GENEREX BIOTECHNOLOGY CORP
Form 424B3
January 24, 2005

PROSPECTUS

GENEREX BIOTECHNOLOGY CORPORATION

25,449,872 Shares of Common Stock

We are registering 25,449,872 shares of our common stock for resale by the selling stockholders listed on pages 10-11.

- 25,449,872 of these shares are issuable upon conversion or exercise, as applicable, of outstanding debentures and warrants, including accrued interest on the debentures not paid in cash, and in connection with additional investment rights.

The prices at which the selling stockholders may sell shares of our common stock will be determined by the prevailing market price for such shares or in negotiated transactions.

Our common stock is quoted on the NASDAQ SmallCap Market under the symbol "GNBT." The last sale price of our common stock on January 18, 2005, as reported by NASDAQ, was $0.78 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 2 TO READ ABOUT THE FACTORS YOU SHOULD CONSIDER BEFORE INVESTING.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 24, 2005

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PROSPECTUS SUMMARY

ABOUT GENEREX

Generex Biotechnology Corporation is a Delaware corporation engaged in the research and development of injection-free methods for delivery of large molecule drugs. We are a development stage company.

To date, we have focused most of our efforts and resources on a platform technology to orally administer large molecule drugs by absorption through the walls of the mouth cavity. The mouth cavity is also known as the "buccal" cavity. Large molecule drugs include proteins, hormones, peptides and vaccines. Large molecule drugs, such as synthetic insulin, are presently administered almost exclusively by injection.

The initial product that we have been trying to develop is an oral insulin formulation for use in the treatment of diabetes. The formulation is sprayed into the mouth using our RapidMist(TM) device, a small and lightweight aerosol applicator that administers a metered dose for absorption. Absorption occurs through the mucous membranes in the buccal cavity.

We have also pursued the application of our technology for the buccal delivery of pharmaceutical products in addition to insulin, such as the buccal delivery of morphine, fentanyl citrate and low molecular weight heparin.

In August 2003 we acquired Antigen Express, Inc. (Antigen). Antigen is engaged in the research and development of technologies for the treatment of malignant, infectious, autoimmune and allergic diseases.

Our principal offices are located at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 and our telephone number is (416) 364-2551.

ABOUT THIS PROSPECTUS

We are registering our common stock for resale by selling stockholders. The selling stockholders and the specific number of shares that they each may resell through this prospectus are listed on pages 10-12.

The shares offered for resale by this prospectus include the following:

- 25,449,872 shares of Common Stock issuable upon exercise of outstanding debentures and warrants, including accrued interest on the debentures not paid in cash, and in connection with additional investment rights.

Pursuant to the terms of a Securities Purchase Agreement, dated November 10, 2004, we issued to certain selling stockholders (i) debentures convertible into a total of 4,878,048 shares of our common stock, (ii) warrants to purchase a total of 4,878,048 shares of our common stock, and (iii) additional investment rights to purchase, for a period of time, debentures and warrants convertible or exercisable, as applicable, into a total of 9,756,096 shares of our common stock. The debentures accrue interest on the outstanding principal amount at the

rate of 6% per annum, which may be paid by us in shares of our common stock. In the event we pay the interest in shares of common stock, we would be obligated to issue an additional 731,704 shares of common, in the aggregate, for interest accrued on all debentures currently outstanding and issuable upon exercise of the additional investment rights. We are obligated to register a number of shares of our common stock equal to 125% of the shares issuable in connection with the foregoing. In addition we issued 145,000 warrants to purchase our common stock to consultants in exchange for services.

This prospectus may only be used where it is legal to offer and sell the shares covered by this prospectus. We have not taken any action to register or obtain permission for this offering or the distribution of this prospectus in any country other than the United States.

INFORMATION ON OUTSTANDING SHARES

The number of shares outstanding before and after this offering are set forth below:

Common stock outstanding before the offering.....35,374,733 shares of Common Sto

Common stock to be outstanding after the offering.....60,824,605 shares of Common Sto

The number set forth above for the shares of common stock outstanding before this offering is the number of shares outstanding on January 18, 2005, excluding the shares of common stock offered for resale by this prospectus.

