

GENEREX BIOTECHNOLOGY CORP
Form S-3/A
August 18, 2003

REGISTRATION NO. 333-106519

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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

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reinvestment plans, check the following box.

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

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

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

Calculation of Registration Fee

| Title of Each Class of Securities To Be Registered* | Amount To Be Registered | Proposed Maximum Offering Price Per Share (1) | Proposed Maximum Aggregate Offering Price (1) | A | R |
|---|-------------------------|---|---|----|---|
| Common Stock, \$.001 par value (2) | 2,996,301 | \$2.18 (3) | \$6,531,936 | \$ | |
| Common Stock \$.001 par value (4) | 70,000 | \$1.25 | \$ 87,500 | \$ | |
| Common Stock, \$.001 par value (2)) | 666,667 | \$2.18 (3) | \$1,453,334 | \$ | |
| Common Stock, \$.001 par value (4) | 666,667 | \$1.80 | \$1,200,000 | \$ | |
| Common Stock, \$.001 par value (4) | 1,269,519 | \$1.71 | \$2,170,877 | \$ | |
| Common Stock \$.001 par value (4) | 60,000 | \$1.88 | \$112,800 | \$ | |
| Common Stock \$.001 par value (4) | 575,000 | \$2.50 | \$1,437,500 | \$ | |
| Common Stock \$.001 par value (4) | 9,091 | \$2.75 | \$25,000 | \$ | |
| Common Stock \$.001 par value (4) | 30,000 | \$3.00 | \$90,000 | \$ | |
| Common Stock \$.001 par value (4) | 172,584 | \$3.75 | \$647,190 | \$ | |
| Common Stock \$.001 par value (4) | 691,667 | \$4.34 | \$3,001,835 | \$ | |
| Common Stock | | | | | |

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| | | | | |
|--------------------------------------|-----------|---------|-------------|----|
| Common Stock \$.001 par value (4) | 19,584 | \$5.00 | \$97,920 | \$ |
| Common Stock \$.001 par value (4) | 188,656 | \$5.09 | \$960,259 | \$ |
| Common Stock \$.001 par value (4) | 30,000 | \$6.00 | \$180,000 | \$ |
| Common Stock \$.001 par value (4) | 214,468 | \$6.50 | \$1,394,042 | \$ |
| Common Stock \$.001 par value (4) | 114,055 | \$6.60 | \$752,763 | \$ |
| Common Stock \$.001 par value (4) | 125,000 | \$4.00 | \$500,000 | \$ |
| Common Stock \$.001 par value (4) | 39,978 | \$11.13 | \$444,955 | \$ |
| Common Stock \$.001 par value (4) | 63,117 | \$12.15 | \$766,871 | \$ |
| Common Stock \$.001 par value (4) | 74,000 | \$12.99 | \$961,260 | \$ |
| Totals | 8,076,354 | | | \$ |

* This registration statement also includes an indeterminate number of additional shares of common stock as may from time to time become issuable upon exercising warrants by reason of stock splits, stock dividends 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.
- (2) These shares are outstanding shares being offered for resale by certain of our stockholders.
- (3) Based on the average of the high and low prices reported on the Nasdaq SmallCap Market for June 24, 2003.
- (4) These shares are issuable upon the exercise of warrants to purchase common stock and are registered for resale. The proposed maximum offering price per share is the exercise price of each such warrant.

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 15, 2003

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The information in this prospectus is not complete and may be changed. 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

8,076,354 Shares of Common Stock

We are registering 8,076,354 shares of our common stock for resale by the selling shareholders listed on pages 10-12

- o 3,662,968 of these shares are currently outstanding
- o 4,413,386 of these shares are issuable upon exercise of outstanding warrants.

Our common stock is quoted on the Nasdaq SmallCap Market under the symbol "GNBT." The last sale price of our common stock on August 11, 2003, as reported by Nasdaq, was \$1.59 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 whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is August __, 2003.

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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.

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:

- o 3,662,968 shares of Common Stock; and
- o 4,413,386 Warrants to purchase shares of Common Stock.

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:

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- o Common stock outstanding before the offering.....25,275,192
shares of Common Stock
- o Common stock to be outstanding after the offering.....29,688,578
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 12, 2003. The number of shares of common stock outstanding after this offering is based on the number of shares outstanding before the offering plus 4,413,386 shares - the maximum number of shares issuable upon the exercise or conversion of options, warrants and convertible securities that may be resold pursuant to this prospectus.

