

TRINITY BIOTECH PLC

Form F-3

June 16, 2004

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM F-3**

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**TRINITY BIOTECH PLC**

(Exact name of registrant as specified in its charter)

**Republic of Ireland**  
(State or other jurisdiction of  
incorporation or organization)

**None**  
(IRS Employer  
Identification Number)

**IDA Business Park  
Bray, Co. Wicklow  
Ireland  
011 353 1 276 9800**

(Address and telephone number of Registrant's principal executive office)

**Alan J. Bernstein, Esq.  
Carter Ledyard & Milburn LLP  
2 Wall Street  
New York, New York 10005  
(212) 732-3200**

(Name, address and telephone number of agent for service)

**Copies to:**

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**Alan J. Bernstein, Esq.  
Carter Ledyard & Milburn LLP  
2 Wall Street  
New York, New York 10005  
(212) 732-3200**

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**Approximate date of commencement of proposed sale to the public:** From time to time after this registration statement becomes effective, as determined by market conditions and other factors.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

## Edgar Filing: TRINITY BIOTECH PLC - Form F-3

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

### CALCULATION OF REGISTRATION FEE

| <b>Title of each class of securities to be registered</b> | <b>Amount to be registered (2)</b> | <b>Proposed maximum offering price per share(3)</b> | <b>Proposed maximum aggregate offering price(3)</b> | <b>Amount of registration fee (3)</b> |
|---|------------------------------------|---|---|---------------------------------------|
| Class A Ordinary Shares, nominal value \$.0109 (1)        | 3,479,000                          | \$2.875   | \$10,002,125  | \$1,267.30                            |

- (1) American Depositary Shares (evidenced by American Depositary Receipts, ADRs ), each representing one Class A Ordinary Share, have been registered on a separate Registration Statement on Form F-6.
- (2) The registration statement also includes an indeterminate number of shares underlying the ADRs that may become offered, issuable or sold to prevent dilution resulting from stock splits, stock dividends and similar transactions, which are included pursuant to Rule 416 under the Securities Act of 1933, as amended.
- (3) Estimated solely for the purpose of computing the amount of the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, on the basis of the average of the high and the low prices (\$2.91 and 2.84, respectively) of one ADR representing one Class A Ordinary Share as reported by Nasdaq on June 10, 2004.

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**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any state where the offer or sale is not permitted.

## PROSPECTUS

**Subject to Completion, dated June 16, 2004**

**3,479,000 Class A Ordinary Shares**

## TRINITY BIOTECH PLC

Class A Ordinary Shares Represented by American Depositary Receipts

The American Depositary Receipts of Trinity Biotech trade in the United States on The Nasdaq SmallCap Market under the symbol "TRIB." On June 10, 2004, the last reported sale price of an American Depositary Receipt of Trinity Biotech, as reported by Nasdaq, was \$2.85.

This prospectus relates to the resale of 3,479,000 American Depositary Receipts which were issued and sold in connection with the acquisition of the business of Fitzgerald Industries International, Inc. pursuant to a private placement to the selling shareholders named in this prospectus. We are registering the resale of the shares underlying the American Depositary Receipts pursuant to commitments with the selling shareholders. Trinity Biotech will not receive any additional proceeds from the sale of the American Depositary Receipts offered by this prospectus.

**See "Summary of Risks" beginning on page 4 to read about certain factors you should consider before buying American Depositary Receipts.**

**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

Prospectus dated \_\_\_\_, 2004.

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## About Trinity Biotech

Trinity Biotech plc, an Irish public limited company, was formed in January 1992 to acquire, develop, manufacture and market rapid and laboratory based diagnostic tests for the detection of various infectious diseases, blood coagulation disorders and other medical conditions. In addition, we manufacture, acquire and market diagnostic tests and antibodies through our German and Swedish subsidiaries as well as our U.S. subsidiaries, Clark Laboratories Inc. (trading as Trinity Biotech (USA) Corp.), MarDx Diagnostics Inc., Biopool U.S., Inc. and Fitzgerald Industries International, Inc. Our address is IDA Business Park, Bray, Co. Wicklow, Ireland, telephone number 011 353 1 276 9800.

## Where You Can Find More Information

We file annual and special reports and other information with the SEC. You may obtain these filings over the internet at the SEC's Web site at <http://www.sec.gov>. You may also read and copy these filings at the SEC's public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330, and may obtain copies of Trinity Biotech's filings from the public reference room by calling (202) 942-8090. Our internet address is <http://www.trinitybiotech.com>.

