GENEREX BIOTECHNOLOGY CORP Form S-3/A July 24, 2008

Registration No. 333-150562

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 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**

(State or Other Jurisdiction of Incorporation or Organization)

#### 98-0178636

(I.R.S. Employer Identification Number)

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
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# Philadelphia, Pennsylvania 19102 (215) 851-8400

-	
Approximate date of commencement of properthis registration statement.	<b>bosed sale to the public:</b> From time to time after the effective date of
<u>-</u>	

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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, as amended, or the Securities Act, 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, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall be become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

#### CALCULATION OF REGISTRATION FEE

<b>Title of Each Class</b>	]				
of Securities to be	•		Aggregate Offering		
Registered	Registered	Share (2)	Price (2)	Registration Fee (2)	
Common Stock, \$.001					
par value per share	30,191,665(1)	)\$ 1.05	\$ 31,701,248	\$ 1,245.86(3)	
1	, , ,			, , ,	

- (1) Includes an estimated 18,772,729 shares of common stock issuable upon conversion of, and as interest payments on, 8% Secured Convertible Notes due September 2009 issued by us to the selling shareholders (the "Notes"), 5,257,729 shares of common stock issuable upon exercise of Series A Warrants (the "Series A Warrants") and 1,355,117 shares of common stock issuable upon exercise of Series A-1 Warrants (the "Series A-1 Warrants") held by the selling shareholders herein. We are including in this Registration Statement the sum of 1.20 times the number of shares issuable as of the date of the Registration Rights Agreement pursuant to the Notes and the Series A Warrants, which is a good faith estimate of the maximum number of shares of common stock issuable pursuant to the Notes and the Series A Warrants. Pursuant to Rule 416 under the Securities Act, this Registration Statement also covers such additional number of shares of common stock as may be issuable upon a stock split, stock dividend or similar transaction.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c), using the average of the high and low prices of the Registrant's common

stock as reported on the NASDAQ Capital Market on April 23, 2008, which was approximately \$1.05 per share.

# (3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Subject to completion, dated July \_\_\_, 2008

The information in this prospectus is not complete and may be changed. The selling shareholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling shareholders named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer and sale is not permitted.

#### **PROSPECTUS**

# GENEREX BIOTECHNOLOGY CORPORATION 30,191,665 Shares of Common Stock

This prospectus relates to the offer and sale from time to time by the selling shareholders identified in this prospectus, and their pledgees, assignees and successors-in-interest, of (i) up to 22,527,275 shares of our common stock issuable upon conversions of, and as interest payments on, a \$20,650,000 principal amount of our 8% Secured Convertible Notes due September 2009, (ii) up to 6,309,275 shares of our common stock issuable upon the exercise of the Series A Warrants and (iii) up to 1,355,117 shares of our common stock issuable upon the exercise of the Series A-1 Warrants.

We are filing the Registration Statement of which this prospectus is a part to register additional shares in order to fulfill contractual obligations which we undertook at the time of the original issuance of the Notes, the Series A Warrants and the Series A-1 Warrants.

The prices at which the selling shareholders may sell shares of our common stock will be determined by the prevailing market price for such shares or in negotiated transactions. We will not receive any of the proceeds from the sale of the shares.

Our common stock is quoted on the NASDAQ Capital Market under the symbol "GNBT." The last sale price of our common stock on July 22, 2008, as reported by NASDAQ, was \$0.91 per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2008.

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You should rely only on the information contained in this prospectus, including information incorporated by reference in this prospectus, or any supplement to which we have referred you. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

#### PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read this prospectus and the information and documents incorporated by reference carefully. Such documents contain important information you should consider when making your investment decision. See "Incorporation of Certain Documents by Reference" on page 22.

Unless we state otherwise or the context indicates otherwise, references to "Generex," "Company," "we," "us" and "our" in prospectus supplement and the accompanying prospectus refer to Generex Biotechnology Corporation.

# **About Generex Biotechnology Corporation**

Generex Biotechnology Corporation is a Delaware corporation engaged primarily in the research, development, and commercialization of drug delivery systems and technologies. Our primary focus at the present time is our proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator. Through our wholly-owned subsidiary, Antigen Express, Inc., we are expanding our focus to include immunomedicines. We are a development stage company and operate in only one segment: the research, development and commercialization of drug delivery systems and technologies for metabolic and immunological diseases.

We have developed a proprietary platform technology for the delivery of drugs into the human body through the oral cavity (with no deposit in the lungs). Our proprietary liquid formulations allow drugs typically administered by injection to be absorbed into the body by the lining of the inner mouth using our proprietary RapidMist<sup>TM</sup> device. We have a limited number of products that are ready for commercial marketing and sale: our flagship oral insulin formulation, Generex Oral-lyn<sup>TM</sup>, has been approved for commercial marketing and sale in Ecuador and India and is in various stages of clinical trials around the world; and our over-the-counter line glucose spray products utilizing our proprietary buccal delivery technology have been launched in retail outlets in the United States and Canada.

Our organizational structure consists of Generex Biotechnology Corporation and five wholly-owned subsidiaries: Generex Pharmaceuticals Inc., which is incorporated in Ontario, Canada and which performs all of our Canadian operations; Generex (Bermuda), Inc., which is incorporated in Bermuda and which currently does not conduct any business activities; Antigen Express, Inc., which is incorporated in Delaware and which we acquired in 2003; Generex Pharmaceuticals (USA) LLC, which we organized in North Carolina in February 2006 and which has not yet commenced any business operations; and Generex Marketing & Distribution Inc., which we organized in Ontario, Canada in September 2006 and which has not yet commenced any business operations.

#### **Recent Developments**

Generex Oral-lyn<sup>TM</sup>

In the remainder of fiscal 2008 and thereafter, our efforts will focus on enrolling patients and dosing of late-stage clinical trials of Generex Oral-lyn<sup>TM</sup> in the United States, Canada, Europe and certain countries in Eastern Europe including Russia, Ukraine, Bulgaria and Romania and assisting our Indian licensee with preparation for the commercialization of Generex Oral-lyn<sup>TM</sup> in India.

We have identified key vendors for the management of Phase III clinical trials of Generex Oral-lyn<sup>TM</sup> and have selected centers to conduct such trials in the United States, Canada, Europe and Eastern Europe. In anticipation of undertaking late-stage clinical trials globally, we have engaged consultants to assist with the design and implementation of clinical trials and regulatory strategies and have secured a manufacturer to produce clinical trial batches of Generex Oral-lyn<sup>TM</sup>.

We have contracted with our third-party manufacturers for sufficient quantities of the RapidMist<sup>TM</sup> device components, the insulin, and the formulary excipients that will be required for the production of clinical trial batches of Generex Oral-lyn<sup>TM</sup>. Patient enrollment has begun at some of the sites with the first dosing taking place in early June 2008 and is expected expand to several global centers over the course of the study. The primary objective of the study is to compare the efficacy of Generex Oral-lyn<sup>TM</sup> and the RapidMist<sup>TM</sup> Diabetes Management System with that of standard regular injectable human insulin therapy as measured by HbA1c, in patients with Type-1 diabetes mellitus. We expect to use the data collected from these trials in the New Drug Submission that will be prepared concurrently with the progression of the late-stage trials for Health Canada, European Union (EMEA) and the U.S. Food and Drug Administration (FDA).

In early November 2007, Generex Oral-lyn<sup>TM</sup> was approved for importation and commercial marketing and sale in India for the treatment of diabetes by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India, which is responsible for authorizing marketing approval of all new pharmaceutical products in India. In August 2007 we entered into a Product Licensing and Distribution Agreement with Shreya Life Sciences Pvt. Ltd., a leading Indian-based pharmaceutical company and the fourth largest distributor of insulin in the Indian insulin product market, for the registration, importation, marketing, distribution, and sale of Generex Oral-lyn<sup>TM</sup> in the Republic of India, the Islamic Republic of Pakistan, the People's Republic of Bangladesh, the Kingdom of Nepal, the Kingdom of Bhutan, the Democratic Socialist Republic of Sri Lanka, and the Union of Myanmar. We are working with Shreya to prepare for the commercial launch of Generex Oral-lyn<sup>TM</sup> in India in the second calendar quarter of 2008. Preparations include marketing plans and post-approval clinical studies. We do not expect to receive revenues from the sale of this product in India in fiscal 2008.

