GENEREX BIOTECHNOLOGY CORP
Form 424B5
October 15, 2009

PROSPECTUS SUPPLEMENT
(To Prospectus dated January 12, 2007)

Filed pursuant to Rule 424(b)(5)
Registration No. 333-139637

GENEREX BIOTECHNOLOGY CORPORATION

30,000,000 SHARES OF COMMON STOCK

You should carefully read this prospectus supplement and the accompanying prospectus before you invest. Both documents contain information you should consider before making your investment decision.

This prospectus supplement relates to the issuance and sale of up to 30,000,000 shares of our common stock through our sales agent, Wm Smith & Co. These sales, if any, will be made pursuant to the terms of an At Market Issuance Sales Agreement entered into between us and our sales agent, the form of which was filed with the Securities and Exchange Commission under a Current Report on Form 8-K dated October 14, 2009 and is incorporated herein by reference. Our sales agreement with Wm Smith is limited to the sale of common stock with gross proceeds aggregating $20,000,000.

Our common stock is quoted on the NASDAQ Capital Market under the symbol "GNBT." On October 13, 2009, the closing price of our common stock as reported on NASDAQ was $0.73 per share. Sales of shares of our common stock under this prospectus supplement, if any, may be made in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, which includes sales made directly on the NASDAQ Capital Market, the existing trading market for our common stock, or sales made to or through a market maker other than on an exchange. The sales agent will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreeable terms between the sales agent and us.

Unless we and our sales agent otherwise agree, the commission to the sales agent for sales of common stock sold pursuant to the sales agreement will be no more than 3% of gross proceeds of the sales price.. The net proceeds to us that we receive from sales of our common stock will depend on the number of shares actually sold and the offering price for such shares. Based on the closing price of our common stock on October 13, 2009, because our sales agreement with Wm Smith is limited to the sale of common stock with gross proceeds aggregating $20,000,000, the maximum number of shares we could sell is 27,397,260. If all 30,000,000 shares of common stock were sold at the October 13, 2009 closing sales price, we would receive $21,900,000 in gross proceeds. The actual proceeds to us will vary.

In connection with the sale of common stock on our behalf, the sales agent may be deemed an "underwriter" within the meaning of the Securities Act of 1933, as amended, and the compensation of the sales agent may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to the sales agent against certain liabilities, including liabilities under the Securities Act of 1933.

Investing in our common stock involves a high degree of risk. Risks associated with an investment in our common stock are described in the section titled "Risk Factors" beginning on page S-8 of this prospectus supplement, which supercede in their entirety the risk factors beginning on page 2 of the accompanying prospectus. You should carefully consider these risk factors before making an investment decision.

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

criminal offense.

Wm Smith & Co.

The date of the Prospectus Supplement is October 14, 2009.

This prospectus supplement is not complete without, and may not be utilized except in connection with, the accompanying prospectus dated January 12, 2007 and any amendments to such prospectus. This prospectus supplement provides supplemental information regarding us and updates certain information contained in the accompanying prospectus and describes the specific terms of this offering. The accompanying prospectus gives more general information, some of which may not apply to this offering. We incorporate important information into this prospectus supplement and the accompanying prospectus by reference.

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Prospectus supplement

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information contained in this prospectus supplement and the accompanying prospectus, as well as the information that we have filed with the Securities and Exchange Commission, or the SEC, and incorporated by reference herein and therein, is accurate only as of the date of the applicable document. This prospectus supplement and the accompanying prospectus do not constitute an offer or solicitation by anyone in any jurisdiction in which an offer or solicitation is not authorized or in which the person making an offer or solicitation is not qualified to do so, or to anyone to whom it is unlawful to make an offer or solicitation.

This prospectus supplement contains the terms of this offering. This prospectus supplement, along with the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, may add, update or change information in the accompanying prospectus. If information in this prospectus supplement, or the documents incorporated by reference in this prospectus supplement, and the accompanying prospectus, is inconsistent with the accompanying prospectus, this prospectus supplement, or the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, will apply and will supersede the information in the accompanying prospectus.

The information contained in this prospectus supplement and the accompanying prospectus is correct only as of the date on the cover, regardless of the date this prospectus supplement was delivered to you or the date on which you acquired any of the shares.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters in prospectus supplement constitute “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. All statements, other than statements of historical facts, included in this prospectus supplement that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "expects," “anticipates,” "plans," “seeks,” "intends," "believes," "will," "estimates," “budgets,” "projects" “likely may result,” “may be,” “may continue,” or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts.

Our forward-looking statements address, among other things:

- our expectations concerning product candidates for our technologies;
- our expectations concerning existing or potential development and license agreements for third-party collaborations and joint ventures;
- our expectations of when different phases of clinical activity may commence and conclude;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received; and
- our expectations of when commercial sales of our products may commence and when actual revenue from the product sales may be received.

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

- the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates;
- the inherent uncertainties associated with commercialization of products that have received regulatory approval;
- our to sell our products successfully if a market develops;
- our ability to attract and retain qualified personnel to implement our growth strategies;
- our ability to develop sales, marketing and distribution capabilities;
- our ability to obtain reimbursement from third party payer for the products that we sell; and

- our ability to obtain the necessary financing to fund our short-term and long-term operating and capital expenditures.

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

Each forward-looking statement should be read in context with, and in understanding of, the various other disclosures concerning our company and our business made elsewhere in this prospectus as well as our public filings with the SEC. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statements contained in this prospectus supplement or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

SUMMARY

This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus supplement and accompanying prospectus and may not contain all of the information that is important to you. This prospectus supplement and the accompanying prospectus include or incorporate by reference information about the shares we are offering as well as information regarding our business and detailed financial data. You should read this prospectus supplement and the accompanying prospectus in their entirety, including the information incorporated by reference.

ABOUT GENEREX

Overview

We are 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, we have expanded our focus to include immunomedicines incorporating proprietary vaccine formulations.

We believe that our buccal delivery technology is a platform technology that has application to many large molecule drugs and provides a convenient, non-invasive, accurate and cost-effective way to administer such drugs. We have identified several large molecule drugs as possible candidates for development, including estrogen, heparin, monoclonal antibodies, human growth hormone and fertility hormone, but to date have focused our development efforts primarily on one pharmaceutical product, Generex Oral-lyn™, an insulin formulation administered as a fine spray into the oral cavity using our proprietary hand-held aerosol spray applicator known as RapidMist™.

To date, we have received regulatory approval in Ecuador, India, Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas. The patient screening at other participating clinical sites in the U.S. and Canada is ongoing. Currently over 350 patients have been enrolled in 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia and Ukraine.

We received a Special Access Program (SAP) authorization from Health Canada for a patient-specific, physician-supervised treatment of Type-1 diabetes with Generex Oral-lyn™ in April 2008. SAP provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are not available or unsuitable. We received a similar authorization from health authorities in Netherlands in September 2008. We will continue to expand our SAP participation in additional countries around the world.

In November 2008 we, together with our marketing partner Shreya Life Sciences Pvt. Ltd. officially launched Generex Oral-lyn™ in India under marketing name of Oral Recosulin. Each package of Oral Recosulin contains two canisters of our product along with one actuator. Product has been available for sale in India since January 2009, and an estimated 50 dialectologists are currently prescribing Oral Recosulin there.

In November 2008, we submitted our product dossier to the Ministry of Health in Damascus, Syria through Generex MENA, our branch office in Dubai. The dossier includes Generex Oral-lyn™. We also submitted a file to register our proprietary over-the-counter products, including Glucose RapidSpray™, 7-Day Diet Aid Spray™ (marketed as Crave-Nx™ in the United States and Canada) and BaBOOM!™ Energy Spray. The Syrian Ministry of Health will review the dossier and inform us of any additional requests for information that it may have. There have been no immediate queries, and we anticipate registration before the end of calendar year 2009. It is estimated that among Syria's population of 20 million, between 3 million and 3.5 million people have diabetes.

