

TRINITY BIOTECH PLC  
Form 6-K  
January 07, 2005

**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 January, 2005**

**TRINITY BIOTECH PLC**

**(Translation of registrant's name into English)**

**IDA BUSINESS PARK,  
BRAY,  
CO. WICKLOW, IRELAND  
(Address of Principal Executive Officers)**

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**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\$6million 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 haemostasis 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 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. 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 transferred the manufacture of the Sigma haemostasis reagent product line and the Sigma clinical chemistry product line from St Louis to the Bray, Ireland facility. In April 2004, Trinity acquired the assets of Adaltis US, Inc for US\$3.5 million in cash. Adaltis US, Inc is the US distribution arm for Adaltis, Inc. As part of the transaction, Trinity has obtained exclusive distribution rights to Adaltis' open-end microplate analytical instrumentation in the US and non-exclusive distribution rights in the rest of the world, except China. In April 2004, Trinity also completed the acquisition of Fitzgerald Industries (["Fitzgeralds"]) for US\$16 million, consisting of cash of US\$8 million and shares in Trinity Biotech plc of US\$8million.

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 wrote 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, 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 to 1,802,676 Class [A] Ordinary shares of the company. In January 2004, 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. These 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 US\$22,500,000 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 the 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 an exercise 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.

Trinity's financial statements include the attributable results of eight trading entities - Trinity Biotech Manufacturing Limited, Biopool US Inc, Trinity Biotech (USA), MarDx Diagnostics Inc, Trinity Biotech GmbH, Trinity Biotech (UK Sales) Limited, Biopool AB and Benen Trading Limited. These entities are engaged in the manufacture and sale of diagnostic test kits. 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.

## **Results of Operations**

### Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003

#### 1. Overview

In US dollars, our consolidated revenues increased by 15%; operating income fell by 41%; and retained profit decreased by 33%.

Geographically, 53% of our sales were generated in the USA, 28% in Europe and 19% in the rest of the world.

The gross margin for the period ended September 30, 2004 was 50.7% compared to 48.0% for the period ended September 30, 2003.

Our operating margin in 2004 was 6.9% of sales, a decrease of approximately 7% from the 13.5% of sales for the previous period. This is primarily due to an increase of approximately US\$7.7 million in Selling, General and Administrative costs which is principally due to a significant increase in the scale of our US salesforce.

#### 2. Revenues

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



	<b>Period ended September 30,</b>		<b>% Change</b>
	<b>2004 (US\$ □000)</b>	<b>2003 (US\$ □000)</b>	
Revenues			
Infectious diseases	29,306	26,596	10
Haemostasis	19,842	18,736	6
Other	8,748	4,859	80
<b>Total</b>	<b>57,896</b>	<b>50,192</b>	<b>15</b>

Trinity Biotech's consolidated revenues for the period ended September 30, 2004 were US\$57,896,000 compared to consolidated revenues of US\$50,192,000 for the period ended September 30, 2003.

Revenues in our infectious disease and haemostasis product ranges have increased by 10% and 6% respectively. The rate of growth in our infectious disease product range is slightly higher due to the ongoing increase in our sales of rapid HIV products primarily in Africa.

Revenues in the Other category have increased significantly due to the acquisition of Fitzgerald Industries on April 20, 2004. Revenues from Fitzgerald in the period since acquisition to September 30, 2004 amounted to US\$2.8 million.

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

	<b>Period ended September 30,</b>		<b>% Change</b>
	<b>2004 (US\$ □000)</b>	<b>2003 (US\$ □000)</b>	
Revenues			
USA	30,690	27,467	12
Europe	16,332	15,314	7
Middle East /Africa	8,516	4,879	75
Other overseas	2,358	2,531	(7)
<b>Total</b>	<b>57,896</b>	<b>50,192</b>	<b>15</b>

The 12% increase in the US is attributable to a combination of increased sales following the expansion of the direct salesforce in the USA and following the acquisitions of Adaltis and Fitzgerald in April 2004.