The numbers set forth above do not include 6,497,103 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding options and warrants other than those covered by this prospectus.

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These additional options and warrants are exercisable at prices ranging from \$1.00 to \$25.15 per share, with a weighted average exercise price of \$6.61 per share.

RISK FACTORS

Investment in our shares involves a high degree of risk. You should carefully consider the following discussion of risks as well as the other information in this prospectus before purchasing and the other reports that we have filed (and will file after the date of this prospectus) with the Securities and Exchange Commission, before purchasing our stock. Each of these risk factors could adversely affect our business, prospects, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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 approximately \$72,000,000 as of April 30, 2003. 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 develop, commercialize, manufacture and

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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.

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:

- o to proceed under our joint venture with Elan, which requires us to fund 80.1% of initial product development costs;
- o to develop our buccal insulin product;
- o to develop new products based on our buccal delivery technology, including clinical testing relating to new products;
- o to develop or acquire other delivery technologies or other lines of business;
- o to establish and expand our manufacturing capabilities; and
- o to finance general and administrative and research activities that are not related to specific products under development.

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 twelve months. However, this expectation is based on our current operating plan, which could

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change as a result of many factors, and we may need additional funding sooner than anticipated. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds 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.

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 shareholders.

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 highly dependent at present 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

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agreements with other pharmaceutical companies that will assist us in developing, testing, obtaining governmental approval for and commercializing products using our platform technology. 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 TECHNOLOGY

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 700 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.

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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.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technology, 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

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proprietary technology 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 period in the US 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, these uncertainties mean that 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.

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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:

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

We may not be able to compete with diabetes treatments now being marketed and

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developed, or which may be developed and marketed in the future by other companies.

Our oral insulin product will compete with existing and new therapies for treating diabetes, including administration of insulin by injection. 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. In the longer term, we also face competition from companies that seek to develop cures for diabetes through techniques for correcting the genetic deficiencies that underlie diseases such as diabetes.

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 alternative drug delivery systems or new drug research and testing including oral delivery systems, intranasal delivery systems, transdermal systems, and colonic absorption systems. 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.

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RISKS RELATING TO POTENTIAL LIABILITIES

We face significant product liability risks, which may have a negative effect on our financial condition.

The administration of drugs to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs 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 has been administered to patients for some time. Product liability claims can be expensive to defend and may result in large

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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 result in adverse effects upon Generex.

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 Generex Biotechnology common stock since outstanding shares of Generex Pharmaceuticals common stock were converted into shares of Generex Biotechnology 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 demanding 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.

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.

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RISKS RELATED TO THE MARKET FOR OUR STOCK

If our stock is relisted 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 you to sell our stock.

On June 5, 2003, our common stock was relisted from the Nasdaq National Market because of our failure to maintain a minimum of \$10,000,000 in stockholders' equity. We have appealed that decision but the appeal does not stop the relisting. On June 5, 2003, our stock began trading on the NASDAQ SmallCap Market. Nasdaq SmallCap has its own standards for continued listing, including a minimum of \$2.5 million stockholders' equity. As of April 30, 2003, our

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stockholders' equity was slightly above the minimum.

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 share price dropped to close to \$1.00 per share. If we do not meet this requirement in the future, we may be subject to relisting by NASDAQ.

If our stock is relisted 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 you to sell your shares.

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 SEC'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 shareholders may have more difficulty selling our common stock in the public market.

The price of our shares may be volatile.

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

- o announcements of research activities and technology innovations or new products by us or our competitors;
- o changes in market valuation of companies in our industry generally;
- o variations in operating results;
- o changes in governmental regulations;
- o developments in patent and other proprietary rights;
- o public concern as to the safety of drugs developed by us or others;
- o results of clinical trials of our products or our competitors products; and
- o regulatory action or in action 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 shares. Such activities may result, among other things, in causing the price of our shares 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 Certificate of Incorporation could delay or prevent the acquisition or sale of Genex.

