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# Generex BIOTECHNOLOGY

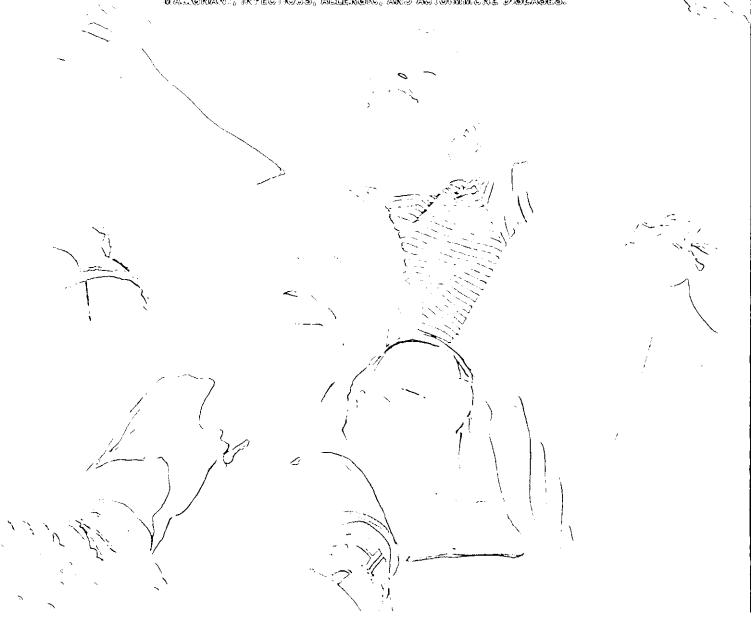
ANNUAL REPORT 2006



# MISSION STATEMENT

Cur mission is to devilop innovative drug delivery tick no locies and drugs that will improve the quality of life for people who suffer from disease.

GENEREX BOTECH NOLOGY COMPORATION IS POCUSED ON THE RESEARCH, DEVILOPMENT, AND COMMUNICALIZATION OF DRUG DELIVERY TECHNOLOGIES AND NOVEL IMMUNION FIXED ES FOR THE EXPATMENT OF WALIGNAMY, INFECTIOUS, ALLERGIC, AND AUTOIMMUNE DISEASES.





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# LETTER TO SHAREHOLDERS



Anna E. Gluskin President & Chief Executive Officer

### DEAR SHAREHOLDERS,

It is always a pleasure to communicate with my fellow shareholders and report on the Company's progress over the past year. In the fiscal year ended July 31, 2006, the Company's shareholder base expanded to over 40,000 shareholders which is indicative of the exposure that the Company is achieving and the support for the Company's innovative proprietary platform technologies. 2006 can be characterized as a year of building blocks and strengthening the Company's foundations in its quest to reach core corporate, research and commercial goals. The steps that we have taken in 2006 are reflected in the milestones met to date and continue to drive the Company's mission to provide practical solutions for the treatment of chronic illnesses to improve and sustain the best quality of life for ourselves and for generations to come.

#### GENEREX ORAL-LYN™

This past year the Company was pleased to launch Generex Oral-lyn™, our buccal insulin spray product, in Ecuador. In association with PharmaBrand, S.A., the Company was able to make available the first non-injectable form of recombinant human insulin commercially available anywhere in the world. The approval by the Ecuadorian Ministry of Public Health allowed the Company to market Generex Oral-lyn™ to Type 1 and Type 2 patients. A successful technology transfer to PharmaBrand took place and the first commercial manufacturing batch was prepared in April 2006.

The Company has been able to determine the level of physician and patient training and education associated with this new form of insulin delivery. Changes in the diabetes treatment paradigm regarding prandial blood glucose control, and in some cases the early — and most often resisted — introduction of insulin in the patient's daily diabetes treatment regimen. The Company is pleased to report that both Type 1 and Type 2 patients are now using Generex Oral-lyn™ routinely.

Doctors are becoming more familiar with the training and education required to transfer this knowledge to the patient population. The Company's addition of noted opinion leaders and clinicians has assisted in communicating with the medical community in Ecuador and beyond its borders into other Latin American countries. Ecuador has proven to be an invaluable preliminary market and the Company anticipates capitalizing upon the marketing lessons acquired in Ecuador into practical and profitable strategies for a seamless transition into other Latin American countries.

