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TRINITY BIOTECH PLC
Form 6-K
February 07, 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 February, 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, 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, primarily, infectious diseases, sexually transmitted diseases, blood coagulation disorders and autoimmune disorders. The Company markets over 200 different diagnostic products in over 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

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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. 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 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. Upon completion of the acquisition, Trinity intends to transfer the Sigma hemostasis test manufacturing from St Louis to the Irish facility, with the transfer scheduled for completion in Q3 2003. Trinity also acquired the speciality clinical chemistry product line from Sigma Diagnostics in December 2002. This business consists of several esoteric products that are clearly differentiated in the marketplace.

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. This combined with certain share purchases from existing shareholders resulted in an increase in Trinity's shareholding to 40%.

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

Trinity's financial statements include the attributable results of five trading entities - Trinity Biotech Manufacturing Limited, Trinity Biotech USA, Trinity Biotech Inc, MarDx Diagnostics Inc and Trinity Biotech GmbH. 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 consolidated statement of cashflows), which conform in all material respects to US GAAP except as indicated in the notes to the condensed financial statements.

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Results of Operations

Six Months Ended June 30, 2002 Compared to Six Months Ended June 30, 2001

Trinity's consolidated revenues for the six month period ended June 30, 2002 were US\$23,173,560 an increase of US\$5,449,561 compared to consolidated revenues of US\$17,723,999 for the six months ended June 30, 2001. This increase in revenues is due to organic growth and the inclusion of the revenues of Biopool for the six months to June 30, 2002.

The gross margin from product sales for the six month period ended June 30, 2002 was 49%.

Normal administrative expenses, including amortization, for the six month period ended June 30, 2002 amounted to US\$6,182,067 compared to US\$4,458,179 for the six month period ended June 30, 2001. The increase in administration expenses of US\$1,723,888 is due to increased costs arising on the expansion of the business in addition to the inclusion of the administration expense of Biopool for the six months to June 30, 2002. An exceptional charge of US\$800,000 was recognized in the six month period to June 30, 2001 relating to the closure of the Bartels facility in Seattle. No comparable charge was recognized in the six month period to June 30, 2002. Research and development expenditure increased to US\$1,918,861 from US\$1,559,025 during the same period last year. This was due to the inclusion of the research and development costs of Biopool for the six months to June 30, 2002. The increase in the taxation charge to US\$435,754 for the period ended June 30, 2002 from US\$73,698 for the comparable period in 2001, reflects the Company's progression to a tax paying environment which is in part due to the near complete utilization of losses carried forward.

Net interest payable increased to US\$243,019 for the six months to June 30, 2002 compared to US\$183,196 for the comparable period in 2001. The increased level of interest reflects the Company's higher level of net debt during the 2002 period.

The net profit for the six month period ended June 30, 2002 was US\$2,360,283 compared to a net profit of US\$1,992,471 for the same period last year.

Liquidity and Capital Resources

As of June 30, 2002 Trinity's consolidated cash and cash equivalents were US\$4,374,048. This compares to cash and cash equivalents of US\$5,281,976 at December 31, 2001. This decrease has been caused primarily by repayments due on certain of the Company's bank borrowings and the purchase of fixed assets offset in part by an increase in operating net cash inflows. The combination of these factors has resulted in net cash outflows of US\$907,928 during the six month period.

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 2002.

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 and its expenses are incurred principally in Euros and US Dollars. 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

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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.