In the remainder of fiscal 2008, we also plan to continue with the commercialization of Generex Oral-lyn<sup>TM</sup> in Ecuador and efforts to obtain regulatory approval of this product in other countries using the approved Ecuadorian dossier. Our business partner for the commercialization of Generex Oral-lyn<sup>TM</sup> in Ecuador, PharmaBrand, S.A., expects additional commercial manufacturing runs of the product at its facilities in Quito, Ecuador later in 2008. We are also working with PharmaBrand to expand extant production facilities to meet the anticipated demand for the product in India and other jurisdictions where governmental approvals are pending. Currently, our relationship with PharmaBrand is governed by a letter of intent, and we are in the process of transitioning PharmaBrand's role into one of a third-party manufacturer with distribution rights for Ecuador. PharmaBrand has generated some commercial sales of Generex Oral-lyn<sup>TM</sup> in Ecuador to date. While we expect to receive revenues from such sales sometime in calendar year 2008, we do not expect that such sales will be reflected in our financial statements until we have entered into a definitive licensing and distribution agreement with PharmaBrand.

Pursuant to a licensing and distribution agreement with Leosons General Trading Company, a multinational distributor, we have submitted applications for registration of Generex Oral-lyn<sup>TM</sup> to some of the public health authorities in the Middle East, but no approvals have been forthcoming to date except for a limited, pharmacy specific importation license in the United Arab Emirates to import Generex Oral-lyn<sup>TM</sup> into Abu Dhabi. We terminated the licensing and distribution agreement with the Armenian Development Agency (the "ADA") and Canada Armenia Trading House Ltd. ("CATH") relating to the regulatory approval and commercialization of Generex Oral-lyn<sup>TM</sup> in Armenia, Georgia, and Kazakhstan as of January 16, 2008, but we are continuing to prosecute the registration submitted to public health authorities in Armenia.

In October, 2007 we entered into a product licensing and distribution agreement with Adcock Ingram Limited and Adcock Ingram Healthcare (Pty) Ltd. for the registration, importation, marketing, distribution and sale of Generex Oral-lyn<sup>TM</sup> in the Republic of South Africa, the Kingdom of Lesotho, the Kingdom of Swaziland, the Republic of Botswana, the Republic of Namibia, the Republic of Mozambique, and the Republic of Zimbabwe. In February, 2008 we entered into a product licensing and distribution agreement with E&V Alca Distribution Corp. for the registration, importation, marketing, distribution, and sale of Generex Oral-lyn<sup>TM</sup> in the Republic of Albania, Montenegro, and the Kosovo. In April, 2008 we entered into a product licensing and distribution agreement with SciGen, Ltd. for the registration, importation, marketing, distribution, and sale of Generex Oral-lyn<sup>TM</sup> in the People's Republic of China, Hong Kong, the Republic of Indonesia, the Republic of Korea, Malaysia, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, and the Socialist Republic of Vietnam. In April 2008, Generex and Medrey S.A.L. (formerly MedGen Corp.) entered into a sub-distribution agreement with Benta S.A.L. in respect of the registration, marketing, distribution, and sale of Generex Oral-lyn<sup>TM</sup> in the Republic of Lebanon.

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, recently announced their decisions to discontinue development and/or sale of their inhalable forms of insulin. Generex Oral-lyn<sup>TM</sup> is not an inhaled insulin; rather, it is a bucally absorbed formulation with no residual pulmonary deposition. We believe that our buccal delivery technology offers several advantages over

inhaled insulin, including the avoidance of pulmonary inhalation, which requires frequent physician monitoring, ease of use and portability.

Buccal Glucose and Energy Products - Glucose RapidSpray<sup>TM</sup>, BaBOOM! <sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup>

With the launch of commercial sales of our over-the-counter oral glucose and energy spray products, GlucoBreak<sup>TM</sup> and BaBOOM!<sup>TM</sup> Energy Spray, in retail outlets in the United States and Canada, we expect to receive increased revenues from product sales in calendar 2008. We plan to achieve this by increasing our over-the-counter product line to three products - the two products mentioned above and Glucose RapidSpray<sup>TM</sup> - and expanding our existing distribution channels. In addition, we will increase our advertising and marketing efforts of our products and expand the availability of our products from North America to the rest of the world. This strategy has already been implemented by the execution of licensing and distribution agreements with Leosons General Trading Company for the distribution and sale of our over-the-counter products in 15 Middle Eastern countries and Adcock Ingram LLP and Adcock Ingram Healthcare (Pty) Ltd. for the distribution and sale of Glucose RapidSpray <sup>TM</sup> in South Africa and six neighboring countries. In December 2007, we received a \$400,000 purchase order for our over-the-counter products, including Glucose Rapid Spray<sup>TM</sup>, from Leosons General Trading Company. We are currently in the process of filling the order and partial shipments have been made.

#### Metformin Gum Product/Strategic Alliance

During the remainder of fiscal 2008 and thereafter, we expect to continue joint development activities with Fertin Pharma A/S with respect to a metformin medicinal chewing gum for the treatment of Type-2 diabetes mellitus and obesity, which we anticipate to be a prospective companion product for Generex Oral-lyn<sup>TM</sup>. Fertin Pharma is in the process of producing clinical materials for a bioequivalence Phase I study which is expected to commence before the end of calendar year 2008.

#### Immunomedicine Technology and Products

We continue clinical development of Antigen's synthetic peptide vaccines designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene for patients with HER-2/neu positive breast cancer in a Phase II clinical trial and patients with prostate cancer and against avian influenza in two Phase I trials. The Phase II clinical trial of the Antigen peptide vaccine in breast cancer patient commenced patient dosing in May 2007. This trial is being conducted with the United States Military Cancer Institute Clinical Trials Group under the direction of Colonel George Peoples, M.D. The trial will compare the rate of relapse after two years in breast cancer patients treated with Antigen's immunotherapeutic plus adjuvant versus adjuvant alone. All patients will have completed standard therapy for node-positive or high-risk node-negative breast cancer expressing at least low levels of the HER-2/neu oncogene and who are at increased risk for recurrence. Patient dosing for Phase I clinical trials with the same compound as being used in breast cancer patients is currently underway for prostate cancer patients at two hospital sites in Athens, Greece. The Lebanese-Canadian Hospital in Beirut, Lebanon commenced a Phase I clinical trial of Antigen's synthetic avian influenza vaccine in April 2007 and is currently ongoing. In addition, Antigen entered into an agreement with Drs. Daopei Lu and Chunrong Tong and Beijing Daopei Hospital in Beijing, China to conduct a Phase I clinical study using Antigen's novel immunotherapeutic strategy involving RNA interference to develop a cancer cell vaccine for use in patients with acute myeloid leukemia. In February 2008, some preliminary pre-clinical work commenced under this clinical trial agreement.

More comprehensive information about us is available through our Internet website at *www.generex.com*. The information on our website is not incorporated by reference into this prospectus. Our principal offices are located at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 and our telephone number is (416) 364-2551.

# The Offering

Common stock offered by selling

shareholders: 30,191,665 shares

Use of Proceeds: We will not receive any proceeds from the sale of

shares in this offering.

Risk Factors: See "Risk Factors" beginning on page 5 for a discussion

of factors that you should read and consider before

investing in our securities

NASDAQ Capital Market Symbol: GNBT

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 16-19.

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

Common stock outstanding before the offering 112,178,519 shares of Common Stock

Common stock to be outstanding after the offering 142,370,184 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 April 23, 2008, including certain of the shares of common stock offered for resale by this prospectus.

The numbers set forth above do not include (i) 6,071,638 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding options and (ii) 50,306,595 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding warrants other than those covered by this prospectus. These additional options and warrants are exercisable at prices ranging from \$0.001 to \$3.75 per share, with a weighted average exercise price for the options of \$0.71 per share and a weighted average exercise price for the warrants of \$1.20 per share.

#### **RISK FACTORS**

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully all the information we have included or incorporated by reference in this prospectus supplement and the accompanying prospectus. In addition, you should carefully consider the risk factors described below related to this offering and an investment in our securities. If any of these risks actually occurs, our business, financial condition, results of operations and cash flow could be seriously harmed. This could cause the trading price of our common stock offered hereby to decline, resulting in a loss of all or part of your investment.