In December 2008, we submitted Generex Oral-lyn™ dossier to the Ministry of Health in Iraq (North) through Generex MENA, our branch office in Dubai and expect to receive an approval to market the product early in 2010.

In December 2008 we, together with our marketing partner Benta SA., received an approval to market Generex Oral-lyn™ in Lebanon. Benta is currently working on reimbursement policy for Generex Oral-lyn™. The official product launch in Lebanon took place in May 2009.

In May 2009, the Algerian health authorities granted us permission to import and sell Generex Oral-lyn™ for the treatment of diabetes in Algeria. We expect commercial launch of the product by the end of calendar year 2009. Through the efforts of our business development team, in association with the Generex MENA, we have entered into a marketing sub-distribution relationship with Algerian company Continental Pharm Laboratoire.

Using our buccal delivery technology, we also have launched a line of over-the-counter glucose and energy sprays , including Glucose RapidSpray™, GlucoBreak™, Crave-NX 7-day Diet Aid Spray, and BaBOOM!™ Energy Spray. We believe these products will complement Generex Oral-lyn™ and may provide us with an additional revenue stream prior to the commercialization of Generex Oral-lyn™ in other major jurisdictions.

In October 2008, we announced the enrollment of subjects in our bioequivalence clinical trial of MetControl™, our proprietary Metformin medicinal chewing gum product. The protocol for the study is an open-label, two-treatment, two-period, randomized, crossover study comparing MetControl™ and immediate release Metformin™ tablets in healthy volunteers. The study results, that we received and analyzed in December 2008, will allow us to proceed with additional research and development initiatives and consider regulatory agency registration applications.

Our subsidiary, Antigen Express, concentrates on developing proprietary vaccine formulations that work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). Our immunomedicine products are based on two platform technologies and are in the early stages of development. 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. Development efforts also are underway for seasonal influenza virus, H5N1, HIV, HPV, melanoma, ovarian cancer, allergy and Type I diabetes mellitus. We have established collaborations with clinical investigators at academic centers to advance these technologies.

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have announced that they will discontinue development and/or sale of their inhalable forms of insulin. Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally 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.

We are a development stage company. From inception through the end of the year ended July 31, 2009, we have received only limited revenues from operations. In the fiscal years ended July 31, 2009 and 2008, we received approximately $1,118,509 and $124,891 in revenue. The revenue in fiscal 2009 included $500,000 relating to an upfront license fee for the signing of a license and distribution agreement for Generex Oral-lyn™, while the remainder of the revenue in both fiscal periods pertained to the sale of our confectionary products. These numbers do not reflect deferred sales to customers during the respective periods with the right of return.

We operate in only one segment: the research, development and commercialization of drug delivery systems and technologies for metabolic and immunological diseases.

We were incorporated in the State of Delaware in 1997. Our principal executive offices are located at 33 Harbour Square, Suite 202, Toronto, Canada, and our telephone number at that address is (416) 364-2551. We maintain an Internet website at www.generex.com. We make available free of charge on or through our website our filings with the SEC.

Our Business Strategy

Our goal is to develop and commercialize our buccal delivery technology to administer large molecule drugs, including insulin, and proprietary vaccine formulations based upon two Antigen platform technologies to provide innovative biopharmaceutical products that offer the potential for superior efficacy and safety over existing products. To achieve these goals, the key elements of our strategy include:

- Conducting and completing Phase III clinical trials of Generex Oral-lyn™ in the United States and Canada, Europe and certain countries in Eastern Europe including Russia, Ukraine, Bulgaria and Romania;

- Commercializing Generex Oral-lyn™ in Ecuador, India, Lebanon and Algeria, the countries where we have obtained regulatory approval for its commercial marketing and sale, by undertaking additional commercial manufacturing runs of Generex Oral-lyn™ at PharmaBrand, S.A.'s facilities in Quito, Ecuador and Catalent Pharma Solutions in North Carolina and expanding such production facilities to meet the anticipated demand for the product in India, Lebanon, Algeria and other jurisdictions where governmental approvals are pending and pursuing post-approval clinical studies and marketing efforts in India, Lebanon and Algeria.

- Expanding the patient-base in Canada wherein Generex Oral-lyn™ is available under the Special Access Program (SAP) authorization from Health Canada for a patient-specific, physician-supervised treatment of Type-1 diabetes.

- Establishing strategic relationships worldwide for product development and distribution and working with our multinational licensed distributors in the Middle East and throughout Eastern Europe, Africa and Asia to obtain regulatory approval for the registration, importation, marketing, distribution and sale of Generex Oral-lyn™ in those countries.

- Conducting and completing Phase II clinical trials 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, a Phase I prostate cancer trial and a Phase I trial in patients with breast or ovarian cancer; and

- Conducting and completing a Phase I clinical trial of Antigen's synthetic peptide vaccines against avian (H5N1) influenza.

Our Corporate Information

We were incorporated in Delaware in 1997. Our principal executive offices are located at 33 Harbour Square, Suite 202, Toronto, Canada M5J2G2 and our telephone number is (416) 364-2551. Our website is located at www.generex.com.

We have not incorporated by reference into this prospectus supplement or the accompanying prospectus the information in, or that can be accessed through, our website, and you should not consider it to be part of this prospectus supplement or the accompanying prospectus.

THE OFFERING

Issuer	Generex Biotechnology Corporation
Common stock we are offering pursuant to this prospectus supplement	Up to 30,000,000 shares
Common stock to be outstanding after this offering if all shares are sold	Up to 276,945,790 shares(1)
Maximum gross proceeds	$20,000,000
Manner of offering	Sales of shares of our common stock under this prospectus supplement, if any, may be made in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, which includes sales made directly on the NASDAQ Capital Market, the existing trading market for our common stock, or sales made to or through a market maker other than on an exchange. The sales agent will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreeable terms between the sales agent and us. See “Plan of Distribution.”
Sales agent	Wm Smith & Co.
NASDAW symbol	GNBT
Use of proceeds	The net proceeds of this offering will be added to our general funds and used for pre-clinical studies and clinical trials in respect of our proprietary platform buccal drug delivery technologies and our proprietary platform synthetic vaccine technologies, internal research and development programs, working capital, capital expenditures and other general corporate purposes as further described in this prospectus supplement under the heading “Use of Proceeds.”
NASDAQ CAPITAL MARKET Symbol	GNBT

(1) The number of shares of common stock shown above to be outstanding after this offering is based on the 246,945,790 shares outstanding as of October 13, 2009 and assumes the sale of all Shares.

RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the risks related to our business set forth in this prospectus supplement, the accompanying prospectus and the other information included and incorporated by reference in this prospectus supplement and accompanying prospectus, you should carefully consider the risks described below before purchasing our common stock. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations Any of the risks, uncertainties and other factors could have a materially adverse effect on our business, financial condition or results of operations and could cause the trading price of our common stock to decline substantially.

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 fiscal year ended July 31, 2009, we received modest revenues from sales of our over-the-counter confectionary products. We did not recognize any revenue from the sale of our oral insulin product in Ecuador or India in fiscal 2009, although we did recognize $500,000 in licensing fee revenue relating to the signing of a licensing and distribution agreement for the sale of Generex Oral-lyn™ in Korea. We do not expect to receive any revenues in Ecuador until we enter into a definitive manufacturing and distribution agreement with our business partner there. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate significant revenue from the initial commercial launch of Generex Oral-lyn™ in India sometime this fiscal year. We also have entered in subdistribution agreements in Lebanon and Algeria but do not expect any signification revenue from the launch of the product in those countries in calendar year 2009.

