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2002 | ANNUAL REPORT

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Genetex BIOTECHNOLOGY

2002 | ANNUAL REPORT



Mark Perri

## Dedication

**E. Mark Perri**  
Chief Financial Officer  
Chairman of the Board

E. Mark Perri, Chief Financial Officer and Chairman of the Board was born in Toronto on February 1, 1961. On November 6, 2002, Mark Perri passed away after a prolonged battle with bone cancer. His struggle with this illness led him to found Generex, a company with a mission to develop alternative methods of drug delivery for drugs previously administered only through injection. Knowing the pain associated with therapy involving multiple injections daily, Mark sought a better way to manage this process.

Mark had been introduced to the work of Dr. Pankaj Modi who had developed and patented an oral administration for insulin. Dr. Modi needed financial assistance to bring this revolutionary project through the regulatory process to patients. Mark Perri, his sister, Rose, and Anna Gluskin formed Generex to realize Mark's dream and to bring the hope of needle-free drug delivery to diabetes patients throughout the world.

It is difficult to put into words the passion and dedication the founders have for this company, exemplified best by the interest Mark took in the people participating in the clinical trials. Mark was concerned about the patients in the trials and personally followed their progress throughout the trials.

Management dedicates this annual report to Mark's memory to commemorate his passion, dedication, and commitment to Generex. Our unwavering commitment to finish the work in which he so deeply believed is our tribute to him.

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imagine.

Imagine a world where patients do not have to suffer through daily injections; where drugs are administered through an aerosol spray into the mouth. Imagine how beneficial that would be for the patient. Imagine how much disease management would improve. Imagine the improvements to a diabetic's quality of life without daily injections. Wouldn't that be something?

This is the world Mark Perri envisioned, and the goal of Generex Biotechnology Corporation, as he co-founded the company. Mark was not only a visionary in founding Generex, but was also passionate about its purpose and mission. The management of Generex remains committed to the ideals that Mark Perri shared with Generex, and is determined to see his vision through.

Generex has pioneered an alternative to injection for Insulin delivery. It is as simple as breathing. Oralin™ has indicated in testing conducted by Generex to be as effective as injection. With Eli Lilly & Company, we will continue this research and bring this product to diabetic patients across the world. In addition, we have a joint venture with Elan Pharmaceuticals to develop our platform for morphine delivered orally. In initial studies, our morphine product has also shown encouraging proof of performance.

But this is just the beginning of the journey: Large molecule applications of Generex' technology platform afford the Company a vast market potential. Independent research reports indicate that there are currently over 2500 macromolecules in clinical and pre-clinical development by companies across the world! We have only so far looked at the proverbial "tip of the iceberg".



LETTER TO OUR SHAREHOLDERS ::

Anna E. Gluskin  
President, CEO, Director

February 8, 2003

To Our Shareholders:

The past year has been a very hard one in many ways. On a personal note, Generex, its employees and shareholders lost a wonderful Chairman, founder, visionary and friend: Mark Perri. Generex was always a personal mission for Mark. He was diagnosed with multiple myeloma in 1990 and at the time of Generex's inception was undergoing a bone marrow transplant. Mark was dedicated to developing novel drug delivery systems that reduced suffering, increased convenience for the patient, and, as a result, improved compliance and quality of life. Mark recognized the vast potential of Dr. Modi's discovery and believed it was vital to financially support its development and commercialization. Generex continues to share this vision. We dedicate this Annual Report to his memory.

I would like to point out to shareholders that the capital markets, particularly in biotechnology, remain distressed and under pressure. Continuing investigations of accounting practices, investment banking and equity research reports add to an environment of inaction and cynicism. Generex is part of this industry, and unfortunately, its stock price has suffered alongside the vast majority of its colleague companies. Nonetheless, Generex has made very meaningful progress in a number of critical areas.

The company's flagship program remains the painless delivery of insulin for the millions of diabetic patients requiring daily injections. It is important to understand that our strategy is not simply to rush through the regulatory process to the diabetic marketplace with a minimally acceptable product. We believe the regulatory authorities, our industry partners and diabetic patients demand and deserve the highest quality product that we can develop. We also believe that in order to maximize the financial potential of this technology, we must offer the very best product that we can deliver, even if it takes longer than we had hoped it might. We are committed to attaining that goal. When our alternative delivery system is made available to the diabetes community, we need to assure them that it meets their needs and is the absolute best we can make.

The need for a convenient, safe, efficacious and cost-effective alternative delivery system for insulin is immense and growing. Competitive technologies have raised a number of questions regarding safety and efficacy. As a result, the industry as a whole has been subject to additional criticism and skepticism. The management of Generex is pleased with the progress we have and continue to make, but we are equally impatient and energized to advance this program to the next step.

We continue our research and continue to accumulate the information and data that will be necessary for regulatory submissions for safety and efficacy on both Type I and Type II diabetic patients. These efforts are proceeding in multiple locations with an increasing number of independent, well-respected clinical investigators.

During 2002, Generex was honored with the opportunity to offer presentations at the American Diabetes Association conference, the Diabetes Technology Meeting, and other conferences. In 2003, Dr. Modi will present to the Artificial Insulin Delivery, Pancreas and Islet Transplantation Study Group of the European Association for the Study of Diabetes Mellitus.

During 2002, four new U.S. patents were granted, including the broad patent for "The Method for administering insulin to the buccal region". Additional patents are pending.

Our technology platform has undergone substantial change and growth. We are now well positioned to take advantage of our platform and build a portfolio of drug applications across a spectrum of therapeutic opportunities. We have initiated this process in areas of pain and cardiovascular management with the rapid progress we have made with morphine, fentanyl and heparin. By doing so and expanding our portfolio of drug candidates, we hope to manage risk and add value to our stock. We firmly believe there are a large number of product applications that are available and appropriate targets for buccal delivery.

We further believe investments in our insulin program can and should be leveraged, and will allow us to more rapidly and efficiently drive products through to commercialization.

During the past year, Generex has taken a number of steps toward strengthening its board and management. I am pleased to announce that we have added members to our management team that bring new insights, experience and expertise to all aspects of our business. We have been fortunate to secure the services of Steve Peltzman, who joined us as Vice President of Development and Licensing. Steve brings a wealth of experience in the biotechnology industry to the company. Peter Levitch was elected as a director and Dr. Gerald Bernstein, who has served as our Vice President of Medical Affairs, was also elected as a director. These individuals, through their experiences and reputation, bring invaluable knowledge and depth to Generex. We are pleased that these individuals have joined our team.

As I stated above, the capital markets have been extraordinarily difficult to navigate. We are optimistic about 2003, but we do not want to be dependent upon a substantial upswing in the global financial markets. We will seek short term financial solutions as we wait for the financial environment to permit a more strategic approach to raising capital. We will need to raise more capital and are evaluating several opportunities with respect to timing, size and suitability. We are striving to realize our mission to develop alternative delivery systems while at the same time maintaining low development costs and reducing risk. We expect that this combination will be attractive to current and potential pharmaceutical partners and will provide lucrative opportunities for Generex as we concentrate our efforts to negotiate attractive license fees, milestones, royalties and overall terms.

In closing, I would like to assure our investors that we will continue to build upon our successes and we will continue to present evidence to the medical community of our revolutionary buccal delivery system. But most importantly, we will continue to pursue our mission to develop and market safe, effective alternative medication delivery systems to improve the quality of life for millions of people worldwide. We invite you to join with us in this endeavour.



Anna Gluskin  
President, CEO  
Acting Chairman of the Board



## oralin. new approach.

A medication's general efficacy is determined by the speed with which it enters the bloodstream. Currently, most large-molecule drugs, such as insulin, are delivered to the patient through an intravenous drip into the vein or by subcutaneous injection. Few of the early attempts at alternate delivery focused upon the buccal mucosa, which consists of the lining of the cheeks and lips. One exception is the application of using the sublingual area of the buccal mucosa (the area of the mouth under the tongue) for absorption of nitroglycerin to treat angina. Dr. Pankaj Modi, however, recognized the potential of the buccal mucosa for drug delivery, and focused his research on the buccal mucosa as a target to deliver insulin.

With Dr. Modi's leadership, Generex has developed and specially engineered Oralin™, a proprietary formulation which permits oral delivery of insulin. Studies by Generex indicated that Oralin™ is rapidly absorbed into the bloodstream and has effects similar to injected insulin. If future studies provide consistent results, upon approval by regulatory authorities, Oralin™ will eliminate the need for painful injections and allow patients to conveniently and painlessly self-medicate wherever and whenever necessary.

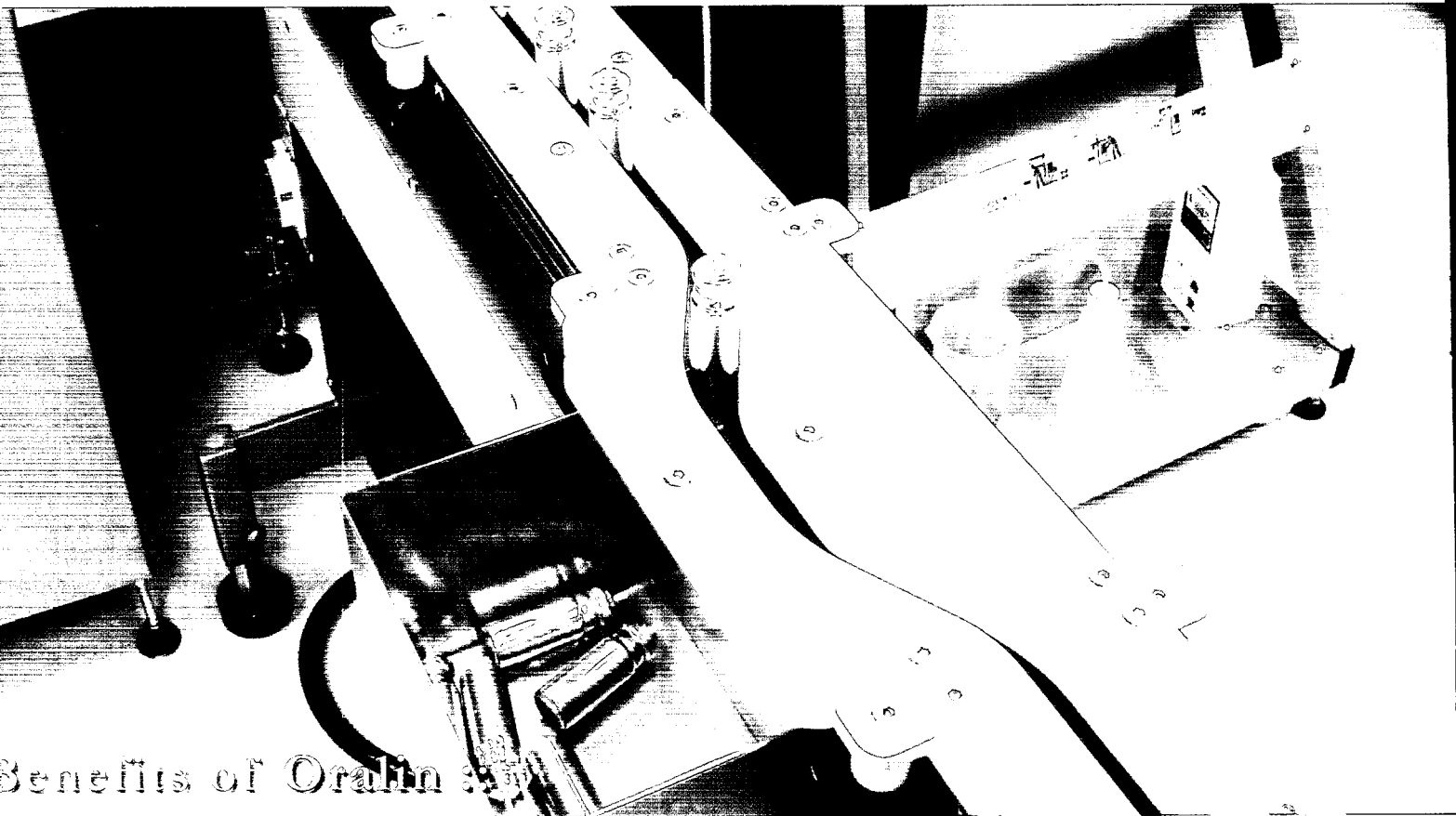
The resulting increased compliance and control over treatment could reduce the risk of further complications and will offer patients a higher quality of life.

