GENEREX BIOTECHNOLOGY CORP
Form S-3/A
August 31, 2004

REGISTRATION NO. 333-117822

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

AMENDMENT NO. 1

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GENEREX BIOTECHNOLOGY CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	98-0178636
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(IRS EMPLOYER IDENTIFICATION NO.)

33 HARBOUR SQUARE, SUITE 202
TORONTO, ONTARIO
CANADA M5J 2G2
416/364-2551

(ADDRESS, INCLUDING ZIP CODE AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

MARK FLETCHER, ESQUIRE
EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL
33 HARBOR SQUARE, SUITE 202
TORONTO, ONTARIO
CANADA M5J 2G2
416/364-2551

COPIES TO:

GARY A. MILLER, ESQUIRE
ECKERT SEAMANS CHERIN & MELLOTT, LLC
1515 MARKET STREET - 9TH FLOOR
PHILADELPHIA, PA 19102
215/851-8472

(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF AGENT FOR SERVICE)

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: FROM TIME TO TIME AFTER THE EFFECTIVE DATE OF THIS REGISTRATION STATEMENT.

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. |X|

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, 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 (1)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (1)
Common Stock, $.001 par value	3,391,441(2)	$1.09(3)	$ 3,696,671
Common Stock $.001 par value	7,137,081(4)	$1.09(3)	$ 7,779,418
Totals	10,528,522		$11,476,089

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* This registration statement also includes an indeterminate number of additional shares of common stock as may from time to time become issuable as a result of any stock split, stock dividend and other similar transactions; which shares are registered hereunder pursuant to Rule 416 under the Securities Act of 1933, as amended.

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457 under the Securities Act of 1933, as amended.

(2) These shares are outstanding shares being offered for resale by certain of our shareholders.

(3) Based on the average of the high and low prices of our common stock reported on the NASDAQ SmallCap Market for July 28, 2004.

(4) These shares are issuable upon the exercise of warrants and additional investment rights to purchase shares of our common stock and are registered for resale.

WE HEREBY AMEND THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL WE 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 COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

Subject to completion, dated August 30, 2004

The information in this prospectus is not complete and may change. The selling shareholders may not sell these securities (except pursuant to a transaction exempt from the registration requirements of the Securities Act of 1933) until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

GENEREX BIOTECHNOLOGY CORPORATION

10,528,522 Shares of Common Stock

We are registering 10,528,522 shares of our common stock for resale by the selling shareholders listed on pages 10-11.

- 3,391,441 of these shares are currently outstanding; and
- 7,137,081 of these shares are issuable upon exercise of outstanding warrants and additional investment rights.

The prices at which the selling shareholders 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 August 27, 2004, as reported by NASDAQ, was $1.08 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 August __, 2004

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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, after the end of our most recent fiscal year, 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 shareholders. The selling shareholders 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:

- 6,012,882 shares of Common Stock; and
- 4,515,640 warrants to purchase shares of Common Stock.

We issued an aggregate of 2,621,441 shares of our common stock to certain selling shareholders, of which 93,750 shares were issued pursuant to the terms of a Securities Purchase Agreement, dated February 11, 2004; 68,675 shares were issued pursuant to the terms of a Securities Purchase Agreement, dated February 13, 2004; and 2,459,016 shares were issued pursuant to the terms of a Securities Purchase Agreement, dated June 23, 2004. Additionally, in accordance with the foregoing Securities Purchase Agreements, we issued to the same selling shareholders (i) warrants to purchase 23,438 shares of our common stock, 17,169 shares of our common stock, and 1,967,213 shares of our common stock, respectively, for a total 2,007,820 shares of our common stock and (ii) additional investment rights to purchase, for a period of time, the same number of shares of common stock and warrants initially purchased by each investor. In addition we issued 770,000 shares and 500,000 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.....34,004,648 shares of Common Stock

- Common stock to be outstanding after the offering.....44,533,170 shares of Common Stock

The number set forth above for the shares of common stock outstanding before this offering is the number of shares outstanding on August 30, 2004, excluding the shares of common stock offered for resale by this prospectus.

The numbers set forth above do not include (i) 8,017,159 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding options and (ii) 7,278,059 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 $3.69 per share and a weighted average exercise price for the warrants of $3.38 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 $89,155,698 at April 30, 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.

OUTCOME OF AN ARBITRATION PROCEEDING WITH SANDS BROTHERS MAY HAVE AN ADVERSE IMPACT ON US.

On October 2, 1998, Sands Brothers & Co. Ltd., a New York City-based investment banking and brokerage firm, initiated an arbitration against us under New York Stock Exchange rules. Sands alleged that it had the right to receive, for nominal consideration, approximately 1.5 million shares of our common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary that we acquired in late 1997. In exchange therefor, the letter agreement purported to grant Sands the right to acquire 17% of Generex Pharmaceuticals' common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals' common stock applies to our common stock since outstanding shares of Generex Pharmaceuticals' common stock were converted into shares of our common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and $144,000 in monthly fees allegedly due under the terms of the purported agreement.

