GENEREX BIOTECHNOLOGY CORP
Form S-3/A
February 05, 2001

REGISTRATION NO. 333-51194

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

AMENDMENT NO. 3 TO FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GENEREX BIOTECHNOLOGY CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	82-0490211
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

33 HARBOR 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)

E. Mark Perri, Chairman
and Chief Financial Officer
33 Harbor Square, Suite 202
Toronto, Ontario
Canada M5J 2G2
416/364-2551

copies to:

John G. Chou, Esquire
Eckert Seamans Cherin & Mellott, LLC
1515 Market Street - 9th Floor
Philadelphia, PA 19102
215/851-8400

(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(1)	Amount To be Registered	Proposed Maximum Offering Price Per Share (1)	Proposed Maximum Aggregate Offering Price (1)
Common Stock, $.001 par value	2,151,093 shares (1)	$12.44 (2)	$26,759,596.00
Common Stock, $.001 par value	538,773 shares (3)	$13.20 (4)	$7,111,803.60
Totals	2,689,866 shares	*	$33,871,399.60

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(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457, based on the average of the high and low prices reported on the Nasdaq National Market for November 29, 2000.

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

(3) These shares are issuable upon the exercise of warrants to purchase common stock and are registered for resale only.

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.

The information set forth in this prospectus is not complete and may be changed. The selling shareholders may not sell these securities (except pursuant to a transation exempt from the registration requirements of the Securities Act of 1993) until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or a solicitation of an offer to buy these securities in any jurisdiction where that would not be permitted or legal.

Subject to completion, dated February __, 2001

Prospectus

2,689,866 Shares

GENEREX BIOTECHNOLOGY CORPORATION

Common Stock

Generex is a development stage company and has not received any revenues from operations to date. This prospectus relates to shares of Generex common stock that certain of our shareholders and warrantholders may resell for their own accounts. We will not receive any proceeds from the sale of these shares.

Of the total of 2,689,866 shares that shareholders and warrantholders may sell according to this prospectus, 2,151,093 shares are presently outstanding and 538,773 shares are reserved for issuance upon the exercise of outstanding warrants. The shareholders and warrantholders who may resell shares according to this prospectus are listed on pages 14-15 of this prospectus. We will refer to these shareholders and warrantsholders as the "Selling Shareholders."

Our common stock is listed on the Nasdaq National Market under the symbol "GNBT." The high, low and last sale prices of our common stock on February __, 2001, as reported by Nasdaq, were $_____, $_____ and $_____, respectively.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus.

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 February __, 2001.

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In making a decision whether or not to buy any shares offered by this prospectus you should rely only on the information contained in the prospectus. We have not authorized anyone to provide information different from the information in the prospectus. The information in the prospectus is accurate only as of the date of the prospectus, regardless of the time the prospectus is delivered or any shares are sold.

In this prospectus, unless the context indicates otherwise, the terms "Generex", "we", "us" and "our" refer to Generex Biotechnology Corporation.

For investors outside the United States: Neither we nor, to our knowledge, any other person has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

General

Generex is a Delaware corporation engaged in the research and development of drug delivery systems and technology. Our executive offices are located at 33 Harbour Square, Suite 202, Toronto, Canada M5J 2G2, and our telephone number at that address is 416/364-2551.

We are a development stage company. To date, we have devoted a substantial majority of our efforts and resources in developing a technology to orally administer "large molecule" drugs. These include proteins, hormones, peptides, vaccines and other pharmaceutical products. Large molecule drugs, such as synthetic insulin, are now administered almost exclusively by injection because their molecular size makes it difficult or impossible for the body to absorb them if they are administered by other means.

The initial application that we have developed of our large molecule drug delivery technology 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 light-weight, easy to use, hand-held aerosol applicator. Absorption occurs through the mucous membranes in the mouth and upper gastro-intestinal tract. On September 5, 2000, we entered into a Development and License Agreement

with Eli Lilly and Company ("Lilly") to continue development of this product. Under the terms of this Agreement (the "Lilly Agreement"), we will receive certain initial fees and milestone payments, and we will be entitled to royalties based on product sales. Depending on the success of this initial product, Lilly has the option of developing a number of additional products using our drug delivery technology.

