



Our Mission

is to develop innovative drug delivery technologies and drugs that will improve the quality of life for people who suffer from chronic disease.

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Generex Biotechnology Corporation

is focused on the research, development, and commercialization of drug delivery technologies and novel immunomedicines for the treatment of malignant, infectious, allergic, and autoimmune diseases.



2003 CORPORATE & CLINICAL MILESTONES

01.Strengthened Management Team

02.Acquired Antigen Express for the Development of Novel Immunomedicines

03.Demonstrated Improved Glucose Control in Patients with Type-2 Diabetes

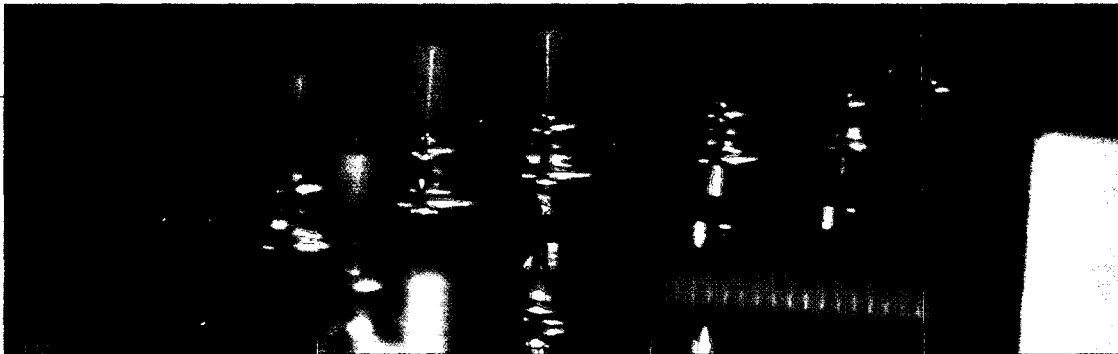
04.Commenced Phase IIB Trial of Oralin in Canada and United States



Collection: Banting House National Historic Site

"The birthplace of Insulin"
Charles Best, Frederick Banting and Dog. August 1921





05. Presented Research Studies at Prestigious Conferences such as the 2003 American Diabetes Association and the 18th International Diabetes Federation Congress

06. Expanded Patent Portfolio to Include an Aerosol Formulation for Buccal and Pulmonary Application

07. Established Oralin is Safe & Effective in Place of Injected Insulin

08. Initiated Research Collaborations on Generex's RapidMist™ Technology and on Antigen Express's Ii Suppression Technology



LETTER TO SHAREHOLDERS



ANNA E. GLUSKIN
PRESIDENT, CEO, CHAIRMAN

Dear Fellow Shareholders:

I am pleased to present to you our 2003 Annual Report, reflecting a year of *Advancing Forward* to achieve our ultimate goal of improving the lives of people who suffer from chronic disease.

Advancing our Clinical Development...

As a leader in the buccal delivery of drugs, we have made significant clinical progress with our most advanced product in development, Oralin, a buccal insulin spray for the treatment of diabetes. Over the past year, we reported that Oralin has demonstrated, among other things, to improve the glucose control in Type-2 diabetics. More importantly, we have initiated a Phase IIB clinical trial of Oralin in the United States, Canada, Italy, and Israel. Clinical data has shown that our buccal insulin formulation, being delivered by our proprietary RapidMist™ drug delivery technology allows for the pain-free and needle-free accurate delivery of insulin into the buccal cavity of diabetics.

In addition, we have begun clinical studies in adolescent youths between 12 and 19 years of age with diabetes. This study is particularly important since Type-2 diabetes is increasing in young people due to rising levels of obesity and lack of exercise. We believe that Oralin will increase compliance and reduce the complications associated with

diabetes. We look forward to report our ongoing clinical success of Oralin throughout the year.

Presenting our Clinical Successes...

As we continued to advance our buccal insulin product, we were honored to present our research studies at numerous prestigious scientific conferences. We presented four posters at the 2003 American Diabetes Association 63rd Scientific Sessions, two posters at the Endocrine Society's ENDO 2003 85th Annual Meeting, and two posters at the 18th International Diabetes Federation Congress. These research studies further indicated that our proprietary buccal insulin formulation has the potential to be used safely and effectively in place of injected insulin to treat patients with Type-1 and Type-2 diabetes.

Advancing our Product Pipeline...

We are currently building our product portfolio to include the buccal delivery of Fentanyl, Morphine and low molecular weight Heparin. We also have initiated feasibility studies for the buccal delivery of a human growth hormone and for the buccal delivery of a natural Interferon. Clinical trials of these products are on-going and we seek to partner with pharmaceutical companies that have drug development expertise and marketing capabilities to bring these innovative drugs to market.

Antigen Express Acquisition...

On August 2003, we announced the acquisition of Antigen Express, Inc.. As a newly created subsidiary of Generex, Antigen brings two additional platform technologies to Generex which focuses on the development of immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Development efforts of Antigen are underway in melanoma, breast cancer, prostate cancer, HIV, SARS, and Type-I diabetes. Since our acquisition of Antigen, over \$650,000 of research grants have been awarded to Antigen for development efforts in cancer vaccines. Generex's drug delivery technology platform combined with Antigen's technology platform will greatly strengthen our efforts to develop novel ways to develop and deliver new and



existing compounds to fill the gaps of underserved disease niche-markets.

Adding to our Management Team...

We have also made it our goal to build a world class management team that will assist Generex in its rapid growth phase of development. Over this past year, we added several key individuals to Generex. On April 1, 2003, we announced the appointment of Mark Fletcher to the newly created position of Executive Vice-President and General Counsel. Previous to Generex, Mr. Fletcher was a partner with Goodman and Carr LLP, a leading Toronto law firm. As well, we have added Dr. Eric von Hofe to the Antigen Express team as Vice President of Technology Development. Prior to joining Antigen, Dr. von Hofe was Director of Programs & Operations, Discovery Research at Millennium Pharmaceuticals. He will be instrumental in advancing Antigen's technology platforms forward into clinical development for the treatment in oncology, infectious disease and autoimmunity.



delivery technology and we look forward to adding new patents to our intellectual property portfolio this year.

Positioned for New Opportunities...

Generex is poised for growth and we are confident that 2004 will be a great year for Generex and its shareholders. We are focused on continuing to expand our product pipeline and lead our main product, Oralin into the late stage of development. Also, we will capitalize on new opportunities to bring new and improved drugs into clinical development. Each milestone and added value opportunity will build upon the core fundamentals of Generex.

On behalf of the Board of Directors and the management team, we would like to express our appreciation for the dedication and hard work of all of our employees, and acknowledge the support of our shareholders as we move forward together toward a common vision of improving the lives of people who suffer from chronic disease.

Strengthening our Intellectual Property Portfolio...

We were granted a European Patent for Aerosol Formulations for Buccal and Pulmonary Application. The patent relates to an improved delivery system for the administration of large-molecule pharmaceuticals. In particular, it relates to pharmaceuticals which may be administered by means of an aerosol into the mouth, for buccal or pulmonary application. Currently, we have 18 patents and patent applications that pertain to our drug

Sincerely,

ANNA E. GLUSKIN
President, CEO, and Chairman



CORPORATE STRATEGY

Generex Biotechnology Corporation is the leader in the buccal delivery of small and large molecule drugs.

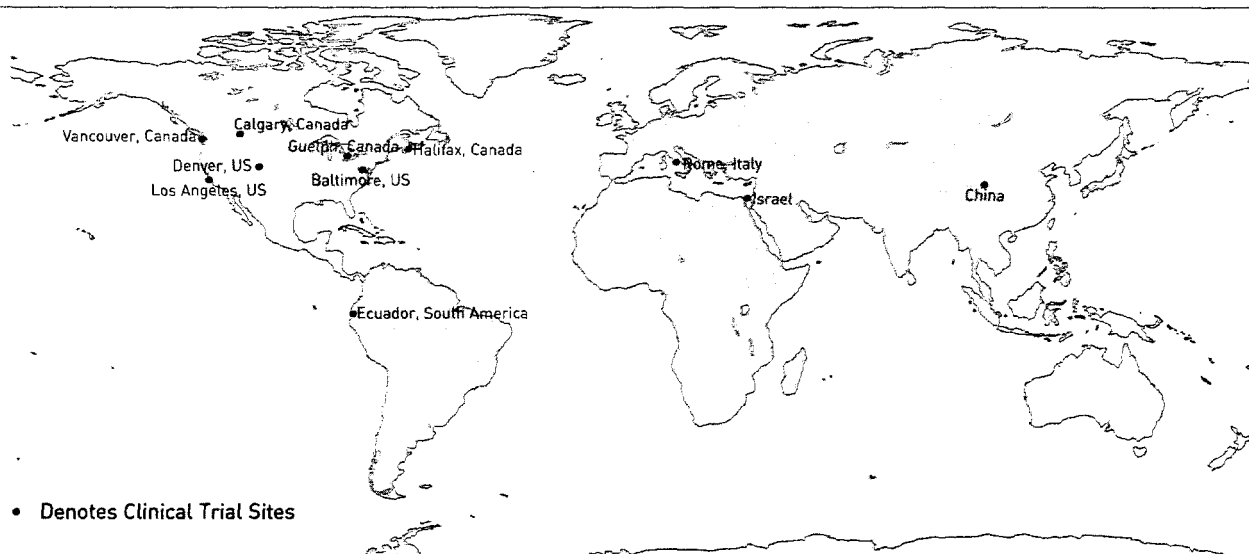
Our proprietary drug delivery platform technology, RapidMist™, administers medications directly into the mouth as a metered-dose spray, for rapid absorption by the buccal mucosa.

Since 1995, we have focused our efforts on the development of RapidMist™. After years of research and development, we are now prepared to leverage our technical expertise to maximize the success of product pipelines of global pharmaceutical and biotechnology companies.

We intend to develop our own products as well as collaborate with pharmaceutical companies to apply RapidMist™ to their proprietary compounds and drug discovery pipelines.

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

We have conducted clinical trials across the world mainly in Canada, United States, Italy, Israel, and South America.



RAPIDMIST™ TECHNOLOGY OVERVIEW

RapidMist™: Our Buccal Delivery Technology

RapidMist™, our drug delivery platform technology, is comprised of a proprietary formulation and a proprietary device that allows for the administration of small and large molecule drugs directly into the mouth as a metered dose spray for rapid absorption by the mucous membranes of the oral cavity - rather than the lungs.

Proprietary Formulation: Involves the preparation of a solution that is combined with a pharmaceutical graded chemical propellant, absorption enhancers and other excipients.

Proprietary Device: A small, lightweight, hand-held, easy-to-use aerosol applicator comprised of a canister, a metered dose valve, an actuator and a dust cap.



RapidMist™ Mechanism of Absorption



Using the device, the patient self-administers the formulation by spraying it into their mouth. Once penetrated through the layers of the buccal mucosa, the formulation is rapidly absorbed into the blood stream and is circulated throughout the body within minutes of application.

RapidMist™ Features & Benefits

- Needle-free, Pain-free Technology
- Rapid Onset of Action
- No Lung Deposition
- Precise Dosage Control
- Uniform Dose Delivery
- Safe to Use
- Improvement in Compliance
- Easy Self-Administration
- Convenient to Carry and Handle



ORALIN

Diabetes Overview

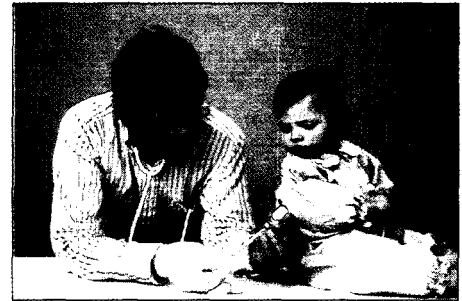
Diabetes is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced.

There are two principle forms of diabetes:

- *Type 1 diabetes* (formerly known as insulin-dependent) in which the pancreas fails to produce the insulin.
- *Type 2 diabetes* (formerly named non-insulin-dependent) which results from the body's inability to respond properly to the action of insulin produced by the pancreas.

Diabetes Facts

- There is no known cure for diabetes.
- 177 million people worldwide suffer from diabetes.
- 370 million people worldwide will have diabetes by year 2025.
- Diabetes is the second largest cause of death by disease in North America.
- In 2002, diabetes cost the United States \$132 billion.



THE PROBLEM: Although there is no known cure, diabetes is a disease that can be managed. However, studies have indicated that the majority of people with diabetes are not managing the disease properly since they do not achieve recommended therapy levels, or in other words, they avoid their multiple daily insulin injections.

According to The Diabetes Control and Complications Trial (DCCT), a clinical study conducted from 1983 to 1993 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), diabetes, if not treated properly, can lead to blindness, kidney disease, nerve disease, amputation, heart disease and stroke.

THE NEED: The DCCT study showed that keeping blood glucose levels as close to normal as possible slows the onset and progression of eye, kidney, and nerve diseases caused by diabetes. As a result, research that is successful in finding a better way of administering insulin could have an immediate and direct impact on millions of lives.

THE SOLUTION: ORALIN will help people with diabetes to continue to self-administer insulin they need to manage their blood sugar levels - eliminating the needle and the pain associated with multiple injections.

Oralin is expected to lead to an enormous improvement in the quality of life, with the elimination of pain and a significant increase in convenience. This will result in improved compliance with relative decrease in complications and the significant reduction in enormous costs associated with treating them.

Our lead product, Oralin, is a proprietary insulin formulation specially engineered to be delivered directly into the mouth as a metered-dose spray, for rapid absorption by the buccal mucosa.



Key Scientific Presentations:

- 2003 American Diabetes Association 63rd Scientific Sessions
- Endocrine Society's ENDO 2003, 85th Annual Meeting
- Third Annual Diabetes Technology Meeting
- The 18th International Diabetes Federation Congress
- 5th Hong Kong Diabetes and Cardiovascular Risk Factors East Meets West Symposium

Important Clinical Study Highlights:

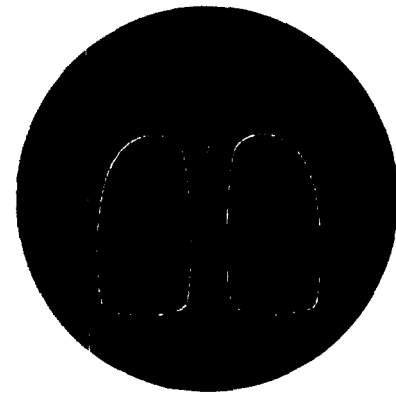
- Improved glucose control in study of patients with Type-2 Diabetes.
- Proved to be effective in controlling meal related glucose excursion in Type-1 diabetics.
- Faster onset of action when compared to s.c. injected insulin.
- Used safely in place of s.c. injections to treat diabetes.
- Well suited for the treatment of diabetes to manage and control meal related glucose levels safely and effectively.
- Used safely on a long-term basis without any adverse affects to treat diabetes.
- Used safely in combination with Metformin to control meal related glucose levels.

Evidence of Buccal Absorption

We conducted an in-vivo human study to show whether there was any lung deposition. As expected there was no lung deposition observed at all and most of the deposition was located in the mouth and the GI areas. The radio-labeled Tc-99m Oralin spray formulation on contact with the buccal mucosa is rapidly absorbed into the bloodstream and has the same effect as injected insulin.

"Our research studies further indicate that Oralin has the potential to be used safely and effectively in place of injected insulin to treat patients with Type-1 and Type-2 diabetes."

Anna Gluskin, President & CEO



Gamma-Scintigraphy Study
Subject 004/JLA

FUTURE APPLICATIONS

After years of successful research and development of RapidMist™, we are now poised to apply our drug delivery platform technology to a number of small and large molecule drugs that will provide a convenient, non-invasive, accurate and cost effective way to administer such drugs, thereby eliminating or reducing the need for multiple injections.

We have identified several drugs as possible candidates for development such as morphine, fentanyl, low molecular weight heparin, estrogen monoclonal antibodies, human growth hormones, interferon, and fertility hormones, as well as a number of vaccines.



PRODUCTS IN DEVELOPMENT

We have conducted clinical research for the buccal delivery of Morphine, Fentanyl and Low Molecular Weight Heparin using RapidMist™.

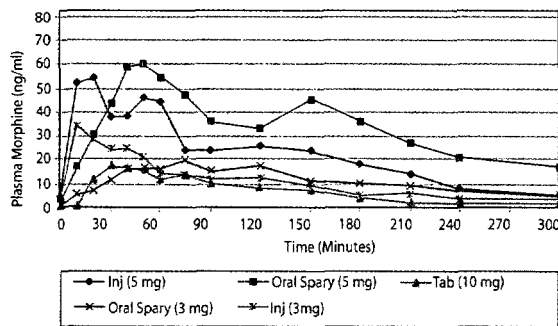
MORPHINE & FENTANYL

THE PROBLEM: Current delivery methods of morphine and fentanyl for the treatment of breakthrough and postoperative pain fail to provide patients with sufficient relief and control of their pain.

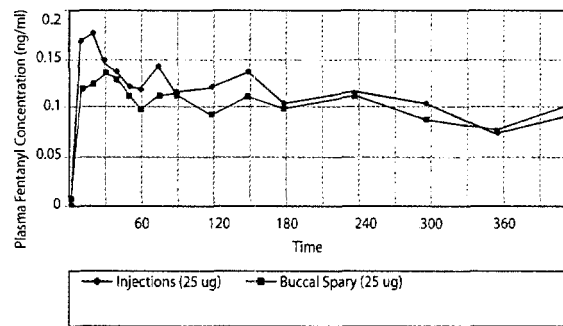
THE NEED: Current delivery methods of morphine and fentanyl have a slow onset of action and patients find it difficult to adjust and control their doses to manage their pain sufficiently.

THE SOLUTION: A Buccal Morphine Spray and a Buccal Fentanyl Spray, offers a novel way for the treatment of breakthrough pain relief with rapid onset of action and suppression of pain.

Buccal Morphine



Buccal Fentanyl



“Our Buccal Morphine and Buccal Fentanyl spray can be safely used in human subjects and addresses the shortcomings of the current delivery routes to treat breakthrough and post operative pain.”

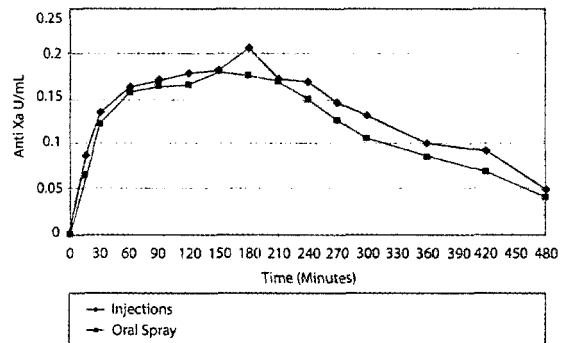
Anna Gluskin, President & CEO

LOW MOLECULAR WEIGHT HEPARIN

THE NEED: Low molecular weight heparin (LMWH) is currently administered by intravenous infusion or by injection for the treatment of deep vein thrombosis and for the prevention of blood clots due to post-surgical complications. An oral alternative will result in better patient compliance and patient comfort.

THE SOLUTION: A Buccal LMWH. We have conducted proof of concept studies of LMWH which have demonstrated that the buccal administration of LMWH were comparable to injection.

Buccal Low Molecular Weight Heparin





ANTIGEN EXPRESS, INC.

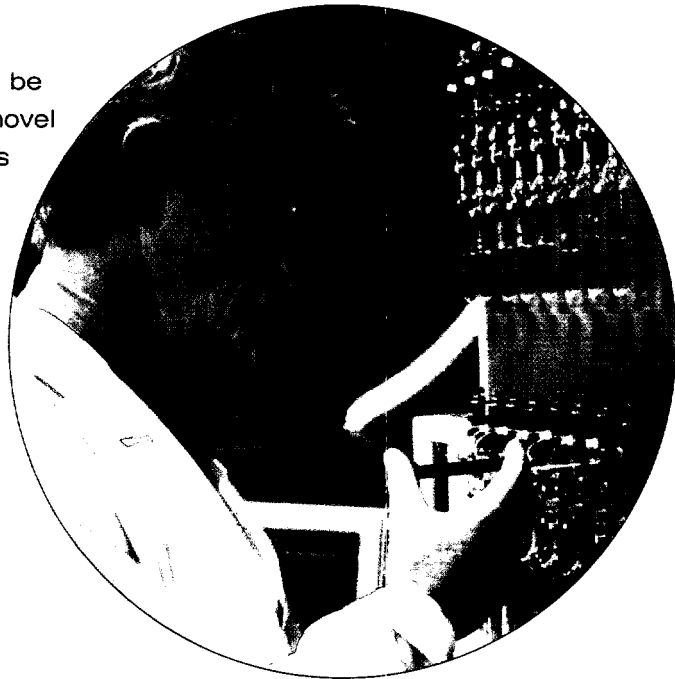


On August 11, 2003, we announced the acquisition of Antigen Express, Inc., a new subsidiary of GenereX Biotechnology Corporation. This brings two additional platform technologies focusing on the development of immunomedicines to GenereX that have good complimentary value to our buccal drug delivery technology.

Antigen Express is engaged in research and development efforts focused on the development of immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases.

"The GenereX drug-delivery technology will be instrumental in the development of these novel immunomedicines, particularly for methods to control autoimmune diseases."

Anna Gluskin, President & CEO
GenereX Biotechnology Corporation



ANTIGEN EXPRESS, INC.

Founded in 1994, by Dr. Robert Humphreys, Antigen Express is focused on developing immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Dr. Humphreys was formerly Professor of Pharmacology and Medicine, University of Massachusetts Medical Center, and interim Chair of Pharmacology. He was trained at Yale, the US Naval Hospital in Bethesda, and Harvard.

Technology Overview

The company's therapeutics are based on two platform technologies discovered by Robert E. Humphreys, MD, PhD the founder of Antigen Express. The focus of the company is on the antigen-specific stimulation of T helper cells. This strategy was not emphasized in the early days of immunotherapy, in preference for a focus on vaccines that stimulate cytotoxic T cells. During the late 1990s, however, work from many laboratories clearly showed that stimulation of T helper cells was an essential step for activation of cytotoxic T cells and for obtaining a robust, long lasting immune response.

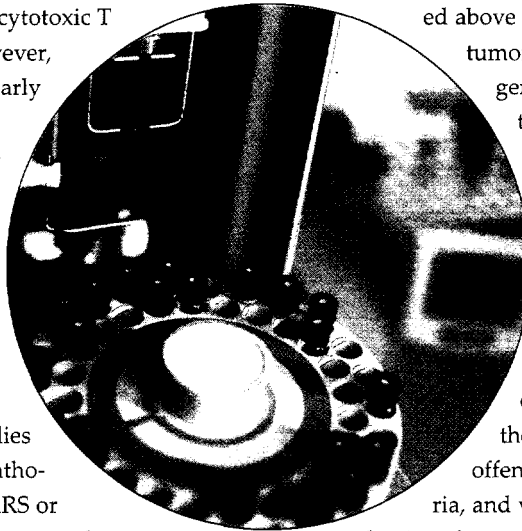
Two novel methods have been developed for selectively stimulating T helper cells. The first relies on stitching together a known pathogenic antigen (e.g., from HIV, SARS or tumor-associated antigens) onto a normal portion of an immune regulatory protein. Such composite or hybrid peptides ensure immunological 'visibility' of the pathogenic antigen and activation of T helper cells. By modifying the administration conditions of the resulting composite or hybrid peptide, one can either stimulate or suppress an immune response. Suppression has clear therapeutic application in autoimmune diseases, such as

multiple sclerosis or various allergic reactions. Stimulation offers therapeutic uses for infectious diseases and cancer.

The second strategy for stimulating T helper cells relies on inhibiting the immune regulatory protein indicated above altogether in specific cells (e.g., tumor cells). By this latter means, antigens that are not normally accessible to the T helper portion of the immune system, such as those produced by tumor cells, are presented for stimulation of a robust immune response against tumor cells anywhere in the body.

Antigen Express's immunomedicine products work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attack against benign elements (i.e., self proteins and allergens).

These products are in the pre-clinical stage of development and are being supported by eminent clinical investigators at leading institutions around the country. Development efforts are underway in melanoma, breast cancer, prostate cancer, HIV, SARS, and Type I diabetes mellitus.



ANTIGEN EXPRESS, INC.

Key Corporate Highlights & Milestones:

- Received 9 US National Institute of Health Small Business Innovative Research and Small Business Technology Transfer grants totaling \$1.85 million.
- The technology is protected by 6 issued US patents with corresponding world filings.
- Scientists have published over 40 papers in peer-reviewed journals on their technology.
- Collaborating with investigators at leading academic institutions in North America, China and Europe to advance products toward clinical trials.
- Recently appointed Dr. Eric von Hofe as Vice President of Technology Development. He was formerly Program Director, Target Validation, Millennium Pharmaceuticals, Inc.
- Cancer Research Collaboration with Transgene SA, Strasburg, France, on Ii Suppression Technology.

AgExp Patent Portfolio:

01. US Patent 5,559,028, Methods of Enhancing or Inhibiting Antigen Presentation to T Cells
02. US Patent 5,679,527, Modification of Polypeptide Structure
03. US Patent 5,726,020, Inhibition of Ii Synthesis
04. US Patent 5,919,639, Ii Peptide Therapeutics to Enhance Antigen Presentation
05. US Patent 6,368,855, MHC Class II Antigen Presenting Cells Containing Oligonucleotides Which Inhibit Ii Protein Expression
06. US Patent 6,432,409, Hybrid Peptides Modulate the Immune Response

“The pipeline of products that are expected to be entering the clinic in the next 24 months is impressive. The addition of the Antigen Express scientists to our team greatly strengthens Generex's technical and development expertise and is another example of the way our proprietary drug delivery technology can enhance other technology platforms.”

Anna Gluskin, CEO of Generex Biotechnology Corporation





CORPORATE INFORMATION

Board of Directors:

Anna E. Gluskin
President, CEO
Chairman

Rose C. Perri
Chief Financial Officer, Chief Operating Officer,
Director

Dr. Pankaj Modi, Ph.D., MD
Vice President, Research and Development,
Director

Dr. Gerald Bernstein, MD
Vice President, Medical Affairs,
Director

Jan Michael Rosen
Director

John Barratt
Director

Peter Levitch
Director

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Harper's Ferry, WV 25425
USA

Quality & Compliance
15-6400 Millcreek Drive, Suite 321
Mississauga, ON L5N 3E7
Canada

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USA

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19102-1909 USA

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Auditors:

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Canada

Accountants:

WithumSmith + Brown
100 Overlook Center
Princeton, NJ 08540 USA

Transfer Agent:

StockTrans, Inc.
44 W. Lancaster Avenue
Ardmore, PA 19003 USA
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

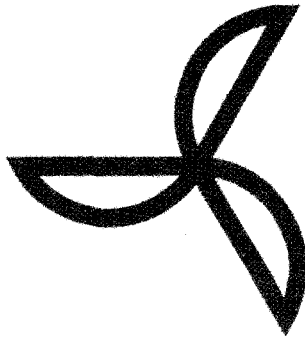
Common Stock is traded on the Nasdaq
Symbol: **GNBT**

Shareholders Meeting:

Wednesday March 9, 2004, 10:00am
The Great Hall
St. Lawrence market Complex
92 Front St. E.
Toronto, ON M5E 1C4
Canada

In memory of Mark Perri, founder of Generex Biotechnology Corporation





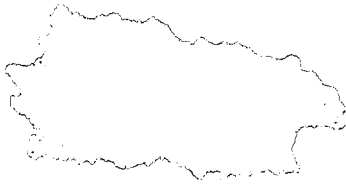
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Generex BIOTECHNOLOGY

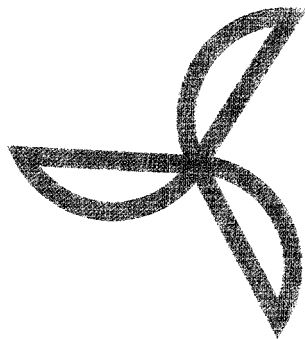
33 Harbour Square, Suite 202, Toronto, Ontario, Canada, M5J 2G2

toll free 1.800.391.6755, fx 416.364.9363, ph 416.364.2551

www.generex.com



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Generex
BIOTECHNOLOGY

FORM

GENEREX BIOTECHNOLOGY CORPORATION

2003

10K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended July 31, 2003

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-25169

GENEREX BIOTECHNOLOGY CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

98-0178636 (IRS Employer Identification No.)

33 Harbour Square
Suite 202, Toronto, Canada
(Address of principal executive offices)

M5J 2G2
(Zip Code)

Telephone Number: (416) 364-2551

Internet Website: www.generex.com

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to section 12(g) of the Act:

Common Stock, par value \$.001 per share
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant at October 14, 2003, based on the closing sales price as of that date, was approximately \$43,889,178.

At October 14, 2003, the registrant had 27,628,593 shares of common stock outstanding.

Documents incorporated by reference: Proxy Statement to be filed within 120 days after the end of the fiscal year.

Forward-Looking Statements

Certain statements in the "Business" (Item 1) and "Management's Discussion and Analysis of Financial Condition and Results of Operation" (Item 7) sections and elsewhere in this Annual Report on Form 10-K of GenereX Biotechnology Corporation for the fiscal year ended July 31, 2003 constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. This Act limits our liability in any lawsuit based on forward looking statements we have made. All statements, other than statements of historical facts, included in this annual report 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", "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
- adverse developments in our joint venture with a subsidiary of Elan Corporation, plc regarding buccal morphine.

Additional factors that could affect future results are set forth throughout the "Business" (Item 1) section, including the subsection entitled "Certain Additional Risk Factors", and elsewhere in this annual report. Because of the risks and uncertainties associated with forward-looking statements, you should not place undue reliance on them. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

PART I

Item 1. Business

Overview

GenereX Biotechnology Corporation is engaged primarily in the research and development of drug delivery 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.