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Holders of our Special Voting Rights Preferred Stock have the ability to prevent any change of control of Generex. Our Vice President of Research and Development, Dr. Pankaj Modi, owns all of our Special Voting Rights Preferred Stock. In addition, our 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 the shareholders. 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 shareholder approval for an acquisition of Generex or increase the cost of any such acquisition.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

We have made some statements in this prospectus that are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. This Act limits our liability in any lawsuit based on forward looking statements we have made. All statements, other than statements of historical facts, included in this prospectus that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. 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:

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

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:

- o the inherent uncertainties of product development based on a new and as yet not fully proven drug delivery technology;
- o the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations when tested clinically;
- o the inherent uncertainties associated with clinical trials of product candidates;
- o the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates; and
- o adverse developments in our joint venture with a subsidiary of Elan Corporation, plc regarding buccal morphine.

Additional factors that we think could cause our actual outcomes and results to differ materially from the forward-looking statements also include those discussed above under the caption "Risk Factors."

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Because of the risks and uncertainties associated with forward-looking statements, you should not place undue reliance on them. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

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., New York, New York 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:

- o Annual Report on Form 10-K for the fiscal year ended July 31, 2002.
- o Quarterly Report on Form 10-Q for the fiscal quarter ended October 31, 2002.
- o Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2003.
- o Quarterly Report on Form 10-Q for the fiscal quarter ended April 30, 2003.
- o Current Reports on Form 8-K filed on October 8, 2002, November 5, 2002, November 15, 2002, February 25, 2003, March 20, 2003, May 27, 2003, and June 5, 2003.
- o Definitive Proxy Statement on Schedule 14A filed on March 25, 2003.
- o 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 February 24, 1999, and including any amendment or report subsequently filed for the purpose of updating the description.

This prospectus is part of a registration statement on Form S-3 (Registration No. 333-106519) 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 registration statement for further information about Generex and our common stock. 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.

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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

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share of the shares. As of April 30, 2003, the book value of our stockholders' equity was approximately \$0.13 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:

- o the number of shares of outstanding common stock beneficially owned by each prior to the offering (as of June 24, 2003);
- o the number of shares registered for sale by each in the offering issuable upon exercise of warrants o the total number of shares registered for sale by each in the offering; and
- o the number of shares of common stock owned by each after the offering, assuming each sells all of the shares registered for his benefit.

| Name | Outstanding Shares (1) | Registered Shares Issuable Upon Exercise of Warrants (2) | Total Shares Registered For Sale (3) |
|------------------------|------------------------|--|--------------------------------------|
| Cranshire Capital | 1,318,840 | 981,590 | 2,300,430 |
| Howard Todd Horberg | 86,956 | 34,782 | 121,738 |
| Gryphon Partners, LP | 434,782 | 173,913 | 608,695 |
| Lakeshore Capital Ltd. | 100,000 | 40,000 | 140,000 |
| Langley Partners, LP | 435,000 | 195,250 | 630,250 |
| Alpha Capital, AG | 217,391 | 86,956 | 304,347 |
| Omicron Capital | 434,782 | 173,913 | 608,695 |
| Photon Fund Ltd. | 217,391 | 86,956 | 304,347 |
| Vertical Ventures LLC | 347,826 | 139,130 | 486,956 |
| Steven Peltzman | 24,000 | 48,000 | 48,000 |
| Gulfstream Capital | 0 | 550,000 | 550,000 |

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| | | | |
|----------------------------|---------|---------|---------|
| Michael Gottlieb | 78,000 | 156,000 | 156,000 |
| Craig Pierson | 78,000 | 156,000 | 156,000 |
| Ken Cerruto | 4,000 | 8,000 | 8,000 |
| Liquid Marketing, Inc. | 0 | 5,000 | 5,000 |
| Edward Chavez | 0 | 63,117 | 63,117 |
| Michael Jacks | 0 | 4,500 | 4,500 |
| Barbara Brooks-Baxter | 909 | 909 | 909 |
| James Baxter | 8,182 | 8,182 | 8,182 |
| Gary Shemano | 0 | 215,389 | 215,389 |
| William and Mary Corbett | 0 | 213,388 | 213,388 |
| Castle Creek Healthcare | 113,857 | 113,857 | 113,857 |
| CCL Fund LLC | 28,464 | 28,464 | 28,464 |
| Montrose Investments, Ltd. | 29,893 | 117,634 | 117,634 |
| Protius Overseas Limited | 509,291 | 509,291 | 509,291 |
| Capital Ventures | 27,027 | 27,027 | 27,027 |
| Gryphon Master Fund | 35,000 | 35,000 | 35,000 |