In last year's Letter to the Shareholders I provided a brief report regarding our detailed discussions with several pharmaceutical contract manufacturers. In June 2006 the Company signed an agreement with Cardinal Health to manufacture a sufficient supply of Generex Oral-lyn™ for its long term clinical trials. This association with Cardinal Health helps the Company realize one of the key New Drug Submission (NDS) requirements put forth by Health Canada.

On March 1, 2006 the Company met with the Regulatory Affairs Division of the Biologics and Genetic Therapeutics Directorate of Health Canada for a Pre-New Drug Submission Meeting. The Company plans to use the experience gained by this meeting as a springboard for other applications to be made to the European Agency for the Evaluation of Medicinal Products (EMEA) and eventually to the United States Food and Drug Administration (FDA).

With the development of Generex Oral-lyn™ and advancement of other products the Company has appointed key personnel to our corporate team. In-house regulatory, project and clinical management personnel will ensure the Company's ability to provide pharmaceutical and manufacturing expertise for the advancement of our pipeline of products into the global markets.

#### METFORMIN GUM

On May 31, 2006 the Company established a collaboration with Fertin Pharma A/S, a world leader in the development and manufacture of medicinal chewing gum, to develop a metformin medicinal chewing gum product for the treatment of Type-2 diabetes mellitus and obesity. Delivering metformin into the body via the inner lining of the mouth will avoid the bitter taste and other adverse side-effects associated with metformin in its current tablet form. Patients may discover that the metformin gum product improves compliance, particularly amongst the growing number of younger patients being diagnosed with Type-2 diabetes. The Company is excited to introduce this new delivery method of metformin into the global \$1.8 Billion metformin market. Along with Fertin's commitment, the metformin gum product is expected to take significant clinical and regulatory steps within the next fiscal year.

## GLUCOSE RAPIDSPRAY™

I am pleased to report to you about the progress made with Glucose RapidSpray™. Last year's Annual Report introduced Glucose RapidSpray™, a newly developed product which serves as an innovative alternative for people who require additional glucose in their diet. Glucose RapidSpray™ was commercially launched in September 2006 and is now being sold in the United States and Canada. Cardinal Health is one of the distributors for the product which can be found in a number of familiar retail chains such as The Medicine Shoppe, Meijer Inc., Kerr Drug Inc., Hy-Vee Inc., Fruth Pharmacy, Bi-Mart, ShopKo and Kinney Drugs, Shoppers Drug Mart and Loblaws. The Company anticipates that the product will be distributed by additional major retail chains during the coming fiscal year.

This milestone is significant for the Company on a number of levels. The product has provided the Company with a revenue stream, opened the door for the introduction of other products utilizing the Company's proprietary platform technologies, and provides brand recognition within the retail marketplace. Finally, it provides an avenue to introduce the Company and its products to pharmagists throughout North America who spend a great deal of time with patients in the marketplace.

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## LETTER TO SHAREHOLDERS CONT.

# VACCINE PLATFORM — AVIAN INFLUENZA, BREAST CANCER, PROSTRATE CANCER

The Company's novel proprietary vaccine program developed by our wholly-owned subsidiary, Antigen Express, had an equally busy and productive 2006.

The prospect of an Avian Influenza pandemic was at the forefront of many news headlines in 2006. On November 6th, the Company announced the first human clinical trial of the Company's synthetic Avian Influenza vaccine at the Canadian Lebanese University Hospital in Beirut. The Company's Avian Influenza vaccine is based upon a peptide-synthesis technology and has the benefits of being manufactured rapidly and easily. Our goal is to file an IND application with the FDA allowing for to the commencement of human clinical trials in the US.

The Company successfully completed its Phase I trial of its AE37 vaccine compound for the treatment of breast cancer this past year. The vaccine—which is an immunotherapeutic vaccine for the treatment of a variety of different cancers—was tested at the Walter Reed Army Medical Center and the results demonstrated that it was safe, well-tolerated and showed good immune-simulatory activity. The Company will initiate Phase II trials in 2007.

