Generex BIOTECHNOLOGY®

Annual Report 2009

Generex Biotechnology Corporation is engaged in the research, development, and commercialization of drug delivery systems and technologies. Generex has developed a proprietary platform technology for the delivery of drugs into the human body through the oral cavity (with no deposit in the lungs).

The Company's flagship product, oral insulin (Generex Oral-lyn™), which has been launched in India, Lebanon, Algeria, and Ecuador for the treatment of subjects with Type-1 and Type-2 diabetes, is in Phase III clinical trials at several sites around the world. Antigen Express, Inc. is a wholly owned subsidiary of Generex. The core platform technologies of Antigen Express comprise immunotherapeutics for the treatment of malignant, infectious, allergic, and autoimmune diseases.

Pain Free Needle Free

Letter to Shareholders

Anna E. Gluskin
President and Chief Executive Officer,
Chairperson of the Board

Dear Generex Shareholders,

It has been a very busy year at Generex Biotechnology Corporation. As a Chairperson and Chief Executive Officer, I look forward to reaching out to our shareholders with our advances and successes. Global circumstances do not always coincide with corporate initiatives but our dedication and conviction seem to overcome these tough economic times to create an impact on human lives. At Generex Biotechnology we have been able to achieve some regulatory, clinical and commercial milestones over the past fiscal year which we believe will serve as a basis from which commercial growth can thrive in the company's future plans.

It was with great pride that we were able to witness the first patients in the United States use the company's flagship product, Generex Oral-lyn™ under the FDA Treatment IND program. Their positive feedback was invaluable to us. We hope that these patients living with diabetes realize that history is being made in the diabetes treatment paradigm. Generex Oral-lyn™ delivers insulin safely and efficaciously through the buccal mucosa (inner lining of the mouth). This possibility would not ever have been imagined within the medical community as little as a decade ago. We are excited about the endless applications that the RapidMist™ platform delivery technology will provide for other molecules.

Important headway is also being made in the field of immunotherapy development at Generex Biotechnology at its wholly-owned subsidiary, Antigen Express. Our cancer vaccine program for both breast cancer and prostate cancer indications moved forward over the past fiscal year. We were excited to announce the initial results of our breast cancer AE37 study in December 2009. Cancer vaccines are a very new concepts to the field of oncology and in 2010 the very first cancer vaccine was approved by the US FDA opening up the door to our vaccine platform. We take pride in the uniqueness of our vaccines - they are synthetic and safe.

At Generex Biotechnology our goals remain the same. We continue to develop and commercialize novel treatments for metabolic and immunotherapy diseases. We are focused on commercializing our most advanced product candidate, Generex Oral-lyn™, which has been approved in India, Lebanon, Algeria, and Ecuador for the treatment of subjects with Type-1 and Type-2 diabetes and is in Phase 3 clinical trials at several sites around the world. We are also dedicated to our clinical and development path with each of our key cancer and influenza vaccines. Lastly, we continue to expand and explore opportunities with our RapidMist™ drug delivery technology in other areas such as pain management and immunotherapy.

Let me share the following highlights of the past fiscal year with you:

GENEREX ORAL-LYN™

Phase III: The Company has enrolled over 400 subjects in its Phase III study for Generex Oral-lyn™. The multi-center study includes clinical sites around the world in countries including the United States, Canada, Russia, Ukraine, Bulgaria, Romania and Ecuador. To date, the product's non-inferiority to injectable meal-time (prandial) insulin appears to be maintained with no significant 'adverse events' or 'serious adverse events'. Once the clinical studies have been completed and analyzed, the Company intends to file a New Drug Application to the FDA, EMEA and Health Canada.

USFDA Treatment Investigational New Drug Approval: In 2009, the U.S. Food and Drug Administration (FDA) granted approval for the treatment use of Generex Oral-lyn™ under the FDA's Treatment Investigational New Drug (IND) program. Under a structured Treatment IND protocol, Generex Oral-lyn™ will be provided to patients with serious or life-threatening Type -1 or Type-2 diabetes mellitus, with no satisfactory alternative therapy available for the treatment of diabetes, and who are not eligible to participate in the Company's ongoing global Phase III pivotal clinical trial.

Product Approvals: Generex Oral-lyn™ has been approved India, Lebanon, Algeria, and Ecuador for the treatment of subjects with Type-1 and Type-2 diabetes. We continue to pursue other markets in order to file our submission with other regional regulatory agencies and to be able to penetrate a larger diabetes population.