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| Name | Outstanding Shares (1) | Registered Shares Issuable Upon Exercise of Warrants (2) | Total Shares Registered For Sale (3) |
|--|------------------------|--|--------------------------------------|
| Rice Opportunity Fund, LLC f/k/a The dotCOM Fund, LLC | 0 | 10,811 | 10,811 |
| WEC Asset Management, LLC | 27,000 | 27,000 | 27,000 |
| Kodiak Opportunity 3c7 LP | 2,539 | 2,534 | 2,534 |
| Kodiak Opportunity LP | 5,028 | 5,028 | 5,028 |
| Kodiak Opportunity Offshore LTD | 7,434 | 7,439 | 7,439 |
| Prism Partners 1, LP | 6,219 | 6,219 | 6,219 |
| Prism Partners II Offshore | 3,109 | 3,109 | 3,109 |

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| Fund, LP | | | |
|--------------------------------------|---------|---------|---------|
| Prism Partners Offshore Fund, LP | 1,036 | 1,020 | 1,020 |
| Jeffrey Volk | 13,000 | 13,000 | 13,000 |
| Clipperbay & Co. | 0 | 27,485 | 27,485 |
| Ram Trading | 0 | 3,184 | 3,184 |
| Nob Hill Capital Partners | 0 | 2,547 | 2,547 |
| AEOW 2000 LP | 50,000 | 1,737 | 1,737 |
| Velocity Investment Partners, LLC | 0 | 1,158 | 1,158 |
| Fidelity National Title Insurance Co | 45,455 | 1,158 | 1,158 |
| Willow Creek Offshore Fund | 0 | 637 | 637 |
| Willow Creek Capital Partners LP | 0 | 637 | 637 |
| Nob Hill Capital Associates | 0 | 509 | 509 |
| Bognor Regis Inc | 0 | 347 | 347 |
| Ascend Partners LP | 0 | 347 | 347 |
| Ascend Offshore Funds LTD | 0 | 232 | 232 |
| CEOcast, Inc | 70,000 | 0 | 70,000 |
| Wolfe Axelrod Weinberger Assoc. LLC | 125,000 | 125,000 | 125,000 |

No selling shareholder has held a position as a director or executive officer nor has a material employment relationship with the Company within the past 3 years, other than Steven Peltzman, who serves as our Vice President-Business Development.

(1) Includes all outstanding shares beneficially owned by the shareholder, including, in some cases, shares not registered for sale under this prospectus.

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(2) Does not include shares issuable upon the exercise of options or warrants registered for sale under another of our registration statements. No shareholder holds other warrants or options, which when added to the outstanding shares held after the offering, will give the shareholder beneficial ownership of more than 1% of the Company's common stock.

(3) Includes outstanding shares registered for sale under this prospectus, which may not be all of the outstanding shares listed as held by the selling shareholders, and the registered shares issuable upon exercise of warrants.

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(4) No selling shareholder will beneficially own more than 1% of the Company's outstanding shares after the offering, other than Protius Overseas Limited, which will own less than 2%. The warrants contain a provision prohibiting exercise to the extent it would result in the holder beneficially owning more than 9.9% of the Company's common stock.

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PLAN OF DISTRIBUTION

We are registering the shares of common stock covered by this prospectus on behalf of the selling shareholders. The selling shareholders may offer and sell shares from time to time. In addition, a selling shareholder's donees, pledgees, transferees and other successors in interest may sell shares received from a named selling shareholder after the date of this prospectus. In that case, the term "selling shareholders" as used in this prospectus includes such donees, pledgees, transferees and other successors in interest. The selling shareholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Sales may be made over the Nasdaq SmallCap Market or otherwise, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares may be sold by way of any legally available means, including in one or more of the following transactions:

- o a block trade in which a broker-dealer engaged by a selling shareholder attempts to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account pursuant to this prospectus; and ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers.

Transactions under this prospectus may or may not involve brokers or dealers. The selling shareholders may sell shares directly to purchasers or to or through broker-dealers, who may act as agents or principals. Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in selling shares. Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling shareholders in amounts to be negotiated in connection with the sale. Broker-dealers or agents also may receive compensation in the form of discounts, concessions or commissions from the purchasers of shares for whom the broker-dealers may act as agents or to whom they sell as principal, or both. This compensation as to a particular broker-dealer might exceed customary commissions.

The selling shareholders have advised us that they have not, as of the date of this prospectus, entered into any agreements, understandings or arrangements with any underwriters or broker-dealers for the sale of shares, nor is there an underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling shareholders. To our knowledge, the selling shareholders have not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the sale of the shares covered by this prospectus.