## 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 sufficient revenues to support our operation in the immediately foreseeable future. In the quarter ended April 30, 2008, we received nominal revenues from sales of Glucose RapidSpray<sup>TM</sup>. We did not recognize any revenue from the sale of our oral insulin product in Ecuador in fiscal 2007 and do not expect to receive any until we enter into a final agreement with PharmaBrand to manufacture commercial orders of Generex Oral-lyn<sup>TM</sup> and to continue its marketing and sales efforts in Ecuador in 2008 with a focus on that portion of the population with the newly identified condition closely related to diabetes known as Impaired Glucose Tolerance (IGT). Individuals with IGT usually do not meet the criteria for the diagnosis of diabetes mellitus but experience abnormally high blood glucose levels several hours after a meal. While Generex Oral-lyn<sup>TM</sup> was approved for importation and commercial marketing and sale in India in November 2007, we do not expect to receive any revenues from sales of the product in fiscal 2008. We have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor and have begun assisting them with preparations for commercial launch in India sometime in 2008. In January 2008, we commenced a marketing campaign with a presentation to key opinion leaders and endocrinologists at a meeting in Mumbai, India.

To date, we have not been profitable and our accumulated net loss was \$235,903,538 at April 30, 2008. 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.

With the exception of Generex Oral-lyn<sup>TM</sup> which is currently available for sale in Ecuador and has been approved for sale in India and our over-the-counter glucose and energy spray products, Glucose RapidSpray<sup>TM</sup>, BaBOOM!<sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup>, 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 must also complete further clinical trials and seek regulatory approvals for Generex Oral-lyn<sup>TM</sup> in countries outside of Ecuador and India. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

#### We will need additional capital.

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

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

- o to proceed with the development of our buccal insulin product;
- o to finance the research and development of new products based on our buccal delivery and immunomedicine technologies, including clinical testing relating to new products;

- o to finance the research and development activities of our subsidiary Antigen with respect to other potential technologies;
- o to commercially launch and market developed products;
- o to develop or acquire other technologies or other lines of business;
- o to establish and expand our manufacturing capabilities;
- o to finance general and administrative activities that are not related to specific products under development; and
- o to otherwise carry on business.

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 12 months. However, this expectation is based on our current operating plan, which could change as a result of many factors, and we may need additional funding sooner than anticipated. Because our operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds in the near future to continue the development and commercialization of our products. Unforeseen problems, including materially negative developments in our 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.

#### Any new equity financing will dilute current stockholders.

The recent sale of the Notes and Warrants, as well as any other securities that we offer and sell pursuant to an equity financing to meet the needs discussed above, will have a dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares issuable upon exercise of the Notes and Warrants 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. Although the Notes and Warrants were not issued at a discount to the market price on the date of issuance, the terms and conditions of the Notes and Warrants contemplate situations where the applicable conversion, redemption or exercise price may be below market.

Our research and development and marketing efforts may be highly dependent on corporate collaborators and other third parties who may not devote sufficient time, resources and attention to our programs, which may limit our efforts to successfully develop and market potential products.

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

will advance as rapidly as it might if we had retained complete control of all research, development, regulatory and commercialization decisions.

With the exception of Generex Oral-lyn<sup>TM</sup>, Glucose RapidSpray<sup>TM</sup>, BaBOOM! <sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup>, our technologies and products are at an early stage of development and we cannot expect revenues in respect thereof in the foreseeable future.

We have no products approved for commercial sale at the present time with the exception of Generex Oral-lyn<sup>TM</sup> which is available only in Ecuador and has recently been approved for commercial sale in India and our glucose sprays which are available over-the-counter in retail outlets in the United States and Canada. To be profitable, we must not only successfully research, develop and obtain regulatory approval for our products under development, but also manufacture, introduce, market and distribute them once development is completed. We may not be successful in one or more of these stages of the development or commercialization of our products, and/or any of the products we develop may not be commercially viable.

Although Generex Oral-lyn<sup>TM</sup>, our proprietary oral insulin spray formulation, has been approved for commercial marketing and sale in Ecuador and India, and our glucose spray products are available for purchase in the United States and Canada, we have yet to manufacture, market and distribute these products on a large-scale commercial basis. We expect to receive nominal revenues from sales of these products in fiscal year 2008. Until we can establish that they are commercially viable products, we will not receive significant revenues from ongoing operations.

Until we receive regulatory approval to sell our pharmaceutical products in additional countries, our ability to generate revenues from operations may be limited and those revenues may be insufficient to sustain operations. Many factors impact our ability to obtain approvals for commercially viable products.

Our only pharmaceutical product that has been approved for commercial sale by drug regulatory authorities is our oral insulin spray formulation, and that approval has been obtained in Ecuador and, recently, in India. We have begun the regulatory approval process for our oral insulin, buccal morphine and fentanyl products in other countries, and we expect to begin late stage clinical trials of Generex Oral-lyn<sup>TM</sup> at some of our clinical trial sites according to the Phase III clinical plan in 2008.

Our immunomedicine products are in the pre-clinical stage of development, with the exception of a Phase II trial in human patients with stage II HER-2/neu positive breast cancer, a Phase I clinical trial in patients with prostate cancer, a Phase I trial in human volunteers of a peptide vaccine for use against the H5N1 avian influenza virus and Phase I trial of our experimental H5N1 prophylactic vaccine in Beirut, Lebanon.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technologies, are subject to extensive, costly and rigorous regulation by governmental authorities in the United States, Canada and other countries. The process of obtaining required regulatory approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the product candidates. For these reasons, it is possible we will not receive regulatory approval for any prescription pharmaceutical product candidate in any country other than Ecuador and India.

In addition, we cannot be sure when or if we will be permitted by regulatory agencies to undertake additional clinical trials or to commence any particular phase of clinical trials. Because of this, statements in this prospectus regarding the expected timing of clinical trials cannot be regarded as actual predictions of when we will obtain regulatory approval for any "phase" of clinical trials.

Delays in obtaining United States or other foreign approvals for our pharmaceutical 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 in any country other than Ecuador and India, the approval may place limitations on the intended use of the product we wish to commercialize, and may restrict the way in which we are permitted to market the product.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights, and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

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

Also because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the United States and other countries, even after reasonable investigation we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. For example, we are aware of certain patents owned by third parties that such parties could attempt to use in the future in efforts to affect our freedom to practice some of the patents that we own or have applied for. Based upon the science and scope of these third-party patents, we believe that the patents that we own or have applied for do not infringe any such third-party patents; however, we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend our intellectual property in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

#### Risks Related to Marketing of Our Potential Products

We may not become, or stay, profitable even if our products are approved for sale.

Even if we obtain regulatory approval to market our oral insulin product or any other prescription pharmaceutical product candidate in another country other than Ecuador and recently India, many factors may prevent the product from ever being sold in commercial quantities. Similarly, the successful commercialization of our confectionary may be hindered. Some of these factors are beyond our control, such as:

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

We will not receive significant revenues from Generex Oral-lyn<sup>TM</sup> in Ecuador or India or Glucose RapidSpray<sup>TM</sup> in the United States or any of our other products that may receive regulatory approval until we can successfully manufacture, market and distribute them in the relevant market.

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.

We may not be able to compete with treatments now being marketed and developed, or which may be developed and marketed in the future by other companies.

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

Numerous pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations are engaged in the development of alternatives to our technologies. Some of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Collaborations or mergers between large pharmaceutical or biotechnology companies with competing drug delivery technologies could enhance our competitors' financial, marketing and other resources. Developments by other drug delivery companies could make our products or technologies uncompetitive or obsolete. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

One of our most significant competitors, Pfizer, announced in mid-October 2007 that it would no longer sell or produce its inhalable form of insulin, marketed as Exubera®, due to disappointing sales and failure to gain traction with patients and physicians. Pfizer also announced that it would discontinue development of a next generation inhaled insulin device. We believe that our buccal delivery technology offers several advantages over inhaled insulin, including: the avoidance of pulmonary inhalation, which requires physician monitoring; ease of use; portability; and accurate dosing.

Other direct competitors have development programs underway for inhaled insulin products, which, if approved, could compete against Generex Oral-lyn<sup>TM</sup>. These companies include MannKind Corporation, Bentley Pharmaceuticals, Inc. and Abbott Laboratories through its acquisition of Kos Pharmaceuticals, all of which are working on various versions of inhaled insulin products in either a liquid or a dry form. Some products are in late stage clinical testing including Mannkind's Technosphere® Insulin System in Phase III clinical development. Other smaller companies, including Emisphere Technologies, Inc., are in various stages of developing oral or buccal insulin formulations.

# If government programs and insurance companies do not agree to pay for or reimburse patients for our products, our success will be impacted.