The numbers set forth above do not include (i) 9,306,159 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding options and (ii) 7,778,059 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding warrants other than those covered by this prospectus. These additional options and warrants are exercisable at prices ranging from $.89 to $25.15 per share, with a weighted average exercise price for the options of $2.92 per share and a weighted average exercise price for the warrants of $3.23 per share. The numbers set forth above also do not include shares of common stock that, as of the date of this prospectus, are issuable upon conversion of outstanding shares of our Series A Preferred Stock.

RISK FACTORS

An investment in our stock is very speculative and involves a high degree of risk. You should carefully consider the following important factors, as well as the other information in this Report and the other reports that we have filed heretofore (and will file hereafter) with the Securities and Exchange Commission, before purchasing our stock. The following discussion outlines certain factors that we think could cause our actual outcomes and results to differ materially from our forward-looking statements.

RISKS RELATED TO OUR FINANCIAL CONDITION

WE HAVE A HISTORY OF LOSSES, AND WILL INCUR ADDITIONAL LOSSES.

We are a development stage company with a limited history of operations, and do not expect ongoing revenues from operation in the immediately foreseeable

future. To date, we have not been profitable and our accumulated net loss before preferred stock dividend was $94,231,316 at July 31, 2004. Our losses have resulted principally from costs incurred in research and development, including clinical trials, and from general and administrative costs associated with our operations. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this objective.

Our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

THE NEED FOR ADDITIONAL CAPITAL

To progress in product development or marketing, we will need additional capital which may not be available to us. This may delay our progress in product development or market.

We will require funds in excess of our existing cash resources:

- to proceed with the development of our buccal insulin product
- to proceed under our joint venture with Elan, which requires us to fund 80.1% of initial product development costs;
- to develop other buccal and immunomedicine products;
- to develop new products based on our buccal delivery and immunomedicine technologies, including clinical testing relating to new products;
- to develop or acquire other technologies or other lines of business;
- to establish and expand our manufacturing capabilities;
- to finance general and administrative and research activities that are not related to specific products under development; and
- to finance the research and development activities of our new subsidiary Antigen. We have agreed to fund at least $2,000,000 of Antigen expenditures during the first two years following the acquisition. To date we have funded approximately $900,000 of those expenditures.

In the past, we have funded most of our development and other costs through equity financing. We anticipate that our existing capital resources will enable us to maintain currently planned operations through the next seven months. However, this expectation is based on our current operating plan, which could change as a result of many factors, and we may need additional funding sooner than anticipated. Because our operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds in the near future to continue the development and commercialization of our products. Unforeseen problems, including materially negative developments in our joint venture with Elan, in our clinical trials or in general economic conditions, could interfere with our ability to raise additional equity capital or materially adversely affect the terms upon which such funding is available. Recent changes in the application of the rules of the NASDAQ Stock Market may also make it more difficult for us to raise private equity capital.

It is possible that we will be unable to obtain additional funding as and when we need it. If we were unable to obtain additional funding as and when needed, we could be forced to delay the progress of certain development efforts. Such a scenario poses risks. For example, our ability to bring a product to market and obtain revenues could be delayed, our competitors could develop products ahead of us, and/or we could be forced to relinquish rights to technologies, products or potential products.

NEW EQUITY FINANCING COULD DILUTE CURRENT STOCKHOLDERS.

If we raise funds through equity financing to meet the needs discussed above, it will have a dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares may be sold at a time when the market price is low because we need the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price.

OUR RESEARCH AND DEVELOPMENT AND MARKETING EFFORTS ARE LIKELY TO BE HIGHLY DEPENDENT ON CORPORATE COLLABORATORS AND OTHER THIRD PARTIES WHO MAY NOT DEVOTE SUFFICIENT TIME, RESOURCES AND ATTENTION TO OUR PROGRAMS, WHICH MAY LIMIT OUR EFFORTS TO SUCCESSFULLY DEVELOP AND MARKET POTENTIAL PRODUCTS.

Because we have limited resources, we have sought to enter into collaboration agreements with other pharmaceutical companies that will assist us in developing, testing, obtaining governmental approval for and commercializing products using our buccal delivery and immunomedicine technologies. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our program may compete for time, attention and resources with such collaborator's internal programs. Therefore, these collaborators may not commit sufficient resources to our program to move it forward effectively, or that the program will advance as rapidly as it might if we had retained complete control of all research, development, regulatory and commercialization decisions.