Generex' technology differs from that of traditional inhalers in that large molecule formulations are directed into the mouth rather than the lungs. In fact, our studies show that when using the RapidMist™ device and the Oralin™ formulation, the greatest percentage of medication is absorbed before it reaches the lungs. Generex's trials also indicate that the medication is absorbed rapidly into the bloodstream and remains effective for a period similar to injected insulin.

The success demonstrated with the Oralin™ formulation in studies to date indicates that the technology will have applications with many well-known, proven large-molecule drugs, currently only administered by injection, which represent low risk targets for development. And, with over 2500 large molecule drugs in clinical and preclinical development by companies across the world, the potential of Generex's technology platform, and the potential benefits to patients, is virtually unlimited.

# Oralin::

## advantages & benefits



### Benefits of Oralin::

- Needle Free, Pain Free Therapy - Intensive insulin therapy for diabetes typically requires at least 3-4 injections per day. If approved, ORALIN™ will provide a needle free administration of insulin for the treatment of diabetes.
- Rapid Insulin Absorption - Our clinical studies have demonstrated that ORALIN™ is absorbed into the bloodstream as fast (or often faster) than injected insulin.
- Stability - ORALIN™ is stable at room temperature and requires no refrigeration.
- Higher Compliance - As a needle free, pain free therapy, ORALIN™ should reduce resistance to treatment and increase compliance.
- Quality of Life - The device's small size will make it convenient to carry and to use comfortably in public. Dosing time before a meal will be greatly reduced, giving patients more flexibility in their treatment. Improved compliance could decrease complications associated with diabetes, which should lead to a higher quality of life. For people on the go, at work, in school or traveling, ORALIN™ will be a convenient, pain free, socially acceptable way to take medication.

Clinical studies on hundreds of patients conducted by Genex show that ORALIN™ is safe to administer. The speed of onset of the hypoglycemic response following ORALIN™ administration is consistent with that required for prandial dosing. It is also comparable to published data from other sources evaluating the speed of onset of injected insulin analogs intended for dosing with a meal. Clinical trials are ongoing and will be used to provide the required data necessary to seek regulatory approval in key markets around the world.

### Diabetes::

#### Statistics (USA)

17 million people, or approximately 8% of the population, suffer from Type 1 and Type 2 diabetes. Of these, 11.1 million people are diagnosed and approximately 5.9 million people remain undiagnosed.

#### Statistics (CAN)

Over 2 million Canadians suffer from Diabetes, and it is estimated that approximately 1,200,000 are diagnosed and 40%, or 600,000 are undiagnosed.

#### Worldwide

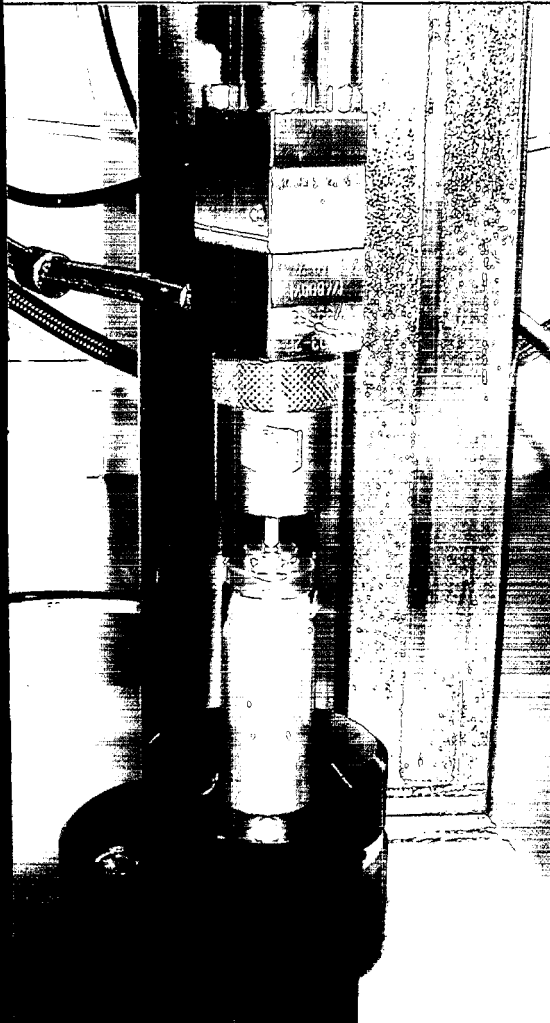
Currently, it is estimated that 150 million people world wide suffer from Diabetes. Experts expect that the number will double by 2025.

In the U.S. and Canada alone, the costs associated with Diabetes, direct and indirect, total approximately \$107 billion USD.

Source - National Institutes of Diabetes & Digestive & Kidney Diseases for US figures, Health Canada for Canadian statistics.



# innovation in drug delivery



## Patents::

US Patent 6,350,432, issued 2/26/2002;  
US Application 09/272,563 filed  
03/19/99  
Pharmaceutical solubilized in aerosol  
propellant.

US Patent 6,312,665, issued 11/6/02;  
US Application 09/386,284 filed 8/31/99  
Aerosol formulations for buccal and  
pulmonary application. CIP of  
09/251,464.

US Patent 6,375,975, issued 4/23/02;  
US Application 09/519,285 filed  
03/06/00  
Pharmaceutical compositions for buccal  
and pulmonary application. CIP of  
09/386,284.

US Patent 6,350,458 issued 2/26/02;  
US Application 09/543,988 filed  
04/6/00  
Method for administering insulin to the  
buccal region. CIP of 09/021,114.

Drugs may be delivered through a variety of methods into the circulatory system. The various drug delivery techniques attempt to deliver the drugs quickly and efficiently into the bloodstream.

The most common delivery route is oral. Drugs delivered orally are formulated as tablets or capsules and once swallowed are absorbed through the gastrointestinal tract.

Drugs delivered by injection can be absorbed through subcutaneous or muscle tissue or are absorbed directly into the bloodstream.

Drugs delivered through inhalation delivery systems rely upon the alveoli (tiny air sacs) within the lungs that facilitate the absorption of the medication.

Drugs delivered by transdermal delivery methods, such as patches, are absorbed through the skin.

Drugs delivered buccally are absorbed through the mucous membranes which line the cheeks and lips.

## Advantages and Disadvantages of Drug Delivery Routes ::

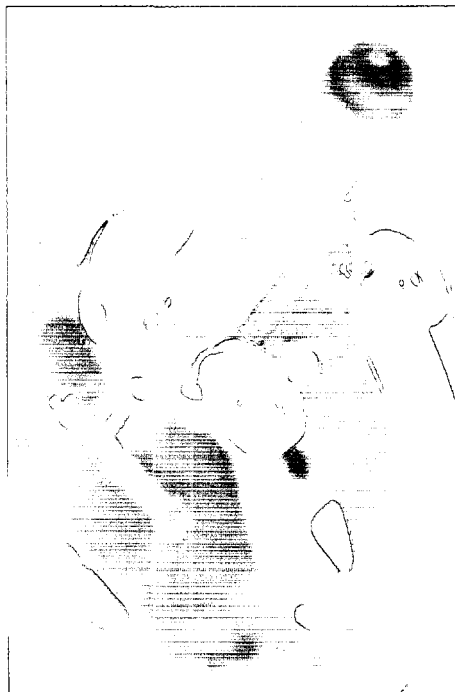
Oral delivery - small molecule medications can be administered via tablet or capsule, but this is not the case with large molecule drugs. The acids and enzymes in the digestive tract break down the large molecules before the drug is absorbed. The main advantage of oral delivery is ease of administration.

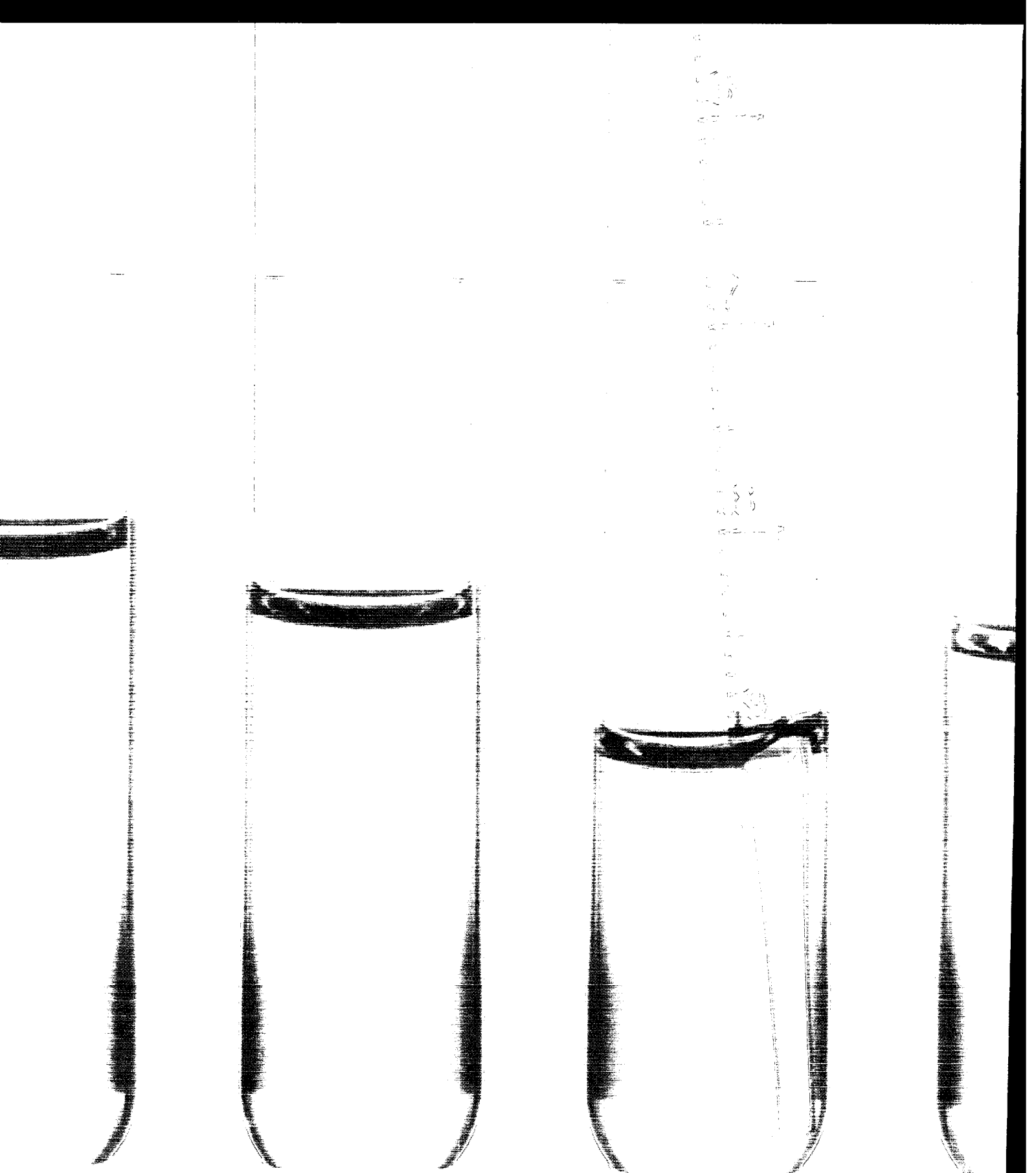
Injected drugs (mostly large molecule) achieve rapid results by direct introduction into the circulatory system. The disadvantage is the pain associated with repeated injections.