The increase of 75% in Middle East/Africa is primarily driven by the ongoing increase in the size of the rapid HIV testing market in Africa and by Trinity's success in winning a sizeable share of this increase.

### 3. Operating Expenses

The following table sets forth our operating expenses.

	Period ended September 30,		% Change
	2004 (US\$ □000)	2003 (US\$ □000)	
Revenues	57,896	50,192	15
Cost of sales	(28,568)	(26,086)	10
Research & development	(3,695)	(4,269)	(13)
Selling, General & Administrative expenses	(19,884)	(12,178)	63
Amortisation	(1,755)	(908)	93
<b>Operating profit</b>	<b>3,994</b>	<b>6,752</b>	<b>(41)</b>

#### *Gross Margin*

Trinity Biotech's gross margin for the period ended September 30, 2004 was 50.7% compared to 48.0% for the period ended September 30, 2003.

#### *Selling, General and Administrative expenses (□SG&A□)*

Overall SG&A expenses account for 34% of consolidated revenues for the period ended September 30, 2004 which compares with 24% for the same period in 2003. The higher percentage is attributable to the strengthening of the Group's sales and marketing and administrative functions. In particular the increase in the SG&A expenses is associated with the US direct salesforce following the increase from 30 people in 2003 to 95 people at the end of September 2004. In addition the Company is incurring additional administrative expenses following the acquisitions of both Adaltis and Fitzgerald which were acquired in April 2004.

#### *Amortisation*

The level of amortisation increased from US\$908,000 for the period ended September 30, 2003 to US\$1,755,000 for the period ended September 30, 2004. This is largely attributable to a reduction during 2004 in the release of negative goodwill and an increase in amortisation associated with the acquisition of Adaltis and Fitzgeralds in April 2004.

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

As of September 30, 2004 Trinity's consolidated cash and cash equivalents were US\$17,079,026. This compares to consolidated cash and cash equivalents of US\$20,563,418 at December 31, 2003.

This decrease of US\$3,484,392 has been caused primarily by cash outflows from operations (US\$2,532,466), payments for tangible and intangible fixed assets (US\$5,666,394), the repayment of bank borrowings and other financial liabilities (US\$4,740,656), and payments for the purchase of businesses (US\$19,089,438). These cash outflows have been offset by the issue of share capital (US\$23,957,310) and the issue of US\$5,000,000 in convertible debentures. 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 (Ireland) Ltd. and Allied Irish Bank plc, US\$6,800,000 of which was drawn down at September 30, 2004. This 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.

In July 2003, the Company completed a private placement of US\$20,000,000 principal amount of 3% convertible debentures. As part of the 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.



In January 2004, the Company completed a US\$22,500,000 private placement of 5,294,118 of Class [A] Ordinary Shares of the Company at a price of US\$4.25 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 an exercise 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.

***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 has an adverse impact on the profitability of the business. 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***

Trinity Biotech derives revenues 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. 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.

**Trinity Biotech plc**  
**Unaudited Condensed Consolidated Balance Sheet as at:**

	<i>September 30, 2004 US\$ (Unaudited)</i>	<i>December 31, 2003 US\$ (Audited)</i>
<b>ASSETS</b>		
Inventories	38,260,639	30,554,618
Accounts receivable and prepayments	24,098,667	13,912,889
Cash and cash equivalents	17,079,026	20,563,418
	<hr/>	<hr/>
	79,438,332	65,030,925
Intangible assets, net	58,199,457	38,850,780
Property, plant & equipment, net	14,759,594	13,659,680
Other assets	1,219,034	550,104
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>153,616,417</b>	<b>118,091,489</b>
	<hr/>	<hr/>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
Accounts payable & accrued expenses	20,886,980	19,400,947
Provision for liabilities and charges (deferred tax)	1,257,098	910,902
Long term liabilities	14,878,265	17,517,713
<b>SHAREHOLDERS' EQUITY</b>		
Called up share capital		
Class [A] ordinary shares	792,756	658,133
Class [B] ordinary shares	12,255	12,255
Share premium account	120,516,200	87,596,132
Currency adjustment	(4,271,611)	(4,091,568)
Profit and loss reserve	(748,176)	(4,168,943)
Other reserves	292,650	255,918
	<hr/>	<hr/>
<b>Total Shareholders' Equity</b>	<b>116,594,074</b>	<b>80,261,927</b>
	<hr/>	<hr/>
<b>Total Liabilities and Shareholders' Equity</b>	<b>153,616,417</b>	<b>118,091,489</b>
	<hr/>	<hr/>