A substantial number of large molecule drugs (i.e., drugs composed of molecules with a higher than specified molecular weight) have been approved for sale in the United States or are presently undergoing clinical trials as part of the process to obtain such approval, including various proteins, peptides, monoclonal antibodies, hormones and vaccines. Unlike small molecule drugs, which generally can be administered by various methods, large molecule drugs historically have been administered predominately by injection. The principal reasons for this have been the vulnerability of large molecule drugs to digestion and the relatively large size of the molecule itself, which makes absorption into the blood stream through the skin or mucosa inefficient or ineffective.

All injection therapies involve varying degrees of discomfort and inconvenience. With chronic and sub-chronic diseases, the discomfort and inconvenience associated with injection therapies frequently results in less than optimal patient acceptance of and compliance with the prescribed treatment plan. Poor acceptance and compliance can lead to medical complications and higher disease management costs. Also, elderly, infirm and pediatric patients with chronic or sub-chronic conditions may not be able to self-inject their medications. In such cases assistance is required which increases both the cost and inconvenience of the therapy.

Our goal is to develop proprietary formulations of large molecule drugs that can be administered through the buccal mucosa, primarily the inner cheek walls, thereby eliminating or reducing the need for injections. 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, but to date have focused our development efforts on a buccal insulin product.

Between January 1998 and September 2000, we conducted clinical trials of our buccal insulin product in the United States, Canada, Europe and Ecuador. In September 2000, we entered into an agreement to develop this product with Eli Lilly and Company ("Lilly"). To date, over 750 patients with diabetes have been dosed with our oral insulin product at approved facilities in seven countries. Lilly did not, however, authorize or conduct any clinical trials or provide financial support for those trials. We did receive a \$1,000,000 up front payment from Lilly. On May 23, 2003, we announced that we had agreed with Lilly to end the development and license agreement for the development and commercialization of buccal delivery of insulin. We are currently negotiating terms for Lilly to continue to supply a specified amount of insulin for further development of our product. We will retain all of the intellectual property and commercialization rights with respect to the buccal spray drug delivery technology, and we will have the continuing right to develop and commercialize the product.

In January 2001, we established a joint venture with a wholly owned subsidiary of Elan Corporation, plc. We agreed the joint venture would pursue the application of certain of our and Elan's drug delivery technologies, including our platform technology for the buccal delivery of pharmaceutical products, for the treatment of prostate cancer, endometriosis and/or the suppression of testosterone and estrogen. The joint venture formed a company to pursue these activities, Generex (Bermuda), Ltd., a Bermuda limited liability company. Generex (Bermuda), Ltd. was granted non-exclusive licenses to utilize our buccal delivery technology and certain Elan drug delivery technologies. In January 2002, the parties expanded the joint venture to include buccal morphine for the management of pain and selected buccal morphine as the initial product for development under Generex (Bermuda), Ltd. This expansion of the joint venture occurred after we successfully completed a proof of concept clinical study of morphine delivery using our proprietary buccal delivery technology. While we have pursued the development of the morphine product, we have had limited assistance from Elan.

In August 2003, after the end of our most recent fiscal year, we acquired Antigen Express, Inc. Antigen is engaged in the research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases.

We are a development stage company, and from inception through the end of fiscal year 2003 had not received any revenues from operations other than the up-front payment from Lilly. We have no products approved for commercial sale by drug regulatory authorities. We have begun the regulatory approval process for only three products, our oral insulin formulation, morphine and fentanyl. We believe that our buccal delivery technology is a platform technology that has application to a large number of large molecule drugs in addition to insulin. Estrogen, heparin, monoclonal antibodies, human growth hormone, fertility hormone, as well as a number of vaccines are among the compounds that we have identified as possible candidates for product development.

Buccal Delivery Technology

Our buccal delivery technology involves the preparation of a proprietary formulation in which an active pharmaceutical agent is placed in a solution with a combination of absorption enhancers and other excipients classified generally recognized as safe ("GRAS") by the Food and Drug Administration ("FDA") when used in accordance with specified quantity and other limitations. The resulting formulation is aerosolized with a pharmaceutical grade chemical propellant and is administered to the patient using our proprietary RapidMist(TM) device. The device is a small, lightweight, hand-held, easy-to-use aerosol applicator comprised of a container for the formulation, a metered dose valve, an actuator and dust cap. Using the device, the patient self-administers the formulation by spraying it into the mouth. The device contains multiple applications, the number being dependent, among other things, on the concentration of the formulation. Absorption of the pharmaceutical agent occurs in the buccal cavity, principally through the inner cheek walls. In clinical studies of our insulin product, insulin absorption in the buccal cavity has been shown to be very rapid. We are also evaluating the use of our RapidMist device for the delivery of both morphine and fentanyl.

Buccal Insulin Product

Insulin is a hormone that is naturally secreted by the pancreas to regulate the level of glucose, a type of sugar, in the bloodstream. The term diabetes refers to a group of disorders that are characterized by the inability of the body to properly regulate blood glucose levels. When glucose is abundant, it is converted into fat and stored for use when food is not available. When glucose is not available from food, these fats are broken down into free fatty acids that stimulate glucose production. Insulin acts by stimulating the use of glucose as fuel and by inhibiting the production of glucose. In a healthy individual, a balance is maintained between insulin secretion and glucose metabolism.

There are two major types of diabetes. Type 1 diabetes (juvenile onset diabetes or insulin dependent diabetes) refers to the condition where the pancreas produces little or no insulin. Type 1 diabetes accounts for 5-10 percent of diabetes cases. It often occurs in children and young adults. Type 1 diabetics must take daily insulin injections, typically three to five times per day, to regulate blood glucose levels.

In Type 2 diabetes (adult onset or non-insulin dependent diabetes mellitus), the body does not produce enough insulin, or cannot properly use the insulin produced. Type 2 diabetes is the most common form of the disease and accounts for 90-95 percent of diabetes cases. In addition to insulin therapy, Type 2 diabetics may take oral drugs that stimulate the production of insulin by the pancreas or that help the body to more effectively use insulin.

If not treated, diabetes can lead to blindness, kidney disease, nerve disease, amputation, heart disease and stroke. Each year, between 12,000 and 24,000 people lose their sight because of diabetes. Diabetes is also the leading cause of end-stage renal disease (kidney failure), accounting for about 40% of new cases.

In addition, about 60-70 percent of people with diabetes have mild to severe forms of diabetic nerve damage, which, in severe forms, can lead to lower limb amputations. Diabetics are also 2 to 4 times more likely to have heart disease, which is present in 75 percent of diabetes-related deaths, and are 2 to 4 times more likely to suffer a stroke.

There is no known cure for diabetes. The World Health Organization estimates that there are currently over 1.5 billion diabetics worldwide. It is further estimated that this number will almost double by the year 2025. There are estimated to be 17 million people suffering from diabetes in North America alone, approximately 5 million of whom are undiagnosed, and diabetes is the second largest cause of death by disease in North America.

We conducted the first clinical trials of our buccal insulin formulation with human subjects in Ecuador in January 1998. We ultimately conducted a number of studies in Ecuador in 1998, each of which involved a selection of between 8 and 10 patients. The principal purpose of these studies was to evaluate the effectiveness of our oral insulin formulation in humans compared with injected insulin and placebos.

On the basis of the test results in Ecuador and other pre-clinical data, we made an Investigatory New Drug submission to the Health Protection Branch in Canada (Canada's equivalent to the United States' Food and Drug Administration) in July 1998, and received permission from the Canadian regulators to proceed with clinical trials in September 1998. We filed an Investigational New Drug Application with the Food and Drug Administration in October 1998, and received FDA approval to proceed with human trials in November 1998.

We began our clinical trial programs in Canada and the United States in January 1999. Between January 1999 and September 2000 we conducted clinical trials of our insulin formulation involving approximately 200 Type 1 and Type 2 diabetic patients and healthy volunteers. The study protocol in most trials involved administration of two different doses of our insulin formulation following either a liquid sustacal meal or a standard meal challenge. The objective of these studies was to evaluate our insulin formulation's efficacy in controlling post-prandial (meal related) glucose levels. These trials demonstrated that our insulin formulation controlled post-prandial hyperglycemia in a manner comparable to injected insulin.

In April 2003, we were granted permission to commence Phase II-B clinical trials in Canada. In September 2003, we commenced a 90 day study in 80 Type 2 diabetic patients with poorly controlled blood glucose. The objective of the study is to determine the metabolic effect of our insulin product. We continue to conduct limited clinical studies in the United States, and other countries.

Other Large Molecule Drug Projects

We have identified numerous compounds, other than insulin, as candidates for product development.

Morphine and Fentanyl

The delivery of morphine and fentanyl by oral formulation (pills) and injection for the treatment of moderate to severe breakthrough and postoperative pain fails to provide patients with adequate relief and control (breakthrough and postoperative pain are characterized as being moderate to severe in intensity, having a rapid onset of action and a short to medium duration). Not only does delivery by pills have a slow onset of action, it is often difficult for patients to adjust their doses, with the result that patients are either over or under medicated. Injections are invasive and require an attendant to administer the medication which reduces the patient's control over the pain and may cause increased anxiety. Often, patients must wait in pain until an attendant can medicate them.

We seek to develop a buccal delivery formulation for morphine and fentanyl that will have a critical series of attributes well suited for the treatment of breakthrough and post operative pain and which will be cost effective and will have a demonstrable improvement over current delivery methods. These include fast access to the circulatory system, precise dosing control and a simple, self-administration procedure.

We made an Investigatory New Drug submission for buccal morphine to the Health Protection Branch in Canada in January 2002, and received permission from the Canadian regulators to proceed with clinical trials in March 2002. We have commenced clinical trials in Ecuador and we are in the process of recruiting investigators to conduct clinical trials in Canada. In January 2002, we filed an Investigational New Drug Application for buccal morphine with the Food and Drug Administration. The buccal morphine product is being developed by Genex Bermuda under our joint venture with a subsidiary of Elan Corporation.

We made an Investigatory New Drug submission for fentanyl to the Health Protection Branch in Canada in August 2002, and received permission from the Canadian regulators to proceed with clinical trials in October 2002.

Other Products

We have had discussions of possible research collaborations with various pharmaceutical companies concerning use of our large molecule drug delivery technology with insulin, morphine, fentanyl and other compounds, including monoclonal antibodies, human growth hormone, fertility hormone, estrogen and heparin, and a number of vaccines.

Prior to September 2000, we had not aggressively pursued development opportunities apart from insulin because we believed it was more advantageous to concentrate our resources, particularly our financial resources, on developing the insulin product. While the insulin product remains our first priority, we continue to develop a buccal delivery formulation for morphine and fentanyl. We believe we have sufficient financial resources to pursue the development of our current products and the initial exploration of additional products.

Immunomedicine Technology and Products

Our new subsidiary, Antigen, is engaged in research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Our immunomedicine products 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 that were discovered by an executive officer of Antigen, the li-Key hybrid peptides and li-Suppression. These technologies are expected to greatly boost immune cell responses which treat the ailments and conditions.

We have not filed an Investigational New Drug application to begin clinical trials. Rather, our immunomedicine products are in the pre-clinical stage of development and trials in human patients are not expected for 12 months. Development efforts are underway in melanoma, breast cancer, prostate cancer, HIV and Type I diabetes. We are establishing collaborations with academic centers to advance the technology, with the ultimate goal of conducting clinical testing. For more details regarding our acquisition of Antigen, see "Management's Discussion and Analysis of Financial Conditions and Results of Operations" (Item 7) below.

Corporate History

We were incorporated in Delaware in September 1997 for the purpose of acquiring Genex Pharmaceuticals, Inc., a Canadian corporation formed in November 1995 to engage in pharmaceutical and biotechnological research and other activities. Our acquisition of Genex Pharmaceuticals was completed in October 1997 in a transaction in which the holders of all outstanding shares of Genex Pharmaceuticals exchanged their shares for shares of our common stock.

In January 1998, we participated in a "reverse acquisition" with Green Mt. P. S., Inc., a previously inactive Idaho corporation formed in 1983. As a result of this transaction, our shareholders (the former shareholders of Genex Pharmaceuticals) acquired a majority (approximately 90%) of the outstanding capital stock of Green Mt., we became a wholly-owned subsidiary of Green Mt., Green Mt. changed its corporate name to Genex Biotechnology Corporation ("Genex Idaho"), and we changed our corporate name to GBC Delaware, Inc. Because the reverse acquisition resulted in our shareholders becoming the majority holders of Genex Idaho, we were treated as the acquiring corporation in the transaction for accounting purposes. Thus, our historical financial statements, which essentially represented the historical financial statements of Genex Pharmaceuticals, were deemed to be the historical financial statements of Genex Idaho.

In April 1999, we completed a reorganization in which we merged with Genex Idaho. In this transaction, all outstanding shares of Genex Idaho were converted into our shares, Genex Idaho ceased to exist as a separate entity, and we changed our corporate name back to "Genex Biotechnology Corporation". This reorganization did not result in any material change in our historical financial statements or current financial reporting.

In August 2003, subsequent to the end of fiscal 2003, we acquired all of the capital stock of Antigen in exchange for approximately 2,800,000 shares of our common stock, and Antigen became a wholly owned subsidiary of Genex.

Government Regulation

Our research and development activities, and the eventual manufacturing and marketing of our products, are subject to extensive regulation by the Food and Drug Administration in the United States (FDA) and comparable regulatory authorities in other countries. Among other things, extensive regulation puts a burden on our ability to bring products to market. While these regulations apply to all competitors in our industry, many of our competitors have extensive experience in dealing with FDA and other regulators, while we do not. Also, other companies in our industry do not depend completely on products which still need to be approved by government regulators, as we now do.

If requisite regulatory approvals are not obtained and maintained, our business will be substantially harmed. In many if not all cases, we expect that our development partners will control or participate extensively in the regulatory approval process once a development agreement is in place. The following discussion summarizes the principal features of food and drug regulation in the United States and other countries as they affect our business.

United States

All aspects of our research, development and foreseeable commercial activities are subject to extensive regulation by FDA and other regulatory authorities in the United States. United States federal and state statutes and regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of pharmaceutical products. The regulatory approval process, including clinical trials, usually takes several years and requires the expenditure of substantial resources. If regulatory approval of a product is granted, the approval may include significant limitations on the uses for which the product may be marketed. The steps required before a pharmaceutical product may be marketed in the United States include:

- preclinical tests;
- the submission to FDA of an Investigational New Drug application, which must become effective before human clinical trials commence;
- human clinical trials to establish the safety and efficacy of the drug;
- the submission of a New Drug Application to FDA; and
- FDA approval of the New Drug Application, including approval of all product labeling and advertising.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of each product. The results of the pre-clinical tests are submitted to FDA as part of the *Investigational New Drug application* and are reviewed by FDA before the commencement of human clinical trials. Unless FDA objects to the Investigational New Drug application, the Investigational New Drug application becomes effective 30 days following its receipt by FDA. The Investigational New Drug application for our oral insulin formulation became effective in November 1998. We filed an Investigational New Drug application for buccal morphine in January 2002.

Clinical trials involve the administration of the new drug to humans under the supervision of a qualified investigator. The protocols for the trials must be submitted to FDA as part of the Investigational New Drug application. Also, each clinical trial must be approved and conducted under the auspices of an Institutional Review Board, which considers, among other things, ethical factors, the safety of human subjects, and the possible liability of the institution conducting the clinical trials.

Clinical trials are typically conducted in three sequential phases (Phase I, Phase II, and Phase III), but the phases may overlap. Phase I clinical trials test the drug on healthy human subjects for safety and other aspects, but not effectiveness. Phase II clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the drug for specific purposes, to determine dosage tolerance and optimal dosages, and to identify possible adverse effects and safety risks. When a compound has shown evidence of efficacy and acceptable safety in Phase II evaluations, Phase III clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at clinical trial sites in different geographical locations. FDA and other regulatory authorities require that the safety and efficacy of therapeutic product candidates be supported through at least two adequate and well-controlled Phase III clinical trials.

In the United States, the results of pre-clinical studies and clinical trials, if successful, are submitted to FDA in a New Drug Application to seek approval to market and commercialize the drug product for a specified use. FDA may deny a New Drug Application if it believes that applicable regulatory criteria are not satisfied. FDA also may require additional testing for safety and efficacy of the drug. We cannot be sure that any of our proposed products will receive FDA approval. Even if approved by FDA, our products and the facilities used to manufacture our products will remain subject to review and periodic inspection by FDA.

To supply drug products for use in the United States, foreign and domestic manufacturing facilities must be registered with, and approved by FDA. Manufacturing facilities must also comply with FDA's Good Manufacturing Practices, and domestic facilities are subject to periodic inspection by FDA. Products manufactured outside the United States are inspected by regulatory authorities in those countries under agreements with FDA. To comply with Good Manufacturing Practices, manufacturers must expend substantial funds, time and effort in the area of production and quality control. FDA stringently applies its regulatory standards for manufacturing.

Discovery of previously unknown problems with respect to a product, manufacturer or facility may result in consequences with commercial significance. These include restrictions on the product, manufacturer or facility, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawals of the product from the market, product recalls, fines, injunctions and criminal prosecution.

Foreign Countries

Before we are permitted to market any of our products outside of the United States, those products will be subject to regulatory approval by foreign government agencies similar to FDA. These requirements vary widely from country to country. Generally, however, no action can be taken to market any drug product in a country until an appropriate application has been approved by the regulatory authorities in that country. FDA approval does not assure approval by other regulatory authorities. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. The Canadian regulatory process is substantially similar to that of the United States. We obtained regulatory approval to begin clinical trials of our oral insulin formulation in Canada in November 1998. In Ecuador, regulatory authorities approved the limited non-commercial distribution of our oral insulin formulation in September 1998. We obtained regulatory approval to begin clinical trials of our buccal morphine product in Canada in March 2002 and received regulatory approval to begin clinical trials of our fentanyl product in Canada in October 2002. We are currently in the process of recruiting investigators to conduct clinical trials of our buccal morphine product.

Marketing

We intend to rely on collaborative arrangements with one or more other companies that possess strong pharmaceutical marketing and distribution resources to perform these functions for us. Accordingly, we will not have the same control over marketing and distribution that we would have if we conducted these functions ourselves.

With respect to the Generex Bermuda joint venture, Elan may, at its option, choose to market morphine or any other product developed under the joint venture. Except for these arrangements, we do not have any agreements with any other companies for marketing or distributing our products. With respect to our insulin product, we possess the worldwide marketing rights to this product after they reverted to us upon the termination in May 2003 of the development and license agreement with Lilly.

Manufacturing

To date, we have produced our oral insulin formulation only under laboratory conditions on a small scale. In December 2000, we completed our pilot manufacturing facility in Toronto in the same commercial complex in which our original laboratory is located, and we are in the process of obtaining regulatory approval for the facility. We believe that this facility will be capable of producing our insulin product at levels necessary to supply our needs for late stage human clinical trials of the product and for initial commercial sales outside the United States, even though we have not yet actually produced product at those levels. We will need to significantly increase our manufacturing capability in order to manufacture any product in commercial quantities.

We own facilities in Brampton and Mississauga, Ontario, all within 25 miles from downtown Toronto, that were purchased with the intention of improving and equipping them for manufacturing. These facilities are currently leased to unrelated third parties, however, we believe we can place these facilities into production of our insulin product or other products within 12 to 18 months lead time if additional production capabilities are necessary.

Our new subsidiary Antigen leases office and laboratory space in Worcester, Massachusetts, which is sufficient for its present needs. The laboratory is approximately 820 square feet and has permission to store and use biohazardous (including recombinant DNA materials) and flammable chemicals.

Raw Material Supplies

The excipients used in our formulation are available from numerous sources in sufficient quantities for clinical purposes, and we believe that they will be available in sufficient quantities for commercial purposes when required, although we have not yet attempted to secure a commercial supply of any such products.

Components suitable for our RapidMist(TM) device are available from a limited number of potential suppliers, as is the chemical propellant used in the device. We believe that the components which now comprise the device will be utilized with the commercial version of our insulin product. We also expect to use the RapidMist(TM) device in connection with our buccal morphine and fentanyl products. We have also secured supply arrangements with the manufacturers of all other components and the propellant that we presently use in our RapidMist(TM) device for commercial quantities of such components and the propellant. All such suppliers are prominent, reputable and reliable suppliers to the pharmaceutical industry. Because we now have a single supplier for each of these components and propellant, however, we are more vulnerable to supply interruptions than would be the case if we had multiple suppliers for each component. We do not believe that the risk of a single source of supply for proprietary raw materials or device components is unusual in the pharmaceutical industry.

Insulin is available worldwide from only a few sources. However, alternative supplies of insulin are under development in Europe. The terms of our License Agreement with Lilly, provide for Lilly to negotiate terms for continued supply of insulin to Generex after termination of the License Agreement. We are currently working with Lilly on terms of a supply agreement under which Lilly will supply a specified amount of insulin for our further development needs, although we have not yet executed an agreement. We believe Lilly will continue to supply insulin for further development needs. We also believe future development and marketing partners under licensing and development agreements, if any, will provide, or assist us to obtain, pharmaceutical compounds that are used in products covered under such agreements.

While morphine is a controlled substance, it is readily available for use in clinical trials. We currently have the appropriate licenses and facilities for acquiring and storing morphine in Canada. Various regulatory issues surround the import of morphine into the United States and we will need to address these issues prior to commencing clinical trials in the United States.

Raw materials for our pre-clinical development stage immunomedicine products include amino acids (for peptide therapeutics) and oligonucleotides (for genetic constructs). These materials are readily available from commercial suppliers. We utilize the services of several commercial laboratories for the manufacturing of our pre-clinical development stage immunomedicine products.

Intellectual Property

We currently have fifteen issued U.S. patents pertaining to aspects of buccal delivery technology and covering our oral insulin formulation. We have six U.S. patent applications and one Canadian patent application pending, which also relate to aspects of our buccal delivery technology, our oral insulin formulation and our oral morphine formulation. In addition, we hold one U.S. patent and two Canadian patents and have one U.S. application pending that pertains to delivery technologies other than our buccal delivery technology.

We also have an indirect interest in three drug delivery patents held by another company, Centrum Biotechnologies, Inc., which is 50% owned by us.

Our new subsidiary Antigen currently holds six issued U.S. patents, one Australian patent, and two pending U.S. patent applications concerning technology for modulating the immune system via activation of antigen-specific helper T lymphocytes. Some of these patents are held under exclusive licenses from the University of Massachusetts. Dr. Humphreys and Dr. Xu, officers of Antigen, are the listed inventors or co-inventors on all of these patents and patent applications, including those licensed from the University of Massachusetts.

Our long-term success will substantially depend upon our ability to obtain patent protection for our technology and our ability to protect our technology from infringement, misappropriation, discovery and duplication. We cannot be sure that any of our pending patent applications will be granted, or that any patents which we own or obtain in the future will fully protect our position. Our patent rights, and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. We believe that our existing technology and the patents which we hold or have applied for do not infringe any one else's patent rights. We believe our patent rights will provide meaningful protection against others duplicating our proprietary technologies. We cannot be sure of this, however, because of the complexity of the legal and scientific issues that could arise in litigation over these issues. (See "Legal Proceedings" (Item 3) for discussion of certain legal proceedings involving intellectual property issues.)

We also rely on trade secrets and other unpatented proprietary information. We seek to protect this information, in part, by confidentiality agreements with our employees, consultants, advisors and collaborators.

Competition

We expect that products based upon our buccal delivery technology and any other products that we may develop will compete directly with products developed by pharmaceutical and biotechnology companies, universities, government agencies and public and private research organizations.

Products developed by our competitors may use a different active pharmaceutical agent or treatment to treat the same medical condition or indication as our product or may provide for the delivery of substantially the same active pharmaceutical ingredient as our products using different methods of administration. For example, a number of pharmaceutical and biotechnology companies are engaged in various stages of research, development and testing of alternatives to insulin therapy for the treatment of diabetes, as well as new methods of delivering insulin. These methods, including nasal, transdermal, needle free (high pressure) injection and pulmonary, may ultimately successfully deliver insulin to diabetic patients. Some biotechnology companies have also developed different technologies to enhance the presentation of peptide antigens. Many of our competitors and potential competitors have substantially greater scientific research and product development capabilities, as well as financial, marketing and human resources, than we do.

Where the same or substantially the same active ingredient is available using alternative delivery means or the same or substantially the same result is achievable with a different treatment or technology, we expect that competition among products will be based, among other things, on product safety, efficacy, ease of use, availability, price, marketing and distribution. When different active pharmaceutical ingredients are involved, these same competitive factors will apply to both the active agent and the delivery method.

We consider other drug delivery and biotechnology companies to be direct competitors for the cooperation and support of major drug and biotechnology companies that own or market proprietary pharmaceutical compounds and technologies, as well as for the ultimate patient market. Of primary concern to us are the competitor companies that are known to be developing delivery systems for insulin and other pharmaceutical agents that we have identified as product candidates and technologies to enhance the presentation of peptide antigens.

Buccal Insulin Product

Inhale Therapeutics, Inc. is developing a customized insulin formulation that is processed into a fine, dry powder and administered to the deep lung using a proprietary inhalation device developed for this purpose. Inhale has announced successful results using its inhaled product in Phase II clinical trials, and is now engaged in Phase III trials. Inhale is developing its insulin product in collaboration with Pfizer, Inc., which in turn has announced agreements to co-develop and co-promote the use of inhaled insulin with Aventis, a leading pharmaceutical company which presently manufactures insulin for sale primarily in Europe. Inhale is also developing pulmonary products with large molecule drugs other than insulin, and has stated that it is investigating the use of its inhalation technology with small molecule drugs.

Aradigm Corporation, which has announced a joint development agreement with Novo Nordisk A/S to jointly develop a pulmonary delivery system for insulin by inhalation, also may be considered a direct competitor of ours in the insulin area. Novo Nordisk is one of the two leading manufacturers of insulin in the world, the other being Eli Lilly and Company. Aradigm began Phase III testing of its inhalation product in the second half of 1998.

Other companies have announced development efforts relating to alternative (to injection) methods of delivering insulin or other large molecule drugs, including Alkermes, which announced a collaboration with Eli Lilly and Company in April 2000 to develop a pulmonary method of administering insulin. Other companies developing alternative means of delivering insulin and other large molecule drugs include: Emisphere Technologies (pills taken orally), Nobex Corporation (pills taken orally), and Natestch Pharmaceuticals (nasal), among others. These companies are at various stages of clinical development.

In addition to other delivery systems for insulin, there are numerous products which have been approved for use in the treatment of Type 2 diabetics in place of or in addition to insulin therapy. These products may also be considered competitive with insulin products.

Buccal Morphine and Fentanyl Products

Cephalon, Inc. currently markets Actiq® in the United States and has recently acquired the rights to the product in Europe. Actiq® delivers buccal transmucosal fentanyl to the cheek walls through the use of a lollipop. On November 4, 1998 the FDA cleared Actiq® for marketing for use in the management of breakthrough cancer pain. The product was launched in March 1999 in the United States.

Aradigm Corporation is developing the hand-held AERx Pain Management System for the treatment of breakthrough cancer pain. The AERx Pain Management System is a pulmonary delivery system to deliver the drug through inhalation. AERx has distinct advantages over the administration by injection of morphine and similar opiate-derived pain control drugs. Aradigm has completed Phase II clinical trials of this formulation.

Natestch Pharmaceuticals is developing an intranasal formulation of morphine that is in Phase II clinical trials. Results reported to date show the product to be safe and efficacious in the treatment of episodes of breakthrough pain. Natestch is currently seeking a licensing partner for this product.

Immunomedicine Technology and Products

A number of companies that are engaged in the development of immunomedicines employ technologies that are competitive to our new subsidiary, Antigen. Zycos Inc. has developed the Biotope® technology, Cel-Sci Corporation has developed the LEAPS delivery technology and Epimmune Inc. has developed the PADRE® technology. These companies have initiated early stage clinical trials for several products for the treatment of cancer, autoimmune, and allergic diseases. These companies also have established collaborations with academic centers and other companies for the development of certain products. We have not initiated clinical trials with any of our immunomedicine products, nor have we established commercial collaborations to date. We have established collaborations with major academic centers for the development of our immunomedicine products.

Environmental Compliance

Our manufacturing, research and development activities involve the controlled use of hazardous materials and chemicals. We believe that our procedures for handling and disposing of these materials comply with all applicable government regulations. However, we cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurred, we could be held liable for damages, and these damages could severely impact our financial condition. We are also subject to many environmental, health and workplace safety laws and regulations, particularly those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of hazardous biological materials. Violations and the cost of compliance with these laws and regulations could adversely affect us. However, we do not believe that compliance with the United States, Canadian or other environmental laws will have a material effect on us in the foreseeable future.

Research and Development Expenditures

A substantial portion of our activities to date have been in research and development. In the period from inception to July 31, 2003, our expenditures on research and development were \$38,864,948. These included \$5,150,075 in the year ended July 31, 2003, \$6,618,820 in the year ended July 31, 2002, and \$19,929,799 in the year ended July 31, 2001. The decrease in our research and development expenses in 2003 compared to 2002 is due principally to contraction of our ongoing research and development activities under our collaboration with Elan and the collaboration with Lilly, which ended in May 2003. The decrease in our research and development expenses in 2002 compared with 2001, is due principally to the accounting treatment for our joint venture with Elan, which resulted in a \$15,000,000 research and development expense for the license fee paid by Generex (Bermuda) Ltd. to Elan for technology rights in 2001 (our consolidated net loss, which includes this expense, however, was partially offset by approximately \$2.9 million of minority interest, reflecting Elan's 19.9% ownership interest in the joint venture).

Employees

At September 30, 2003, we had twenty-six full-time employees, including our executive officers and other individuals who work for us full time but are employed by management companies that provide their services and including six employees of our new subsidiary Antigen. Fourteen of our employees are executive and administrative, nine are scientific and technical personnel who engage primarily in development activities and in preparing formulations for testing and clinical trials, and three are engaged in corporate and product promotion, public relations and investor relations. We believe our employee relations are good. None of our employees are covered by a collective bargaining agreement.