After several arbitration and court proceedings, on October 29, 2002, the Appellate Division of the New York Supreme Court issued a decision remanding the issue of damages to a new panel of arbitrators and limiting the issue of damages before the new panel to reliance damages which is not to include an award of lost profits. Reliance damages are out-of-pocket damages incurred by Sands.

On November 27, 2002, Sands filed with the Appellate Division a motion to reargue the appeal, or, in the alternative, for leave to appeal to the Court of Appeals of New York from the order of the Appellate Division. On March 18, 2003, the Appellate Division denied Sands' motion. A new arbitration hearing was held

in early June, 2004. A decision has not yet been rendered by the new arbitration panel which held that hearing.

Despite the recent favorable decisions, the case is still ongoing and our ultimate liability cannot yet be determined with certainty. Our financial condition would be materially adversely affected to the extent that Sands receives shares of our common stock for little or no consideration or substantial monetary damages as a result of this legal proceeding. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

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 April 30, 2004, our stockholders' equity was $2,549,472.

In addition, for continued listing on both the NASDAQ National Market and SmallCap Market, our stock price must be at least $1.00. During periods in fiscal 2002 and the beginning of fiscal 2003, our stock price dropped close to $1.00 per share. If we do not meet this requirement in the future, we may be subject to delisting by NASDAQ.

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, 2003, as amended.

- Quarterly Reports on Form 10-Q for the fiscal quarters ended October 31, 2003, January 31, 2004 and April 30, 2004, respectively.

- Current Reports on Form 8-K filed on August 15, 2003 and 8-K/A filed on September 9, 2003.

- Current Reports on Form 8-K filed on January 6, 2004 and 8-K/A filed on March 24, 2004.

- Current Reports on Form 8-K filed on February 3, 2004, on February 12, 2004, on March 1, 2004, on March 22, 2004 and on July 14, 2004.

- Definitive Proxy Statement on Schedule 14A filed on October 14, 2003.

- Preliminary Proxy Statements on Schedule 14A filed on filed on October 3, 2003 and October 7, 2003.

- Definitive Proxy Statement on Schedule 14A filed on April 8, 2004.

- Preliminary Proxy Statement on Schedule 14A filed on January 27, 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 is part of a registration statement on Form S-3 (Registration No. 333-117822) filed with the SEC under the Securities Act of 1933. 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.

DILUTION

Purchasers of common stock offered pursuant to this prospectus will incur dilution in their investment that is approximately equal to the difference between the price which they pay for the shares and stockholders' equity per share of the shares. As of April 30, 2004, the book value of our stockholders' equity was approximately $0.08 per share of common stock.

USE OF PROCEEDS

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

SELLING SHAREHOLDERS

The following table lists each person who may resell shares pursuant to this prospectus and, in addition, sets forth:

- the number of shares of outstanding common stock registered for sale and beneficially owned by each prior to the offering;
- the number of shares registered for sale by each in the offering and issuable upon exercise of warrants and additional investment rights;
- the total number of shares registered for sale by each in the offering; and
- the number of shares of common stock owned by each after the offering, assuming each sells all of the shares registered for his or her benefit.

NAME	OUTSTANDING SHARES(1)	REGISTERED SHARES ISSUABLE UPON EXERCISE OF WARRANTS(2)	TOTAL SHARES REGISTERED FOR SALE (3)

CityPlatz Limited	3,688,524(5)	1,639,344	3,688,524
Omicron Master Trust	3,294,801(5)(6)	1,311,476	2,950,820
Iroquois Capital, LP	1,475,410(5)	655,738	1,475,410
Howard Horberg	772,486(5)	327,868	772,486
Michael Sourlis	234,376	46,876	234,376
Zapfe Holdings, Inc.	191,688	34,338	191,688
CEOcast Inc.	225,000	0	225,000
Charmed Investments Limited	100,000	0	100,000
Sound Capital, Inc.	875,000(5)	500,000	875,000
Quickstringer Limited	50,000	0	50,000
TOTAL STOCK	10,907,285	4,515,640	10,528,522

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(1) Includes all outstanding shares beneficially owned by the shareholder as of the date hereof.

(2) Includes all warrants owned by the shareholder which are exercisable within 60 days of the date hereof.

(3) See (1) and (2).

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

(5) Beneficially own more than 1% of our common stock.

(6) All warrants and additional investment rights held by Omicron contain provisions that prevent Omicron from exercising any such securities if, as a result, Omicron would own greater than 9.9% of Generex's then issued and outstanding shares of common stock. Accordingly, Omicron beneficially owns 9.9% of the issued and outstanding shares of common stock of Generex.

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

PLAN OF DISTRIBUTION

The Selling Stockholders and any of their pledgees, donees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on any 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. The Selling Stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits Investors;
- 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;

- short sales (other than short sales established prior to the effectiveness of the Registration Statement to which this Prospectus is a part)

- 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; and

- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under 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. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of Common Stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon the Company being notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of Common Stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of Common Stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon the Company being notified in writing by a Selling Stockholder of any changes in the "Selling Stockholder" table, including, without limitation, that a donee or pledgee intends to sell more than 500 shares of Common Stock, such changes will be identified in pre-effective or post-effective amendment(s) or prospectus supplement(s), as necessary.