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Trinity Biotech plc

Unaudited Consolidated Balance Sheet as at:

| | June 30, 2002 US\$ (Unaudited) | December 31, 2001 US\$ |
|---|--------------------------------------|---------------------------|
| ASSETS | | |
| Cash and cash equivalents | 4,374,048 | 5,281,976 |
| Accounts receivable and prepayments | 9,480,022 | 7,684,575 |
| Inventories | 17,491,247 | 16,342,308 |
| | ----- | ----- |
| Total Current Assets | 31,345,317 | 29,308,859 |
| Property, plant & equipment, net | 6,095,051 | 5,967,443 |
| Intangible assets, net | 39,283,558 | 40,402,394 |
| Financial assets | 1,158,322 | 1,350,517 |
| | ----- | ----- |
| TOTAL ASSETS | 77,882,248 | 77,029,213 |
| | ----- | ----- |
| LIABILITIES & SHAREHOLDERS' EQUITY | | |
| Accounts payable & accrued expenses | 11,834,896 | 12,692,405 |
| Long term liabilities | 6,762,608 | 7,805,237 |
| SHAREHOLDERS' EQUITY | | |
| Called up share capital | | |
| Class 'A' ordinary shares | 591,165 | 591,165 |
| Class 'B' ordinary shares | 12,255 | 12,255 |
| Share premium account | 75,175,361 | 75,132,118 |
| Currency adjustment | (4,704,538) | (5,054,186) |
| Retained deficit | (12,099,445) | (14,459,727) |
| Minority interest | 309,946 | 309,946 |
| | ----- | ----- |
| Total Shareholders' Equity | 59,284,744 | 56,531,571 |
| | ----- | ----- |
| Total Liabilities and Shareholders' Equity | 77,882,248 | 77,029,213 |
| | ----- | ----- |

Note: The balance sheet at December 31, 2001 has been derived from the audited financial statements at that date but does not include all of the information

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and footnotes required by generally accepted accounting principles for complete financial statements.

See notes to condensed consolidated financial statements.

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Trinity Biotech plc Unaudited Consolidated Profit and Loss Account

| | Six months end 2002 US\$ (Unaudited) |
|--|---|
| Revenues | 23,173,560 |
| | ----- |
| Costs and Expenses | |
| Cost of goods sold | (11,883,576) |
| Selling, general and administrative - normal | (4,985,386) |
| Selling, general and administrative - exceptional | -- |
| Research and development | (1,918,861) |
| Amortisation | (1,196,681) |
| | ----- |
| Operating profit | 3,189,056 |
| Share of operating loss in associate | (150,000) |
| Interest and other income | 24,715 |
| Interest expense | (267,734) |
| | ----- |
| Profit on ordinary activities before taxation | 2,796,037 |
| Tax on profit on ordinary activities | (435,754) |
| | ----- |
| Net profit | 2,360,283 |
| | ----- |
| Net profit per ordinary share (US\$) | 0.058 |
| Weighted average number of ordinary shares outstanding | 40,496,198 |
| CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES months ended June 30 | |
| | 2002 US\$ (Unaudited) |
| Profit for the financial period attributable to group shareholders excluding share of loss in associate | 2,510,283 |
| Share of operating loss in associate | (150,000) |
| Currency adjustment | 349,648 |
| | ----- |
| Total recognised gains and losses for the period | 2,709,931 |

Trinity Biotech plc
Unaudited Consolidated Statement of Cash Flows

| | Six months ended June 30 | |
|--|-----------------------------|-----------------------------|
| | 2002 US\$ (Unaudited) | 2001 US\$ (Unaudited) |
| Net cash flow from operating activities | 1,867,328 | (5,911) |
| Investing activities | | |
| Interest receivable | 24,715 | 43,200 |
| Purchase of fixed assets | (632,041) | (527,112) |
| Purchase of intangible assets | (35,650) | (337,156) |
| | ----- | ----- |
| | (642,976) | (821,068) |
| | ----- | ----- |
| Financing activities | | |
| Interest payable | (309,781) | (226,396) |
| Issue of ordinary shares | 43,243 | 145,448 |
| Capital element of loan repayments | (1,865,742) | (224,675) |
| Loans received | -- | 3,098,716 |
| | ----- | ----- |
| | (2,132,280) | 2,793,093 |
| | ----- | ----- |
| (Decrease) increase in cash and cash equivalents | (907,928) | 1,966,114 |
| Balance at beginning of period | 5,281,976 | 4,275,595 |
| | ----- | ----- |
| Balance at end of period | 4,374,048 | 6,241,709 |
| | ----- | ----- |

TRINITY BIOTECH PLC
NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

1. BASIS OF PREPARATION AND ACCOUNTING POLICIES The unaudited results for the six months to June 30, 2002 and June 30, 2001 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 is 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

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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, 2002 are not necessarily indicative of the results for the full fiscal year.