In connection with distributions of the shares or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with these transactions, broker-dealers or financial institutions may engage in short sales of the shares in the course of hedging the positions they assume with selling shareholders. The selling shareholders may also:

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- o sell shares short and redeliver the shares to close out these short positions;
- o enter into option or other transactions with broker-dealers or other financial institutions that require the delivery to the broker-dealer or financial institution of the shares, which the broker-dealer or financial institution may resell or otherwise transfer under this prospectus;
- o loan or pledge the shares to a broker-dealer or other financial institution that may sell the shares so loaned under this prospectus upon a default; or
- o sell shares covered by this prospectus that qualify for sale under Rule 144 under the Securities Act of 1933 pursuant to that Rule rather than under this prospectus.

The selling shareholders and any broker-dealers participating in the sale of shares covered by this prospectus may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with sales of such shares.

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Any commission, discount or concession received by a broker-dealer and any profit on the resale of shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act of 1933.

We have agreed to pay the expenses of registering the shares under the Securities Act of 1933, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees. The selling shareholders will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as fees and disbursements for legal counsel retained by any selling shareholder.

Generex and some of the selling shareholders have agreed to indemnify each other and other related parties against specified liabilities, including liabilities arising under the Securities Act of 1933. The selling shareholders also may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of shares against liabilities, including liabilities arising under the Securities Act of 1933.

A supplement to this prospectus will be filed, if required, under Rule 424(b) under the Securities Act of 1933 to include additional disclosure before offers and sales of the securities in question are made.

The selling shareholders and any other persons participating in a distribution of the shares will be subject to applicable provisions of the Securities Exchange Act 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 shares by the selling shareholders and other persons participating in a distribution of the shares. Furthermore, under Regulation M, persons engaged in a distribution of the shares 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 class A common stock by the selling stockholders. Rule 102 under Regulation M provides, with some exceptions, that it is unlawful for the selling stockholders or their affiliated purchasers to, directly or indirectly, bid for or purchase, or attempt to induce

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any person to bid for or purchase, for an account in which the selling stockholders or affiliated purchasers have a beneficial interest, any securities that are the subject of the distribution during the applicable restricted period under Regulation M. All of the above may affect the marketability of the shares of class A common stock. To the extent required by law, we may require the selling stockholders, and their brokers, if applicable, to provide a letter that acknowledges compliance with Regulation M under the Exchange Act before authorizing the transfer of the selling stockholders' shares of class A common stock.

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 the Company's 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.

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EXPERTS

Our consolidated financial statements as of July 31, 2002 and 2001, and for each of the years then ended incorporated by reference in this registration statement from the Company's Annual Report on Form 10-K for the year ended July 31, 2002 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report which is incorporated by reference herein (which report expresses an unqualified opinion and includes an explanatory paragraph referring to the restatement of the 2001 financial statements), and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Our consolidated financial statements for the year ended July 31, 2000 incorporated by reference in this registration statement from the Company's Annual Report on Form 10-K for the year ended July 31, 2002 have been audited by WithumSmith+Brown, P.C., independent auditors, as stated in their report which is incorporated by reference herein and has 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.

The Registrant 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.

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| | |
|-----------------------------------|-------------|
| SEC registration fee..... | \$2,099.08 |
| Legal fees and expenses..... | \$15,000.00 |
| Accounting fees and expenses..... | \$10,000.00 |
| Other..... | \$5,000.00 |
| Total..... | \$32,099.08 |

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the Delaware General Corporation's 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. The Registrant's Restated Certificate of Incorporation (Exhibit 3.1 hereto) and Bylaws (Exhibit 3.2 hereto) provide indemnification of its directors and officers to the maximum extent permitted by the Delaware General Corporation Law.

Under the registration rights agreements applicable to certain of the securities registered hereby, the Registrant has agreed to indemnify the selling stockholders and persons controlling the selling stockholders against certain liabilities, including liabilities under the Securities Act of 1933, and the selling stockholders have agreed to indemnify the Registrant, its directors, its officers and certain control and related persons against certain liabilities, including liabilities under the Securities Act of 1933.

ITEM 16. EXHIBITS.

| Exhibit Number ----- | Description ----- |
|----------------------------|----------------------|
|----------------------------|----------------------|

3.1 Restated Certificate of Incorporation of GenereX Biotechnology Corporation filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended April 30, 1999, filed June 14, 1999, is incorporated herein by reference.