Note: The balance sheet at December 31, 2003 has been derived from the audited financial statements 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**

	<i>Nine months ended</i>	
	<i>September 30</i>	
	<b>2004</b>	<b>2003</b>
	<b>US\$</b>	<b>US\$</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Revenues</b>	57,895,988	50,191,754
Cost of goods sold	(28,568,219)	(26,085,421)
Gross Profit	<u>29,327,769</u>	<u>24,106,334</u>
Selling, general and administrative	(19,883,658)	(12,177,570)
Research and development	(3,695,334)	(4,268,644)
Amortisation	(1,754,634)	(908,001)
Operating profit	<u>3,994,143</u>	<u>6,752,119</u>
Share of operating loss in associate	□	(157,000)
Interest and other income	235,536	86,714
Interest expense	(616,201)	(604,429)
Profit on ordinary activities before taxation	<u>3,613,478</u>	<u>6,077,404</u>
Tax on profit on ordinary activities	(192,712)	(942,795)
Net profit	<u>3,420,766</u>	<u>5,134,609</u>
Net profit per ordinary share (US\$)	0.06	0.12

Weighted average number of ordinary shares outstanding 54,748,831 42,626,493

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF TOTAL RECOGNISED GAINS AND LOSSES**

	<i>Nine months ended</i>	
	<i>September 30</i>	
	<b>2004</b>	<b>2003</b>
	<b>US\$</b>	<b>US\$</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Profit for the financial period attributable to group shareholders excluding share of operating loss in associate company	3,420,766	5,291,609
Share of operating loss in associate	□	(157,000)
Currency adjustment	(180,043)	576,147
Total recognised gains and losses for the period	<u>3,240,723</u>	<u>5,710,756</u>



**Trinity Biotech plc**  
**Unaudited Condensed Consolidated Statement of Cash Flows**

	<i>Nine months ended</i>	
	<i>September 30</i>	
	<b>2004</b>	<b>2003</b>
	<b>US\$</b>	<b>US\$</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Net cash flow from operating activities	(2,988,144)	2,460,622
Investing activities		
Interest received	219,953	93,560
Payment for tangible fixed assets	(2,664,598)	(1,456,544)
Payment for licenses and deferred development costs	(2,479,452)	(1,219,930)
Payments to acquire trades or businesses	(19,156,104)	(474,913)
Deferred acquisition consideration paid	□	(3,574,053)
	<u>(24,080,201)</u>	<u>(6,631,880)</u>
Financing activities		
Interest paid	(624,423)	(377,437)
Issue of ordinary share capital including premium and issuance costs	23,957,310	318,983
(Decrease)/Increase in long term debt	(2,491,601)	1,285,734
Repayment of other financial liabilities	(2,249,055)	(2,150,985)
Issue of convertible debentures	5,000,000	20,000,000
Repayment of minority interest	□	(309,946)
	<u>23,592,231</u>	<u>18,766,349</u>
Decrease in cash and cash equivalents	(3,476,114)	14,595,091
Non cash exchange movement	(8,278)	312,589
Balance at beginning of period	20,563,418	5,807,514
Balance at end of period	<u>17,079,026</u>	<u>20,715,194</u>

**TRINITY BIOTECH PLC****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****1. BASIS OF PREPARATION AND ACCOUNTING POLICIES**

The unaudited results for the nine months to September 30, 2004 and September 30, 2003 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 nine months to September 30, 2004 are not necessarily indicative of the results for the full fiscal year.

