GENEREX BIOTECHNOLOGY CORP
Form 424B5
June 15, 2009

424B5

PROSPECTUS SUPPLEMENT
(To Prospectus dated January 12, 2007)

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

17,200,000 Shares of Common Stock
Warrants for the purchase of up to 8,600,000 Shares of Common Stock
Placement Agent Warrants for the Purchase of up to 1,290,000 Shares of Common Stock

GENEREX BIOTECHNOLOGY CORPORATION

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering up to 17,200,000 shares of our common stock ("Shares") and warrants to purchase up to 8,600,000 shares of our common stock ("Warrants") (and the shares of common stock issuable from time to time upon exercise of the Warrants) to investors (collectively, the "Securities"). The Warrants have an initial exercise price of $0.76 per share are exercisable for a period of five years commencing 183 days after their issue date. The securities offered hereby initially will be issued as units, with each unit comprising one common share and a Warrant to purchase one-half of one share of our common stock, but will not trade as units. The units will be sold at a negotiated price of $0.6389 per share. As compensation for its services in connection with this offering we will be issuing the placement agent a warrant to purchase up to 1,290,000 shares of our common stock at a price of $0.76 per share ("Placement Agent Warrant"). In addition to the Shares, the Warrants, and the Placement Agent Warrant, we are also registering the shares of common stock underlying the Warrants, and the Placement Agent Warrant.

Neither the Warrants nor the Placement Agent Warrant will be listed on any national securities exchange. Our common stock is quoted on the NASDAQ Capital Market under the symbol "GNBT." On June 12, 2009, the last reported sale price of our common stock on the NASDAQ Capital Market was $0.76 per share. As of June 12, 2009, the number of outstanding voting and non-voting common shares held by non-affiliates was 178,492,689. The aggregate market value of our outstanding voting and non-voting common equity computed by reference using the last reported sale of such common equity held by non-affiliates, as of June 12, 2009, was $135,654,444. The aggregate market value of all securities offered pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on, and includes, the date of this prospectus is $15,989,080 consisting of 32,351,515 Shares.

Investing in our securities involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our common stock under the heading "Risk factors" of this prospectus supplement.

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

We have retained Midtown Partners & Co., LLC to act as our placement agent in connection with this offering. We have agreed to pay the placement agent the cash fees set forth in the table below (subject to certain exceptions), which assumes that we sell all of the Shares we are offering. Additionally, we have agreed to issue the placement agent a Placement Agent Warrant equal to 5% of the Shares sold and the shares of common stock issuable upon exercise of the Warrants sold (subject to certain exceptions). The terms of the Placement Agent Warrant are described under the section of this prospectus supplement entitled "Description of Securities." We have also agreed to reimburse the placement agents for certain of its expenses as described under "Plan of Distribution" in this prospectus supplement. The placement agent is not required to arrange for the sale of any specific number of Securities or dollar amount but will

use best efforts to arrange for the sale of all of the Securities. The placement agent is also the holder of a warrant issued prior to the date hereof as compensation for advisory services rendered to us and unrelated to this offering pursuant to which the placement agent may acquire up to 450,000 shares of our common stock at $0.33 per share (the "Midtown Warrant"). Neither the Midtown Warrant nor the shares of our common stock issuable thereunder are offered hereunder.

	Per share	Maximum Offering Amount
Offering price	$0.6389	$ 10,989,080
Placement agent fees (maximum) (1)	$	$ 439,563
Proceeds, before expenses, to us (maximum) (2)	$	$ 10,549,517

(1) The placement agent fees shown are the maximum cash fees payable by the Company to the placement agent (not including expense reimbursement). We have agreed to pay the placement agent a placement agent cash fee equal to: (i) 2.0% of the gross proceeds of this offering (which will not include any monies received by us in respect of the exercise of the Warrants) other than proceeds received from certain specified prospective investors and other than proceeds received from the former holders of the Company's 8% senior secured convertible promissory notes issued on March 31, 2008 (in respect of which no compensation will be due and payable other than expense reimbursement); and (ii) 4.0% of the gross proceeds of this offering from those certain specified investors (which will not include any monies received by us in respect of the exercise of the Warrants).

(2) The proceeds shown exclude proceeds that we may receive upon exercise of the Warrants or the Placement Agent Warrant or the Midtown Warrant.

We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately $100,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount, the placement agent fees and proceeds to us, if any, in this offering may be substantially less than the maximum offering amounts set forth above.

The date of this prospectus supplement is June 15, 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.