Supply Agreement: The Company has entered into a long-term agreement with Sanofi-Aventis Deutschland GmbH for the manufacture and supply of recombinant human insulin crystals for commercial and clinical trial use in Generex Oral-lyn™. This will provide the Company with a source of insulin for major regulatory markets including the U.S. and Canada and a number of other regions where the Company is pursuing regulatory approvals for Generex Oral-lyn™.

Veterinary Product: The Company is pursuing the regulatory path for the submission of Generex Oral-lyn™ with the veterinary arms of global health agencies for therapeutic use in companion animals, specifically for cats and dogs with diabetes where one in every 500 develop diabetes in its lifetime. In July 2009, the Company had a Pre-New Drug Submission meeting with the Veterinary Drugs Directorate (VDD) of Health Canada for the purpose of outlining the Company's proposed development plan for the veterinary application of Generex Oral-lyn™. To date, the Company has conducted a two-year safety study on dogs as well as drafted a preliminary clinical design in order to meet some of the regulatory requirements for the IND application.

Diabetes Conferences: The Company is very proud to have presented its positive clinical data of Generex Oral-lyn™ in a number of leading diabetes conferences and symposiums such as the 69th American Diabetes Association Scientific Sessions, the 45th Annual Meeting of the European Association for the Study of Diabetes, The Endocrine Society's Annual Meeting, the 20th World Diabetes Congress of the International Diabetes Federation, the International Conference on Advances in Diabetes and Insulin Therapy, the 2nd IDF Regional MENA Diabetes Conference and the 17th Annual Meeting of the Syrian Diabetes Association.

GENEREX MENA

The Company established Generex MENA (Middle East North Africa) in 2008 located in the prestigious Dubai Healthcare City Center in order to service its customers, partners and drug regulatory authorities in the MENA countries. Generex MENA has expanded its reach into territories such as Africa, Australia, New Zealand, Eastern Europe, and the countries of the European Union. Currently the Company has attracted a number of distributors in over 20 countries for its over-the-counter product line that provide solutions in the diabetes, diet and energy categories. More importantly, Generex MENA continues to focus its efforts on the preparation of submissions for Generex Oral-lyn™ for regulatory approvals in a number of countries in the MENA territories.

METCONTROL™

We have made great progress with the development of MetControl™, the Company's proprietary metformin chewing gum product, over the past year. Recent results of the fully compliant ICH-GCP conducted study indicate

that MetControl™ chewing gum and traditional Metformin tablets are bioequivalent in respect of both the rate and the extent of systemic absorption, thus therapeutically equivalent and therefore interchangeable. The Company is currently preparing the data in a form for submission to various regulatory authorities throughout the world.

OVER-THE-COUNTER PRODUCTS

The Company continues to leverage its buccal drug delivery platform in the over-the-counter space while increasing retail and wholesale distribution throughout the globe. Glucose RapidSpray™, a glucose spray product, which serves as an innovative alternative for people who require additional glucose in their diet, continues to be available in the United States and Canada at major retail chains. The Glucose RapidSpray™ brand also expanded into the veterinarian field and launched a companion animal label to veterinarians throughout North America. As for Crave-NX™ 7-Day Diet Aid Spray, the product was initially launched in Duane Reade. With its success it has recently became available in all 7,000+ CVS stores nationwide. BaBoom!™ Energy Spray launched in all 7-11 stores in Canada and listed in major regional convenience store wholesalers throughout the USA. We are also developing other products that are expected to launch in the near-term and entertaining private-label opportunities.

VACCINE PLATFORM - INFLUENZA, BREAST CANCER, PROSTATE CANCER

The Company's subsidiary, Antigen Express, continued to make tremendous progress in the development of novel immunotherapeutic and prophylactic vaccines for critical unmet medical needs, including cancer and infectious diseases. The Antigen Express product pipeline includes four encouraging clinical trial stage drugs. They are a Phase II trial in breast cancer patients (AE 37); a Phase I trial in prostate cancer patients (AE 37); a Phase I trial in patients with ovarian cancer (AE 37); and a Phase I trial testing H5N1 vaccine peptides in healthy volunteers. The Company is also working with Pevion Biotech Ltd., to develop next-generation vaccines and immunotherapeutic products and with the Immune Tolerance Network to develop a diagnostic test for Type-1 Diabetes. Antigen Express clinical data has been presented at major scientific conferences such as the 45th Annual Meeting of the American Society of Clinical Oncology, 1st Annual International Congress of Antibodies, the 100th Annual Meeting of the American Association for Cancer Research, Influenza Congress USA 2009, the 1st International Swine Flu Conference, and leading medical journals such as Vaccine and Expert Opinion on Biological Therapy.