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 until the selling shareholders sell all the shares. This prospectus is part of a registration statement we filed with the SEC (Registration No 333-\_\_\_\_\_).

- Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 7, 2004;
- Report on Form 6-K filed on April 27, 2004; and
- Report on Form 6-K filed on June 16, 2004;

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Corporate Secretary  
Trinity Biotech plc  
IDA Business Park  
Bray, Co. Wicklow, Ireland  
Tel: 011 353 1 276 9800



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You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of those documents.

Trinity Biotech is a “foreign private issuer” as defined in Rule 3b-4 under the Securities Exchange Act of 1934. As a result, our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act and transactions in Trinity Biotech’s equity securities by its officers and directors are exempt from Section 16 of the Exchange Act. In addition, Trinity Biotech is not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

Our ADRs are listed for quotation on The Nasdaq SmallCap Market, and reports and other information filed by us can be inspected at the offices of Nasdaq. Each ADR represents one Class A Ordinary Share of Trinity Biotech.

**Enforceability of Civil Liabilities Against Foreign Persons**

We are a public limited company organized under the laws of the Republic of Ireland. Several of our directors and officers and certain experts named in the registration statement are residents of Ireland or other non-U.S. jurisdictions. Substantial portions of the assets of these persons and of Trinity Biotech are located in Ireland or other non-U.S. jurisdictions.

We have appointed Alan Bernstein of Carter Ledyard & Milburn LLP as our agent to receive service of process in any legal action against us. However, it may not be possible for investors to effect service of process upon Trinity Biotech or its non-U.S. directors, officers or experts named in the registration statement or to enforce any judgment obtained against these persons in U.S. courts. Also, it may not be possible to enforce U.S. securities laws or judgments obtained in U.S. courts against these persons in a non-U.S. jurisdiction.

Pursuant to Irish law, Trinity Biotech must maintain a register of its shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of Trinity Biotech are required to be kept at the registered office of the company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. Trinity Biotech is obliged to keep proper books of account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges Trinity Biotech to file information relating to certain events within the company (new share capital issues, changes to share rights, changes to the Board of Directors) this information is filed with the Companies Registration Office (the “CRO”) in Dublin and is open to public inspection. The Articles of Association of Trinity Biotech permit ordinary shareholders to approve corporate matters in writing provided that it is signed by all the members for the time being entitled to vote and attend at general meeting. Ordinary shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the company carrying the right of voting at general meetings of the company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the company. Any shareholder who complains that the affairs of the company are being conducted or that the powers of the directors of the company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the company.



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

**Currency Translation**

Trinity Biotech publishes its financial statements in United States dollars. Unless otherwise specified, all references to "U.S. dollars", "dollars", "\$" or "U.S. \$" are to United States dollars and references to "Euro," or "€" are to the European Euro. No representation is made that the Euro or U.S. dollar amounts shown in this prospectus could have been or could be converted into U.S. dollars or Euros, as the case may be, at any particular rate or at all.

**Trinity Biotech's American Depositary Receipts**

An American Depositary Receipt or ADR is a receipt for the shares of a foreign corporation held in the vault of a U.S. bank and entitling the holder to all dividends and capital gains. Instead of buying shares of foreign-based companies in overseas markets, U.S. persons can buy shares in the United States in the form of an ADR. An American Depositary Share or ADS is the share issued under a depositary agreement representing the underlying ordinary share that trades in the issuer's home market. Technically, ADS is the instrument that actually is traded, whereas the ADR is the certificate that represents a number of ADSs.

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The Bank of New York acts as the depository for Trinity's ADSs pursuant to an amended and restated deposit agreement which is an exhibit to the Form F-6 registration statement filed by Trinity on January 15, 2004, registration no. 333-111946. One ADS represents one Class A Ordinary Share of Trinity. The depository's offices are located at 101 Barclay Street, New York, NY 10286.

**Summary of Risks**

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

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

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

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

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

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

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

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

- The diagnostics industry is extremely competitive. Trinity Biotech is competing directly with companies which have greater capital resources and larger marketing and business organizations than Trinity Biotech. Trinity Biotech's ability to grow revenue and earnings may be adversely impacted by competitive product and pricing pressures and by its inability to gain or retain market share as a result of the action of competitors. We have significantly invested in research and development ("R&D") but there can be no guarantees that our R&D programmes will not be rendered technologically obsolete or financially non-viable by the technological advances of our competitors, which would also adversely affect our existing product lines and inventory. The main competitors of Trinity Biotech (and their principal products with which Trinity Biotech competes) are Dade Behring (Sysmex® CA, D-Dimer plus, Enzygnost®), bioMerieux (MDA®, VIDAS®), Zeus Scientific Inc. (Zeus EIA, IFA), Diasorin Inc. (ETI®), Abbott Diagnostics (AxSYM®, IMx®), Diagnostic Products Corp. - DPC (Immulite®), Bio-Rad (ELISA & WB) and Roche Diagnostics (COBAS AMPLICOR®, Ampliscreen®, Accutrend®).