We will continue to need qualified scientific personnel and personnel with experience in clinical testing, government regulation and manufacturing. We may have difficulty in obtaining qualified scientific and technical personnel as there is strong competition for these people from other pharmaceutical and biotechnology companies as well as universities and research institutions. Our business could be materially harmed if we are unable to recruit and retain qualified scientific, administrative and executive personnel to support our expanding activities, or if one or more members of our limited scientific and management staff were unable or unwilling to continue their association with us. We do not have fixed term agreements with any of our key management or scientific staff, other than Dr. Pankaj Modi. The fact that we have a fixed term contract with Dr. Modi, however, does not guarantee his continued availability.

We also use non-employee consultants to assist us in formulating research and development strategy, in preparing regulatory submissions, in developing protocols for clinical trials, and in designing, equipping and staffing our manufacturing facilities. We also use non-employee consultants to assist us in business development. These consultants and advisors usually have the right to terminate their relationship with us on short notice. Loss of some of these key advisors could interrupt or delay development of one or more of our products or otherwise adversely affect our business plans.

EXECUTIVE OFFICERS AND DIRECTORS

| Name* | Age | Position Held with Generex |
|---|-----|---|
| Anna E. Gluskin | 52 | President, Chief Executive Officer and Director |
| Rose C. Perri Secretary and Director | 36 | Chief Operating Officer, acting Chief Financial Officer, Treasurer, |
| Pankaj Modi, Ph.D. | 49 | Vice President, Research and Development and Director |
| Gerald Bernstein | 70 | Vice President and Director |
| Mark Fletcher, Esq. | 38 | Executive Vice President and General Counsel |
| J. Michael Rosen | 52 | Director |
| Peter Levitch | 71 | Director |
| John P. Barratt | 59 | Director |

**Mark Perri, our former Chairman and Chief Financial Officer, passed away on November 6, 2002.*

Anna E. Gluskin -- Director since September 1997. Ms. Gluskin has served as our President and Chief Executive Officer since October 1997. She held comparable positions with Generex Pharmaceuticals, Inc. from its formation in 1995 until its acquisition by us in October 1997.

Rose C. Perri -- Director since September 1997. Ms. Perri has served as our Treasurer and Secretary since October 1997, and as Chief Operating Officer since August 1998. She was an officer of Generex Pharmaceuticals, Inc. from its formation in 1995 until its acquisition by us in October 1997. Effective November 2002, Ms. Perri became acting Chief Financial Officer.

Pankaj Modi, Ph.D. -- Director since September 1997. Dr. Modi has served as our Vice President, Research and Development since October 1997. Prior to that time, Dr. Modi was Director of Insulin Research for Generex Pharmaceuticals, Inc., a position he assumed in October 1996. Prior to joining Generex Pharmaceuticals, Dr. Modi was engaged in independent research and was employed as a senior researcher at McMaster University in Hamilton, Ontario from February 1994 through October 1996.

Gerald Bernstein, M.D. -- Director since October 2002. Dr. Gerald Bernstein has served as our Vice President since October 1, 2001. Dr. Bernstein acts as a key liaison for us on medical and scientific affairs to the medical, scientific and financial communities and consults us under a consulting agreement on research and medical affairs and on development activities. Dr. Bernstein has been an associate clinical professor at the Albert Einstein College of Medicine in New York and an attending physician at Beth Israel Medical Center, Lenox Hill Hospital and Montefiore Medical Center, all in New York. He is a former president of the American Diabetes Association.

Mark Fletcher, Esq. -- Mr. Fletcher has served as our Executive Vice President and General Counsel since April 2003. From October 2001 to March 2003, Mr. Fletcher was engaged in the private practice of law as a partner at Goodman and Carr LLP, a leading Toronto law firm. From March 1993 to September 2001, Mr. Fletcher was a partner at Brans, Lehun, Baldwin LLP in Toronto. Mr. Fletcher received his LL.B. from the University of Western Ontario in 1989 and was admitted to the Ontario Bar in 1991.

J. Michael Rosen -- Director since August 2000. Mr. Rosen has been a principal in a number of related travel management and hotel marketing businesses since 1978. The principal companies in this group, all of which are headquartered in Ontario, are Uniworld Travel & Tours, Inc., Nevada Vacations, Inc., Casino Vacations, Inc. and Casino Tours, Inc. Mr. Rosen presently serves as the President or a Vice President, and the Chief Financial Officer, of each of these companies. Mr. Rosen is an accountant by training, and was engaged in the private practice of accounting prior to 1978.

Peter Levitch - Director since October 2002. Mr. Levitch has been President of Peter Levitch & Associates, an independent consulting firm to health professionals since 1981. In this capacity, he advises companies through the various stages of the development of pharmaceuticals, medical devices, biologics and diagnostics, including clinical evaluation and the FDA regulatory approval phases. He has served as an advisor to more than 200 leading biotechnology and biological firms, including Amgen, Genentech, Immunex, DuPont, Baxter and Johnson and Johnson. Prior to 1981, Mr. Levitch was Vice President, Clinical and Regulatory Affairs at Oxford Research International Corp. and held senior positions managing the regulatory and clinical programs at Ortho Diagnostic Systems (a subsidiary of Johnson & Johnson).

John P. Barratt -- Director since March 2003. Mr. Barratt is Chief Operating Officer of Beyond.com, a company in which he has been employed since 2000. From January 1996 to September 2000, Mr. Barratt served as partner-in-residence for the Quorum Group of Companies, an international investment partnership specializing in providing debt and equity capital to the emerging high growth technology sector. From 1988 to December 1995, Mr. Barratt was Executive Vice President and Chief Operating Officer of Coscan Development Corporation. He previously held a number of senior-level management positions, including Deputy Chief Executive of Lloyds Bank Canada. Mr. Barratt also currently serves as a director of GLP NT Corporation and BNN Split Corporation.

We entered into a joint venture with Elan Corporation, plc ("Elan") and certain affiliates of Elan in January 2001. Pursuant to a Securities Purchase Agreement dated January 16, 2001 between us, Elan and Elan International Services, Ltd. ("EIS"), a subsidiary of Elan, EIS has the right to nominate one director to our Board of Directors for so long as EIS or its affiliates own at least 1.0% of the issued and outstanding shares of common stock. Dr. Lieberburg, a former director nominated by EIS, resigned effective August 1, 2002. EIS has not informed us of its nominee to replace Dr. Lieberburg. Under the terms of the Securities Purchase Agreement, the EIS-nominated director may not in any event have more than 15% of the aggregate voting power of the Board of Directors as a whole.

Dr. Modi holds the position of Vice President, Research and Development pursuant to a consulting agreement that was originally entered into as of October 1, 1996, that was amended and supplemented as of January 7, 1998, and that was amended and supplemented as of December 31, 2000. An amendment to Dr. Modi's consulting agreement was approved by the Board of Directors in January 2002. Under the consulting agreement, we must use our best efforts to cause Dr. Modi to be nominated for election and elected as our director for as long as the consulting agreement is in force.

There are no family relationships among our officers and directors.

Other Key Employees and Consultants

Slava Jarnitskii is our Financial Controller. He began his employment with Generex Pharmaceuticals in September 1996 and has been in our employ since our acquisition of Generex Pharmaceuticals in October 1997. Before his employment with Generex Pharmaceuticals, Mr. Jarnitskii received a Masters of Business Administration degree from York University in September 1996.

Dr. Joseph V. Gulfo, MD, MBA is Chief Executive Officer and President of Antigen. Dr. Gulfo joined Antigen in August 1999 as CEO. Dr. Gulfo has over 15 years experience in the management and development of biopharmaceutical companies and products. He has overseen development of several FDA-approved products for diagnosis and treatment of cancer including ProstaScint® and Valstar®, and negotiated numerous licensing arrangements. From 1984 to 1988, he was Chief Operating Officer and a Director of Anthra Pharmaceuticals, Inc. and Chairman of that company's UK subsidiary. Dr. Gulfo holds an MD from the University of Medicine and Dentistry of New Jersey and MBA in Finance from Seton Hall University.

Dr. Robert E. Humphreys, MD, PhD, is currently Executive Vice-President and Chief Operating Officer of Antigen. Dr. Humphreys founded Antigen in 1999 and was its President. He has extensive experience in the National Institute of Health, arthritis, cancer and diabetes study sections. Dr. Humphreys is the principal inventor on 6 awarded US patents and has over 150 peer-reviewed publications to his credit. Prior to founding Antigen, Dr. Humphreys was Professor of Medicine and Pharmacology at University of Massachusetts Medical School. He received his MD and PhD degrees from Yale University and post-doctoral fellow degree in immunology from Harvard University. He also received his initial training at Bethesda Naval Hospital.

Dr. Minzhen Xu is Vice President - Biology of Antigen. Dr. Xu received an MD from the Shanghai Medical University in China and a PhD in immunology from University of Massachusetts Medical School. He has been with Antigen since its inception and is the company's chief experimentalist.

Certain Additional Risk Factors

In addition to historical facts or statements of current condition, this Annual Report on Form 10-K contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events.

The following discussion outlines certain factors that we think could cause our actual outcomes and results to differ materially from our forward-looking statements. These factors are in addition to those set forth elsewhere in this Annual Report on Form 10-K.

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 ongoing revenues from operation in the immediately foreseeable future. To date, we have not been profitable and our accumulated net loss before preferred stock dividend was approximately \$76,000,000 at July 31, 2003. 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.

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.

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 under our joint venture with Elan, which requires us to fund 80.1% of initial product development costs;
- to develop buccal and immunomedicine products;
- to develop new products based on our buccal delivery and immunomedicine technologies, including clinical testing relating to new products;
- to develop or acquire other technologies or other lines of business;
- to establish and expand our manufacturing capabilities;
- to finance general and administrative and research activities that are not related to specific products under development; and
- to finance the research and development activities of our new subsidiary Antigen. We have agreed to fund at least \$2,000,000 of Antigen expenditures during the first two years following the acquisition.

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, and we may need additional funding sooner than anticipated. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our products. Unforeseen problems, including materially negative developments in our joint venture with Elan, 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.

New equity financing could dilute current shareholders.

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 are likely to 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

Because our technologies and products are at an early stage of development, we cannot expect revenues in the foreseeable future.

We have no products approved for commercial sale at the present time. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products under development. We may not be successful in one or more of these stages of the development of our products, and/or any of the products we develop may not be commercially viable.

While over 750 patients with diabetes have been dosed with our oral insulin formulation at approved facilities in seven countries, our clinical program has not reached a point where we are prepared to apply for regulatory approvals to market the product in any country. Until we have developed a commercially viable product which receives regulatory approval, we will not receive revenues from ongoing operations.

We will not receive revenues from operations until we receive regulatory approval to sell our products. Many factors impact our ability to obtain approvals for commercially viable products.

We have no products approved for commercial sale by drug regulatory authorities. We have begun the regulatory approval process for our oral insulin formulation, buccal morphine and fentanyl products. Our immunomedicine products are in the pre-clinical stage of development.

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 never receive approval for one or more product candidates.

Delays in obtaining United States or 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, 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 period 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 ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

Risks Related to Marketing of Our Potential Products

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

Even if we obtain regulatory approval to market our oral insulin product or any other 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 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 alternatives 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.

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.

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. Many 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.

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

Sales of our potential products depend in part on the availability of reimbursement by third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. FDA approval of health care products does not guarantee that these third-party payors will pay for the products. Even if third party payors 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.

Outcome of an Arbitration Proceeding with Sands Brothers may have an adverse impact on us.

On October 2, 1998, Sands Brothers & Co. Ltd., a New York City-based investment banking and brokerage firm, initiated an arbitration against us under New York Stock Exchange rules. Sands alleged that it had the right to receive, for nominal consideration, approximately 1.5 million shares of our common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary that we acquired in late 1997. In exchange therefor, the letter agreement purported to grant Sands the right to acquire 17% of Generex Pharmaceuticals' common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals' common stock applies to our common stock since outstanding shares of Generex Pharmaceuticals' common stock were converted into shares of our common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and \$144,000 in monthly fees allegedly due under the terms of the purported agreement.

After several arbitration and court proceedings, on October 29, 2002, the Appellate Division of the New York Supreme Court issued a decision remanding the issue of damages to a new panel of arbitrators and limiting the issue of damages before the new panel to reliance damages which is not to include an award of lost profits. Reliance damages are out-of-pocket damages incurred by Sands.

On November 27, 2002, Sands filed with the Appellate Division a motion to reargue the appeal, or, in the alternative, for leave to appeal to the Court of Appeals of New York from the order of the Appellate Division. On March 18, 2003, the Appellate Division denied Sands' motion.

Despite the recent favorable decisions, the case is still ongoing and our ultimate liability cannot yet be determined with certainty. Our financial condition would be materially adversely affected to the extent that Sands receives shares of our common stock for little or no consideration or substantial monetary damages as a result of this legal proceeding. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

Risks Related to the Market for Our Stock

If our stock is delisted from the NASDAQ SmallCap Market and/or becomes subject to Penny Stock regulations, the market price for our stock may be reduced and it may be more difficult for us to obtain financing.

On June 5, 2003, our common stock was delisted from the NASDAQ National Market because of our failure to maintain a minimum of \$10,000,000 in stockholders' equity. On June 5, 2003, our stock began trading on the NASDAQ SmallCap Market. The NASDAQ SmallCap Market has its own standards for continued listing, including a minimum of \$2.5 million stockholders' equity. As of July 31, 2003, our stockholders' equity was \$5,856,965.

In addition, for continued listing on both the NASDAQ National Market and SmallCap Market, our stock price must be at least \$1.00. During periods in fiscal 2002 and the beginning of fiscal 2003, our stock price dropped close to \$1.00 per share. If we do not meet this requirement in the future, we may be subject to delisting by NASDAQ.

If our stock is delisted from NASDAQ, 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 Stock may be volatile.

There may be wide fluctuation in the price of our 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 stock. Such activities may result, among other things, in causing the price of our 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.

Our outstanding Special Voting Rights Preferred Stock and provisions of our Certificate of Incorporation could delay or prevent the acquisition or sale of our business.

Holders of our Special Voting Rights Preferred Stock have the ability to prevent any change of control in us. Our Vice President of Research and Development, Dr. Pankaj Modi, owns all of our Special Voting Rights Preferred Stock. In addition, our 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 the shareholders. 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 shareholder approval for an acquisition of our business or increase the cost of any such acquisition.

Item 2. Properties

Our executive and principal administrative offices occupy approximately 5,000 square feet of office space in the Business Centre at 33 Harbour Square in downtown Toronto, Ontario, Canada. We own the Business Centre, which comprises approximately 9,100 square feet of usable space. The space in the Centre that is not used by us is leased to third parties.

We own a laboratory facility in Toronto that we have used for limited production of our oral insulin formulation for clinical purposes, and have completed a pilot manufacturing facility for our insulin product in the same commercial complex. Our laboratory facility is approximately 2,650 square feet. Our pilot manufacturing facility, which also includes laboratory facilities, is approximately 4,800 square feet. We also own two additional spaces at this location one of which is currently leased to third parties and one of which is used for storage. Both of these spaces could be used for manufacturing facilities if necessary. We have obtained regulatory approval for the laboratory facility, and we are currently in the process of obtaining regulatory approval for the pilot manufacturing facility.

In August we purchased an additional 23,500 square feet of property at the same location in Toronto for \$2,400,000 CAN, or approximately \$1,525,000 US for investment purposes. The property is located adjacent to our current laboratory facility, and could be used by us for expansion of our facilities. It is currently leased to third parties.

We have mortgages on our Toronto properties totaling \$1,895,475 at July 31, 2003. These mortgages require the payment of interest, with minimal principal reduction, prior to their due dates. These mortgages currently require an aggregate \$13,850 in monthly debt service payments. Aggregate principal maturities for these mortgages will be \$426,767 in fiscal 2004, \$1,296,386 in fiscal 2005 and \$172,322 in fiscal 2006.

We lease approximately 1,710 square feet of office and laboratory space in Worcester, Massachusetts that Antigen uses for its research and development activities. We assumed the lease in August 2003 when we acquired Antigen. The lease is for a term of 2 years with an annual rental of \$103,500. This space is sufficient for Antigen's present activities.

We do not expect to need manufacturing capabilities related to our insulin product beyond our pilot facility before the end of the current fiscal year. We own an 11,625 square foot building in Brampton, Ontario, which is approximately 25 miles outside Toronto, and a 13,500 square foot building in Mississauga, Ontario, which is about 20 miles from downtown Toronto, for ultimate use in manufacturing. We have done preliminary work on these facilities, but we do not expect to make a substantial investment in improving and equipping them for manufacturing operations until our requirements in this area are better defined. Both properties are currently leased to third parties.

We could use our other properties to expand research, development or testing of our buccal and immunomedicine products if current facilities prove inadequate for our needs.

Item 3. Legal Proceedings

Sands Brothers & Co. Ltd. v. Generex Biotechnology Corporation. On October 2, 1998, Sands Brothers & Co. Ltd., a New York City-based investment banking and brokerage firm, initiated an arbitration against us under New York Stock Exchange rules. Sands alleged that it had the right to receive, for nominal consideration, approximately 1.5 million shares of our common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary of us that was acquired in late 1997. In exchange, the letter agreement purported to grant Sands the right to acquire 17% of Generex Pharmaceuticals' common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals' common stock applies to our common stock since outstanding shares of Generex Pharmaceuticals' common stock were converted into shares of our common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and \$144,000 in monthly fees allegedly due under the terms of the purported agreement.

Pursuant to an arbitration award dated September 22, 1999, the arbitration panel that heard this case awarded Sands \$14,070 and issued a declaratory judgment requiring us to issue to Sands a warrant to purchase 1,530,020 shares of our common stock pursuant to and in accordance with the terms of the purported October 1997 letter agreement. On October 13, 1999, Sands commenced a special proceeding to confirm the arbitration award in the Supreme Court of the State of New York, County of New York (the "New York Supreme Court"). On November 10, 1999, we moved to vacate the arbitration award. On March 20, 2000, the New York Supreme Court granted Sands' petition to confirm the award and denied our motion to vacate the award. We appealed and on January 23, 2001, the New York State Appellate Division, First Department (the "Appellate Division"), modified the judgment of the New York Supreme Court that had confirmed the arbitration award against us. The Appellate Division affirmed the portion of the New York Supreme Court judgment that had confirmed the granting of monetary relief of \$14,070 to Sands but modified the judgment to vacate the portion of the arbitration award directing the issuance to Sands of a warrant to purchase 1,530,020 shares of our common stock. The Appellate Division held that the portion of the award directing us to issue warrants to Sands is too indefinite to be enforceable and remanded the matter to the arbitration panel for a final and definite award with respect to such relief or its equivalent (including possibly an award of monetary damages). The arbitration panel commenced hearings on the matters remanded by the Appellate Division in June 2001.

On November 7, 2001, the arbitration panel issued an award again requiring us to issue to Sands a warrant to purchase 1,530,020 shares of our common stock purportedly pursuant to and in accordance with the terms of the October 1997 letter agreement. Thereafter, Sands submitted a motion to the New York Supreme Court to modify and confirm the arbitration panel's award while we filed a motion with the court to vacate the arbitration award. On February 25, 2002, the New York Supreme Court vacated the arbitration panel's award. The Supreme Court concluded that the arbitration panel had "disregarded the plain meaning" of the directive given by the Appellate Division in the Appellate Division's January 23, 2001 decision that remanded the matter of the warrant for reconsideration by the panel. The Supreme Court found that the arbitration panel's award "lacks a rational basis". The Supreme Court also remanded the matter to the New York Stock Exchange on the issue of whether the arbitration panel should be disqualified. Sands has appealed the February 25, 2002 order of the Supreme Court to the Appellate Division. We filed a cross-appeal on issues relating to the disqualification of the arbitration panel.

On October 29, 2002, the Appellate Division issued a decision and order unanimously modifying the lower court's order by remanding the issue of damages to a new panel of arbitrators and otherwise affirming the lower court's order. The Appellate Division's decision and order limits the issue of damages before the new panel of arbitrators to reliance damages which is not to include an award of lost profits. Reliance damages are out-of-pocket damages incurred by Sands. The Appellate Division stated that the lower court properly determined that the arbitration award, which had granted Sands warrants for 1,530,020 shares of our stock, was "totally irrational."

On March 18, 2003, the Appellate Division of the Supreme Court of New York denied a motion by Sands for re-argument of the October 29, 2002 decision, or, in the alternative, for leave to appeal to the Court of Appeals. At the present time, we are not able to predict the ultimate outcome of this legal proceeding or to estimate a range of possible loss from this legal proceeding. Therefore, no provision has been recorded in the accompanying financial statements.

Subash Chandarana et al. v Generex Biotechnology Corporation et al. In February 2001, a former business associate of our Vice President of Research and Development ("VP") and an entity called Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against the VP and us seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and the VP that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by us of three patents allegedly owned by the company called CTI. On July 20, 2001, we filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by us. Consequently, the shareholders of CBI are in a deadlock. The court granted our motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in name

of or on behalf of CBI. The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against the VP and us. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against the VP and us. We intend to continue our vigorous defense of this legal proceeding. We are not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

Hope Manufacturing, Inc. and Steven Wood. In July 2002, Hope Manufacturing and Steven Wood commenced actions against certain defendants, including us and certain of our officers, in the Ontario Superior Court of Justice claiming compensatory damages, punitive damages and various forms of injunctive and declaratory relief for breach of contract and various business torts. We believe the claims against us are frivolous and completely without merit. We are not a party to any agreement with the plaintiffs. Most of the requested relief relates to restrictions on the use of patents and information allegedly owned by the plaintiffs, and an accounting for the use of such items. We have not used any patents or information owned by the plaintiffs. All of the patents and information claimed to be owned by the plaintiffs are completely unrelated to any product or technology we are currently developing or intend to develop. Therefore, even if the court were to award some declaratory or injunctive relief, we would not be affected. The parties have now signed Minutes of Settlement resolving all outstanding issues in the action. The settlement is presently in the process of being finalized.

We are involved in certain other legal proceedings in addition to those specifically described herein. Subject to the uncertainty inherent in all litigation, we do not believe at the present time that the resolution of any of these legal proceedings is likely to have a material adverse effect on our consolidated financial position, results of operations and cash flows.

We maintain product liability coverage for claims arising from the use of our products in clinical trials, but do not have any insurance that covers our potential liability in any of the legal proceedings described above.

Item 4. Submission of Matters to a Vote of Security Holders

We did not submit any matters to a vote of stockholders in the fourth quarter of the fiscal year ended July 31, 2003. We have called a meeting of stockholders to be held on November 4, 2003 to vote on three matters.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

Our common stock has been listed on the NASDAQ SmallCap Market since June 5, 2003. From May 5, 2000 to June 4, 2003, our common stock was listed on the NASDAQ National Market. From February 1998 to May 2000, the "bid" and "asked" prices for our common stock were quoted on the OTC Bulletin Board operated by the National Association of Securities Dealers. Prior to February 1998, there was no public market for our common stock.

The table below sets forth the high and low, intra-day sales prices of our common stock reported on the NASDAQ National Market for each fiscal quarter (or portion thereof) in the prior two years ended July 31, 2003. The table below also sets forth the high and low closing "bid" prices for our common stock reported on the NASDAQ SmallCap Market for the period from June 5, 2003 to July 31, 2003.

| | Sales Prices (except where indicated) | |
|----------------------|--|--------|
| | High | Low |
| Fiscal 2002 | | |
| First Quarter | \$8.75 | \$2.91 |
| Second Quarter | \$7.76 | \$5.26 |
| Third Quarter | \$6.20 | \$3.31 |
| Fourth Quarter | \$5.24 | \$1.75 |
| Fiscal 2003 | | |
| First Quarter | \$2.63 | \$0.85 |
| Second Quarter | \$2.60 | \$1.00 |
| Third Quarter | \$1.42 | \$0.65 |
| Fourth Quarter | | |
| 05/01/03 - 06/04/03 | \$1.72 | \$0.87 |
| 06/05/03 - 07/31/03* | \$2.63 | \$1.35 |

*High and low closing "bid" prices, which represent prices between dealers and do not include retail markup, markdown or commission and may not represent actual transactions.

The closing sales price for our common stock reported on October 14, 2003, was \$2.05.

At October 14, 2003, there were 720 holders of record of our common stock.

Existing Stock Compensation Plans

The following table sets forth information as of October 14, 2003 regarding our existing compensation plans and individual compensation arrangements pursuant to which our equity securities are authorized for issuance to employees or non-employees (such as directors, consultants and advisors) in exchange for consideration in the form of services:

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|--|--|--|--|
| Equity compensation plans approved by security holders | | | |
| 1998 Stock Option Plan | 995,500 | \$6.68 | 0 |
| 2000 Stock Option Plan | 1,774,500 | \$8.90 | 225,500 |
| 2002 Stock Option Plan | 3,825,159 | \$3.78 | 174,841 |
| Total | 6,595,159 | \$4.38 | 400,341 |
| Equity compensation plans not approved by security holders | 0 | 0 | 0 |
| Total | 6,595,139 | \$4.38 | 253,341 |

Dividends

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

Recent Sales of Unregistered Securities

In the fiscal year ended July 31, 2003 and the subsequent interim period ended October 14, 2003, we sold common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act of 1933 as follows:

- In November 2002 and March 2003, we issued an aggregate of 100,000 shares of common stock to two financial consultants as compensation for services rendered. We recognized an aggregate expense of \$133,000 in connection with these shares. The expense amount was determined by attributing to each share the market price on the date of issuance. We relied on Section 4(2) of the Securities Act of 1933 in issuing these shares. The issuances were not part of a public offering, the shares bore restrictive legends, and each of the financial consultants had sufficient sophistication in financial affairs so as to not require the protection of the Securities Act of 1933.
- Effective May 13, 2003, we offered all holders of our outstanding warrants the opportunity to exercise their warrants at a reduced price of \$1.50 per share on or before June 12, 2003. After June 12, 2003 the exercise price on all of the unexercised warrants reverted to the price stated in the original warrant. In addition, any holder exercising a reduced-priced warrant was entitled to receive a new warrant with an exercise price equal to the greater

of one half of the original exercise price of the prior warrant or the market price on the day the prior warrant was exercised. We received gross proceeds of approximately \$2,300,000 from this offer as holders elected to exercise warrants for 1,531,001 shares within the reduced price period. We issued new warrants exercisable for 1,635,121 shares, with exercise prices calculated in the manner stated above, to holders who exercised their original warrants within the reduced price period. The exercise price of the new warrants ranged from a high of \$6.50 to a low of \$1.25. The number of new warrants exceeds the number of shares issued on exercise of old warrants because some old warrants included "cashless" or "net" exercise provisions. We relied on Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder in issuing the shares and warrants without registration under the Securities Act of 1933.

- On May 29, 2003, we completed a private placement sale of 2,926,301 units of securities ("Units") for cash at a price of \$1.15 per Unit to 9 accredited investors. Each Unit consisted of one share of our common stock and a warrant to purchase four tenths of one share (0.4 shares) of our common stock at an exercise price of \$1.71 per share, with a three-year exercise period. We raised \$3,365,250, with net proceeds to us of approximately \$3,100,000, in the private placement. The Shemano Group, a San Francisco investment banking firm, acted as the placement agent and received an aggregate commission of \$235,568 and warrants to purchase 99,000 shares of our common stock at an exercise price of \$1.71 per share. We relied on Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder in issuing the Units, shares and warrants without registration under the Securities Act of 1933.
- On June 10, 2003, we completed the private placement sale of 666,667 units of securities ("Units") for cash to one accredited investor at a price of \$1.50 per Unit. Each Unit consisted of one share of our common stock and one warrant to purchase one share of our common stock at an exercise price of \$1.80 per share, with a three-year exercise period. We raised \$1,000,000 in the private placement. No commissions or similar fees were paid in connection with this transaction. We relied on Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder in issuing the Units, shares and warrants without registration under the Securities Act of 1933.
- On August 8, 2003, we acquired all of the outstanding capital stock of Antigen Express, Inc. pursuant to an Agreement and Plan of Merger. Pursuant to the merger agreement, Antigen became our wholly-owned subsidiary. We issued approximately 2,800,000 shares of our common stock to the former shareholders of Antigen in exchange for the all of the outstanding shares of capital stock of Antigen. No commissions or similar fees were paid in connection with this transaction. We relied on Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder in issuing these shares without registration under the Securities Act of 1933.

Item 6. Selected Financial Data

The following selected financial data is derived from and should be read in conjunction with our financial statements and related notes, which appear elsewhere in this Annual Report on Form 10-K. Our financial statements for the year ended July 31, 2003 were audited by BDO Dunwoody, LLP. Our financial statements for the years ended July 31, 2002 and 2001 were audited by Deloitte & Touche LLP. Our financial statements for the year ended July 31, 2000 and 1999 were audited by WithumSmith+Brown.

In thousands, except per share data

| | Year Ended July 31 | | | | |
|--|--------------------|------------|------------|-----------|-----------|
| | 2003 | 2002 | 2001 | 2000 | 1999 |
| Operating Results: | | | | | |
| Revenue | -- | -- | \$1,000 | -- | -- |
| Net Loss | \$(13,262) | \$(13,693) | \$(27,097) | \$(8,841) | \$(6,240) |
| Net Loss Available to Common Stockholders | \$(14,026) | \$(14,414) | \$(27,097) | \$(8,841) | \$(6,240) |
| Cash Dividends per share | -- | -- | -- | -- | -- |
| Common Stockholders | | | | | |
| Loss per Common Share: | | | | | |
| Basic and Diluted Net Loss Per Common Share | (.67) | (.70) | (1.44) | (.58) | (.47) |
| Financial Positions: | | | | | |
| Total Assets | \$22,639 | \$28,161 | \$42,666 | \$10,341 | \$8,890 |
| Long-Term Debt | \$1,895 | \$663 | \$693 | \$722 | \$996 |
| Series A, Preferred Stock | \$13,501 | \$12,736 | \$12,015 | -- | -- |
| Stockholder's Equity | \$5,857 | \$12,863 | \$27,307 | \$8,415 | \$7,310 |

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

General

Corporate History

We were incorporated in Delaware in September 1997 for the purpose of acquiring Generex Pharmaceuticals, Inc., a Canadian corporation formed in November 1995 to engage in pharmaceutical and biotechnological research and other activities. Our acquisition of Generex Pharmaceuticals was completed in October 1997 in a transaction in which the holders of all outstanding shares of Generex Pharmaceuticals exchanged their shares for shares of our common stock.