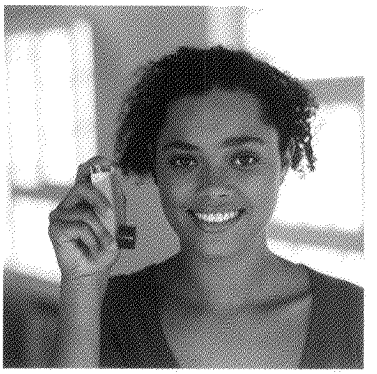
In Closing…

We believe we have a strong foundation in place that will enable us to deliver on key milestones. I wish to thank all shareholders for their continuing support to the company and its dedication to improving the quality of life for those who are seeking novel alternative treatments. We look forward to taking on the challenges that lie ahead, achieving our objectives, providing novel treatments for patients, and creating value for our shareholders.

We hope you continue to join us in this journey.

Generex BIOTECHNOLOGY™

GENEREX
ORAL-LYN™



Generex Oral-lyn™ is an oral insulin spray for the treatment of both Type-1 and Type-2 diabetes.

Generex Oral-lyn™ will offer a safe, simple, fast, effective and painfree alternative to meal-time insulin injections which will improve patient compliance with therapeutic regimes thereby delaying the progress of diabetes and the onset of its myriad complications.

Clinical Data Presented At:

- American Diabetes Association's 69th Annual Scientific Sessions
- 45th Annual Meeting of the European Association for the Study of Diabetes
- The Endocrine Society's 91st Annual Meeting
- 20th World Diabetes Congress of the International Diabetes Federation
- 2nd IDF Regional MENA Diabetes Conference
- International Conference on Advances in Diabetes and Insulin Therapy

Notable Milestones:

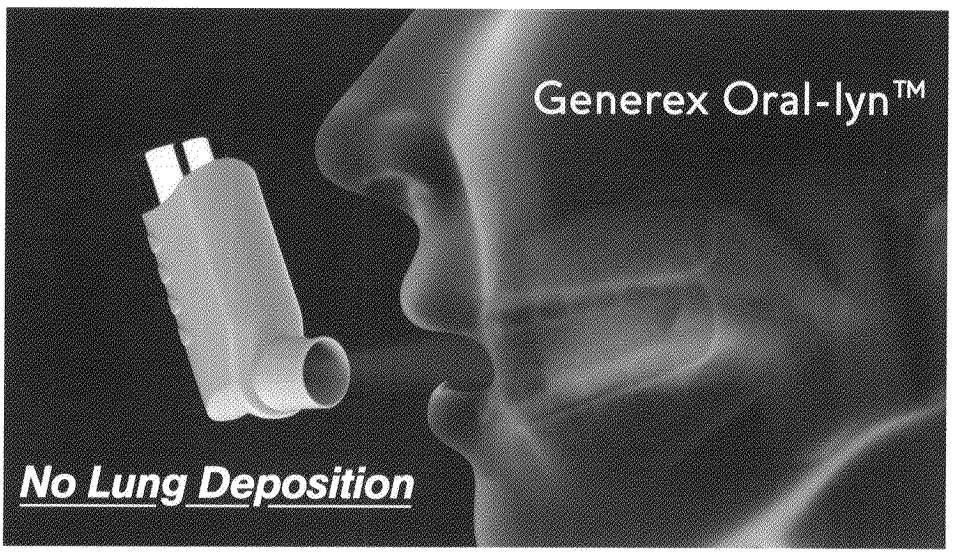
- Over 400 patients enrolled in Phase 3 clinical trials.
- Commercial launch in Algeria and Lebanon.
- Signed a long-term insulin supply agreement with Sanofi-Aventis Deutschland GmbH for themanufacture and supply of recombinant human insulin crystals for commercial and clinical trial use in Generex Oral-lyn™.