RISKS RELATED TO OUR TECHNOLOGIES

BECAUSE OUR TECHNOLOGIES AND PRODUCTS ARE AT AN EARLY STAGE OF DEVELOPMENT, WE CANNOT EXPECT REVENUES IN THE FORESEEABLE FUTURE.

We have no products approved for commercial sale at the present time. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products under development. We may not be successful in one or more of these stages of the development of our products, and/or any of the products we develop may not be commercially viable.

While over 750 patients with diabetes have been dosed with our oral insulin formulation at approved facilities in seven countries, our clinical program has not reached a point where we are prepared to apply for regulatory approvals to market the product in any country. Until we have developed a commercially viable product which receives regulatory approval, we will not receive revenues from ongoing operations.

WE WILL NOT RECEIVE REVENUES FROM OPERATIONS UNTIL WE RECEIVE REGULATORY APPROVAL TO SELL OUR PRODUCTS. MANY FACTORS IMPACT OUR ABILITY TO OBTAIN APPROVALS FOR COMMERCIALLY VIABLE PRODUCTS.

We have no products approved for commercial sale by drug regulatory authorities.

We have begun the regulatory approval process for our oral insulin formulation, buccal morphine and fentanyl products. Our immunomedicine products are in the pre-clinical stage of development.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technologies, are subject to extensive, costly and rigorous regulation by governmental authorities in the United States, Canada and other countries. The process of obtaining required regulatory approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the product candidates. For these reasons, it is possible we will never receive approval for one or more product candidates.

Delays in obtaining United States or foreign approvals for our products could result in substantial additional costs to us, and, therefore, could adversely affect our ability to compete with other companies. If regulatory approval is ultimately granted, the approval may place limitations on the intended use of the product we wish to commercialize, and may restrict the way in which we are permitted to market the product.

DUE TO LEGAL AND FACTUAL UNCERTAINTIES REGARDING THE SCOPE AND PROTECTION AFFORDED BY PATENTS AND OTHER PROPRIETARY RIGHTS, WE MAY NOT HAVE MEANINGFUL PROTECTION FROM COMPETITION.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights, and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the

future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

Because a substantial number of patents have been issued in the field of alternative drug delivery and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subject to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

Also because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the United States and other countries, even after reasonable investigation we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. For example, we are aware of certain patents owned by third parties that such parties could attempt to use in the future in efforts to affect our freedom to

practice some of the patents that we own or have applied for. Based upon the science and scope of these third party patents, we believe that the patents that we own or have applied for do not infringe any such third party patents, however, we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

RISKS RELATED TO MARKETING OF OUR POTENTIAL PRODUCTS

WE MAY NOT BECOME, OR STAY, PROFITABLE EVEN IF OUR PRODUCTS ARE APPROVED FOR SALE.

Even if we obtain regulatory approval to market our oral insulin product or any other product candidate, many factors may prevent the product from ever being sold in commercial quantities. Some of these factors are beyond our control, such as:

- acceptance of the formulation or treatment by health care professionals and diabetic patients;
- the availability, effectiveness and relative cost of alternative diabetes or immunomedicine treatments that may be developed by competitors; and
- the availability of third-party (i.e., insurer and governmental agency) reimbursements.

WE MAY NOT BE ABLE TO COMPETE WITH TREATMENTS NOW BEING MARKETED AND DEVELOPED, OR WHICH MAY BE DEVELOPED AND MARKETED IN THE FUTURE BY OTHER COMPANIES.

Our products will compete with existing and new therapies and treatments. We are aware of a number of companies currently seeking to develop alternative means of delivering insulin, as well as new drugs intended to replace insulin therapy at least in part. We are also aware of a number of companies currently seeking to develop alternative means of enhancing and suppressing peptides. In the longer term, we also face competition from companies that seek to develop cures for diabetes and other malignant, infectious, autoimmune and allergic diseases through techniques for correcting the genetic deficiencies that underlie such diseases.