To date, we have not been profitable and our accumulated net loss available to shareholders was 294,041,489 at July 31, 2009. 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™ which is currently available for sale in Ecuador and has been approved for sale in India, Lebanon and Algeria and our over-the-counter glucose and energy spray products, Glucose RapidSpray™, BaBOOM!™ Energy Spray and GlucoBreak™, 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™ in countries outside of Ecuador, India, Lebanon and Algeria. 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:

- to proceed with the development of our buccal insulin product;
- to finance the research and development of new products based on our buccal delivery and immunomedicine technologies, including clinical testing relating to new products;
- to finance the research and development activities of our subsidiary Antigen with respect to other potential technologies;
- to commercially launch and market developed products;
- to develop or acquire other technologies or other lines of business;
- to establish and expand our manufacturing capabilities;
- to finance general and administrative activities that are not related to specific products under development; and
- 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 twelve months. However, this expectation is based on our current operating plan, which could change as a result of many factors, including a further decline in the price of our stock, 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.

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.

Risks Related to Our Technologies

With the exception of Generex Oral-lyn™, Glucose RapidSpray™, BaBOOM! ™ Energy Spray and GlucoBreak™, ou technologies and products are at an early stage of development and we cannot expect significant 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™ in Ecuador, India, Lebanon and Algeria and our glucose sprays which are available over-the-counter in certain 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 have yet to manufacture, market and distribute these products on a large-scale commercial basis, and we expect to receive only modest revenues from product sales in fiscal year 2010. 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. 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 was obtained in Ecuador, India, Lebanon and Algeria. We have begun the regulatory approval process for our oral insulin, buccal morphine and fentanyl products in other countries, and we have initiated late stage clinical trials of Generex Oral-lyn™ at some of our clinical trial sites in North America according to the Phase III clinical plan.

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 (U.S.), a Phase I trial in human patients with prostate cancer (Athens, Greece), a Phase I trial in human patients with breast or ovarian cancer (U.S.) and a Phase I trial in human volunteers of a peptide vaccine for use against the H5N1 avian influenza virus (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 countries 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 supplement 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 countries other than Ecuador, India, Lebanon and Algeria, 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 pharmaceutical products are approved for sale.

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

- acceptance of the formulation or treatment by health care professionals and diabetic patients;
-

the availability, effectiveness and relative cost of alternative diabetes or immunomedicine treatments that may be developed by competitors; and

- the availability of third-party (i.e., insurer and governmental agency) reimbursements.

We will not receive significant revenues from Generex Oral-lyn™ or any of our other pharmaceuticals products that may receive regulatory approval until we can successfully manufacture, market and distribute them in the relevant markets.

Similarly, the successful commercialization of our over-the-counter glucose spray products may be hindered by manufacturing, marketing and distribution limitations.

We 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.

Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, announced that they will discontinue development and/or sale of their inhalable forms of insulin. Unlike inhaled insulin formulations, Generex Oral-lyn™ is a buccally 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.

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

Sales of our oral insulin formulation in Ecuador, India, Algeria and Lebanon and our other potential pharmaceutical products in other markets will 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 pharmaceutical 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.

On July 23, 2008, we received notice from The NASDAQ Stock Market that we were not compliance with Marketplace Rule 4310(c)(4) (now known as Listing Rule 5550(a)(2)), which requires us to have a minimum bid price per share of at least $1.00 for thirty (30) consecutive business days. In accordance with this Rule, we had 180 calendar days, or until January 20, 2009, subject to extension, to regain compliance with this Rule.

On October 16, 2008, NASDAQ temporarily suspended enforcement of the minimum bid price requirement until January 19, 2009. On December 16, 2008, NASDAQ extended the temporary suspension of enforcement until April 20, 2009. On March 9, 2009, NASDAQ further extended the temporary suspension until July 20, 2009. On July 14, 2009, NASDAQ further extended the temporary suspension until July 31, 2009. With the extended suspension, we now have until November 6, 2009 to comply with the minimum bid price requirement. Therefore, if, at anytime prior to November 6, 2009, the bid price of our common stock closes at $1.00 per share or more for a minimum period of ten (10) consecutive business days, we will regain compliance with the Rule.

In the event that we cannot demonstrate compliance with the minimum bid price requirement by the specified deadline and are not eligible for an additional compliance period, the staff will notify us that our stock would be delisted, at which time we can appeal the staff’s determination to a Listing Qualifications Panel. Pending the decision of the Listing Qualification Panel, our common stock will continue to trade on the NASDAQ Capital Market. If we are 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:

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

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

Furthermore, the stock market generally and the market for stocks of companies with lower market capitalizations and small biopharmaceutical companies, like us, have from time to time experienced, and likely will again experience significant price and volume fluctuations that are unrelated to the operating performance of a particular company. During the third calendar quarter of 2008 and continuing to date, we, like many other publicly traded companies, have experienced a sharp decline in the price of our stock attributable to concerns about the current global recession. The widespread decline in stock prices led The NASDAQ Stock Market to further extend its temporary suspension of enforcement of the minimum bid price requirement until July 31, 2009.

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.

This offering will dilute current stockholders and could prevent the acquisition or sale of our business.

Sale of the shares of common stock, warrants to purchase shares of common stock and the placement agent warrants will dilute current stockholders. We are issuing up to 30,000,000 shares of our common stock to investors which represents approximately 12% of the shares of our common stock immediately prior to the sale of such securities. Additionally, approximately 23,789,736 shares of common stock are issuable upon the exercise of the outstanding warrants that we issued or re-priced in connection with the private placement that we entered into on March 31, 2008 (without regard to additional shares which may become issuable due to anti-dilution adjustments), approximately 8,844,926 shares of common stock are issuable upon the exercise of the warrants that we issued in

connection with the registered direct offering we completed on June 15, 2009, approximately 2,995,305 shares of common stock are issuable upon the exercise of the warrants we issued in connection with the registered direct offering we completed on August 6, 2009, and approximately 5,053,125 shares of common stock are issuable upon the exercise of the warrants we issued in connection with the registered direct offering we completed on September 14, 2009 which represents approximately 16% of the shares of common stock outstanding immediately prior to the transaction. Assuming that the holders of the outstanding warrants issued or re-priced in connection with the March 31, 2008 transaction and the holders of the warrants issued in connection with the June 15, 2009, August 6, 2009, and September 14, 2009 transactions and the holders of the warrants issued in connection with this transaction exercise all of the warrants into shares of common stock, the number of shares of issued and outstanding common stock will increase significantly, and current stockholders will own a smaller percentage of the outstanding common stock of the company. The issuance of shares of common stock pursuant to the warrants sold in this and prior equity financings will also have a dilutive effect on earnings per share and may adversely affect the market price of the common stock.

In addition, the issuance of the shares of common stock to the investors in this investment and the issuance of shares of common stock upon exercise of the warrants sold in this offering and the offerings that closed on June 15, 2009, August 6, 2009, and September 14, 2009 and sold or re-priced in our March 31, 2008 private placement could have an anti-takeover effect because such issuance will make it more difficult for, or discourage an attempt by, a party to obtain control of the Company by tender offer or other means. The issuance of common stock upon the exercise of the warrants will increase the number of shares entitled to vote, increase the number of votes required to approve a change of control of the Company, and dilute the interest of a party attempting to obtain control of the Company.