Drugs delivered through pulmonary technology are easier to administer, however, the long term effects such as possible scarring and tissue damage are as yet unknown.

Transdermal patches are more effective for small molecule drugs, and are not as effective in large molecule applications.

Buccal administration has so far been shown to be safe, easy, non-invasive and free of detrimental effects, while allowing medication to be rapidly absorbed and effectiveness maintained for a satisfactory time period. Genex Biotechnology Corporation has formulated the platform technology which allows large molecule drugs to be administered very effectively through the mouth and throat tissue, without reaching the lungs.





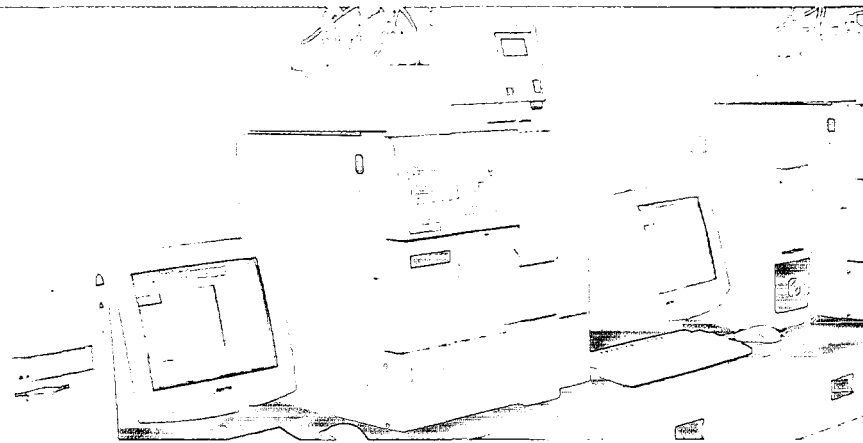
[www.generex.com](http://www.generex.com)

# clinical

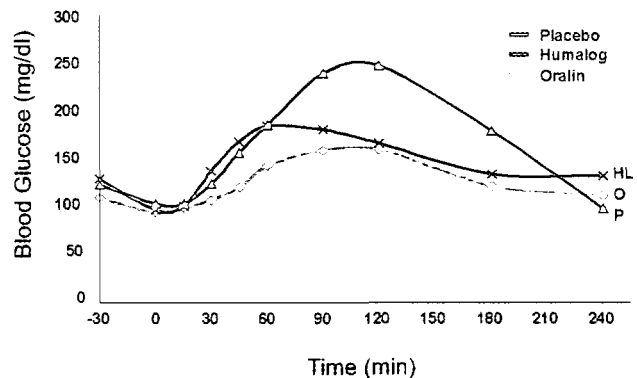
Studies indicate to date that buccal delivery is an extremely effective method of delivering large molecule drugs such as insulin. The inner mouth mucosa, called the buccal cavity, contains a large number of blood vessels, which facilitate the absorption of the drug into the bloodstream. Because the buccal cavity can be viewed easily by both the doctor and patient, adverse effects can be visually recognized and monitored. To date, Generex has had no indication of adverse effects during testing of its buccal delivery system.

## Studies In Progress

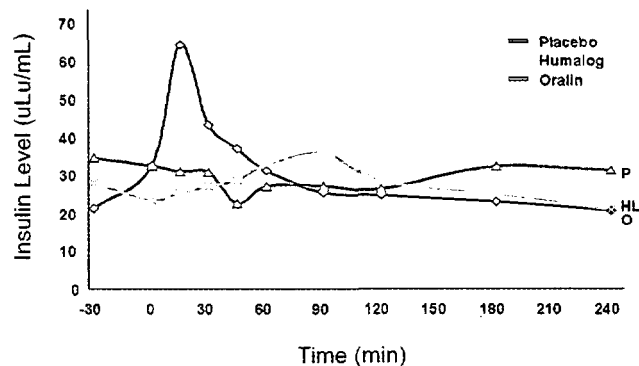
- Dose Response Study of Oral Insulin Formulation and Comparison with Injected Insulin in Type-1 Diabetic Patients using Uglycemic Clamps (University of Montreal, Diabetes Research Clinic, Montreal, Canada)
- Pharmacokinetic and Pharmacodynamic Evaluation of Buccal Insulin Formulation in Comparison with s.c. Regular Insulin in Type-1 Subjects under Uglycemic Clamps (Hadassah University, Jerusalem, Israel)
- Addition of Oral Insulin in Subjects with Type-2 Diabetes Failing on Combination Therapy of Oral Hypoglycaemic Agents, long term Phase-2 study (University of Calgary, University of Alberta, Dalhousie University and University of British Columbia, Canada)
- Comparison of Efficacy and Reproducibility of Oral Insulin Spray Formulation with Subcutaneous Bolus Dose of Human Insulin in Subjects with Type 1 Diabetes (Barbara Davis Center, University of Colorado)
- A Double-Blind Study of the Long-term Safety and Efficacy of Oral Insulin 70 Units in Combination with Metformin and Sulfonylurea Tablets in Type 2 Diabetic Patients. (University of Calgary, University of Alberta, Dalhousie University and University of British Columbia, Canada)
- Addition of Oralin at Meal-times in Subjects with Type-2 Diabetes Maintained on Once a Day Glargine Insulin Injection Therapy (University of Calgary, University of Alberta, Dalhousie University and University of British Columbia, Canada)



Mean Blood Glucose Levels in Patients with Type-1 Diabetes on 3 Different Days



Mean Free Insulin Levels in Patients with Type-1 Diabetes on 3 Different Days



# clinical study results

-Studies conducted in Type-1 diabetic patients on multiple daily injections showed that Oralin™ was absorbed faster than injected insulin and was able to control the post-prandial glucose levels after a standard meal challenge in a manner similar to injection. If future studies provide consistent results and upon regulatory approval, Oralin™ could be used safely in Type-1 diabetic patients for a meal related glucose control in the place of injected insulin as a meal insulin.

-A study proved quantitatively that Oralin™ could be introduced as meal insulin in place of injection and as the add-on therapy in combination with the failing OHAs treatment in Type-2 diabetics. If future studies provide consistent results and upon regulatory approval, Oralin™ spray could be used as an add-on therapy in combination with the failing OHAs for treatment of type-2 diabetes.

-A long-term study on insulin naïve patients (strictly maintained on diet and exercise or newly diagnosed diabetics) indicated that the Oral insulin spray formulation is safe to administer in human subjects for treatment of diabetes. Oralin™ showed better glucose control throughout the study when compared to placebo puffs and diet and exercise alone. This difference emerged after the first 30 days of treatment and was more pronounced toward the end of the study (90 days). The HbA1c showed a significant drop within a month and continued falling throughout the study period. At the end of the study period this difference was more significant and HbA1c in Oralin™ group dropped more than 2 points when compared to the placebo puffs treatment arm, where glucose levels continued to rise and HbA1c rose by 1 point (indicating the failure of diet and exercise and the need for added therapy). If future studies provide consistent results and upon regulatory approval, Oralin™ could be introduced early in patients failing on diet and exercise alone as the monotherapy in place of oral agents (sulfonylureas, Metformin, etc.) to achieve better control of blood glucose levels. This therapy could be very useful in the prevention of long-term diabetic complications and may help preserve the residual beta cell activities for a longer period of time.

-A long-term study (90 days+) of Oralin™ administration in Type-2 diabetic patients with Pioglitazone indicated that the Oral insulin spray formulation is safe to administer in human subjects chronically for the treatment of diabetes. Oralin™ showed better glucose control throughout the study when compared to the placebo puffs and Pioglitazone treatment alone. This difference emerged after the first 30 day treatment and was more pronounced toward the end of the study (90 days). The HbA1c showed a significant drop within a month and kept falling throughout the study period. At the end of the study period this difference became more significant and HbA1c in Oralin™ + Pioglitazone was lowered more than 3 points when compared to the placebo puffs and Pioglitazone treatment arm.

-A long-term study dealing with replacement of sulfonylurea drugs (such as glicizide, diamicron, glyburide and other drugs) and insulin secretory agents such as Ripaglinide to treat diabetes on a chronic basis indicated that Oralin™ could be used safely in place of sulfonylurea drugs. These trials appear to have demonstrated that Oralin™ caused no hypoglycemic episodes when compared to the regular insulin injections.

If future studies provide consistent results and upon regulatory approval, Oralin™ therapy could be used in patients who refuse to take injections and show severe insulin resistance, as oral insulin is an easy to administer, pain free and needle free therapy.

Generex was solely responsible for commissioning the studies described above. These studies were conducted outside of the scope of Generex's research and development activities under the agreement with Lilly.

The prevalence of Type-2 diabetes is increasing. The knowledge that intensive therapy in this population is both safe and efficacious and could reduce the incidence of key complications is critically important to the management of treatment for these patients. A simplified means for prandial insulin delivery, such as that potentially offered by Oral Insulin (RapidMist™ System) may be one such tool.

We intend the disclosures and information regarding forward looking statements in our annual report on Form 10-K for the fiscal year ended July 31, 2002 to apply to any forward-looking statements that may be contained in any of the information included in this mailing to shareholders.

## Scientific Presentations

"Buccal Delivery of Insulin Using Rapidmist™ Aerosolized Spray Formulation," was presented at the 2nd Annual Diabetes Technology Meeting held in Atlanta, Georgia, from October 31st through November 2nd.

## 2002 Diabetes Presentations

MODI, GUEVARA-AGUIRRE, GUEVARA, SAAVEDRA, BALDEON, MONCAYO, LLORE, BENITEZ  
Oral Insulin Spray as a Meal Insulin in Treatment of Type-2 Diabetes

GUEVARA-AGUIRRE, MODI, GUEVARA, SAAVEDRA, BALDEON, MONCAYO, LLORE, CANDO  
Oral Insulin Spray as an Add-on Therapy in Combination with Failing Oral Agents (OHAs) for Treatment of Type-2 Diabetes

LEVIN, MODI, YUTZY, KLINE  
Oral Insulin Increases Post-prandial Insulin Peaks and Improves Glucose Control in Type-2 Diabetic Patients

POZZILLI, MODI, MANFRINI, COPPOLINO, COSTANZA, FIORITI  
Pharmacokinetics of Oral Spray Insulin vs. Regular Insulin and Lispro Insulin in Type-1 Diabetes

MANFRINI, MODI, FIORITI, COPPOLINO, COSTANZA, POZZILLI  
Evaluation of the Compliance in the Use of Oral Spray Insulin in Patients with Type-1 Diabetes

2003 Pain Management (controlled release society)  
Breakthrough Pain Relief; RapidMist™  
Fentanyl/Morphine Breakthrough Pain Management Systems  
Pankaj Modi, Generex Biotechnology Corp., Toronto, ON, Canada M5J 2G2

2003 European Association for the Study of Diabetes Mellitus, Artificial Insulin Delivery, Pancreas and Islet Transplantation Study Group meeting in Igis, Austria, presentation entitled "Evolving Role of Oralin™ In the Treatment of Diabetes." Dr. Pankaj Modi

As Generex continues to develop its products, we will add to our team knowledgeable and experienced people who will help us to fully realize this company's potential as a world leader in alternative drug delivery systems. As part of this ongoing effort, the following key additions were made during this past year. We expect this expansion to continue into the future as we strive to fulfill our corporate mission.

**Steven Peltzman has been named Vice President, Business Development and Licensing .**

Mr. Peltzman has thirty years of business experience as a senior executive and advisor to companies within the biotechnology industry. Mr. Peltzman will advise and consult with the company on a variety of issues, including commercial and scientific collaborations, licensing opportunities, joint ventures, alliances and potential acquisitions.