In January 1998, we participated in a "reverse acquisition" with Green Mt. P. S., Inc., a previously inactive Idaho corporation formed in 1983. As a result of this transaction, our shareholders (the former shareholders of Generex Pharmaceuticals) acquired a majority (approximately 90%) of the outstanding capital stock of Green Mt., we became a wholly-owned subsidiary of Green Mt., Green Mt. changed its corporate name to Generex Biotechnology Corporation ("Generex Idaho"), and we changed our corporate name to GBC Delaware, Inc. Because the reverse acquisition resulted in our shareholders becoming the majority holders of Generex Idaho, we were treated as the acquiring corporation in the transaction for accounting purposes. Thus, our historical financial statements, which essentially represented the historical financial statements of Generex Pharmaceuticals, were deemed to be the historical financial statements of Generex Idaho.

In April 1999, we completed a reorganization in which we merged with Generex Idaho. In this transaction, all outstanding shares of Generex Idaho were converted into our shares, Generex Idaho ceased to exist as a separate entity, and we changed our corporate name back to "Generex Biotechnology Corporation". This reorganization did not result in any material change in our historical financial statements or current financial reporting.

In August 2003, we acquired Antigen Express, Inc. Antigen is engaged in the research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. For details about the this acquisitions, See "Developments Subsequent to Fiscal 2003" below.

Business History

We are engaged in the development of proprietary drug delivery technology. Our principal business focus has been to develop a technology for buccal delivery (absorption through the inner cheek walls) of large molecule drugs, i.e., drugs composed of molecules with molecular weights above a specified level. Large molecule drugs historically have been administered only by injection because their size inhibits or precludes absorption if administered by oral, transdermal, transnasal or other means.

Our first product is an insulin formulation that is administered as a fine spray into the oral cavity using a hand-held aerosol spray applicator. Between January 1999 and September 2000, we conducted limited clinical trials on this product in the United States, Canada, Europe and Ecuador. In September 2000, we entered into an agreement to develop this product with Eli Lilly and Company ("Lilly"). To date, over 750 patients with diabetes have been dosed with our oral insulin product at approved facilities in seven countries. We have conducted several clinical trials with insulin supplied by Lilly under our agreement. Lilly did not, however, authorize or conduct any clinical trials or provide financial support for those trials. We did receive a \$1,000,000 up front payment from Lilly. On May 23, 2003, we announced that we had agreed with Lilly to end the development and license agreement for the development and commercialization of buccal delivery of insulin. We are currently negotiating terms for Lilly to continue to supply a specified amount of insulin for further development of our product. We will retain all of the intellectual property and commercialization rights with respect to the buccal spray drug delivery technology, and we will have the continuing right to develop and commercialize the product.

In January 2001, we established a joint venture with Elan International Services, Ltd. ("EIS"), a wholly owned subsidiary of Elan Corporation, plc (EIS and Elan Corporation, plc being collectively referred to as "Elan"). The joint venture will pursue the application of certain of our and Elan's drug delivery technologies, including our platform technology for the buccal delivery of pharmaceutical products, for the treatment of prostate cancer, endometriosis and/or the suppression of testosterone and estrogen. In January 2002, the parties expanded the joint venture to include buccal morphine for the management of pain and selected buccal morphine as the initial product for development under Generex (Bermuda) Ltd. This expansion of the joint venture occurred after we successfully completed a proof of concept clinical study of morphine delivery using our proprietary buccal delivery technology.

In connection with the joint venture, EIS purchased 1,000 shares of a new series of our preferred stock, designated as Series A Preferred Stock, for \$12,015,000. We applied the proceeds from the sale of the Series A Preferred Stock to subscribe for an 80.1% equity ownership interest in Generex (Bermuda), Ltd. EIS paid in capital of \$2,985,000 to subscribe for a 19.9% equity interest in Generex (Bermuda), Ltd. While we initially own 80.1% of the joint venture entity, EIS has the right, subject to certain conditions, to increase its ownership up to 50% by exchanging the Series A Preferred Stock for 30.1% of our interest in the joint venture entity. In January 2002 and 2003, pursuant to the terms of the agreement with EIS, EIS received a 6% stock dividend of Series A Preferred Stock.

Generex (Bermuda), Ltd. was granted non-exclusive licenses to utilize our buccal delivery technology and certain Elan drug delivery technologies. Using the funds from its initial capitalization, Generex (Bermuda), Ltd. paid a non-refundable license fee of \$15,000,000 to Elan in consideration for being granted the rights to utilize the Elan drug delivery technologies.

EIS also purchased 344,116 shares of our common stock for \$5,000,000. We may use the proceeds of this sale for any corporate purpose. If the joint venture achieves certain milestones, we may require EIS to purchase an additional \$1,000,000 of our common stock at a 30% premium to the then prevailing fair market value of our common stock.

Our new subsidiary Antigen is engaged in research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Our immunomedicine products 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 that were discovered by an executive officer of Antigen, the li-Key hybrid peptides and li-Suppression. Our immunomedicine products are in the pre-clinical stage of development and trials in human patients are not expected for 12 months. Development efforts are underway in melanoma, breast cancer, prostate cancer, HIV and Type I diabetes. We are establishing collaborations with academic centers to advance the technology, with the ultimate goal of conducting clinical testing.

We do not expect to receive any revenues from product sales in the current fiscal year. We expect, however, to satisfy all of our cash needs during the current year from capital raised through prior equity financing.

Disclosure Regarding Research and Development Projects

Our major research and development projects are the refinement of our basic buccal delivery technology, our buccal insulin project and our buccal morphine product.

Both our insulin product and our morphine product are in clinical trials. In Canada, we have recently begun Phase II-B trials for insulin. In order to obtain FDA and Canadian HPB approval for any of our product candidates, we will be required to complete "Phase III" trials which involve testing our product with a large number of patients over a significant period of time. The conduct of Phase III trials will require significantly greater funds than we either have on hand or have in experience in raising in any year or two years' time. We will therefore need to receive funding from a corporate collaborator, or engage in fundraising on a scale with which we have no experience.

Because of various uncertainties, we cannot predict the timing of completion of our buccal insulin or buccal morphine products. These uncertainties include the success of current studies, our ability to obtain the required financing and the time required to obtain regulatory approval even if our research and development efforts are completed and successful. For the same reasons, we cannot predict when any products may begin to produce net cash inflows.

Most of our research and development activities to date have involved developing our platform technology for use with insulin and morphine. Insubstantial amounts have been expended on projects with other drugs, and those projects involved a substantial amount of platform technology development. Therefore, in the past, we have not made significant distinctions in the accounting for research and development expenses among products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all our potential products. In the fiscal year ended July 31, 2003, approximately 94% of our \$5,150,075 in research expenses was attributable to insulin and platform technology development, and approximately 5.5% was attributable to morphine and fentanyl projects. As morphine and fentanyl are both narcotic painkillers, the research is related. In the fiscal year ended July 31, 2002, approximately 98% of our \$6,618,820 of research and development was expended for insulin and platform technology, and approximately 1.6% for morphine and fentanyl.

Developments in Fiscal 2003

In August 2002, we purchased approximately \$1.6 million of property for investment purposes, which is included at book value in assets held for investment, net. The property is situated in the same location as our pilot plant. In conjunction with the purchase, we incurred approximately \$1.21 million of additional long-term debt based upon exchange rates in effect during the period. The debt is held by a Canadian Chartered Bank (the "Bank") and the seller. As of July 31, 2003, approximately \$804,000 is due to the Bank and is to be repaid in 35 monthly principal installments of approximately \$4,760 plus interest, with final payment of the remaining principal balance due on the 36th month. The loan bears interest at a fixed rate of 5.8% per annum, and is secured by the property acquired, assignment of rental income of the property, funds on deposit of approximately \$189,000 and a general guarantee by us. The guarantee is limited to \$1.2 million Canadian Dollars (approximately \$857,000), and is extended for as long as a balance is outstanding on the original loan. As of July 31, 2003, approximately \$357,000 is due to the seller with monthly interest payments at 10% per annum for 24 months with the principal due on July 31, 2004 and which is subordinated to the amount due to the Bank. We intend to hold this property for investment purposes and collect rental income. Included in income from rental operations, net is \$252,416 of rental income and \$231,626 of rental expenses, including interest charges of \$77,033, for the fiscal year ended July 31, 2003.

Developments Subsequent to Fiscal 2003

In August 2003, we acquired all of the outstanding capital stock of Antigen pursuant to an Agreement and Plan of Merger (the "Merger Agreement") between us, Antigen and AGEXP Acquisition, Inc. ("AGEXP"), our wholly owned subsidiary that was formed for purposes of the transaction. Pursuant to the Merger Agreement:

- AGEXP merged with and into Antigen (the "Merger");
- Antigen became our wholly owned subsidiary; and
- all of the former shareholders Antigen are entitled to receive shares of our common stock in exchange for their shares of Antigen capital stock.

Antigen has facilities and its headquarters located at Worcester, Massachusetts. Antigen is engaged in research and development to develop immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Antigen's potential products are based on two platform technologies (Ii-Key hybrid peptides and Ii-Suppression) discovered by an officer of Antigen.

The Merger Agreement provides that each holder of Antigen common stock and each holder of each of the four outstanding series of Antigen preferred stock will receive shares of our common stock for each share of Antigen common stock or preferred stock held by such holder. The Merger Agreement establishes exchange rates for the conversion of Antigen common and

the various series of preferred stock into our common stock. Assuming that no Antigen stockholder exercises appraisal rights, an aggregate of approximately 2,800,000 shares of our common stock will be issued to the former Antigen stockholders in connection with the Merger. In addition, pursuant to the Merger Agreement, we assumed Antigen common stock purchase options. If these options are fully exercised, the option holders will receive 112,400 shares of our common stock.

The shares of our common stock issued in connection with the Merger will be restricted securities. However, we have undertaken to register the shares for resale.

We have committed to funding at least \$2,000,000 for Antigen's research and development projects in the next two years.

Restatement

Subsequent to the issuance of its financial statements for the year ended July 31, 2001, management determined that its Series A Preferred stock should be reclassified from stockholders' equity, in accordance with Emerging Issues Task Force Topic D-98, "Classification and Measurement of Redeemable Securities," because the redemption feature of the Series A Preferred stock is beyond our control. This restatement did not affect net loss for the year ended July 31, 2001, nor did it affect total assets. The Series A Preferred stock should have been included outside the statement of stockholders' equity from the date of its issuance in January 2001.

Results of Operations - - 2003 Compared with 2002

We had a net loss of \$13,261,764 for the year ended July 31, 2003 (fiscal 2003) compared to a loss of \$13,693,034 in the year ended July 31, 2002 (fiscal 2002). The net loss for fiscal 2003 and 2002 excludes \$764,154 and \$720,900, respectively in preferred stock dividend on preferred shares. The decrease in our fiscal 2003 net loss resulted from a decrease in research and development expenses (to \$5,150,075 from \$6,618,820) that was offset in part by an increase in general and administrative expenses (to \$8,698,615 from \$7,911,626)

The increase in general and administrative expenses for fiscal 2003 reflects the issuance of common stock, options and warrants to employees, consultants and advisors for services rendered that resulted in an increase in non-cash charges of \$882,698 (to \$1,313,585 from \$430,887). The increase in general and administrative expenses was partially offset by a decrease in legal and litigation expenses and a reduction in travel expenses. The decrease in research and development expenses for fiscal 2003 reflects the decreased level of research and development activities under our collaboration with Elan and under the collaboration with Lilly, which terminated in May 2003.

Our interest and miscellaneous income (net of interest expense) in fiscal 2003 decreased to \$565,511 from \$784,852 in fiscal 2002 due to decreases in our cash and short-term investments and lower interest rates. We received income from rental operations (net of expense) of \$20,790 in fiscal 2003. We did not receive any revenues in fiscal 2003.

In both of the last two fiscal years, we incurred substantial expenses for financial advisory and other financing services that were not related to a specific financing and, therefore, were accounted for as general and administrative expenses. These expenses (\$2,239,431 in fiscal 2003 and \$1,144,252 in fiscal 2002) were paid partially through the issuance of common stock and/or warrants and options to purchase common stock.

In addition, in fiscal 2003, the minority shareholder's share of the loss generated by Generex (Bermuda), Ltd., was \$625 as compared to a \$52,560 in fiscal 2002.

Results of Operations - - 2002 Compared with 2001

We had a net loss of \$13,693,034 for the year ended July 31, 2002 (fiscal 2002) compared to a loss of \$27,097,210 in the year ended July 31, 2001 (fiscal 2001). The net loss for fiscal 2002 excludes \$720,900 in preferred stock dividend on preferred shares. No preferred stock dividend was payable in fiscal 2001. The decrease in our fiscal 2002 net loss resulted from decreases in research and development expenses (to \$6,618,820 from \$19,929,799) and general and administrative expenses (to \$7,911,626 from \$12,507,740).

The decrease in our expenses was partially offset by a decrease in interest and other income. Our interest and miscellaneous income (net of interest expense) in fiscal 2002 decreased to \$784,852 from \$1,355,329 in fiscal 2001 due to decreases in our cash and short-term investments. We did not receive any revenues in fiscal 2002. In fiscal 2001, we received \$1,000,000 in revenue from our agreement with Lilly.

The principal reasons for the decrease in our research and development expense from fiscal 2002 to 2001 resulted from the accounting treatment for our joint venture with Elan, which resulted in a \$15,000,000 research and development expense for the license fee paid by Generex (Bermuda) Ltd. to Elan for technology rights in 2001 (our consolidated net loss, which includes this expense, however, was partially offset by approximately \$2.9 million of minority interest, reflecting Elan's 19.9% ownership interest in the joint venture).

Our general and administrative expenses decreased due to reductions in various categories of these expenses, including a reduction of approximately \$4,000,000 in financial services expenses principally due to a decrease in the number and value of compensatory warrants and options issued and a reduction of approximately \$700,000 in the amount of consulting fees paid.

Our expense reductions were partially offset by an increase in executive compensation of approximately \$900,000 and small increases in other expense categories.

In both fiscal 2002 and 2001, we incurred substantial expenses for financial advisory and other financing services that were not related to a specific financing and, therefore, were accounted for as general and administrative expenses. These expenses (\$1,144,252 in fiscal 2002 and \$5,100,361 in fiscal 2001) were paid partially through the issuance of shares of common stock and/or warrants and options to purchase common stock.

In addition, in fiscal 2002, the minority shareholder's share of the loss generated by Generex (Bermuda), Ltd., was \$52,560 as compared to a \$2,985,000 minority interest share of loss in fiscal 2001.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States of America. It requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We consider certain accounting policies related to impairment of long-lived assets, intangible assets and accrued liabilities to be critical to our business operations and the understanding of our results of operations:

Impairment of Long-Lived Assets. We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Statement of Operations.

Intangible Assets. We have intangible assets related to patents. The determination of the related estimated useful lives and whether or not these assets are impaired involves significant judgments. In assessing the recoverability of these intangible assets, we use an estimate of undiscounted operating income and related cash flows over the remaining useful life, market conditions and other factors to determine the recoverability of the asset. If these estimates or their related assumptions change in the future, we may be required to record impairment charges against these assets.

Estimating accrued liabilities, specifically litigation accruals. Our current estimated range of liabilities related to pending litigation is based on management's best estimate of future costs. While the final resolution of the litigation could result in amounts different than current accruals, and therefore have an impact on our consolidated financial results in a future reporting period, we believe the ultimate outcome will not have a significant effect on our consolidated results of operations, financial position or cash flows.

Liquidity and Capital Resources

To date we have financed our development stage activities primarily through private placements of common stock. In the fourth quarter of fiscal 2003, we raised an aggregate of approximately \$6.5 million from private placements and from exercise of outstanding warrants. In fiscal 2003 we granted stock options, warrants and shares of common stock to employees, consultants and advisors with a value of \$1,313,585 for services rendered, all of which are included in general and administrative expenses. In September 2001, we began a program to repurchase up to \$1 million of our common stock from the open market. Through July 31, 2003, we repurchased a total of 149,500 shares of common stock to be held in treasury for \$483,869, at an average price of \$3.24 per share. Notwithstanding the repurchase of additional 53,000 shares of common stock, our net loss resulted in a decrease in stockholders' equity to \$5,856,965 at July 31, 2003, versus \$12,862,592 at July 31, 2002.

At July 31, 2003, we had on hand cash and short term investments (primarily notes of U.S. corporations) of approximately \$14.7 million versus approximately \$21 million at July 31, 2002.

We believe that our current cash position is sufficient to meet all of our working capital needs for at least the next 12 months. Beyond that, we may require additional funds to support our working capital requirements or for other purposes and may seek to raise funds through private or public equity financing or from other sources. If we were unable to raise additional capital as needed, we could be required to "scale back" or otherwise revise our business plan. Any significant scale back of operations or modification of our business plan due to a lack of funding could be expected to materially and adversely affect our prospects.

In the past we have funded most of our development and other costs with equity financing. While we have been able to raise equity capital as required, unforeseen problems with our clinical program or materially negative developments in general economic conditions could interfere with our ability to raise additional equity capital as needed, or materially adversely affect the terms upon which such capital is available.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Transactions with Affiliates

On May 3, 2001, we advanced \$334,300 to each of three senior officers, who are also our shareholders, in exchange for promissory notes. These notes bore interest at 8.5 percent per annum and were payable in full on May 1, 2002. These notes were guaranteed by a related company owned by these officers and secured by a pledge of 2,500,000 shares of our common stock owned by this related company. On June 3, 2002, our Board of Directors extended the maturity date of the loans to October 1, 2002. The other terms and conditions of the loans and guaranty remained unchanged and in full force and effect. As of July 31, 2002, the balance outstanding on these notes, including accrued interest, was \$1,114,084. Pursuant to a decision made by the Compensation Committee as of August 30, 2002, these loans were satisfied through the application of 592,716 shares of pledged stock, at a value of \$1.90 per share, which represented the lowest closing price during the sixty days prior to August 30, 2002.

Prior to January 1, 1999, a portion of our general and administrative expenses resulted from transactions with affiliated persons, and a number of capital transactions also involved affiliated persons. Although these transactions were not the result of "arms-length" negotiations, we do not believe that this fact had a material impact on our results of operations or financial position. Prior to December 31, 1998, we classified certain payments to executive officers for compensation and expense reimbursements as "Research and Development - related party" and "General and Administrative - related party" because the executive officers received such payments through personal services corporations rather than directly. After December 31, 1998, these payments have been and will continue to be accounted for as though the payments were made directly to the officers, and not as a related party transaction. We do not foresee a need for, and therefore do not anticipate, any related party transactions in the current fiscal year.

On August 7, 2002, we purchased real estate with an aggregate purchase price of approximately \$1.6 million from an unaffiliated party. In connection with that transaction, Angara Enterprises, Inc., a licensed real estate broker that is an affiliate of Anna Gluskin, received a commission from the proceeds of the sale to the seller in the amount of 3% of the purchase price, or \$45,714. We believe that this is less than the aggregate commission which would have been payable if a commission had been negotiated with an unaffiliated broker on an arm's length basis.

We utilize a management company to manage all of our real properties. The property management company is owned by Rose Perri, Anna Gluskin and the estate of Mark Perri, our former Chairman of the Board. For the fiscal years ended July 31, 2003, 2002 and 2001, we have paid the management company \$33,237, \$37,535 and \$38,450, respectively, in management fees.

New Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 addresses the recognition and measurement of goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 also addresses the measurement of intangible assets acquired outside of a business combination whether acquired individually or with a group of other assets. Intangible assets previously recorded in the Company's financial statements will be affected by the provisions of SFAS No. 142. This statement provides that intangible assets with finite useful lives be amortized and that intangible assets with indefinite lives and goodwill will not be amortized, but will rather be tested at least annually for impairment. SFAS No. 142 became effective for the Company's current fiscal year. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In June 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 requires companies to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred, which is adjusted to its present value each period. In addition, companies must capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of," and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business. SFAS No. 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The adoption of this statement did not have a significant impact on the Company's consolidated financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," which supercedes Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit and Activity (Including Certain Costs Incurred in a Restructuring)." SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and requires that a liability be recognized when it is incurred and should initially be measured and recorded at fair value. This statement is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement did not have an impact on the Company's consolidated financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" which amends SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation, and requires disclosure about those effects in both annual and interim financial statements. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148 did not have a significant impact on the Company's consolidated financial position or results of operations.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities". FIN No. 46 clarifies the application of Accounting Research Bulletin No. 51 for certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 applies to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the second quarter of fiscal 2004 to variable interest entities in which the Company may hold a variable interest that it acquired before February 1, 2003. The provisions of FIN No. 46 require that the Company immediately disclose certain information if it is reasonably possible that the Company will be required to consolidate or disclose variable interest entities when FIN No. 46 becomes effective. The Company has determined that it does not have a significant interest in such entities requiring the related disclosure based on its preliminary analysis and assessment.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The changes are intended to improve financial reporting by requiring that contracts with comparable characteristics be accounted for similarly. Additionally, those changes are expected to result in more consistent reporting of contracts as either derivatives or hybrid instruments. SFAS No. 149 is effective for contracts and hedging relationships entered into or modified after June 30, 2003, and for provisions that relate to SFAS No. 133 implementation issues that have been effective for fiscal quarters that began prior to June 15, 2003, apply in accordance with their respective effective dates. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liability and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. It also requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for mandatorily redeemable financial instruments of nonpublic entities. It is to be implemented by reporting a cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The Company's initial adoption of this statement on August 1, 2003, will require the reclassification of its Series A, Preferred stock to long-term liabilities within its Consolidated Balance Sheets. Additionally, on a prospective basis, the mandatory dividends will be classified as Interest expense within its Consolidated Statements of Operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks associated with changes in the exchange rates between U.S. and Canadian currencies and with changes in the interest rates related to our fixed rate debt. We do not believe that any of these risks will have a material impact on our financial condition, results of operations and cash flows.

At the present time, we maintain our cash in short term government or government guaranteed instruments, short term commercial paper, interest bearing bank deposits or demand bank deposits which do not earn interest. A substantial majority of these instruments and deposits are denominated in U.S. dollars, with the exception of funds denominated in Canadian dollars on deposit in Canadian banks to meet short term operating needs in Canada. At the present time, with the exception of professional fees and costs associated with the conduct of clinical trials in the United States and Europe, substantially all of our operating expense obligations are denominated in Canadian dollars. We do not presently employ any hedging or similar strategy intended to mitigate against losses that could be incurred as a result of fluctuations in the exchange rates between U.S. and Canadian currencies.

As of July 31, 2003, we have fixed rate debt totaling \$1,895,475, of which \$804,325, \$551,859 and \$539,291 bears interest at a fixed rate of 5.8%, 9.7% and 10%, respectively. These debt instruments mature from July 2004 through October 2005. As our fixed rate debt mature, we will likely refinance such debt at their existing market interest rates which may be more or less than interest rates on the maturing debt. Since this debt is fixed rate debt, if interest rates were to increase 100 basis points prior to maturity, there would be no impact on earnings or cash flows.

We have neither issued nor own any long term debt instruments, or any other financial instruments, for trading purposes and as to which we would be subject to material market risks.

Item 8. Financial Statements and Supplementary Data

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INDEPENDENT AUDITORS' REPORT

To the Directors and Stockholders of Genorex Biotechnology Corporation (A Development Stage Company)

We have audited the consolidated balance sheet of Genorex Biotechnology Corporation (a development stage company) as at July 31, 2003 and the consolidated statements of operations, changes in stockholders' equity and cash flows for the year then ended and for the period from November 2, 1995 (date of inception) to July 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We did not audit the consolidated financial statements of Genorex Biotechnology Corporation for the period from November 2, 1995 (date of inception) to July 31, 2002. Such statements are included in the cumulative inception to July 31, 2003 totals on the consolidated statements of operations and cash flows and reflect a net loss of 83% of the related cumulative total. Those statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to amounts for the period from November 2, 1995 (date of inception) to July 31, 2003 included in the cumulative totals, is based solely upon the report of the other auditors.

We conducted our audit in accordance with United States generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, these consolidated financial statements present fairly, in all material respects, the financial position of Genorex Biotechnology Corporation (a development stage company) as at July 31, 2003 and the results of its operations and its cash flows for the year then ended and for the period from November 2, 1995 (date of inception) to July 31, 2003 in conformity with United States generally accepted accounting principles.

/s/ BDO Dunwoody LLP
Chartered Accountants

Toronto, Ontario
September 22, 2003

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of Generex Biotechnology Corporation:

We have audited the accompanying consolidated balance sheet of Generex Biotechnology Corporation and subsidiaries (a development stage company) as of July 31, 2002 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended July 31, 2002 and 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform an audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, such financial statements present fairly, in all material respects, the financial position of the Company as at July 31, 2002 and the results of its operations and its cash flows for the years ended July 31, 2002 and 2001, in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche, LLP

Chartered Accountants

Toronto, Ontario
October 7, 2002

CONSOLIDATED BALANCE SHEETS

| ASSETS | July 31, | |
|---|----------------------|----------------------|
| | 2003 | 2002 |
| Current Assets: | | |
| Cash and cash equivalents | \$ 12,356,578 | \$ 8,131,463 |
| Restricted cash | 188,967 | -- |
| Short-term investments | 2,362,071 | 12,862,757 |
| Officers' loans receivable | -- | 1,114,084 |
| Miscellaneous receivables | -- | 12,493 |
| Other current assets | 319,293 | 221,629 |
| Total Current Assets: | 15,226,909 | 22,342,426 |
| Property and Equipment, Net | 4,218,832 | 4,033,094 |
| Assets Held For Investment, Net | 1,906,312 | -- |
| Patents, Net | 898,876 | 830,142 |
| Deposits | 25,000 | 632,401 |
| Due From Related Party | 362,779 | 322,685 |
| TOTAL ASSETS: | 22,638,708 | 28,160,748 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued expenses | 1,386,214 | 1,898,943 |
| Current maturities of long-term debt | 426,767 | 172,453 |
| TOTAL CURRENT LIABILITIES | 1,812,981 | 2,071,396 |
| Long Term Debt, Less Current Maturities | 1,468,708 | 490,860 |
| COMMITMENTS AND CONTINGENCIES (NOTE 8) | | |
| Series A, Preferred stock, \$.001 par value; authorized 1,000,000 shares, issued and outstanding 1,123 and 1,060 at July 31, 2003 and 2002, respectively | 13,500,054 | 12,735,900 |
| STOCKHOLDERS' EQUITY: | | |
| Special Voting Rights Preferred stock, \$.001 par value; authorized, issued and outstanding 1,000 shares at July 31, 2003 and 2002 | 1 | 1 |
| Common stock, \$.001 par value; authorized 50,000,000 shares, issued 26,017,524 and 20,697,326 shares at July 31, 2003 and 2002, respectively, and outstanding 25,275,308 and 20,600,826 shares at July 31, 2003 and 2002, respectively | 26,017 | 20,697 |
| Treasury stock, at cost; 742,216 and 96,500 shares of common stock at July 31, 2003 and 2002, respectively | (1,610,026) | (395,531) |
| Additional paid-in capital | 85,065,980 | 77,220,231 |
| Notes receivable - common stock | (359,998) | (336,885) |
| Deficit accumulated during the development stage | (77,353,787) | (63,327,869) |
| Accumulated other comprehensive (loss) income | 88,778 | (318,052) |
| TOTAL STOCKHOLDERS' EQUITY | 5,856,965 | 12,862,592 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 22,638,708 | \$ 28,160,748 |

The Notes to Consolidated Financial Statements are an integral part of these statements.

CONSOLIDATED STATEMENTS OF OPERATIONS

| | For the Years Ended July 31, | | | Cumulative November 2, 1995 (Date of Inception) to July 31, 2003 |
|--|---------------------------------|------------------------|------------------------|--|
| | 2003 | 2002 | 2001 | |
| REVENUES | \$ -- | \$ -- | \$ 1,000,000 | \$ 1,000,000 |
| Operating Expenses: | | | | |
| Research and development | 5,150,075 | 6,618,820 | 19,929,799 | 38,644,730 |
| Research and development - related party | -- | -- | -- | 220,218 |
| General and administrative | 8,698,615 | 7,911,626 | 12,507,740 | 43,581,771 |
| General and administrative - related party | -- | -- | -- | 314,328 |
| Total Operating Expenses | 13,848,690 | 14,530,446 | 32,437,539 | 82,761,047 |
| Operating Loss | (13,848,690) | (14,530,446) | (31,437,539) | (81,761,047) |
| Other Income (Expense): | | | | |
| Miscellaneous income | 94,376 | 15,995 | 10,664 | 128,941 |
| Income (loss) from rental operations, net | 20,790 | -- | -- | 20,790 |
| Interest income | 543,336 | 833,167 | 1,417,847 | 3,122,348 |
| Interest expense | (72,201) | (64,310) | (73,182) | (417,950) |
| Net Loss Before Undernoted | (13,262,389) | (13,745,594) | (30,082,210) | (78,906,918) |
| Minority Interest Share of Loss | 625 | 52,560 | 2,985,000 | 3,038,185 |
| Net Loss | (13,261,764) | (13,693,034) | (27,097,210) | (75,868,733) |
| Preferred Stock Dividend | 764,154 | 720,900 | -- | 1,485,054 |
| Net Loss Available to Common Stockholders | \$ (14,025,918) | \$ (14,413,934) | \$ (27,097,210) | \$ (77,353,787) |
| Basic and Diluted Net Loss Per Common Share | \$ (.67) | \$ (.70) | \$ (1.44) | |
| Weighted Average Number of Shares of Common Stock Outstanding | 20,885,164 | 20,660,079 | 18,769,077 | |

The Notes to Consolidated Financial Statements are an integral part of these statements.