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

USE OF PROCEEDS

We currently intend to use the net proceeds from this offering for a variety of corporate uses, including pre-clinical and clinical studies of our proprietary platform buccal drug delivery technologies and our proprietary platform synthetic vaccine technologies, internal research and development programs, working capital, capital expenditures and other general corporate purposes.

At this time, we have not determined the approximate amount of net proceeds that will be allocated to each of the uses of proceeds stated above. In addition, we may use the net proceeds we receive from this offering for a variety of other corporate uses, including in-licenses or acquisitions of other products, technologies or companies, although we currently have no commitments or agreements for any such transactions. Our management will retain broad discretion as to the allocation of the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the proceeds in highly liquid, investment-grade securities and money market funds.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value of our common stock as of July 31, 2009 was approximately $10,521,356, or approximately $0.04 per share of common stock based upon 246,945,790 shares outstanding. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares outstanding as of October 13, 2009. While 30,000,000 shares are offered hereunder, our sales agreement with Wm Smith & Co. is limited to the sale of common stock with gross proceeds aggregating $20,000,000. Based on our closing price on October 13, 2009, the maximum number of shares we could sell is 27,397,260. Assuming 27,397,260 shares offered hereunder are sold and after giving effect to such sale, our as-adjusted net tangible book value would have been approximately $30,521,356 or approximately $0.11 per share of common stock based upon 274,343,050 shares outstanding. This represents an immediate increase in net tangible book value of $0.07 per share to our existing stockholders and an immediate dilution in net tangible book value of $0.66 per share to new investors. The following table illustrates this calculation on a per share basis:

Offering price for one share of common stock	$	0.73(1)
Net tangible book value per share as of July 31, 2009	$	0.04
Increase in net tangible book value per share attributable to the offering(2)	$	0.07
Adjusted net tangible book value per share after this offering(2)	$	0.11
Dilution in net tangible book value per share to new investors	$	0.66

(1) Assuming a purchase price of $0.73, the closing price of our common stock on October 13, 2009.

(2) While we are offering up to 30,000,000 shares hereunder, our sales agreement with Wm Smith & Co. is limited to the sale of common stock with gross proceeds aggregating $20,000,000. Based on the closing price of our common stock on October 13, 2009, the maximum number of shares we could sell is 27,397,260.

The foregoing table excludes the following, each stated as of October 13, 2009:

5,023,388 shares of our common stock issuable upon the exercise of exercisable stock options at a weighted average exercise price of $0.43 per share;

898,750 shares of our common stock issuable upon the exercise of outstanding stock options that are not exercisable;

42,937,132 shares of our common stock issuable upon the exercise of outstanding warrants at exercise prices ranging from $0.33 to $2.66; and

31,691,608 shares of our common stock reserved for future issuance under our stock plans.

DESCRIPTION OF SECURITIES

In this offering, we are offering a maximum of 30,000,000 shares of common stock.

Common Stock

The material terms and provisions of our common stock are described under the caption “Description of Our CapitalStock” starting on page 8 of the accompanying prospectus.

PLAN OF DISTRIBUTION

We have entered into a sales agreement, dated as of October 14, 2009, with Wm Smith & Co. ("Wm Smith"), under which we may sell an aggregate of $20,000,000 in gross proceeds of our common stock from time to time through Wm Smith, as our agent for the offer and sale of the common stock. Based on the trading price of our common stock, we may not be able to sell all 30,000,000 shares offered herein or we may not be able to raise the full $20,000,000 in gross proceeds permitted under the sales agreement. Wm Smith may sell the common stock by any method permitted by law, including sales deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on the NASDAQ Capital Market, on any other existing trading market for the common stock or to or through a market maker. Wm Smith may also sell the common stock in privately negotiated transactions, subject to our prior approval.

Each time that we wish to issue and sell common stock under the sales agreement, we will provide Wm Smith with a placement notice describing the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares of common stock that may be sold in any one day and any minimum price below which sales may not be made.

Upon receipt of a placement notice from us, and subject to the terms and conditions of the sales agreement, Wm Smith has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms. The settlement between us and Wm Smith of our common stock will occur on the third trading day following the date on which the sale was made. The obligation of Wm Smith under the sales agreement to sell our common stock pursuant to a placement notice is subject to a number of conditions.

We will pay Wm Smith a commission equal to no more than 3% of gross proceeds of the sales price of all common stock sold through it as sales agent under the sales agreement. Based on the closing price of our common stock on October 13, 2009, because our sales agreement with Wm Smith is limited to the sale of common stock with gross proceeds aggregating $20,000,000, the maximum number of shares we could sell is 27,397,260. If all 30,000,000 shares of common stock were sold at the October 13, 2009 closing sales price, we would receive $21,900,000 in gross proceeds, or $21,243,000 in aggregate net proceeds assuming the foregoing maximum sales agent fees. The actual proceeds to us will vary. Because there is no minimum offering amount required as a condition to the closing, the actual total may be less than the maximum amount set forth above.

In connection with the sale of our common stock contemplated in this prospectus supplement, Wm Smith may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended, and the compensation paid to Wm Smith may be deemed to be underwriting commissions or discounts. We have agreed to indemnify Wm Smith against certain civil liabilities, including liabilities under the Securities Act of 1933.

Sales of our common stock as contemplated in this prospectus supplement will be settled through the facilities of The Depository Trust Company or by such other means as we and Wm Smith may agree upon.

The offering of our common stock pursuant to the sales agreement will terminate on the earliest of (1) the sale of all of our common stock subject to the sales agreement, or (2) termination of the sales agreement by us or Wm Smith. Wm Smith may terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in Wm Smith's reasonable judgment, may impair its ability to sell the common stock, our failure to satisfy any condition under of the sales agreement or a suspension or limitation of trading of our common stock on NASDAQ. We may terminate the sales agreement at any time upon 10 days' prior notice, and Wm Smith may terminate the sales agreement at any time upon 10 days' prior notice.

This is a brief summary of the material provisions of the sales agreement and does not purport to be a complete statement of its terms and conditions. A copy of the sales agreement is filed with the SEC and incorporated by reference into the registration statement of which this prospectus supplement forms a part. See “Where You Can Find More Information” on page S-22.

LEGAL MATTERS

Certain legal matters with respect to the securities offered hereby have been passed upon by Eckert Seamans Cherin Mellott, LLC. Certain legal matters in connection with this offering will be passed upon for the sales agent by Holme Roberts & Owen LLP.

EXPERTS

The audited financial statements for the fiscal year ended July 31, 2009 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 supplement, the accompanying prospectus and elsewhere in the registration statement by reference to the Annual Report on Form 10-K for the year ended July 31, 2009 have been so incorporated in reliance on the report of MSCM LLP, an independent registered public accounting firm (successor to Danziger Hochman Partners, LLP), given on the authority of said firm as experts in auditing and accounting. The audited financial statements for the fiscal years ended July 31, 2007 and 2006 incorporated in this prospectus supplement, the accompanying prospectus and elsewhere in the registration statement by reference to the Annual Report on Form 10-K for the year ended July 31, 2009 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.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 and an amendment thereto with the SEC. This prospectus supplement and accompanying prospectus, which are a part of the registration statement, do not contain all of the information contained in the registration statement. Because some information is omitted, you should refer to the registration statement, as amended, and its exhibits for additional information. For example, the descriptions in this prospectus supplement and accompanying prospectus regarding the contents of any of our contracts, agreements or other documents, are not necessarily complete and you should refer to the exhibits attached to the registration statement or incorporated by reference for copies of the actual contract, agreement or other document. You may obtain a copy of the registration statement from the SEC at the address listed below or from the SEC's web site.