We will have to depend upon others for marketing and distribution of our products, and we may be forced to enter into contracts limiting the benefits we may receive and the control we have over our products. We intend to rely on

collaborative arrangements with one or more other companies that possess strong marketing and distribution resources to perform these functions for us. We may not be able to enter into beneficial contracts, and we may be forced to enter into contracts for the marketing and distribution of our products that substantially limit the potential benefits to us from commercializing these products. In addition, we will not have the same control over marketing and distribution that we would have if we conducted these functions ourselves.

Numerous pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations are engaged in the development of alternatives to our technologies. Many of these

companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

IF GOVERNMENT PROGRAMS AND INSURANCE COMPANIES DO NOT AGREE TO PAY FOR OR REIMBURSE PATIENTS FOR OUR PRODUCTS, WE WILL NOT BE SUCCESSFUL.

Sales of our potential products depend in part on the availability of reimbursement by third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. FDA approval of health care products does not guarantee that these third party payors will pay for the products. Even if third party payors do accept our product, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement.

RISKS RELATED TO POTENTIAL LIABILITIES

WE FACE SIGNIFICANT PRODUCT LIABILITY RISKS, WHICH MAY HAVE A NEGATIVE EFFECT ON OUR FINANCIAL CONDITION.

The administration of drugs or treatments to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs or treatments are actually at fault for causing an injury. Furthermore, our products may cause, or may appear to have caused, serious adverse side effects (including death) or potentially dangerous drug interactions that we may not learn about or understand fully until the drug or treatment has been administered to patients for some time. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a severe negative effect on our financial condition. We maintain product liability insurance in amounts we believe to be commercially reasonable for our current level of activity and exposure, but claims could exceed our coverage limits. Furthermore, due to factors in the insurance market generally and our own experience, we may not always be able to purchase sufficient insurance at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with our business.

RISKS RELATED TO THE MARKET FOR OUR COMMON STOCK

IF OUR COMMON STOCK IS DELISTED FROM THE NASDAQ SMALLCAP MARKET AND/OR BECOMES SUBJECT TO PENNY STOCK REGULATIONS, THE MARKET PRICE FOR OUR STOCK MAY BE REDUCED AND IT MAY BE MORE DIFFICULT FOR US TO OBTAIN FINANCING. On June 5, 2003, our common stock was delisted from the NASDAQ National Market because of our failure to maintain a minimum of $10,000,000 in stockholders' equity. On June 5, 2003, our stock began trading on the NASDAQ SmallCap Market. The NASDAQ SmallCap Market has its own standards for continued listing, including a minimum of $2.5 million stockholders' equity. As of July 31, 2004, our stockholders' equity was $529,751. As a result, on November 19, 2004, we received notice from

The Nasdaq Stock Market informing us that we do not comply with Market Place Rule 4310(c)(2)(B), which requires us to have a minimum of $2,500,000 in stockholders' equity or $35,000,000 market value of listed securities or $500,000 of net income from continuing operations for the most recently

completed fiscal year or two of the three most recently completed fiscal years. Although we provided to the Nasdaq Stock Market specific elements of a plan, including the proposed conversion of $14,300,000 of mezzanine equity to common equity on our balance sheet, to achieve and sustain compliance with all of The Nasdaq SmallCap Market listing requirements, there is no guarantee that we will achieve compliance with The Nasdaq SmallCap Market listing requirements, or sustain compliance with the requirements if achieved. In the event we cannot achieve or sustain compliance, our shares of common stock may be delisted from The Nasdaq SmallCap Market and begin trading on the over-the-counter bulletin board.

In addition, for continued listing on both the Nasdaq National Market and SmallCap Market, our stock price must be at least $1.00. During October and November of 2004, our stock price traded below this minimum per share requirement for thirty (30) consecutive business days. As a result, on November 24, 2004, we received notice from The Nasdaq Stock Market informing us that we do not comply with Market Rule 4310(c)(4), which requires us to have a minimum bid price per share of at least $1.00 for thirty (30) consecutive business days. Although we have 180 calendar days, subject to extension by The Nasdaq Stock Market under certain circumstances, to regain compliance with the Rule, there is no guarantee that the bid price of our common stock will close at $1.00 per share or more for a minimum period of ten (10) consecutive business days, which is the minimum period of time The Nasdaq Stock Market requires to regain compliance.