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

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

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

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

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

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

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

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

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

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

| <b>Patent Number</b> | <b>Description</b>  | <b>Patent life remaining from<br/>May 30, 2004</b> |
|----------------------|---|--|
| 5,006,474            | Bi-Directional Lateral Chromatography Test Device   | 3 years 11 months                                  |
| 5,114,845            | Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin  | 3 years 2 months                                   |
| 5,175,087            | Method of Performing Tissue Plasminogen Activator Assay   | 3 years 2 months                                   |
| 5,985,582            | Thrombin-Based Assay for Antithrombin - III   | 13 years 7 months                                  |
| 6,194,394            | Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays                                  | 14 years 2 months                                  |
| 6,528,273            | Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls | 14 years 6 months                                  |
| 6,391,609            | Thromboplastin Reagents and Methods for Preparing and Using Such Reagents   | 15 years 5 months                                  |
| 6,653,066            | Device and Method for Detecting Polyvalent Substances   | 19 years 6 months                                  |

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

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

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

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

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

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

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

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

- The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. Although Trinity Biotech does not expect to be dependent upon any one source for these raw materials and although we have recently acquired a significant source for antibodies and antigens (see the section below entitled *Recent Developments - Corporate Acquisitions* ), other sources of antibodies with the specificity and sensitivity desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

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

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

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

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

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

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

***The issuance of shares in connection with a recent corporate acquisition, the conversion of our outstanding convertible Series A and B Notes and the recent issuance of shares and warrants would dilute the ownership interest of existing shareholders.***

- Through the issuance of approximately 3,479,000 ADRs in connection with the corporate acquisition described below under “Recent Developments - *Corporate Acquisitions*”, the ownership interests of the currently existing shareholders will be diluted by approximately 6.3% based on 51,868,917 shares currently outstanding. The resale in the public market of these ADRs could adversely affect prevailing market prices of our ADRs.
- The convertible notes described below under “Recent Developments - *Sale of Convertible Notes*” are convertible into ADRs representing our Class A Ordinary Shares. In the event that the conversion price for the Series A or Series B Notes is less than the trading price of our ADRs, conversion of these notes is likely to occur, which would dilute the ownership interests of existing shareholders. In addition, any sales in the public market of the ADRs issuable upon conversion of the notes could adversely affect prevailing market prices of our ADRs.
- Through the issuance of 5,725,735 shares in connection with the transaction described below under “Recent Developments - *Sale of Class A Ordinary Shares and Warrants*”, the ownership interests of existing shareholders have been diluted. Further, should the warrants described below under “Recent Developments - *Sale of Class A Ordinary Shares and Warrants*” be exercised, further dilution of shareholder interests would occur. Any resales of ADRs issued or issuable upon exercise of the warrants could affect prevailing market prices of our ADRs.



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

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

**Market Price Data****The Nasdaq SmallCap Market**

Our shares are traded on the Nasdaq SmallCap Market.

***Quarterly Stock Information***

The following table sets forth, for the periods indicated, the high and low sale prices for our ADRs, as reported by Nasdaq.

|                                       | <b>Per Ordinary Share (US\$)</b> |            |
|---------------------------------------|----------------------------------|------------|
|                                       | <b>High</b>                      | <b>Low</b> |
| <b><u>Fiscal Year Ended 2002:</u></b> |                                  |            |
| First Quarter                         | 1.86                             | 1.42       |
| Second Quarter                        | 1.64                             | 1.24       |
| Third Quarter.                        | 1.49                             | 0.89       |
| Fourth Quarter                        | 1.67                             | 0.93       |
| <b><u>Fiscal Year Ended 2003:</u></b> |                                  |            |
| First Quarter                         | 2.44                             | 1.25       |
| Second Quarter                        | 3.50                             | 2.09       |
| Third Quarter.                        | 4.01                             | 2.26       |
| Fourth Quarter                        | 6.72                             | 2.61       |