TABLE OF CONTENTS

Prospectus supplement

We are offering to sell, and seeking offers to buy, shares of our common stock and warrants only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock and warrants in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and warrants and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

ABOUT THIS PROSPECTUS

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the shares of our common stock and other securities we may offer from time to time under our shelf registration statement, some of which may not apply to the securities offered by this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying base prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and contained or incorporated by reference in the accompanying prospectus. We have not authorized anyone, including the placement agent, and the placement agent has not authorized anyone, to provide you with different information. We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The information contained or incorporated by reference in this prospectus supplement and contained, or incorporated by reference in the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus, or of any sale of our securities offered hereby. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents we have referred you to in "Incorporation of Certain Information by Reference" in this prospectus supplement and "Where You Can Find More Information" in the accompanying prospectus.

Unless otherwise indicated, "Generex" the "Company," "we," "us," "our" and similar terms refer to Generex Biotechnolo Corporation.

This offering of common stock is being made under a registration statement on Form S-3, as amended by Pre-Effective Amendment No. 1 thereto (Registration File no. 333-139637) that we filed with the Securities and Exchange Commission as part of a "shelf" registration process, as supplemented by the filing of the Prospectus Supplement on Form 424(b)5, filed on May 15, 2009. Under the shelf registration process, we may offer to sell shares of our common stock, $0.001 par value, shares of our preferred stock, $0.001 par value, warrants to purchase shares of our common stock and/or preferred stock, and/or units consisting of two or more of any such securities from time to time in one or more offerings up to a total dollar amount of $150,000,000.

We are not making any representation to you regarding the legality of an investment in the common stock and warrants by you under applicable law. You should consult with your own legal advisors as to the legal, tax, business, financial and related aspect of a purchase of the common stock and warrants.

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 347 patients have been enrolled in 74 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 was available for sale since January 2009, and an estimated 50 dialectologists are currently prescribing Oral Recosulin in India.

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 in spring of 2009.

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, 2008, we have received only limited revenues from operations. In the fiscal year ended July 31, 2008, we received approximately $128,039 in revenues from sales of Glucose RapidSpray™. In the fiscal quarter ended April 30, 2009, we received approximately $45,251 in revenues from sales of Glucose RapidSpray™. These numbers do not reflect deferred sales to the customers during the respective period 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 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.

- 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 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

Common stock we are offering	17,200,000 shares
Common stock to be outstanding after this offering(1)	206,375,778
Warrants offered by us	Warrants to purchase up to 8,600,000 shares of our common stock. Each Warrant has an exercise price of $0.76 per share, and is exercisable for a period of 5 years commencing 183 days after its issue date. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the Warrants.
Placement Agent Warrant	A warrant to purchase up to 1,290,000 shares of our common stock will be issued to the placement agent as compensation for its services in connection with this offering. The Placement Agent Warrant has an exercise price of $0.76 per share, and is exercisable for a period of 5 years commencing 183 days after its issue date. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the Placement Agent Warrant.(2)
Use of proceeds	Repayment of debt and/or general corporate purposes.
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 189,175,778 shares outstanding as of June 12, 2009 and assumes the sale of all Shares.

(2) The placement agent is also the holder of a warrant issued prior to the date hereof as compensation for advisory services rendered to us and unrelated to this offering pursuant to which the placement agent may acquire up to 450,000 shares of our common stock at $0.33 per share. Neither that warrant nor the shares of common stock issuable thereunder are offered hereunder.

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 nine months ended April 30, 2009, we received modest revenues from sales of Glucose RapidSpray™ . We did not recognize any revenue from the sale of our oral insulin product in Ecuador or India in fiscal 2008. 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 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 $283,591,400 at April 30, 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 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 2009. 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 and India 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, and, on March 9, 2009, NASDAQ further extended the temporary suspension until July 20, 2009. With the extended suspension, we now have until October 26, 2009 to comply with the minimum bid price requirement. Therefore, if, at anytime prior to October 26, 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 20, 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 warrant will dilute current stockholders. We are issuing up to 17,200,000 shares of our common stock and warrants to purchase up to 8,600,000 shares of our common stock to investors, plus the placement agent warrant to purchase up to 1,290,000 shares of our common stock, which, in the aggregate, represent approximately 14.32% of the shares of our common stock immediately prior to the sale of such securities.. Additionally, approximately 46,515,115 shares of common stock are issuable upon the exercise of the 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), which represents approximately 24.59% of the shares of common stock outstanding immediately prior to the transaction. Assuming that the holders of the warrants issued or re-priced in connection with the March 31, 2008 transaction 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 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 estimate that the net proceeds from the sale of the 17,200,000 Shares and the Warrants will be approximately $10,549,517, assuming that we sell the maximum number of Shares and Warrants we are offering pursuant to this prospectus supplement. Because of the difference between the minimum offering amount required as a condition to the closing of this offering, and the maximum amount of the offering, it is difficult to estimate the actual number of Shares sold and net proceeds to us and may be substantially less than the amount set forth above.

We intend to use the net proceeds from this offering for repayment of debt and/or 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.

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.