The application of the AE37 vaccine compound was expanded to prostrate cancer patients. In August, 2006 the Company entered into an agreement with the Euroclinic in Athens, Greece to commence clinical trials for prostrate cancer utilizing the same compound used at the Walter Reed Army center for breast cancer indication. We look forward to updating everyone on the results in the future and we continue to explore other applications of this proprietary synthetic peptide vaccine.

#### **FINANCES**

The Company's finances took a very positive turn in 2006. The Company disclosed in its Form 10- K Annual Report that our cash-on-hand and short term investments were in excess of \$50,000,000 as at July 31, 2006. This sound financial base will be a driving force behind the execution of the Company's major corporate and R&D programs. In order to strengthen its financial prospects and put the Company in a position to access the capital markets when it is most advantageous to do so, the Company filed a shelf registration statement with the Securities and Exchange Commission in December 2006 in the amount of up to \$150 million in anticipation of any future financing requirements or acquisition opportunities. The shelf registration statement became effective in February 2007. We believe that this model reflects that of other companies who have made the transition from a development stage company to that of a company whose focus is on specialty pharmaceuticals.

I am also pleased to report that the Company has achieved SOX 404 compliance (the Sarbanes Oxley Act, 2002) with respect to corporate governance procedures. This illustrates the integrity of management and its efforts to carefully address procedures that focus on the Company's resources for the development of its platform technologies that ultimately increase shareholder value.

#### PATENT PORTFOLIO

The Company believes that its patent portfolio is one of its most important assets, and continues to protect its existing and newly-developed intellectual property through new patent and trademark applications. In 2006, the Company was granted 26 new patents worldwide and presently has a total of 97 patents and 85 pending patent applications throughout the world.

#### SCIENTIFIC AND MEDICAL EXPOSURE

This past year, the Company presented its updated clinical data at major diabetes and vaccine conferences around the world. The scientific community was able to learn firsthand about the safety and efficacy of each of the products within the pipeline and their treatment applications.

The Company's exposure continues to grow having opportunities this year to sponsor two episodes of Medical Missions for Children "Plain Talk About Health". The program covered both Avian Influenza and Obesity. Medical Missions for Children's global network broadcasts to more than 100 countries and creates a communications bridge between pediatric healthcare facilities in Latin America, Africa, India, the Middle East, Eastern Europe and Central Asia.

Finally we were proud recipients of the 2006 North American Frost & Sullivan Award for Technology Innovation. In bestowing the award, Frost & Sullivan recognized that "the Company's committed research and development of a highly unique insulin product would revolutionize the insulin market" and acknowledged that the RapidMist™ technology "already has market attention, which takes the Company on a further commercial stand."

The Company is poised to advance its research and commercialization developments forward into all major markets. We anticipate 2007 to be a highly productive year.

We certainly wish to thank all employees and key consultants who continue to serve the Company and for their complete dedication to the vision of E. Mark Perri, the Company's former Chairman and founder and continued inspiration of the Company.

The Board of Directors and Management also want to thank all shareholders for their support for the Company's absolute commitment to improving the quality of life for individuals who suffer from chronic, debilitating disease.

We hope you will continue the journey with us.