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

#### Risks Related to Potential Liabilities

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

The administration of drugs or treatments to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs or treatments are actually at fault for causing an injury. Furthermore, our

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

# Risks Related to the Market for Our Common Stock

#### Our common stock could be delisted from The NASDAQ Capital Market.

In the past, we have failed to comply with certain of NASDAQ's listing requirements. In late 2004, we did not comply with NASDAQ Rule 4310(c)(2)(B) which requires us to have a minimum of \$2,500,000 in stockholders' equity or \$35,000,000 market value of listed securities or \$500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. While we regained compliance with this standard, we are still in the development stage. Consequently, there is no guarantee that we will sustain compliance with this standard. In the event we cannot sustain compliance, our shares of common stock may be delisted from the NASDAQ Capital Market and begin trading on the over-the-counter bulletin board, assuming we meet the requisite criteria.

In addition, from October 2004 until October 2005, we failed to comply with NASDAQ Rule 4310(c)(4) which requires us to have a minimum bid price per share of at least \$1.00. Although we regained compliance with the minimum bid price requirement in November 2005, there is no guarantee that the bid price of our common stock will remain at or above \$1.00 per share. In the event that the price of our common stock falls below \$1.00 per share for thirty (30) consecutive trading days, we would likely receive a notice from the NASDAQ Stock Market LLC informing us of our noncompliance with NASDAQ Rule 4310(c)(4) and giving us 180 calendar days, subject to extension, to regain compliance with the rule. In the event that we could not demonstrate compliance with NASDAQ Rule 4310(c)(4) by the specified deadline and were not eligible for an additional compliance period, the staff would notify us that our stock would be delisted, at which time we could appeal the staff's determination to a Listing Qualifications Panel. Pending the decision of the Listing Qualification Panel, our common stock would continue to trade on the NASDAQ Capital Market. If we were not successful in such an appeal, our stock would likely trade on NASDAQ's over-the-counter bulletin board, assuming we meet the requisite criteria.

If we fail to maintain compliance with applicable NASDAQ Rules and our stock is delisted from the NASDAQ Capital Market, it may become subject to Penny Stock Regulations and there will be less interest for our stock in the market. This may result in lower prices for our stock and make it more difficult for us to obtain financing.

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

#### The price of our common stock may be volatile.

There may be wide fluctuations in the price of our common stock. 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 or treatments developed by us or others;

- o results of clinical trials of our products or our competitors' products; and
- o regulatory action or inaction on our products or our competitors' products.

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

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

# Provisions of our Restated Certificate of Incorporation could delay or prevent the acquisition or sale of our business.

Our Restated Certificate of Incorporation permits our Board of Directors to designate new series of preferred stock and issue those shares without any vote or action by our stockholders. Such newly authorized and issued shares of preferred stock could contain terms that grant special voting rights to the holders of such shares that make it more difficult to obtain stockholder approval for an acquisition of our business or increase the cost of any such acquisition.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words "believe," "expect," "will," "anticipate," "intend," "estimate," "project," "plan," "assume" or other similar expression negatives of those expressions, although not all forward-looking statements contain these identifying words. All statements contained or incorporated by reference in this prospectus regarding our future strategy, future operations, projected financial position, estimated future revenues, projected costs, future prospects, the future of our products and the biotechnology industry and results that might be obtained by pursuing management's current plans and objectives are forward-looking statements.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus or, in the case of forward-looking statements incorporated by reference, as of the date of the filing that includes the statement. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our shareholders. We do not undertake and specifically decline any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this prospectus under the caption "Risk Factors" as well as in our most recent Annual Report on Form 10-K, including, without limitation, under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other documents that we may file with the Securities and Exchange Commission ("SEC"), all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus.

## **USE OF PROCEEDS**

The proceeds from the sale of each selling shareholder's shares of common stock will belong to that selling shareholder. We will not receive any proceeds from those sales, although we may receive proceeds from the exercise of Warrants by the selling shareholders, if exercised. We cannot guarantee that the selling shareholders will exercise any Warrants. If and when we receive such proceeds, we would use them to support our working capital requirements or for other purposes.

#### DESCRIPTION OF PRIVATE PLACEMENT AND CONVERTIBLE NOTES

On March 31, 2008, we entered into a Securities Purchase Agreement and related agreements pursuant to which we agreed to issue 8% Secured Convertible Notes (the "Notes") and common stock warrants (the "Warrants") for an aggregate purchase price of \$20,650,000 in a private placement (the "March Private Placement") with six existing institutional investors (the "Investors"). The March Private Placement closed on March 31, 2008. This prospectus is being delivered in connection with the resale of shares of our common stock issuable upon the conversion of the Notes, as payment of principal and accrued interest thereon, and upon the exercise of only the Series A Warrants and certain of the Series A-1 Warrants issued in connection with the March Private Placement.

The Notes were issued pursuant to a Securities Purchase Agreement, dated March 31, 2008, among our company and the Investors. The principal purposes of the March Private Placement were to strengthen our cash position and to support ongoing clinical development programs, including undertaking global Phase III clinical trials of Generex Oral-lyn<sup>TM</sup>, our proprietary oral insulin formulation, at sites in the United States, Canada, and Europe. The March Private Placement resulted in gross proceeds to us of \$20,650,000 before placement agent fees and other expenses associated with the transaction.

The Notes mature September 30, 2009 and amortize over fifteen months in fifteen equal installments beginning on August 1, 2008. Interest on the principal amount outstanding accrues at the rate of eight percent per annum. We may pay installments of principal and accrued interest in cash or, at our option, in shares of common stock. Our ability to pay with common stock is subject to certain conditions noted below. If we elect to pay principal and interest in shares of our common stock, the value of each share of common stock will be equal to the lower of (a) the initial conversion price of \$1.21 per share, and (b) 90% of the average of the volume weighted average prices of our common stock on each of the twenty (20) consecutive trading days immediately preceding the applicable payment date. In addition, at the option of the holder of each Note, all or any part of the principal amount outstanding under each Note is convertible at any time and from time to time into shares of our common stock at an initial conversion price of \$1.21 per share. However, the conversion price may be reduced if we issue securities at a price per share less than the conversion price of the Notes then in effect.

Beginning on August 1, 2008, and on the first of each month thereafter, we will be required to convert one fifteenth of the face value of the Notes into shares of our common stock or, at our election, redeem such amount in cash. Our ability to convert installment payments into shares of our common stock, however, is conditioned on shareholder approval. In addition, our ability to convert installment payments into shares of common stock will be subject to other conditions, including the existence of an effective registration statement covering the resale of the shares issued in payment of the installment amount and certain minimum trading volumes in the stock to be issued. No payment in shares of our common stock may exceed 25% of the total dollar traded volume in our common stock for the 20 trading days prior to the installment notice date. Any shares of our common stock delivered in satisfaction of an amortization payment will be valued at the lesser of (i) the conversion price in effect at the time of the amortization payment or (ii) 90% of the average of the daily volume weighted average price of the applicable shares for the 20 trading days prior to the amortization payment.

Each Note lists certain "Events of Default", which include, without limitation, any default in the payment of principal of, interest on or other charges in respect of the Notes as and when they become due and payable, and our failure to observe or perform any other covenant, agreement or warranty contained in, or otherwise commit any breach or default of any provision of the Notes, the Securities Purchase Agreement or the Security Agreement. Upon the occurrence of an Event of Default, the holder may require us to redeem all or any portion of a Note by delivering written notice to us at a default redemption price as calculated pursuant to certain formulas set forth in the Note ("Event of Default Redemption Right"). Until the default redemption price (together with any interest thereon) is paid in full, the amount of any Note submitted for redemption (together with any interest thereon) may be converted, in whole or in part, by the holder into common stock. In the event of a partial redemption, the principal amount redeemed shall be

deducted from the installment amounts relating to the applicable installment date(s) as set forth in the notice of default and redemption.

The Warrants issued to the Investors in the March Private Placement include the following:

• Series A and A-1 Warrants, which are exercisable for a period of 7 years into an aggregate of 75% of the number of shares of our common stock initially issuable upon conversion of the Notes, with the Series A Warrants being exercisable into 5,257,729 shares immediately upon issuance and the Series A-1 warrants being exercisable into 7,541,857 shares beginning October 1, 2008;

Series B Warrants, which are exercisable beginning October 1, 2008 into 100% of the shares of our common stock initially issuable upon conversion of the Notes (initially 17,066,117 shares) and remaining exercisable for a period of 18 months after a registration statement covering the shares of our common stock issuable upon conversion or exercise (as the case may be) of the Notes and Warrants is declared effective by the SEC; and

Series C Warrants, which are exercisable for a period of 7 years beginning October 1, 2008, but only to the extent that the Series B Warrant are exercised and only in the same percentage that the Series B Warrants are exercised, up to a maximum percentage of 75% of the number of shares of our common stock initially issuable upon conversion of the Notes (initially a maximum of 12,799,586 shares).