S-14

DETERMINATION OF OFFERING PRICE

We established the price following negotiations with prospective investors and with reference to the prevailing market price of our common stock, recent trends in such price, daily average trading volume of our common stock, our current stage of development, future capital needs and other factors.

DIVIDEND POLICY

We have not paid dividends on our common stock in the past and have no present intention of paying dividends in the foreseeable future.

DILUTION

If you invest in our common stock, you will experience dilution to the extent of the difference between the price per share you pay in this offering and the net book value per share of our common stock immediately after this offering.

Our net book value as of April 30, 2009 was approximately $2,265,222, or $0.01 per share of common stock. Net book value per share is equal to our total assets minus total liabilities, all divided by the number of shares of common stock outstanding as of June 12, 2009. Assuming we sell 17,200,000 shares of common stock, the maximum number of shares we are offering pursuant to this prospectus supplement, at an offering price of $0.6389 per share, and after deducting our estimated offering expenses payable by us, our as adjusted net book value would have been approximately $12,814,739, or approximately $0.06 per share of common stock, as of June 12, 2009. This represents an immediate increase in net book value of approximately $0.05 per share to existing stockholders and an immediate dilution of approximately $0.58 per share to new investors. The following table illustrates this calculation on a per share basis:

Offering price for one share of common stock	$	0.6389
Book value per share as of April 30,2009	$	0.01
Increase per share attributable to the offering	$	0.05
Adjusted net book value per share after this offering	$	0.06
Dilution per share to new investors		0.58

Because there is no minimum offering amount required as a condition to the closing of this offering, the dilution per share to new investors may be more than that indicated above in the event that the actual number of Shares sold, if any, is less than the maximum number of Shares we are offering.

The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options or warrants to purchase our common stock. The exercise of outstanding options and warrants having an exercise price less than the offering price will increase dilution to new investors.

DESCRIPTION OF SECURITIES

In this offering, we are offering a maximum of 17,200,000 units, consisting of 17,200,000 shares of common stock and warrants to purchase up to 8,600,000 shares of common stock. Each unit consists of one share of common stock and warrants to purchase one-half of one share of common stock at an exercise price of $0.76 per share. We are also issuing a warrant to purchase up to 1,290,000 shares of common stock as compensation to the placement agent for its services in connection with this offering. Prior to the date hereof, we issued to the placement agent a warrant to purchase up to 450,000 shares of common stock as compensation to the placement agent for advisory services provided to us unrelated to this offering. This prospectus supplement also relates to the offering of shares of our

common stock upon the exercise, if any, of the warrants issued in this offering.

Common Stock

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

Warrants

The material terms and provisions of the Warrants being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. This summary is subject to, and qualified in its entirety by, the form of Warrant, which will be provided to the investors in this offering and will be filed as an exhibit to a Current Report on Form 8-K.

The Warrants will provide for an exercise price of $0.76 per share and will be exercisable at the option of the holder for a period of five years commencing 183 days after the issue date of the Warrants. The exercise price of the warrants will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The holder will not have the right to exercise any portion of the Warrant if the holder, together with its affiliates, would, subject to limited exceptions, beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after the exercise. The holder may elect to change this beneficial ownership limitation from 4.99% to 9.99% of the number of shares of our common stock outstanding immediately after the exercise upon 61 days' prior written notice to us.

The Warrant holders must surrender payment in cash of the exercise price of the shares being acquired upon exercise of the Warrants. If, however, we are unable to offer and sell the shares underlying these Warrants pursuant to this prospectus supplement due to the ineffectiveness of the registration statement of which this prospectus supplement is a part, then the Warrants may be exercised on a "net" or "cashless" basis.

Placement Agent Warrant

The material terms and provisions of the Placement Agent Warrant being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. This summary is subject to, and qualified in its entirety by, the form of Placement Agent Warrant, which will be provided to the investors in this offering and will be filed as an exhibit to a Current Report on Form 8-K.

The Placement Agent Warrant will provide for an exercise price of $0.76 per share and will be exercisable at the option of the holder for a period of five years commencing 183 days after the issue date of the Placement Agent Warrant.

The exercise price of the Placement Agent Warrant will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would, subject to limited exceptions, beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after the exercise. The holder may elect to change this beneficial ownership limitation from 4.99% to 9.99% of the number of shares of our common stock outstanding immediately after the exercise upon 61 days' prior written notice to us.

The holder must surrender payment in cash of the exercise price of the shares being acquired upon exercise of the Placement Agent Warrant. The Placement Agent Warrant may be exercised on a "net" or "cashless" basis.

The Placement Agent Warrant shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the public offering, except as provided by FINRA Rules.

PLAN OF DISTRIBUTION

Pursuant to a letter agreement between us and Midtown Partners & Co., LLC (“Midtown”) we have engaged Midtown as our placement agent in connection with this offering. The placement agent is not purchasing or selling any of the Securities we are offering, and they are not required to arrange the purchase or sale of any specific number of Securities or dollar amount, but they have agreed to use best efforts to arrange for the sale of the Securities.

