

TRINITY BIOTECH PLC  
Form F-3  
April 28, 2005

As filed with the Securities and Exchange Commission on April 27, 2005

Registration No. 333-

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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)

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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.

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.

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

#### CALCULATION OF REGISTRATION FEE

| Title of each class of securities to be registered    | Amount to be registered | Proposed maximum offering price per share | Proposed maximum aggregate offering price | Amount of registration fee (1) |
|---|-------------------------|---|---|--------------------------------|
| Class A Ordinary Shares, nominal value \$.0109 (2)(3) | (4)                     | (4)                                       | (4)                                       |                                |
| Equity Warrants                                       | (4)                     | (4)                                       | (4)                                       |                                |
| <b>Total</b>  | <b>\$75,000,000</b>     |   | <b>\$75,000,000</b>                       | <b>\$8,827.50</b>              |

- (1) The registration fee is calculated in accordance with Rule 457(o) under the Securities Act.
- (2) 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.
- (3) Class A Ordinary Shares may be issued in primary offerings or upon exercise of equity warrants registered hereby. The aggregate amount of Class A ordinary Shares registered hereby that may be sold in at-the-market offerings is limited to that which is permissible under Rule 415(a)(4) under the Securities Act.
- (4) Omitted pursuant to General Instruction II(c) of Form F-3 under the Securities Act.

**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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# PRELIMINARY PROSPECTUS

Subject to Completion, dated \_\_\_\_, 2005

## TRINITY BIOTECH PLC

### Class A Ordinary Shares and Equity Warrants

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Trinity Biotech plc may offer from time to time, in one or more series or issuances and at prices and on terms that will determine at the time of offering, up to \$75,000,000 in gross proceeds to Trinity Biotech of

☐ Class A Ordinary Shares; or

☐ warrants to purchase Class A Ordinary Shares.

The American Depositary Receipts of Trinity Biotech trade in the United States on the Nasdaq SmallCap Market under the symbol "TRIB".

We will provide specific terms of these securities in supplements to this prospectus at the time when we offer them. You should read this prospectus and the applicable supplement carefully before you invest in any of these securities.

**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.**

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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.

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We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or a prospectus supplement. This prospectus and any accompanying prospectus supplement do not contain an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, or an offer to sell or the solicitation of an offer to buy securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus and any accompanying prospectus supplement is accurate as of the dates on their covers. When we deliver this prospectus or a supplement or make a sale pursuant to this prospectus, we are not implying that the information is current as of the date of the delivery or sale.

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Whenever we refer to “Trinity Biotech” or to “us,” or use the terms “we” or “our” in this prospectus, we are referring to Trinity Biotech plc an Irish public limited company, and its consolidated subsidiaries. However, for purposes of the sections entitled “Description of Class A Ordinary Shares” and “Description of Equity Warrants,” whenever we refer to “Trinity Biotech” plc or to “us,” or use the terms “we” or “our,” we are referring only to Trinity Biotech plc.

### **About This Prospectus**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission utilizing a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings resulting in gross proceeds to us of up to \$75,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, you should assume that the statements made in the prospectus supplement modify or supersede those made in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “Where You Can Find More Information.”

### **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 UK, 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 termination of this offering of Trinity Biotech’s securities. This prospectus is part of a registration statement we filed with the SEC (Registration No 333-\_\_\_\_\_).

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□ Annual Report on Form 20-F for the year ended December 31, 2004, filed on April 1, 2005.

You may request a copy of these filings as well as any agreements relating to Trinity Biotech's securities offered hereby, 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

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.

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### **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 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.

### **Description of Class A Ordinary Shares**

Trinity Biotech is authorized to issue 75,000,000 Class A Ordinary Shares, par value \$0.0109 per share. At the close of business on February 28, 2005, it had 55,588,050 Class A Ordinary Shares outstanding. Our Class A Ordinary Shares are represented by American Depositary Receipts or ADRs. An 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.