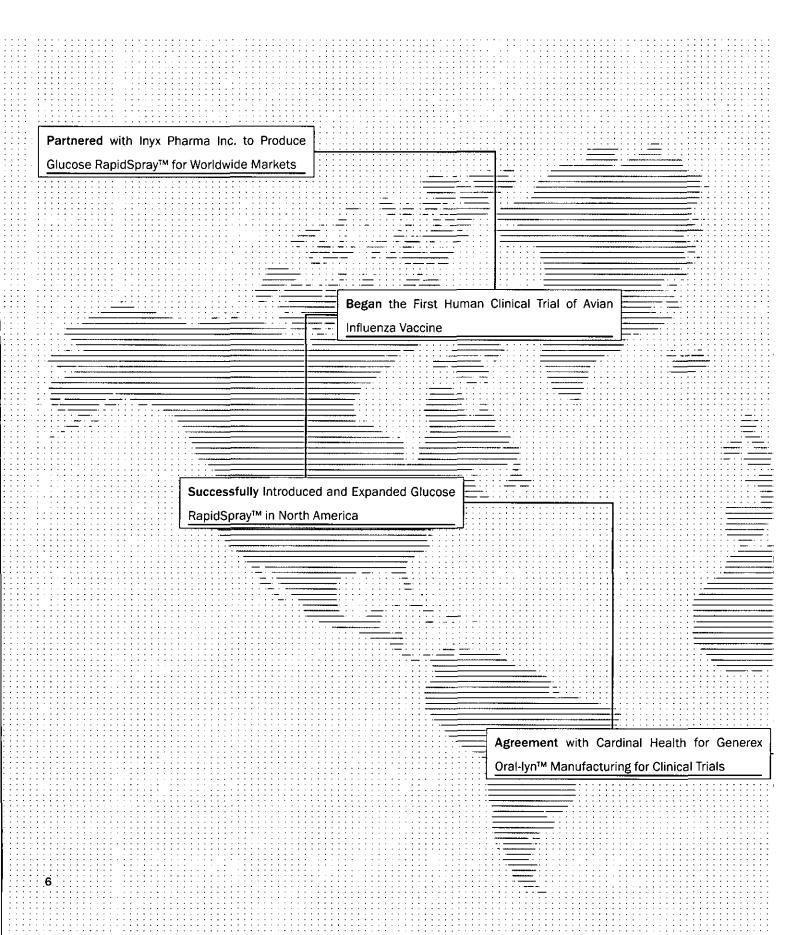
Sincerely.

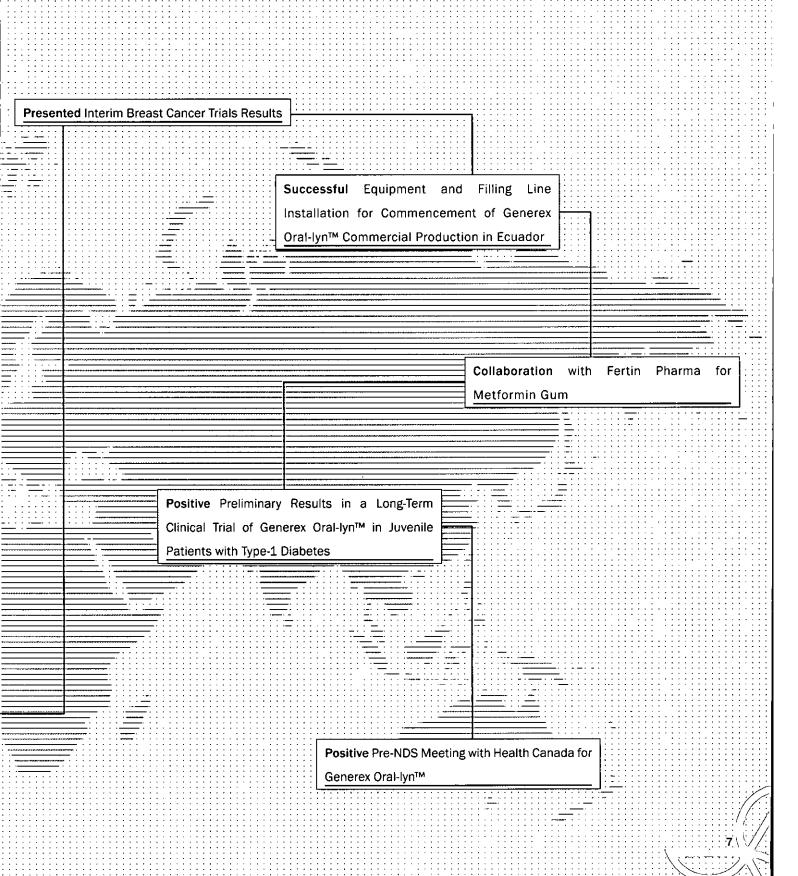
Anna E. Gluskin

President & Chief Executive Officer

Chairperson of the Board

# 2006 CORPORATE MILESTONES





# **COMPANY STRATEGY**

GENEREX BIOTECHNOLOGY CORPORATION IS THE LEADER IN THE BUCCAL DELIVERY OF DRUGS AND IN THE RESEARCH AND DEVELOPMENT OF NOVEL IMMUNOMEDICINES.