The initial exercise price of each Series A Warrant, Series A-1 Warrant, Series B Warrant and Series C Warrant will be the same as the initial conversion price under the Notes (\$1.21 per share). Like the conversion price of the Notes, the exercise price of the Warrants is subject to a full-ratchet adjustment upon the occurrence of certain events, including our issuance of securities at a price per share less than the exercise price then in effect. If we issue shares of common stock or options exercisable for or securities convertible into common stock at an effective price per share of common stock less than the exercise price then in effect, the exercise price will be reduced to the effective price of the new issuance.

Prior to obtaining shareholder approval of the issuance of shares of our common stock in connection with the March Private Placement, we are prohibited from paying installments of principal and accrued interest in shares of common stock and from issuing any common stock or equivalents below \$1.21. At the Annual Meeting of Stockholders scheduled for May 27, 2008, we obtained shareholder approval of the issuance of shares of common stock upon conversion of the Notes, as payment of accrued interest thereon, and upon exercise of the Warrants at a conversion or exercise price (as the case may be) less than the closing bid price on March 31, 2008.

In connection with the March Private Placement, we entered into a Registration Rights Agreement with the Investors under which we are required, on or before April 30, 2008, to file a registration statement with the SEC covering the resale of the shares of our common stock issuable pursuant to the Notes and Warrants, including as payment of principal and interest on the Notes, and to use our best efforts to have the registration statement declared effective at the earliest date, but in no event later than 90 days after filing if there is no SEC review of the registration statement, or 120 days if there is an SEC review. The Registration Rights Agreements provides for certain monetary penalties if the registration statement is not filed or does not become effective on a timely basis.

# **Dollar Value of Underlying Securities and Potential Profits on Conversion**

With respect to the Notes issued in the March Private Placement, the conversion price of the Notes was \$1.21 per share on March 31, 2008 and the closing bid price of our common stock on March 31, 2008 (the date the Notes were issued) was \$1.10. Therefore, the Notes were issued at a premium (not discount) to the market value of our common stock on the date of the closing of the March Private Placement.

Market price per share at March 31, 2008	\$	1.10
Conversion Price per share at March 31, 2008	\$	1.21
Total shares underlying Notes based on conversion price	17,0	66,117
Aggregate market value of underlying shares based on market price as of		
March 31, 2008	\$ 18,7	72,729
Aggregate conversion price of underlying shares	\$ 20,6	50,000

Total Premium to market price of underlying shares after taking into account
original issue discount

\$ 1,877,271

In the event that we elect to deliver shares of our common stock in satisfaction of an amortization payment, such shares will be valued at the lesser of (i) the conversion price in effect at the time of the amortization payment or (ii) 90% of the average of the daily volume weighted average price of the applicable shares for the 20 trading days prior to the amortization payment. For purposes of the following table, we have assumed that we will pay all installment payments in shares of our common stock and have valued such shares at \$0.9704 per share, which represents 90% of the average of the daily volume weighted average price of the shares for the 20 trading days prior to March 31, 2008. Under this scenario, the Notes would be deemed to be issued at a discount to the market value of our common stock on the date of the closing of the March Private Placement.

Market price per share at March 31, 2008	\$	1.10
90% of Average VWAP for 20 Trading Days Prior to March 31, 2008	\$	0.9704
Total shares underlying Notes based on VWAP price	19	,173,187
Aggregate market value of underlying shares based on market price as of		
March 31, 2008	\$21	,090,506
Aggregate VWAP price of underlying shares	\$18	,605,660
Total Discount to market price of underlying shares after taking into account		
original issue discount	\$ 2	,484,846

With respect to the Series A and Series A-1 Warrants issued in the March Private Placement, the exercise price of the Series A Warrants and the Series A-1 Warrants was \$1.21 per share and, therefore, the Series A and Series A-1 Warrants were issued at a premium (not discount) to the market value of our common stock on the date of the closing of the March Private Placement.

The Investors hold no other warrants, options, notes, or other securities convertible into shares of our common stock, other than the Notes and Warrants issued in connection with the March Private Placement, and certain warrants described in the following sentence. In connection with the March Private Placement, we (a) reduced the strike price of our outstanding common stock purchase warrants that are held by certain of the Investors and that had strike prices ranging from \$1.25 to \$3.00 and (b) extended the expiration date of such warrants to March 31, 2015. We reduced the strike price of these warrants to \$1.10, which equaled the closing bid price of the common stock on the NASDAQ Capital Market on March 31, 2008. Therefore, these other outstanding warrants held by certain of the Investors were issued at a premium (not discount) to the market value of our common stock on the date of the closing of the March Private Placement.

#### **Net Proceeds from March Private Placement of Notes**

The following table sets forth the gross proceeds received from the March Private Placement of the Notes and calculates the net proceeds from the March Private Placement of the Notes after deduction of the anticipated payments pursuant to the Notes and the other March Private Placement documents. The net proceeds do not include the payment of any contingent payments, such as repayment premiums in the case of default or a fundamental transaction. The net proceeds assumes that all interest and principal will be paid in cash notwithstanding that we may pay interest and principal in shares of our common stock under specified circumstances, as described above. The interest amount reflected below assumes that all payments are made when due without any event of default, and the table assumes that none of the Notes are converted prior to maturity. Based on the foregoing assumptions, the net proceeds represent approximately 85.5% of the gross proceeds.

Gross Proceeds	\$ 20,650,000
Approximate Aggregate Interest Payments	\$ 2,478,000
Approximate Transaction Costs (including Placement Agent Fees)	\$ 922,750
Net Proceeds	\$ 17,249,250
14	
14	

# **Comparison of Issuer Proceeds to Potential Investor Profit**

We plan to use the proceeds from the sale of the Notes and Warrants to strengthen our cash position and to support ongoing clinical development programs, including undertaking global Phase III clinical trials of Generex Oral-lyn<sup>TM</sup>, our proprietary oral insulin formulation, at sites in the United States, Canada, and Europe. The following table summarizes the potential proceeds we will receive pursuant to the Securities Purchase Agreement, Notes, and Warrants. For purposes of this table, we have assumed that the Investors will exercise all of the Warrants on a cash basis. We have also assumed that the Notes will be held by the Investors through the maturity date of the Notes.

		Discount for
	Premium for	Company's
	Investor	Installment Payment
	Conversion	in Shares
	(\$1.21/share)	(\$0.09704/per share)
	(+ )	(+****/
Total Gross Proceeds Payable to Company in the Current Transaction (1)	\$ 72,275,000	72,275,000
All Payments that have been made or may be required to be made by		
Company until Maturity (2)	\$ 14,847,733	14,847,733
Net Proceeds to Company Assuming Maximum Payments made by		
Company (3)	\$ 57,427,267	57,427,267
Total Possible Profit to the Investors (4)	\$ 0	2,484,846
Percentage (%) of Payments and Profit over Net Proceeds (5)	25.85%	% 30.18%
Percentage (%) of Payments and Profit over Net Proceeds per year of		
Term (6)	17.24%	% 20.12%

<sup>(1)</sup> Includes gross proceeds payable to our company on the sale of the Notes in the amount of \$20,650,000 and assumes full exercise of the Series A, Series A-1, Series B and Series C Warrants to yield an aggregate exercise price of \$51,625,000. However, there is no assurance that any Warrants will actually be exercised.

- (3) Total net proceeds to us calculated by subtracting the result in footnote (2) from the results in footnote (1).
- (4) Total possible profit to the Investors includes only the aggregate premium or discount to market price of the shares underlying the Notes as discussed above under "Dollar Value of Underlying Securities and Potential Profits on Conversion."
- (5) Percentage of the total possible payments to the Investors as calculated in footnote (2) plus profit calculated in footnote (4) compared to the net proceeds disclosed in footnote

<sup>(2)</sup> Total possible payments (excluding repayment of principal) payable by us to the Investors or their affiliates assuming the Notes remain outstanding until the maturity date and that interest is paid in cash. Assumes that no default redemption premium on the Notes will be applicable.

(3).

(6) Based on 18-month term of the Notes.