The Bank of New York acts as the depositary 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. The depositary's offices are located at 101 Barclay Street, New York, NY 10286.

Trinity Biotech ADSs are listed on the NASDAQ Small Cap Market under the symbol "TRIB". The number of record holders of Trinity Biotech's ADS's as at February 28, 2005 amounted to 1,681, inclusive of those brokerage firms and/or clearing houses holding Trinity Biotech's securities for their clientele (with each such brokerage house and/or clearing house being considered as one holder).

Our Class A Ordinary Shares and our Class B Ordinary Shares rank pari passu in all respects save that the Class B Ordinary Shares have two votes per share and the right to receive dividends and participate in the distribution of the assets of Trinity Biotech upon liquidation or winding up at a rate of twice that of the Class A Ordinary Shares.

Where a shareholder or person who appears to be interested in shares fails to comply with a request for information from Trinity Biotech in relation to the capacity in which such shares or interest are held, who is interested in them or whether there are any voting arrangements, that shareholder or person may be disenfranchised and thereby restricted from transferring the shares and voting or receiving any sums in respect thereof (except in the case of a liquidation). In addition, if cheques in respect of the last three dividends paid to a shareholder remain uncashed, we are, subject to compliance with the procedure set out in our Articles of Association, entitled to sell the shares of that shareholder.

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At a general meeting, on a show of hands, every Class A Shareholder who is present in person or by proxy and entitled to vote shall have one vote (so, however, that no individual shall have more than one vote) and upon a poll, every Class A Shareholder present in person or by proxy shall have one vote for every share. In the case of joint holders, the vote of the senior (being the first person named in the register of members in respect of the joint holding) who tendered a vote, whether in person or by proxy, shall be accepted to the exclusion of votes of the other joint holders.

One third of the directors other than an executive director or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at each annual general meeting. If, however, the number of directors subject to retirement by rotation is two, one of such directors shall retire. If the number is one, that director shall retire. The directors to retire at each annual general meeting shall be the ones who have been longest in office since their last appointment. Where directors are of equal seniority, the directors to retire shall, in the absence of agreement, be selected by lot. A retiring director shall be eligible for re-appointment and shall act as director throughout the meeting at which he retires. A separate motion must be put to a meeting in respect of each director to be appointed unless the meeting itself has first agreed that a single resolution is acceptable without any vote being given against it.

We may, subject to the provisions of the Companies Acts, 1963 to 2003 of Ireland, issue any share on the terms that it is to be redeemed on such terms and in such manner as we may determine by special resolution. Before recommending a dividend, the directors may reserve out of our profits such sums as they think proper which shall be applicable for any purpose to which our profits may properly be applied and, pending such application, may be either employed in our business or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

Subject to any conditions of allotment, the directors may from time to time make calls on members in respect of monies unpaid on their shares. At least 14 days notice must be given of each call. A call shall be deemed to have been made at the time when the directors resolve to authorize such call.

The Articles do not contain any provisions discriminating against any existing or prospective holder of securities as a result of such shareholder owning a substantial number of shares.

In order to change the rights attaching to any class of shares, including Class A Ordinary Shares, a special resolution passed at a class meeting of the holders of such shares is required. The provisions in relation to general meetings apply to such meetings except the quorum shall be two persons holding or representing by proxy at least one third in nominal amount of the issued shares of that class. In addition, in order to amend any provisions of the Articles of Association in relation to rights attaching to shares, including Class A Ordinary Shares, a special resolution of the shareholders as a whole is required.

We must hold a general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. Every general meeting shall be held in Ireland unless all of the members entitled to attend and vote at it consent in writing to it being held elsewhere or a resolution providing that it be held elsewhere was passed at the preceding annual general meeting. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Companies Acts, 1963 to 2003 of Ireland. In the case of an annual general meeting or a meeting at which a special resolution is proposed, 21 clear days notice of the meeting is required and in any other case it is 7 clear days notice. Notice must be given in writing to all members and to the auditors and must state the details specified in the Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided in the Companies Acts, 1963 to 2003 of Ireland, extended notice is required. These include removal of a director. No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the ordinary shares shall be a quorum. Trinity Biotech is not obliged to serve notices upon members who have addresses outside of Ireland and the USA but otherwise there are no limitations in the Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in Trinity Biotech.