Prior to entering into the Lilly Agreement, we had conducted clinical trials of our oral insulin product in the United States, Canada and Europe. Our clinical program, however, had not reached a point at which we were prepared to apply for regulatory approvals to market the product in any country. We did not anticipate receiving any such approvals until 2003 at the earliest. Under the terms of the Lilly Agreement, Lilly, generally, will be responsible for conducting clinical trials and securing regulatory approvals on a worldwide basis for all products developed under the Lilly Agreement. Lilly also will have the exclusive right to market the products worldwide. Our principal responsibilities under the Lilly Agreement will be to continue development, as required, on our oral insulin formulation and on the RapidMist(TM) device.

Notwithstanding Lilly's participation and support, we continue to face numerous risks and uncertainties in developing our oral insulin product and other products that may be considered for development under the Lilly Agreement. There is no assurance that any products will be successfully developed or marketed, or that we will receive significant revenues, under the Lilly Agreement.

We believe that we can use the technology upon which our oral insulin product is based successfully with other large molecule drugs. We have engaged in pre-clinical research and development work on two other applications, but we have not devoted significant resources to this effort to date. On January 16, 2001, we entered into a joint venture with Elan Corporation, plc to pursue the application of certain of our and Elan's drug delivery technologies -- including our large molecule drug delivery technology -- to pharmaceutical products for the treatment of prostate cancer and endometriosis and/or the suppression of testosterone and estrogen. There has been no product yet identified for research and development under the joint venture.

Information on Outstanding Shares

Common stock outstanding before the offering..... 19,181,018 shares

Common stock to be outstanding after the offering..... 19,719,791 shares

In the above table, the number of shares of common stock outstanding before the offering is the number of shares outstanding on January 25, 2001. The number of shares of common stock outstanding after the offering is based on the number of shares outstanding before the offering plus the maximum number of shares issuable upon the exercise of warrants that may be resold pursuant to this prospectus. Thus, the number of shares stated to be outstanding after the offering assumes that all of the warrants issued in the October 2000 Private Placement are exercised. The holders of the warrants are not required to exercise them, however, and it is unlikely that any holder would do so unless the market price of our common stock exceeded the exercise price of the warrants. The exercise price of the warrants is $13.20 per share.

Other Outstanding Options, Warrants and Convertible Securities

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The figures on outstanding shares in this prospectus do not include:

- 5,891,030 shares of our common stock that, as of the date of this prospectus, are reserved for issuance upon the exercise of outstanding options and warrants other than the October 2000 Private Placement warrants. These options and warrants are exercisable at prices ranging from $2.50 per share to $25.15 per share, with a weighted average exercise price of $7.39 per share.

- 467,328 shares that may be issued upon the conversion of 1,000 shares of Series A Preferred Stock that are outstanding as of the date of this prospectus. The Series A Preferred Stock may be converted into our common stock after January 16, 2004.

- Up to $50,000,000 of our common stock that we may elect to sell to Tradersbloom Limited, a British Virgin Islands corporation, under an "equity draw down line" facility.

- Issuance of any other shares of our common stock after the date of this prospectus other than the shares that may be issued upon the exercise of the October 2000 Private Placement warrants.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

We have made statements under the captions "Risk Factors" in this prospectus that are forward-looking statements. Similar statements are made in documents that we have incorporated by reference into this prospectus. You can identify these statements by forward-looking words such as "may", "will", "expect", "anticipate", "believe," "estimate," and similar terminology. Forward-looking statements address, among other things:

- implementing our clinical programs and other aspects of our business plans;

- financing goals and plans; and

- our expectations of when regulatory approvals will be received or other actions will be taken by parties other than us.

We believe it is important to communicate our expectations to our investors. However, there may be events in the future that we are not able to accurately predict and/or which we do not fully control that will cause actual results to differ materially from those expressed or implied by our forward-looking statements. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Our forward-looking statements are made as of the date of this prospectus, and we assume no duty to update them or to explain why actual results may differ except as we are

required to do by law.

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RISK FACTORS

You should carefully consider the following risks and other information in this prospectus before deciding to purchase our common stock. The market price of our common stock could decline due to any of these risks, and you could lose all or part of your investment. This statement of risks is not intended to be exhaustive, i.e., these are not the only risks relating to our common stock, this offering or our business.

Our Technologies And Products Are At An Early Stage Of Development, And We Have Not Received Any Revenues From Operations To Date.

We are a development stage company. We have a very limited history of operations, and we have not received any revenues from operations. We have no products approved for commercial sale at the present time. We may not be successful in obtaining regulatory clearance for the sale of existing or any future products, or any of these products maynot be commercially viable.