#### SELLING SHAREHOLDERS

This prospectus relates to the resale from time to time of up to a total of 30,191,665 shares of our common stock by the selling shareholders, comprising:

• 22,527,275 shares of common stock issuable upon conversion of, and as interest payments on, the Notes;

6,309,275 shares of common stock issuable upon exercise of the Series A Warrants issued to the holders of the Notes; and

**4**,355,117 shares of common stock issuable upon exercise of some of the Series A-1 Warrants issued to the holders of the Notes

The Notes and the Series A and Series A-1 Warrants were issued in the March Private Placement and are described above under the caption "DESCRIPTION OF PRIVATE PLACEMENT AND CONVERTIBLE NOTES." We are registering the shares being offered under this prospectus pursuant to a Registration Rights Agreement, dated March 31, 2008, that was entered into between us and the selling shareholders in connection with the private placement.

We are registering the shares to permit the selling shareholders to offer these shares for resale from time to time. The selling shareholders may sell all, some or none of the shares covered by this prospectus. All information with respect to beneficial ownership has been furnished to us by the selling shareholders. For more information, see the section of this prospectus entitled "PLAN OF DISTRIBUTION."

The aggregate numbers of 22,527,275 and 6,309,275 shares of common stock set forth in the table above represent 120% of the number of shares issuable as of the date of the Registration Rights Agreement pursuant to the Notes and the Series A Warrants, which is a good faith estimate of the maximum number of shares of common stock issuable pursuant to the Notes and the Series A Warrants. The aggregate number of 1,355,117 shares of common stock set forth in the table above represents approximately 18% of the shares of common stock issuable as of the date of the Registration Rights Agreement upon the exercise of the Series A-1 Warrants. The total aggregate number of 30,191,665 shares of common stock being registered represents 30% of our public float prior to the March Private Placement.

The following table, based upon information currently known by us, sets forth as of April 23, 2008: (i) the number of shares held of record or beneficially by the selling shareholders as of such date and assuming conversion or exercise (as the case may be) of all Notes, Warrants and other warrants and rights held by the selling shareholders as of such date, (ii) the number of shares that may be offered under this prospectus, and (iii) a footnote reference to any material relationship between us and the selling shareholder, if any. The table below includes 100% (not 120%) of the shares issuable upon conversion of the Notes and as interest payments thereon and upon exercise of the Series A Warrants; therefore, the sum of the shares listed in the "Number of Shares Offered by Selling shareholder" column does not reflect the additional 4,806,090 shares we are registering under this prospectus based upon our good faith estimate of the maximum number of shares of common stock issuable pursuant to the Notes and the Series A Warrants. Beneficial ownership is determined under Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. None of the selling shareholders set forth in the following table is a broker-dealer or an affiliate of a broker-dealer.

For each selling shareholder, the table below assumes the sale by that selling shareholder of all of its shares of common stock available for resale under this prospectus. Percentage calculations are based on 142,370,184 shares of our common stock issued and outstanding after this offering.

Name of Selling Shareholder	Common Stock Beneficially Owned Prior to the Offering (1),(2)	Number of Shares Offered by Selling Shareholder (2),(3)	Common Stock Owned Upon Completion of this Offering (2),(3)	Common Stock Owned Upon Completion of this Offering (3)
Cranshire Capital,				
L.P.(4)	6,899,463	6,146,629(2)	5,368,538	3.77%
Smithfield Fiduciary				
$LLC^{(5)}$	23,586,175	8,605,279(2)	7,104,272	4.99%
Iroquois Master Fund				
Ltd. (6)	10,859,505	4,487,038(2)	6,372,467	4.48%
Iroquois Capital				
Opportunity Fund, LP <sup>(6)</sup>	2,975,207	1,229,326(2)	1,745,881	1.23%
Portside Growth and				
Opportunity Fund <sup>(7)</sup>	6,744,759	2,458,651(2)	4,286,108	3.01%
<b>Rockmore Investment</b>				
Master Fund Ltd.(8)	7,318,101	2,458,652(2)	4,859,449	3.41%

<sup>(1)</sup> Includes all shares beneficially owned by selling shareholder as of April 23, 2008.

Accordingly, the number of shares of common stock set forth in the table as being registered for a selling shareholder may exceed the number of shares of common stock that the selling shareholder could own beneficially at any given time through its ownership of the Notes and Warrants. Additionally, for purposes of calculating the "Shares Owned After Sale of Registered Shares," the registered shares are being treated as though they were all sold on the same day, and therefore because of the foregoing conversion and exercise limitations, the number of shares reflected as being owned after the sale of the registered shares may be less than the shares underlying other remaining Notes and Warrants, if any, held by the selling shareholder (including any Notes and Warrants issued in our the March Private Placement). The number of shares offered by

<sup>(2)</sup> Includes shares of common stock issuable upon conversion of, and as interest payments on, the Notes and shares of common stock issuable upon exercise of the Series A and Series A-1 Warrants. The Notes and Series A and Series A-1 Warrants contain conversion and exercise limitations providing that a holder thereof may not convert or exercise (as the case may be) - and that Generex shall not effect any conversion of a Note or otherwise convert any installment payment and accrued interest under a Note into shares of common stock - to the extent (but only to the extent) that, if after giving effect to such conversion or exercise (as the case may be), the holder or any of its affiliates would beneficially own in excess of 4.99% or 9.99%, as applicable (the "Maximum Percentage") of the outstanding shares of common stock immediately after giving effect to such conversion or exercise (as the case may be). To the extent the above limitation applies, the determination of whether a Note or Warrant shall be convertible (vis-à-vis other convertible, exercisable or exchangeable securities owned by the holder) shall, subject to such Maximum Percentage limitation, be determined on the basis of the first submission to Generex for conversion, exercise or exchange (as the case may be).

the Selling Shareholders in the table above reflects 100% of the shares issuable upon conversion of the Notes and as interest payments thereon and upon the exercise of the Series A Warrants and a portion of the Series A-1 Warrants; we are registering 120% of the number of shares issuable pursuant to the Notes and the Series A Warrants, which is a good faith estimate of the maximum number of shares of common stock that may be issuable pursuant to the Notes and the Series A Warrants. In the event such additional shares become issuable the additional shares shall be allocated among the Selling Shareholders holding the Notes and the Series A Warrants proportionally with their holdings.

(3) Assumes that the shareholders dispose of all the shares of common stock covered by this prospectus and do not acquire or dispose of any additional shares of common stock. The selling shareholders are not representing, however, that any of the shares covered by this prospectus will be offered for sale, and the selling shareholders reserve the right to accept or reject, in whole or in part, any proposed sale of shares. On March 31, 2008, we entered into a Registration Rights Agreement with the selling shareholders listed above. See the section of this prospectus entitled "DESCRIPTION OF PRIVATE PLACEMENT AND CONVERTIBLE NOTES." Under the Registration Rights Agreement, we are required to file a resale registration statement for the shares underlying the Notes and Warrants to enable the resale of such shares by the selling shareholders on a delayed or continuous basis under Rule 415 of the Securities Act. Pursuant to the terms of the Notes, we also may make installment and interest payments with shares of our common stock.

- (3) Assumes that the shareholders dispose of all the shares of common stock covered by this prospectus and do not acquire or dispose of any additional shares of common stock. The selling shareholders are not representing, however, that any of the shares covered by this prospectus will be offered for sale, and the selling shareholders reserve the right to accept or reject, in whole or in part, any proposed sale of shares. On March 31, 2008, we entered into a Registration Rights Agreement with the selling shareholders listed above. See the section of this prospectus entitled "DESCRIPTION OF PRIVATE PLACEMENT AND CONVERTIBLE NOTES." Under the Registration Rights Agreement, we are required to file a resale registration statement for the shares underlying the Notes and Warrants to enable the resale of such shares by the selling shareholders on a delayed or continuous basis under Rule 415 of the Securities Act. Pursuant to the terms of the Notes, we also may make installment and interest payments with shares of our common stock.
- (4) Downsview Capital, Inc. ("Downsview") is the general partner of Cranshire Capital, L.P. ("Cranshire") and consequently has voting control and investment discretion over securities held by Cranshire. Mitchell P. Kopin ("Mr. Kopin"), President of Downsview, has voting control over Downsview. As a result, each of Mr. Kopin, Downsview and Cranshire may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the shares owned by Cranshire which are being registered hereunder.