We are subject to the information and periodic reporting requirements of the Exchange Act, and in accordance therewith file periodic reports, current reports, proxy statements and other information with the SEC. Such periodic reports, current reports, proxy statements, other information and a copy of the registration statement on Form S-3 may be inspected by anyone without charge and copies of these materials may be obtained upon the payment of the fees prescribed by the SEC, at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The registration statement on Form S-3 and the periodic reports, current reports, proxy statements and other information filed by us are also available through the Internet web site maintained by the SEC at the following address: http://www.sec.gov.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus supplement the information we have filed with the SEC. The information we incorporate by reference into this prospectus supplement is an important part of this prospectus supplement. Any statement in a document we incorporate by reference into this prospectus supplement or the accompanying prospectus will be considered to be modified or superseded to the extent a statement contained in this prospectus supplement or any other subsequently filed document that is incorporated by reference into this prospectus supplement modifies or supersedes that statement. The modified or superseded statement will not be considered to be a part of this prospectus supplement or accompanying prospectus, as applicable, except as modified or superseded.

We incorporate by reference into this prospectus supplement the information contained in the documents listed below, which is considered to be a part of this prospectus supplement:

- Our Annual Report on Form 10-K filed with the Commission on October 14, 2009 , for the year ended July 31, 2009;

- The portions of our Definitive Proxy Statement on Schedule 14A that are deemed "filed" with the SEC under the Securities Exchange Act of 1934, as amended, filed on June 18, 2009;

- Our Current Reports on Form 8-K filed with the Commission on August 6, 2009, September 15, 2009, October 1, 2009 and October 14, 2009;

- The description of our common stock contained in our Registration Statement on Form S-3 (Registration No. 333-139637), as amended (the "Registration Statement"), filed under the Securities Act of 1933, as amended, with the Commission on January 12, 2007 and declared effective February 23, 2007;

- The description of our common stock contained in the Prospectus Supplement on Form 424(b)5, filed with the Commission on May 15, 2009;

- The description of our common stock contained in the Prospectus Supplement on Form 424(b)(5), filed with the Commission on June 15, 2009;

- The description of our common stock contained in the Prospectus Supplement on Form 424(b)(5), filed with the Commission on August 6, 2009; and

- The description of our common stock contained in the Prospectus Supplement on Form 424(b)(5), filed with the Commission on September 14, 2009.

We also incorporate by reference all documents filed pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and prior to the termination of this offering; provided, however, that we are not incorporating any information furnished under Item 2.02 or Item 7.01 of any current report on Form 8-K we may subsequently file.

Statements made in this prospectus supplement or the accompanying prospectus or in any document incorporated by reference in this prospectus supplement or the accompanying prospectus as to the contents of any contract or other document referred to herein or therein are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the documents incorporated by reference, each such statement being qualified in all material respects by such reference.

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 & General Counsel
33 Harbour Square, Suite 202
Toronto, Ontario
Canada M5J 2G2

(416) 364-2551

PROSPECTUS

GENEREX BIOTECHNOLOGY CORPORATION

$150,000,000

Common Stock
Preferred Stock
Warrants
Units

We may offer and sell, from time to time, shares of our common stock, preferred stock, warrants and/or units consisting of two or more of any such securities on terms to be determined at the time of sale. The preferred stock may be convertible into shares of our common stock and the warrants may be exercisable for shares of our common stock or shares of our preferred stock. We may offer these securities separately or together in one or more offerings with a maximum aggregate offering price of $150,000,000.

Specific terms of the securities being sold as well specific terms of these offerings will be provided in supplements to this prospectus. You should read this prospectus and any prospectus supplements, including any information incorporated herein or therein, carefully before you invest.

The securities being sold may be sold on a delayed basis or continuous basis directly by us, through dealers, agents or underwriters designated from time to time, or through any combination of these methods. If any dealers, agents or underwriters are involved in the sale of the securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in any prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in the applicable prospectus supplement.

Our common stock is listed on the NASDAQ Capital Market under the symbol "GNBT." The last sale price of our common stock on January 9, 2007, as reported by NASDAQ, was $1.68 per share. None of the other securities offered under this prospectus are publicly traded.

Investing in our common stock involves risks. See “Risk Factors” beginning on page 2 to read about the factors you should consider before investing.

This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for the securities being sold.

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

The date of this prospectus is January 12, 2007

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SUMMARY

The summary description of our business may not contain all information that may be important to you. You should read this entire prospectus and any accompanying prospectus supplement, including the information set forth “Risk Factors” and our financial statements and related notes, included or incorporated by reference in this prospectus or any prospectus supplement before making an investment decision.

References in this prospectus to “we,” “us,” “our,” “Generex” or the “company,” unless the context requires otherwise, refer to Generex Biotechnology Corporation.

Our Company

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

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

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

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

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

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.

Our principal offices are located at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2. Our telephone number is (416) 364-2551 and our Internet address is www.generex.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

About This Prospectus

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, or SEC, using the “shelf” registration process. By using a shelf registration statement, we may, from time to time, issue and sell in one or more series or classes our common stock, preferred stock and/or warrants in one or more offerings up to an aggregate maximum offering price of $150,000,000 (or its equivalent in foreign or composite currencies).

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering and the terms of the securities being sold. We will file each prospectus supplement with the SEC. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “Where You Can Find More Information” below.

You should rely only on the information contained or incorporated by reference in this prospectus and in any prospectus supplement. We have not authorized anyone to provide you with different information. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus and any prospectus supplement is accurate only as of the date of this prospectus or such prospectus supplement, and the information contained in any document incorporated herein or therein by reference is accurate only as the date of such document incorporated by reference, regardless of the time of delivery or any sale of our securities.

RISK FACTORS

An investment in our stock is very speculative and involves a high degree of risk. You should carefully consider the following important factors, as well as the other information in this prospectus, any accompanying prospectus supplement and the other reports that we have filed heretofore (and will file hereafter) with the SEC, before purchasing our stock. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations and financial results. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face described below.

2

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 quarterly period ending October 31, 2006, we have received nominal revenues from sales of our confectionary, Glucose RapidSpray™, and we expect to receive some revenue from the sale of our oral insulin product in Ecuador in the second quarter of fiscal 2007. To date, we have not been profitable and our accumulated net loss available to common shareholders was $192,153,357 at October 31, 2006. 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™ which is currently selling in Ecuador and Glucose RapidSpray™ which we began selling in the United States in October 2006, our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

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:

- to proceed with the development of our buccal insulin product;
- to finance the research and development of new products based on our buccal delivery and immunomedicine technologies, including clinical testing relating to new products;
- to finance the research and development activities of our subsidiary Antigen with respect to other potential technologies;
- to commercially launch and market developed products;
- to develop or acquire other technologies or other lines of business;
- to establish and expand our manufacturing capabilities;
- to finance general and administrative activities that are not related to specific products under development; and
- 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.

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

Our research and development and marketing efforts 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.

Risks Related to Our Technologies

With the exception of Generex Oral-lyn™ and Glucose RapidSpray™, 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™ and Glucose RapidSpray™. 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™, our proprietary oral insulin spray formulation, has been approved for commercial marketing and sale in Ecuador, and Glucose RapidSpray™, our confectionary product, will be available for purchase in the United States, we have yet to manufacture, market and distribute these products on a large-scale commercial basis. 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 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.

Only our oral insulin product has been approved for commercial sale by drug regulatory authorities, and that approval was obtained in Ecuador. We have begun the regulatory approval process for our oral insulin, buccal morphine and

fentanyl products in other countries. Our immunomedicine products are in the pre-clinical stage of development, with the exception of our Phase 1 trial in human patients with stage II HER-2/neu positive breast cancer.