[Back to Contents](#)**Monthly Stock Information**

The following table sets forth, for each of the most recent last six months, the high and low sale prices for our ADRs, as reported by Nasdaq.

|               | Per Ordinary Share (US\$) |      |
|---------------|---------------------------|------|
|               | High                      | Low  |
| <b>Month</b>  |                           |      |
| December 2003 | 6.72                      | 2.61 |
| January 2004  | 5.99                      | 4.25 |
| February 2004 | 4.75                      | 3.75 |
| March 2004    | 4.47                      | 3.52 |
| April 2004    | 3.81                      | 2.81 |
| May 2004      | 3.15                      | 2.70 |

**Notice Regarding Forward-Looking Statements**

This prospectus and the documents incorporated in it by reference contain forward-looking statements which involve known and unknown risks and uncertainties. We include this notice for the express purpose of permitting Trinity Biotech to avail itself of the protections of the safe harbor provided by the Private Securities Litigation Reform Act of 1995 for all such forward looking statements. Examples of forward-looking statements include: (1) projections of capital expenditures, revenues, growth, prospects, financial resources and other financial matters; (2) statements of our plans or objectives; and (3) statements using the words “anticipate,” “believe,” “estimate,” “expect,” “may,” “intend,” “plan,” “project,” “understand” and other verbs suggesting uncertainty.

Our ability to predict results of Trinity Biotech's operations or the effects of certain events on Trinity Biotech's operating results is inherently uncertain. Therefore, we caution you to consider carefully the matters described under the caption “Summary of Risks” and certain other matters discussed in this prospectus, the documents incorporated by reference in this prospectus, and other publicly available sources. Such risks and many other factors beyond the control of Trinity Biotech's management could cause the actual results, performance or achievements of Trinity Biotech to be materially different from any future results, performance or achievements that may be expressed or implied by the forward-looking statements.

**Recent Developments***Corporate Acquisitions**Fitzgerald Industries International*

On April 15, we completed the acquisition of the business of Fitzgerald Industries International, Inc. in Massachusetts, which is engaged in the distribution of immunodiagnostic products to pharmaceutical companies, reference laboratories, diagnostic manufacturers, universities and research facilities throughout the world. In that acquisition, our wholly-owned subsidiary Benen Trading Ltd. entered into an Asset Purchase Agreement with Fitzgerald Industries and its shareholders pursuant to which we acquired all business related assets of Fitzgerald Industries for a consideration consisting of \$8,000,000 in cash, and shares issued in a private placement in an amount being determined by dividing \$8,000,000 by the average closing price less 6% of our ADRs for the ten trading days prior to the effective date of a registration statement registering the resale of the shares underlying such ADRs, and the assumption of certain liabilities in an asset purchase agreement entered into in connection with the acquisition. Pursuant to a stock purchase agreement entered into in connection with the acquisition, we are obliged to file with the SEC a registration statement by June 16, 2004, providing for the public resale of the shares issuable to the shareholders of Fitzgerald Industries, identified below as the selling shareholders. We must use our reasonable best efforts to have such registration statement declared effective as soon as reasonably practicable. Pursuant to the stock purchase agreement, upon effectiveness of the registration statement, all the shares issued to the selling shareholders in connection with the acquisition may be sold by a broker designated by us, and in the event that the sale of the shares does not generate \$8,000,000 for the selling shareholders, we will compensate the selling shareholders.

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For purposes of this prospectus only, we have based the calculation of the number of shares issuable to, and resold by, the selling shareholders, on the average reported sale price per share for Trinity Biotech's ADRs on the Nasdaq SmallCap Market on June 10, 2004, which was \$2.875 per ADR, and have deducted approximately 20% from such price to cover any additional shares issuable in the event that the 10 day average closing price pre-effectiveness less 6% should be up to 20% lower than the average reported sale price on June 10, 2004.

The selling shareholders also continue as executive employees of our newly formed subsidiary Fitzgerald Industries International, Inc. under employment agreements negotiated in connection with the acquisition.

The description of the terms of the acquisition set forth herein does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the detailed provisions of the underlying agreements filed as exhibits to the registration statement of which this prospectus forms a part.

*Adaltis U.S.*

On April 7, 2004, we bought the business of Adaltis U.S., Inc. in Pennsylvania, a subsidiary of the Canadian company Adaltis Inc., which is engaged in the distribution of diagnostic instruments and reagents for the infectious disease market in the U.S. in an asset deal for a price of approximately \$2,800,000 in cash.