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However, the Financial Transfers Act, 1992 and regulations made thereunder prevent transfers of capital or payments between Ireland and certain countries. These restrictions on financial transfers are more comprehensively described in "Exchange Controls" below. In addition, Irish competition law may restrict the acquisition by a party of shares in Trinity Biotech but this does not apply on the basis of nationality or residence.

The Memorandum and Articles of Association do not contain any provisions:

- ☐ which would have an effect of delaying, deferring or preventing a change in control of Trinity Biotech and which would operate only with respect to a merger, acquisition or corporate restructuring involving Trinity Biotech (or any of its subsidiaries); or
- ☐ governing the ownership threshold above which a shareholder ownership must be disclosed; or
- ☐ imposing conditions governing changes in the capital which are more stringent than is required by Irish law. Trinity Biotech incorporates by reference all other information concerning its Memorandum and Articles of Association from the Registration Statement on Form F-1 on June 12, 1992.

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 Trinity Biotech 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 Trinity Biotech (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 a written consent 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 Trinity Biotech carrying the right of voting at general meetings of Trinity Biotech. 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 Trinity Biotech. Any shareholder who complains that the affairs of Trinity Biotech are being conducted or that the powers of the directors of Trinity Biotech 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 Trinity Biotech.

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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 Trinity Biotech, 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.

#### **Description of Equity Warrants**

Trinity Biotech may issue warrants to purchase ADRs, or "equity warrants." Equity warrants may be issued independently or together with any securities and may be attached to or separate from those securities. We will issue equity warrants under warrant agreements to be entered into either between us and the warrant holders directly or between us and a bank or trust company, as warrant agent.

A prospectus supplement will describe the terms of equity warrants offered thereby, the warrant agreement relating to the equity warrants and the equity warrant certificates representing the equity warrants, including the following:

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- ☐ the title of the equity warrants;
- ☐ the price or prices at which the equity warrants will be issued;
- ☐ if applicable, the number of equity warrants issued with Trinity Biotech ADRs;
- ☐ any date on and after which the equity warrants and such ADRs will be separately transferable;
- ☐ the date on which the right to exercise the equity warrants will commence, and the date on which those rights will expire;
- ☐ the maximum or minimum number of equity warrants which may be exercised at any time;
- ☐ information with respect to any book-entry procedures for the registration and transfer of equity warrants;
- ☐ a discussion of any material federal income tax considerations applicable to holding, transferring or exercising equity warrants; and
- ☐ any other terms of the equity warrants, including terms, procedures and limitations relating to the exercise of the equity warrants.

Unless we specify otherwise in a prospectus supplement, holders of equity warrants will not be entitled, by virtue of being such holders, to vote, consent, receive dividends, receive notice as shareholders with respect to any meeting of Trinity Biotech shareholders, or to exercise any rights whatsoever as Trinity Biotech shareholders.

As described in a prospectus supplement, the exercise price payable and the number of ADRs purchasable upon the exercise of each equity warrant will be adjusted in certain events, including the issuance of a stock dividend to holders of common stock or a stock split, reverse stock split, combination, subdivision or reclassification of common stock. Instead of adjusting the number of ADRs purchasable upon exercise of each equity warrant, Trinity Biotech may elect to adjust the number of equity warrants. Unless otherwise provided in a prospectus supplement, no adjustments in the number of ADRs purchasable upon exercise of the equity warrants will be required until cumulative adjustments require an adjustment of at least 1% thereof. Trinity Biotech may, at its option, reduce the exercise price at any time. No fractional ADRs will be issued upon exercise of equity warrants, but we will pay the cash value of any fractional ADRs otherwise issuable. Unless we specify otherwise in a prospectus supplement, in case of any consolidation, merger, or sale or conveyance of Trinity Biotech's property as an entirety or substantially as an entirety, the holder of each outstanding equity warrant shall have the right to the kind and amount of shares of stock and other securities and property (including cash) receivable by a holder of the number of ADRs into which the equity warrant was exercisable immediately prior to the particular triggering event.