We continue to develop our own products as well as collaborate with pharmaceutical companies to apply RapidMist™ and the immunomedicines platform technology to their proprietary compounds and drug discovery pipelines. Similarly, we will continue to seek licensing, partnership and acquisition opportunities that complement our core capabilities in drug delivery technologies.

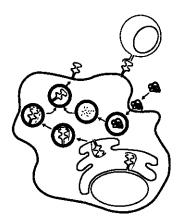
We plan to advance our drug candidates into early clinical development prior to establishing partnerships for further development and commercialization. We will focus our efforts on compounds with known efficacy, which will result in a reduction of time and risk, and therefore the cost of developing drugs.

# **TECHNOLOGY PLATFORM AND PRODUCT PIPELINE**



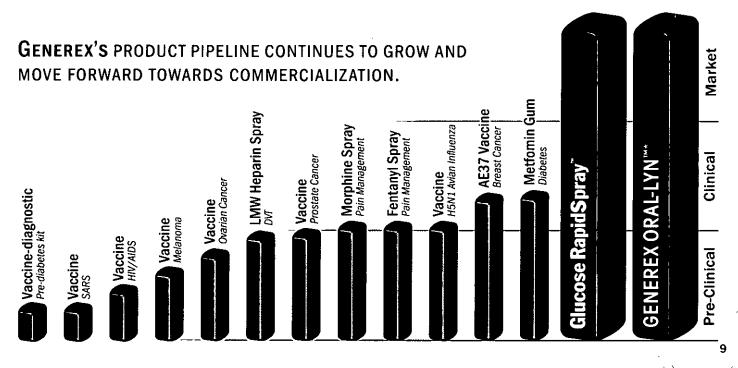
#### DRUG DELIVERY

RapidMist™, Generex's advanced buccal drug delivery technology, is comprised of a proprietary formulation and a proprietary device design that is able to deliver drugs through the buccal mucosa safely, thereby eliminating the pain from and need for multiple injections. RapidMist™ has been shown to have a rapid onset of action with no lung deposition, precise dosage control, easy use and handling, and improved patient compliance.



#### **IMMUNOMEDICINES**

Antigen Express technology focuses on modulating immune responses mediated by T helper (Th) cells, a class of lymphocytes that plays a multifaceted role in the immune system, both enhancing and suppressing immune responses. The cells are essential both for obtaining a robust and long lasting response against infectious agents or cancer cells and for down regulating immune responses when the immune system becomes appropriately stimulated, e.g. in autoimmune disease and allergy.



# GENEREX ORAL-LYNTM

# GENEREX ORAL-LYN™ IS AN INSULIN SPRAY FOR THE TREATMENT OF BOTH TYPE-1 AND TYPE-2 DIABETES.

An aerosolized liquid insulin formulation, Generex Oral-lyn™, is rapidly and safely absorbed into the human body through the lining of the inner mouth (the buccal cavity) when delivered using the RapidMist™ device which resembles an asthma inhaler and is therefore nondescript and easy to use.

GENEREX ORAL-LYN™



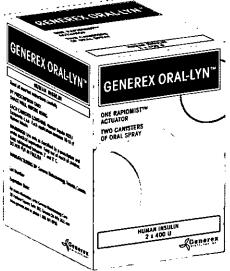
Unlike certain other alternative insulin delivery products presently under development, Generex Oral-lyn<sup>™</sup> does not enter the lungs; the formulation is absorbed in the buccal cavity with insignificant residual deposition in the gastrointestinal tract. Generex Oral-lyn<sup>™</sup> is a prandial (mealtime) insulin and numerous clinical studies have consistently demonstrated that the use of Generex Oral-lyn<sup>™</sup> allows the human body to mimic normal pancreatic insulin secretion and that Generex Oral-lyn<sup>™</sup> is a safe, effective, fast, flexible, pain-free and simple alternative to prandial insulin injections.