Includes (i) 1,324,106 shares of common stock, (ii) 4,132,231 shares of common stock issuable upon conversion of a Senior Secured Convertible Note (the "Note"), (iii) 170,068 shares of common stock issuable upon exercise of a warrant (the "Warrant") and (iv) 1,273,058 shares of common stock issuable upon exercise of a Series A Warrant (the "Series A Warrant"), in each case, held by Cranshire, which determination is based on (1) 111,675,275 shares of common stock issued and outstanding as of March 31, 2008, plus (2) (A) 4,132,231 shares of common stock issuable upon conversion of the Note, (B) 170,068 shares of common stock issuable upon exercise of the Warrant and (C) 1,273,058 shares of common stock issuable upon exercise of the Series A Warrant, in each case, held by Cranshire. Excludes (x) an aggregate of 3,874,363 shares of Common Stock issuable upon exercise of warrants held by Cranshire because each of such warrants contain a blocker provision under which the holder thereof does not have the right to exercise such warrants to the extent that such exercise would result in beneficial ownership by the holder thereof, together with its affiliates, of more than 4.99% or 4.999% (as the case may be) of the shares of common stock outstanding after giving effect to such exercise and (y) an aggregate of 9,057,519 shares of common stock issuable upon exercise of warrants held by Cranshire (that were acquired on March 31, 2008) because each of such warrants is not exercisable until the six month and one day anniversary of the issuance date thereof (which was March 31, 2008) (each of such warrants also contain a blocker provision under which the holder thereof does not have the right to exercise such warrants to the extent that such exercise would result in beneficial ownership by the holder thereof, together with its affiliates, of more than 9.99% of the shares of common stock outstanding after giving effect to such exercise). Without such blocker provisions (and assuming the warrants described in clause (y) are currently exercisable), each of Mr. Kopin, Downsview and Cranshire would be deemed to beneficially own 19,831,345 shares of common stock.

- (5) Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield Fiduciary LLC. Glenn Dubin and Henry Swieca control Highbridge Capital Management, LLC. Each of Highbridge Capital Management, LLC, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield Fiduciary LLC. Shares of common stock beneficially owned prior to the offering includes all shares of common stock issuable upon conversion of, and as interest payments on, the Notes and shares of common stock issuable upon exercise of the Warrants without regard to the blocker provisions as described in footnote 2 and exercise limitations on certain Warrants. Shares of common stock owned upon completion of the offering does not include 7,876,624 shares of common stock issuable upon exercise of warrants held by Smithfield because each of such warrants contains a blocker provision under which the holder thereof does not have the right to exercise such warrants to the extent that such exercise would result in beneficial ownership by the holder thereof, together with its affiliates, of more than 4.99% of the shares of common stock outstanding after giving effect to such exercise
- (6) Joshua Silverman, indirectly through respective investment management companies, has voting control and investment discretion over securities held by Iroquois Master Fund Ltd. and Iroquois Capital Opportunity Fund, LP. Mr. Silverman disclaims beneficial ownership of the shares held by Iroquois Master Fund Ltd. and Iroquois Capital Opportunity Fund, LP. Iroquois Capital, LP, an affiliated investment fund of Iroquois Master Fund Ltd. and Iroquois Capital Opportunity Fund, LP beneficially owns 3,087,597 shares of our common stock. Shares of common stock beneficially owned prior to the offering includes all shares of common stock issuable upon conversion of, and as interest payments on, the Notes and shares of common stock issuable upon exercise of the Warrants without regard to the blocker provisions as described in footnote 2 and exercise limitations on certain Warrants.

- (7) Ramius LLC ("Ramius") is the investment adviser of Portside Growth and Opportunity Fund ("Portside") and consequently has voting control and investment discretion over securities held by Portside. Ramius disclaims beneficial ownership of these securities. C4S & Co., L.L.C. ("C4S") is the managing member of Ramius and may be considered the beneficial owner of any securities deemed to be beneficially owned by Ramius. C4S disclaims beneficial ownership of these securities. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S and may be considered beneficial owners of any securities deemed to be beneficially owned by C4S. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these securities. Shares of common stock beneficially owned prior to the offering includes all shares of common stock issuable upon conversion of, and as interest payments on, the Notes and shares of common stock issuable upon exercise of the Warrants without regard to the blocker provisions as described in footnote 2 and exercise limitations on certain Warrants.
- (8) Rockmore Capital, LLC ("Rockmore Capital") and Rockmore Partners, LLC ("Rockmore Partners"), each a limited liability company formed under the laws of the State of Delaware, serve as the investment manager and general partner, respectively, to Rockmore Investments (US) LP, a Delaware limited partnership, which invests all of its assets through Rockmore Investment Master Fund Ltd., an exempted company formed under the laws of Bermuda ("Rockmore Master Fund"). By reason of such relationships, Rockmore Capital and Rockmore Partners may be deemed to share dispositive power over the shares of our common stock owned by Rockmore Master Fund. Rockmore Capital and Rockmore Partners disclaim beneficial ownership of such shares of our common stock. Rockmore Partners has delegated authority to Rockmore Capital regarding the portfolio management decisions with respect to the shares of common stock owned by Rockmore Master Fund and, as of April 23, 2008 Mr. Bruce T. Bernstein and Mr. Brian Daly, as officers of Rockmore Capital, are responsible for the portfolio management decisions of the shares of common stock owned by Rockmore Master Fund. By reason of such authority, Messrs, Bernstein and Daly may be deemed to share dispositive power over the shares of our common stock owned by Rockmore Master Fund. Messrs. Bernstein and Daly disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such authority. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. No person or "group" (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Rockmore Master Fund. Shares of common stock beneficially owned prior to the offering includes all shares of common stock issuable upon conversion of, and as interest payments on, the Notes and shares of common stock issuable upon exercise of the Warrants without regard to the blocker provisions as described in footnote 2 and exercise limitations on certain Warrants.

#### PLAN OF DISTRIBUTION

We are registering the shares of common stock issuable upon conversion of the notes and exercise of the warrants to permit the resale of these shares of common stock by the holders of the notes and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling shareholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling shareholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions.

·on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

in the over-the-counter market;

- · in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- · ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- ·block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
  - purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
  - an exchange distribution in accordance with the rules of the applicable exchange;
    - privately negotiated transactions;
- ·short sales made after the date the Registration Statement is declared effective by the SEC, subject to any applicable limitations on short sales contained in any agreement between a selling shareholder and the Company;
  - sales pursuant to Rule 144;
- ·broker-dealers may agree with the selling shareholder to sell a specified number of such shares at a stipulated price per share;
  - a combination of any such methods of sale; and
  - any other method permitted pursuant to applicable law.

If the selling shareholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of

discounts, concessions or commissions from the selling shareholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling shareholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling shareholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling shareholders may pledge or grant a security interest in some or all of the notes, warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus. The selling shareholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling shareholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling shareholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement, of which this prospectus forms a part.

The selling shareholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling shareholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be \$38,245.86 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws: provided, however, that a selling shareholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling shareholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling shareholders will be entitled to contribution. We may be indemnified by the selling shareholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling shareholder specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

Once sold under the shelf registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

#### **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed on by Eckert Seamans Cherin & Mellott, LLC, Two Liberty Place, 50 South 16th Street, 22nd Floor, Philadelphia, PA 19102. Certain members of the firm of Eckert Seamans Cherin & Mellott hold options that are exercisable for 30,000 shares at \$7.56 per share. These options were granted under our 2000 Stock Option Plan. Members of the firm also own additional shares (less than one percent in total) that they purchased from time to time for cash, either from us or in the public market.

#### **EXPERTS**

The audited financial statements for the fiscal years ended July 31, 2007, and July 31, 2006 and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated in this prospectus and elsewhere in the registration statement by reference to the Annual Report on Form 10-K for the year ended July 31, 2007 have been so incorporated in reliance on the report of Danziger Hochman Partners LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The audited financial statements for the fiscal year ended July 31, 2005 incorporated in this prospectus and elsewhere in the registration statement by reference to the Annual Report on Form 10-K for the year ended July 31, 2007 have been so incorporated in reliance on the report of BDO Dunwoody LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file with the SEC at the Public Reference Room (Room 1580), 100 F Street, N.E., Washington, D.C. 20549. You may also obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (www.sec.gov) that contains the reports, proxy and information statements, and other information that we file electronically with the SEC.