Each equity warrant will entitle the holder to purchase the principal amount or number of securities at the exercise price as shall in each case be set forth in, or be determinable as set forth in, the applicable prospectus supplement. Equity warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void.

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We will describe the procedures for exercising warrants in a prospectus supplement. Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, Trinity Biotech will, as soon as practicable, forward the securities purchasable upon that exercise. If less than all of the warrants represented by a particular warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

### **Summary of Risks**

Before you invest in our securities, 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 securities.

#### ***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 are dependent to a high degree on its relationship with Wampole Laboratories, a former affiliate of Carter Wallace, Inc.***

- During the financial years ended December 31, 2004, December 31, 2003 and December 31, 2002, approximately 7%, 12% and 20% 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, Trinity Biotech negotiated an amendment to the distribution agreement whereby the exclusivity of Inverness Medical's 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 Medical attempting to convert customers from the Trinity Biotech product to an alternative product. Accordingly, in December 2003, we 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 Medical and sourced by other suppliers. The Superior Court of Middlesex County, Massachusetts, denied the motion for preliminary injunction on January 28, 2004. In April 2004, Trinity Biotech amended its complaint to add additional claims alleging breaches of the distribution agreement by Inverness Medical. In May of 2004, Inverness Medical amended their counterclaims to add claims alleging, among other things, that Trinity Biotech was selling certain products without a license. Following the expiration of Inverness Medical's exclusive distribution rights under the distribution agreement on October 1, 2004, Trinity Biotech moved to amend its complaint to eliminate the declaratory judgment claims and add additional claims for breach of the distribution agreement and tortious interference with advantageous business relations that had arisen after December 2003. Inverness Medical filed a cross-motion to amend their complaint. There has been no ruling by the court on either party's motion. The case is currently in the discovery phase. For further information relating to this matter, please refer to Item 8 "Legal Proceedings" in our Annual Report on Form 20-F. We have decided to sell our products directly in the U.S. and have increased our direct sales force. Any inability to recapture lost sales from Inverness Medical may have a material adverse effect on our business.

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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 ADRs and securities convertible into ADRs, 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 existing 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 ADRs 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), Roche Diagnostics (COBAS AMPLICOR□, Ampliscreen□, Accutrend□) and OraSure Technologies, Inc. (OraQuick®).

***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.

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***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 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 March 31, 2005</b> |
|----------------------|---|--|
| 5,006,474            | Bi-Directional Lateral Chromatography Test Device   | 3 years 1 month                                  |
| 5,114,845            | Improved Assays for Plasminogen Activator Inhibitor and Soluble Fibrin  | 2 years 4 months                                 |
| 5,175,087            | Method of Performing Tissue Plasminogen Activator Assay   | 2 years 4 months                                 |
| 5,985,582            | Thrombin-Based Assay for Antithrombin □ III   | 12 years 9 months                                |
| 6,194,394            | Coagulation controls for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays                                  | 13 years 4 months                                |
| 6,528,273            | Methods for quality control of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Assays Using Coagulation Controls | 13 years 8 months                                |
| 6,391,609            | Thromboplastin Reagents and Methods for Preparing and Using Such Reagents   | 14 years 7 months                                |
| 6,653,066            | Device and method for detecting polyvalent substances   | 18 years and 8 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.

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***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 €533,000. 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 US, 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.