As an effective, safe, simple, fast, convenient, flexible and pain-free alternative to the traditional method of subcutaneous insulin injection, Generex Oral-lyn™ is designed to improve the quality of life for people with diabetes by allowing them to manage the disease more effectively.

Generex Oral-lyn™ is poised to forever change the manner in which diabetes is treated.







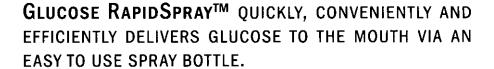
#### **BENEFITS:**

- Eliminates the pain that is associated with injections
- Enters bloodstream via the inner lining of the mouth
- Fast absorbing
- Rapid relief
- Convenient Spray
- · Stable in room temperature

#### CLINICAL DATA PRESENTED AT:

- 66th Annual Meeting & Scientific Sessions of the American Diabetes Association
- 42nd Annual Meeting of the European Association for the Study of Diabetes
- International Diabetes Federation 19th World Diabetes Congress
- Endocrine Society's Annual Meeting 2006
- 6th Annual Diabetes Technology Meeting
- World Congress on Controversies in Obesity, Diabetes and Hypertension
- · Controlled Release Society Annual Meeting
- Clinical Data at European Society for Pediatric Endocrinology 2006
- Lebanese Scientific Congress
- · Ecuadorian Scientific Symposium
- Pediatric Academic Societies' 2006 Annual Meeting

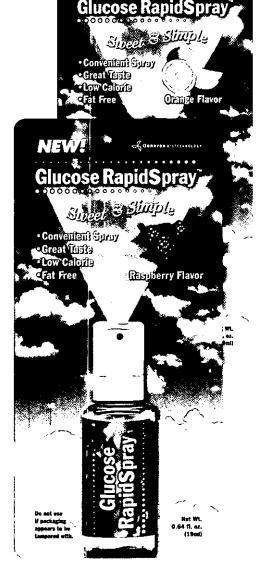
# GLUCOSE RAPIDSPRAYTM



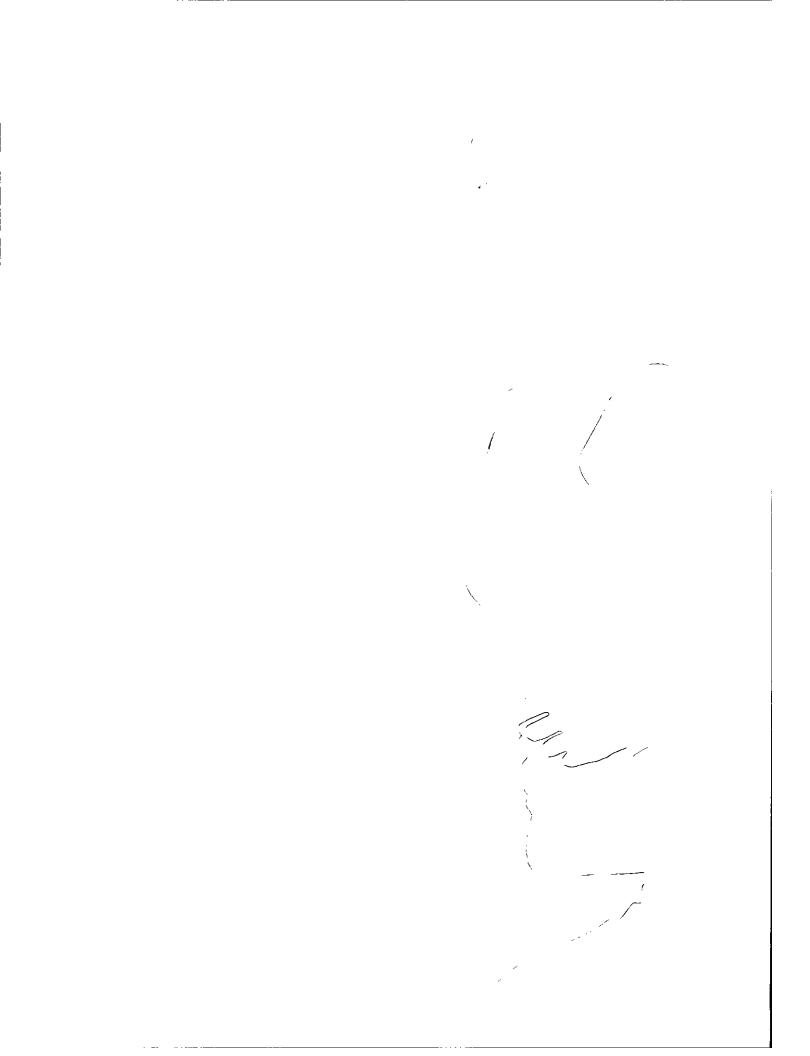
Glucose RapidSpray™ is a glucose spray product, used at the first sign of needing additional glucose in your diet, between meals, during exercise and even before bedtime. It can be stored easily in your home, office, car, pocket, purse, gym bag or any other convenient place. Available in great tasting orange and raspberry flavors and is available in over 2,500 drugstores across the USA, and over 1,000 drugstores across Canada.