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.

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 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, 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.

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Risks Related to Marketing of Our Potential Products

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

Even if we obtain regulatory approval to market our oral insulin product or any other prescription pharmaceutical product candidate in another country other than Ecuador, 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:

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

We will not receive significant revenues from Generex Oral-lyn™ in Ecuador or Glucose RapidSpray™ 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. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

In January, 2006, the FDA approved Pfizer, Inc.’s inhalable form of insulin, the first non-injected insulin to be approved by the FDA. Pfizer’s product in inhaled through the mouth and absorbed in the lungs. Initial supplies of this product, which is marketed as Exubera®, became available in the U.S. in September 2006. We understand that an expanded roll-out of Exubera® to primary-care physicians in the U.S., which Pfizer previously targeted for November 2006, will begin in January 2007. While we believe that absorption though the buccal cavity offers several advantages

over absorption through the lungs, Pfizer's early approval could allow it to capture a large portion of the market.

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:

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

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

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

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.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

- The inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- The risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- The inherent uncertainties associated with clinical trials of product candidates;
- The inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates; and
- The inherent uncertainties associated with commercialization of products that have received regulatory approval.

Additional factors that could affect future results are set forth above under the caption “Risk Factors”. We caution investors that the forward-looking statements contained in this prospectus must be interpreted and understood in light of conditions and circumstances that exist as of the date of this prospectus. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements made in this prospectus to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based. You are advised, however, to consult any further disclosures we make on related subjects in our 10-K, 10-Q and 8-K reports to the SEC.

USE OF PROCEEDS

Except as described in any prospectus supplement, we currently intend to use the net proceeds from this offering for general corporate purposes, including to continue the clinical trials of, and commercialization of, our oral insulin formulation, in the research and development of other products, and for general and administrative expenses. We may also issue the securities offered under this prospectus in connection with product license and supply agreements, research collaboration agreements and to our commercial vendors and suppliers in exchange for products and services.

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Each time we issue securities, we will provide a prospectus supplement that will contain information about how we intend to use the proceeds from each such offering.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment grade, interest-bearing securities. We cannot predict whether the proceeds invested will yield a favorable return. We have not yet determined the amount or timing of the expenditures for the categories listed above, and these expenditures may vary significantly depending on a variety of factors. As a result, we will retain broad discretion over the use of the net proceeds from this offering.

We cannot guarantee that we will receive any proceeds in connection with any offering hereunder because we may choose not to issue any of the securities covered by this prospectus.

DESCRIPTION OF OUR CAPITAL STOCK

Set forth below is a summary of the material terms of our capital stock. This summary is not complete. We encourage you to read our Restated Certificate of Incorporation (the "Certificate of Incorporation") and our By-Laws that we have previously filed with the SEC. See "Where You Can Find More Information."

General

Our authorized capital stock consists of: (i) 500,000,000 shares of common stock, par value $.001 per share, of which 108,157,688 shares were outstanding as of January 9, 2007 (ii) 1,000,000 shares of undesignated preferred stock, par value $.001 per share, and (iii) 1,000 shares of Special Voting Rights Preferred Stock outstanding.

Common Stock

Holders of common stock are entitled to one vote for each share owned of record on all matters on which shareholders may vote. Holders of common stock do not have cumulative voting rights in the election of directors. Therefore, the holders of more than 50% of the outstanding shares can elect the entire Board of Directors. The holders of common stock are entitled, upon liquidation or dissolution of the company, to receive pro rata all remaining assets available for distribution to stockholders after payment to any preferred shareholders who may have preferential rights. The common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption provisions. All outstanding shares of common stock are validly issued, fully paid, and nonassessable.

Special Voting Rights Preferred Stock

We have 1,000 shares of Special Voting Rights Preferred Stock outstanding. Dr. Pankaj Modi, our former director and Vice President, Research and Development, is the owner of all of these shares. The Special Voting Rights Preferred Stock is not convertible into shares of our common stock.

The Special Voting Rights Preferred Stock has the following special voting rights:

- The Special Voting Rights Preferred Stock has the right to elect a majority of our Board of Directors if a "Change of Control" (as specifically defined) occurs;

- The Special Voting Rights Preferred Stock has the right to approve any transaction that would result in a Change of Control; and

- The Special Voting Rights Preferred Stock has the right to vote whenever specifically required by Delaware law.

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The Special Voting Rights Preferred Stock is entitled to share in dividends paid on the common stock.

We have the right to redeem the Special Voting Rights Preferred Stock at any time for $.10 per share. We expect that the Board of Directors will take action in due course to redeem the Special Voting Rights Preferred Stock.

Undesignated Preferred Stock

Our Board of Directors has the authority to issue up to 1,000,000 shares of preferred stock in one or more series and fix the number of shares constituting any such series, the voting powers, designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof, including the dividend rights, dividend rate, terms of redemption (including sinking fund provisions), redemption price or prices, conversion rights and liquidation preferences of the shares constituting any series, without any further vote or action by the stockholders. For example, the Board of Directors is authorized to issue a series of preferred stock that would have the right to vote, separately or with any other series of preferred stock, on any proposed amendment to our Certificate of Incorporation or on any other proposed corporate action, including business combinations and other transactions.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to the offering of shares of that particular series of preferred and may include, among other things:

- the title and stated value;
- the number of shares authorized;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date, and method of calculation (including whether cumulative or non-cumulative);

- terms and amount of any sinking fund;
- provisions for redemption or repurchase, if applicable, and any restrictions on the ability of the company to exercise such redemption and repurchase rights;
- conversion rights and rates, if applicable, including the conversion price and how and when it will be calculated and adjusted;
- voting rights, if any;
- preemptive rights, if any;
- restrictions on sale, transfer and assignment, if any;
- the relative ranking and preferences of the preferred stock; and
- any other specific terms, rights or limitations of, or restrictions on, such preferred stock.

Anti-Takeover Provisions

We are not aware of any pending takeover attempt or interest in making such an attempt. Our Certificate of Incorporation and Bylaws contain certain provisions which may be deemed to be "anti-takeover" in that they may deter, discourage or make more difficult the assumption of control of Generex by another corporation or person through a tender offer, merger, proxy contest or similar transaction or series of transactions.

Special Voting Rights Preferred Stock: As indicated above, our outstanding Special Voting Rights Preferred Stock prevents a "Change of Control" of Generex without the consent of the holders of those shares. At the present time, all of these shares are owned by Dr. Modi, our former director and Vice President, Research and Development.

Authorized but Unissued Shares: The authorized but unissued shares of our common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the NASDAQ Stock Market. The Board of Directors may set the rights, preferences and terms of new preferred stock, without shareholder approval. Shares of preferred stock could be issued quickly without shareholder approval, with terms calculated to delay or prevent a change in control of Generex. Our stockholders do not have preemptive rights with respect to the purchase of these shares. Therefore, such issuance could result in a dilution of voting rights and book value per share of the common stock. No shares of preferred stock other than the Special Voting Rights Preferred Stock are currently outstanding, and we have no present plan to issue any preferred stock.

Advance Notice Requirements for Stockholder Proposals and Director Nominations: Our Bylaws provide that a stockholder seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors, must provide timely notice of such stockholder’s intention in writing. To be timely, a stockholder’s notice must be received not less than 60 days nor more than 90 days prior to the meeting at which such proposal or candidate is to be considered. However, if the company does not give prior notice or make public disclosure of the date of the meeting at least 70 days prior to the meeting date, notice by the stockholder is considered timely if it is received no later than the close of business on the 10th day following the day on which such notice was mailed or public disclosure was made. If a stockholder desires to have a proposal included in the company’s proxy statement, notice of such proposal must be received not less than 120 days prior to the first anniversary of the date of the company’s notice of the previous year’s annual meeting. These advance notice provisions may preclude stockholders from bringing matters before a meeting or from making nominations for directors.