Companies Acts, 1963 to 2001

The financial information included in this document does not comprise statutory financial statements as referred to in Section 19 of the Companies (Amendment) Act, 1986. The auditors have made report without qualification under Section 163 of the Companies Act, 1963 in respect of such financial statements for the year ended 31 December 2001 which have been annexed to the relevant annual return and filed with the Companies Registration Office.

2. ANALYSIS OF REVENUE AND OPERATING INCOME

Trinity operates in one business segment, the market for rapid diagnostic tests for infectious 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 Company'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:

| | Six months ended | |
|-------------------------|------------------|------------|
| | June 30 | June 30 |
| | 2002 | 2001 |
| | US\$ | US\$ |
| U.S.A. | 15,686,368 | 12,108,029 |
| Europe | 3,738,863 | 3,475,506 |
| Middle East/Africa/Asia | 3,251,868 | 2,140,464 |
| Other | 496,461 | -- |
| | ----- | ----- |
| | 23,173,560 | 17,723,999 |
| | ----- | ----- |

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

| | Six months ended | |
|---------------|------------------|------------|
| | June 30 | June 30 |
| | 2002 | 2001 |
| | US\$ | US\$ |
| Ireland | 9,143,473 | 5,373,085 |
| United States | 14,030,087 | 12,350,914 |
| | ----- | ----- |
| | 23,173,560 | 17,723,999 |
| | ----- | ----- |

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

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| | Six months ended | |
|------------------------|------------------|-----------|
| | June 30 | June 30 |
| | 2002 | 2001 |
| | US\$ | US\$ |
| Ireland | 1,853,000 | 1,497,768 |
| United States | 1,336,056 | 811,597 |
| | ----- | ----- |
| Total operating income | 3,189,056 | 2,309,365 |
| | ----- | ----- |

d) The distribution of intersegmental sales is as follows:

| | Six months ended | |
|--------------------------------|------------------|-------------|
| | June 30 | June 30 |
| | 2002 | 2001 |
| | US\$ | US\$ |
| Ireland | 9,104,401 | 5,110,057 |
| Ireland - Intersegmental Sales | 5,379,528 | 5,544,750 |
| United States | 14,030,087 | 12,350,914 |
| Less Intercompany Sales | (5,340,456) | (5,281,722) |
| | ----- | ----- |
| | 23,173,560 | 17,723,999 |
| | ----- | ----- |

3. INVENTORIES

| | As at | |
|------------------|------------|-------------|
| | June 30 | December 31 |
| | 2002 | 2001 |
| | US\$ | US\$ |
| Raw materials | 6,383,809 | 5,120,345 |
| Work in progress | 5,510,326 | 7,014,487 |
| Finished goods | 5,597,112 | 4,207,476 |
| | ----- | ----- |
| | 17,491,247 | 16,342,308 |
| | ----- | ----- |

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

4. 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 material adjustments are shown in the table set out below:

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

- (1) Goodwill:
In prior years under Irish GAAP, goodwill was either written off immediately on completion of the acquisition against

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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 was not permitted; rather, goodwill had to be amortised 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 has been adopted for the purposes of the reconciliation in previous periods.

Under US GAAP, following the introduction of SFAS No. 142, "Goodwill and Intangible Assets", which is effective for accounting periods starting 15 December 2001 and, transitionally, for acquisitions completed after 30 June 2001, goodwill is capitalised and not amortised, but tested for impairment, at least annually, in accordance with SFAS No. 142. No impairment charges have been recorded under US GAAP for the periods presented.