We Have Not And May Not Receive Regulatory Approval To Sell Our Products.

We have engaged primarily in research and development activities since our inception. We have no products approved for commercial sale by drug regulatory authorities. We have begun the regulatory approval process for only one product, our oral insulin formulation.

In September 2000, we entered into a Development and License Agreement with Eli Lilly and Company that covers our oral insulin product. Under the Lilly Agreement, Lilly is responsible for conducting clinical trials and securing regulatory approvals for a formulation of insulin administered as a fine spray to the buccal (oral) cavity using technology that is proprietary to Generex. Our principal role in the future development of this product is to continue development, as required, of our proprietary insulin formulation and the RapidMist(TM) device used to administer the formulation.

Notwithstanding the Lilly Agreement and the support that we expect to receive from Lilly under that Agreement, we may not be able to develop our insulin product successfully. In order to obtain regulatory approvals for our insulin product, it will be necessary to demonstrate, among other things, that:

- the product is physically and chemically stable under a range of storage, shipping and usage conditions;
- the results of administering the product to patients are reproducible in terms of the amounts of insulin delivered to the oral cavity and absorbed in the bloodstream; and
- that there are no serious adverse safety issues associated with use of the product.

There is even greater uncertainty and risk related to the regulatory approval process for other products besides our insulin product that may be developed under the Lilly Agreement or independently of Lilly. This is because no other product candidate has progressed to the point of development of the insulin product.

We May Not Become Or Stay Profitable Even If Our Products Are Approved For Sale.

Even if regulatory approval to market our oral insulin product is obtained, 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 by health care professionals and diabetic patients;
- the availability, effectiveness and relative cost of alternative diabetes treatments that may be developed by competitors; and
- the availability of third-party (i.e., insurer and governmental agency) reimbursements.

We Will Need Additional Capital, Which May Not Be Available To Us.

We have incurred substantial losses from operations from our inception, and we expect to continue to incur substantial losses for at least another 12 to 18 months. Under the Lilly Agreement, we expect Lilly to fund substantially all costs relating to the clinical program and securing regulatory approvals for our insulin product and other products that may be developed under the Agreement. We may, however, incur significant costs to fulfill our responsibilities under the Lilly Agreement. We also may require funds in excess of our existing cash resources:

- to develop new products based on our oral delivery technology, including clinical testing relating to new products;
- to establish and expand our manufacturing capabilities; and
- to finance general and administrative and research activities that are not related to specific products under development.

Over the next 12 to 18 months, we expect to receive revenues in the form of signing fees, license fees, milestone payments and similar payments from companies with which we collaborate on the development of products. At the present time, apart from the Lilly Agreement, we have no collaboration agreements with other companies that provide for such payments. The Lilly Agreement provides for a signing fee and for milestone payments at various stages of the development process for our insulin product and other products that may be developed under that Agreement. However, except for the initial signing fee, payments to us under the Lilly Agreement are contingent upon attaining the milestones provided in the Agreement. We cannot be certain of when or if we will receive any further payments from Lilly. In any event, we do not expect to receive revenues under the Lilly Agreement or under any future development agreements that are sufficient to satisfy all of our cash requirements.

As of January 25, 2001, we had options and warrants outstanding (including the warrants underlying the 538,773 shares issuable upon their exercise that are covered by this prospectus) to purchase 6,429,803 shares of our common stock at an average exercise price of $7.87. From July 31, 2000 through January 25, 2001, we have received approximately $2.21 million from the exercise of warrants. We cannot rely upon this source of funds, however, since the timing of option and warrant exercises is wholly within the discretion of the holders of the options and warrants. We also have arranged a $50,000,000 "equity draw down line" facility with Tradersbloom Limited, a British Virgin

Islands corporation, but our ability to draw upon this facility is subject to a number of conditions that we have not yet satisfied.

Any funds received through the equity draw down line facility with Tradersbloom will be from sales of common stock at a 10% discount to the then prevailing market price of our common stock. Similarly, we expect that the exercise price of any options or warrants exercised will be below the then prevailing market price of our common stock. The terms on which we obtain

additional financing from other sources also could result in dilution in the investment of existing shareholders, could or otherwise adversely affect their position.

In the past, we have funded most of our development and other costs through equity financing. Unforeseen problems, including materially negative developments 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 also 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. A scenario like this 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.