Mr. Peltzman has extensive business experience in the health care technology industry, from biopharmaceuticals to medical devices and diagnostics. In 1984, he was chief executive officer of Applied bioTechnology, Inc., whose cancer business was sold to OSI Pharmaceuticals, Inc. in 1991, at which time he became chief operating officer of the consolidated entity. From 1994 through 1997 he served as president and chief operating officer of OSIP and remained on its board of directors through 1999. From 1986 to 1990, Mr. Peltzman served as president of Oncogenetics Partners, a joint venture between Applied bioTechnology, Inc. and E.I. du Pont de Nemours and Company, which focused on development of products relating to the prevention, treatment, and diagnosis of cancer. Prior to that time, Mr. Peltzman held a number of senior executive positions with Millipore and other positions in Corning's medical diagnostic and device businesses. During the past several years he has been active in several small health care and technology start-ups as interim senior executives, or in an advisory capacity to their Boards of Directors.



**Peter Levitch was appointed a director of Generex Biotechnology Corporation, beginning in October of 2002.**

Mr. Levitch has been president of Peter Levitch & Associates (PLA) since 1981. PLA is an independent consulting firm to health professionals, providing informed guidance in the development of pharmaceuticals, medical devices, biologics and diagnostics. PLA's primary focus is to guide products through the clinical evaluation and FDA regulatory approval phases. Mr. Levitch has participated in over 250 INDs as well as a number of successful marketing applications for drugs, biologicals and medical devices. Mr. Levitch previously worked with companies such as Amgen, Genentech, Centocor, Cytogen Hybritech/Eli Lilly, Baxter, Monsanto, Becton Dickenson and Seragen, among many others. From 1980 to 1981, Mr. Levitch was Vice President, Clinical and Regulatory Affairs for Oxford Research International Corp. From 1969 to 1980 he was employed by Ortho Diagnostics, Inc., a division of Johnson & Johnson, first as Manager of Clinical Research and, from 1973 to 1980, as Director of Regulatory and Clinical Affairs. Mr. Levitch also serves on the audit committee and compensation committee of the board of directors.

**Gerald Bernstein, M.D., F.A.C.P., was appointed to the company's Board of Directors in December, 2002.**

Dr. Bernstein will continue to serve as Generex's Vice President, Medical Affairs, a position he has held since October 2001. Dr. Bernstein is a past president of the American Diabetes Association (ADA) and a former member of the ADA's Board of Directors and its Executive Committee.

Dr. Bernstein graduated from Dartmouth College and Tufts University School of Medicine. He is board certified in internal medicine (1966) and endocrinology and metabolism (1973). Dr. Bernstein is an associate clinical professor at the Albert Einstein College of Medicine in New York. He is an attending physician at Beth Israel Medical Center, and physician emeritus at Lenox Hill Hospital and Montefiore Medical Center, all in New York. He was formerly Director of the Beth Israel Health Care Systems Diabetes Management Program. Dr. Bernstein was president of the American Diabetes Association in 1998-99 and was for many years a member of the ADA's Board of Directors and its Executive Committee. He received the ADA's Banting Medal for Service in 1999. Dr. Bernstein presently serves on several ADA committees and on the Board of Directors of the American Diabetes Association Research Foundation. He has published many clinical and scientific studies and papers and is also the author of the book "If It Runs In Your Family: Diabetes Mellitus, Reducing Your Risk."

# information

## Board of Directors::

Anna E. Gluskin  
Chief Executive Officer and President  
Acting Chairman of the Board

Rose C. Perri  
Chief Operating Officer  
Acting Chief Financial Officer

Pankaj Modi, Ph.D.  
Vice President,  
Research and Development

Gerald Bernstein, M.D., F.A.C.P.  
Vice President,  
Medical Affairs  
Director

William M. Hawke, M.D.  
Director

Peter Levitch  
Director

Jan Michael Rosen  
Director

## Outside Consultants ::

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

Crawford Consulting Centre  
1951 Fiddler's Lane  
RR #4  
Lakefield, ON  
K0L 2H0

McCarthy Consultant Services Inc.  
1151 Gorham Street, Unit 8  
Newmarket, ON  
L3Y 7V1

Integrated Research  
1351 Sunnybrooke Blvd.  
Dollard-des-Ormeaux (Montreal)  
Quebec  
H9B 3K9

## US Counsel::

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

## Canadian Counsel::

Brans, Lehun Baldwin  
Richmond Adelaide Centre  
120 Adelaide St. W. Suite 2401  
Toronto, Ontario M5H 1T1  
Canada

## Auditors::

Deloitte & Touche, LLP  
BCE Place  
181 Bay Street  
Suite 1400  
Toronto, ON M5J 2V1  
Canada

## Accountants::

WithumSmith+Brown  
100 Overlook Center  
Princeton, NJ 08540 USA

## Transfer Agent::

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

Telephone: (610) 649-7300  
Facsimile: (610) 649-7302

## Corporate Communications & Investor Relations::

The Liquid Consulting Group, Inc.  
116 Bent Oak Trail  
Fairport, NY 14450 USA  
Telephone (585) 425-1775  
Facsimile (509)277-8300

## Patent Counsel::

Eckert Seamans Cherin & Mellott,  
LLC  
U.S. Steel Tower  
600 Grant Street, 44th Floor  
Pittsburgh, PA 15219

## Trademark Counsel::

Torys LLP  
Suite 3000  
79 Wellington St. W.  
Box 270, TD Centre  
Toronto, Ontario M5K 1N2

## Public Relations::

Wolfe Axelrod Weinberger  
Associates LLC  
317 Madison Avenue  
Suite 515  
New York, NY 10017 USA  
Telephone: (212) 370-4500  
Facsimile: (212) 370-4505


## Generex Biotechnology Corporation

NASDAQ: NMS  
Symbol: GNBT

## Shareholders Meeting::

Wednesday, March 19, 2003  
10:00 a.m..

The Great Hall  
St. Lawrence Market Complex  
92 Front St. E.  
Toronto, Ontario  
M5E 1C4  
CANADA



33 Harbour Street  
Suite 202  
Toronto, Ontario, Canada, M5J 2G2  
800.391.6755

[www.generex.com](http://www.generex.com)



FORM GENEREX BIOTECHNOLOGY  
2002

**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, 2002

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 (I.R.S. Employer Identification No.)

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

M5J 2G2  
(Zip Code)

Registrant's telephone number, including area code: (416) 364-2551

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)

Name of Exchange on which registered The Nasdaq National Market

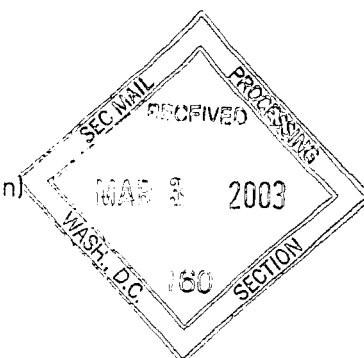
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such 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.

The aggregate market value of the voting stock held by non-affiliates of the registrant at October 10, 2002, based on the closing price as of that date, was approximately \$20,659,926.

At October 10, 2002, the registrant had 20,100,718 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) section, "Management's Discussion and Analysis of Financial Conditions and Results of Operations" (Item 7) and elsewhere in this Annual Report on Form 10-K constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects", "plans", "intends", "believes", "will", "estimates", "forecasts", "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements address, among other things, our expectations concerning the efficacy of our platform buccal delivery technology, our expectations concerning product candidates for our technology, our expectations concerning our development and license agreement with Lilly and other third party collaborations including our joint venture with a subsidiary of Elan Corporation, 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 can 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 a new and as yet not fully proven drug delivery technology,
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations 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
- diverse developments in our collaboration with Lilly regarding oral insulin; and
- adverse developments in our joint venture with a subsidiary of Elan Corporation.

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 on Form 10-K.

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## PART I

### Item 1. Business.

#### Overview

Generex Biotechnology Corporation is engaged 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 1999 and September 2000, we conducted clinical trials of our buccal insulin product in the United States, Canada and Europe. In September 2000, we entered into a Development and License Agreement with Eli Lilly and Company to develop this product. Prior to entering into the agreement with Lilly, we had not reached a point in our clinical program at which we were prepared to apply for regulatory approvals to market the product in any country, and we did not anticipate receiving any such approvals for a number of years. Under the terms of our agreement with Lilly, Lilly will be responsible generally for clinical trials and regulatory approvals on a worldwide basis for all products developed under the agreement. Lilly also will have the exclusive right to market the products worldwide. Our principal responsibilities under the Lilly agreement will be to continue development, as required, of our proprietary formulation and on our RapidMist(TM) device, which is described below.

In January 2001, we established a joint venture with a wholly owned subsidiary of Elan Corporation, plc. 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 of 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.

The parties will conduct the joint venture through 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.

We are a development stage company, and prior to the first quarter of the prior fiscal year had not received any revenues from operations. 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 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, from 12,000 to 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 September 2000 we entered into a Development and License Agreement with Eli Lilly and Company covering an insulin product based upon our buccal delivery technology. Under this agreement, Lilly will be responsible generally for clinical trials and regulatory approvals for this product on a worldwide basis. Lilly has not yet authorized the commencement of clinical trials under the agreement. However, in furtherance of our product development responsibilities under the agreement with Lilly, we are conducting limited clinical studies in the United States, Canada, Europe and Ecuador.

#### **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 fail 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 and injection 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. In addition, 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 are attempting 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 of 2002, we filed an Investigational New Drug Application for buccal morphine with the Food and Drug Administration. The buccal morphine product is being developed 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 these compounds, including monoclonal antibodies, human growth hormone, fertility hormone, estrogen and heparin, and a number of vaccines.

Prior to entering into our agreement with Lilly covering the insulin product, 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 believe that Lilly's involvement will relieve us of a substantial portion of the costs associated with conducting the clinical program for the insulin product. We believe we have sufficient financial resources to pursue the development of our current products and the initial exploration of additional products.

### **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.

### **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 regu-

lations 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, manufacture, 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 of 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 our insulin product, Lilly has exclusive, worldwide marketing rights to the product under our development and license agreement. With respect to the joint venture with Elan, 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.

## 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. However, we have not yet actually produced product at those levels.

Under our agreement with Lilly, Lilly may select us, but is not required to select us, to manufacture products developed under that agreement. In order to qualify for consideration in this role, we will have to satisfy Lilly that we can supply such products at the requisite levels of quality, cost and reliability in compliance with all applicable regulatory requirements. We have no experience in resolving the staffing, manufacturing, regulatory and quality control problems that are likely to come up in developing and running a large scale manufacturing operation. Our failure to solve problems of this nature would lead to loss of any opportunity to manufacture products developed under our agreement with Lilly, and could delay or prevent our ability to bring other products to market and inhibit sales after a product comes to market. In any event, we will need to significantly increase our manufacturing capability in order to manufacture any product in commercial quantities.

We own facilities in Brampton, Ontario, 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.

## 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 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 irrespective of what manufacturing arrangements are ultimately chosen by Lilly, i.e., whether or not we perform the formulating and filling function. We also expect to use the RapidMist device in connection with our buccal morphine and fentanyl products. We have secured supply arrangements with the manufacturers of all components and the propellant that we presently use in our RapidMist 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.

Lilly will supply the pharmaceutical compounds that are used in products developed under our agreement with Lilly. We expect that similar arrangements will be made with future development and marketing partners under licensing and development agreements covering other products. 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.

## Intellectual Property

We currently have fifteen issued U.S. patents pertaining to aspects of buccal delivery technology and covering our oral insulin formulation, and we have three U.S. patent applications and one Canadian patent application pending, also related 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 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 companies, universities, government agencies and public and private research organizations.