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|--|---------------------------|--------|------------------|-----------------|-------------------|--------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance November 2, 1995 (Inception) | - | \$ - | - | \$ - | - | \$ - | \$ - |
| Issuance of common stock for cash, February 1996, \$.0254 | - | - | 321,429 | 321 | - | - | 7,838 |
| Issuance of common stock for cash, February 1996, \$.0510 | - | - | 35,142 | 35 | - | - | 1,757 |
| Issuance of common stock for cash, February 1996, \$.5099 | - | - | 216,428 | 216 | - | - | 110,142 |
| Issuance of common stock for cash, March 1996, \$10.2428 | - | - | 2,500 | 3 | - | - | 25,604 |
| Issuance of common stock for cash, April 1996, \$.0516 | - | - | 489,850 | 490 | - | - | 24,773 |
| Issuance of common stock for cash, May 1996, \$.0512 | - | - | 115,571 | 116 | - | - | 5,796 |
| Issuance of common stock for cash, May 1996, \$.5115 | - | - | 428,072 | 428 | - | - | 218,534 |
| Issuance of common stock for cash, May 1996, \$10.2302 | - | - | 129,818 | 130 | - | - | 1,327,934 |
| Issuance of common stock for cash, July 1996, \$.0051 | - | - | 2,606,528 | 2,606 | - | - | 10,777 |
| Issuance of common stock for cash, July 1996, \$.0255 | - | - | 142,857 | 143 | - | - | 3,494 |
| Issuance of common stock for cash, July 1996, \$.0513 | - | - | 35,714 | 36 | - | - | 1,797 |
| Issuance of common stock for cash, July 1996, \$10.1847 | - | - | 63,855 | 64 | - | - | 650,282 |
| Costs related to issuance of common stock | - | - | - | - | - | - | (10,252) |
| Founders Shares transferred for services rendered | - | - | - | - | - | - | 330,025 |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss) Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | - | - | - | - | - | - | - |
| Balance, July 31, 1996 | - | \$ - | 4,587,764 | \$ 4,588 | - | \$ - | \$ 2,708,501 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--|--|--|----------------------------------|
| Balance November 2, 1995 (Inception) | \$ - | \$ - | \$ - | \$ - |
| Issuance of common stock for cash, February 1996, \$.0254 | - | - | - | 8,159 |
| Issuance of common stock for cash, February 1996, \$.0510 | - | - | - | 1,792 |
| Issuance of common stock for cash, February 1996, \$.5099 | - | - | - | 110,358 |
| Issuance of common stock for cash, March 1996, \$10.2428 | - | - | - | 25,607 |
| Issuance of common stock for cash, April 1996, \$.0516 | - | - | - | 25,263 |
| Issuance of common stock for cash, May 1996, \$.0512 | - | - | - | 5,912 |
| Issuance of common stock for cash, May 1996, \$.5115 | - | - | - | 218,962 |
| Issuance of common stock for cash, May 1996, \$10.2302 | - | - | - | 1,328,064 |
| Issuance of common stock for cash, July 1996, \$.0051 | - | - | - | 13,383 |
| Issuance of common stock for cash, July 1996, \$.0255 | - | - | - | 3,637 |
| Issuance of common stock for cash, July 1996, \$.0513 | - | - | - | 1,833 |
| Issuance of common stock for cash, July 1996, \$10.1847 | - | - | - | 650,346 |
| Costs related to issuance of common stock | - | - | - | (10,252) |
| Founders Shares transferred for services rendered | - | - | - | 330,025 |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net loss | - | (693,448) | - | (693,448) |
| Other comprehensive income (loss) | | | | |
| Currency translation adjustment | - | - | (4,017) | (4,017) |
| Total Comprehensive Income (Loss) | - | (693,448) | (4,017) | (697,465) |
| Balance, July 31, 1996 | \$ - | \$ (693,448) | \$ (4,017) | \$ 2,015,624 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|---|---------------------|--------|------------------|-----------------|----------------|--------|----------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 1996 | - | \$ - | 4,587,764 | \$ 4,588 | - | \$ - | \$ 2,708,501 |
| Issuance of common stock for cash, September 1996, \$.0509 | - | - | 2,143 | 2 | - | - | 107 |
| Issuance of common stock for cash, December 1996, \$10.2421 | - | - | 1,429 | 1 | - | - | 14,635 |
| Issuance of common stock for cash, January 1997, \$.0518 | - | - | 1,466 | 1 | - | - | 75 |
| Issuance of common stock for cash, March 1997, \$10.0833 | - | - | 12 | - | - | - | 121 |
| Issuance of common stock for cash, May 1997, \$.0512 | - | - | 4,233 | 4 | - | - | 213 |
| Issuance of common stock for cash, May 1997, \$.5060 | - | - | 4,285,714 | 4,286 | - | - | 2,164,127 |
| Costs related to issuance of common stock, May 1997 | - | - | - | - | - | - | (108,421) |
| Issuance of common stock for cash, May 1997, \$10.1194 | - | - | 18,214 | 18 | - | - | 184,297 |
| Issuance of common stock for cash, June 1997, \$.0504 | - | - | 10,714 | 11 | - | - | 529 |
| Issuance of common stock for cash, June 1997, \$.5047 | - | - | 32,143 | 32 | - | - | 16,190 |
| Issuance of common stock for cash, June 1997, \$8.9810 | - | - | 29,579 | 30 | - | - | 265,618 |
| Issuance of common stock for cash, June 1997, \$10.0978 | - | - | 714 | 1 | - | - | 7,209 |
| Issuance of common stock for cash, July 1997, \$10.1214 | - | - | 25,993 | 26 | - | - | 263,060 |
| Costs related to issuance of common stock | - | - | - | - | - | - | (26,960) |
| Founders Shares transferred for services rendered | - | - | - | - | - | - | 23,481 |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss) | | | | | | | |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | - | - | - | - | - | - | - |
| Balance, July 31, 1997 | - | \$ - | 9,000,118 | \$ 9,000 | - | \$ - | \$ 5,512,782 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--|--|--|----------------------------------|
| Balance, August 1, 1996 | \$ - | \$ (693,448) | \$ (4,017) | \$ 2,015,624 |
| Issuance of common stock for cash, September 1996, \$.0509 | - | - | - | 109 |
| Issuance of common stock for cash, December 1996, \$10.2421 | - | - | - | 14,636 |
| Issuance of common stock for cash, January 1997, \$.0518 | - | - | - | 76 |
| Issuance of common stock for cash, March 1997, \$10.0833 | - | - | - | 121 |
| Issuance of common stock for cash, May 1997, \$.0512 | - | - | - | 217 |
| Issuance of common stock for cash, May 1997, \$.5060 | - | - | - | 2,168,413 |
| Costs related to issuance of common stock, May 1997 | - | - | - | (108,421) |
| Issuance of common stock for cash, May 1997, \$10.1194 | - | - | - | 184,315 |
| Issuance of common stock for cash, June 1997, \$.0504 | - | - | - | 540 |
| Issuance of common stock for cash, June 1997, \$.5047 | - | - | - | 16,222 |
| Issuance of common stock for cash, June 1997, \$8.9810 | - | - | - | 265,648 |
| Issuance of common stock for cash, June 1997, \$10.0978 | - | - | - | 7,210 |
| Issuance of common stock for cash, July 1997, \$10.1214 | - | - | - | 263,086 |
| Costs related to issuance of common stock | - | - | - | (26,960) |
| Founders Shares transferred for services rendered | - | - | - | 23,481 |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net loss | - | (1,379,024) | - | (1,379,024) |
| Other comprehensive income (loss) | | | | |
| Currency translation adjustment | - | - | 3,543 | 3,543 |
| Total Comprehensive Income (Loss) | - | (1,379,024) | 3,543 | (1,375,481) |
| Balance, July 31, 1997 | \$ - | \$ (2,072,472) | \$ (474) | \$ 3,448,836 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|---|---------------------|-------------|-------------------|------------------|----------------|-------------|----------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 1997 | - | \$ - | 9,000,118 | \$ 9,000 | - | \$ - | \$ 5,512,782 |
| Issuance of warrants in exchange for services rendered, October 1997, \$.50 | - | - | - | - | - | - | 234,000 |
| Issuance of common stock in exchange for services rendered, December 1997, \$0.05 | - | - | 234,000 | 234 | - | - | 10,698 |
| Issuance of SVR Preferred Stock in exchange for services rendered, January 1998, \$.001 | 1,000 | 1 | - | - | - | - | 99 |
| Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation | - | - | 1,105,000 | 1,105 | - | - | (1,105) |
| Issuance of common stock for cash, March 1998, \$2.50 | - | - | 70,753 | 71 | - | - | 176,812 |
| Issuance of common stock for cash, April 1998, \$2.50 | - | - | 60,000 | 60 | - | - | 149,940 |
| Issuance of common stock in exchange for services rendered, April 1998, \$2.50 | - | - | 38,172 | 38 | - | - | 95,392 |
| Issuance of common stock for cash, May 1998, \$2.50 | - | - | 756,500 | 757 | - | - | 1,890,493 |
| Issuance of common stock in exchange for services rendered, May 1998, \$2.50 | - | - | 162,000 | 162 | - | - | 404,838 |
| Issuance of warrants in exchange for services rendered, May 1998, \$.60 | - | - | - | - | - | - | 300,000 |
| Issuance of common stock for cash, June 1998, \$2.50 | - | - | 286,000 | 286 | - | - | 714,714 |
| Exercise of warrants for cash, June 1998, \$0.0667 | - | - | 234,000 | 234 | - | - | 15,374 |
| Issuance of common stock in exchange for services rendered, June 1998, \$2.50 | - | - | 24,729 | 24 | - | - | 61,799 |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net loss | | | | | | | |
| Other comprehensive income (loss) | | | | | | | |
| Currency translation adjustment | | | | | | | |
| Total Comprehensive Income (Loss) | - | - | - | - | - | - | - |
| Balance, July 31, 1998 | 1,000 | \$ 1 | 11,971,272 | \$ 11,971 | - | \$ - | \$ 9,565,836 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--|--|--|----------------------------------|
| Balance, August 1, 1997 | \$ - | \$ (2,072,472) | \$ (474) | \$ 3,448,836 |
| Issuance of warrants in exchange for services rendered, October 1997, \$.50 | - | - | - | 234,000 |
| Issuance of common stock in exchange for services rendered, December 1997, \$0.05 | - | - | - | 10,932 |
| Issuance of SVR Preferred Stock in exchange for services rendered, January 1998, \$.001 | - | - | - | 100 |
| Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation | - | - | - | - |
| Issuance of common stock for cash, March 1998, \$2.50 | - | - | - | 176,883 |
| Issuance of common stock for cash, April 1998, \$2.50 | - | - | - | 150,000 |
| Issuance of common stock in exchange for services rendered, April 1998, \$2.50 | - | - | - | 95,430 |
| Issuance of common stock for cash, May 1998, \$2.50 | - | - | - | 1,891,250 |
| Issuance of common stock in exchange for services rendered, May 1998, \$2.50 | - | - | - | 405,000 |
| Issuance of warrants in exchange for services rendered, May 1998, \$.60 | - | - | - | 300,000 |
| Issuance of common stock for cash, June 1998, \$2.50 | - | - | - | 715,000 |
| Exercise of warrants for cash, June 1998, \$0.0667 | - | - | - | 15,608 |
| Issuance of common stock in exchange for services rendered, June 1998, \$2.50 | - | - | - | 61,823 |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net loss | | (4,663,604) | | (4,663,604) |
| Other comprehensive income (loss) | | | | |
| Currency translation adjustment | | - | (198,959) | (198,959) |
| Total Comprehensive Income (Loss) | - | (4,663,604) | (198,959) | (4,862,563) |
| Balance, July 31, 1998 | \$ - | \$ (6,736,076) | \$ (199,433) | \$ 2,642,299 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|--|---------------------------|--------|-----------------|-----------|-------------------|--------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 1998 | 1,000 | \$ 1 | 11,971,272 | \$ 11,971 | - | \$ - | \$ 9,565,836 |
| Issuance of common stock for cash, August 1998, \$3.00 | - | - | 100,000 | 100 | - | - | 299,900 |
| Issuance of common stock for cash, August 1998, \$3.50 | - | - | 19,482 | 19 | - | - | 68,168 |
| Redemption of common stock for cash, September 1998, \$7.75 | - | - | (15,357) | (15) | - | - | (119,051) |
| Issuance of common stock for cash, September - October 1998, \$3.00 | - | - | 220,297 | 220 | - | - | 660,671 |
| Issuance of common stock for cash, August - October 1998, \$4.10 | - | - | 210,818 | 211 | - | - | 864,142 |
| Issuance of common stock in exchange for services rendered, August - October 1998, \$2.50 | - | - | 21,439 | 21 | - | - | 53,577 |
| Issuance of common stock in exchange for services rendered, August - October 1998, \$4.10 | - | - | 18,065 | 18 | - | - | 74,048 |
| Issuance of common stock in exchange for services rendered, September 1998 \$4.10 | - | - | 180,000 | 180 | - | - | 737,820 |
| Issuance of warrants in exchange for services rendered, October 1998, \$0.26 | - | - | - | - | - | - | 2,064 |
| Issuance of stock options in exchange for services rendered, November 1998, \$1.85 | - | - | - | - | - | - | 92,500 |
| Issuance of warrants in exchange for services rendered, November 1998, \$1.64 | - | - | - | - | - | - | 246,000 |
| Issuance of common stock for cash, November 1998 - January 1999, \$3.50 | - | - | 180,000 | 180 | - | - | 629,820 |
| Issuance of common stock for cash, November 1998 - January 1999, \$4.00 | - | - | 275,000 | 275 | - | - | 1,099,725 |
| Issuance of common stock for cash, November 1998 - January 1999, \$4.10 | - | - | 96,852 | 97 | - | - | 397,003 |
| Issuance of common stock in exchange for services rendered, November 1998 - January 1999, \$4.10 | - | - | 28,718 | 29 | - | - | 117,715 |
| Issuance of common stock for cash, November 1998 - January 1999, \$5.00 | - | - | 20,000 | 20 | - | - | 99,980 |
| Issuance of common stock for cash, November 1998 - January 1999, \$5.50 | - | - | 15,000 | 15 | - | - | 82,485 |
| Issuance of common stock in exchange for services rendered, January 1999, \$5.00 | - | - | 392 | - | - | - | 1,960 |
| Issuance of common stock for cash, February 1999, \$5.00 | - | - | 6,000 | 6 | - | - | 29,994 |
| Issuance of common stock in exchange for services rendered, February 1999, \$6.00 | - | - | 5,000 | 5 | - | - | 29,995 |
| Issuance of common stock for cash, March 1999, \$6.00 | - | - | 11,000 | 11 | - | - | 65,989 |
| Issuance of common stock for cash, April 1999, \$5.50 | - | - | 363,637 | 364 | - | - | 1,999,640 |
| Issuance of warrants in exchange for services rendered, April 1999, \$3.21 | - | - | - | - | - | - | 160,500 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--|--|--|----------------------------------|
| Balance, August 1, 1998 | \$ - | \$ (6,736,076) | \$ (199,433) | \$ 2,642,299 |
| Issuance of common stock for cash, August 1998, \$3.00 | - | - | - | 300,000 |
| Issuance of common stock for cash, August 1998, \$3.50 | - | - | - | 68,187 |
| Redemption of common stock for cash, September 1998, \$7.75 | - | - | - | (119,066) |
| Issuance of common stock for cash, September - October 1998, \$3.00 | - | - | - | 660,891 |
| Issuance of common stock for cash, August - October 1998, \$4.10 | - | - | - | 864,353 |
| Issuance of common stock in exchange for services rendered, August - October 1998, \$2.50 | - | - | - | 53,598 |
| Issuance of common stock in exchange for services rendered, August - October 1998, \$4.10 | - | - | - | 74,066 |
| Issuance of common stock in exchange for services rendered, September 1998 \$4.10 | - | - | - | 738,000 |
| Issuance of warrants in exchange for services rendered, October 1998, \$2.26 | - | - | - | 2,064 |
| Issuance of stock options in exchange for services rendered, November 1998, \$1.85 | - | - | - | 92,500 |
| Issuance of warrants in exchange for services rendered, November 1998, \$1.64 | - | - | - | 246,000 |
| Issuance of common stock for cash, November 1998 - January 1999, \$3.50 | - | - | - | 630,000 |
| Issuance of common stock for cash, November 1998 - January 1999, \$4.00 | - | - | - | 1,100,000 |
| Issuance of common stock for cash, November 1998 - January 1999, \$4.10 | - | - | - | 397,100 |
| Issuance of common stock in exchange for services rendered, November 1998 - January 1999, \$4.10 | - | - | - | 117,744 |
| Issuance of common stock for cash, November 1998 - January 1999, \$5.00 | - | - | - | 100,000 |
| Issuance of common stock for cash, November 1998 - January 1999, \$5.50 | - | - | - | 82,500 |
| Issuance of common stock in exchange for services rendered, January 1999, \$5.00 | - | - | - | 1,960 |
| Issuance of common stock for cash, February 1999, \$5.00 | - | - | - | 30,000 |
| Issuance of common stock in exchange for services rendered, February 1999, \$6.00 | - | - | - | 30,000 |
| Issuance of common stock for cash, March 1999, \$6.00 | - | - | - | 66,000 |
| Issuance of common stock for cash, April 1999, \$5.50 | - | - | - | 2,000,004 |
| Issuance of warrants in exchange for services rendered, April 1999, \$3.21 | - | - | - | 160,500 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 3 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|---|---------------------------|-------------|-------------------|------------------|-------------------|-------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Issuance of warrants in exchange for services rendered, April 1999, \$3.17 | - | - | - | - | - | - | 317,000 |
| Issuance of warrants in exchange for services rendered, April 1999, \$2.89 | - | - | - | - | - | - | 144,500 |
| Issuance of warrants in exchange for services rendered, April 1999, \$3.27 | - | - | - | - | - | - | 184,310 |
| Stock adjustment | - | - | 714 | 1 | - | - | (1) |
| Issuance of common stock for cash, May 1999, \$5.50 | - | - | 272,728 | 273 | - | - | 1,499,731 |
| Issuance of common stock in exchange for services rendered, May - June 1999, \$5.50 | - | - | 60,874 | 61 | - | - | 334,746 |
| Exercise of warrants for cash, June 1999, \$5.50 | - | - | 388,375 | 389 | - | - | 1,941,484 |
| Exercise of warrants in exchange for note receivable, June 1999, \$5.00 | - | - | 94,776 | 95 | - | - | 473,787 |
| Exercise of warrants in exchange for services rendered, June 1999, \$5.00 | - | - | 13,396 | 13 | - | - | 66,967 |
| Reduction of note receivable in exchange for services rendered | - | - | - | - | - | - | - |
| Shares tendered in conjunction with warrant exercise, June 1999, \$7.8125 | - | - | (323,920) | (324) | - | - | (2,530,301) |
| Exercise of warrants for shares tendered, June 1999, \$5.00 | - | - | 506,125 | 506 | - | - | 2,530,119 |
| Cost of warrants redeemed for cash | - | - | - | - | - | - | (3,769) |
| Cost related to warrant redemption, June 1999 | - | - | - | - | - | - | (135,431) |
| Costs related to issuance of common stock | - | - | - | - | - | - | (1,179,895) |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net Loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss): | | | | | | | |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | | | | | | | |
| Balance, July 31, 1999 | 1,000 | \$ 1 | 14,740,683 | \$ 14,741 | - | \$ - | \$ 20,903,728 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 4 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--|--|--|----------------------------------|
| Issuance of warrants in exchange for services rendered, April 1999, \$3.17 | - | - | - | 317,000 |
| Issuance of warrants in exchange for services rendered, April 1999, \$2.89 | - | - | - | 144,500 |
| Issuance of warrants in exchange for services rendered, April 1999, \$3.27 | - | - | - | 184,310 |
| Stock adjustment | - | - | - | - |
| Issuance of common stock for cash, May 1999, \$5.50 | - | - | - | 1,500,004 |
| Issuance of common stock in exchange for services rendered, May - June 1999, \$5.50 | - | - | - | 334,807 |
| Exercise of warrants for cash, June 1999, \$5.50 | - | - | - | 1,941,873 |
| Exercise of warrants in exchange for note receivable, June 1999, \$5.00 | (473,882) | - | - | - |
| Exercise of warrants in exchange for services rendered, June 1999, \$5.00 | - | - | - | 66,980 |
| Reduction of note receivable in exchange for services rendered | 38,979 | - | - | 38,979 |
| Shares tendered in conjunction with warrant exercise, June 1999, \$7.8125 | - | - | - | (2,530,625) |
| Exercise of warrants for shares tendered, June 1999, \$5.00 | - | - | - | 2,530,625 |
| Cost of warrants redeemed for cash | - | - | - | (3,769) |
| Cost related to warrant redemption, June 1999 | - | - | - | (135,431) |
| Costs related to issuance of common stock | - | - | - | (1,179,895) |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net Loss | - | (6,239,602) | - | (6,239,602) |
| Other comprehensive income (loss): | | | | |
| Currency translation adjustment | - | - | 1,393 | 1,393 |
| Total Comprehensive Income (Loss) | - | (6,239,602) | 1,393 | (6,238,209) |
| Balance, July 31, 1999 | \$ (434,903) | \$ (12,975,678) | \$ (198,040) | \$ 7,309,849 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|---|---------------------------|-------------|-------------------|------------------|-------------------|-------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 1999 | 1,000 | \$ 1 | 14,740,683 | \$ 14,741 | - | \$ - | \$ 20,903,728 |
| Adjustment for exercise of warrants recorded June 1999, \$5.00 | - | - | (2,300) | (2) | - | - | 2 |
| Issuance of common stock for cash, September 1999, \$6.00 | - | - | 2,500 | 2 | - | - | 14,998 |
| Issuance of common stock for cash pursuant to private placement, January 2000, \$4.25 | - | - | 470,590 | 471 | - | - | 1,999,537 |
| Financing costs associated with private placement, January, 2000 | - | - | - | - | - | - | (220,192) |
| Issuance of stock in exchange for services rendered, January 2000, \$5.00 | - | - | 8,100 | 8 | - | - | 40,492 |
| Granting of stock options for services rendered, January 2000 | - | - | - | - | - | - | 568,850 |
| Granting of warrants for services rendered, January 2000 | - | - | - | - | - | - | 355,500 |
| Exercise of warrants for cash, February 2000, \$5.50 | - | - | 2,000 | 2 | - | - | 10,998 |
| Exercise of warrants for cash, March 2000, \$5.50 | - | - | 29,091 | 29 | - | - | 159,972 |
| Exercise of warrants for cash, March 2000, \$6.00 | - | - | 2,000 | 2 | - | - | 11,998 |
| Exercise of warrants for cash, March 2000, \$7.50 | - | - | 8,000 | 8 | - | - | 59,992 |
| Issuance of common stock for cash pursuant to private placement, June 2000, \$6.00 | - | - | 1,041,669 | 1,042 | - | - | 6,248,972 |
| Financing costs associated with private placement, June 2000 | - | - | - | - | - | - | (385,607) |
| Issuance of common stock for services, June 2000, \$6.00 | - | - | 4,300 | 4 | - | - | 25,796 |
| Exercise of warrants for cash, July 2000, \$6.00 | - | - | 3,000 | 3 | - | - | 17,997 |
| Exercise of warrants for cash, July 2000, \$7.50 | - | - | 16,700 | 17 | - | - | 125,233 |
| Granting of stock options for services rendered, July 2000 | - | - | - | - | - | - | 496,800 |
| Reduction of note receivable in exchange for services rendered | - | - | - | - | - | - | - |
| Accrued interest on note receivable | - | - | - | - | - | - | - |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net Loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss): | | | | | | | |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | | | | | | | |
| Balance, July 31, 2000 | 1,000 | \$ 1 | 16,326,333 | \$ 16,327 | - | \$ - | \$ 30,435,066 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--|--|--|----------------------------------|
| Balance, August 1, 1999 | \$ (434,903) | \$ (12,975,678) | \$ (198,040) | \$ 7,309,849 |
| Adjustment for exercise of warrants recorded June 1999, \$5.00 | - | - | - | - |
| Issuance of common stock for cash, September 1999, \$6.00 | - | - | - | 15,000 |
| Issuance of common stock for cash pur- suant to private placement, January 2000, \$4.25 | - | - | - | 2,000,008 |
| Financing costs associated with private placement, January, 2000 | - | - | - | (220,192) |
| Issuance of stock in exchange for services rendered, January 2000, \$5.00 | - | - | - | 40,500 |
| Granting of stock options for services rendered, January 2000 | - | - | - | 568,850 |
| Granting of warrants for services rendered, January 2000 | - | - | - | 355,500 |
| Exercise of warrants for cash, February 2000, \$5.50 | - | - | - | 11,000 |
| Exercise of warrants for cash, March 2000, \$5.50 | - | - | - | 160,001 |
| Exercise of warrants for cash, March 2000, \$6.00 | - | - | - | 12,000 |
| Exercise of warrants for cash, March 2000, \$7.50 | - | - | - | 60,000 |
| Issuance of common stock for cash pur- suant to private placement, June 2000, \$6.00 | - | - | - | 6,250,014 |
| Financing costs associated with private placement, June 2000 | - | - | - | (385,607) |
| Issuance of common stock for services, June 2000, \$6.00 | - | - | - | 25,800 |
| Exercise of warrants for cash, July 2000, \$6.00 | - | - | - | 18,000 |
| Exercise of warrants for cash, July 2000, \$7.50 | - | - | - | 125,250 |
| Granting of stock options for services rendered, July 2000 | - | - | - | 496,800 |
| Reduction of note receivable in exchange for services rendered | 384,903 | - | - | 384,903 |
| Accrued interest on note receivable | (4,118) | - | - | (4,118) |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net Loss | - | (8,841,047) | - | (8,841,047) |
| Other comprehensive income (loss): | | | | |
| Currency translation adjustment | - | - | 32,514 | 32,514 |
| Total Comprehensive Income (Loss) | | (8,841,047) | 32,514 | (8,808,533) |
| Balance, July 31, 2000 | \$ (54,118) | \$ (21,816,725) | \$ (165,526) | \$ 8,415,025 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|--|---------------------------|--------|-----------------|-----------|-------------------|--------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 2000 | 1,000 | \$ 1 | 16,326,333 | \$ 16,327 | - | \$ - | \$ 30,435,066 |
| Exercise of warrants for cash, August 2000, \$6.00 | - | - | 2,000 | 2 | - | - | 11,998 |
| Issuance of common stock for services rendered August 2000 | - | - | 35,000 | 35 | - | - | 411,215 |
| Issuance of warrants in exchange for equity line agreement, August 2000 | - | - | - | - | - | - | 3,406,196 |
| Exercise of warrants for cash, August 2000, \$7.50 | - | - | 30,300 | 30 | - | - | 227,220 |
| Exercise of warrants for cash, August 2000, \$8.6625 | - | - | 30,000 | 30 | - | - | 259,845 |
| Cashless exercise of warrants, August 2000 | - | - | 8,600 | 9 | - | - | (9) |
| Exercise of warrants for cash, August 2000, \$10.00 | - | - | 10,000 | 10 | - | - | 99,990 |
| Exercise of warrants for cash, September 2000, \$8.6625 | - | - | 63,335 | 63 | - | - | 548,576 |
| Exercise of warrants for cash, September 2000, \$5.50 | - | - | 16,182 | 16 | - | - | 88,986 |
| Exercise of warrants for cash, September 2000, \$6.00 | - | - | 53,087 | 53 | - | - | 318,470 |
| Exercise of warrants for cash, September 2000, \$10.00 | - | - | 9,584 | 10 | - | - | 95,830 |
| Exercise of warrants for cash, September 2000, \$7.50 | - | - | 32,416 | 32 | - | - | 243,088 |
| Issuance of common stock for cash pursuant to private placement, October 2000, \$11.00 | - | - | 2,151,093 | 2,151 | - | - | 23,659,872 |
| Exercise of warrants for cash, Oct. 2000, \$6.00 | - | - | 1,000 | 1 | - | - | 5,999 |
| Financing costs associated with private placement, October 2000 | - | - | - | - | - | - | (1,956,340) |
| Exercise of warrants for cash, November - December 2000, \$4.25 | - | - | 23,528 | 23 | - | - | 99,971 |
| Cashless exercise of warrants, December 2000 | - | - | 3,118 | 3 | - | - | (3) |
| Exercise of warrants for cash, November - December 2000, \$6.00 | - | - | 22,913 | 23 | - | - | 137,455 |
| Exercise of warrants for cash, December 2000, \$7.00 | - | - | 8,823 | 9 | - | - | 61,752 |
| Issuance of common stock as employee compensation, December 2000 | - | - | 8,650 | 8 | - | - | 100,548 |
| Exercise of warrants for cash, January 2001, \$6.00 | - | - | 3,000 | 3 | - | - | 17,997 |
| Issuance of common stock for cash pursuant to private placement, January 2001, \$14.53 | - | - | 344,116 | 344 | - | - | 4,999,656 |
| Financing costs associated with private placement, January 2001 | - | - | - | - | - | - | (200,000) |
| Issuance of common stock pursuant to litigation settlement, January 2001 | - | - | 2,832 | 2 | - | - | 21,096 |
| Granting of stock options in exchange for services rendered, January 2001 | - | - | - | - | - | - | 745,000 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--|--|--|----------------------------------|
| Balance, August 1, 2000 | \$ (54,118) | \$ (21,816,725) | \$ (165,526) | \$ 8,415,025 |
| Exercise of warrants for cash, August 2000, \$6.00 | - | - | - | 12,000 |
| Issuance of common stock for services rendered August 2000 | - | - | - | 411,250 |
| Issuance of warrants in exchange for equity line agreement, August 2000 | - | - | - | 3,406,196 |
| Exercise of warrants for cash, August 2000, \$7.50 | - | - | - | 227,250 |
| Exercise of warrants for cash, August 2000, \$8.6625 | - | - | - | 259,875 |
| Cashless exercise of warrants, August 2000 | - | - | - | - |
| Exercise of warrants for cash, August 2000, \$10.00 | - | - | - | 100,000 |
| Exercise of warrants for cash, September 2000, \$8.6625 | - | - | - | 548,639 |
| Exercise of warrants for cash, September 2000, \$5.50 | - | - | - | 89,002 |
| Exercise of warrants for cash, September 2000, \$6.00 | - | - | - | 318,523 |
| Exercise of warrants for cash, September 2000, \$10.00 | - | - | - | 95,840 |
| Exercise of warrants for cash, September 2000, \$7.50 | - | - | - | 243,120 |
| Issuance of common stock for cash pursuant to private placement, October 2000, \$11.00 | - | - | - | 23,662,023 |
| Exercise of warrants for cash, Oct. 2000, \$6.00 | - | - | - | 6,000 |
| Financing costs associated with private placement, October 2000 | - | - | - | (1,956,340) |
| Exercise of warrants for cash, November - December 2000, \$4.25 | - | - | - | 99,994 |
| Cashless exercise of warrants, December 2000 | - | - | - | - |
| Exercise of warrants for cash, November - December 2000, \$6.00 | - | - | - | 137,478 |
| Exercise of warrants for cash, December 2000, \$7.00 | - | - | - | 61,761 |
| Issuance of common stock as employee compensation, December 2000 | - | - | - | 100,556 |
| Exercise of warrants for cash, January 2001, \$6.00 | - | - | - | 18,000 |
| Issuance of common stock for cash pursuant to private placement, January 2001, \$14.53 | - | - | - | 5,000,000 |
| Financing costs associated with private placement, January 2001 | - | - | - | (200,000) |
| Issuance of common stock pursuant to litigation settlement, January 2001 | - | - | - | 21,098 |
| Granting of stock options in exchange for services rendered, January 2001 | - | - | - | 745,000 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 3 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|--|---------------------------|-------------|-------------------|------------------|-------------------|-------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Granting of stock options in exchange for services rendered, February 2001 | - | - | - | - | - | - | 129,600 |
| Exercise of stock options for cash, February 2001, \$5.00 | - | - | 50,000 | 50 | - | - | 249,950 |
| Exercise of warrants for cash, March 2001, \$6.00 | - | - | 500 | 1 | - | - | 2,999 |
| Exercise of stock options in exchange for note receivable, March 2001 | - | - | 50,000 | 50 | - | - | 249,950 |
| Issuance of common stock in exchange for services rendered, March 2001, \$5.50 | - | - | 8,000 | 8 | - | - | 43,992 |
| Granting of stock options in exchange for services rendered, May 2001 | - | - | - | - | - | - | 592,300 |
| Exercise of stock options for cash, June 2001, \$5.00 | - | - | 75,000 | 75 | - | - | 374,925 |
| Exercise of stock options for cash, June 2001, \$5.50 | - | - | 12,500 | 12 | - | - | 68,738 |
| Exercise of warrants for cash, June 2001, \$6.00 | - | - | 4,000 | 4 | - | - | 23,996 |
| Exercise of stock options for cash, July 2001, \$5.00 | - | - | 7,500 | 8 | - | - | 37,492 |
| Exercise of stock options for cash, July 2001, \$5.50 | - | - | 2,500 | 3 | - | - | 13,747 |
| Exercise of warrants for cash, July 2001, \$6.00 | - | - | 2,000 | 2 | - | - | 11,998 |
| Issuance of common stock for cash pursuant to private placement, July 2001, \$9.25 | - | - | 1,254,053 | 1,254 | - | - | 11,598,736 |
| Financing costs associated with private placement, July 2001 | - | - | - | - | - | - | (768,599) |
| Shares issued in exchange for services rendered, July 2001, \$9.25 | - | - | 23,784 | 24 | - | - | 219,978 |
| Shares issued for Anti-Dilution Provisions, July 2001 | - | - | 5,779 | 6 | - | - | 53,450 |
| Issuance of warrants in exchange for services rendered, July 2001 | - | - | - | - | - | - | 19,134 |
| Accrued interest on note receivable | - | - | - | - | - | - | - |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net Loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss): | | | | | | | |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | | | | | | | |
| Balance at July 31, 2001 | 1,000 | \$ 1 | 20,681,526 | \$ 20,681 | - | \$ - | \$ 76,761,860 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 4 OF 4