If our stock is delisted from NASDAQ, there will be less interest for our stock in the market. This may result in lower prices for our stock and make it more difficult for us to obtain financing.

If our stock is not listed on NASDAQ and fails to maintain a price of $5.00 or more per share, our stock would become subject to the Securities and Exchange Commission's "Penny Stock" rules. These rules require a broker to deliver, prior to any transaction involving a Penny Stock, a disclosure schedule explaining the Penny Stock Market and its risks. Additionally, broker/dealers who recommend Penny Stocks to persons other than established customers and accredited investors must make a special written suitability determination and receive the purchaser's written agreement to a transaction prior to the sale. In the event our stock becomes subject to these rules, it will become more difficult for broker/dealers to sell our common stock. Therefore, it may be more difficult for us to obtain financing.

THE PRICE OF OUR COMMON STOCK MAY BE VOLATILE.

There may be wide fluctuation in the price of our common stock. These fluctuations may be caused by several factors including:

- announcements of research activities and technology innovations or new products by us or our competitors;
- changes in market valuation of companies in our industry generally;
- variations in operating results;
- changes in governmental regulations;
- developments in patent and other proprietary rights;
- public concern as to the safety of drugs or treatments developed by us or others;
- results of clinical trials of our products or our competitors' products; and
- regulatory action or inaction on our products or our competitors' products.

From time to time, we may hire companies to assist us in pursuing investor relations strategies to generate increased volumes of investment in our common stock. Such activities may result, among other things, in causing the price of

our common stock to increase on a short-term basis.

Furthermore, the stock market generally and the market for stocks of companies with lower market capitalizations and small biopharmaceutical companies, like us, have from time to time experienced, and likely will again experience significant price and volume fluctuations that are unrelated to the operating performance of a particular company.

OUR OUTSTANDING SPECIAL VOTING RIGHTS PREFERRED STOCK AND PROVISIONS OF OUR RESTATED CERTIFICATE OF INCORPORATION COULD DELAY OR PREVENT THE ACQUISITION OR SALE OF OUR BUSINESS.

Holders of our Special Voting Rights Preferred Stock have the ability to prevent any change of control in us. Our Vice President of Research and Development, Dr. Pankaj Modi, owns all of our Special Voting Rights Preferred Stock. In addition, our Restated Certificate of Incorporation permits our Board of Directors to designate new series of preferred stock and issue those shares without any vote or action by our stockholders. Such newly authorized and issued shares of preferred stock could contain terms that grant special voting rights to the holders of such shares that make it more difficult to obtain stockholder approval for an acquisition of our business or increase the cost of any such acquisition.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

We have made statements in this prospectus that may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plans," "intends," "believes," "will," "estimates," "forecasts," "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

- our expectations concerning product candidates for our technology;
- our expectations concerning existing or potential development and license agreements for third party collaborations and joint ventures;
- our expectations of when different phases of clinical activity may commence;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received; and
- our expectations of receiving additional financing.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- the inherent uncertainties of product development based on a new and as yet not fully proven drug delivery technology;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations when tested clinically;
- the inherent uncertainties associated with identification and initial development of product candidates;
- the inherent uncertainties associated with clinical trials of product candidates; and
- the inherent uncertainties associated with the process of obtaining

regulatory approval to market product candidates.

Additional factors that could affect future results are set forth above under the caption "Risk Factors". We caution investors that the forward-looking statements contained in this prospectus must be interpreted and understood in light of conditions and circumstances that exist as of the date of this prospectus. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements made in this prospectus to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based.

AVAILABILITY OF ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission ("SEC"). Our filings are available to the public over the internet at the SEC's web site at http://www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Rooms in Washington, D.C. and Chicago, Illinois. The Public Reference Room in Washington, D.C. is located at 450 Fifth Street, N.W. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Rooms.

The SEC allows us to "incorporate by reference" in this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is an important part of this prospectus, and information that we file later 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 all shares offered by this prospectus are sold:

- Annual Report on Form 10-K for the fiscal year ended July 31, 2004.
- Quarterly Report on Form 10-Q for the fiscal quarter ended October 31, 2004.
- Current Report on Form 8-K filed on November 12, 2004.
- Current Report on Form 8-K filed on November 26, 2004.
- Current Report on Form 8-K filed on December 1, 2004.
- Current Report on Form 8-K filed on December 22, 2004.
- Current Report on Form 8-K filed on December 30, 2004.
- The description of our common stock contained in our registration statement on Form 10 filed on December 14, 1998, as amended by a Form 10/A filed on February 24, 1999, and including any amendment or report subsequently filed for the purpose of updating the description.

