TRINITY BIOTECH PLC
Form F-3/A
December 10, 2003
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**As filed with the Securities and Exchange Commission on December 10, 2003**

**Registration No. 333-107363**

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# AMENDMENT NO. 2

# to

# FORM F-3

# REGISTRATION STATEMENT

**UNDER**

**THE SECURITIES ACT OF 1933**

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# TRINITY BIOTECH PLC

**(Exact Name of Registrant as Specified in its Charter)**

| **Republic of Ireland** | **None** |
|---|---|
| **(State or Other Jurisdiction of Incorporation or Organization)** | **(I.R.S. Employer Identification Number)** |

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

**(Address, Including Zip Code, and Telephone Number,**

**Including Area Code, of Registrant's Principal**

**Executive Offices)**

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

**(Name, Address, Including Zip Code, and**

**Telephone Number, Including Area Code,**

**of Agent For Service)**

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***Copies to:***

**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.

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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: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, other than securities offered only in connection with dividend or interest reinvestment plans, 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. ¨

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

_____

**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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**PROSPECTUS**

**<R>**

**Subject to Completion, dated December 10, 2003**

**7,042,254 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 December 8, 2003, the last reported sale price of an American Depositary Receipt of Trinity Biotech, as reported by Nasdaq, was $3.36.
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This prospectus relates to the resale of 7,042,254 American Depositary Receipts which are issuable upon conversion or repayment of Trinity Biotech s 3% Convertible Notes Due 2007. All of the American Depositary Receipts were issued and sold pursuant to a private placement to the selling shareholders named in this prospectus. We are registering 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.**

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**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 _____, 2003.

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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 and market diagnostic tests 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. and Biopool U.S., 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 333-107363).

**<R>**

- Annual Report on Form 20-F/A for the year ended December 31, 2002, filed on December 10, 2003
- Report on Form 6-K filed on July 11, 2003
- Report on Form 6-k filed on December 10, 2003

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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
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 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.

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The requisition must be signed by ordinary shareholders holding not less than one-tenth of the paid up capital of the company carrying the right of voting at general meetings of the company. Trinity Biotech is generally permitted, subject to company law, to issue shares with preferential rights, including preferential rights as to voting, dividends or rights to a return of capital on a winding up of the company. Any shareholder who complains that the affairs of the company are being conducted or that the powers of the directors of the company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to the company.

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

## 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 depositary for Trinity's ADSs pursuant to a deposit agreement which is an exhibit to the Form F-6 registration statement filed by Trinity on September 7, 1992, registration no. 33-49744. One ADS represents one Class A Ordinary Share of Trinity. The depositary's offices are located at 48 Wall Street, New York, NY 10286.
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## 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.

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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 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.
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***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

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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.

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

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- During the financial years ended December 31, 2002, December 31, 2001 and December 31, 2000, approximately 20%, 27% and 30% respectively of Trinity Biotech's revenues were derived from a distribution agreement between our subsidiary, Trinity Biotech (USA) Corp. (trading name of Clark Laboratories, Inc.) and Wampole. In 2001, Wampole was acquired by Medpointe, Inc. and was subsequently acquired by Inverness Medical in 2002. In 2002 we negotiated an amendment to the distribution agreement whereby the exclusivity of Wampole's right to sell our products in the US will be removed in stages throughout 2004. During 2003, Trinity Biotech has experienced declining sales revenues under the Wampole distribution agreement, which we believe is due to Wampole attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, Trinity Biotech filed an action against Inverness Medical for breach of contract. For further information on this matter, we refer you to the section below entitled "Recent Developments — *Lawsuit against Inverness Medical*." Any ongoing material reduction in sales arising from this matter will have a material adverse effect on Trinity Biotech.

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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.

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- 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:

| Patent Number | Description | Patent life remaining from November 30, 2003 |
|---|---|---|
| 5,006,474 | Bi-Directional Lateral Chromatography Test Device | 4 years 5months |
| 5,114,845 | Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin | 3 years 8 months |
| 5,175,087 | Method of Performing Tissue Plasminogen Activator Assay | 3 years 8 months |
| 5,985,582 | Thrombin-Based Assay for Antithrombin - III | 14 years 1 month |
| 6,194,394 | Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays | 14 years 8 months |
| 6,528,273 | Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls | 15 years |
| 6,391,609 | Thromboplastin Reagents | 15 years 11 months |

and Methods for Preparing
and Using Such Reagents

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In addition to these US patents, Trinity Biotech owns a total of 21 non-US patents.