Received USFDA Approval of Generex Oral-lyn™ Under the USFDA'S Treatment Investigational New Drug (IND) Program

The FDA's Treatment IND program allows companies to provide early access to investigational drugs for patients with serious or life-threatening conditions for which there is no satisfactory alternative treatment. Drugs that are granted approval by the FDA for the Treatment IND program must demonstrate the prospect of efficacy through clinical testing as well as no unreasonable risks regarding safety.

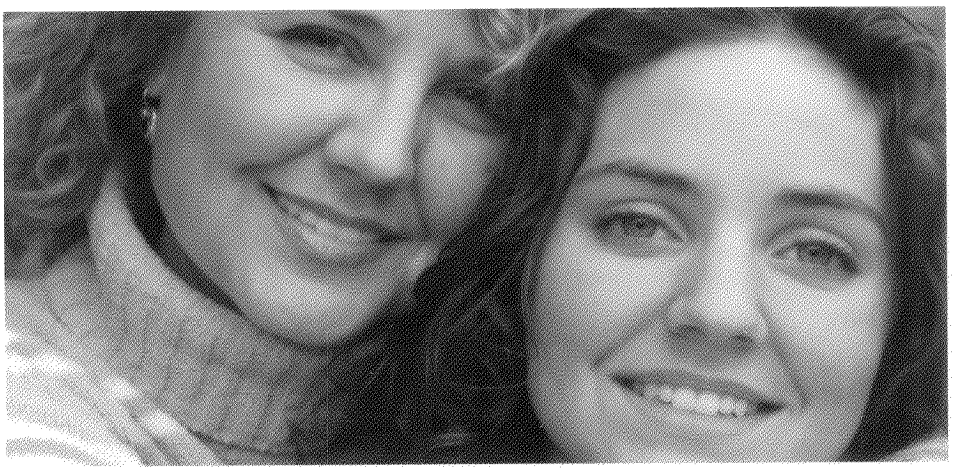
Under a structured Treatment IND protocol, Generex Oral-lyn™ will be available only through physicians who are registered in the Treatment IND program. Generex Oral-lyn™ can be provided to patients with serious or life-threatening Type-1 or Type-2 diabetes mellitus, with no satisfactory alternative therapy available for the treatment of diabetes, and who are not eligible to participate in the Company's ongoing global Phase III pivotal clinical trial.

This Treatment IND is open to eligible patients that comply with the inclusion/exclusion criteria of the protocol, including those who are taking currently approved anti-diabetic medications. There are no oral or injectable medications contraindicated for this IND program.



ANTIGEN EXPRESS, INC.

Antigen Express, Inc. 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.



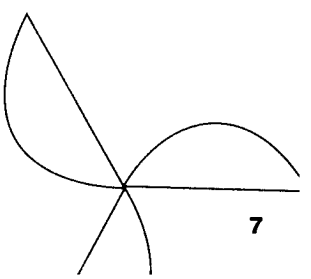
The Company's most advanced compound (AE37) has been shown to be safe, well tolerated and to generate a good immunological response in breast cancer patients in a Phase I clinical trial. This immunotherapeutic vaccine is currently being examined in a randomized, controlled Phase II study designed to 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 conducted 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 completed a trial 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.

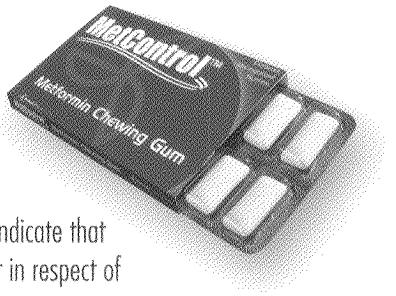
Synthetic Avian Influenza Vaccine

The vaccine being developed by Antigen Express, Inc. for the potentially pandemic H5N1 and 2009 H1N1 viruses 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 or H1N1 infection when used alone.