- (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, 2002 is US\$279,751 (December 31, 2001 : US\$291,211).
- (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. SFAS 130 requires disclosure of the cumulative amounts of other comprehensive income.
- (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:**
Under Irish GAAP deferred tax is provided in full on timing differences that result in an obligation at the balance sheet date to pay more tax, or a right to pay less tax, at a future date, at rates expected to apply when they crystallise based on current tax rates and law. Under SFAS 109 - "Accounting for Income Taxes", deferred taxation is computed using the liability method under which deferred income tax liabilities are fully provided and deferred tax assets are recognised to the extent that their realisation is more likely than not. In addition, deferred taxation would also be provided under US GAAP on the difference between the accounting and tax bases of assets and liabilities of subsidiaries acquired.
- (6) **Minority Interests:**
Under Irish GAAP, Minority Interests are included as a portion of Shareholders' Equity. Under US GAAP, Minority Interests are

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excluded from Shareholders' Equity.

- (7) **Restructuring Costs:**
 Under Irish GAAP, certain provisions made for restructuring costs (principally payments to employees) incurred as a result of acquisitions would not be recognisable under US GAAP, because EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination", would also not permit such costs to be included in the purchase price allocation but contains more stringent criteria for expense recognition, and such restructuring costs will be expensed in the subsequent period.

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

- (8) **Research and Development:**
 Under US GAAP, 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.
- (9) **Derivatives and financial instruments:**
 In June 1998, the FASB issued SFAS No 133 "Accounting for Derivative Instruments and Hedging Activities". SFAS 133 requires that (for US GAAP purposes only) 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.
- (10) **Sales on Extended Credit Terms:**
 In 2000 the Company made certain sales on extended credit terms. Under US GAAP, SAB 101 "Revenue Recognition in Financial Statements", such sales on extended credit terms would not be recognisable as revenue. No similar provisions exist under Irish GAAP to preclude revenue recognition. Sales were not made on extended credit terms in 2001.

| CUMULATIVE EFFECT ON SHAREHOLDERS' EQUITY | 30 June 2002 US\$ |
|--|-------------------------|
| Total shareholders' equity before Minority Interests under Irish GAAP | 58,974,798 |
| US GAAP adjustments: | |
| Goodwill | 9,295,463 |
| Share capital not paid | (279,751) |
| Adjustment for sale and leaseback | (887,320) |
| Adjustment for restructuring costs | 1,644,363 |

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| | |
|---|-------------|
| Adjustment for research and development costs | (2,134,850) |
| Adjustment for fair value of derivative instruments | 519,595 |
| Other | 127,567 |
| | ----- |
| Shareholders' equity under US GAAP | 67,259,865 |
| | ----- |

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

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

| EFFECT ON NET PROFIT | 30 June 2002 US\$ |
|--|-------------------------|
| Profit on ordinary activities after taxation under Irish GAAP | 2,360,283 |
| US GAAP adjustments: | |
| Goodwill amortisation | 1,196,681 |
| Adjustment for sale and leaseback | 25,352 |
| Adjustment for sales on extended credit | -- |
| Adjustment for restructuring costs | (1,205,637) |
| Adjustment for research and development costs | (224,767) |
| Adjustment for fair value of derivative instruments | 519,595 |
| Other | 461,455 |
| | ----- |
| Profit under US GAAP | 3,132,962 |
| | ----- |
| Profit per ordinary share (US\$) | 0.077 |
| Diluted profit per ordinary share (US\$) | 0.076 |
| Weighted average number of ordinary shares used in computing basic earnings per ordinary share | 40,496,198 |
| Diluted weighted average number of ordinary shares used in computing diluted profit per ordinary share | 41,051,754 |
| STATEMENT OF COMPREHENSIVE INCOME | |
| Estimated income under US GAAP | 3,132,962 |
| Currency adjustment | 349,648 |
| | ----- |
| Comprehensive income for the period | 3,482,610 |
| | ----- |

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Signatures

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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 authorized.

TRINITY BIOTECH PLC

/s/ Rory Nealon

Rory Nealon
Chief Financial Officer

February 7, 2002