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- 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.

  A premarket application or PMA for the UniGold HIV Test is currently undergoing FDA review. No assurance can be given that the FDA will grant PMA approval to the UniGold HIV Test on a timely basis or at all. A delay or failure to receive such approval could have a material adverse effect on our revenues, earnings and financial standing.

  We are required to comply with extensive postmarket 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.***

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- 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, 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

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is intense, and the loss of such personnel or the inability to attract and retain the additional highly skilled employees required for the expansion of our activities, could adversely affect its business. In the USA, Germany and Sweden we were able to attract and retain qualified staff. In Ireland, we have experienced some difficulties in attracting and retaining staff due to competition from other employers in our industry and due to the strength of the Irish economy. We are not aware of any plans by qualified staff to retire or leave Trinity Biotech in the near future.

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

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

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

- Trinity Biotech may be subject to claims for personal injuries or other damages resulting from its products or services. Trinity Biotech has product liability insurance in place for its US subsidiaries up to a maximum of $4,000,000 for any one accident, limited to a maximum of $4,000,000 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 ($4,327,200) for any one accident, limited to a maximum of €4,000,000 ($4,327,200) 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 2002 consolidated revenue denominated in US$ was approximately 80%. Of the remaining 20% revenue, the breakdown was as follows: Euro (17%), Yen (2%) and Sterling and Swedish Kroner (1%). Thus, a 10% decrease in the value of each of the Euro, Yen, Sterling and Swedish Kroner would have approximately a 2% adverse impact on consolidated revenues. As part of the process of mitigating foreign exchange risk, the principal exchange risk identified by Trinity

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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 this mismatch through the use of forward contracts. Trinity Biotech entered into a series of forward contracts to sell US$ and Japanese Yen forward for Euro. These contracts remain in place until early 2004. Trinity Biotech continues to monitor its exposure to foreign currency movements. In the medium term, our objective is to increase the level of non-US$ denominated revenue, thus creating a natural hedge of the non-US$ expenditure.

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

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

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

- The convertible notes described below under "Recent Developments - *Sale of Convertible Notes*" are convertible into ADRs representing our Class A Ordinary Shares. Conversion of the notes will likely occur only when the conversion price is below the trading price of our ADRs and will dilute the ownership interests of existing shareholders. For instance, should the holders of the Series A Convertible Notes decide to convert the total principal amount of $20,000,000 million into ADRs at a conversion price of $3.55, Trinity Biotech would have to issue 5,633,803 additional ADRs. On the basis of 42,423,294 outstanding shares, this would effectively dilute the ownership interest of the existing shareholders by approximately 12%. 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.

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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.

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## 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

*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, Smithfield Fiduciary LLC, Portside Growth and Opportunity Fund, and Mainfield Enterprises, Inc., identified below as the selling shareholders in the section "Selling Shareholders". The Series A Notes mature on January 1, 2007 and bear annual interest at the rate of 3.00%. Rodman & Renshaw, Inc., a US registered broker-dealer, received a finder□s fee of $800,000. Series B Convertible Notes, in the aggregate principal amount of up to $5,000,000, shall be issued at the option of the Series A Note holders by delivery of written notice to us up to and including the later of January 9, 2004 and the three month anniversary of the effective date of the registration statement described below. The Series A Notes and the Series B Notes are collectively referred to as the Notes.