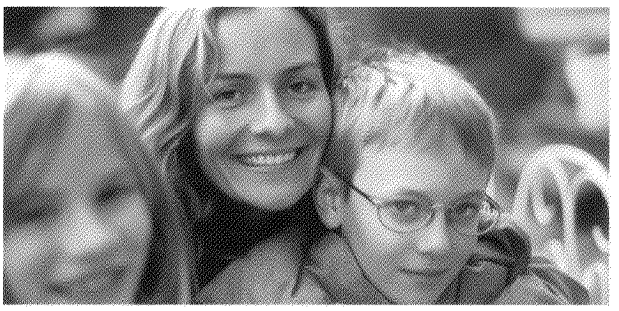


Additional Products

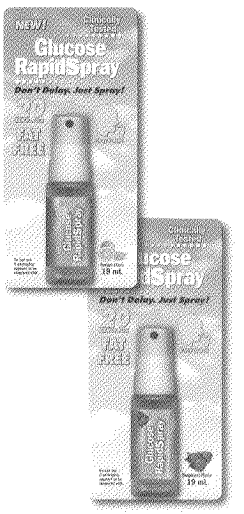
MetControl™ Metformin gum



In May 2006, Generex established a collaborative alliance with Fertin Pharma A/S, a leading Danish manufacturer of medicinal chewing gum, for the development of a metformin medicinal chewing gum for the treatment of Type-2 diabetes mellitus and obesity. Results of the fully compliant ICH-GCP conducted study indicate that MetControl™ and traditional Metformin tablets are bioequivalent in respect of both the rate and the extent of systemic absorption.



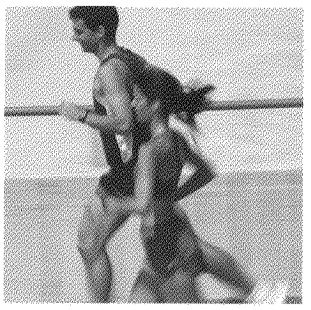
Glucose RapidSpray™

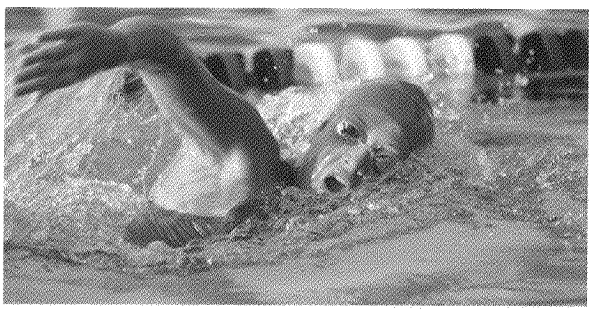


Glucose RapidSpray™ offers another aid to diabetics who require or need additional glucose to their diets or daily intake. Recent studies conducted by scientists at the University Campus Bio-Medico, Rome, Italy in conjunction with Generex have demonstrated that Glucose RapidSpray™ used early in the onset of low blood sugar episode can stop such an episode and prevent a further drop in blood glucose and the nauseous feelings that ensue.

Crave-NX™ 7-Day Diet Aid Spray

A scientifically formulated and clinically tested oral glucose spray designed to fuel the mind and control sweet tooth cravings (i.e. cookies) and carb cravings (i.e. potato chips) resulting in saved calories. It is encouraged to be used with other diet products (i.e. fat burners) and weight-loss plans. Studies have indicated that the use of Crave-NX™ may help to lose body weight in obese subjects over a short period of time.



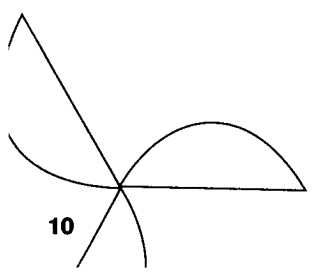


BaBOOM!™ Energy Spray

BaBOOM!™ Energy Spray is an instant and sustaining energy product that is positioned as a standalone energy supplement. Typical users of BaBOOM!™ are those who want that quick burst of energy without overloading their bodies with extra calories and liquids. The product contains 30 Servings, 150 Sprays and fewer than 2 calories per serving. Whether for sports, work, study, or long-distance travel, BaBOOM!™ Energy Spray is easy to use and convenient to store.