*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:

	<i>Nine months ended</i>	
	<i>September</i>	<i>September</i>
	<i>30</i>	<i>30</i>
	<i>2004</i>	<i>2003</i>
	<i>US\$</i>	<i>US\$</i>
U.S.A.	30,689,971	27,467,379
Europe	16,331,901	15,313,882
Middle East/Africa	8,515,614	4,879,162
Other	2,358,502	2,531,332
	<u>57,895,988</u>	<u>50,191,754</u>

**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:

	<i>Nine months ended</i>	
	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>
Rest of the World	38,207,330	34,927,097
United States	19,688,658	15,264,657
	<hr/>	<hr/>
	57,895,988	50,191,754
	<hr/>	<hr/>

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

	<i>Nine months ended</i>	
	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>
Rest of the World	4,558,111	1,955,578
United States	(563,968)	4,796,541
	<hr/>	<hr/>
Total operating income	3,994,143	6,752,119
	<hr/>	<hr/>

d) The distribution of intersegmental sales was as follows:

	<i>Nine months ended</i>	
	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>
Rest of the World	18,489,235	20,099,589
Rest of the World □ Intersegmental Sales	11,322,913	12,164,695
United States	37,585,891	27,753,668
Less Intercompany Sales	(9,502,051)	(9,826,198)
	<hr/>	<hr/>
	57,895,988	50,191,754
	<hr/>	<hr/>

e) The distribution of revenue by major product group was as follows:

	<i>Nine months ended</i>	
	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>

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Infectious diseases	29,305,780	26,596,334
Haemostasis	19,842,029	18,736,183
Other	8,748,179	4,859,237
	<u>57,895,988</u>	<u>50,191,754</u>



**TRINITY BIOTECH PLC****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Continued)****3. INVENTORIES**

	<i>As at</i>	
	<i>September 30 2004 US\$</i>	<i>December 31 2003 US\$</i>
Raw materials	14,036,554	11,712,402
Work in progress	10,874,277	9,206,838
Finished goods	13,349,808	9,635,378
	<u>38,260,639</u>	<u>30,554,618</u>

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

**4 SIGNIFICANT NON-CASH TRANSACTIONS**

During the nine month period to September 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

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 debentures and US\$44,500 of the related accrued interest was converted to 1,802,676 Class [A] Ordinary Shares of the Company. In January 2004, 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. These 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 US\$22,500,000 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 the 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 an exercise 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.

**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:



**TRINITY BIOTECH PLC****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Continued)****5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED  
ACCOUNTING PRINCIPLES (Continued)***(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 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 twenty one months to September 30, 2004. 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:

	<i>September 30 2004 US\$</i>	<i>December 31 2003 US\$</i>
Rest of World	(7,865,256)	(1,937,465)
United States	□	□
Total	<u>(7,865,256)</u>	<u>(1,937,465)</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 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 negative goodwill is recognized in US GAAP income as an extraordinary gain for the periods beginning after December 15, 2001. At September 30, 2004 and 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 have been recognised as an extraordinary gain in the year ended December 31, 2003. Depreciation of US\$46,730 for the period ended September 30, 2004, 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.

**TRINITY BIOTECH PLC**

**NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Continued)**

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

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 nine month period ended September 30, 2004 was US\$268,275 and US\$159,140 for the nine month period ended September 30, 2003.

The net book value of goodwill at September 30, 2004 was US\$56,262,730.

*(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 September 30, 2004 is US\$205,605 (December 31, 2003: US\$252,580).

*(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 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) 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.

*(6) 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.

*(7) 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.

**TRINITY BIOTECH PLC****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Continued)****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\$ 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 a portion of 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 nine month period to September 30, 2004 an unrealised loss of US\$69,373 (September 30, 2003: loss of US\$582,879) was taken to comprehensive income in respect of such contracts in accordance with the standard.