We Will Have To Depend Upon Others For Marketing And Distribution Of Our Products, And We May Be Forced To Enter Into Contracts Hindering 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. Except for the Lilly Agreement with respect to our oral insulin product, we do not have any agreements with other companies for marketing or distributing our products. 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.

We Have No Experience In Manufacturing And Insufficient Capacity To Produce Product In Large Quantities.

To date, we have produced our oral insulin formulation only under laboratory conditions on a small scale. We have established a pilot manufacturing facility that we believe is capable of producing the product at levels necessary to supply our needs for late stage human clinical trials of the product and for initial commercial sales outside the United States. However, we have not yet actually produced product at those levels. In any event, we will need to significantly increase our manufacturing capability to manufacture our product in commercial quantities. Under the Lilly Agreement, Lilly may select, but is not required to select, Generex to manufacture products developed under that Agreement. In order to qualify for consideration in this role, we will have to satisfy Lilly that Generex can supply such products at the requisite levels of quality, cost and reliability in compliance with all applicable regulatory requirements.

Under the Lilly Agreement, Lilly may select Generex to manufacture products developed under that Agreement. Lilly, however, is not required to select Generex for these functions. In order to qualify for consideration in this role, we will have to satisfy Lilly that Generex can supply such products at the requisite levels of quality, cost and reliability in compliance with all applicable regulatory requirements.

We have no experience in resolving the staffing, manufacturing, regulatory and quality control problems that are likely to come up in developing and running a large scale manufacturing operation. Our failure to solve problems of this nature would lead to loss of any opportunity to manufacture products developed under the Lilly Agreement, and could delay or prevent our ability to bring other products to market and inhibit sales after a product comes to market.

If We Fail To Retain Executive Management And Other Key Personnel And Hire, Train And Retrain Qualified Employees, We May Not Be Able To Develop Or Commercialize Our Products.

If one or more members of our limited scientific and management staff discontinued their association with us this could materially harm our business. We do not have fixed term agreements with any of our key management or scientific staff, other than Dr. Pankaj Modi. Our fixed term contract with Dr. Modi, however, does not guarantee his continued availability.

We depend upon non-employee consultants to assist us in

- formulating research and development strategy;
- preparing regulatory submissions;
- developing protocols for clinical trials; and
- designing, equipping and staffing our manufacturing facilities.

These consultants and advisors usually have the right to terminate their relationship with us on short notice. Loss of some of these key advisors could interrupt or delay development of one or more of our products or otherwise adversely affect our business plans.

We will continue to need qualified scientific personnel and personnel with experience in clinical testing, government regulation and manufacturing. We may have difficulty in obtaining qualified scientific and technical personnel due to strong competition for these people from other pharmaceutical and biotechnology companies as well as universities and research institutions.

We Depend On Patents And Other Proprietary Technologies That We May Not Obtain, And The Patents We Hold May Not Protect Our Position.

Our long-term success will substantially depend upon protecting our technology from infringement, misappropriation, discovery and duplication. The first patent applicable to our large molecule delivery technology was issued in the US on January 25, 2000. We also have twelve patent applications pending in the US and one Canadian patent, which cover our drug delivery technologies. We also own an indirect interest in three drug delivery patents held by another company that is fifty (50%) percent owned by us.

We cannot be sure that any of our pending patent applications will be granted, or that any patents that we own or will obtain in the future will fully protect our position. Our patent rights, and the patent rights of biotechnology

and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. We believe that our existing technology and the patents we hold or have applied for do not infringe any one else's patent rights. We believe our patent rights will provide meaningful protection against others duplicating our proprietary technologies. We cannot be sure of this, however, because of the complexity of the legal and scientific issues that could arise in litigation over these issues. Furthermore, patent applications are maintained in secrecy in the United States until the patents are approved, and in most foreign countries for a period of time following the date from which priority is claimed. A third party's pending patent applications may cover any technology that we currently are developing.

We have been threatened with litigation by an individual named as a co-inventor of a patented buccal delivery technology in which we now hold a 50% interest. We do not believe that any of our existing or planned products or technology incorporates or infringes upon any intellectual proprietary interest of this individual.

We also rely on trade secrets and other unpatented proprietary information. We seek to protect this information, in part, by confidentiality agreements with our employees, consultants, advisors and collaborators. These agreements may be breached, however, in which case the remedies available to us may not adequately compensate us for our loss. Furthermore, trade secrets protection does not protect us against a competitor's independent development of the same technology.