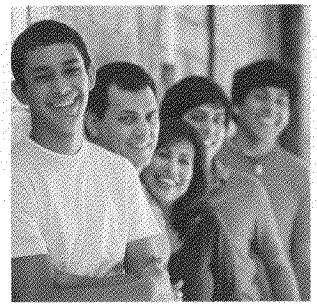
2009 Corporate Milestones

- Received USFDA Approval of Generex Oral-lyn™ under the USFDA'S Treatment Investigational New Drug (IND) Program.
- Commercial launch of Generex Oral-lyn™ in Algeria and Lebanon.
- Signed a long-term insulin supply agreement with Sanofi-Aventis Deutschland GmbH for the manufacture and supply of recombinant human insulin crystals for commercial and clinical trial use in Generex Oral-lyn™.
- Data presented at leading diabetes conferences such as The Endocrine Society's Annual Meeting , American Diabetes Association Scientific Sessions, European Association for the Study of Diabetes, World Diabetes Congress of the International Diabetes Federation.
- Announces Successful Phase III Study Data for Generex Oral-lyn™.
- Pursued Regulatory Path for Application of Generex Oral-lyn™ for Veterinary Market.
- Submitted Generex Oral-lyn™ Dossier in Syria.
- Enrolled over 400 Patients in Phase III Trial of Generex Oral-lyn™.
- Favorable Results from MetControl™ Chewing Gum Bio-equivalency Study Leading to Global Product Submissions.
- Raised over $15 million in fiscal 2009 and over $20 million in fiscal 2010 to date.
- Presented Positive Results of Phase 1 Prostate Cancer Vaccine Trial at the American Society of Clinical Oncology.
- Treatment of First Patient with its Novel Immunotherapeutic Vaccine.
- Launch of Crave-NX™ 7-Day Diet Aid Spray and Glucose RapidSpray™ for Companion Pets.



Product Pipeline

Generex's product pipeline continues to grow and move forward towards commercialization. We are currently conducting pre-clinical and human clinical trials using our proprietary technology platforms in the areas of diabetes, obesity, pain management, cancer and over-the-counter opportunities.


PRODUCT / DRUG	DISEASE	PRECLINICAL	CLINICAL	MARKET
RAPIDMIST™				
GENEREX ORAL-LYN™	DIABETES	------------------------------------		
GLUCOSE RAPIDSPRAY™	DIABETES	------------------------------------		
BABOOM!™ ENERGY SPRAY	ENERGY	------------------------------------		
CRAVE-NX™ 7-DAY DIET AID SPRAY	DIET	------------------------------------		
METCONTROL™ METFORMIN GUM	DIABETES	--------------------		
FENTANYL ORAL SPRAY	PAIN	---------------		
MORPHINE ORAL SPRAY	PAIN	---------------		
LMW HEPARIN ORAL SPRAY	DVT	--------------		
IMMUNOMEDICINES				
AE37 VACCINE	BREAST CANCER	--------------------		
AE37 VACCINE	PROSTATE CANCER	--------------------		
AE-AI VACCINE	AVIAN FLU	----------------		
AE-O VACCINE	OVARIAN CANCER	------------		
AE-IG VACCINE	GENETIC	------------		
AE-M VACCINE	MELANOMA CANCER	------------		
AE-H VACCINE	HIV	------------		

Generex BIOTECHNOLOGY
MENA Middle East & North Africa

Generex MENA (Middle East North Africa) has been working hard on putting together a comprehensive distribution network that covers the entire MENA region. Generex MENA currently has distributors in over 20 countries actively seeking marketing and sales for its OTC line and regulatory approvals for its flagship product, Generex Oral-lyn™. Generex MENA has also put together a comprehensive catalogue of OTC products which rounds out the diabetic category including artificial sweetener, blood glucose monitoring device, and other items geared towards diabetic patients. Generex MENA, spearheaded by experienced management, is positioning itself as a true multinational pharmaceutical company and aims at increasing revenue and regulatory milestones in the year to come.

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

John P. Barratt
Independent Director

Brian McGee
Independent Director

Nola E. Masterson
Independent Director

Generex Subsidiary:
Antigen Express, Inc.
Biotech 3
One Innovation Drive
Worcester, MA 01605

Common Stock is traded
on the Nasdaq CM Symbol: GNBT

Shareholders' Meeting:

July 28, 2010 at 10:00AM
University of Toronto
Terrence Donnelly Centre for Cellular
and Biomolecular Research
160 College Street
Toronto, ON M5S 3E1

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

Canadian Counsel:
Aird & Berlis LLP
181 Bay Street, Suite 1800
Toronto, ON, Canada M5J 2T9

Patent and Trademark Agents:
Perry+Currier Inc.
1300 Yonge Street, Suite 500
Toronto, ON, Canada M4T 1X3

Auditors:
MSCM LLP
701 Evans Avenue, 8th Floor
Toronto, ON, Canada M9C 1A3

Transfer Agent:
StockTrans a Broadridge Company
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

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) filings, including the Company's annual report on Form 10-K.

EMP