- · Based on Generex's proprietary buccal drug delivery technology
- · Quickly absorbed into the mouth and does not need to be digested
- · Fat free and low calorie
- · Convenient to carry and handle
- Easy to use and is similar to a breath freshening mouth spray
- · Comes in orange and raspberry flavors







# **ANTIGEN EXPRESS, INC.**

ANTIGEN EXPRESS IS FOCUSED ON THE DEVELOPMENT OF NOVEL IMMUNOTHERAPEUTIC AND PROPHYLACTIC VACCINES FOR CANCER AND INFECTIOUS DISEASES.

The vaccines under development utilize specific fragments of known pathogenic agents or markers of disease modified by proprietary means to increase their immune-stimulatory activity. The company's most advanced compound (AE37) has been shown to be safe, well tolerated and to generate a good immunological response in breast cancer patients in a Phase I clinical trial. This immunotherapeutic vaccine is currently being examined in a randomized, controlled Phase II study designed to examine efficacy in breast cancer patients as well as a new Phase I study in prostate cancer patients. In addition to cancer, a Phase I trial has been initiated to test a synthetic H5N1 avian influenza vaccine in volunteers.

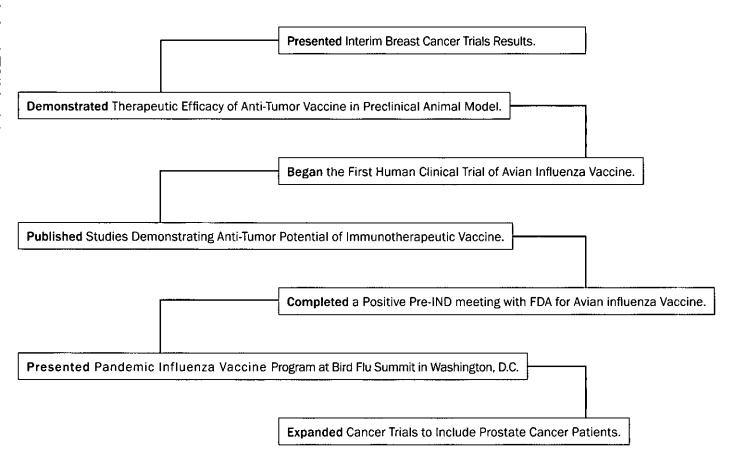
#### IMMUNOTHERAPY CANCER VACCINE PLATFORM

AE37 is an immunotherapeutic vaccine for the treatment of a variety of different cancers. The advantage of this type of immunotherapy is that it has none of the toxicities associated with classical chemotherapy. This is because it works by generating a specific immune response against a protein that is present on cancer cells and which contributes to their unregulated growth (HER-2/neu protein). We are currently conducting a randomized Phase II efficacy study in patients with breast cancer. Roughly 60% to 70% of breast cancers express HER-2/neu at levels qualifying them for our immunotherapeutic vaccine (in contrast to only approximately 25% that qualify for Herceptin therapy). We have also initiated trials in patients with prostate cancer, a significant percentage of which also express HER-2/neu. Other cancers that express HER-2/neu include: lung, ovarian, colorectal, stomach, and pancreatic.