Our Ability To Respond To Business Opportunities And Introduce New Products Is Subject To Extensive Government Regulation Of Our Business.

Our research and development activities, and the eventual manufacture and marketing of our products, are subject to extensive regulation by the Food and Drug Administration in the United States and comparable regulatory authorities in other countries. Among other things, extensive regulation puts a burden on our ability to bring products to market. These regulations apply to all competitors in our industry. However, many of our competitors have extensive experience in dealing with FDA and other regulators while we do not. Also, other companies in our industry do not depend completely on products that still need to be approved by government regulators, as we now do. If we do not obtain regulatory approvals for our products, or if we fail to comply with government regulations in the future, our business will be substantially harmed.

We May Not Be Able To Compete With Diabetes Treatments Now Being Marketed And Developed 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.

Enforcement Of An Arbitration Award May Result In Dilution To Stockholders Or Adverse Effects Upon Generex.

Sands Brothers and Co. Ltd., a New York City based investment banking and brokerage firm, initiated an arbitration against us in 1998 claiming that it had the right to receive warrants to purchase, for nominal consideration, shares of our common stock pursuant to a letter agreement dated October 9, 1997. We defended the claim on the basis that the letter agreement was not a binding contract. In October 1999 we were informed that the arbitration panel that heard

this case had awarded Sands Brothers $14,070 and issued a declaratory judgment to the effect that we are required to issue to Sands Brothers a warrant to purchase 1,530,020 shares of our common stock pursuant to and in accordance with the terms of the October 9, 1997 letter agreement. We filed a motion in the Supreme Court of the State of New York, County of New York (the "Supreme Court") to set the award aside. On March 16, 2000, the Supreme Court denied our motion and granted Sands Brothers' petition to confirm the award. We then appealed this decision. On January 23, 2001, the New York State Appellate Division, First Department (the "Appellate Division"), affirmed the portion of the Supreme Court's judgment that had confirmed the granting of monetary relief of $14,070 to Sands Brothers but modified the judgment to vacate the portion of the arbitration award directing the issuance to Sands Brothers of a warrant to purchase 1,530,020 shares of our common stock. The Appellate Division held that the portion of the award directing us to issue warrants to Sands Brothers is too indefinite to be enforceable and remanded the matter to the arbitration panel for a final and definite award with respect to such relief or its equivalent (including possibly an award of monetary damages).

Our ultimate legal and financial liability in this matter, including a range of possible losses with respect to the award, cannot be estimated at this

time. To the extent that Sands Brothers receives shares of our common stock for little or no consideration as a result of this legal proceeding, our existing shareholders' investment would be proportionately diluted.

We Have Substantial Exposure To Product Liability, And Our Insurance Coverage May Provide Insufficient Protection.

The use of our products in clinical trials and the commercial sale of our products exposes us to liability claims by consumers and pharmaceutical companies. We have obtained limited product liability insurance of two million dollars per occurrence and total coverage. We cannot be sure that this would be sufficient coverage in the case of any substantial liability claim.

The Price Of Our Shares May Be Volatile, And You Could Lose All Or Part Of Your Investment.

There may be wide fluctuation in the price of our shares. Because of this potential volatility, our shares may be an unsuitable investment for investors who might be required to sell the shares at a time when the market price of the shares is depressed. 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;
- results of clinical trials of our products or our competitors' products; and
- regulatory action or inaction on our products or our competitors' products.

Our Outstanding Special Voting Rights Preferred Stock And Provisions Of Our

Certificate of Incorporation Could Delay Or Prevent The Acquisition Or Sale Of Generex.

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.

Future Sales Of Shares By Current Shareholders May Adversely Affect The Price Of Our Stock.

The market price of our common stock could decline as a result of sales of shares by:

- Selling Shareholders following the exercise of options and warrants now held by them;

- other existing shareholders many of whom purchased shares from us in private transactions at prices below the then current market price for such shares, and who now are free to sell the shares publicly; or

- holders of other outstanding options and warrants who may exercise such options and warrants and resell the shares so purchased to the public.

We Have Engaged In Numerous Transactions With Our Affiliates.

We previously have engaged in numerous transactions with our affiliates that were not the result of arms-length negotiations. For that reason, institutional investors and other potential purchasers of our shares may be less willing to make these purchases due to a belief that the terms of these transactions may not be as favorable to Generex as could have been obtained through arms-length negotiations with nonaffiliated parties.