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Accrued interest on the Notes is paid quarterly in cash. Commencing on October 1, 2004, we are required to repay quarterly, in cash or, subject to the satisfaction of certain conditions, in ADRs (or a combination thereof), at our option, the principal amounts due under the Notes until the maturity date.
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The Notes are convertible into our ADRs representing our Class A Ordinary Shares, nominal value of $.0109. The holders of the Notes may exercise their right to convert at any time and from time to time before we have fully repaid the Notes. The number of ADRs to be received upon conversion is calculated by dividing the outstanding principal amount being converted by (a) in the case of the Series A Notes, $3.55 or (b) in the case of the Series B Notes, $4.00, in each case subject to adjustment for stock dividends, stock splits, stock combination or issuance of additional shares. Should Trinity Biotech make certain distributions to its shareholders, the holders of the Notes shall be entitled to participate in these distributions.
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If a change of control in Trinity Biotech occurs, the holders of the Notes may either (i) convert the Notes and receive the same consideration as Trinity Biotech□s shareholders are entitled to receive from any acquiring entity, (ii) demand redemption of the Notes at a premium or (iii), under certain conditions, demand similar notes from any acquiring entity.

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The entire $25,000,000 principal amount of the Notes (assuming the Series B Notes are issued) is initially convertible into 6,883,803 ADRs, which we are authorized to issue based on a shareholder vote at an extraordinary general meeting held on September 9, 2003.

We have complied with our contractual obligation to file a registration statement with the Securities and Exchange Commission no later than August 9, 2003, covering the public resale of 125% of the ADRs to be issued upon full conversion or repayment in ADRs of the Series A Notes. We have agreed to use our best efforts to have this registration statement declared effective by the SEC. The governing agreement with the investors provides that if (i) the registration statement was not declared effective by the SEC by November 22, 2003, (ii) after the registration statement has been declared effective by the SEC sales cannot be made pursuant to the registration statement, (iii) the ADRs or the shares to be registered are not listed on The Nasdaq National Market, The Nasdaq SmallCap Market, the New York Stock Exchange or the American Stock Exchange, or (iv) we do not issue the ADRs upon conversion of the Notes in a timely manner, we must pay monthly liquidated damages in an amount up to 2% of the principal outstanding under the Series A Notes after and as long as one of these events have occurred and continue. Since the registration statement was not declared effective by November 22, 2003, we are contractually obliged to make payments to the investors of 0.0417% per day of the aggregate principal amount outstanding, or $8,340 per day, until December 22, 2003, in addition to regular interest payments. Should the registration statement not be declared effective by December 22, 2003, we would have to make payments of 1.25% of the aggregate principal amount outstanding for each month (or portion thereof) during which the registration statement is not declared effective, in addition to the regular interest payments.
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Trinity Biotech will be in default under the Notes if (i) it defaults in payments of principal or interest; (ii) it does not deliver ADRs after conversion of the Notes; (iii) it fails to comply with any material provision governing the financing transaction; (iv) any representations, warranties or statements made by Trinity Biotech in the documents governing the financing

transaction were materially false and resulted in, or could reasonably be expected to result in, a material adverse effect; (v) any acceleration of any indebtedness or guarantee in excess of $1 million of Trinity Biotech or any of its subsidiaries has occurred; (vi) Trinity Biotech or any of its significant subsidiaries is dissolved or terminated; (vii) Trinity Biotech becomes insolvent or files for bankruptcy protection; (viii) the registration statement described above is not declared effective within 210 days after the registration date described above or becomes unavailable for 15 consecutive days or an aggregate 30 days in any 365-day period; (ix) the ADRs are suspended from trading or delisted for ten consecutive days or an aggregate of fifteen days in any 365-day period; (x)

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an uninsured final judgment in excess of $1 million is entered against Trinity Biotech or any of its subsidiaries. Upon the occurrence of such an event of default, the holders of the Notes can accelerate any outstanding principal amounts and interest due thereon. In the event of such an acceleration, the principal amount shall be increased to the greater of (i) up to 115% of the outstanding principal amount and (ii) an amount equal to the number of ADRs into which the outstanding principal amount of the Notes could be converted multiplied by the trading price of the ADRs.

The Notes shall generally rank pari passu with all other notes of Trinity Biotech and shall be senior to all other indebtedness, unless such other indebtedness in the aggregate does not exceed an amount equal to the consolidated EBITDA of Trinity Biotech and its subsidiaries multiplied by four. Trinity Biotech and its subsidiaries shall not grant any encumbrance in any property or assets owned by Trinity Biotech, except for certain permitted liens.

The description of the terms and provisions of the financing transaction set for herein does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the detailed provisions of those documents. Copies of these documents were filed with our Report on Form 6-K, dated July 11, 2003, which is incorporated by reference herein.