***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, 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 \$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 (approximately \$5,456,000) for any one accident, limited to a maximum of €4,000,000 (approximately \$5,456,000) 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, U.S. dollars and Swedish Kroner 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 2004 consolidated revenue denominated in US\$ was approximately 67%. Of the remaining 33% revenue, the breakdown was as follows: Euro (27%), Sterling (5%), and Swedish Kroner and Yen (1%). Thus, a 10% decrease in the value of each of the Euro, Sterling, Swedish Kroner and Yen 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 ADRs.***

- SEC regulations concerning “penny stock” apply to Trinity Biotech’s ADRs. 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 ADRs in the secondary market and thus adversely affect our share price.

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

- The Convertible Notes issued in July 2003 and March 2004, described in the Financial Statements contained in our Annual Report on Form 20-F, Item 18, Note 9 (e), and the warrants described in Item 18, Note 10, are convertible into ADRs representing our Class “A” Ordinary Shares. Conversion of the remainder of the notes and exercise of the warrants 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 Convertible Notes issued in July 2003 decide to convert the balance of the US\$20,000,000 total principal amount of US\$11,896,000 and the holders of the Convertible Notes issued in March 2004 decide to convert the balance of the US\$5,000,000 total principal amount of US\$4,500,000 into ADRs at conversion prices of US\$3.55 and US\$4, respectively, and should the 1,317,324 warrants be exercised, Trinity Biotech would have to issue 5,793,239 additional ADRs. On the basis of 55,588,050 outstanding shares at February 28, 2005, this would effectively dilute the ownership interest of the existing shareholders by approximately 9.4%. Management also has the option of repaying the Convertible Notes in ordinary shares. Any such repayment would effectively dilute the ownership interest of the existing shareholders. In addition, any sales in the public market of the ADRs issuable upon conversion of the Convertible 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.

***Trinity Biotech is exposed to potential risks and increased costs from the requirements of Section 404 of the Sarbanes Oxley Act of 2002 to evaluate internal controls over financial reporting.***

- Section 404 of the Sarbanes Oxley Act of 2002 requires that Trinity Biotech evaluates and reports on the internal controls over financial reporting and have an auditor attest to such evaluation. We have prepared an internal plan for compliance and are in the process of documenting and testing the system of internal controls to provide the basis for this report for the year ended December 31, 2006. Due to ongoing evaluation and testing of our internal controls and the uncertainties of the interpretation of these new requirements, we cannot assure that there may not be significant deficiencies or material weaknesses (in addition to the material weaknesses disclosed in Item 15 of our Annual Report on Form 20-F) that would be required to be reported. In the event that significant deficiencies or additional material weaknesses are reported, investor perceptions may be adversely affected and could cause a decline in the market price of our stock.

We are spending increased costs and an increased amount of management time and external resources in order to comply with the above legislation by the end of 2006. The process of documenting and testing the internal control systems and procedures and considering improvements has required us to hire additional personnel and outside advisory services, resulting in additional accounting and consultancy expenses.

**Market Price Data**

***The Nasdaq SmallCap Market***

Our ADRs are traded on the Nasdaq SmallCap Market.

[Back to Contents](#)**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.

|                                       | Per Ordinary Share (US\$) |      |
|---------------------------------------|---------------------------|------|
|                                       | High                      | Low  |
| <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 |

**Fiscal Year Ended 2004:**

|                |      |      |
|----------------|------|------|
| First Quarter  | 5.99 | 3.52 |
| Second Quarter | 3.81 | 2.70 |
| Third Quarter  | 3.42 | 2.36 |
| Fourth Quarter | 3.18 | 2.60 |

**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  |
| Month         |                           |      |
| October 2004  | 3.18                      | 2.60 |
| November 2004 | 3.15                      | 2.66 |
| December 2004 | 2.99                      | 2.61 |
| January 2005  | 3.02                      | 2.65 |
| February 2005 | 2.83                      | 2.50 |
| March 2005    | 2.82                      | 2.40 |

**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.

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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.

#### **Use of Proceeds**

Unless we identify other uses of proceeds in a prospectus supplement, we intend to use the net proceeds from the sale of the securities for our general corporate purposes, which may include repayment of debt, capital expenditures, acquisitions, and working capital. Pending uses, the net proceeds may also be temporarily invested in short-term securities.