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:

- Annual Report on Form 10-K for the fiscal year ended July 31, 2000.
- Quarterly Report on Form 10-Q for the fiscal quarter ended October 31, 2000, as amended by a Form 10-Q/A filed December 19, 2000.
- Current Report on Form 8-K filed on August 28, 2000.
- Current Report on Form 8-K filed on September 6, 2000, as amended by a Form 8-K/A filed on September 7, 2000 and by a Form 8-K/A filed on January 24, 2001.
- Current Report on Form 8-K filed on September 7, 2000.
- Current Report on Form 8-K filed on October 16, 2000, as amended by a Form 8-K/A filed on December 6, 2000.
- Current Report on Form 8-K filed on January 23, 2001, as amended by a Form 8-K/A filed on February 1, 2001.
- Current Report on Form 8-K filed on January 25, 2001.
- 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. 333-51194) 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 Rose C. Perri, Secretary and Chief Operating Officer, 33 Harbor 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.

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 the net tangible book value of the shares. As of October 31, 2000, our net tangible book value was approximately $1.76 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 common stock beneficially owned by each prior to the offering;
- the number of shares of common stock registered for sale by each in the offering; and
- the percentage of common stock owned by each after the offering, assuming each sells all of the shares registered for his benefit.

	Shares Beneficially Owned Prior to Offering		
Name	Outstanding Shares	Shares Issuable Upon Exercise of Warrants	Shares Register for Sa
Clipperbay & Co.	1,079,000	161,850	1,240,85
Protius Overseas Limited	163,636	25,545 (2)	189,18
Montrose Investments Ltd.	136,364	20,455 (3)	156,81
Ram Trading Ltd.	125,000	18,750 (4)	143,75
Nob Hill Capital Partners, L.P.	100,000	15,000	115,00
Castle Creek Healthcare Partners LLC	90,910	13,637 (5)	104,54
AEOW 2000 L.P.	68,182	10,227	78,40
Kodiak Opportunity Offshore Ltd.	49,590	7,439	57,02
Fidelity National Title Insurance Co.	45,455	6,818	52,27
Velocity Investment Partners LTD	45,455	6,818	52,27
Prism Partners 1, L.P.	40,800	6,120	46,92
Kodiak Opportunity, L.P.	33,520	5,028	38,54
Willow Creek Capital Partners, Ltd.	25,000	3,750	28,75

	Shares Beneficially Owned Prior to Offering		
Name	Outstanding Shares	Shares Issuable Upon Exercise of Warrants	Shares Register for Sa
Willow Creek Offshore Fund	25,000	3,750	28,75
CCL Fund LLC	22,728	3,409 (6)	26,13
Prism Partners II Offshore Fund	20,400	3,060	23,46
Nob Hill Capital Associates L.P.	20,000	3,000	23,00

Kodiak Opportunity 3C7, L.P.	16,890	2,534	19,42
Ascend Partners L.P.	13,637	2,045	15,68
Bognor Regis, Inc.	13,636	2,045	15,68
Ascend Offshore Funds Ltd.	9,090	1,364	10,45
Prism Partners Offshore Fund	6,800	1,020	7,82
Gary J. Shemano	- 0 -	101,055 (7)	101,05
William and Mary Corbett	- 0 -	101,054 (8)	101,05
Jeffrey Volk	- 0 -	13,000	13,00
	2,151,093	538,773	2,689,86

(1) Assuming all shares registered in resale are sold.

(2) Does not include 483,333 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(3) Does not include 83,334 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(4) Does not include 90,000 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(5) Does not include 100,000 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(6) Does not include 25,000 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(7) Does not include 67,984 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

(8) Does not include 65,084 shares issuable upon the exercise of warrants held by this Selling Shareholder as of November 27, 2000 that are covered by a previous registration statement.

POSSIBLE ISSUANCE OF EQUITY DRAW DOWN LINE

Under our agreement with Tradersbloom Ltd., we may elect to sell to Tradersbloom up to $50,000,000 of our Common Stock. Tradersbloom's commitment to purchase shares under this agreement, however, is subject to a number of terms and conditions. These include the condition that we register for resale under the Securities Act of 1933 (the "Securities Act") the shares that may be sold under the agreement and the limitation that Tradersbloom may not be required to purchase more than $5,000,000 of common stock during any 22-consecutive-trading-day period.