Products developed by our competitors may use a different active pharmaceutical agent 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 prod-



ucts 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 and pulmonary, may ultimately successfully deliver insulin to diabetic patients. 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, 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 companies to be direct competitors for the cooperation and support of major drug and biotechnology companies that own or market proprietary pharmaceutical compounds, as well as for the ultimate patient market. Among drug delivery companies, those that are known to be developing delivery systems for insulin and other pharmaceutical agents that we have identified as product candidates using our technology are of primary concern.

### **Oral Insulin**

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 Nastech 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.

### **Pain Management: Morphine and Fentanyl**

Cephalon, Inc. currently markets Actiq(R) 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(R) 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.

Nastech 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. Nastech is currently seeking a licensing partner for this product.

## 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, 2002, our expenditures on research and development were \$33,806,737. These included \$6,618,820 in the year ended July 31, 2002; \$19,929,799 in the year ended July 31, 2001, and \$3,568,300 in the year ended July 31, 2000. The increase in our research and development expenses from 2000 to 2001, and the decrease in our research and development expenses in from 2001 to 2002, are 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 (the Company's 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). Without the charge related to this license fee, our research and development expenses would have been \$4,929,799 in 2001. This amount has not been adjusted for minority share of loss.

## Employees

At September 30, 2002, we had twenty-three 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. Thirteen of our employees are executive and administrative, six are scientific and technical personnel who engage primarily in development activities and in preparing formulations for testing and clinical trials, and four are engaged in corporate and product promotion, public relations and investor relations. We believe our employee relations are good. None of our employees is 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
Gerald Bernstein	69	Director
Anna E. Gluskin	51	President, Chief Executive Officer and Director
Michael Hawke, M.D.	61	Director
Peter Levitch	70	Director
Pankaj Modi, Ph.D.	48	Vice President, Research and Development and Director
Rose C. Perri	35	Chief Operating Officer, Treasurer, Secretary and Director
J. Michael Rosen	51	Director

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

Gerald Bernstein, M.D. -- Director since October 2002. Dr. Gerald Bernstein was elected a Vice President of the Company effective as of October 1, 2001. Dr. Bernstein acts as a key liaison for the Company on medical and scientific affairs to the medical, scientific and financial communities and consults with the company 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. Dr. Bernstein was elected a director of the Company on October 23, 2002.

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

Michael Hawke, M.D. -- Director since March 2000. Dr. Hawke presently is a Professor in the Departments of Otolaryngology and Pathology at the University of Toronto, and is on the staff of the Departments of Otolaryngology at St. Joseph's Health Center, The Toronto Hospital and Mount Sinai Hospital, all located in Toronto. He has held these positions for more than the previous five years. Dr. Hawke has approximately thirty years experience as a medical researcher, educator and practitioner.

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).

Pankaj Modi, Ph.D. -- Director since September 1997. Dr. Modi has served as Vice President, Research and Development of Generex 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.

Rose C. Perri -- Director since September 1997. Ms. Perri has served as Treasurer and Secretary of Generex 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 Generex in October 1997.

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.

Generex 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 Generex, Elan and Elan International Services, Ltd. ("EIS"), a subsidiary of Elan, EIS has the right to nominate one director to Generex's 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 was the nominee of EIS thereunder. Dr. Lieberburg resigned effective August 1, 2002. EIS has not informed Generex 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, Generex must use its best efforts to cause Dr. Modi to be nominated for election and elected a director of Generex 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 the employment of the Company since its 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.

#### **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.

#### **Our technologies and products are at an early stage of development.**

We are a development stage company. We have a very limited history of operations, and we do not expect ongoing revenues from operations in the immediately 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, or any of the products we develop may not be commercially viable.

In September 2000 we entered into a development and license agreement to work with Eli Lilly and Company on the development of our oral insulin product. Under the terms of the agreement with Lilly, we will receive milestone payments only if the project reaches specified development milestones and we will be entitled to license royalties based on product sales only if the product is successfully brought to market.

Prior to entering into the agreement with Lilly, we had conducted some preliminary clinical trials of our oral insulin product in the United States, Canada and Europe. Our clinical program, however, had not reached a point where we were prepared to apply for regulatory approvals to market the product in any country. Going forward under the agreement, Lilly will be responsible generally for clinical trials and regulatory approvals on a worldwide basis. Lilly also will have the exclusive right to market the product worldwide. Our principal responsibilities will be to continue development, as required, on our oral insulin formulation and on the RapidMist(TM) device.

Clinical trials under the agreement have not yet commenced. At this time, we cannot predict when or if we will reach any of the development milestones under the agreement and when or if any clinical trials might commence under the agreement.

We believe that we can use our buccal delivery technology successfully with other large molecule drugs in addition to insulin. In January 2001, we entered into a joint venture with a subsidiary of Elan Corporation, plc. The purpose of the joint venture is to pursue the application of certain of our and Elan's drug delivery technologies -- including our large molecule drug delivery technology -- to pharmaceutical products for the treatment of prostate cancer and endometriosis and/or the suppression of testosterone and estrogen. In January 2002, we and Elan agreed to expand the joint venture to encompass the buccal delivery of morphine for the treatment of pain and agreed to pursue buccal morphine as the initial pharmaceutical product under the joint venture. We cannot be certain that we can successfully research, develop, obtain regulatory approval for, manufacture, introduce, market or distribute the buccal morphine product to be developed under the joint venture with Elan, nor can we be certain that any buccal morphine product we may develop will be commercially viable.

Similarly, we cannot be certain that we can successfully research, develop, obtain regulatory approval for and eventually commercialize any product for which we have completed proof of concept studies. Proof of concept studies are the very first step in

the long process of product development. It can be years before we will know whether a product for which we might have completed a successful proof of concept will be commercially viable.

**We have not, and may not, receive regulatory approval to sell our products.**

We have engaged primarily in research and development activities since our inception. 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.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technology, 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. We cannot assure you that any technologies or products developed by us, either independently or in collaboration with others, will meet the applicable regulatory criteria in order to receive the required approvals for manufacturing and marketing. 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.

Notwithstanding our development and license agreement with Lilly and the participation of Lilly in the research and development process, we may not be able to develop our insulin product successfully. In order to obtain regulatory approvals for our insulin product, it will be necessary to demonstrate, among other things, that:

- the product is physically and chemically stable under a range of storage, shipping and usage conditions;
- the results of administering the product to patients are reproducible in terms of the amounts of insulin delivered to the oral cavity and absorbed in the bloodstream; and
- there are no serious adverse safety issues associated with use of the product.

Under our agreement, Lilly also has the option of developing a number of additional products using our platform buccal delivery technology. There is even greater uncertainty and risk related to the regulatory approval process for other products besides our insulin product that may be developed, whether with Lilly or independently of Lilly. This is because we have not developed any other product candidate to the extent that we have developed the insulin product.

For similar reasons, we also cannot be certain that we will be able to successfully secure regulatory approval or develop a buccal morphine product or any other product chosen for development under the joint venture with Elan.

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

Even if regulatory approval to market our oral insulin product or any other product candidate is obtained, 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 by health care professionals and diabetic patients;
- the availability, effectiveness and relative cost of alternative diabetes treatments that may be developed by competitors; and
- the availability of third-party (i.e., insurer and governmental agency) reimbursements.

**We are in a highly competitive market and our competitors may develop alternative therapies.**

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies that are currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, and colonic absorption systems. Many of these companies may 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.

**We may not be able to compete with diabetes treatments now being marketed and developed by other companies.**

Our oral insulin product will compete with existing and new therapies for treating diabetes, including administration of insulin by injection. 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. In the longer term, we also face competition from companies that seek to develop cures for diabetes through techniques for correcting the genetic deficiencies that underlie diseases such as diabetes.

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. Except for the agreement with Lilly relating to our oral insulin product and the agreement with Elan relating to products developed under our joint venture with Elan, we do not have any agreements with other companies for marketing or distributing our products. 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.

**If our stock price drops, our stock may be delisted from NASDAQ and become subject to Penny Stock regulations.**

During periods in fiscal 2001 and the beginning of fiscal 2002, our share price dropped to close to \$1.00 per share. The Nasdaq National Market requires our stock price to be at least \$1.00. If we do not meet this requirement in the future, we may be subject to delisting by Nasdaq. We may also be subject to delisting by Nasdaq for failure to meet other criteria, which we currently now meet, such as minimum net tangible assets and net income requirements. 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 you to sell your shares. In addition, 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 SEC'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. In addition, 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 shareholders may have more difficulty selling our common stock in the public market.

**We will need additional capital, which may not be available to us when we need it.**

We have incurred substantial losses from operations since our inception, and we expect to continue to incur substantial losses for the immediately foreseeable future. Under our agreement with Lilly, we expect Lilly to fund a substantial portion of the costs relating to the clinical program and regulatory approvals for our insulin product, and for any other products that may be developed under the agreement should we reach that stage of activity. We have, and may continue to, incur significant costs to fulfill our responsibilities under the agreement with Lilly. We also may require funds in excess of our existing cash resources:

- to proceed under our joint venture with Elan, which requires us to fund 80% of initial product development costs;
- to develop new products based on our buccal delivery technology, including clinical testing relating to new products;
- to develop or acquire other delivery technologies or other lines of business;
- to establish and expand our manufacturing capabilities; and
- to finance general and administrative and research activities that are not related to specific products under development.

Our agreement with Lilly provides for us to receive milestone payments if the project reaches specified development milestones and for us to receive license royalties based on product sales if the product is successfully brought to market. Given that these payments are contingent on events that we cannot be sure will occur, we cannot be certain of when or if we will receive any further payments from Lilly. In any event, we do not expect to receive revenues under the agreement with Lilly or under any future development agreements that are sufficient to satisfy all of our cash requirements.

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 relationship with Lilly or 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.

Even if we raise funds through equity financing, 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.

It is also 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.

#### **We depend upon proprietary technology and the status of patents and proprietary technology is uncertain.**

Our long-term success will substantially depend upon our ability to protect our proprietary technology from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. We currently have fifteen issued U.S. patents pertaining to aspects of buccal delivery technology and covering our oral insulin formulation, and we have three U.S. patent applications and one Canadian patent application pending, also related 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 patent rights, and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. We cannot be sure that any of our pending patent applications will be granted, or that any patents that we own or will obtain in the future will be valid and enforceable and provide us with meaningful protection from competition. There can be no assurance that we will possess the financial resources necessary to enforce any of our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us. There can also be no assurance that any products that we (or a licensee) may develop will not infringe upon any patent or other intellectual property right of a third party.

Furthermore, patent applications are in some situations maintained in secrecy in the United States until the patents are approved, and in most foreign countries for a period of time following the date from which priority is claimed. A third party's pending patent applications may cover technology that we currently are developing.

We have conducted original research on a number of aspects relating to buccal drug delivery. While we cannot assure you that any of our products will provide significant commercial advantage, these patents are intended to provide protection for important aspects of our technology, including our insulin formulation and the delivery of our insulin formulation as a spray. 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. The coverage claimed in a patent can be significantly reduced before a patent is issued, either in the United States or abroad. 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.

There can be no assurance that any products that we (or a licensee) may develop will not 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, there can be no assurance that 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 and we cannot assure you that any license required under any such patent would be made available to us on acceptable terms, if at all. Litigation may also be necessary to enforce our patents against others or to protect our trade secrets. Such litigation could result in substantial expense, and we cannot assure you that any litigation would be resolved in our favor.

In addition, intellectual property for our technologies and products will be a crucial factor in our ability to develop and commercialize our products. Large pharmaceutical companies consider a strong patent estate critical when they evaluate whether to enter into a collaborative arrangement to support the research, development and commercialization of a technology. Without the prospect of reasonable intellectual property protection, it would be difficult for a corporate partner to justify the time and money that is necessary to complete the development of a product.

We also hold some of our technology as trade secrets. We seek to protect this information, in part, by confidentiality agreements with our employees, consultants, advisors and collaborators.