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--|--|--|----------------------------------|
| Granting of stock options in exchange for services rendered, February 2001 | - | - | - | 129,600 |
| Exercise of stock options for cash, February 2001, \$5.00 | - | - | - | 250,000 |
| Exercise of warrants for cash, March 2001, \$6.00 | - | - | - | 3,000 |
| Exercise of stock options in exchange for note receivable, March 2001 | (250,000) | - | - | - |
| Issuance of common stock in exchange for services rendered, March 2001, \$5.50 | - | - | - | 44,000 |
| Granting of stock options in exchange for services rendered, May 2001 | - | - | - | 592,300 |
| Exercise of stock options for cash, June 2001, \$5.00 | - | - | - | 375,000 |
| Exercise of stock options for cash, June 2001, \$5.50 | - | - | - | 68,750 |
| Exercise of warrants for cash, June 2001, \$6.00 | - | - | - | 24,000 |
| Exercise of stock options for cash, July 2001, \$5.00 | - | - | - | 37,500 |
| Exercise of stock options for cash, July 2001, \$5.50 | - | - | - | 13,750 |
| Exercise of warrants for cash, July 2001, \$6.00 | - | - | - | 12,000 |
| Issuance of common stock for cash pursuant to private placement, July 2001, \$9.25 | - | - | - | 11,599,990 |
| Financing costs associated with private placement, July 2001 | - | - | - | (768,599) |
| Shares issued in exchange for services rendered, July 2001, \$9.25 | - | - | - | 220,002 |
| Shares issued for Anti-Dilution Provisions, July 2001 | - | - | - | 53,456 |
| Issuance of warrants in exchange for services rendered, July 2001 | - | - | - | 19,134 |
| Accrued interest on note receivable | (10,182) | - | - | (10,182) |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net Loss | - | (27,097,210) | - | (27,097,210) |
| Other comprehensive income (loss): | | | | |
| Currency translation adjustment | - | - | (81,341) | (81,341) |
| Total Comprehensive Income (Loss) | | (27,097,210) | (81,341) | (27,178,551) |
| Balance at July 31, 2001 | \$ (314,300) | \$ (48,913,935) | \$ (246,867) | \$ 27,307,440 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|--|---------------------|-------------|-------------------|------------------|-----------------|---------------------|----------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 2001 | 1,000 | \$ 1 | 20,681,526 | \$ 20,681 | - | \$ - | \$ 76,761,860 |
| Exercise of stock options for cash, August 2001, \$5.50 | - | - | 5,000 | 5 | - | - | 27,495 |
| Purchase of Treasury Stock for cash October 2001, \$3.915 | - | - | - | - | (10,000) | (39,150) | - |
| Issuance of stock options in exchange for services rendered, December 2001 | - | - | - | - | - | - | 25,000 |
| Issuance of common stock as employee compensation, January 2002 | - | - | 10,800 | 11 | - | - | 71,161 |
| Preferred stock dividend paid January 2002 | - | - | - | - | - | - | - |
| Purchase of Treasury Stock for cash February 2002, \$4.693 | - | - | - | - | (31,400) | (147,346) | - |
| Issuance of warrants in exchange for services rendered, March 2002 | - | - | - | - | - | - | 202,328 |
| Purchase of Treasury Stock for cash March 2002, \$4.911 | - | - | - | - | (7,700) | (37,816) | - |
| Purchase of Treasury Stock for cash April 2002, \$4.025 | - | - | - | - | (12,800) | (54,516) | - |
| Issuance of stock options in exchange for services rendered, June 2002 | - | - | - | - | - | - | 132,387 |
| Purchase of Treasury Stock for cash July 2002, \$4.025 | - | - | - | - | (34,600) | (116,703) | - |
| Accrued interest on note receivable | - | - | - | - | - | - | - |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net Loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss): | | | | | | | |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | - | - | - | - | - | - | - |
| Balance at July 31, 2002 | 1,000 | \$ 1 | 20,697,326 | \$ 20,697 | (96,500) | \$ (395,531) | \$ 77,220,231 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--|--|--|----------------------------------|
| Balance, August 1, 2001 | \$ (314,300) | \$ (48,913,935) | \$ (246,867) | \$ 27,307,440 |
| Exercise of stock options for cash, August 2001, \$5.50 | - | - | - | 27,500 |
| Purchase of Treasury Stock for cash October 2001, \$3.915 | - | - | - | (39,150) |
| Issuance of stock options in exchange for services rendered, December 2001 | - | - | - | 25,000 |
| Issuance of common stock as employee compensation, January 2002 | - | - | - | 71,172 |
| Preferred stock dividend paid January 2002 | - | (720,900) | - | (720,900) |
| Purchase of Treasury Stock for cash February 2002, \$4.693 | - | - | - | (147,346) |
| Issuance of warrants in exchange for services rendered, March 2002 | - | - | - | 202,328 |
| Purchase of Treasury Stock for cash March 2002, \$4.911 | - | - | - | (37,816) |
| Purchase of Treasury Stock for cash April 2002, \$4.025 | - | - | - | (54,516) |
| Issuance of stock options in exchange for services rendered, June 2002 | - | - | - | 132,387 |
| Purchase of Treasury Stock for cash July 2002, \$4.025 | - | - | - | (116,703) |
| Accrued interest on note receivable | (22,585) | - | - | (22,585) |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net Loss | - | (13,693,034) | - | (13,693,034) |
| Other comprehensive income (loss): | | | | |
| Currency translation adjustment | - | - | (71,185) | (71,185) |
| Total Comprehensive Income (Loss) | - | (13,693,034) | (71,185) | (13,764,219) |
| Balance at July 31, 2002 | \$ (336,885) | \$ (63,327,869) | \$ (318,052) | \$ 12,862,592 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | SVR Preferred Stock | | Common Stock | | Treasury Stock | | Additional Paid-In Capital |
|---|---------------------------|-------------|-------------------|------------------|-------------------|-----------------------|----------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | |
| Balance, August 1, 2002 | 1,000 | \$ 1 | 20,697,326 | \$ 20,697 | (96,500) | \$ (395,531) | \$ 77,220,231 |
| Receipt of restricted shares of common stock as settlement for executive loan, September 2002, \$1.90 | - | - | - | - | (592,716) | (1,126,157) | - |
| Purchase of Treasury Stock for cash October 2002, \$1.5574 | - | - | - | - | (40,000) | (62,294) | - |
| Issuance of warrants in exchange for the services rendered, November 2002, \$2.50 | - | - | - | - | - | - | 988,550 |
| Issuance of stock options in exchange for services receivable, November 2002, \$2.10 | - | - | - | - | - | - | 171,360 |
| Issuance of common stock in exchange for services rendered, November 2002, \$2.10 | - | - | 30,000 | 30 | - | - | 62,970 |
| Issuance of common stock as employee compensation, January 2003, \$2.10 | - | - | 9,750 | 10 | - | - | 20,465 |
| Purchase of Treasury Stock for cash December 2002, \$2.0034 | - | - | - | - | (13,000) | (26,044) | - |
| Preferred stock dividend paid January 2003 | - | - | - | - | - | - | - |
| Issuance of common stock in exchange for services rendered, March 2003, \$1.00 | - | - | 70,000 | 70 | - | - | 69,930 |
| Issuance of common stock for cash pursuant to private placement, May 2003, \$1.15 | - | - | 2,926,301 | 2,926 | - | - | 3,362,324 |
| Financing costs associated with private placement, May 2003 | - | - | - | - | - | - | (235,568) |
| Exercise of warrants for cash, May 2003, \$1.50 | - | - | 35,000 | 35 | - | - | 52,465 |
| Issuance of common stock for cash pursuant to private placement, June 2003, \$1.50 | - | - | 666,667 | 667 | - | - | 999,333 |
| Issuance of common stock as employee compensation, June 2003, \$2.00 | - | - | 100 | - | - | - | 200 |
| Exercise of warrants for cash, June 2003, \$1.50 | - | - | 1,496,001 | 1,496 | - | - | 2,242,506 |
| Cashless exercise of warrants, June 2003 | - | - | 16,379 | 16 | - | - | (16) |
| Exercise of stock options for cash, June 2003, \$1.59 | - | - | 70,000 | 70 | - | - | 111,230 |
| Accrued interest on note receivable | - | - | - | - | - | - | - |
| <i>Comprehensive Income (Loss):</i> | | | | | | | |
| Net Loss | - | - | - | - | - | - | - |
| Other comprehensive income (loss) | - | - | - | - | - | - | - |
| Currency translation adjustment | - | - | - | - | - | - | - |
| Total Comprehensive Income (Loss) | - | - | - | - | - | - | - |
| Balance at July 31, 2003 | 1,000 | \$ 1 | 26,017,524 | \$ 26,017 | (742,216) | \$ (1,610,026) | \$ 85,065,980 |

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2003

| | Notes Receivable - Common Stock | Deficit Accumulated During the Development Stage | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--|--|--|----------------------------------|
| Balance, August 1, 2002 | \$ (336,885) | \$ (63,327,869) | \$ (318,052) | \$ 12,862,592 |
| Receipt of restricted shares of common stock as settlement for executive loan, September 2002, \$1.90 | - | - | - | (1,126,157) |
| Purchase of Treasury Stock for cash October 2002, \$1.5574 | - | - | - | (62,294) |
| Issuance of warrants in exchange for the services rendered, November 2002, \$2.50 | - | - | - | 988,550 |
| Issuance of stock options in exchange for services receivable, November 2002, \$2.10 | - | - | - | 171,360 |
| Issuance of common stock in exchange for services rendered, November 2002, \$2.10 | - | - | - | 63,000 |
| Issuance of common stock as employee compensation, January 2003, \$2.10 | - | - | - | 20,475 |
| Purchase of Treasury Stock for cash December 2002, \$2.0034 | - | - | - | (26,044) |
| Preferred stock dividend paid January 2003 | - | (764,154) | - | (764,154) |
| Issuance of common stock in exchange for services rendered, March 2003, \$1.00 | - | - | - | 70,000 |
| Issuance of common stock for cash pursuant to private placement, May 2003, \$1.15 | - | - | - | 3,365,250 |
| Financing costs associated with private placement, May 2003 | - | - | - | (235,568) |
| Exercise of warrants for cash, May 2003, \$1.50 | - | - | - | 52,500 |
| Issuance of common stock for cash pursuant to private placement, June 2003, \$1.50 | - | - | - | 1,000,000 |
| Issuance of common stock as employee compensation, June 2003, \$2.00 | - | - | - | 200 |
| Exercise of warrants for cash, June 2003, \$1.50 | - | - | - | 2,244,002 |
| Cashless exercise of warrants, June 2003 | - | - | - | - |
| Exercise of stock options for cash, June 2003, \$1.59 | - | - | - | 111,300 |
| Accrued interest on note receivable | (23,113) | - | - | (23,113) |
| <i>Comprehensive Income (Loss):</i> | | | | |
| Net Loss | - | (13,261,764) | - | (13,261,764) |
| Other comprehensive income (loss) | | | | |
| Currency translation adjustment | - | - | 406,830 | 406,830 |
| Total Comprehensive Income (Loss) | - | (13,261,764) | 406,830 | (12,854,934) |
| Balance at July 31, 2003 | \$ (359,998) | \$ (77,353,787) | \$ 88,778 | \$ 5,856,965 |

CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the Years Ended July 31, | | | Cumulative From November 2, 1995 (Date of Inception) to July 31, 2003 |
|--|---------------------------------|---------------------|----------------------|--|
| | 2003 | 2002 | 2001 | |
| Cash Flows From Operating Activities: | | | | |
| Net loss | \$ (13,261,764) | \$ (13,693,034) | \$ (27,097,210) | \$ (75,868,733) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | 589,836 | 431,547 | 230,600 | 1,462,660 |
| Minority interest share of loss | (625) | (52,560) | (2,985,000) | (3,038,185) |
| Reduction of notes receivable - common stock in exchange for services rendered | -- | -- | -- | 423,882 |
| Write-off of deferred offering costs | -- | -- | 3,406,196 | 3,406,196 |
| Write-off of abandoned patents | 9,134 | -- | -- | 9,134 |
| Common stock issued for services rendered | 153,675 | 71,172 | 829,264 | 2,294,839 |
| Stock options and warrants issued for services rendered | 1,159,910 | 359,715 | 1,486,036 | 6,107,685 |
| Preferred stock issued for services rendered | -- | -- | -- | 100 |
| Founders' shares transferred for services rendered | -- | -- | -- | 353,506 |
| Changes in operating assets and liabilities: | | | | |
| Miscellaneous receivables | 13,192 | -- | 2,747 | 43,812 |
| Other current assets | (78,886) | (108,610) | (14,858) | (305,102) |
| Accounts payable and accrued expenses | (553,606) | (740,319) | 1,479,803 | 2,198,196 |
| Other, net | -- | -- | -- | 110,317 |
| Net Cash Used in Operating Activities | (11,969,134) | (13,732,089) | (22,662,422) | (62,801,693) |
| Cash Flows From Investing Activities: | | | | |
| Purchase of property and equipment | (506,108) | (779,519) | (1,623,017) | (3,582,598) |
| Costs incurred for patents | (108,576) | (440,698) | (197,434) | (1,016,207) |
| Change in restricted cash | (177,488) | -- | -- | (183,083) |
| Increase in officers' loans receivable | (12,073) | (90,341) | (1,023,743) | (1,126,157) |
| Proceeds from maturity of short-term investments | 20,570,283 | 59,309,515 | 39,097,000 | 119,686,192 |
| Purchases of short-term investments | (10,069,597) | (45,279,543) | (62,023,466) | (122,048,263) |
| Change in deposits | 107,755 | (614,464) | 27,396 | (477,194) |
| Change in notes receivable - common stock | (23,113) | (22,585) | (10,182) | (59,998) |
| Change in due from related parties | -- | -- | -- | (2,255,197) |
| Other, net | -- | -- | -- | 89,683 |
| Net Cash Provided By (Used in) Investing Activities | 9,781,083 | 12,082,365 | (25,753,446) | (10,972,822) |
| Cash Flows From Financing Activities: | | | | |
| Proceeds from issuance of long-term debt | -- | -- | -- | 993,149 |
| Repayment of long-term debt | (60,004) | (9,363) | (5,208) | (1,035,351) |
| Change in due to related parties | -- | -- | -- | 154,541 |
| Proceeds from exercise of warrants | 2,296,502 | -- | 2,256,482 | 4,552,984 |
| Proceeds from exercise of stock options | 111,300 | 27,500 | 745,000 | 883,800 |
| Proceeds from minority interest investment | 625 | 52,560 | 2,985,000 | 3,038,185 |
| Proceeds from issuance of common stock, net | 4,129,682 | -- | 37,337,074 | 66,128,976 |
| Proceeds from issuance of preferred stock | -- | -- | 12,015,000 | 12,015,000 |
| Purchase and retirement of common stock | -- | -- | -- | (119,066) |
| Purchase of treasury stock | (88,338) | (395,531) | -- | (483,869) |
| Net Cash Provided By (Used In) Financing Activities | 6,389,767 | (324,834) | 55,333,348 | 86,128,349 |
| Effect of Exchange Rate Changes on Cash | 23,399 | (3,538) | (12,826) | 2,744 |
| Net Increase (Decrease) in Cash and Cash Equivalents | 4,225,115 | (1,978,096) | 6,904,654 | 12,356,578 |
| Cash and Cash Equivalents, Beginning of Year | 8,131,463 | 10,109,559 | 3,204,905 | -- |
| Cash and Cash Equivalents, End of Year | \$ 12,356,578 | \$ 8,131,463 | \$ 10,109,559 | \$ 12,356,578 |

The Notes to Consolidated Financial Statements are an integral part of these statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Organization and Business:

Generex Biotechnology Corporation (the Company) is engaged in the research and development of drug delivery systems and technology. Since its inception, the Company has devoted its efforts and resources to the development of a platform technology for the oral administration of large molecule drugs, including proteins, peptides, monoclonal antibodies, hormones and vaccines, which historically have been administered by injection, either subcutaneously or intravenously.

The Company is a development stage company, which has a limited history of operations and has not generated any revenues from operations with the exception of the \$1 million received in conjunction with the execution of a development agreement (see Note 8). The Company has no products approved for commercial sale at the present time. There can be no assurance that the Company will be successful in obtaining regulatory clearance for the sale of existing or any future products or that any of the Company's products will be commercially viable.

Note 2 - Summary of Significant Accounting Policies:

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. For those consolidated subsidiaries where the Company ownership is less than 100 percent, the outside stockholders' interests are shown as minority interests. All significant intercompany transactions and balances have been eliminated.

Development Stage Corporation

The accompanying consolidated financial statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standard (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises."

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Short-Term Investments

Short-term investments consisted primarily of short-term notes of U.S. corporations and Canadian government savings bonds with original maturities of between three to twelve months and one to five years at July 31, 2003 and 2002, respectively. These short-term notes are classified as held to maturity and are valued at amortized cost. At July 31, 2003 and 2002, the cost of the investments approximated market value.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is provided on the straight-line method over the estimated useful lives of the assets, which range from three to thirty years. Gains and losses on depreciable assets retired or sold are recognized in the statement of operations in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

Patents

Legal costs incurred to establish patents are capitalized. Capitalized costs are amortized on the straight-line method over the related patent term. As patents are abandoned, the net book value of the patent is written off.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (Continued):

Impairment or Disposal of Long-Lived Assets

The Company assesses the impairment of patents under SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" whenever events or changes in circumstances indicate that the carrying value may not be recoverable. A determination of impairment (if any) is made based on estimates of future cash flows.

Research and Development Costs

Expenditures for research and development are expensed as incurred and include, among other costs, those related to the production of experimental drugs, including payroll costs, and amounts incurred for conducting clinical trials. Amounts expected to be received from governments under research and development tax credit arrangements are offset against current income tax expense.

Income Taxes

Income taxes are accounted for under the asset and liability method prescribed by SFAS No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax asset will not be realized.

Stock-Based Compensation

The Company has elected to continue to account for its stock compensation plans under the recognition and measurement principles of Accounting Principles Board Opinion (APB) No. 25, "Accounting for Stock Issued to Employees" and related interpretations. No stock-based employee compensation cost related to stock options is reflected in the Company's Statements of Operations, as all options granted under the plan had an exercise price more than or equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123.

| | For the Years Ended July 31, | | |
|--|------------------------------|-----------------|-----------------|
| | 2003 | 2002 | 2001 |
| Net Loss Available to Common Stockholders, as Reported | \$ (14,025,918) | \$ (14,413,934) | \$ (27,097,210) |
| Deduct: Total Stock-Based Employee Compensation Expense Determined Under Fair Value Based Method | 3,335,731 | 2,777,400 | 4,658,300 |
| Pro Forma Net Loss Available to Common Stockholders | \$ (17,361,649) | \$ (17,191,334) | \$ (31,755,510) |
| Loss Per Share: | | | |
| Basic and diluted, as reported | \$ (0.67) | \$ (0.70) | \$ (1.44) |
| Basic and diluted, pro forma | \$ (0.83) | \$ (0.83) | \$ (1.69) |

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 2 - Summary of Significant Accounting Policies (Continued):****Net Loss Per Common Share**

Basic EPS is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period. The computation of Diluted EPS does not assume conversion, exercise or contingent exercise of securities that would have an antidilutive effect on earnings. Refer to Note 15 for methodology for determining net loss per share.

Comprehensive Loss

Other comprehensive income (loss), which includes only foreign currency translation adjustments, is shown in the Statement of Changes in Stockholders' Equity.

Concentration of Credit Risk

The Company maintains cash balances, at times, with financial institutions in the amount which are more than amounts insured by the Canada Deposit Insurance Corporation and the Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions and considers the Company's risk negligible.

The Company places its short-term investments in short-term debt instruments of high quality U.S. corporations and government instruments. The Company does not believe there is a significant credit risk relating to these investments.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Foreign Currency Translation

Foreign denominated assets and liabilities of the Company are translated into U.S. dollars at the prevailing exchange rates in effect at the end of the reporting period. Income statement accounts are translated at a weighted average of exchange rates which were in effect during the period. Translation adjustments that arise from translating the foreign subsidiary's financial statements from local currency to U.S. currency are recorded in the other comprehensive loss component of stockholders' equity.

Financial Instruments

The carrying values of officers' loans receivable, miscellaneous receivables, accounts payable and accrued expenses approximate their fair values due to their short-term nature. Due from related party approximates its fair value as it is due on demand and long-term debt approximates its fair value based upon the borrowing rates available for the nature of the underlying debt.

The Company follows the provisions of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 2 - Summary of Significant Accounting Policies (Continued):****Reclassifications**

Certain amounts reported in the 2002 and 2001 financial statements have been reclassified to conform to the 2003 presentation.

Effects of Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 addresses the recognition and measurement of goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 also addresses the measurement of intangible assets acquired outside of a business combination whether acquired individually or with a group of other assets. Intangible assets previously recorded in the Company's financial statements will be affected by the provisions of SFAS No. 142. This statement provides that intangible assets with finite useful lives be amortized and that intangible assets with indefinite lives and goodwill will not be amortized, but will rather be tested at least annually for impairment. SFAS No. 142 became effective for the Company's current fiscal year. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In June 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 requires companies to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred, which is adjusted to its present value each period. In addition, companies must capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business. SFAS No. 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The adoption of this statement did not have a significant impact on the Company's consolidated financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," which supercedes Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit and Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and requires that a liability be recognized when it is incurred and should initially be measured and recorded at fair value. This statement is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement did not have an impact on the Company's consolidated financial position or results of operations.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 2 - Summary of Significant Accounting Policies (Continued):****Effects of Recent Accounting Pronouncements (Continued)**

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure" which amends SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation, and requires disclosure about those effects in both annual and interim financial statements. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148 did not have a significant impact on the Company's consolidated financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation (FIN) No. 46, "Consolidation of Variable Interest Entities". FIN No. 46 clarifies the application of Accounting Research Bulletin No. 51 for certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 applies to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the second quarter of fiscal 2004 to variable interest entities in which the Company may hold a variable interest that it acquired before February 1, 2003. The provisions of FIN No. 46 require that the Company immediately disclose certain information if it is reasonably possible that the Company will be required to consolidate or disclose variable interest entities when FIN No. 46 becomes effective. The Company has determined that it does not have a significant interest in such entities requiring the related disclosure based on its preliminary analysis and assessment.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The changes are intended to improve financial reporting by requiring that contracts with comparable characteristics be accounted for similarly. Additionally, those changes are expected to result in more consistent reporting of contracts as either derivatives or hybrid instruments. SFAS No. 149 is effective for contracts and hedging relationships entered into or modified after June 30, 2003, and for provisions that relate to SFAS No. 133 implementation issues that have been effective for fiscal quarters that began prior to June 15, 2003, apply in accordance with their respective effective dates. The adoption of this statement did not have a significant effect on the Company's consolidated financial position or results of operations.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 2 - Summary of Significant Accounting Policies (Continued):

Effects of Recent Accounting Pronouncements (Continued)

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liability and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. It also requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for mandatorily redeemable financial instruments of nonpublic entities. It is to be implemented by reporting a cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The Company's initial adoption of this statement on August 1, 2003, will require the reclassification of its Series A Preferred Stock to long-term liabilities within its Consolidated Balance Sheets. Additionally, on a prospective basis, the mandatory dividends will be classified as Interest expense within its Consolidated Statements of Operations.

Note 3 - Property and Equipment:

The costs and accumulated depreciation of property and equipment are summarized as follows:

| | July 31, | |
|-------------------------------|--------------|--------------|
| | 2003 | 2002 |
| Land | \$ 320,869 | \$ 285,407 |
| Buildings and Improvements | 2,030,819 | 1,936,548 |
| Furniture and Fixtures | 81,214 | 76,956 |
| Office Equipment | 108,076 | 93,491 |
| Lab Equipment | 3,026,529 | 2,434,409 |
| Total Property and Equipment | 5,567,507 | 4,826,811 |
| Less Accumulated Depreciation | 1,348,675 | 793,717 |
| Property and Equipment, Net | \$ 4,218,832 | \$ 4,033,094 |

Depreciation expense amounted to \$474,764, \$393,655 and \$209,114 for the years ended July 31, 2003, 2002 and 2001, respectively.

Note 4 - Property Held for Investment, Net:

The costs and accumulated depreciation of assets held for investment are summarized as follows:

| | July 31, | |
|---------------------------------|--------------|-------|
| | 2003 | 2002 |
| Assets Held For Investment | \$ 1,967,933 | \$ -- |
| Less: Accumulated Depreciation | 61,621 | -- |
| Assets Held For Investment, Net | \$ 1,906,312 | \$ -- |

Depreciation expense amounted to \$57,877, \$-0- and \$-0- for the years ended July 31, 2003, 2002 and 2001, respectively.

