selling, general and administrative costs in the six month period to June 30, 2003 and (v) as offset by reductions in selling, general and administrative costs of US$130,237, principally relating to redundancy costs incurred in the Company's Swedish subsidiary, Biopool AB in the six month period ended June 30, 2002 for which there was no equivalent in the six month period ended June 30, 2003.

Research and development ("R&D") expenditure for the six month period ended June 30, 2003 increased by US$910,272 to US$2,829,133 when compared to the similar 6

month period in 2002. Expenditure to June 2003 represented 8.5% of consolidated revenues for the period and is thus at a similar level to that incurred for the comparable period in 2002 (8.3% of consolidated revenue). The absolute increase in expenditure in 2003 is principally accounted for by increases at Trinity's main facility in Bray, Ireland (an increase of US$1,005,311). This was offset by a reduction in R&D expenditure in subsidiaries in the U.S. of US$95,039 which included the impact of R&D activities ceasing at the Biopool facility in Ventura following its closure in September 2002. The increased expenditure at the main facility in Ireland was attributable to a number of individual projects which included the development of new products for the Company's existing market base and enhancements to a number of products within its existing product range. Projects included (i) redevelopment of the Capita Products, making these kits more user friendly and compatible with automated assay systems, (ii) the development of Recombinant HIV UniGold(TM) test, which has now been completed and is awaiting FDA approval, using recombinant proteins manufactured by Trinity, (iii) the adaptation of assays to Microtrak XL units which will allow Trinity to increase sales of these tests, (iv) the development of a rapid test for influenza A and B using the UniGold(TM) technology and (v) the development of the Influenza A/B DFA kit and Influenza RSV DFA kit.

The level of amortization decreased from US$1,181,181 for the six month period ended June 30, 2002 to US$905,235 for the corresponding period in 2003. This decrease was primarily attributable to negative goodwill of US$393,485 amortised during the period in relation to the acquisition of the hemostasis division of Sigma Diagnostics in August 2002. This was partly offset by the amortization of positive goodwill in relation to the acquisition of the Sigma Clinical Chemistry product line of US$95,273, acquired in November 2002.

The increase in interest expense of US$104,694 was largely due to an increase in the overall level of the Group's debt. The impact of this increase was partially mitigated by the fall in prevailing interest rates on the non-fixed interest rate portion of Trinity's debt.

Interest income remains at low levels given the net debt position of the Group. The Group continues its policy of placing any temporary surplus funds on deposit as they occur.

The net profit for the six month period ended June 30, 2003 was US$3,326,515 compared to a net profit of US$2,338,360 for the same period last year, an increase of US$988,155.

Liquidity and Capital Resources
As of June 30, 2003 Trinity's consolidated cash and cash equivalents were US$1,608,290. This compares to consolidated cash and cash equivalents of US$5,807,514 at December 31, 2002.

This decrease of US$4,199,224 has been caused primarily by (i) the payment of deferred consideration of US$3,601,500 in respect of the acquisitions of Biopool in 2001 and the Sigma clinical chemistry business in 2002, (ii) the purchase of tangible fixed assets of US$1,530,768, (iii) the investment in intangible fixed assets of US$694,483, and (iv) as offset by an inflow of US$865,440 from operating activities and US$652,939 from financing activities. For further details please see the accompanying unaudited condensed consolidated statement of cashflows.

In June 2003 Trinity signed a new US$10,000,000 club banking facility which was provided by Bank of Scotland and Allied Irish Banks, US$8,000,000 of which was drawn down by June 30, 2003. 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 deferred consideration payable in relation to the Biopool acquisition.

Impact of Inflation

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

Impact of Currency Fluctuation

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

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

Exchange Rates

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

Legal Settlements/Litigation

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

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

Events Subsequent to Balance Sheet Date

In July 2003, the Company completed a private placement of US$20 million of convertible notes to a group of private investors. The notes have a final maturity date of January 1, 2007, bear interest at a rate of 3% per annum, and are convertible at the investor's option at any time into the Company's common stock at a fixed conversion price of US$3.55.

In November 2003, the Company announced that the recent fundraising process undertaken by HiberGen had not been successful and that HiberGen had ceased trading. The Company has a 42.9% interest in HiberGen and treats the investment in its financial statements as an investment in an associated company. The Company intends to write off the carrying value of the investment in quarter four of the 2003 financial year.