**Enforcement of an arbitration award may result in adverse effects upon Generex.**

*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 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 Generex Biotechnology common stock since outstanding shares of Generex Pharmaceuticals common stock were converted into shares of Generex Biotechnology 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 Generex Biotechnology 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 Generex Biotechnology common stock purportedly pursuant to and in accordance with the terms of the October 1997 letter agreement. Thereafter, Sands submitted a motion to the Supreme Court to modify the judgment and to confirm the arbitration panel's award while we filed a motion with the court to vacate the arbitration award.

On February 25, 2002, the Supreme Court vacated the arbitration panel's November 7, 2001 award to Sands of a warrant to purchase 1,530,020 shares of the our common stock. 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. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

Our consolidated 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 face significant product liability risks, which may have a negative effect on our financial performance.***

The administration of drugs to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs 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 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 negative effect on our financial per-



formance. 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, we cannot be certain that we will 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.

The results and timing of our research and development activities, including future clinical trials, are difficult to predict, subject to future setbacks and, ultimately, may not result in any additional pharmaceutical products, which may adversely affect our business.

In developing our products, we may undertake a range of activities, which include engaging in discovery research and process development, conducting pre-clinical and clinical studies, and seeking regulatory approval in the United States and abroad. In all of these areas, we have relatively limited resources and compete against larger multinational pharmaceutical companies. Moreover, even if we undertake these activities in an effective and efficient manner, regulatory approval for the sale of new pharmaceutical products remains highly uncertain since, in our industry, the majority of compounds discovered do not enter clinical studies and the majority of therapeutic candidates fail to show the human safety and efficacy necessary for regulatory approval and successful commercialization.

Pre-clinical testing and clinical trials must demonstrate that a product candidate is safe and efficacious. The results from pre-clinical testing and early clinical trials may not be predictive of results obtained in subsequent clinical trials, and we cannot be sure that these clinical trials would demonstrate the safety and efficacy necessary to obtain regulatory approval for any product candidates. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. In addition, certain clinical trials are conducted with patients having the most advanced stages of disease. During the course of treatment, these patients may die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested. Such events can have a negative impact on the statistical analysis of clinical trial results.

The completion of clinical trials of product candidates may be delayed by many factors. One such factor is the rate of enrollment of patients. We cannot control the rate at which patients would present themselves for enrollment, and we cannot be sure that the rate of patient enrollment would be consistent with our expectations or be sufficient to enable clinical trials of product candidates to be completed in a timely manner or at all. Any significant delays in, or termination of, clinical trials of product candidates can have a material adverse effect on our business.

We cannot be sure that we will be permitted by regulatory authorities to undertake additional clinical trials for any product candidates, or that if such trials are conducted, any product candidates will prove to be safe and efficacious or will receive regulatory approvals. Any delays in or termination of these clinical trial efforts can have a material adverse effect on product development.

**Our research and development and marketing efforts are highly dependent at present 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 platform technology. Our primary collaboration agreement at present is our development and license agreement with Eli Lilly and Company. As is often the case in such collaboration agreements, Lilly has substantial control over the supply of bulk drugs for commercial use or for use in clinical trials; the design and execution of clinical studies; the process of obtaining regulatory approval to market the product; and/or the eventual marketing and selling of any approved product. In each of these areas, Lilly, or any other 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. As such, we cannot be sure that either Lilly or any other corporate collaborators will share our perspectives on the relative importance of our program, that they will 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. Additionally, we may find it necessary from time to time to seek new or additional partners to assist us in commercializing our products. It is uncertain whether we would be successful in establishing any such new or additional relationships.

**Third party reimbursement for our products is uncertain.**

In both domestic and foreign markets, sales of our potential products depends in part on the availability of reimbursement for 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. Significant uncertainty exists as to the reimbursement status of newly approved health care products. We cannot assure you that any of our products will be reimbursable by third-party payors. In addition, we cannot assure you that our products will be considered cost effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient 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.

**We have a history of losses and may incur additional losses.**

To date, we have not been profitable and our accumulated net loss is approximately \$63 million at July 31, 2002. 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 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.

**The price of our shares may be volatile.**

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

Holders of our Special Voting Rights Preferred Stock have the ability to prevent any change of control of GenereX. 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 GenereX 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 also 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 of 2002, we purchased approximately 23,500 square feet of property located at 11 Carlaw Avenue 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 is currently leased to third parties.

Any additional properties that we own could be used for research, development and tests related to our current and anticipated drug indications as well as potential acquisitions if our current facilities prove inadequate for our needs.

We have first mortgages on our Toronto properties (excluding the property purchased in August 2002) totaling \$663,313 at July 31, 2002. Our mortgages require the payment of interest, with minimal principal reduction, prior to their due date (November 1, 2002 with respect to \$166,032 and May 25, 2005 with respect to \$497,281).

At this time, we do not expect to need manufacturing capabilities 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.

### **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 Generex Biotechnology 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 Generex Biotechnology common stock since outstanding shares of Generex Pharmaceuticals common stock were converted into shares of Generex Biotechnology 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 Generex Biotechnology 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 Generex Biotechnology 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 Generex Biotechnology 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 the judgment and to 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 November 7, 2001 award to Sands of a warrant to purchase 1,530,020 shares of Genex Biotechnology common stock. The New York 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 New York Supreme Court found that the arbitration panel's award "lacks a rational basis". The New York 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 New York Supreme Court to the Appellate Division. We filed a cross-appeal on issues relating to the disqualification of the arbitration panel. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

*Subash Chandarana et al. v Genex Biotechnology Corporation et al.* In February 2001, Subash Chandarana, a former business associate of Dr. Pankaj Modi, and an entity called Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against us and Dr. Modi seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between Chandarana and Modi 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 Chandarana 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 plaintiff's cross motion without prejudice to Chandarana to seek leave to bring a derivative action in the name of or on behalf of CBI. Chandarana 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 Dr. Modi and us. We have opposed the application which is now pending before the Court. We intend to defend this action vigorously. 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. We are defending this action vigorously. 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.

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, 2002.

PART II

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

"Bid" and "asked" prices for our common stock were quoted on the Nasdaq OTC Electronic Bulletin Board from February 1998 to May 2000. On May 5, 2000, our common stock began trading on The Nasdaq National Market (the "Nasdaq National Market"). Prior to February 1998, there was no public market for our common stock.

The table below sets forth the high and low sales prices of our common stock reported by The Nasdaq National Market for the calendar quarters beginning January 1, 2001.

**Sales Prices (actual transactions)**

2001	High	Low
First quarter	\$ 11.50	\$ 4.25
Second quarter	\$ 11.60	\$ 4.58
Third quarter	\$ 10.00	\$ 2.91
Fourth quarter	\$ 7.76	\$ 3.55
<b>2002</b>		
First quarter	\$ 7.40	\$ 3.86
Second quarter	\$ 5.24	\$ 2.62
Third quarter	\$ 3.20	\$ 0.85
Fourth quarter (through October 10, 2002)	\$ 1.55	\$ 1.05

The closing sales price for our common stock reported on October 10, 2002, was \$1.41.

At October 10, 2002, there were 634 holders of record of our common stock.

### Existing Stock Compensation Plans

The following table sets forth information 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	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in warrants and rights column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
1998 Stock Option Plan	1,292,500	\$5.12	0
2000 Stock Option Plan	1,924,500	\$7.70	75,500
2002 Stock Option Plan	1,665,159	\$8.73	2,334,841
<b>Total</b>	<b>4,882,159*</b>	<b>\$8.68</b>	<b>2,410,341</b>
Equity compensation plans not approved by security holders	0	0	0
<b>Total</b>	<b>4,882,159</b>	<b>\$8.68</b>	<b>2,410,341</b>

\*Does not include 125,000 options granted to consultants in 2001 that were not granted pursuant to a stock option plan.

### 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 period from August 1, 2001 until July 31, 2002, we did not offer or sell common stock and other securities in transactions in reliance upon exemptions from the registration requirements of 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 as of July 31, 2002 and for the years ended July 31, 2002 and 2001 have been audited by Deloitte & Touche LLP. Our financial statements for the year ended July 31, 2000 were audited by WithumSmith+Brown.

In thousands, except per share data

	Year Ended July 31					
	2002	2001	2000	1999	1998	2002*
Operating Results		As Restated**				
Revenue	--	\$ 1,000	--	--	--	\$ 1,000
Net Loss	\$ (13,693)	\$ (27,097)	\$ (8,841)	\$ (6,240)	\$ (4,664)	\$ (62,706)
Net Loss Available to Common Stockholders	\$ (14,414)	\$ (27,097)	\$ (8,841)	\$ (6,240)	\$ (4,664)	\$ (63,328)
Cash Dividends per share	--	--	--	--	--	--
Common Stockholders						
Loss per Common Share:						
Basic and diluted Net loss per common share	(.70)	(1.44)	(.58)	(.47)	(.46)	--
Financial Positions:						
Total Assets	\$ 28,161	\$ 42,666	\$ 10,341	\$ 8,890	\$ 5,456	--
Long-term Debt	\$ 663	\$ 693	\$ 772	\$ 996	\$ 1,324	--
Stockholder's Equity	\$ 12,863	\$ 27,307	\$ 8,415	\$ 7,310	\$ 2,642	--

\*Cumulative from November 2, 1995 (Date of Inception) to July 31, 2002.

\*\*See Note 17 to the Consolidated Financial Statements included in Item 8.

## 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 Genorex Pharmaceuticals, Inc., a Canadian corporation formed in November 1995 to engage in pharmaceutical and biotechnological research and other activities. Our acquisition of Genorex Pharmaceuticals was completed in October 1997 in a transaction in which the holders of all outstanding shares of Genorex 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.

**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 clinical trials on this product in the United States, Canada and Europe. In September 2000, we entered into an agreement to develop this product with Eli Lilly and Company. Under this agreement, Lilly is responsible for conducting clinical trials of the product, securing regulatory approvals and marketing on a worldwide basis. Lilly also has the option to develop certain additional products using our buccal delivery technology depending on the success of the initial product. We received \$1,000,000 in connection with our entry into the agreement and will receive certain other initial fees and milestone payments subject to the attainment of certain product development milestones, as well as royalty payments based on product sales should any products be approved for commercial sale. Lilly also has the option to develop certain additional products using our buccal delivery technology depending on the success of the initial 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 of 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 of 2002, 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.

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.

#### **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 the control of the Company. 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 - - 2002 Compared with 2001**

We had a net loss of \$13,693,034 for the year ended July 31, 2002 (FY 2002) compared to a loss of \$27,097,210 in the year ended July 31, 2001 (FY 2001). The net loss for FY 2002 excludes \$720,900 in preferred stock dividend on preferred shares. The decrease in our FY 2002 net loss resulted from:

- decreases in research and development expenses (to \$6,618,820 from \$19,929,799) and
- decreases in 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 income expense) in FY 2002 decreased to \$784,852 from \$1,355,329 in FY 2001 due to decreases in our cash and short-term investments. We did not receive any revenues in FY 2002. In FY 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 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 (the Company's 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 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 (\$1,144,252 in FY 2002 and \$5,100,361 in FY 2001) were paid partially through the issuance of shares of common stock and/or warrants and options to purchase common stock.

In addition, in FY 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 FY 2001.

#### **Results of Operations - - 2001 Compared with 2000**

We had a net loss of \$27,097,210 in the year ended July 31, 2001 (FY 2001) compared to a loss of \$8,841,047 in the year ended July 31, 2000 (FY 2000). The increase in our FY 2001 net loss resulted from increases in research and development expenses (to \$19,929,799 from \$3,568,300) and in general and administrative expenses (to \$12,507,740 from \$5,475,656). Our interest and miscellaneous income (net of interest expense) in FY 2001 increased to \$1,355,329 from \$202,909 in FY 2000. The accounting treatment of the minority shareholder's share of the loss generated by Generex (Bermuda), Ltd., resulted in a \$2,985,000 minority interest share of loss. In addition, we received \$1,000,000 in revenues in connection with the agreement with Lilly.