You may request a copy of these filings at no cost. Please direct your requests to Mark Fletcher, Executive Vice President and General Counsel, 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 (telephone 416/364-2551).

You should rely only on the information incorporated by reference or provided in

this prospectus or any prospectus 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 prospectus supplement is accurate as of any date other than the date on the front page of those documents. This prospectus does not contain all of the information set forth in the registration statement. You should read the entire registration statement for further information about us and our common stock.

USE OF PROCEEDS

We will not receive any proceeds from the resale of shares covered by this prospectus.

SELLING STOCKHOLDERS

The following table shows certain information as of the date of this prospectus regarding the number of shares of common stock owned by the selling stockholders and the number of shares of common stock that are included for sale in this prospectus. The table assumes that all shares offered for sale in the prospectus are sold.

NAME	OUTSTANDING SHARES OWNED BEFORE OFFERING (1,2)	NUMBER OF SHARES OFFERED BY SELLING STOCKHOLDER(3)	O OWN
Cranshire Capital, L.P.	10,000	6,326,218	
Iroquois Capital, LP	0	6,326,218	
Omicron Master Trust	819,672 (5)	6,326,218	
Smithfield Fiduciary LLC	0	6,326,218	
The Shemano Group	0	145,000	
TOTAL STOCK	829,672	25,449,872	

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(1) Includes all outstanding shares owned by the selling stockholder as of the date hereof.

(2) Does not include: (i) 1,660,889 shares of common stock issuable upon exercise of warrants owned by Cranshire Capital, L.P.; (ii) 2,475,129 shares of common stock issuable upon exercise of warrants and an additional investment right owned by Omicron Master Trust; and (iii) 1,065,574 shares of common stock issuable upon exercise of warrants and an additional investment right owned by Iroquois Capital, LP.

(3) Includes 125% of (i) 1,219,512 shares of common stock issuable upon conversion of the outstanding debentures owned by the selling stockholders as of the date hereof, 91,463 shares of common stock issuable upon payment of interest on the debentures and 1,219,512 shares of common stock issuable upon exercise of outstanding warrants owned by the selling stockholders as of the date hereof, and (ii) 2,530,487 shares of common stock issuable in connection with the additional investment right held by the selling stockholder.

(4) Assumes sale of all shares offered by this prospectus.

(5) Omicron Master Trust owns 2.3% of our outstanding common stock.

No selling stockholder has held a position as a director or executive officer nor has had a material employment relationship with us or any of our affiliates, or our or their predecessors, within the past 3 years.

PLAN OF DISTRIBUTION

Each Selling Stockholder (the "Selling Stockholders") of the common stock ("Common Stock") of Generex Biotechnology Corporation, a Delaware corporation (the "Company") and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on the Trading Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this prospectus;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each Selling Stockholder does not expect these commissions and

discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each Selling Stockholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period

of two business days prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered in this prospectus will be passed upon for us by Eckert Seamans Cherin & Mellott, LLC, 1515 Market Street, 9th Floor, Philadelphia, PA 19102. The firm of Eckert Seamans Cherin & Mellott owns 128,172 shares of common stock which it received in payment of legal fees and expenses in 1998 (60,000 shares of which the firm currently owns 30,000 shares) and upon the exercise of warrants in June 1999 (98,172 shares). The firm also has been granted options exercisable for 30,000 shares at $7.56 per share under our 2000 Stock Option Plan. Members of the firm own additional shares (less than one percent in total) that they purchased from time to time for cash, either from us or in the public market.

EXPERTS

The consolidated financial statements incorporated by reference in this prospectus have been audited by BDO Dunwoody LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their report incorporated herein by reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

The financial statements as of July 31, 2002 incorporated by reference in this prospectus from the Company's Annual Report on Form 10-K for the year ended July 31, 2004 have been audited by Deloitte & Touche LLP, independent registered chartered accountants, as stated in their report, which is incorporated by reference herein, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.