*Sale of Convertible Notes*

On July 10, 2003, we issued Series A Convertible Notes in the aggregate principal amount of \$20,000,000 for an aggregate sale price in the same amount to three institutional investors. The Series A Notes mature on January 1, 2007 and bear annual interest at the rate of 3.00%. In addition, Series B Convertible Notes, in the aggregate principal amount of up to \$5,000,000, were issued at the option of the Series A Note holders on March 1, 2004. The Notes are convertible into our ADRs representing our Class A Ordinary Shares. The conversion price of the Series A Notes is \$3.55; the conversion price of the Series B Notes is \$4.00. We have complied with our contractual obligations to file registration statements for the resale of the shares underlying the ADRs into which the Series A and B Notes are convertible.

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*Sale of Class A Ordinary Shares and Warrants*

On January 6, 2004, pursuant to a Securities Purchase Agreement, we issued 5,294,118 Class A Ordinary Shares for an aggregate sale price of \$22,500,000. Under that agreement, the investors also have exercised their right to purchase an additional 431,617 shares at a price of \$4.25 per share by February 5, 2004. Also, under the same agreement, the investors received Warrants to purchase an aggregate of 1,058,824 shares at an exercise price of \$5.25 per share. The Warrants became exercisable immediately and will expire on January 6, 2009. We have complied with our obligation under a Registration Rights Agreement with the investors, to file and have declared effective a registration statement covering the public resale of all of the shares issued to the investors on January 6, 2004, issued upon exercise of their right to purchase additional shares or issuable upon exercise of the Warrants.

*Approval of HIV Test*

On December 29, 2003, Trinity Biotech received approval from the U.S. Food and Drug Administration (FDA) to market its Uni-Gold Recombigen<sup>™</sup> HIV test in the United States. The product is approved for the detection of antibodies to HIV in human serum, plasma or whole blood and is the only device to be approved for use with all three sample types. Uni-Gold Recombigen<sup>™</sup> HIV produces a result within 10 minutes. Uni-Gold Recombigen<sup>™</sup> HIV was approved by the FDA on the basis of clinical trial results on over 9,000 patient specimens.

*Lawsuit against Inverness Medical*

In December 2003, Trinity Biotech filed an action against Inverness Medical for breach of contract. Inverness acts as exclusive distributor for certain of Trinity Biotech's infectious disease products in the US. This exclusivity is due to end on September 30, 2004, at which time it had been agreed that both Trinity Biotech and Inverness would sell the products under their respective labels. The suit alleges that Inverness is attempting to convert customers from the Trinity Biotech product to a product manufactured by Zeus Scientific by claiming that the Trinity biotech product is unavailable and being discontinued. The lawsuit alleges that under the terms of the contract, Trinity Biotech is entitled to sell directly in the US any product which Inverness sells in competition with Trinity Biotech, and Trinity Biotech has begun to approach Inverness customers in December 2003. As a consequence thereof, Inverness has filed a counterclaim in January 2004 against Trinity Biotech alleging breach of contract by Trinity. However, the court has denied a motion for preliminary injunction by Inverness to prevent Trinity from selling direct in the United States. The outcome of the litigation is pending.

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### **Use of Proceeds**

Trinity Biotech will not receive any additional proceeds from the sale of the ADRs offered by this prospectus.

### **Material US Federal and Irish Tax Consequences**

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

#### ***US Federal Income Tax Consequences to US Holders***

The following is a summary of the material US federal income tax consequences that generally would apply with respect to the ownership and disposition of Trinity Biotech ADRs, in the case of a purchaser of such ADRs who is a US Holder (as defined below) and who holds the ADRs as capital assets. This summary is based on the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and judicial and administrative interpretations thereof, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. Unless otherwise indicated, all statements describing US federal income tax consequences that are contained in this summary represent the opinion of Carter Ledyard & Milburn LLP, United States counsel for Trinity Biotech. For purposes of this summary, a US Holder is: an individual who is a citizen or a resident of the United States; a corporation created or organized in or under the laws of the United States or any political subdivision thereof; an estate whose income is subject to US federal income tax regardless of its source; or a trust that (a) is subject to the primary supervision of a court within the United States and the control of one or more US persons or (b) has a valid election in effect under applicable US Treasury regulations to be treated as a US person.