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

Trinity Biotech plc

Unaudited Condensed Consolidated Balance Sheet as at:

J

ASSETS
Cash and cash equivalents
Accounts receivable and prepayments
Inventories

Total Current Assets

Property, plant & equipment, net
Intangible assets, net
Financial assets

TOTAL ASSETS

===

LIABILITIES & SHAREHOLDERS' EQUITY	
Accounts payable & accrued expenses	
Long term liabilities	
SHAREHOLDERS' EQUITY	
Called up share capital	
Class 'A' ordinary shares	
Class 'B' ordinary shares	
Share premium account	
Other reserves	
Currency adjustment	
Profit and loss reserve	
Total Shareholders' Equity	
Minority interest	
Total Liabilities and Shareholders' Equity	

Note: The balance sheet at December 31, 2002 has been derived from the audited financial statements, as restated, at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See notes to unaudited interim condensed consolidated financial statements.

Trinity Biotech plc
Unaudited Condensed Consolidated Profit and Loss Account

Revenues	
Costs and Expenses	
Cost of goods sold	
Selling, general and administrative - normal	
Research and development	
Amortisation	
Operating profit	
Share of operating loss in associate	
Interest and other income	
Interest expense	

Profit on ordinary activities before taxation	
Tax on profit on ordinary activities	
Net profit	
Net profit per ordinary share (US$)	
Weighted average number of ordinary shares outstanding	

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES

Profit for the financial period attributable to group shareholders excluding share of loss in associate	
Share of operating loss in associate	
Currency adjustment	
Total recognised gains and losses for the period	

Trinity Biotech plc
Unaudited Condensed Consolidated Statement of Cash Flows

Net cash flow from operating activities	
Investing activities	
Interest received	
Purchase of fixed assets	
Investment in intangible assets	
Deferred acquisition consideration paid	

Financing activities	
Interest paid	
Issue of ordinary shares	
Capital element of loan repayments	
Repayment of minority interest	
Loans received	
Decrease in cash and cash equivalents	
Non cash exchange movement	
Balance at beginning of period	
Balance at end of period	

TRINITY BIOTECH PLC
NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

The unaudited results for the six months to June 30, 2003 and June 30, 2002 have been prepared in accordance with Irish generally accepted accounting principles with the exception of the classification of cashflows in the unaudited consolidated statement of cashflows, which are presented in accordance with the classifications required under US GAAP per SFAS 95. The accounting policies and the basis of preparation of these unaudited results are consistent with those used in the Company's annual financial statements.

The information included in the interim consolidated financial statements is unaudited but reflects all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. The results for the six months to June 30, 2003 are not necessarily indicative of the results for the full fiscal year.

Restatement

In December 2003, Trinity filed a restated Form 20-F/A restating its financial statements for 2002, 2001 and 2000. Consequently Trinity has restated the prior period comparatives contained in this document where applicable. This resulted in a reduction of US$21,923 in Net Profit for the six months ended June 30, 2002. Details of the nature of the adjustments to the original reported numbers can be found in the restated Form 20-F/A.

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.

2. ANALYSIS OF REVENUE AND OPERATING INCOME

Trinity operates in one business segment, the market for rapid diagnostic tests for a range of diseases and other medical conditions, and in two reportable segments, which are based on a geographical split. 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.

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

U.S.A
Europe
Middle East/Africa
Other

===

TRINITY BIOTECH PLC
NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Continued)

2. ANALYSIS OF REVENUE AND OPERATING INCOME (Continued)

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

Rest of the World
United States

---

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

Rest of the World	
United States	
Total operating income	

d) The distribution of intersegmental sales is as follows:

Rest of the World	
Rest of the World - Intersegmental Sales	
United States	
Less Intercompany Sales	

3. INVENTORIES

Raw materials	
Work in progress	
Finished goods	

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

TRINITY BIOTECH PLC
NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Continued)

4 SIGNIFICANT NON-CASH TRANSACTIONS

During the six month period to June 30, 2003, US$1,000,000 of 6% convertible debentures were fully converted into 666,667 Class "A" Ordinary shares of the Company at a conversion price of $1.50 and US$2,500,000 of 5.25% convertible debentures were fully converted into 1,666,667 Class "A" Ordinary shares of the Company also at a conversion price of $1.50

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES

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:

(1) Goodwill:
In prior years under Irish GAAP, goodwill was either written off immediately on completion of the acquisition against shareholders' equity, or capitalised in the balance sheet and amortised through the income statement on a systematic basis over its useful economic life. From 1998, goodwill must be capitalised and amortised over the period of its expected useful life, however, historic goodwill continues to remain an offset against shareholders' equity. Under US GAAP, accounting for goodwill as an offset against shareholders' equity is not permitted. Prior to January 1, 2002 goodwill was amortised, except for goodwill arising on acquisitions after June 30, 2001, over the period of its expected 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 the statements. On January 1, 2002 the Group performed the required impairment review of goodwill and indefinite-lived intangible assets and determined that there was no impairment. On December 31, 2002 the Group performed a further impairment test of goodwill and indefinite-lived intangible assets and concluded that there was no impairment in the carrying value of these assets at this date. There are no impairment losses recognised in the periods presented.

There has not been a disposal of all or a portion of a reporting unit in the eighteen months to June 30, 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:

Rest of World
United States

Total

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

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

which the non-monetary assets acquired are amortized or sold. Any negative goodwill in excess of the fair values of the non-monetary assets acquired is recognized 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 goodwill is recognized in US GAAP income, as an extraordinary gain, for the periods beginning after December 15, 2001. At June 30, 2003, gross negative goodwill of US$1,378,617 (December 31, 2002: US$1,278,461) within intangible fixed assets under Irish GAAP would be disclosed as a reduction from property, plant and equipment under US GAAP. Amortisation of negative goodwill would be disclosed as a reduction from depreciation under US GAAP.

Net income and earnings per share for the periods ended June 30, 2003 and 2002, adjusted to exclude amortization of goodwill are as follows:

Reported net income under US GAAP
Excluded goodwill amortization

Adjusted net income

Reported basic earnings per share (US$)
Excluded goodwill amortization

Adjusted basic earnings per share (US$)	
Reported diluted earnings per share (US$)	
Excluded goodwill amortization (US$)	
Adjusted diluted earnings per share (US$)	

Identifiable intangible assets comprise goodwill, which is not amortizable and certain intangible other non-current assets, which are amortizable. Other non-current asset amortization under US GAAP for the six month period ended June 30 2003 was US$69,010 and US$69,443 for the six month period ended June 30, 2002.

(2) 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 June 30, 2003 is US$375,820 (December 31, 2002: US$260,203).

(3) 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 "Reporting Comprehensive Income" requires disclosure of the cumulative amounts of other comprehensive income.

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

(4) 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).

(5) Deferred Income Taxes:
Deferred tax differences arise between Irish GAAP and US GAAP due to the impact of the nature and timing of the reconciling items arising.

(6) 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 such costs that meet certain criteria

to 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.

(7) 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.

(8) Sales on Extended Credit Terms:
During the period the Company made certain sales on extended credit terms. Under US GAAP, SAB 101 "Revenue Recognition in Financial Statements", a portion of such sales on extended credit terms would not be recognisable as revenue until after June 30, 2003. No similar provisions exist under Irish GAAP to preclude revenue recognition.

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

(10) Derivatives and Financial Instruments:
In June 1998, the FASB issued SFAS No 133 "Accounting for Derivative Instruments and Hedging Activities". SFAS 133 requires that all derivatives be recognised on the balance sheet at fair value. Derivatives which are not hedges or where hedge correlation cannot be demonstrated must be adjusted to fair value through income.

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

Under Irish GAAP, derivatives are not recognised until settled. Realised gains and losses on transactions where derivatives are used to hedge cross-currency cashflows are ultimately recorded in the income statement on settlement.

As part of a managed hedging policy Trinity has entered into a series of forward contracts to sell US$ and Japanese Yen forward for Euro. These contracts were entered into by the Company to mitigate its foreign exchange risk. The principal exchange risk identified by Trinity was with respect to fluctuations in the Euro as a substantial portion of its expenses is denominated in Euro but its revenues are

primarily denominated in US dollars. These forward contracts are cashflow hedging instruments whose objective is to cover this Euro mismatch. In the medium term, the Company's objective is to increase the level of non-US$ denominated revenue, thus creating a natural hedge of its non-US$ expenditure.

During 2001 Trinity began documenting its hedging transactions in accordance with the requirements of SFAS 133. In the six month period to June 30, 2003 an unrealised loss of US$112,567 (June 30, 2002: gain of US$947,273) was taken to comprehensive income in respect of such contracts in accordance with the standard.