Special Meetings of Stockholders: Our Bylaws provide that special meetings of stockholders may be called only by the Board of Directors, the Chairman of the Board or the President, and may be called by the Board upon the request of the holders of a majority of the outstanding shares of stock of the company entitled to vote at the meeting. Further, business transacted at any special meeting of stockholders is limited to matters relating to the purpose or purposes stated in the notice of meeting.

General Effect of Anti-Takeover Provisions: The overall effect of these provisions may be to deter a future tender offer or other takeover attempt that some stockholders might view to be in their best interests at that time. In addition, these provisions may have the effect of assisting our current management in retaining its position and place it in a better position to resist changes which some stockholders may want to make if dissatisfied with the conduct of our business.

Stockholder Rights Plan

At our annual meeting on May 30, 2006, our stockholders approved the adoption of a stockholder rights plan that will allow our Board of Directors to declare a dividend of one share purchase right for each outstanding share of our common stock. Our Board of Directors has considered adoption of this plan but has not yet approved its adoption. We expect that any stockholder rights plan adopted by our Board will contain terms substantially as described below:

The terms of the rights plan will provide for a dividend distribution of one preferred share purchase right, which we refer to as a “Right,” for each outstanding share of our common stock. The dividend will be payable on a date established by the Board to the stockholders of record on that date. Each Right will entitle the registered holder to purchase from Generex one one-hundredth of a share of preferred stock (each a “Preferred Share” and, collectively, the “Preferred Shares”) at a price of $.01 per one one-hundredth of a share of preferred stock, subject to certain adjustments. Each Preferred Share will have designations and powers, preferences and rights, and the qualifications, limitations and restrictions which make its value approximately equal to the value of one share of our common stock.

The Rights will not be exercisable until the earlier to occur of:

(i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of our outstanding shares of common stock, which we refer to as an "Acquiring Person", or

(ii) 10 business days (or such later date as may be determined by action of the Board of Directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date").

Until the Distribution Date, the Rights will be transferable with and only with shares of our common stock. The Rights will expire ten years after adoption of the stockholders rights plan unless the Rights are earlier redeemed or exchanged by Generex.

Preferred Shares purchasable upon exercise of the Rights will not be redeemable. Each Preferred Share will be entitled to a minimum preferential quarterly dividend payment of $1.00 but will be entitled to an aggregate dividend of 100 times the dividend declared per share of common stock. In the event of liquidation, the holders of the Preferred Shares would be entitled to a minimum preferential liquidation payment of $100 per share, but would be entitled to receive an aggregate payment equal to 100 times the payment made per share of common stock. Each Preferred Share will have 100 votes, voting together with the common stock. Finally, in the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, each Preferred Share will be entitled to receive 100 times the amount of consideration received per share of common stock. These rights will be protected by customary anti-dilution provisions. Because of the nature of the Preferred Shares' dividend and liquidation rights, the value of one one-hundredth of a Preferred Share should approximate the value of one share of common stock. The Preferred Shares would rank junior to any other series of our preferred stock.

In the event that any person or group of affiliated or associated persons becomes an Acquiring Person, proper provision will be made so that each holder of a Right, other than Rights beneficially owned by the Acquiring Person and its associates and affiliates (which will thereafter be void), will for a 60-day period have the right to receive upon exercise that number of shares of Preferred Stock having a market value of two times the exercise price of the Right (or, if such number of shares is not and cannot be authorized, Generex may issue Preferred Shares, cash, debt, stock or a combination thereof in exchange for the Rights). This right will terminate 60 days after the date on which the Rights become nonredeemable (as described below), unless there is an injunction or similar obstacle to exercise of the Rights, in which event this right will terminate 60 days after the date on which the Rights again become exercisable.

The rights plan will contain certain exceptions to the characterization of a person or group as an "Acquiring Person." That term shall not be deemed to include:

· Generex,

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- a subsidiary of Generex,
- any employee benefit or compensation plan of Generex,
- any entity holding shares of common stock for or pursuant to the terms of any such employee benefit or compensation plan or
- any officer, director or current 5% holder as of the date the rights plan is implemented.

The right plan may also except certain institutional shareholders from the definition of "Acquiring Person." In addition, except under limited circumstances, no person or entity shall become an Acquiring Person as the result of the acquisition of shares of common stock by Generex which, by reducing the number of shares outstanding, increases the proportionate number of shares beneficially owned by such person or entity to 20% or more of the shares of common stock then outstanding.

The stockholders rights plan may also contain what is commonly known as a "flip-over" provision. In the event that Generex is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold to an Acquiring Person, its associates or affiliates or certain other persons in which such persons have an interest, the plan will require that proper provision be made so that each holder of a Right will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right.

At any time after an Acquiring Person becomes an Acquiring Person and prior to the acquisition by such Acquiring Person of 50% or more of the outstanding shares of Generex's common stock, our Board of Directors may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of common stock, or one one-hundredth of a Preferred Share, per Right (or, at our election, Generex may issue cash, debt, stock or a combination thereof in exchange for the Rights), subject to adjustment.

At any time prior to the earliest of (i) the day of the first public announcement that a person has become an Acquiring Person or (ii) the final expiration date of the rights, our Board of Directors may redeem the Rights in whole, but not in part, at a price of $.001 per Right. Following the expiration of the above periods, the Rights become nonredeemable. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the redemption price.

The Rights would have certain anti-takeover effects. The Rights would cause substantial dilution to a person or group that attempts to acquire Generex on terms not approved by our Board of Directors. The Rights should not interfere with any merger or other business combination approved by our Board of Directors since the Rights could be amended to permit such acquisition or redeemed by us at $.001 per Right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our shares of common stock or (ii) the final expiration date of the rights.

Dividend Policy

Holders of our common stock are entitled to receive such dividends as the Board of Directors may from time to time declare. The Board may declare dividends only when dividends are legally available. Under the Delaware General Corporation Law, the Board may only declare dividends out of our capital surplus (generally the amount of its paid-in capital above the par value of the outstanding stock) or out of net profits for the fiscal year with respect to which the

dividends are paid. Holders of our Special Voting Rights Preferred Stock are entitled to receive a dividend per share equal to the dividends paid on share of common stock when and if such dividends are declared and paid. We have never paid any dividends on our common stock and do not anticipate paying dividends in the foreseeable future.

Transfer Agent

StockTrans, Inc., 44 West Lancaster Avenue, Ardmore, PA 19003, is the transfer agent and registrar for our common stock.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "GNBT."

DESCRIPTION OF OUR WARRANTS

This description summarizes only the terms of any warrants that we may offer under this prospectus and related warrant agreements and is not complete. You should refer to the warrant agreement, including the form of the warrant, relating to the specific warrants being offered for complete terms, which will be described and included in an accompanying prospectus supplement. Such warrant agreement, together with the form of the warrant, will be filed with the SEC in connection with the offering of the specific warrants.

We may issue warrants for the purchase of common or preferred stock. Warrants may be issued independently or together with common or preferred stock, and may be attached to or separate from any offered securities.

We will issue each series of warrants under a separate warrant agreement. We may enter into the warrant agreement with a warrant agent and, if so, we will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to the particular series of warrants.