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

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

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

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

Dividends received by individuals from domestic and certain foreign corporations, and long-term capital gain realized by individuals, generally are subject to US federal income tax at a reduced maximum tax rate of 15 percent. Dividends received by a US Holder with respect to the underlying shares represented by the holder's ADRs should qualify for the 15 percent rate. The reduced tax rate on capital gains applies to sales and exchanges occurring before January 1, 2009. The reduced tax rate on dividend income applies to dividends received before January 1, 2009. The reduced tax rate will not apply to dividends received from PFICs, see discussion below, or in respect of certain short-term or hedged positions in common stock or in certain other situations. The Code contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the reduced tax rate. US Holders of Trinity Biotech ADRs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

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

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

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

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

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

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

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

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

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

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

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



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***Republic of Ireland Taxation***

Unless otherwise noted, the statements contained in the following discussion of Republic of Ireland tax consequences represent the opinion of Ernst & Young.

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

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

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

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

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

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

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

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

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

Irish holders are holders of ordinary shares or ADRs that (i) beneficially own the ordinary shares or ADRs registered in their name; (ii) in the case of individual holders, are resident, ordinarily resident and domiciled in Ireland under Irish taxation laws; (iii) in the case of holders that are companies, are resident in Ireland under Irish taxation laws; and (iv) are not also resident in any other country under any double taxation agreement entered into by Ireland.

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

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

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

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## Selling Shareholders

The registration statement of which this prospectus forms a part covers up to 3,479,000 Class A Ordinary Shares represented by ADRs issuable to the selling shareholders on the effective date of the registration statement of which this prospectus forms a part, as described in the section above entitled “Recent Developments - *Corporate Acquisitions - Fitzgerald Industries International*”. We have registered the shares underlying the ADRs to permit the selling shareholders and their respective pledgees, donees, transferees or other successors-in-interest that receive their ADRs from a selling shareholder as a gift, partnership distribution or other non-sale related transfer to resell the ADRs when they deem appropriate.

The table below identifies the selling shareholders and other information regarding the beneficial ownership of the ADRs by each of the selling shareholders. The first and second columns list the number and percentage, respectively, of ADRs beneficially owned by each selling shareholder prior to the offering covered by this prospectus. Because the number of shares to be issued to the selling shareholders is being determined by dividing \$8,000,000 by the average closing price less 6% of our ADRs for the 10 trading days prior to the effective date of the registration statement of which this prospectus forms a part, which average closing price is unknown to us as of the date of the filing of the registration statement of which this prospectus forms a part, we have based the calculation of the number of shares issuable to the selling shareholders on the average reported sale price per share for Trinity Biotech’s ADRs on the Nasdaq SmallCap Market on June 10, 2004, which was \$2.875 per ADR, and have deducted approximately 20% from such price to cover any additional shares issuable in the event that the 10 day average closing price pre-effectiveness less 6% should be up to 20% lower than the average reported sale price on June 10, 2004. Therefore, the numbers in columns one and two may change.

The third column lists each selling shareholder’s portion, based on agreements with us, of the 3,479,000 ADRs being offered by this prospectus. The number of ADRs being offered by this prospectus was determined in accordance with the terms of the Stock Purchase Agreement with the selling shareholders described in the section above entitled “Recent Developments - *Corporate Acquisitions - Fitzgerald Industries International*”, in which we agreed to register the resale of all ADRs issuable to the selling shareholders under such agreement. The fourth and fifth columns assume the sale of all of the ADR issuable to the selling shareholders under such agreement. The fourth and fifth columns assume the sale of all the ADRs offered by each selling shareholder. The selling shareholders may sell all, some or none of their ADRs in this offering. See “Plan of Distribution” below.



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| <b>Name of Shareholder</b>   | <b>Number of ADRs Beneficially Owned Before Offering</b> | <b>Percentage of ADRs Beneficially Owned Before Offering</b> | <b>Number of ADRs Being Offered</b> | <b>Number of ADRs Owned After Offering</b> | <b>Percentage of ADRs Owned After Offering</b> |
|--|--|--|-------------------------------------|--|--|
| Edward G. Fitzgerald<br>Fitzgerald Industries International, Inc.<br>34 Junction<br>Square Drive<br>Concord, MA<br>01742 | 1,739,500  | 3.15%  | 1,739,500                           | 0  | 0%   |
| Kevin Fitzgerald<br>Fitzgerald Industries International, Inc.<br>34 Junction<br>Square Drive<br>Concord, MA<br>01742     | 1,739,500  | 3.15%  | 1,739,500                           | 0  | 0%   |

Both selling shareholders are, since the acquisition of the business of Fitzgerald Industries by our wholly owned subsidiary Benen Trading Ltd., directors, managerial employees and officers of our newly formed subsidiary, Fitzgerald Industries International, Inc. The ADRs may be offered from time to time by the selling shareholders named above. However, the selling shareholders are under no obligation to sell any portion of their ADRs. All information about share ownership has been furnished by the selling shareholders.