The Company's intent is to hold this property for investment purposes and collect rental income. Included in income from rental operations, net is \$252,416 of rental income and \$231,626 of rental expenses, including interest charges of \$77,033, for the year ended July 31, 2003.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 5 - Patents:

The costs and accumulated amortization of patents are summarized as follows:

| | July 31, | |
|--------------------------------|-------------------|-------------------|
| | 2003 | 2002 |
| Patents | \$ 1,020,805 | \$ 890,061 |
| Less: Accumulated Amortization | 121,929 | 59,919 |
| Patents, Net | \$ 898,876 | \$ 830,142 |

Note 6 - Income Taxes:

The Company has incurred losses since inception, which have generated net operating loss carryforwards. The net operating loss carryforwards arise from both United States and Canadian sources. Pretax losses arising from domestic operations (United States) was \$10,794,200 and from foreign operations (Canada and Bermuda) was \$2,467,564 for the year ended July 31, 2003. As of July 31, 2003, the Company has net operating loss carryforwards in Generex Biotechnology Corporation of approximately \$39,259,987, which expire in 2014 through 2023, and in Generex Pharmaceuticals Inc. of approximately \$16,040,901, which expire in 2006 through 2010. These loss carryforwards are subject to limitation in future years should certain ownership changes occur.

For the years ended July 31, 2003, 2002 and 2001, the Company's effective tax rate differs from the federal statutory rate principally due to net operating losses and other temporary differences for which no benefit was recorded.

Deferred income taxes consist of the following:

| | July 31, | |
|----------------------------------|---------------------|---------------------|
| | 2003 | 2002 |
| Deferred Tax Assets: | | |
| Net operating loss carryforwards | \$ 18,160,666 | \$ 13,530,4272 |
| Other timing difference | 1,594,982 | ,027,664 |
| Total Deferred Tax Assets | 19,755,648 | 15,558,091 |
| Valuation Allowance | (19,755,648) | (15,558,091) |
| Net Deferred Income Taxes | \$ -- | \$ -- |

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 6 - Income Taxes (Continued):

A reconciliation of the United States Federal Statutory rate to the Company's effective tax rate for the years ended July 31, 2003, 2002 and 2001 is as follows:

| | 2003 | 2002 | 2001 |
|---|------------|------------|------------|
| Federal statutory rate | (34.0)% | (34.0)% | (34.0)% |
| Increase (decrease) in income taxes resulting from: | | | |
| Loss incurred in Bermuda for which no benefit is recognized | -- | 2.9 | 15.1 |
| Imputed interest income on intercompany receivables from foreign subsidiaries | 1.4 | 1.4 | .5 |
| Foreign taxes booked at different rates | .7 | .7 | .4 |
| Nondeductible items | 1.9 | 1.8 | .1 |
| Other | .1 | .1 | (1.5) |
| Change in valuation allowance | 29.9 | 27.1 | 19.4 |
| Effective tax rate | --% | --% | --% |

Note 7 - Accounts Payable and Accrued Expenses:

Accounts payable and accrued expenses consist of the following:

July 31,

| | 2003 | 2002 |
|------------------------|---------------------|---------------------|
| Accounts Payable | \$ 1,094,129 | \$ 853,184 |
| Accrued Legal | 292,085 | 460,840 |
| Executive Compensation | -- | 584,919 |
| Total | \$ 1,386,214 | \$ 1,898,943 |

Note 8 - Commitments and Contingent Liabilities:

Consulting Services

The Company's Consulting Agreement with its Vice President of Research and Development (the V.P.), as amended and supplemented, continues through July 31, 2010, subject to termination without cause by the V.P. or the Company at any time after January 31, 2003 upon 12 months prior written notice. The Consulting Agreement provides for an annual base compensation of \$250,000 per year (starting August 1, 2000), subject to annual increases. In addition, the Consulting Agreement provides for certain bonus compensation to be paid to the V.P. for achievement of certain milestones under the Company's development agreements with pharmaceutical companies. During the 2001 fiscal year, the Company paid the V.P. \$300,000 for his involvement in securing a development agreement for a specific product with a pharmaceutical company. The Consulting Agreement also provides for the V.P. to be granted options to purchase 150,000 shares of common stock in each of the next 10 fiscal years, starting with the 2001 fiscal year. The options must be granted under option plans approved by the Company's stockholders.

In connection with amending and supplementing the Consulting Agreement in January 1998, the Company issued 1,000 shares of Special Voting Rights Preferred Stock to the V.P. See Note 12 for description of Special Voting Rights Preferred Stock.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 - Commitments and Contingent Liabilities (Continued):

Leases

The Company has entered into various operating lease agreements for the use of vehicles and office equipment.

Aggregate minimum annual lease commitments of the Company under non-cancelable operating leases as of July 31, 2003 are as follows:

| Year | Amount |
|-------------------------------------|------------------|
| 2004 | \$ 28,331 |
| 2005 | 18,581 |
| 2006 | 13,145 |
| 2007 | 4,190 |
| Thereafter | -- |
| Total Minimum Lease Payments | \$ 64,247 |

Lease expense amounted to \$23,712, \$13,766 and \$20,753 for the years ended July 31, 2003, 2002 and 2001, respectively.

The preceding data reflects existing leases and does not include replacements upon their expiration. In the normal course of business, operating leases are generally renewed or replaced by other leases.

Rental Operations

The Company leases a portion of the floor that it owns in an office building located in Toronto, Canada, as well as two commercial buildings. The following represents the approximate minimum amount of sublease income under current lease agreements to be received in years ending after July 31, 2003:

| Year | Amount |
|--------------|-------------------|
| 2004 | \$ 151,978 |
| 2005 | 151,978 |
| 2006 | 25,330 |
| Thereafter | -- |
| Total | \$ 329,286 |

Property Held for Investment

The Company leases units of property that it owns located in Toronto, Canada. The following represents the approximate minimum amount in lease income under current lease agreements to be received in years ending after July 31, 2003:

| Year | Amount |
|--------------|-------------------|
| 2004 | \$ 202,276 |
| 2005 | 174,251 |
| 2006 | 123,131 |
| 2007 | 68,770 |
| 2008 | 46,066 |
| Thereafter | 37,761 |
| Total | \$ 652,255 |

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 8 - Commitments and Contingent Liabilities (Continued):****Supply Agreements**

The Company has a supply agreement with Valois, S.A. and Valois of America, Inc. (collectively Valois), to supply the Company with certain products developed and manufactured by Valois. Pursuant to the agreement, the Company shall pay milestone payments to Valois within 30 days of July 19 beginning in fiscal 2001 for the next five years. These milestone payments are based on exceeding certain specified levels of product purchases. If the milestone obligations are not met after a five-year period, the Company may elect to pay Valois an annual payment of \$50,000 until the milestone obligation is met in order to maintain exclusive rights under the agreement. In the event the Company chooses to end the agreement after the fifth anniversary, the Company shall pay Valois a one-time payment of \$350,000. There were no milestone payments required by the agreement in the years ended July 31, 2003, 2002 and 2001.

The Company has a supply agreement with Presspart Manufacturing Limited, whereby the Company will purchase its entire requirements for products to use in the administration of insulin through the buccal mucosa and shall not purchase the products or any metal containers competitive to the products from any other person in exchange for an exclusive non-transferable royalty-free irrevocable license to use the products. The contract shall continue for a minimum period of four contract years from the end of the first contract year in which the quantity of products purchased by the Company from Presspart exceeds 10,000,000 units, and thereafter, shall continue until terminated by either party by giving twelve months written notice.

Concentrations In Development Arrangements

The Company has a development arrangement with a major pharmaceutical company, whereby the pharmaceutical company is primarily responsible for conducting clinical trials related to a specific agreed upon product, securing regulatory approvals and marketing on a worldwide basis. The Company is primarily responsible for completing all necessary product research and development. Although the Company presently has sufficient funds to meet its foreseeable obligations, the costs of the Company's obligations may be significant, and may exceed current funds. If the development arrangement were to be curtailed or terminated, the market perception of the prospects for the Company's product, the timing of regulatory approvals, and the Company's ability to raise funds could be adversely affected.

In conjunction with the execution of this development arrangement, the Company received an agreement signing fee of \$1,000,000 during the fiscal year ended July 31, 2001, which was included in revenues as all necessary requirements have been satisfied.

On May 23, 2003, the Company announced the termination of this development arrangement for the development and commercialization of the buccal delivery of insulin. Pursuant to the provisions of the development and license agreement, both parties are working on terms for the pharmaceutical company to continue to supply a specified amount of insulin for the Company's further development work. All of the Company's intellectual property and commercialization rights with respect to the buccal spray drug delivery technology will revert to the Company, which will have the continuing right to develop and commercialize the product at its own expense.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 8 - Commitments and Contingent Liabilities (Continued):**Pending Litigation**

On October 2, 1998, Sands Brothers & Co. Ltd., a New York City-based investment banking and brokerage firm, initiated an arbitration against the Company under New York Stock Exchange rules. Sands alleged that it had the right to receive, for nominal consideration, approximately 1.5 million shares of the Company's common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary of the Company that was acquired in late 1997. In exchange, the letter agreement purported to grant Sands the right to acquire 17 percent of Generex Pharmaceuticals' common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals' common stock applies to the Company's common stock since outstanding shares of Generex Pharmaceuticals' common stock were converted into shares of the Company's common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and \$144,000 in monthly fees allegedly due under the terms of the purported agreement.

Pursuant to an arbitration award dated September 22, 1999, the arbitration panel that heard this case awarded Sands \$14,070 and issued a declaratory judgment requiring the Company to issue to Sands a warrant to purchase 1,530,020 shares of the Company's common stock pursuant to and in accordance with the terms of the purported October 1997 letter agreement. On October 13, 1999, Sands commenced a special proceeding to confirm the arbitration award in the Supreme Court of the State of New York, County of New York (the "New York Supreme Court"). On November 10, 1999, the Company moved to vacate the arbitration award. On March 20, 2000, the New York Supreme Court granted Sands' petition to confirm the award and denied the Company's motion to vacate the award. The Company appealed and on January 23, 2001, the New York State Appellate Division, First Department (the "Appellate Division"), modified the judgment of the New York Supreme Court that had confirmed the arbitration award against the Company. The Appellate Division affirmed the portion of the New York Supreme Court judgment that had confirmed the granting of monetary relief of \$14,070 to Sands but modified the judgment to vacate the portion of the arbitration award directing the issuance to Sands of a warrant to purchase 1,530,020 shares of the Company's common stock. The Appellate Division held that the portion of the award directing the Company to issue warrants to Sands is too indefinite to be enforceable and remanded the matter to the arbitration panel for a final and definite award with respect to such relief or its equivalent (including possibly an award of monetary damages). The arbitration panel commenced hearings on the matters remanded by the Appellate Division in June 2001. On November 7, 2001, the arbitration panel issued an award again requiring the Company to issue to Sands a warrant to purchase 1,530,020 shares of the Company's common stock purportedly pursuant to and in accordance with the terms of the October 1997 letter agreement. Thereafter, Sands submitted a motion to the New York Supreme Court to modify and confirm the arbitration panel's award while the Company filed a motion with the court to vacate the arbitration award. On February 25, 2002, the New York Supreme Court vacated the arbitration panel's award. The Supreme Court concluded that the arbitration panel had "disregarded the plain meaning" of the directive given by the Appellate Division in the Appellate Division's January 23, 2001 decision that remanded the matter of the warrant for reconsideration by the panel. The Supreme Court found that the arbitration panel's award "lacks a rational basis". The Supreme Court also remanded the matter to the New York Stock Exchange on the issue of whether the arbitration panel should be disqualified. Sands has appealed the February 25, 2002 order of the Supreme Court to the Appellate Division. The Company filed a cross-appeal on issues relating to the disqualification of the arbitration panel.

On October 29, 2002, the Appellate Division issued a decision and order unanimously modifying the lower court's order by remanding the issue of damages to a new panel of arbitrators and otherwise affirming the lower court's order. The Appellate Division's decision and order limits the issue of damages before the new panel of arbitrators to reliance damages which is not to include an award of lost profits. Reliance damages are out-of-pocket damages incurred by Sands. The Appellate Division stated that the lower court properly determined that the arbitration award, which had granted Sands warrants for 1,530,020 shares of the registrant's stock, was "totally irrational."

On March 18, 2003, the Appellate Division of the Supreme Court of New York denied a motion by Sands for re-argument of the October 29, 2002 decision, or, in the alternative, for leave to appeal to the Court of Appeals.

At the present time, the Company is not able to predict the ultimate outcome of this legal proceeding or to estimate a range of possible loss from this legal proceeding. Therefore, no provision has been recorded in the accompanying financial statements.

In February 2001, a former business associate of the Vice President of Research and Development (VP), and an entity called Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against the Company and the VP seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and the VP that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by the Company of three patents allegedly owned by the company called CTI. On July 20, 2001, the Company filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 8 - Commitments and Contingent Liabilities (Continued):****Pending Litigation (Continued)**

want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by the Company. Consequently, the shareholders of CBI are in a deadlock. The court granted the Company's motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in the name of or on behalf of CBI. The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against the VP and the Company. The Company has opposed the application which is now pending before the Court. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against Modi and the Company. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

In February 1997, an individual alleging to be a former employee of Generex Pharmaceuticals, Inc., commenced an action in the Ontario Superior Court of Justice for wrongful dismissal. The Ontario Superior Court of Justice rendered judgment in favor of the plaintiff for approximately \$127,000 plus interest in November 1999 and further awarded costs to the plaintiff in March 2000. An appeal of the judgment was filed with the Court of Appeal for Ontario in April 2000. The appeal was heard on February 26, 2003, and on February 28, 2003, the Court of Appeals dismissed the appeal with costs. Generex Pharmaceuticals, Inc., has sought leave to appeal the Courts of Appeal's decision to the Supreme Court of Canada. The Company intends to continue its vigorous defense of this action. The Company does not believe that the ultimate resolution of this legal proceeding will have a material effect on the consolidated financial position of the Company. The Company has established a reserve for potential loss contingencies related to the resolution of this legal proceeding, the amount of which is not material to the financial position, operations and cash flows of the Company.

In July 2002 an individual and his related corporation commenced actions against certain defendants, including the Company and certain officers of the Company, in the Ontario Superior Court of Justice, claiming compensatory damages, punitive damages and various forms of injunctive and declaratory relief for breach of contract and various business torts. Management believes the claims against the Company and the officers are frivolous and completely without merit. Neither the Company nor its officers are a party to any agreement with the plaintiffs. Most of the requested relief relates to restrictions on the use of patents and information allegedly owned by the plaintiffs, and an accounting for the use of such items. Neither the Company nor its officers have used any patents or information owned by the plaintiffs. All of the patents and information claimed to be owned by the plaintiffs are completely unrelated to any product or technology the Company is currently developing or intends to develop. Therefore, even if the court were to award some declaratory or injunctive relief, neither the Company nor its officers would be affected. Management is defending this action vigorously. The parties have now signed Minutes of Settlement resolving all outstanding issues in the action. The settlement is presently in the process of being finalized and the Company believes that the resolution will not have a material adverse effect on the Company's financial position, operations or cash flows.

The Company is involved in certain other legal proceedings in addition to those specifically described herein. Subject to the uncertainty inherent in all litigation, the Company does not believe at the present time that the resolution of any of these legal proceedings is likely to have a material adverse effect on the Company's financial position, operations or cash flows.

With respect to all litigation, as additional information concerning the estimates used by the Company become known, the Company reassesses its position both with respect to accrued liabilities and other potential exposures.

Employment Agreement

On March 17, 2003, the Company entered into an employment agreement for an initial term of five years, whereby the Company is required to pay an annual base salary and bonus of \$130,000 to the employee. In the event the agreement is terminated within the initial five-year term, by reason other than cause, death, voluntary retirement or disability, the Company is required to pay the employee in one lump sum twelve months base salary and the average annual bonus.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 9 - Related Party Transactions:

The amount due from a related party at July 31, exclusive of the officers' loans receivable, is as follows:

| | <u>EBI, Inc.</u> |
|--|-------------------|
| Beginning Balance, August 1, 2001 | \$ 332,289 |
| Effect of Foreign Currency Translation Adjustments | (9,604) |
| Ending Balance, July 31, 2002 | 322,685 |
| Effect of Foreign Currency Translation Adjustments | 40,094 |
| Ending Balance, July 31, 2003 | \$ 362,779 |

This amount, which is due from EBI, Inc., is non-interest bearing, unsecured and has no fixed terms of repayment. EBI, Inc. is a shareholder of the Company and is controlled by the estate of the Company's former Chairman of the Board.

The Company estimates the following additional amounts would have been recorded if such transaction was consummated under arms-length agreements:

| | <u>For the Years Ended July 31,</u> | | |
|------------------------|-------------------------------------|-------------|-------------|
| | <u>2003</u> | <u>2002</u> | <u>2001</u> |
| Interest Income | \$ 12,207 | \$ 31,250 | \$ 32,209 |

The interest income amounts were computed at estimated prevailing rates based on the average receivable balance outstanding during the periods reflected.

During the years ended July 31, 2003, 2002 and 2001, the Company's four senior officers, who are also shareholders of the Company, were compensated indirectly by the Company through management services contracts between the Company and management firms of which they are owners. The amounts paid to these management firms amounted to \$1,319,238, \$1,075,847 and \$672,477 for the years ended July 31, 2003, 2002 and 2001, respectively.

See Note 8 for a discussion of the consulting agreement with the Company's Vice President of Research and Development.

On May 3, 2001, three of the Company's senior officers, who are also shareholders of the Company, were given loans of \$334,300 each, in exchange for promissory notes. These notes bear interest at 8.5 percent per annum and were originally payable in full on May 1, 2002. The notes were extended until October 1, 2002, at terms comparable to the original notes. These notes are guaranteed by a related company owned by these officers and secured by 2,500,000 pledged shares of the Company's common stock currently owned by this related company.

In September 2002, the notes were redeemed pursuant to the Stock Pledge Agreement. The outstanding balance of \$1,126,157 was repaid with 592,716 shares of common stock, as determined by the Compensation Committee. These shares effectively became treasury stock.

On August 7, 2002 the Company purchased real estate with an aggregate purchase price of approximately \$1.6 million from an unaffiliated party. In connection with that transaction, Angara Enterprises, Inc., a licensed real estate broker that is an affiliate of a senior officer of the Company, received a commission from the proceeds of the sale to the seller in the amount of 3% of the purchase price. Management believes that this is less than the aggregate commission which would have been payable if an unaffiliated broker had been used.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 9 - Related Party Transactions (Continued):

The Company utilizes a management company to manage all of its real properties. The property management company is owned by two of the Company's senior officers and the estate of the Company's former Chairman of the Board. For the years ended July 31, 2003, 2002 and 2001, the Company has paid the management company \$33,237, \$37,535 and \$38,450, respectively, in management fees.

Note 10 - Long-Term Debt:

Long-term debt consists of the following:

| | For the Years Ended July 31, | |
|--|------------------------------|-------------------|
| | 2003 | 2002 |
| Mortgage payable - interest at 9.7 percent per annum, monthly payments of principal and interest of \$4,453, final payment due May 25, 2005, secured by first mortgage over real property located at 17 Carlaw Avenue and 33 Harbour Square, Toronto, Canada | \$ 551,859 | \$ 497,281 |
| Mortgage payable - interest at 10 percent per annum, monthly payments of principal and interest of \$1,662, final payment due October 2005, secured by real property located at 11 Carlaw Avenue, Toronto, Canada | 182,341 | 166,032 |
| Demand Term Loan payable - interest at 5.8 percent per annum, monthly principal payments of \$4,760 plus interest, final payment due July 2005, secured by real property located at 11 Carlaw Avenue, Toronto, Canada and restricted cash of \$188,967 | 804,325 | -- |
| Mortgage payable - interest at 10 percent per annum, monthly interest payments only, principal due July 2004, secured by secondary rights to real property located at 11 Carlaw Avenue, Toronto, Canada | 356,950 | -- |
| Total Debt | 1,895,475 | 663,313 |
| Less Current Maturities | 426,767 | 172,453 |
| Long-Term Debt, Less Current Maturities | \$ 1,468,708 | \$ 490,860 |

Aggregate maturities of long-term debt of the Company due within the next five years ending July 31, are as follows:

| Year | Amount |
|--------------|---------------------|
| 2004 | \$ 426,767 |
| 2005 | 1,296,386 |
| 2006 | 172,322 |
| Thereafter | -- |
| Total | \$ 1,895,475 |

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 11 - Series A Preferred Stock**

During 2001, the Company issued 1,000 shares of Series A Preferred Stock (Series A) with a par value of \$.001 per share. The holder has the right at any time after January 16, 2004 to convert Series A shares into shares of common stock of the Company; the number of shares of common stock issuable upon conversion is variable based on a formula which reflects the common stock price. The holder also has the option to exchange the shares of the Company's Series A Preferred stock for 3,612 shares of the Company's convertible preferred shares of Generex (Bermuda), Ltd. which represents 30.1 percent of the Company's equity ownership in Generex (Bermuda) Ltd. Upon exercise, the holder and the Company would each own 50 percent of Generex (Bermuda) Ltd. (See Note 18 for discussions of Generex (Bermuda), Ltd.) Holders of Series A shares are not entitled to vote. In addition, the holders of Series A shares are entitled to receive a dividend per share equal to the dividend declared and paid on shares of the Company's common stock as and when dividends are declared and paid on the Company's common stock, and are also entitled to receive a mandatory annual dividend equal to 6 percent per year on the original issue price of \$12,015 per share. This dividend is to be compounded each anniversary of the date of issuance of the Series A shares and payable by issuance of additional Series A shares valued at the original issue price. Any Series A shares outstanding on January 16, 2007, are to be redeemed for cash or shares of common stock.

On January 15, 2002, the Company paid a 6 percent stock dividend on the Company's Series A Preferred Stock. The dividend was paid in shares of Series A Preferred Stock, and resulted in a charge to accumulated deficit of \$720,900, which was calculated based upon the original issue price of the preferred shares.

On January 15, 2003, the Company paid a 6 percent stock dividend on the Company's Series A Preferred Stock. The dividend was paid in shares of Series A Preferred Stock, and resulted in a charge to accumulated deficit of \$764,154, which was calculated based upon the original issue price of the preferred shares.

At July 31, 2003 and 2002, the Series A had an aggregate liquidation preference of \$13,500,054 and \$12,735,900, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 12 - Stockholders' Equity:

Warrants

As of July 31, 2003, the Company has the following warrants to purchase common stock outstanding:

| Number of Shares To be Purchased | Warrant Exercise Price Per Share | Warrant Expiration Date |
|-------------------------------------|-------------------------------------|----------------------------|
| 568,647 | \$ 12.15 | August 12, 2003 |
| 150,000 | \$ 10.00 | November 17, 2003 |
| 112,584 | \$ 3.75 | January 31, 2004 |
| 3,500 | \$ 6.00 | February 17, 2004 |
| 53,000 | \$ 6.00 | April 6, 2004 |
| 9,091 | \$ 2.75 | April 26, 2004 |
| 125,000 | \$ 4.00 | June 15, 2004 |
| 3,243 | \$ 14.53 | July 6, 2004 |
| 11,764 | \$ 4.25 | January 7, 2005 |
| 691,667 | \$ 4.34 | May 17, 2005 |
| 19,584 | \$ 5.00 | May 17, 2005 |
| 256,667 | \$ 8.66 | May 17, 2005 |
| 214,484 | \$ 6.50 | September 29, 2005 |
| 114,055 | \$ 6.60 | September 29, 2005 |
| 239,222 | \$ 11.13 | September 29, 2005 |
| 226 | \$ 12.99 | September 29, 2005 |
| 75,000 | \$ 25.15 | January 16, 2006 |
| 666,667 | \$ 1.80 | June 6, 2006 |
| 188,656 | \$ 5.09 | July 6, 2006 |
| 124,859 | \$ 10.18 | July 6, 2006 |
| 50,000 | \$ 12.99 | March 18, 2007 |
| 1,269,519 | \$ 1.71 | May 27, 2007 |
| 70,000 | \$ 1.25 | November 29, 2007 |
| 60,000 | \$ 1.88 | November 29, 2007 |
| 505,000 | \$ 2.50 | November 29, 2007 |
| 30,000 | \$ 3.00 | November 29, 2007 |

Notes Receivable - Common Stock

Notes receivable - common stock consist of two separate promissory notes. The first promissory note was issued in conjunction with the redemption of Series A Redeemable Common Stock Purchase Warrants in June 1999, and was for \$50,000. This note, which was originally due on December 1, 1999, was initially extended until October 1, 2000, and then extended until June 1, 2001. On July 31, 2001, the uncollected balance on this note, including accrued interest at 7 percent per annum, was \$57,720 and a new promissory note was signed. Under the terms of the July 31, 2001 note, the principal of \$57,720, together with accrued interest at 7 percent per annum, was due July 31, 2002. On July 31, 2002, the uncollected balance on this note, including accrued interest, was \$61,867 and a new promissory note was signed. Under the terms of the July 31, 2002 note, the principal of \$61,867, together with accrued interest at 7 percent per annum, was due July 31, 2003. On July 31, 2003, the uncollected balance on this note, including accrued interest, was \$66,198 and a new promissory note was signed. Under the terms of the July 31, 2003 note, the principal of \$66,198, together with accrued interest at 7 percent per annum, is due July 31, 2004.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**Note 12 - Stockholders' Equity (Continued):****Notes Receivable - Common Stock (Continued)**

The second promissory note was issued in conjunction with the exercise of 50,000 Common Stock Options in March 2001, and was for \$250,000. This note was originally due on March 15, 2002, when a new promissory note was signed, effectively extending the due date to March 15, 2003. On March 15, 2003 a new promissory note was signed, effectively extending the due date to March 15, 2004. As of July 31, 2003 and 2002, the outstanding balance on this note, including accrued interest at 7 percent per annum, was \$293,800 and \$275,018, respectively.

Preferred Stock

The Company has authorized 1,000,000 shares of preferred stock with a par value of one-tenth of a cent (\$.001) per share. The preferred stock may be issued in various series and shall have preference as to dividends and to liquidation of the Company. The Company's Board of Directors is authorized to establish the specific rights, preferences, voting privileges and restrictions of such preferred stock, or any series thereof.

Special Voting Rights Preferred Stock

In 1997, the Company issued 1,000 shares of Special Voting Rights Preferred Stock (SVR Shares) with a par value of \$.001. The Company has the right at any time after December 31, 2000, upon written notice to all holders of preferred shares, to redeem SVR Shares at \$.10 per share. Holders of SVR Shares are not entitled to vote, except as specifically required by applicable law or in the event of change in control, as defined. In addition, holders of SVR Shares are entitled to receive a dividend per share equal to the dividend declared and paid on shares of the Company's common stock as and when dividends are declared and paid on the Company's common stock.

Treasury Stock

In September 2001, the Board of Directors of the Company authorized the repurchase of up to \$1 million of the Company's common stock from the open market. During the fiscal years ended July 31, 2003 and 2002, the Company purchased 53,000 and 96,500 shares of common stock to be held in treasury at a cost of \$88,338 and \$395,531, respectively. Also included in treasury stock are 592,716 shares of common stock valued at \$1,126,157 received as repayment of officer loans receivable (see Note 9). As of July 31, 2003 and 2002, there were 742,216 and 96,500 shares held in treasury valued at \$1,610,026 and \$395,531, respectively.

Note 13 - Stock Based Compensation:**Stock Option Plans**

The Company has three stock option plans under which options exercisable for shares of common stock have been or may be granted to employees, directors, consultants and advisors. A total of 1,500,000 shares of common stock are reserved for issuance under the 1998 Stock Option Plan (the 1998 Plan), a total of 2,000,000 shares of common stock are reserved for issuance under the 2000 Stock Option Plan (the 2000 Plan) and a total of 4,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the 2001 Plan).

The 1998, 2000 and 2001 Plans (the Plans) are administered by the Compensation Committee (the Committee). The Committee is authorized to select from among eligible employees, directors, advisors and consultants those individuals to whom options are to be granted and to determine the number of shares to be subject to, and the terms and conditions of, the options. The Committee is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Committee.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13 - Stock Based Compensation (Continued):

Stock Option Plans (Continued)

The Plans provide that options may or may not be Incentive Stock Options (ISOs) within the meaning of Section 422 of the Internal Revenue Code. Only employees of the Company are eligible to receive ISOs, while employees and non-employee directors, advisors and consultants are eligible to receive options which are not ISOs, i.e. "Non-Qualified Options." The options granted by the Board in connection with its adoption of the Plans are Non-Qualified Options.

The following is a summary of the common stock options granted, canceled or exercised under the Plan:

| | Shares | Weighted Average Exercise Price Per Share |
|------------------------------|-----------|---|
| Outstanding - August 1, 2000 | 3,054,500 | 6.38 |
| Granted | 1,455,000 | 6.14 |
| Canceled | -- | -- |
| Exercised | 197,500 | 5.04 |
| Outstanding - July 31, 2001 | 4,312,000 | 6.36 |
| Granted | 780,159 | 5.42 |
| Canceled | 80,000 | 5.65 |
| Exercised | 5,000 | 5.50 |
| Outstanding - July 31, 2002 | 5,007,159 | 6.22 |
| Granted | 2,860,000 | 1.85 |
| Canceled | 1,077,000 | 5.95 |
| Exercised | 195,000 | 5.70 |
| Outstanding - July 31, 2003 | 6,595,159 | \$ 4.38 |

The following table summarizes information on stock options outstanding at July 31, 2003:

| Range of Exercise Price | Options Outstanding | | | Options Exercisable | |
|-------------------------|--|---|---------------------------------|-------------------------------------|---------------------------------|
| | Number Outstanding ^a at July 31, 2003 | Weighted Average Contractual Life (Years) | Weighted Average Exercise Price | Number Exercisable at July 31, 2003 | Weighted Average Exercise Price |
| \$ 1.00 - \$ 2.19 | 2,905,000 | 4.01 | \$ 1.87 | 2,268,500 | \$ 1.80 |
| \$ 5.00 - \$ 6.54 | 1,980,659 | 2.35 | \$ 5.11 | 1,880,659 | \$ 5.10 |
| \$ 7.50 - \$ 8.70 | 1,609,500 | 2.10 | \$ 7.68 | 1,609,500 | \$ 7.68 |
| \$10.21 | 100,000 | 2.50 | \$ 10.21 | 100,000 | \$ 10.21 |

Options typically vest over a period of two years and have a contractual life of five years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 13 - Stock Based Compensation (Continued):

Stock Option Plans (Continued)

Options exercisable at July 31, are as follows:

| Year | Number of Options | Weighted Average Exercise Price |
|------|-------------------|---------------------------------|
| 2001 | 3,182,000 | \$ 6.63 |
| 2002 | 4,685,659 | \$ 6.26 |
| 2003 | 5,858,659 | \$ 4.62 |

During the years ended July 31, 2003, 2002 and 2001, no amount was charged to compensation expense with respect to options granted to employees and directors of the Company.