During the period ended September 30, 2004 US\$160,118 of foreign exchange losses were recognised in the Income Statement. This included realised foreign exchange losses of US\$118,210 (2003: US\$176,560) 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 September 30, 2004 the Company anticipates that US\$32,076 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 September 30, 2004 will expire in December 2005.

**(8) 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.

<b>CUMULATIVE EFFECT ON</b>	<i>September 30</i>	<i>December</i>
<b>SHAREHOLDERS' EQUITY</b>	<i>2004</i>	<i>31</i>
	<i>US\$</i>	<i>2003</i>
		<i>US\$</i>
Total shareholders' equity before minority interests under Irish GAAP	116,594,074	80,261,927
<i>US GAAP adjustments:</i>		
Goodwill		
□ Gross	21,776,683	21,776,683
□ Aggregate amortization	(8,367,191)	(9,853,550)
Property, plant and equipment	123,364	76,634
Share capital not paid	(205,605)	(252,580)
Adjustment for sale and leaseback	(773,236)	(811,264)
Adjustment for sales on extended credit	□	(144,345)
Adjustment for research and development costs	(6,803,509)	(4,667,646)
Adjustment for fair value of derivative instruments	158,109	345,691
Deferred tax	696,737	502,375
	<hr/>	<hr/>
Shareholders' equity under US GAAP	123,199,426	87,233,925
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**TRINITY BIOTECH PLC**  
**NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Continued)**

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

EFFECT ON NET PROFIT	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>
Profit on ordinary activities after taxation under Irish GAAP	3,420,766	5,134,609
<i>US GAAP adjustments:</i>		
Goodwill amortisation	1,486,359	748,861
Property, plant and equipment	46,730	41,885
Adjustment for sale and leaseback	38,028	38,028
Adjustment for research and development costs	(2,135,863)	(1,219,930)
Adjustment for sales on extended credit	144,345	(126,221)
Adjustment for fair value on derivative instruments	(118,210)	(176,560)
Deferred tax	194,362	221,997
Profit under US GAAP	<u>3,076,517</u>	<u>4,662,669</u>
Profit per ordinary share (US\$)	0.06	0.11
Diluted profit per ordinary share (US\$)	0.05	0.10
Weighted average number of ordinary shares used in computing basic earnings per ordinary share	54,748,831	42,626,493
Diluted weighted average number of ordinary shares used in computing diluted profit per ordinary share	63,767,124	48,084,810
 <b>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</b>		
	<i>September 30 2004 US\$</i>	<i>September 30 2003 US\$</i>
Profit under US GAAP	3,076,517	4,662,669
Translation adjustment	(180,043)	576,147
Fair value of derivative instruments	(69,373)	(582,879)
Total Comprehensive Income	<u>2,827,101</u>	<u>4,655,937</u>



**TRINITY BIOTECH PLC****NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Continued)****5. DIFFERENCES BETWEEN IRISH AND US GENERALLY ACCEPTED  
ACCOUNTING PRINCIPLES (Continued)**CHANGES IN US GAAP EQUITY FOR THE PERIOD FROM JANUARY 1, 2004 TO SEPTEMBER 30, 2004  
US\$

US GAAP Shareholders' Equity at January 1, 2004	87,233,925
Net profit for the period	3,076,517
Class [A] shares issued for cash	24,334,372
Class [A] shares issued for conversion of debenture	427,500
Class [A] shares issued for exercise of warrant	174,000
Class [A] shares issued as compensation for acquisition	8,000,000
Options exercised	1,509,803
Share issue expenses	(1,390,982)
Share capital not paid in previous periods now paid	46,975
Stock compensation [ ] additional paid in capital	36,732
<u>Other comprehensive income</u>	
Translation adjustment	(180,043)
Fair value of derivative instruments	(69,373)
	<hr/>
US GAAP Shareholders' Equity at September 30, 2004	123,199,426
	<hr/>

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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

January 7, 2005