*Acquisitions*

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Effective as of November 27, 2002, Trinity Biotech and several of its subsidiaries acquired from Sigma certain assets of its clinical chemistry and cardiac chemistry business lines for a total purchase price of $4,350,000.

## 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. With immediate effect Trinity is exercising this right.
**</R>**

## 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

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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***

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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.
**</R>**

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

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

Irish withholding tax imposed on any dividends paid by Trinity Biotech will constitute a foreign income tax eligible for credit against a US Holder's US federal income tax liability, subject to certain limitations set out in the Code. Alternatively, the Irish withholding tax may be claimed by the US Holder as a deduction against income in determining such tax liability.

The rules relating to the determination of the allowable foreign tax credit are complex, and US Holders should consult with their own tax advisors to determine whether and to what extent they may be entitled to this credit.

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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.

Under recently enacted amendments to the Code, 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 on or after May 6, 2003 and before January 1, 2009. The reduced tax rate on dividend income applies to dividends received after December 31, 2002 and before January 1, 2009. The reduced tax rate will not apply to dividends received in respect of certain short-term or hedged positions in common stock or in certain other situations. The legislation enacting the reduced tax rate contains special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the reduced tax rate. US Holders of Trinity Biotech ADRs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

For US federal income tax purposes, a foreign corporation is treated as a "passive foreign investment company" (or PFIC) in any taxable year in which, after taking into account the income and assets of the corporation and certain of its subsidiaries pursuant to the applicable "look through" rules, either (1) at least 75 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.

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

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applicable to the holder in the prior tax year or years. The holder also would be subject to an interest charge, in the year in which the excess distribution is made, on the amount of taxes deemed to have been deferred with respect to the excess distribution. In addition, any gain recognized on a sale or other disposition of a US Holder's ADRs, including any gain recognized on a liquidation of Trinity Biotech, would be treated in the same manner as an excess distribution. Any such gain would be treated as ordinary income rather than as capital gain. Finally, the 15% reduced US federal income tax rate otherwise applicable to dividend income as discussed above, will not apply to any distribution made by Trinity Biotech in any taxable year in which it is a PFIC (or made in the taxable year following any such year), whether or not the distribution is an "excess distribution".

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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.

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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% reduced tax rate applicable to dividend income, and thus would be subject to US federal income tax at regular ordinary income rates. If Trinity Biotech were to distribute in a subsequent tax year any undistributed foreign person holding company income so taxed, the amount so distributed would not be counted as part of an "excess distribution" under the PFIC rules discussed above.

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

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

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

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

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

***Republic of Ireland Taxation***

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

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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.

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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.

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:

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- 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.

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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.

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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.
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A gift or inheritance of ordinary shares or ADRs will be within the charge to capital acquisitions tax, regardless of where the disponer 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 E.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 exchange in the U.S. or Canada.

## Selling Shareholders

The registration statement of which this prospectus forms a part covers up to 7,042,254 Class A Ordinary Shares represented by ADRs issued or issuable upon conversion or in payment of principal of the Series A Notes issued to the selling shareholders on July 10, 2003. 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.

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The table below identifies the selling shareholders and other information regarding the beneficial ownership of the ADRs by each of the selling shareholders. The second column lists the number and percentage of ADRs beneficially owned by each selling shareholder prior to the offering covered by this prospectus, based on each selling shareholder's ownership of Series A Notes, and assumes the conversion of all the Series A Notes at the initial conversion price of $3.55. Because the conversion price of the Series A Notes is subject to adjustment and the value attributed to the ADRs in the event we exercise our right to repay all or any portion of the Series A Notes in ADRs, rather than cash, varies, the numbers listed in the second column may change.