The terms of any such offering will be subject to market conditions and private negotiations between us and prospective purchasers, including investors holding pre-existing participation rights. The placement agency agreement does not give rise to any commitment by the placement agent to purchase any of our Securities, and the placement agent will have no authority to bind us by virtue of the placement agency agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering.

We will enter into securities purchase agreements directly with the purchasers in connection with this offering, and we will only sell to purchasers who have entered into securities purchase agreements.

We will deliver the Securities being issued to the purchasers upon receipt of purchaser funds for the purchase of the Shares offered pursuant to this prospectus supplement. We expect to deliver the Securities being offered pursuant to this prospectus supplement on June 15, 2009.

We have agreed to pay Midtown a placement agent fee equal to: (i) a cash fee equal to 2.0% of the gross proceeds of this offering (which will not include any monies received by us in respect of the exercise of the Warrants) other than proceeds received from certain specified prospective investors and other than proceeds received from the former holders of the Company's 8% senior secured convertible promissory notes issued on March 31, 2008 (in respect of which no compensation will be due and payable other than expense reimbursement); (ii) a cash fee equal to 4.0% of the gross proceeds of this offering from those certain specified investors (which will not include any monies received by us in respect of the exercise of the Warrants); and (ii) a Placement Agent Warrant equal to 5.0% of the number of Shares sold in this offering (other than Shares sold to the former holders of the Company's 8% senior secured convertible promissory notes issued on March 31, 2008) plus the number of shares of common stock issuable upon exercise of the Warrants sold in this offering (other than Warrants sold to the former holders of the Company's 8% senior secured convertible promissory notes issued on March 31, 2008). The Placement Agent Warrant has an exercise price equal to $0.76, will be exercisable at the option of the holder for a period of five years commencing 183 days after the issue date of the Placement Agent Warrant, and will otherwise comply with the rules of the Financial Industry Regulatory Authority, or FINRA.

In compliance with the guidelines of FINRA, the maximum consideration or discount to be received by the placement agent or any other FINRA member may not exceed 8% of the gross proceeds to us in this offering or any other offering in the United States.

The placement agency agreement with Midtown will be included as an exhibit to a Current Report on Form 8-K that we will file with the SEC and that will be incorporated by reference into the registration statement.

We may also reimburse the placement agent for certain fees and legal expenses reasonably incurred in connection with this offering. The estimated offering expenses payable by us, in addition to the placement agent fees, are approximately $100,000, which includes legal, accounting and printing costs and various other fees associated with registering and listing the common stock. After deducting certain fees due to the placement agent and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $10,549,517.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed on by Sichenzia Ross Friedman Ference LLP, 61 Broadway, 32nd Floor, New York, NY 10006. Members of the firm own additional shares (less than one percent in total) that they purchased from time to time for cash, either from us or in the public market.

EXPERTS

The audited financial statements for the fiscal year ended July 31, 2008 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, 2008 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, 2008 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:

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Our Annual Report on Form 10-K filed with the Commission on October 10, 2008 , for the year ended July 31, 2008;

- Amendment No. 1 to our Annual Report, for the year ended July 31, 2008, on Form 10-K/A filed with the Commission on November 26, 2008;

- Our Quarterly Report on Form 10-Q for the quarter ended October 31, 2008, filed with the Commission on December 9, 2009;

- Our Quarterly Report on Form 10-Q for the quarter ended January 31, 2009 filed with the Commission on March 11, 2009;

- Our Quarterly Report on Form 10-Q for the quarter ended April 30, 2009 filed with the Commission on June 9, 2009;
- Our Current Report on Form 8-K filed with the Commission on August 1, 2008;
- Our Current Report on Form 8-K filed with the Commission on August 25, 2008;
- Our Current Report on Form 8-K filed with the Commission on September 10, 2008;
- Our Current Report on Form 8-K/A filed with the Commission on September 19, 2008;
- Our Current Report on Form 8-K filed with the Commission on September 25, 2008;
- Our Current Report on Form 8-K filed with the Commission on December 23, 2008;
- Our Current Report on Form 8-K filed with the Commission on February 17, 2009;
- Our Current Report on Form 8-K filed with the Commission on March 2, 2009;
- Our Current Report on Form 8-K filed with the Commission on March 20, 2009;
- Our Current Report on Form 8-K filed with the Commission on March 27, 2009;
- Our Current Report on Form 8-K filed with the Commission on April 6, 2009;
- Our Current Report on Form 8-K filed with the Commission on May 18, 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; and
- The description of our common stock contained in the Prospectus Supplement on Form 424(b)5, filed with the Commission on May 15, 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

TABLE OF CONTENTS

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 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.

5

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.

8

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.

9

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.

10

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;