The principal reasons for the increase in our research and development expense in FY 2001 were:

- 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 (The Company's 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.); and
- increased expenditures relating to clinical studies of our oral insulin formulation.

The principal reasons for the increase in our general and administrative expenses in FY 2001 were:

- expenses incurred in connection with the termination in August 2001 of the equity line facility, pursuant to which the Company paid \$245,000 to Tradersbloom Limited, \$750,000 to Ladenburg Thalmann & Co., and expensed the deferred financing costs (the fair value of the warrants, approximately \$3,406,196), all of which were included in FY 2001;
- increased travel and other costs of \$1,524,997 (to \$2,663,059 from \$538,062) associated with attendance at and sponsorship of industry seminars and exhibitions and other promotional activities;
- an increase of \$959,124 in legal and accounting fees and expenses (to \$2,479,850 from \$1,520,726) related primarily to legal and accounting services in connection with reporting requirements under the Securities and Exchange Act of 1934, litigation defense costs and increased legal activity necessitated by increased equity financing and business activity;
- increased personnel costs of \$207,658 (to \$576,665 from \$369,007) related primarily to additions in our technical and administrative staff during FY 2001; and
- expenses associated with the 2001 annual meeting of stockholders.

### Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States. 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.** Management reviews 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. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of". If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized on the Statement of Operations.
- **Intangible Assets.** The Company has 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, the Company uses an estimate of undiscounted operating income and related cash flow 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, the Company may be required to record impairment changes for these assets not previously recorded. ◦ **Estimating accrued liabilities, specifically litigation accruals.** Management's current estimated ranges of liabilities related to pending litigation are 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 the Company's consolidated financial results in a future reporting period, management believes the ultimate outcome will not have a significant effect on the Company's 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 FY 2002, we granted stock options, warrants and shares of common stock to consultants, advisors and employees with a value of \$430,887 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, 2002, we repurchased a total of 96,500 shares of common stock to be held in treasury for \$395,531, at an average price of \$4.10 per share. Notwithstanding the repurchase of 96,500 shares of common stock, our net loss resulted in a decrease in stockholders' equity to \$25,598,492 at July 31, 2002, versus \$39,322,440 at July 31, 2001.

At July 31, 2002, we had on hand cash and short term investments (primarily notes of U.S. corporations) of approximately \$21 million versus approximately \$37 million at July 31, 2001.

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.

#### **Transactions with Affiliates**

On May 3, 2001, the Company's three senior officers, who are also shareholders of the Company, were advanced \$334,300 each, 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 the Company's common stock owned by this related company. On June 3, 2002, the Company's 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. Subsequent to July 31, 2002, pursuant to a decision made as of August 30, 2002, these loans were satisfied by application 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" 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.

## Contractual Obligations

The following is a summary of our contractual obligations as of July 31, 2002:

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-Term Debt	\$ 663,313	172,453	490,860	None	None
Operating Leases	\$ 50,195	22,352	27,033	810	None
<b>Total Contractual Cash Obligations</b>	<b>\$ 713,508</b>	<b>194,805</b>	<b>571,893</b>	<b>810</b>	<b>None</b>

## New Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 141, "Business Combinations". SFAS No. 141 addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 141 is applicable to business combinations beginning July 1, 2001. The adoption of this statement did not have a significant impact on the Company's financial position or results of operations.

In June 2001, the 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 initial recognition and 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 will be effective for the Company's fiscal year 2003, and management does not expect the adoption of SFAS No. 142 will have a significant effect on the Company's financial position and 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. The Company will adopt SFAS No. 143 on January 1, 2003, and does not expect that this statement will have a material impact 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 retains the provisions of APB No. 30 for presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The Company's management does not expect the adoption of SFAS No. 144 to have a significant impact on our 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 and the Company's management does not expect the adoption to have an impact on the Company's consolidated financial position or results of operations.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Price

We are not presently subject to any material market risk exposures. We are exposed to market risk associated with interest rate changes in the exchange rates between U.S. and Canadian currencies.

We have neither issued nor own any long term debt instruments, or any other financial instruments as to which we would be subject to material risks, including market risks, related to interest rate movements. 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.

## Item 8. Financial Statements and Supplementary Data

### Supplementary Financial Information

The following schedule sets forth certain unaudited financial data for the preceding eight quarters ending July 31, 2002. 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.

#### Fiscal Year July 31, 2002:

As Previously Reported	Q1	Q2	Q3	Q4
Contract research revenue	\$ --	\$ --	\$ --	\$ --
Operating loss	\$ (2,904,564)	\$ (3,781,525)	\$ (3,401,056)	\$ (3,927,708)
Net loss	\$ (2,583,235)	\$ (3,558,703)	\$ (3,239,150)	\$ (3,812,708)
Net loss available to common Shareholders	\$ (2,583,235)	\$ (4,279,603)	\$ (3,239,150)	\$ (3,812,708)
Net loss per share	\$ (0.12)	\$ (0.21)	\$ (0.16)	\$ (.18)
Series A Preferred stock	\$ --	\$ --	\$ --	\$ 12,735,900
Stockholders' Equity:				
Series A Preferred stock	1	1	1	--
Special Voting Rights, preferred stock	1	1	1	1
Common stock	20,686	20,697	20,697	20,697
Treasury stock	(39,150)	(39,150)	(278,828)	(395,531)
Additional paid in capital	88,804,354	89,621,415	89,823,743	77,220,231
Notes receivable - common stock	(319,861)	(325,520)	(331,091)	(336,885)
Accumulated deficit	(51,497,170)	(55,776,773)	(59,015,923)	(63,327,869)
Accumulated other comprehensive loss	(329,486)	(346,168)	(307,970)	318,052)
<b>Total Stockholders' Equity</b>	<b>\$ 36,639,375</b>	<b>\$ 33,154,503</b>	<b>\$ 29,910,630</b>	<b>\$ 12,862,592</b>
<b>As Restated</b>				
Contract research revenue	\$ --	\$ --	\$ --	\$ --
Operating loss	\$ (2,904,564)	\$ (3,781,525)	\$ (3,401,056)	\$ (3,927,708)
Net loss	\$ (2,583,235)	\$ (3,558,703)	\$ (3,239,150)	\$ (3,812,708)
Net loss available to common Shareholders	\$ (2,583,235)	\$ (4,279,603)	\$ (3,239,150)	\$ (3,812,708)
Net loss per share	\$ (0.12)	\$ (0.21)	\$ (0.16)	\$ (.18)
Series A Preferred stock(1)	\$ 12,015,000	\$ 12,735,900	\$ 12,735,900	\$ 12,735,900
Stockholders' Equity:				
Special Voting Rights, preferred stock	\$ 1	\$ 1	\$ 1	\$ 1
Common stock	20,686	20,697	20,697	20,697
Treasury stock	(39,150)	(39,150)	(278,828)	(395,531)
Additional paid in capital	76,789,355	76,885,516	77,087,844	77,220,231
Notes receivable - common stock	(319,861)	(325,520)	(331,091)	(336,885)
Accumulated deficit	(51,497,170)	(55,776,773)	(59,015,923)	(63,327,869)
Accumulated other comprehensive loss	(329,486)	(346,168)	(307,970)	(318,052)
<b>Total Stockholders' Equity(1)</b>	<b>\$ 24,624,375</b>	<b>\$ 20,418,603</b>	<b>\$ 17,174,730</b>	<b>\$ 12,862,592</b>

Fiscal Year July 31, 2002:

As Previously Reported	Q1	Q2	Q3	Q4
Contract research revenue	\$ 1,000,000	\$ --	\$ --	\$ --
Operating loss	\$ (1,344,532)	\$ (17,673,192)	\$ (3,087,422)	\$ (8,587,393)
Net loss	\$ (1,144,207)	\$ (14,205,305)	\$ (2,714,097)	\$ (8,288,601)
Net loss per share	\$ (0.07)	\$ (0.75)	\$ (0.14)	\$ (0.42)
Series A Preferred stock	--	--	--	--
Stockholders' Equity:				
Series A Preferred stock	--	1	1	1
Special Voting Rights, preferred stock	1	1	1	1
Common stock	18,769	19,185	19,294	20,681
Additional paid in capital	57,855,993	75,109,464	75,785,956	88,776,859
Notes receivable - common stock	(54,118)	(55,949)	(308,992)	(314,300)
Accumulated deficit	(22,960,932)	(37,166,237)	(39,880,334)	(48,913,935)
Accumulated other comprehensive loss	(254,735)	(214,075)	(284,181)	(246,867)
<b>Total Stockholders' Equity</b>	<b>\$ 34,604,978</b>	<b>\$ 37,692,390</b>	<b>\$ 35,331,745</b>	<b>\$ 39,322,440</b>
<b>As Restated</b>				
Contract research revenue	\$ 1,000,000	\$ --	\$ --	\$ --
Operating loss	\$ (1,344,532)	\$ (18,418,192)	\$ (3,087,422)	\$ (8,587,393)
Net loss	\$ (1,144,207)	\$ (14,950,305)	\$ (2,714,097)	\$ (8,288,601)
Net loss per share	\$ (0.07)	\$ (0.79)	\$ (0.14)	\$ (0.42)
Series A Preferred stock(1)	\$ --	\$ 12,015,000	\$ 12,015,000	\$ 12,015,000
Stockholders' Equity:				
Special Voting Rights, preferred stock	1	1	1	1
Common stock	18,769	19,185	19,294	20,681
Additional paid in capital	57,855,993	63,094,465	63,770,957	76,761,860
Notes receivable - common stock	(54,118)	(55,949)	(308,992)	(314,300)
Accumulated deficit	(22,960,932)	(37,166,237)	(39,880,334)	(48,913,935)
Accumulated other comprehensive loss	(254,735)	(214,075)	(284,181)	(246,867)
<b>Total Stockholders' Equity(1)</b>	<b>\$ 34,604,978</b>	<b>\$ 25,677,390</b>	<b>\$ 23,316,745</b>	<b>\$ 27,307,440</b>

(1) The Company's interim financial information for Q2 of fiscal year ended July 31, 2001 through Q3 of fiscal year ended July 31, 2002, has been restated to reflect a management's determination that its Series A preferred stock should be reclassified from stockholders' equity to the mezzanine section of the balance sheet. See Note 17 to audited financial statements.





GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
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## INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheets of GenereX Biotechnology Corporation and subsidiaries (a development stage company) as of July 31, 2002 and 2001 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended, and for the period from November 2, 1995 (date of inception) to July 31, 2002. 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. The Company's financial statements as of and for the year ended July 31, 2000, and for the period from November 2, 1995 (date of inception) through July 31, 2000 were audited by other auditors whose report, dated September 14, 2000, expressed an unqualified opinion on those statements. The financial statements for the period November 2, 1995 (date of inception) through July 31, 2000 reflect total revenues and net loss of \$-0- and \$21,816,725, respectively, of the related totals. The other auditors' report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such prior period, is based solely on the report of such other auditors.

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 and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, such financial statements present fairly, in all material respects, the financial position of the Company as at July 31, 2002 and 2001 and the results of its operations and its cash flows for the years then ended, and for the period from November 2, 1995 (date of inception) to July 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 17, the financial statements for the year ended July 31, 2001 have been restated.

/s/ DELOITTE & TOUCHE LLP

DELOITTE & TOUCHE LLP  
Chartered Accountants

Toronto, Ontario  
October 7, 2002

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders, Genex Biotechnology Corporation:

We have audited the accompanying consolidated statements of operations, changes in stockholders' equity and cash flows the year ended July 31, 2000, and the cumulative amounts of operations and cash flows for the period November 2, 1995 (date of inception) to July 31, 2000 of Genex Biotechnology Corporation and Subsidiaries (a development stage company). 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows for the year ended July 31, 2000, and the cumulative amounts of operations and cash flows for the period November 2, 1995 (date of inception) to July 31, 2000 of Genex Biotechnology Corporation and Subsidiaries in conformity with accounting principles generally accepted in the United States of America.