The third column lists each selling shareholder's portion, based on agreements with us, of the 7,042,254 ADRs being offered by this prospectus. The number of ADRs being offered by this prospectus was determined in accordance with the terms of the registration rights agreement with the selling shareholders, in which we agreed to register the resale of 125% of the number of ADRs issuable upon conversion of the Series A Notes at the initial conversion price of $3.55. Because the conversion price of the Series A Notes may be adjusted, the number of ADRs that will actually be issued may be more or less than the 7,042,254 ADRs being offered by this prospectus. The fourth column assumes the sale of all of 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.

| Name of Shareholder | Number of ADRs Beneficially Owned Before Offering [1] | Percentage of ADRs Beneficially Owned Before Offering [1] | Number of ADRs Being Offered [2] | Number of ADRs Owned After Offering | Percenta ADRs O After Of |
|---|---|---|---|---|---|
| Smithfield Fiduciary LLC[3] | 3,380,282 | 7.4% | 4,225,352 | 0 | 0% |
| Portside Growth and Opportunity Fund [4] | 1,408,451 | 3.2% | 1,760,564 | 0 | 0% |
| Mainfield Enterprises, Inc.[5] | 846,571 | 2% | 1,056,338 | 1,500 | 0% |

(1) ADRs issuable upon conversion of the Notes issued to the selling shareholders on July 10, 2003.

(2) Representing 125% of the ADRs issuable upon conversion of the Notes issued to the selling shareholders on July 10, 2003, assuming the Series A Notes were converted in full at the initial conversion price of $3.55.

(3) Highbridge Capital Management, LLC ("Highbridge") is the trading manager of Smithfield Fiduciary LLC ("Smithfield") and consequently has voting control and investment discretion over the securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge and Messrs. Dubin and Swieca disclaims beneficial ownership of the securities held by Smithfield.

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(4) Ramius Capital Group, LLC ("Ramius Capital") is the investment adviser of Portside Growth & Opportunity Fund, Ltd. ("Portside") and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the securities held by Portside. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S& Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark, Strauss and Solomom may be considered

beneficial owners of any securities deemed to be beneficially owned by Ramius Capital. Each of Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of any securities held by Portside.

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(5) Includes an additional 1,500 ADRs owned by Mainfield Enterprises, Inc. ("Mainfield") which are not being registered hereby. Pursuant to an investment management agreement, Avi Vigder has voting control and investment discretion over securities held by Mainfield. Mr. Vigder disclaims beneficial ownership of the securities held by Mainfield.

None of the selling shareholders has held any position, office or other material relationship with Trinity Biotech or any of its affiliates within the past three years other than as a result of his or its ownership of Trinity Biotech ADRs or notes. 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. Because the selling shareholders may sell all or part of their ADRs, no estimate can be given for the number of ADRs that will be held by any selling shareholder upon termination of this offering.

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Each of the investors has advised us that it is not a broker-dealer, but that it is affiliated with a broker-dealer and that it has made its investment in the notes in the ordinary course of business and at the time of making the investment in the notes, it has no agreements or understandings, directly or indirectly, with any person to distribute the ADRs.

## 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 may use one or more, or a combination, of the following methods to sell their ADRs:

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- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale,
- in the over-the-counter market,
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market,
- through the writing of options, whether such options are listed on an options exchange or otherwise,
- ordinary brokerage transactions and transactions in which the broker solicits purchasers,
- privately negotiated transactions,
- block trades in which the broker or dealer will attempt to sell the ADRs as agent but may position and resell a portion of the block as principal to facilitate the transaction,
- purchases by a broker or dealer as principal and resale by that broker or dealer for the selling shareholder s account under this prospectus,
- sales under Rule 144 rather than by using this prospectus,
- through the settlement of short sales,
- a combination of any of these methods of sale, or
- any other legally permitted method.

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The selling shareholders currently own notes convertible into ADRs. Until the time that a selling shareholder converts the notes or a portion thereof, it will not actually hold any of the underlying ADRs. The selling shareholders may enter into hedging transactions with broker-dealers in connection with distributions of the ADRs or otherwise. In these transactions, broker-dealers may engage in short sales of the ADRs in the course of hedging the positions they assume with the selling shareholders. The selling shareholders also may sell ADRs short and redeliverdeliver the ADRs to close out these short positions. The selling shareholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the ADRs. The broker-dealer may then resell or otherwise transfer these ADRs through this prospectus. The selling shareholders also may loan or pledge the ADRs to a broker-dealer. The broker-dealer may sell the ADRs so loaned, or upon a default the broker-dealer may sell the pledged ADRs by use of this prospectus. In either case, a prospectus supplement will be filed to name the broker-dealer as a selling shareholder.