The fair value of each option granted is estimated on grant date using the Black-Scholes option pricing model which takes into account as of the grant date the exercise price and expected life of the option, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk-free interest rate for the term of the option. The following is the average of the data used to calculate the fair value:

| | Risk-Free Interest Rate | Expected Life (Years) | Expected Volatility | Expected Dividends |
|---------------|-------------------------|-----------------------|---------------------|--------------------|
| July 31, 2003 | .90% | 4.59 | 1.0219 | -- |
| July 31, 2002 | 1.74% | 4.81 | .9641 | -- |
| July 31, 2001 | 4.66% | 4.25 | .9332 | -- |

The weighted average fair value of the Company's stock options calculated using the Black-Scholes option-pricing model for options granted during the years ended July 31, 2003, 2002 and 2001 was \$1.35, \$4.33 and \$4.12 per share, respectively.

Equity Instruments Issued for Services Rendered

During the years ended July 31, 2003, 2002 and 2001, the Company issued stock options, warrants and shares of common stock in exchange for services rendered to the Company. The fair value of each stock option and warrant was valued using the Black Scholes pricing model which takes into account as of the grant date the exercise price and expected life of the stock option or warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk free interest rate for the term of the stock option or warrant. Shares of common stock are valued at the quoted market price on the date of grant. Each the fair value of each grant was charged to the related expense in the statement of operations for the services received.

Note 14 - Net Loss Per Share:

Basic EPS and Diluted EPS for the years ended July 31, 2003, 2002 and 2001 have been computed by dividing the net loss available to common stockholders for each respective period by the weighted average shares outstanding during that period. All outstanding warrants and options and shares to be issued upon conversion of Series A Preferred stock, representing approximately 12,741,679 incremental shares, have been excluded from the 2003 computation of Diluted EPS as they are antidilutive due to the losses generated.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 15 - Supplemental Disclosure of Cash Flow Information:

For the Years Ended July 31,

| | 2003 | 2002 | 2001 |
|---|------------|-----------|-----------|
| Cash paid during the year for: | | | |
| Interest | \$ 149,233 | \$ 64,310 | \$ 77,230 |
| Income taxes | \$ -- | \$ -- | \$ -- |
| Disclosure of non-cash investing and financing activities: | | | |
| Year Ended July 31, 2003 | | | |
| Issuance of Series A Preferred Stock as preferred stock dividend | | | 764,154 |
| Settlement of officer loans receivable in exchange for shares of common stock held in treasury | | | 1,126,157 |
| Assumption of long-term debt in conjunction with building purchase | | | 1,080,486 |
| Utilization of deposit in conjunction with building purchase | | | 501,839 |
| Year Ended July 31, 2002 | | | |
| Issuance of Series A Preferred stock as preferred stock dividend | | | 720,900 |
| Year Ended July 31, 2001 | | | |
| The fair value of warrants issued as consideration for an equity financing agreement was initially capitalized as deferred offering costs and subsequently expensed | | | 3,406,196 |
| Note receivable was accepted in conjunction with exercise of common stock options | | | 250,000 |
| Common stock was issued as settlement of an accrued liability | | | 21,098 |

Note 16 - Segment Information:

The Company follows SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information" (SFAS No. 131). SFAS No. 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS No. 131 also establishes standards for related disclosures about products and services, geographic areas, and major customers.

The Company has three reportable operating segments, United States, Canada and Bermuda, which are organized, managed and analyzed geographically and operate in one industry segment: the development of proprietary drug delivery technology focused on formulations to administer large molecule drugs by mouth. The Company evaluates operating segment performance based primarily on certain operating expenses.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 16 - Segment Information (Continued):

The regions in which the Company had identifiable assets and operating losses are presented in the following table. Additions to long-lived assets and identifiable assets are those that can be directly associated with a geographic area. Operating loss by geographic segment does not include an allocation of general corporate expenses.

| | Additions to Long-Lived Assets | Identifiable Assets | Operating Loss |
|-------------------|--------------------------------------|------------------------|----------------------|
| 2003 | | | |
| General Corporate | \$ 108,576 | \$ 15,080,988 | \$ 7,557,126 |
| Canada | 2,088,433 | 7,557,720 | 6,291,564 |
| United States | -- | -- | -- |
| Bermuda | -- | -- | -- |
| Total | \$ 2,197,009 | \$ 22,638,708 | \$ 13,848,690 |
| 2002 | | | |
| General Corporate | \$ 440,698 | \$ 22,575,641 | \$ 6,252,134 |
| Canada | 779,519 | 5,585,107 | 8,248,622 |
| United States | -- | -- | -- |
| Bermuda | -- | -- | 29,690 |
| Total | \$ 1,220,217 | \$ 28,160,748 | \$ 14,530,446 |
| 2002 | | | |
| General Corporate | \$ 197,434 | \$ 38,227,315 | \$ 11,768,696 |
| Canada | 1,623,017 | 4,438,558 | 19,668,843 |
| United States | -- | -- | -- |
| Bermuda | -- | -- | -- |
| Total | \$ 1,820,451 | \$ 42,665,873 | \$ 31,437,539 |

Note 17 - Collaborative Agreements:

The Company has a joint venture with Elan International Services, Ltd. ("EIS"), a wholly owned subsidiary of Elan Corporation, plc (EIS and Elan Corporation, plc being collectively referred to as "Elan"). Through the joint venture, the parties agreed to pursue the application of certain of the Company's and Elan's drug delivery technologies, including the Company's platform technology for the buccal delivery of large molecule drugs, to pharmaceutical products for the treatment of prostate cancer, endometriosis and/or the suppression of testosterone and estrogen. In January 2002, the parties expanded the joint venture agreement to include buccal morphine for the management of pain. The parties will conduct the joint venture through Generex (Bermuda), Ltd. (Generex Bermuda), a Bermuda limited liability company. The parties are free to develop other products on their own outside the field of the joint venture.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 17 - Collaborative Agreements (Continued):

The Company applied the \$12,015,000 that it received from EIS for the shares of the Company's Series A Preferred Stock (see Note 12) to form Generex Bermuda. The Company's interest in this company consists of 6,000 shares of Generex Bermuda common stock and 3,612 shares of convertible preferred stock, representing an 80.1 percent equity ownership interest in Generex Bermuda. At the same time, EIS remitted \$2,985,000 to purchase 2,388 shares of Generex Bermuda convertible preferred stock, representing a 19.9 percent equity ownership interest in Generex Bermuda. The Series A Preferred stock has an exchange feature which allows EIS to acquire an additional 30.1 percent equity ownership interest in Generex Bermuda. As of July 31, 2003, 2002 and 2001, the minority interest has been reduced to \$-0- due to their share of Generex Bermuda's net loss.

Generex Bermuda was granted rights to use the Company's buccal delivery technology and certain Elan drug delivery technologies for purposes of the joint venture. Using the funds from the initial capitalization, Generex Bermuda paid a nonrefundable license fee of \$15,000,000 to Elan in consideration for being granted rights to use the Elan drug delivery technologies during the year ended July 31, 2001. The Company expensed the entire cost of the license as a research and development expense because of the uncertainties surrounding the future realization of revenue from the use of the license. During the years ended July 31, 2003 and 2002, Generex Bermuda continued to incur research and development and operational expenses in conjunction with the joint venture's operations.

Note 18 - Quarterly Information (Unaudited):

The following schedule sets forth certain unaudited financial data for the preceding eight quarters ending July 31, 2003. In our opinion, the unaudited information set forth below has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the information set forth herein. The operating results for the quarter are not indicative of results for any future period.

| | Q1 | Q2 | Q3 | Q4 |
|---|----------------|----------------|----------------|----------------|
| Fiscal Year July 31, 2003: | | | | |
| Contract research revenue | \$ -- | \$ -- | \$ -- | \$ -- |
| Operating loss | \$ (2,805,371) | \$ (4,700,645) | \$ (2,763,741) | \$ (3,578,933) |
| Net loss | \$ (2,668,662) | \$ (4,575,030) | \$ (2,607,871) | \$ (3,410,201) |
| Net loss available to common stockholders | \$ (2,668,662) | \$ (5,331,975) | \$ (2,607,871) | \$ (3,417,410) |
| Net loss per share | \$ (0.13) | \$ (0.27) | \$ (0.13) | \$ (0.14) |
| Fiscal Year July 31, 2002: | | | | |
| Contract research revenue | \$ -- | \$ -- | \$ -- | \$ -- |
| Operating loss | \$ (2,904,564) | \$ (3,781,525) | \$ (3,401,056) | \$ (4,443,301) |
| Net loss | \$ (2,583,235) | \$ (3,558,703) | \$ (3,239,150) | \$ (4,311,946) |
| Net loss available to common stockholders | \$ (2,583,235) | \$ (4,279,603) | \$ (3,239,150) | \$ (4,311,946) |
| Net loss per share | \$ (0.12) | \$ (0.21) | \$ (0.16) | \$ (0.21) |

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 19 - Subsequent Events:

The following event occurred subsequent to July 31, 2003:

Antigen Express, Inc.

On August 8, 2003, the Company acquired all of the outstanding capital stock of Antigen Express, Inc. ("Antigen") pursuant to an Agreement and Plan of Merger ("Merger Agreement"). Pursuant to the Merger Agreement, Antigen became a wholly-owned subsidiary of the Company.

Antigen's facilities and headquarters are located in Worcester, Massachusetts. Antigen is engaged in research and development efforts focused on the development of immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases.

The acquisition of Antigen brings two additional platform technologies to the Company. The immunomedicines based on these technologies allow for specific modulation of the immune system to allow for activation and re-activation against cancer and infectious agents and de-activation in the case of if allergy and autoimmune disease. The delivery technologies currently possessed by the Company, when used with Antigen's active immunotherapies may provide for breakthrough therapeutics.

The Merger Agreement provides that each holder of Antigen common stock and each holder of each of the four outstanding series of Antigen preferred stock will receive shares of the Company's common stock, par value \$0.001 per share, for each share of Antigen common stock or preferred stock held by such holder. The Merger Agreement establishes exchange rates for the conversion of Antigen common and the various series of preferred stock into the Company's common stock. Assuming that no Antigen stockholder exercises appraisal rights, an aggregate of 2,779,974 shares of the Company's common stock will be issued to the former Antigen stockholders in connection with the Merger. These shares have been valued based upon the average trading price as quoted on the NASDAQ for the five days prior and subsequent to the announcement of the acquisition for a total of \$4,645,059 or \$1.6709 per share. In addition, pursuant to the Merger Agreement, the Company assumed Antigen common stock purchase options. If these options are fully exercised, the option holders will receive 112,400 shares of the Company's common stock.

The Merger Agreement also calls for the Company to fund an aggregate amount of not less than \$2,000,000 ratably over the two year period following the effective date of the agreement. The advances will be debt, equity or a combination thereof in the sole discretion of the Company.

The determination of the fair value of the assets acquired and liabilities assumed as a result of this acquisition is in progress.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Effective July 1, 2003, we dismissed Deloitte & Touche, LLP ("Deloitte") and engaged BDO Dunwoody, LLP ("BDO Dunwoody") to serve as the independent public accountants to audit our financial statements for the fiscal year ending July 31, 2003.

The appointment of BDO Dunwoody as independent public accountants replacing Deloitte was approved by the audit committee of our Board of Directors. Deloitte did not decline to stand for re-election.

Deloitte's reports on our financial statements for the last two fiscal years did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During our past two fiscal years, and the subsequent interim period preceding Deloitte's dismissal, we had no disagreements with Deloitte, as the term "disagreement" is defined in Item 304(a)(1)(iv) of Regulation S-K, on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which disagreements, if not resolved to Deloitte's satisfaction, would have caused Deloitte to make reference to the subject matter of the disagreements in its reports. During our past two fiscal years, and the subsequent interim period preceding Deloitte's dismissal, there were no "reportable events" as that term is defined in Item 304 (a)(1)(v) of Regulation S-K.

Effective July 1, 2003, we engaged BDO Dunwoody as our independent public accountants. During the past two fiscal years, we have had no consultations with BDO Dunwoody concerning: (a) the application of accounting principles to a specific transaction or the type of opinion that might be rendered on our financial statements, as to which a written report was provided to us or as to which we received oral advice from BDO Dunwoody, that BDO Dunwoody concluded was an important factor in reaching a decision on any accounting, auditing or financial reporting issue; or (b) any matter that was the subject of a disagreement or a reportable event, as those terms are defined in Item 304(a)(1)(iv) and (v) of Regulation S-K.

Item 9A. Controls and Procedures

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this Annual Report on Form 10-K, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this Item is incorporated by reference from the Proxy Statement, or an amendment to this Annual Report on Form 10-K, to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference from the Proxy Statement, or an amendment to this Annual Report on Form 10-K, to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this Item is incorporated by reference from the Proxy Statement, or an amendment to this Annual Report on Form 10-K, to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

Item 13. Certain Relationships and Related Transactions

The information required by this Item is incorporated by reference from the Proxy Statement, or an amendment to this Annual Report on Form 10-K, to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

Item 14. Principal Accounting Fees and Services

This Item is not yet applicable to us.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 2 | Agreement and Plan of Merger among GenereX Biotechnology Corporation, Antigen Express, Inc. and AGEXP Acquisition Inc. filed as Exhibit 2.1 to our Current Report on Form 8-K filed with the Commission on August 15, 2003 is incorporated herein by reference. |
| 3.1 | Restated Certificate of Incorporation of GenereX Biotechnology Corporation filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended April 30, 1999 filed with the Commission on June 14, 1999 is incorporated herein by reference. |
| 3.2 | Bylaws of the Company filed as Exhibit 3.2 to our Registration Statement on Form S-1 (File No. 333-82667) filed with the Commission on July 12, 1999 ("1999 S-1") is incorporated herein by reference. |
| 4.1.1 | Form of common stock certificate filed as Exhibit 4.1 to our 1999 S-1 is incorporated herein by reference. |
| 4.1.2 | Certificate of Designations, Preferences and Rights of Series A Preferred Stock filed as Exhibit 4.4 to our Report on Form 8-K filed with the Commission on January 23, 2001 ("January 2001 8-K") is incorporated here in by reference. |
| 4.2.1 | 1998 Stock Option Plan filed as Exhibit 4.3 to our 1999 S-1 is incorporated herein by reference. |
| 4.2.2 | 2000 Stock Option Plan filed as Exhibit 4.3.2 to our Form 10-K for the fiscal year ended July 31, 2000 filed with the Commission on October 30, 2000 is incorporated herein by reference. |
| 4.2.3 | 2001 Stock Option Plan filed as Exhibit 4.2.3 to our Form 10-K for the fiscal year ended July 31, 2001 filed with the Commission on October 29, 2001 ("2001 10-K"). |
| 4.3 | Form of Warrant issued to Ladenburg Thalmann & Co., Inc. dated July 6, 2001, filed as Exhibit 4.15 to our Registration Statement on Form S-3 (File No. 333-67118) filed with the Commission on August 8, 2001 is incorporated herein by reference. |
| 4.4.1 | Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; RAM Trading Ltd.; Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 3, 2001, filed as Exhibit 1 to our Report on Form 8-K dated July 6, 2001 and filed with the Commission on July 17, 2001 ("July 2001 8-K") is incorporated herein by reference. |
| 4.4.2 | Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; RAM Trading Ltd.; Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 3, 2001, filed as Exhibit 2 to our July 2001 8-K is incorporated herein by reference. |
| 4.4.3 | Form of Warrant granted to Cranshire Capital, L.P.; RAM Trading Ltd.; Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 6, 2001, filed as Exhibit 3 to our July 2001 8-K is incorporated herein by reference. |
| 4.5.1 | Securities Purchase Agreement entered into with Capital Ventures International, dated July 3, 2001, filed as Exhibit 4 to our July 2001 8-K is incorporated herein by reference. |
| 4.5.2 | Registration Rights Agreement entered into with Capital Ventures International, dated July 3, 2001, filed as Exhibit 5 to our July 2001 8-K is incorporated herein by reference. |
| 4.5.3 | Warrant granted to Capital Ventures International, dated July 3, 2001, filed as Exhibit 6 to our July 2001 8-K is incorporated herein by reference. |

Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 4.6.1 | Form of Securities Purchase Agreement entered into with Elliott International, L.P. and Elliott Associates, L.P., dated July 3, 2001, filed as Exhibit 7 to our July 2001 8-K is incorporated herein by reference. |
| 4.6.2 | Form of Registration Rights Agreement entered into with Elliott International, L.P. and Elliott Associates, L.P., dated July 3, 2001, filed as Exhibit 8 to our July 2001 8-K is incorporated herein by reference. |
| 4.6.3 | Warrant issued to Elliott International, L.P. and Elliott Associates, L.P., dated July 5, 2001, filed as Exhibit 9 to our July 2001 8-K is incorporated herein by reference. |
| 4.7.1 | Securities Purchase Agreement between GenereX Biotechnology Corporation, Elan International Services, Ltd. and Elan Corporation, plc., dated January 16, 2001, filed as Exhibit 4.1 to our Report on Form 8-K/A dated January 16, 2001 filed with the Commission on February 1, 2001 is incorporated herein by reference. |
| 4.7.2 | Registration Rights Agreement between GenereX Biotechnology Corporation and Elan International Services, Ltd. dated January 16, 2001 filed as Exhibit 4.2 to our January 2001 8-K is incorporated herein by reference. |
| 4.7.3 | Form of Warrant issued to Elan International Services, Ltd. filed as Exhibit 4.3 to our January 2001 8-K is incorporated herein by reference. |
| 4.8.1 | Form of Securities Purchase Agreement entered into with certain parties to October 2000 Private Placement filed as Exhibit 2 to our Report on Form 8-K dated October 4, 2000 and filed on October 16, 2000 ("October 2000 8-K") is incorporated herein by reference. |
| 4.8.2 | Form of Registration Rights Agreement entered into with certain parties to October 2000 Private Placement filed as Exhibit 3 to our October 2000 8-K is incorporated herein by reference. |
| 4.8.3 | Form of Warrant issued to certain parties to October 2000 Private Placement filed as Exhibit 4 to our October 2000 8-K is incorporated herein by reference. |
| 4.9 | Securities Purchase Agreement entered into with Smallcap World Fund, Inc. dated September 29, 2000 filed as Exhibit 1 to our October 2000 8-K is incorporated herein by reference. |
| 4.10 | Form of Warrant (GCR Series) held by Robert P. Carter, Harvey Kaye, Fittube, Inc., Edward Maskaly and Gulfstream Capital Group, L.C. filed as Exhibit 4.4.2 to our Registration Statement on Form 10 filed with the Commission December 14, 1998, as amended February 24, 1999 ("Form 10"), is incorporated herein by reference. |
| 4.11 | Letter Agreement and Warrant with M. H. Meyerson & Co., Inc. dated November 17, 1998 filed as Exhibit 4.4.4 to our Form 10 is incorporated herein by reference. |
| 4.12 | Option Agreement with Wolfe Axelrod Weinberger LLC dated January 3, 2000, filed as Exhibit 4.5 to our Quarterly Report on Form 10-Q for the quarter ended January 31, 2000 filed with the Commission on March 14, 2000 is incorporated herein by reference. |
| 4.13.1 | Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 filed as Exhibit 4.1 to our Quarterly Report on Form 10-Q/A for the quarter ended April 30, 2003 ("3Q 2003 10-Q/A") filed with the Commission on August 13, 2003 is incorporated herein by reference. |
| 4.13.2 | Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 filed as Exhibit 4.2 to our 3Q 2003 10-Q/A is incorporated herein by reference. |
| 4.13.3 | Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 filed as Exhibit 4.3 to our 3Q 2003 10-Q/A is incorporated herein by reference. |
| 4.13.4 | Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P. dated June 6, 2003 filed as Exhibit 4.4 to our 3Q 2003 10-Q/A is incorporated herein by reference. |

Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 4.13.5 | Form of Registration Rights Agreement entered into with Cranshire Capital, L.P. dated June 6, 2003 filed as Exhibit 4.5 to our 3Q 2003 10-Q/A is incorporated herein by reference. |
| 4.13.6 | Form of Warrant granted to Cranshire Capital, L.P. dated June 6, 2003 filed as Exhibit 4.6 to our 3Q 2003 10-Q/A is incorporated herein by reference. |
| 4.13.7 | Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003.* |
| 10.1.1 | Memorandum of Agreement dated January 7, 1998 between Generex Pharmaceuticals, Inc., GHI Inc., Generex Biotechnology Corporation, Dr. Pankaj Modi and Galaxy Technology, Canada and Consulting Agreement between Generex Pharmaceuticals and Pankaj Modi dated October 1, 1996 filed as Exhibit 10.1.1 to our Form 10 is incorporated herein by reference. |
| 10.1.2 | Assignment and Assumption Agreement between Generex Pharmaceuticals and Pankaj Modi dated October 1, 1996 filed as Exhibit 10.1.2 to our Registration Statement on Form 10/A filed with the Commission on February 24, 1999 is incorporated herein by reference |
| 10.1.3 | Supplemental Agreement dated December 31, 2000 between Generex Pharmaceuticals, Inc., Generex Biotechnology Corporation and Dr. Pankaj Modi, filed as Exhibit 10.1.4 to our 2001 10-K. |
| 10.2.1 | Development and License Agreement dated September 5, 2000 between Generex Biotechnology Corporation and Eli Lilly and Company filed as Exhibit 10.1 to our Report on Form 8-K/A dated September 5, 2000 and filed with the Commission on January 24, 2001 is incorporated herein by reference. |
| 10.3.1 | Amended and Restated Subscription, Joint Development and Operating Agreement dated January 15, 2002, between Elan Corporation, plc, Elan International Services, Ltd. and Generex Biotechnology Corporation and Generex (Bermuda), Ltd. filed as Exhibit 10.1 to our Current Report on Form 8-K/A ("September 2003 8-K/A") filed with the Commission on September 9, 2003 is incorporated herein by reference. |
| 10.3.2 | Amended and Restated License Agreement dated January 15, 2002, between Elan Corporation, plc and Generex (Bermuda), Ltd. filed as Exhibit 10.2 to our September 2003 8-K/A is incorporated herein by reference. |
| 10.3.3 | Amended and Restated License Agreement dated January 15, 2002, between Generex Biotechnology Corporation and Generex (Bermuda), Ltd. filed as Exhibit 10.3 to our September 2003 8-K/A is incorporated herein by reference. |
| 10.4 | Stockholders Agreement among Generex Biotechnology Corporation and the former holders of capital stock of Antigen Express, Inc.* |
| 16. | Letter from Deloitte & Touche, LLP regarding its concurrence with the statements made by Generex in this Report regarding its dismissal as principal accountant filed as Exhibit 16 to our Current Report on Form 8-K/A filed with the Commission on July 11, 2003 is incorporated herein by reference. |
| 21 | Subsidiaries of the Registrant.* |
| 23.1 | Consent of BDO Dunwoody, LLP, independent auditors.* |
| 23.2 | Consent of Deloitte & Touche LLP, independent auditors.* |
| 24 | Powers of Attorney, filed as Exhibit 24 to our 2001 10-K. |
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 32 | Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |

* Filed herewith. All other exhibits are incorporated by reference, as described.

Reports on Form 8- K

The following Reports on Form 8-K were filed during the last quarter of the fiscal year ended July 31, 2003 and subsequent interim period ended October 14, 2003:

- Report on Form 8-K, filed with the Commission May 27, 2003, relating to the private placement of unregistered common stock under Item 5 - Other Events.
- Report on Form 8-K, filed with the Commission June 5, 2003, relating to the NASDAQ National Market delisting under Item 5 - Other Events.
- Report on Form 8-K, filed with the Commission July 7, 2003, relating to the change in independent auditor under Item 4 - Change in Registrant's Certifying Accountant and Item 7 - Financial Statements and Exhibits.
- Report on Form 8-K/A, filed with the Commission July 11, 2003, relating to the change in independent auditor under Item 4 - Change in Registrant's Certifying Accountant and Item 7 - Financial Statements and Exhibits.
- Report on Form 8-K, filed with the Commission July 17, 2003, relating to the redacted agreements with respect to the transaction with Elan Corporation, plc and its affiliate under Item 7 - Financial Statements and Exhibits.
- Report on Form 8-K, filed with the Commission August 15, 2003, relating to the acquisition by merger of Antigen Express, Inc. under Item 2 - Acquisition of Assets and Item 7 - Financial Statements and Exhibits.
- Report on Form 8-K/A, filed with the Commission September 9, 2003, relating to the redacted agreements with respect to the transaction with Elan Corporation, plc and its affiliate under Item 7 - Financial Statements and Exhibits.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 29th day of October, 2003.

GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin
Name: Anna E. Gluskin
Title: President
Date: October 29, 2003

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Name | Capacity in Which Signed | Date |
|---|--|------------------|
| <u>/s/ Anna E. Gluskin</u> Anna E. Gluskin | President, Chief Executive Officer and Director | October 29, 2003 |
| <u>/s/ Rose C. Perri</u> Rose C. Perri | Chief Operating Officer, Treasurer, Acting CFO, Secretary and Director | October 29, 2003 |
| <u>/s/ Pankaj Modi, Ph.D.</u> Pankaj Modi, Ph.D. | Vice President, Research and Development and Director | October 29, 2003 |
| <u>/s/ Gerald Bernstein</u> Gerald Bernstein | Vice President and Director | October 29, 2003 |
| <u>/s/ J. Michael Rosen</u> J. Michael Rosen | Director | October 29, 2003 |
| <u>/s/ Peter Levitch</u> Peter Levitch | Director | October 29, 2003 |
| <u>/s/ John P. Barratt</u> John P. Barratt | Director | October 29, 2003 |
| <u>/s/ Slava Jarnitskii</u> Slava Jarnitskii | Controller | October 29, 2003 |

| Name | Place of Incorporation |
|-------------------------------|-------------------------------|
| Generex Pharmaceuticals, Inc. | Ontario, Canada |
| Generex (Bermuda), Inc. | Bermuda |
| Antigen Express, Inc. | Massachusetts, USA |

All subsidiaries are 100% owned except for Generex (Bermuda), which is 80.1% owned.

All subsidiaries conduct business only under their respective corporate names.

CONSENT OF INDEPENDENT AUDITORS

EXHIBIT 23.1

We consent to the incorporation by reference in Registration Statements No. 333-67118, 333-51194 and No. 333-42452 of Generex Biotechnology Corporation and Subsidiaries (the Company) on Forms S-3, of our report dated September 22, 2003 relating to the financial statements appearing in this Annual Report on Form 10-K of the Company for the year ended July 31, 2003.

/s/ BDO Dunwoody, LLP
Toronto, Ontario
October 29, 2003

CONSENT OF INDEPENDENT AUDITORS

EXHIBIT 23.2

We consent to the incorporation by reference in Registration Statements No. 333-67118, 333-51194 and No. 333-42452 of Generex Biotechnology Corporation and Subsidiaries (the Company) on Forms S-3, of our report dated October 7, 2002 (which expresses an unqualified opinion and includes an explanatory paragraph relating to the Restatement described in Note 17) appearing in this Annual Report on Form 10-K of the Company for the year ended July 31, 2003.

/s/ DELOITTE & TOUCHE LLP
DELOITTE & TOUCHE LLP
Toronto, Ontario
October 29, 2003

CERTIFICATION

I, Anna E. Gluskin, certify that:

1. I have reviewed this annual report on Form 10-K of Generex Biotechnology Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE: October 29, 2003

By: /s/ Anna E. Gluskin
Anna E. Gluskin, Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

Rose C. Perri, certify that:

I have reviewed this annual report on Form 10-K of Generex Biotechnology Corporation;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

DATE: October 29, 2003

By: /s/ Rose C. Perri
Rose C. Perri, Chief Operating Officer
(Principal Financial and Accounting Officer)

CERTIFICATIONS

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. ss. 1350, as adopted), Anna E. Gluskin, Chief Executive Officer and President of Genex Biotechnology Corporation (the "Company"), and Rose C. Perri, Chief Operating Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the period ended July 31, 2003, and to which this Certification is attached as Exhibit 32 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of the period covered by the Report.

DATE: October 29, 2003

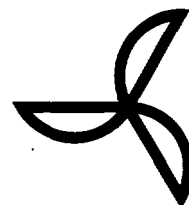
By: /s/ Anna E. Gluskin
Anna E. Gluskin, Chief Executive Officer
(Principal Executive Officer)

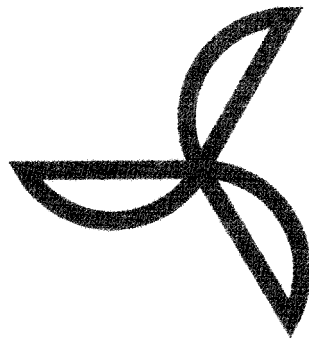
DATE: October 29, 2003

By: /s/ Rose C. Perri
Rose C. Perri, Chief Operating Officer
(Principal Financial and Accounting Officer)

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