The Selling Stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders are not broker-dealers and are not affiliated with any broker-dealers. Accordingly, the Selling Stockholders will not be deemed "underwriters" within the meaning of the Securities Act in connection with any sales of the securities. Any broker-dealers or agents that are involved in selling the shares are "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 will be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholders has represented and warranted to 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 all fees and expenses 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.

The Selling Stockholders and any other persons participating in a distribution of the shares of Common Stock will be subject to applicable provisions of the Securities Exchange Act of 1934 and the rules and regulations thereunder, including Regulation M, which may restrict certain activities of, and limit the timing of purchases and sales of the Common Stock by the Selling Stockholders and other persons participating in a distribution of the shares of Common Stock. Furthermore, under Regulation M, persons engaged in a distribution of the shares of Common Stock are prohibited from simultaneously engaging in market making and certain other activities with respect to the shares for a specified period of time prior to the commencement of such distributions subject to specified exceptions or exemptions. All of the foregoing may affect the marketability of the shares offered hereby. We have notified the Selling Stockholders that they will be subject to applicable provisions of the Securities Exchange Act of 1934 and its rules and regulations, including, among others, Rule 102 under Regulation M. These provisions may limit the timing of purchases and sales of any of the shares of Common Stock by the Selling Stockholders.

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, and for each of the two years in the period ended 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, 2003 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.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

We will pay all reasonable expenses incident to the registration of shares other than any commissions and discounts of underwriters, dealers or agents. Such expenses are set forth in the following table. All of the amounts shown are estimates except the SEC registration fee.

SEC registration fee	$ 1,494.04
Legal fees and expenses	$ 5,000.00
Accounting fees and expenses	$ 10,000.00
Other	$ 500.00
Total	$ 16,994.04

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the Delaware General Corporation Law authorizes a corporation to indemnify its directors, officers, employees or other agents in terms sufficiently broad to permit indemnification (including reimbursement for expenses incurred) under certain circumstances for liabilities arising under the Securities Act. Our Restated Certificate of Incorporation (Exhibit 3.1 hereto) and Bylaws (Exhibit 3.2 hereto) provide indemnification of our directors and officers to the maximum extent permitted by the Delaware General Corporation Law.

ITEM 16. EXHIBITS.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation, as amended, of Generex Biotechnology Corporation filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q filed March 15, 2004 is incorporated herein by reference.
3.2	Bylaws of Generex Biotechnology Corporation filed as Exhibit 3.2 to our Registration Statement on Form S-1 filed July 12, 1999 ("1999 S-1") is incorporated herein by reference.
4.1	Form of common stock certificate filed as Exhibit 4.2 to our 1999 S-1 is incorporated herein by reference.
4.2	Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein, filed as Exhibit 4.1 to our Current Report on Form 8-K filed July 14, 2004 is incorporated herein by reference.
4.3	Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors

named therein, filed as Exhibit 4.2 to our Current Report on Form 8-K filed July 14, 2004 is incorporated herein by reference.

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4.4	Form of Warrant issued in connection with 4.2, filed as Exhibit 4.3 to our Current Report on Form 8-K filed July 14, 2004 is incorporated herein by reference.
4.5	Form of Additional Investment Right issued in connection with 4.2, filed as Exhibit 4.4 to our Current Report on Form 8-K filed July 14, 2004 is incorporated herein by reference.
5.	Opinion of Eckert Seamans Cherin & Mellott, LLC (included in Exhibit 23.1.3).*
23.1.1	Consent of BDO Dunwoody, LLP.*
23.1.2	Consent of Deloitte & Touche LLP.*
23.1.3	Consent of Eckert Seamans Cherin & Mellott, LLC.*

ITEM 17. UNDERTAKINGS.

We hereby undertake:

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;

   (ii) To reflect in the prospectus any facts or events arising after the effective date of the 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.

   (iii) To include any material information with respect to the plan of distribution not previously disclosed in the 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 us pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, 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. That, for the purpose of determining any liability under the Securities Act of 1933, each filing of our annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the 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.

5. To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X is not set forth in the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

6. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by our director, officer, or controlling person 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, we 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 us is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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 S-3 and has duly caused this amendment no. 1 to registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Toronto, Province of Ontario, Canada, on the 30th day of August, 2004.

GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin

Anna E. Gluskin, President

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement was signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Anna E. Gluskin Anna E. Gluskin	President, Chief Executive Officer and Director	Augu
/s/ Rose C. Perri Rose C. Perri	Chief Financial Officer, Chief Operating Officer and Director	Augu
/s/ Gerald Bernstein, M.D. Gerald Bernstein, M.D.	Vice President, Director	Augu
/s/ Mindy Allport-Settle Mindy Allport-Settle	Director	Augu
/s/ John Baratt John Barratt	Director	Augu
/s/ J. Michael Rosen J. Michael Rosen	Director	Augu
/s/ Brian T. McGee Brian T. McGee	Director	Augu
/s/ Slava Jarnitskii Slava Jarnitskii	Controller	Augu