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In effecting sales, broker-dealers engaged by the selling shareholders 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.

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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.

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If Trinity Biotech enters into any material arrangement with a broker-dealer for the sale of any ADRs offered by this prospectus, through a block trade, special offering, exchange distribution or a purchase by a broker or dealer, Trinity Biotech will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing

- the name of the participating broker-dealer(s),
- the number of ADRs involved,
- the price at which such ADRs were sold,
- the commission paid or discounts or concessions allowed to the broker-dealer(s), where applicable,
- whether the broker-dealer(s) conducted any investigation to verify the information in or incorporated by reference in this prospectus, and
- other material facts of the transaction required to be disclosed under the securities laws.

Trinity Biotech has agreed to reimburse in certain circumstances the selling shareholders against certain liabilities, including liabilities under the Securities Act. The selling shareholders have agreed to reimburse in certain circumstances Trinity Biotech and certain related persons against certain liabilities, including liabilities under the Securities Act.

**<R>**
Expenses of this offering (other than brokerage commissions) are payable by Trinity Biotech and are estimated not to exceed $10,000.

The last reported sale price per share for Trinity Biotech's ADRs on The Nasdaq SmallCap Market was $3.36 per ADR on December 8, 2003.
**</R>**

## Legal Matters

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

## Experts

**<R>**
Ernst & Young, independent auditors, have audited our consolidated financial statements included in our Annual Report on Form 20-F/A for the year ended December 31, 2002, 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.
**</R>**

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7,042,254 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.**

| Exhibit Number | Description of Exhibit |
|---|---|
| 5* | Opinion of O'Donnell Sweeney |
| 8.1** | Tax Opinion of Carter Ledyard & Milburn LLP |
| <R> 8.2 | Tax Opinion of Ernst & Young, Dublin, Ireland. |
| 23.1 | Consent of Independent Auditors. </R> |
| 23.2* | Consent of O'Donnell Sweeney (contained in Exhibit 5). |
| 24* | Power of Attorney (included in the signature page of the Registration Statement) |
| 99.1 | Securities Purchase Agreement among Trinity Biotech plc, Smithfield Fiduciary LLC, Portside Growth and Opportunity Fund and Mainfield Enterprises Inc., dated July 10, 2003, incorporated by reference to item 3 of the Report on Form 6-K filed on July 11, 2003, SEC File Number 000-22320. |
| 99.2 | Registration Rights Agreement among Trinity Biotech plc, Smithfield LLC, Portside Growth and Opportunity Fund and Mainfield Enterprises Inc., dated July 10, 2003, incorporated by reference to item 4 of the Report on Form 6-K, filed on July 11, 2003, SEC File Number 000-22320. |
| 99.3 | Form of Series A Convertible Note, incorporated by reference to item 5 of the Report on Form 6-K, filed on July 11, 2003, SEC File Number 000-22320. |

<R>* Previously filed as an exhibit to the Registration Statement.
** Previously filed as an exhibit to Amendment No. 1 to the Registration Statement.
</R>

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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

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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.

(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

<R>
Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this amendment to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Dublin, Ireland on the 10th day of December, 2003.
</R>

TRINITY BIOTECH PLC

By: /s/ Ronan O'Caoimh
Ronan O'Caoimh
Chairman and Chief Executive Officer

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<R>
Pursuant to the requirements of the Securities Act of 1933, this amendment to Registration Statement has been signed below by the following persons in the capacities indicated on December 10, 2003.
</R>

| Signature | Title |
|---|---|
| /s/ Ronan O'Caoimh<br>Ronan O'Caoimh | Chairman, Chief Executive Officer and Director<br>(Principal Executive Officer) |
| *<br>Denis Burger | Non-executive Director<br>(Authorized U.S. representative) |
| *<br>Brendan Farrell | President and Director |
| * | Chief Operating Officer and Director |

James Walsh

| | |
|---|---|
| * | Chief Financial Officer, Secretary and Director |

Rory Nealon

| | |
|---|---|
| * | Non-executive Director |

Peter Coyne

* By: /s/ Ronan O'Caoimh

Ronan O'Caoimh
*Attorney-in-Fact*

**EXHIBIT INDEX**

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