During the period ended June 30, 2003 realised foreign exchange losses of US$176,560 were charged to normal administrative expenses in the Income Statement on the exercise of forward contracts under US GAAP. During the six month period ended June 30, 2002 realised foreign exchange gains of US$320,429 were credited to normal administrative expenses in the Income Statement on the exercise of forward contracts. At June 30, 2003 contracts with a fair value of US$779,611 exist which the Company anticipates will be reclassified into earnings from comprehensive income on the exercise of forward contracts. The last of the Company's forward contracts in existence at June 30,2003 will expire in March 2004.

CUMULATIVE EFFECT ON SHAREHOLDERS' EQUITY	
Total shareholders' equity before minority interests under Irish GAAP	
US GAAP adjustments:	
Goodwill	
- Gross	
- Aggregate amortization	
Share capital not paid	
Adjustment for sale and leaseback	
Adjustment for research and development costs	
Adjustment for fair value of derivative instruments	
Adjustment for sales on extended credit	
Deferred tax	
Shareholders' equity under US GAAP	

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

Restatement

In December 2003, Trinity filed a restated Form 20-F/A restating its financial statements for 2002, 2001 and 2000. Consequently Trinity has

restated the prior year comparatives contained in this document where applicable. Details of the nature of the adjustments to the original reported numbers can be found in the restated Form 20-F/A.

EFFECT ON NET PROFIT

Profit on ordinary activities after taxation under Irish GAAP	
US GAAP adjustments:	
Goodwill amortisation	
Adjustment for sale and leaseback	
Adjustment for restructuring costs	
Adjustment for research and development costs	
Adjustment for sales on extended credit	
Adjustment for fair value on derivative instruments	
Deferred tax	
Profit under US GAAP	
Profit under US GAAP, as previously stated	
Impact of restatements from Irish GAAP (Note 1)	
Deferred tax (ii)	
Fair value of financial instruments (iii)	
Licence and patent amortisation (iv)	
Goodwill (v)	
Profit under US GAAP, as restated	
Profit per ordinary share (US$)	
Diluted profit per ordinary share (US$)	
Weighted average number of ordinary shares used in computing basic earnings per ordinary share	
Diluted weighted average number of ordinary shares used in computing diluted profit per ordinary share	

(ii) - (v) See footnotes on pages 15 and 16

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Profit under US GAAP	
Translation adjustment	
Fair value of derivative instruments	
Total Comprehensive Income	

Total Comprehensive Income, as previously stated	
Impact of restatements from Irish GAAP (Note 1)	
Translation adjustment (i)	
Deferred tax (ii)	
Fair value of financial instruments (iii)	
Licence and patent amortisation (iv)	
Goodwill (v)	
Total Comprehensive Income, as restated	

CHANGES IN US GAAP EQUITY FOR THE PERIOD FROM JANUARY 1, 2003 TO JUNE 30, 2003

	US$
US GAAP Shareholders' Equity at January 1, 2003	70,944,268
Net profit for the period	3,489,403
'A' shares issued for conversion of debenture	3,500,000
Options exercised	530,674
Share issue expenses	(2,474)
Share capital not paid	(115,617)
Stock compensation - additional paid in capital	58,009
Other comprehensive income	
Translation adjustment	237,570
Fair value of derivative instruments	(112,567)
US GAAP Shareholders' Equity at June 30, 2003	78,529,266

(i) The cumulative and annual effects of the restatement for translation adjustment arising on consolidation of non-US$ functional subsidiaries are excluded from the effect on Total Comprehensive Income, as the effect on net income is matched by a corresponding effect on the translation adjustment reserve.

(ii) The restatement corrects the deferred taxation effect on net income and Shareholders' Equity and Total Other Comprehensive Income to incorporate the appropriate tax rates for the deferred tax impact on reconciling items and the allocation of the restatement items to the appropriate period under US GAAP.

5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (Continued)

(iii) The Company has corrected its calculation of the fair values of forward contracts at June 30, 2002 to take account of an exchange rate error in the exchange rates used by the Company at June 30, 2002 to the official rate; and to reclassify the fair value of certain forward contracts that were entered into after the formalisation of the Company's hedge documentation, to Shareholders' Equity from Income.

(iv) The Company has amended the US GAAP adjustment for goodwill amortisation to correctly include amortisation on licence and patent assets in determining net income under US GAAP.

(v) The Company has corrected an error in the calculation of the goodwill to be excluded in determining net income under US GAAP.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorised.

TRINITY BIOTECH PLC

/s/ Rory Nealon

Rory Nealon
Chief Financial Officer

December, 2003