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**Plan of Distribution**

Trinity Biotech is registering all of the shares underlying the ADRs on behalf of the selling shareholders. Selling shareholders, as used in this prospectus, includes anyone who receives the ADRs from the named selling shareholders after the date of this prospectus. The selling shareholders may sell their ADRs from time to time. The selling shareholders will act independently of Trinity Biotech in making decisions about the timing, manner and size of each sale. The selling shareholders may sell ADRs on one or more exchanges or in the over-the-counter market or otherwise, at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The selling shareholders will sell their ADRs through ordinary brokerage transactions and transactions in which the broker solicits purchasers.

In effecting sales, broker-dealers engaged by the selling shareholders or by us may arrange for other broker-dealers to participate. Broker-dealers may receive commissions or discounts from the selling shareholders in amounts to be negotiated immediately prior to the sale. In offering the ADRs covered by this prospectus, the selling shareholders and any broker-dealers who execute sales for the selling shareholders may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. Any profits realized by the selling shareholders and the compensation of any broker-dealers may be deemed to be underwriting discounts and commissions. The selling shareholders have advised Trinity Biotech that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the ADRs. No underwriter or coordinating broker is acting in connection with the selling shareholders' proposed sale of ADRs.

The selling shareholders will sell their ADRs only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in some states the selling shareholders may not sell their ADRs unless the ADRs have been registered or qualified for sale in the applicable state or the selling shareholders comply with an available exemption from the registration or qualification requirements.

Under applicable rules and regulations of the Securities Exchange Act of 1934, or the Exchange Act, any person engaged in the distribution of the ADRs may not simultaneously engage in market making activities with respect to Trinity Biotech's common stock for a period of two business days before the commencement of this distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of the selling shareholders' purchases and sales of Trinity Biotech's ADRs. Trinity Biotech will make copies of this prospectus available to the selling shareholders and has informed the selling shareholders of the need for delivery of copies of this prospectus to potential purchasers at or before the time of any sale of the ADRs.

Expenses of this offering (including brokerage commissions) are payable by Trinity Biotech and are estimated not to exceed \$50,000.

The last reported sale price per share for Trinity Biotech's ADRs on the Nasdaq SmallCap Market was \$2.85 per ADR on June 10, 2004.

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**Expenses Associated with the Registration**

We have agreed to bear all expenses relating to the registration of the ADRs registered pursuant to the registration statement of which this prospectus is a part. We estimate these expenses to be approximately US\$50,000, which include the following categories of expenses:

|  |                      |
|--|----------------------|
| SEC registration fee                           | US\$1,267.30         |
| Printing and photocopying                      | 2,000.00             |
| Legal fees and expenses                        | 20,000.00            |
| Accounting fees and expenses                   | 25,000.00            |
| Transfer agent and registrar fees and expenses | 1,000.00             |
| Miscellaneous expenses                         | 732.70               |
|  | <hr/>                |
| <b>Total Expenses</b>                          | <b>US\$50,000.00</b> |

**Legal Matters**

The validity of the shares will be passed upon for Trinity Biotech by O'Donnell Sweeney, Dublin, Ireland.

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**Experts**

Ernst & Young, independent auditors, have audited our consolidated financial statements included in our Annual Report on Form 20-F for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young's report, given on their authority as experts in accounting and auditing.

Mr. John Brozowski, independent auditor, has audited the financial statements of Fitzgerald Industries International, Inc. for the years ended December 31, 2002 and December 31, 2003, included in our Report on Form 6-K filed on June 16, 2004, as set forth in his report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Fitzgerald's financial statements are incorporated by reference in reliance on Mr. Brozowski's report, given on his authority as expert in accounting and auditing.

Raymond Chabot Grant Thornton, independent auditors, have audited the financial statements of Adaltis U.S., Inc. for the years ended December 31, 2002 and December 31, 2003, included in our Report on Form 6-K filed on June 16, 2004, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Adaltis' financial statements are incorporated by reference in reliance on Raymond Chabot Grant Thornton's report, given on their authority as expert in accounting and auditing.