This prospectus is part of a Registration Statement on Form S-3 that we filed with the SEC. The Registration Statement contains more information than this prospectus regarding us and the securities, including certain exhibits and schedules. You can obtain a copy of the Registration Statement from the SEC at the above address or from the SEC's Internet site.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information contained in documents that we file with the SEC, which means that we can disclose important information to you by referring you to those other documents. The 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 we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering:

- our Annual Report on Form 10-K for the fiscal year ended July 31, 2007, filed with the SEC on October 15, 2007;
- Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended July 31, 2007, filed with the SEC on November 28, 2007;

- Amendment No. 2 to our Annual Report on Form 10-K for the fiscal year ended July 31, 2007, filed with the SEC on March 13, 2008;
- our Quarterly Report on Form 10-Q for the quarter ended October 31, 2007, filed with the SEC on December 7, 2007;

- our Quarterly Report on Form 10-Q for the quarter ended January 31, 2008, filed with the SEC on March 11, 2008;
- our Quarterly Report on Form 10-Q for the quarter ended April 30, 2008, filed with the SEC on June 9, 2008;
- our Current Reports on Form 8-K filed with the SEC on August 23, 2007,
   December 5, 2007, March 14, 2008, April 2, 2008, May 1, 2008, May 9, 2008 and May 29, 2008;
- our definitive Proxy Statement filed with the SEC on April 23, 2008 in connection with our 2008 Annual Meeting of Stockholders; and
- the description of our common stock contained in our registration statement on Form 10 filed on December 14, 1998, as amended by a Form 10/A filed on February 24, 1999, and including any amendment or report subsequently filed for the purpose of update the description.

All documents that we subsequently file pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, prior to the termination of this offering shall be deemed to be incorporated by reference in this registration statement and to be a part hereof from the date of filing of such documents; except as to any portion of any future annual or quarterly report to stockholders or document that is not deemed filed under such provisions. For the purposes of this prospectus, any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of these documents (other than an exhibit to a filing unless that exhibit is specifically incorporated by reference into that filing), which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Generex Biotechnology Corporation
Attention: Mark Fletcher, Executive Vice President and General Counsel
33 Harbour Square, Suite 202
Toronto, Ontario
Canada M5J 2G2
(416) 364-2551

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth all costs and expenses to be incurred by Generex in connection with the preparation and filing of this Registration Statement. All amounts shown are estimates except for the SEC registration fee. We will pay all expenses in connection with the distribution of the shares of common stock being registered hereby, except for the fees and expenses of any counsel and other advisors that any selling shareholders may employ to represent them in connection with the offering and any brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

SEC Registration Fee	\$ 1,245.86
Printing and Engraving Expenses	\$ 1,000.00
Accountants' Fees and Expenses	\$ 10,000.00
Legal Fees and Expenses	\$ 25,000.00
Miscellaneous	\$ 1,000.00
Total Expenses	\$ 38,245.86

#### ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

### **General Corporation Law of Delaware**

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

#### **Bv-Laws**

Article V of our Amended and Restated By-Laws provides that Generex shall indemnify any person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (collectively, a "proceeding"), by reason of the fact such person is or was (a) a director or executive officer of Generex or a constituent corporation absorbed in a consolidation or merger (hereinafter, a "constituent corporation"), or, (b) is or was serving at the request of Generex or a constituent corporation as a director, officer, partner, employee or agent of another corporation, partnership, joint venture or other enterprise or entity, or (c) is or was a director or officer of Generex serving at its request as an administrator, trustee or other fiduciary of one or more of the employee benefit plans, if any, of Generex or another entity which may be in effect from time to time, against all expenses, liability and loss actually and reasonably incurred or suffered by such person in connection with such proceeding, whether or not the indemnified liability arises or arose from any proceeding by or in the right of Generex, to the extent that such person is not otherwise indemnified and to the extent that such indemnification is not prohibited by law as it presently exists or may hereafter be amended. We shall advance all expenses reasonably incurred by a person entitled to indemnification as provided above in defending a proceeding in advance of the final disposition of such proceeding, and may, but shall not be obligated to, advance expenses of other persons entitled to indemnification pursuant to any other agreement or provision of law. To determine whether any indemnification under Article V of our Amended and Restated By-Laws is permissible, our Board of Directors by a majority vote of a quorum consisting of directors not parties to such proceeding may, and on request of a person seeking indemnification shall be required to, determine in each case whether the applicable

standards in any applicable statute have been met, or such determination shall be made by independent legal counsel if such quorum is not obtainable, or, even if obtainable, a majority vote of a quorum of disinterested directors so directs. If a claim for indemnification under Article V of our Amended and Restated By-Laws is not paid in full within ninety (90) days after a written claim therefore has been received by us, the claimant may file suit to recover the unpaid amount of such claim, and we shall have the burden of proving that the claimant was not entitled to the requested indemnification under applicable law. The reasonable expenses of any person in prosecuting a successful claim for indemnification thereunder, and the fees and expenses of any independent legal counsel engaged to determine permissibility of indemnification, shall be borne by us. For purposes of Article V of our Amended and Restated By-Laws, "independent legal counsel" means legal counsel other than that regularly or customarily engaged by or on behalf of Generex. Notwithstanding any other provision of Article V, we shall be required to indemnify a person in connection with a proceeding initiated by such person only if the proceeding was authorized by the Board of Directors.

Article V of our Amended and Restated By-Laws further provides that indemnification provided therein shall not be deemed exclusive of any other right to which one seeking indemnification may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, the By-Laws, agreement, vote of stockholders or disinterested directors or otherwise, and shall inure to the benefit of the heirs, executors and administrators of any such person. Any modification or repeal of any provision of Article V of our Amended and Restated By-Laws shall not adversely affect any right or protection of an authorized representative existing thereunder with respect to any act or omission occurring prior to such modification or repeal.

Pursuant to Article V of our Amended and Restated By-Laws, our Board of Directors has the power to (i) authorize the company to purchase and maintain, at the company's expenses, insurance on behalf of the company and on behalf of others to the extent that power to do so has not been prohibited by applicable law, and (ii) give other indemnification to the extent not prohibited by applicable law. We currently maintain insurance under which the insurers will reimburse us for amounts that it has paid to its directors and officers as indemnification for claims against such persons in their official capacities. The insurance also covers such persons as to amounts paid by them as a result of claims against them in their official capacities that are not reimbursed by us. The insurance is subject to certain limitations and exclusions.

#### **ITEM 16. EXHIBITS**

The exhibits are described on the Exhibit Index to this Amendment No. 3.

#### ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *provided, however*, that paragraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for purposes of determining liability under the Securities Act of 1933 to any purchaser:
- (i) If the registrant is relying on Rule 430B:
- (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
- (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided*, *however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

- (7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.
- (8) The undersigned registrant hereby undertakes that:
- (i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 3 to Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Toronto, Province of Ontario, Canada, on July 24, 2008.

# GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin Anna E. Gluskin

President and Chief Executive Officer

Signature	Title	Date
/s/ Anna E. Gluskin Anna E. Gluskin	President, Chief Executive Officer And Director	July 24, 2008
/s/ Rose C. Perri Rose C. Perri	Chief Financial Officer, Chief Operating Officer and Director	July 24, 2008
* John Barratt	Director	July 24, 2008
* Brian T. McGee	Director	July 24, 2008
* Nola E. Masterson	Director	July 24, 2008
/s/ Slava Jarnitskii Slava Jarnitskii	Controller	July 24, 2008
*By: /S/ Anna E. Gluskin Anna E. Gluskin Attorney-in-Fact		
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# **EXHIBIT INDEX**

Exhibit Number 4.1(1)	<b>Description of Document</b> Securities Purchase Agreement, dated as of March 31, 2008 among the Registrant and each of the purchasers named therein	
4.2(2)	Form of 8% Secured Convertible Note, as amended	
4.3(2)	Form of Series A Warrant, as amended	
4.4(2)	Form of Series A-1 Warrant, as amended	
4.5(2)	Form of Series B Warrant, as amended	
4.6(2)	Form of Series C Warrant, as amended	
4.7(1)	Registration Rights Agreement, dated March 31, 2008, among Registrant and each of the purchasers under Securities Purchase Agreement	
4.8(1)	Security Agreement	
4.9(1)	Form of Guaranty	
5	Opinion of Eckert Seamans Cherin & Mellott, LLC	
23.1	Consent of Danziger Hochman Partners LLP	
23.2	Consent of BDO Dunwoody LLP	
23.3	Consent of Eckert Seamans Cherin & Mellott, LLC (included in Exhibit 5)	
* In the case of incorporation by reference to documents filed by the Registrant under the Exchange Act, the Registrant's file number under the Exchange Act is 000-25169.		

Previously filed as exhibits to the Registrant's Form 8-K filed April 1, 2008

Previously filed as exhibits to the Registrant's Form S-3 (File No. 333-150562) filed on April 30, 2008.

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