The particular terms of any issue of warrants will be described in the prospectus supplement relating to the series. Those terms may include:

- The title of such warrants;
- The aggregate number of such warrants;
- The price or prices at which such warrants will be issued;
- The currency or currencies (including composite currencies) in which the price of such warrants may be payable;
- the terms of the securities issuable upon exercise of such warrants and the procedures and conditions relating to the exercise of such warrants;
- The price at which the securities issuable upon exercise of such warrants may be acquired;
- The dates on which the right to exercise such warrants will commence and expire;
- any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;
- if applicable, the minimum or maximum amount of such warrants that may be exercised at any one time;

- if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security or principal amount of such security;

- if applicable, the date on and after which such warrants and the related securities will be separately transferable;

- if applicable, the redemption or call provisions of such warrants;

- information with respect to book-entry procedures, if any; and

- any other terms of such warrants, including terms, procedures and limitations relating to the exchange or exercise of such warrants.

The prospectus supplement relating to any warrants to purchase equity securities may also include, if applicable, a discussion of certain U.S. federal income tax and ERISA considerations.

Exercise of Warrants

Each warrant will entitle its holder to purchase the number of shares of common or preferred stock at the exercise price set forth in, or calculable as set forth in, the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void. We will specify the place or places where, and the manner in which, warrants may be exercised in the applicable prospectus supplement. We will set forth on the reverse side of the applicable certificate (or in the form of exercise notice attached to each warrant) and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver upon exercise.

Upon receipt of payment and the warrant properly completed and duly executed, we will, as soon as practicable, forward the purchased securities. If less than all of the warrants represented by the warrant are exercised, a new warrant will be issued for the remaining warrants.

Enforceability of Rights by Holders of Warrants

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, such holder’s warrants.

Prior to the exercise of any warrants to purchase preferred stock or common stock, holders of the warrants will not have any of the rights of holders of the preferred stock or common stock purchasable upon exercise, including the right to vote or to receive any payments of dividends.

DESCRIPTION OF OUR UNITS

We may issue units comprised of two or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The units will be issued

under units agreements, and we may enter into such unit agreements with a bank or trust company, as unit agent, as detailed in the prospectus supplement relating to units being offered.

The prospectus supplement will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances the securities comprising the units may be held or transferred separately;
- a description of the terms of any unit agreement governing the units;
- a description of the provisions for the payment, settlement, transfer or exchange of the units;
- a discussion of material U.S. federal income tax considerations, if applicable; and
- whether the units will be issued in fully registered or global form.

The descriptions of the units in this prospectus and in any prospectus supplement are summaries of the material provisions of the applicable agreements. These descriptions do not restate those agreements in their entirety and may not contain all the information that you may find useful. We urge you to read the applicable agreements because they, and not the summaries, define your rights as holders of the units. For more information, please review the form of the relevant agreements, which will be filed with the SEC promptly after the offering of units and will be available as described under the heading “Where You Can Find Additional Information”.

PLAN OF DISTRIBUTION

We may sell any of the securities being offered pursuant to this prospectus from time to time in one or more of the following ways:

- directly to purchasers;
- to or through underwriters;
- through dealers or agents;
- in privately negotiated transactions; or
- through a combination of methods.

We may distribute the securities from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices. We may also determine the price or other terms of the securities offered under this prospectus by use of an electronic auction.

The prospectus supplement with respect to the securities being offered will set forth the terms of the offering, including:

- the names of the underwriters, dealers or agents, if any,
- the terms of the securities being offered, including the purchase price of the securities and the net proceeds to us,
- any underwriting discounts and other items constituting underwriters’ compensation,

· any over-allotment options under which underwriters may purchase additional securities from us, and

· any discounts or concessions allowed or reallowed or paid to dealers and any securities exchanges on which the securities may be listed.

Also, if applicable, we will describe in the prospectus supplement how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations with respect to the auction.

We have not entered into any agreements, understandings or arrangements with any underwriters, broker-dealers or other parties regarding the sale of securities. As of the date of this prospectus, there were no special selling arrangements between any broker-dealer or other person and the company. No period of time has been fixed within which the securities will be offered or sold.

If required under applicable state securities laws, we will sell the securities only through registered or licensed brokers or dealers. In addition, in some states, we may not sell securities unless they have been registered or qualified for sale in the applicable state or unless we have complied with an exemption from any registration or qualification requirements.

If underwriters are used in an offering, we will sign an underwriting agreement with the underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

If dealers are used in an offering, we will sell the securities to the dealers as principals. The dealers then may resell the securities to the public at varying prices which they determine at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

The securities may be sold directly by us or through agents we designate. If agents are used in an offering, the names of the agents and the terms of the agency will be specified in a prospectus supplement. Unless otherwise indicated in a prospectus supplement, the agents will act on a best-efforts basis for the period of their appointment.

Dealers and agents named in a prospectus supplement may be deemed to be underwriters (within the meaning of the Securities Act of 1933, as amended, or the Securities Act) of the securities described therein.

We may sell securities directly to one or more purchasers, in which case underwriters or agents would not be involved in the transaction. In addition, we may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any resales thereof.

Further, we may authorize agents, underwriters or dealers to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in an applicable prospectus supplement.

Underwriters, dealers and agents may be entitled to indemnification by us against specific civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which the underwriters or agents may be required to make in respect thereof, under underwriting or other agreements. Certain underwriters, dealers or agents and their associates may engage in transactions with, and perform services for us in the ordinary course of business.

Any underwriter may engage in over-allotment transactions, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. We make no representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of the securities. For a description of these activities, see the information under the heading "Underwriting" in the applicable prospectus supplement.

Any common stock sold pursuant to a prospectus supplement will be eligible for listing and trading on the NASDAQ Capital Market, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

LEGAL MATTERS

The validity of the issuance of the securities offered in this prospectus will be passed upon for us by Eckert Seamans Cherin & Mellott, LLC, 1515 Market Street, 9th 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.

Any underwriters will also be advised about legal matters by their own counsel, which will be named in the prospectus supplement.

EXPERTS

The audited financial statements for the fiscal year ended 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 by reference to the Annual Report on Form 10-K for the year ended July 31, 2006 have been so incorporated in reliance on the report of Danziger & Hochman, Chartered Accountants, 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 years ended July 31, 2005 and 2004 incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended July 31, 2006 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 file reports, proxy statements and other documents with the SEC. You may read any copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site at www.sec.gov, from which you can electronically access our SEC filings.

You should rely only on the information contained or incorporated by reference in this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with information different from

that contained in this prospectus. The securities offered under this prospectus are offered only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of this Prospectus or any sale of the securities.

This prospectus constitutes a part of a Registration Statement we filed with the Commission under the Securities Act. This prospectus does not contain all of the information set forth in the Registration Statement, certain parts of which are omitted in accordance with the rules and regulations of the Commission. For further information with respect to the company and our securities, reference is hereby made to the Registration Statement. The Registration Statement may be inspected at the public reference facilities maintained by the Commission at the addresses set forth in the preceding paragraph. Statements contained herein concerning any document filed as an exhibit are not necessarily complete, and, in each instance, reference is made to the copy of such document filed as an exhibit to the Registration Statement. Each such statement is qualified in its entirety by such reference.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information contained in documents that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus and any prospectus supplement. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede this information. The following documents have been filed by us with the SEC and are incorporated herein by reference:

- Our Annual Report on Form 10-K for the fiscal year ended July 31, 2006;
- Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended July 31, 2006;
- Our Quarterly Report on Form 10-Q for the quarter ended October 31, 2006;
- Our Current Report on Form 8-K filed on September 14, 2006; 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 subsequently filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), prior to the termination of the 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, 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

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