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3,479,000 Class A Ordinary Shares

## **TRINITY BIOTECH PLC**

Class A Ordinary Shares Represented by American Depositary Receipts

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different. The prospectus does not contain an offer to sell or the solicitation of an offer to buy any securities other than the ADRs, or contain an offer to sell or the solicitation of an offer to buy the ADRs in any circumstances which would be unlawful. By delivering this prospectus to you and by selling the ADRs with it, we do not mean to imply that no change has occurred in the affairs of Trinity Biotech since the date of this prospectus or that the information contained in this prospectus is correct as of any time after that date.

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 8. Indemnification of Directors and Officers.**

Trinity Biotech's Articles of Association provide that every Director, Managing Director, agent secretary or other officer of Trinity Biotech shall be entitled to be indemnified out of the assets of Trinity Biotech against all losses or liabilities which he may sustain or incur in or about the execution of the duties of his office or otherwise in relation thereto, including any liability incurred by him in defending any proceeding, whether civil or criminal, in which judgment is given in his favor or in which he is acquitted, and no Director or other officer shall be liable for any loss, damage or misfortune which may happen to or be incurred by Trinity Biotech in the execution of the duties of his office or in relation thereto.

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**Item 9. Exhibits.**

| <b><u>Exhibit<br/>Number</u></b> | <b><u>Description of Exhibit</u></b>  |
|----------------------------------|---|
| 5                                | Opinion of O'Donnell Sweeney  |
| 8.1                              | Tax Opinion of Carter Ledyard & Milburn LLP   |
| 8.2                              | Tax Opinion of Ernst & Young, Dublin, Ireland.  |
| 23.1                             | Consent of Ernst & Young, Independent Auditors.   |
| 23.2                             | Consent of Mr. John Brozowski, Independent Auditor.   |
| 23.3                             | Consent of Raymond Chabot Grant Thornton, Independent Auditors.   |
| 23.4                             | Consent of O'Donnell Sweeney (contained in Exhibit 5).  |
| 24                               | Power of Attorney (included in the signature page of the Registration Statement)  |
| 99.1                             | Asset Purchase Agreement among Benen Trading Ltd., Fitzgerald Industries International, Inc. and Messrs. Edward and Kevin Fitzgerald, dated April 15, 2004. |
| 99.2                             | Stock Purchase Agreement among Trinity Biotech plc and Messrs. Edward and Kevin Fitzgerald, dated April 15, 2004.   |

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**Item 10. Undertakings.**

The undersigned Registrant hereby undertakes as follows:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
  - (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933 (the “Securities Act”);
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement;
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs (i) and (ii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) that are incorporated by reference in this Registration Statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) To file a post-effective amendment to this Registration Statement to include any financial statements required by Item 8.A. of Form 20-F at the start of any delayed offering or throughout a continuous offering, provided that a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Securities Act or Item 8.A. of Form 20-F if such financial statement and information are contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this Registration Statement.

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- (5) That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (6) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions referred to in Item 15, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Dublin, Ireland on the 16th day of June, 2004.

TRINITY BIOTECH PLC

By: /s/ Ronan O Caoimh \_\_\_\_\_

Ronan O'Caoimh  
Chairman and Chief Executive Officer

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**POWER OF ATTORNEY**

Each person whose signature appears below hereby constitutes Ronan O’Caoimh his true and lawful attorney-in-fact with full power to execute in the name of such person, in the capacities stated below, and to file, such one or more amendments to this Registration Statement as the Registrant deems appropriate, and generally to do all such things in the name and on behalf of such person, in the capacities stated below, to enable the Registrant to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission thereunder, and hereby ratifies and confirms the signature of such person as it may be signed by such attorney-in-fact to any and all amendments to this Registration Statement.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement and the above power of attorney have been signed below by the following persons in the capacities indicated on June 16, 2004.

| <b><u>Signature</u></b>                       | <b><u>Title</u></b>   |
|---|---|
| <u>/s/ Ronan O Caoimh</u><br>Ronan O’Caoimh   | Chairman, Chief Executive Officer and Director<br>(Principal Executive Officer) |
| <u>/s/ Denis Burger</u><br>Denis Burger       | Non-executive Director<br>(Authorized U.S. representative)                      |
| <u>/s/ Brendan Farrell</u><br>Brendan Farrell | President and Director  |
| <u>/s/ James Walsh</u><br>James Walsh         | Chief Operating Officer and Director  |
| <u>/s/ Rory Nealon</u><br>Rory Nealon         | Chief Financial Officer, Secretary and Director                                 |
| <u>/s/ Peter Coyne</u><br>Peter Coyne         | Non-executive Director  |

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**EXHIBIT INDEX**

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