3.2 Bylaws of the Company filed as Exhibit 3.2 to our Registration Statement on Form S-1 filed July 12, 1999 ("1999 S-1") is incorporated hereby by reference.

4.1 Form of common stock certificate filed as Exhibit 4.2 with our 1999 S-1 is incorporated herein by reference.

4.2 Form of Securities Purchase Agreement entered into with Langley Partners, LP, Gryphon Partners, LP, Cranshire Capital, LP, Omicron Capital, Alpha Capital, AG, Lakeshore Capital, Vertical Ventures, LLC, Howard Todd Horberg and Photon Fund, Ltd., dated May 29, 2003 filed as exhibit 4.2 to our Quarterly Report on Form 10-Q dated June 13, 2003 ("June 2003 10-Q") is incorporated herein by

reference.

4.3 Form of Registration Rights Agreement entered into with Langley Partners, LP, Gryphon Partners, LP, Cranshire Capital, LP, Omicron Capital, Alpha Capital, AG, Lakeshore Capital, Vertical Ventures, LLC, Howard Todd Horberg and Photon Fund, Ltd., dated May 29, 2003 filed as a exhibit 4.2 to our June 2003 10-Q is incorporated herein by reference.

4.4 Form of Warrant granted to Langley Partners, LP, Gryphon Partners, LP, Cranshire Capital, LP, Omicron Capital, Alpha Capital, AG, Lakeshore Capital, Vertical Ventures, LLC, Howard Todd Horberg and Photon Fund, Ltd. dated May 29,

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2003 filed as exhibit 4.3 to our June 2003 10-Q is incorporated herein by reference.

4.5 Form of Securities Purchase Agreement entered into with Cranshire Capital, LP dated June 6, 2003 filed as exhibit 4.4 to our June 2003 10-Q is incorporated herein by reference.

4.6 Form of Registration Rights Agreement entered into with Cranshire Capital, LP, dated June 6, 2003 filed as exhibit 4.5 to our June 2003 10-Q is incorporated herein by reference.

4.7 Form of Warrant granted to Langley Partners, LP, Gryphon Partners, LP, Cranshire Capital, LP dated June 6, 2003 filed as exhibit 4.6 to our June 2003 10-Q is incorporated herein by reference.

5. Opinion of Eckert Seamans Cherin & Mellott, LLC (included in Exhibit 23.1.2)

23.1.1 Consent of Deloitte & Touche LLP

23.1.2 Consent of WithumSmith+Brown, P.C.

23.1.2 Consent of Eckert Seamans Cherin & Mellott, LLC*

*Previously Filed

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:

(a) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(b) 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;

(c) 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 (a) and (b) 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 Exchange Act that are incorporated by reference in the Registration Statement.

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2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the

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offering.

4. That, for the purpose of determining any liability under the Securities Act, 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 Exchange Act) 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 Exchange Act; and, where interim financial information required to be presented by Article 3 of Regulation S-X are 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 may be permitted to directors, officers and controlling persons of Generex pursuant to the foregoing provisions, or otherwise, Generex has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by Generex of expenses incurred or paid by a director, officer, or controlling person of Generex 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, Generex will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, we certify that we have reasonable grounds to believe that we meet all of the requirements of filing on Form S-3 and have authorized this Amendment to the Registration Statement to be signed on our behalf by the undersigned, our President, on the 15th day of August, 2003.

GENEREX BIOTECHNOLOGY CORPORATION

By: Anna E. Gluskin

Anna E. Gluskin, President

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, this Amendment No. 1 Registration Statement was signed by the following persons in the capacities and on the dates stated:

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| Signature | Title | Date |
|---|--|-----------------|
| Anna E. Gluskin ----- Anna E. Gluskin | President, Chief Executive Officer and Director | August 15, 2003 |
| Rose C. Perri ----- Rose C. Perri | Chief Financial Officer, Chief Operating Officer and Director | August 15, 2003 |
| Pankaj Modi, Ph.D. ----- Pankaj Modi, Ph.D. | Vice President and Director | August 15, 2003 |
| Gerald Bernstein, M.D. ----- Gerald Bernstein, M.D. | Vice President, Director | August 15, 2003 |
| Slava Jarnitskii ----- Slava Jarnitskii | Controller | August 15, 2003 |

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Until [date], all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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