#### SYNTHETIC AVIAN INFLUENZA

The vaccine being developed by Antigen Express for the potentially pandemic H5N1 influenza virus is based upon simple peptide-synthesis technology similar to their immunotherapeutic cancer vaccine. Consequently, it can be manufactured rapidly, easily, and at inexpensive cost. This is in sharp contrast to traditional egg-based vaccines that rely on biological systems for vaccine production, making their availability to at-risk populations during a pandemic extremely limited. The preclinical studies conducted with the synthetic vaccine suggest that it may be used with more traditional vaccines to extend their utility as well as to prevent mortality associated with H5N1 infection when used alone.

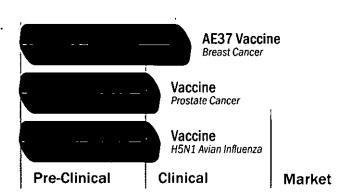
#### 2006 HIGHLIGHTS & MILESTONES



#### **PIPELINE**

The company continued clinical trials using its proprietary T helper stimulatory technology in patients with breast cancer. In addition to the efforts in cancer, Antigen Express is pursuing applications of its technology in HIV and influenza as well as other infectious agents.

ANTIGEN EXPRESS, INC.



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## CORPORATE INFORMATION

#### **BOARD OF DIRECTORS:**

Anna E. Gluskin

President and Chief Executive Officer, Chairperson of the Board

Rose C. Perri

Chief Financial Officer, Chief Operating Officer, Treasurer, Secretary, Director

Dr. Gerald Bernstein, MD

Vice President, Medical Affairs, Director

John P. Barratt

Independent Director

**Brain McGee** 

Independent Director

Mindy Allport-Settle

Independent Director

**Peter Amanatides** 

Independent Director

**David Wires** 

Independent Director

Generex Subsidiary:

Antigen Express, Inc.

100 Barber Ave.

Worcester, MA 01606

www.antigenexpress.com

Common Stock is traded on the NasdaqCM Symbol: GNBT

Shareholders' Meeting:

May 29, 2007 10:00AM

University of Toronto

Terrence Donnelly Centre for Cellular and Biomolecular Research

(Donnelly CCBR)

160 College Street,

Toronto, Ontario

M5S 1E2

#### **US Counsel:**

Eckert Seamans Cherin & Mellott, LLC 1515 Market Street — Ninth Floor Philadelphia, PA 19102-1909

#### Canadian Counsel:

Wires Jolley LLP 90 Adelaide Street West, Suite 200 Toronto, ON, Canada M5H 3V9

#### **Patent and Trademark Counsel:**

Hamilton Brook Smith & Reynolds, P.C. 530 Virginia Road Concord, MA 01742-9133

Ridout & Maybee LLP One Queen Street East, Suite 2400 Toronto, ON, Canada M5C 3B1

#### **Auditors:**

Danziger & Hochman LLP 202 Bentworth Avenue Toronto, ON, Canada M6A 1P8

#### **Accountants:**

WithumSmith + Brown 100 Overlook Center Princeton, NJ 08540

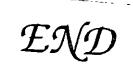
#### **Transfer Agent:**

StockTrans, Inc. 44 W. Lancaster Avenue Ardmore, PA 19003 Telephone: 610-649-7300 Fax: 610-649-7302

#### **Shareholder Information:**

Investor Relations Department E-mail: info@generex.com Telephone: 1-800-391-6755 Website: www.generex.com





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Except for historical information contained herein, this report contains forward-looking statements that involve risks and uncertainties, including clinical results, regulatory approval of the Company's products, the timely availability and acceptance of new products, the impact of competitive products and pricing, and the management of growth, as well as the other risks detailed from time to time in Generex Biotechnology Corporation's Securities and Exchange Commission (SEC) fillings, including the Company's annual report on Form 10-K.

All images used in the Generex Biotechnology 2006 Annual Overview are owned by the Company.

In memory of Mark Perri, founder of Generex Biotechnology Corporation