Depending on market conditions and our financial needs, we may, from time to time, undertake additional financings. We cannot at this time estimate the amount and timing of such financings, if any.

#### **Plan of Distribution**

We may sell the offered securities:

- ☐ through underwriters or dealers;
- ☐ directly to a limited number of purchasers or to a single purchaser; or
- ☐ through agents.

Any underwriters or agents will be identified and their compensation described in the applicable prospectus supplement.

We directly or through agents, may sell, and the underwriters may resell, the offered securities in one or more transactions, including negotiated transactions, at a fixed public offering price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices.

In connection with the sale of offered securities, the underwriters or agents may receive compensation from us or from purchasers of the offered securities for whom they may act as agents. The underwriters may sell offered securities to or through dealers, who may also receive compensation from purchasers of the offered securities for whom they may act as agents. Compensation may be in the form of discounts, concessions, commissions or warrants. Any underwriters, dealers and agents that participate in the distribution of the offered securities may be underwriters as defined in the Securities Act, and any discounts, concessions, commissions or warrants received by them from us and any profit on the resale of the offered securities by them may be treated as underwriting discounts and commissions under the Securities Act.

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We will indemnify the underwriters and agents against certain civil liabilities, including liabilities under the Securities Act.

Underwriters, dealers and agents may engage in transactions with, or perform services for, us or our affiliates in the ordinary course of their businesses.

If so indicated in the prospectus supplement relating to an issue of offered securities, we will authorize underwriters, dealers or agents or solicit offers by certain institutions to purchase the offered securities from us under delayed delivery contracts providing for payment and delivery at a future date. These contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth the commission payable for solicitation of these contracts.

#### **Expenses Associated with the Registration**

The expenses relating to the registration of the securities registered pursuant to the registration statement of which this prospectus is a part are estimated to be approximately US\$35,000, which include the following categories of expenses:

|                              |                   |
|------------------------------|-------------------|
| SEC registration fee         | US\$8,827.50      |
| Printing and photocopying    | 5,000             |
| Legal fees and expenses      | 10,000            |
| Accounting fees and expenses | 10,000            |
| Miscellaneous expenses       | 1,172.50          |
| <b>Total Expenses</b>        | <b>US\$35,000</b> |

#### **Legal Matters**

The validity of any offered securities will be passed upon for Trinity Biotech by O'Donnell Sweeney, Dublin, Ireland, our Irish counsel. Carter Ledyard & Milburn LLP has acted as our U.S. securities counsel. Certain legal matters with respect to offered securities will be passed upon for the underwriters, dealers or agents, if any, by their counsel.

#### **Experts**

Ernst & Young, Independent Registered Public Accounting Firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 20-F for the year ended December 31, 2004, 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.

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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   |
| 23.1 | Consent of Ernst & Young, Independent Registered Public Accounting Firm          |
| 23.2 | Consent of O'Donnell Sweeney (contained in Exhibit 5)                            |
| 24   | Power of Attorney (included in the signature page of the Registration Statement) |

**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.

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- (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.
- (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 27<sup>th</sup> day of April, 2005.

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'Caomh 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 April 27, 2005.

| <b><u>Signature</u></b>                       | <b><u>Title</u></b>   |
|---|---|
| <u>/s/ Ronan O'Caomh</u><br>Ronan O'Caomh     | 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**

| <b><u>Exhibit<br/>Number</u></b> | <b><u>Description of Exhibit</u></b>   |
|----------------------------------|--|
| 5                                | Opinion of O'Donnell Sweeney   |
| 23.1                             | Consent of Ernst & Young, Independent Registered Public Accounting Firm          |
| 23.2                             | Consent of O'Donnell Sweeney (contained in Exhibit 5)                            |
| 24                               | Power of Attorney (included in the signature page of the Registration Statement) |

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