Subject to these terms and conditions in the Common Stock Purchase Agreement, we may elect to sell shares to Tradersbloom over an 18-month period commencing on the effective date of the registration of shares referred to in the preceding paragraph. The price of shares sold to Tradersbloom, if any, will be 90% of the weighted average market price of shares of our common stock traded on the date of sale, subject to a minimum sale price that we may establish in our discretion. If the weighted average market price of our common stock on a scheduled date of sale is less than the minimum price that we establish, we will

not be obligated to sell and Tradersbloom will not be obligated to purchase any of the shares scheduled for sale on that day.

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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 National Market or otherwise, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares may be sold in one or more of the following transactions:

- 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;

- 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.

Holders of the warrants may use a "cashless" form of exercise in which the difference between the exercise price of the warrant and the market price for our publicly traded shares is applied to pay the exercise price of the warrants. Fewer shares would be outstanding after the offering if the "cashless exercise" method were used, than if all warrants were exercised for cash.

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:

- sell shares short and redeliver the shares to close out these short positions;
- 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;
- 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
- sell shares covered by this prospectus that qualify for sale under Rule 144 under the Securities Act 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 in connection with sales of such shares. 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. Selling Shareholders who are underwriters within the meaning of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

We have agreed to pay the expenses of registering the shares under the Securities Act, 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.

The Company and the Selling Shareholders have agreed to indemnify each other and other related parties against specified liabilities, including liabilities arising under the Securities Act. 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.

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

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 128,181 shares of common stock which it received in payment of legal fees and expenses in 1998 (60,000 shares) and upon the exercise of warrants in June 1999 (98,172 shares). 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

Our consolidated financial statements as of July 31, 2000 and 1999 and for the years ended July 31, 2000, 1999 and 1998, included in our Annual Report on Form 10-K for the year ended July 31, 2000 (our "2000 10-K"), have been audited by WithumSmith & Brown, independent accountants, as set forth in their reports on such financial statements

Our consolidated financial statements as of July 31, 2000 and 1999 and for the years ended July 31, 2000, 1999 and 1998 are incorporated by reference in this prospectus, and elsewhere in the registration statement, in reliance upon the reports of WithumSmith & Brown on the financial statements, given on their authority as experts in accounting and auditing.

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.

SEC registration fee.....	$9,240.00
Legal fees and expenses.....	15,000.00
Accounting fees and expenses.....	5,000.00
Other.....	1,000.00
Total.....	$30,240.00

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 agreement (Exhibit 4.4 hereto) applicable to 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	Securities Purchase Agreement entered into with Smallcap World Fund, Inc. filed as an exhibit to our Report on Form 8-K dated October 4, 2000, filed October 16, 2000, is incorporated herein by reference.

Exhibit Number	Description
4.3	Form of Securities Purchase Agreement entered into with certain other parties to October 2000 Private Placement filed as an exhibit to our Report on Form 8-K dated October 4, 2000, filed October 16, 2000, is incorporated herein by reference.
4.4	Form of Registration Rights Agreement entered into with certain parties to October 2000 Private Placement filed as an exhibit to our Report on Form 8-K dated October 4, 2000, filed October 16, 2000, is incorporated herein by reference.
4.5	Form of Warrant issued to certain parties to October 2000 Private Placement filed as an exhibit to our Report on Form 8-K dated October 4, 2000, filed October 16, 2000, is incorporated herein by reference.
*5	Opinion of Eckert Seamans Cherin & Mellott, LLC regarding the legality of the securities being registered
*23.1.1	Consent of WithumSmith & Brown, independent auditors
23.1.2	Consent of Eckert Seamans Cherin & Mellott, LLC (included in Exhibit 5)

* 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 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 5th day of February, 2001.

GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin

Anna E. Gluskin, President

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, this Amendment to the Registration Statement was signed by the following persons in the capacities and on the dates stated:

Signature	Title	Date
/s/ Anna E. Gluskin --- Anna E. Gluskin	President, Chief Executive Officer and Director	February 5, 2001
/s/ E. Mark Perri --- E. Mark Perri	Chairman of the Board, Chief Financial Officer and Director	February 5, 2001
/s/ Rose C. Perri --- Rose C. Perri	Director	February 5, 2001
/s/ Pankaj Modi, Ph.D. --- Pankaj Modi, Ph.D.	Director	February 5, 2001