/s/ WithumSmith+Brown  
New Brunswick, New Jersey  
September 14, 2000

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

ASSETS	July 31,	
	2002	2001
		As Restated (see Note 17)
Current Assets:		
Cash and cash equivalents	\$ 8,131,463	\$ 10,109,559
Short-term investments	12,862,757	26,892,729
Officers' loans receivable	1,114,084	1,023,743
Miscellaneous receivables	12,493	12,865
Other current assets	221,629	112,620
<b>Total Current Assets</b>	<b>\$ 22,342,426</b>	<b>\$ 38,151,516</b>
Property and Equipment, Net	4,033,094	3,727,761
Patents, Net	830,142	434,307
Deposits	632,401	20,000
Due From Related Party	322,685	332,289
<b>TOTAL ASSETS</b>	<b>\$ 28,160,748</b>	<b>\$ 42,665,873</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,898,943	\$ 2,650,773
Current maturities of long-term debt	172,453	9,634
<b>Total Current Liabilities:</b>	<b>\$ 2,071,39</b>	<b>\$ 2,660,407</b>
Long-Term Debt, Less Current Maturities	490,860	683,026
Commitments and Contingencies (Note 7)		
Series A Preferred stock, \$.001 par value; authorized 1,000,000 shares, issued and outstanding 1,060 and 1,000 at July 31, 2002 and 2001, respectively	12,735,900	12,015,000
<b>Stockholders' Equity:</b>		
Special Voting Rights Preferred stock, \$.001 par value; authorized, issued and outstanding 1,000 shares at July 31, 2002 and 2001	1	1
Common stock, \$.001 par value; authorized 50,000,000 shares, issued 20,697,326 and 20,681,526 shares at July 31, 2002 and 2001, respectively and outstanding 20,600,826 and 20,681,526 shares at July 31, 2002 and 2001, respectively	20,697	20,681
Treasury stock, at cost; 96,500 shares of common stock at July 31, 2002	(395,531)	--
Additional paid-in capital	77,220,231	76,761,860
Notes receivable - common stock	(336,885)	(314,300)
Deficit accumulated during the development stage	(63,327,869)	(48,913,935)
Accumulated other comprehensive loss	(318,052)	(246,867)
<b>Total Stockholders' Equity</b>	<b>\$ 12,862,592</b>	<b>\$ 27,307,440</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 28,160,748</b>	<b>\$ 42,665,873</b>

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

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended July 31,			Cumulative
	2002	2001	2000	November 2, 1995 (Date of Inception) to 2002
Revenues	\$ -	\$ 1,000,000	\$ -	\$ 1,000,000
Operating Expenses:				
Research and development	6,618,820	19,929,799	3,568,300	33,586,519
Research and development - related party	-	-	-	220,218
General and administrative	7,911,626	12,507,740	5,475,656	34,791,292
General and administrative- related party	-	-	-	314,328
<b>Total Operating Expenses</b>	<b>14,530,446</b>	<b>32,437,539</b>	<b>9,043,956</b>	<b>68,912,357</b>
Operating Loss	(14,530,446)	(31,437,539)	(9,043,956)	(67,912,357)
Other Income (Expense):				
Miscellaneous income	15,995	10,664	7,906	34,565
Interest income	833,167	1,417,847	272,808	2,579,012
Interest expense	(64,310)	(73,182)	(77,805)	(345,749)
Net Loss Before Undernoted	(13,745,594)	(30,082,210)	(8,841,047)	(65,644,529)
Minority Interest Share of Loss	52,560	2,985,000	-	3,037,560
Net Loss	(13,693,034)	(27,097,210)	(8,841,047)	(62,606,969)
Preferred Stock Dividend	720,900	-	-	720,900
Net Loss Available to Common Stockholders	\$ (14,413,934)	\$ (27,097,210)	\$ (8,841,047)	\$ (63,327,869)
Basic and Diluted Net Loss Per Common Share	\$ (1.70)	\$ (1.44)	\$ (1.58)	
Weighted Average Number of Shares of Common Stock Outstanding	20,660,079	18,769,077	15,189,781	

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

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance November 2, 1995 (Inception)	-	\$ -	-	\$ -	-	\$ -
Issuance of common stock for cash, February 1996, \$.0254	-	-	321,429	321	-	-
Issuance of common stock for cash, February 1996, \$.0510	-	-	35,142	35	-	-
Issuance of common stock for cash, February 1996, \$.5099	-	-	216,428	216	-	-
Issuance of common stock for cash, March 1996, \$10.2428	-	-	2,500	3	-	-
Issuance of common stock for cash, April 1996, \$.0516	-	-	489,850	490	-	-
Issuance of common stock for cash, May 1996, \$.0512	-	-	115,571	116	-	-
Issuance of common stock for cash, May 1996, \$.5115	-	-	428,072	428	-	-
Issuance of common stock for cash, May 1996, \$10.2302	-	-	129,818	130	-	-
Issuance of common stock for cash, July 1996, \$.0051	-	-	2,606,528	2,606	-	-
Issuance of common stock for cash, July 1996, \$.0255	-	-	142,857	143	-	-
Issuance of common stock for cash, July 1996, \$.0513	-	-	35,714	36	-	-
Issuance of common stock for cash, July 1996, \$10.1847	-	-	63,855	64	-	-
Costs related to issuance of common stock	-	-	-	-	-	-
Founders Shares transferred for services rendered -	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net loss	-	-	-	-	-	-
<b>Other comprehensive income (loss)</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)	-	-	-	-	-	-
<b>Balance, July 31, 1996</b>	-	\$ -	<b>4,587,764</b>	\$ <b>4,588</b>	-	\$ -

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	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	7,838	-	-	-	8,159
Issuance of common stock for cash, February 1996, \$.0510	1,757	-	-	-	1,792
Issuance of common stock for cash, February 1996, \$.5099	110,142	-	-	-	110,358
Issuance of common stock for cash, March 1996, \$10.2428	25,604	-	-	-	25,607
Issuance of common stock for cash, April 1996, \$.0516	24,773	-	-	-	25,263
Issuance of common stock for cash, May 1996, \$.0512	5,796	-	-	-	5,912
Issuance of common stock for cash, May 1996, \$.5115	218,534	-	-	-	218,962
Issuance of common stock for cash, May 1996, \$10.2302	1,327,934	-	-	-	1,328,064
Issuance of common stock for cash, July 1996, \$.0051	10,777	-	-	-	13,383
Issuance of common stock for cash, July 1996, \$.0255	3,494	-	-	-	3,637
Issuance of common stock for cash, July 1996, \$.0513	1,797	-	-	-	1,833
Issuance of common stock for cash, July 1996, \$10.1847	650,282	-	-	-	650,346
Costs related to issuance of common stock	(10,252)	-	-	-	(10,252)
Founders Shares transferred for services rendered	330,025	-	-	-	330,025
<b>Comprehensive Income (Loss):</b>					
Net loss	-	-	(693,448)	-	(693,448)
<b>Other comprehensive income (loss)</b>					
Currency translation adjustment	-	-	-	(4,017)	(4,017)
Total Comprehensive Income (Loss)	-	-	(693,448)	(4,017)	(697,465)
Balance, July 31, 1996	\$ 2,708,501	-	(\$693,448)	(\$4,017)	\$ 2,015,624

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 1996	-	\$ -	4,587,764	\$ 4,588	-	\$ -
Issuance of common stock for cash, September 1996, \$.0509	-	-	2,143	2	-	-
Issuance of common stock for cash, December 1996, \$10.2421	-	-	1,429	1	-	-
Issuance of common stock for cash, January 1997, \$.0518	-	-	1,466	1	-	-
Issuance of common stock for cash, March 1997, \$10.0833	-	-	12	-	-	-
Issuance of common stock for cash, May 1997, \$.0512	-	-	4,233	4	-	-
Issuance of common stock for cash, May 1997, \$.5060	-	-	4,285,714	4,286	-	-
Costs related to issuance of common stock, May 1997	-	-	-	-	-	-
Issuance of common stock for cash, May 1997, \$10.1194	-	-	18,214	18	-	-
Issuance of common stock for cash, June 1997, \$.0504	-	-	10,714	11	-	-
Issuance of common stock for cash, June 1997, \$.5047	-	-	32,143	32	-	-
Issuance of common stock for cash, June 1997, \$8.9810	-	-	29,579	30	-	-
Issuance of common stock for cash, June 1997, \$10.0978	-	-	714	1	-	-
Issuance of common stock for cash, July 1997, \$10.1214	-	-	25,993	26	-	-
Costs related to issuance of common stock	-	-	-	-	-	-
Founders Shares transferred for services rendered	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net loss	-	-	-	-	-	-
<b>Other comprehensive income (loss)</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)	-	-	-	-	-	-
<b>Balance, July 31, 1997</b>	-	\$ -	9,000,118	\$ 9,000	-	\$ -



GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 1996	\$ 2,708,501	\$ -	(\$693,448)	(\$4,017)	\$ 2,015,624
Issuance of common stock for cash, September 1996, \$.0509	107	-	-	-	109
Issuance of common stock for cash, December 1996, \$10.2421	14,635	-	-	-	14,636
Issuance of common stock for cash, January 1997, \$.0518	75	-	-	-	76
Issuance of common stock for cash, March 1997, \$10.0833	121	-	-	-	121
Issuance of common stock for cash, May 1997, \$.0512	213	-	-	-	217
Issuance of common stock for cash, May 1997, \$.5060	2,164,127	-	-	-	2,168,413
Costs related to issuance of common stock, May 1997	(108,421)	-	-	-	(108,421)
Issuance of common stock for cash, May 1997, \$10.1194	184,297	-	-	-	184,315
Issuance of common stock for cash, June 1997, \$.0504	529	-	-	-	540
Issuance of common stock for cash, June 1997, \$.5047	16,190	-	-	-	16,222
Issuance of common stock for cash, June 1997, \$8.9810	265,618	-	-	-	265,648
Issuance of common stock for cash, June 1997, \$10.0978	7,209	-	-	-	7,210
Issuance of common stock for cash, July 1997, \$10.1214	263,060	-	-	-	263,086
Costs related to issuance of common stock	(26,960)	-	-	-	(26,960)
Founders Shares transferred for services rendered	23,481	-	-	-	23,481
<b>Comprehensive Income (Loss):</b>					
Net loss	-	-	(1,379,024)	-	(1,379,024)
<b>Other comprehensive income (loss)</b>					
Currency translation adjustment	-	-	-	3,543	3,543
Total Comprehensive Income (Loss)	-	-	(1,379,024)	3,543	(1,375,481)
<b>Balance, July 31, 1997</b>	<b>\$ 5,512,782</b>	<b>\$ -</b>	<b>(\$2,072,472)</b>	<b>(\$474)</b>	<b>\$ 3,448,836</b>

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 1997	-	\$ -	9,000,118	\$ 9,000	-	\$ -
Issuance of warrants issued in exchange for services rendered, October 1997, \$.50	-	-	-	-	-	-
Issuance of common stock in exchange for services rendered, December 1997, \$.05	-	-	234,000	234	-	-
Issuance of SVR Preferred Stock in exchange or services rendered, January 1998, \$.001	1,000	1	-	-	-	-
Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation	-	-	1,105,000	1,105	-	-
Issuance of common stock for cash, March 1998, \$2.50	-	-	70,753	71	-	-
Issuance of common stock for cash, April 1998, \$2.50	-	-	60,000	60	-	-
Issuance of common stock in exchange for services rendered, April 1998, \$2.50	-	-	38,172	38	-	-
Issuance of common stock for cash, May 1998, \$2.50	-	-	756,500	757	-	-
Issuance of common stock in exchange for services rendered, May 1998, \$2.50	-	-	162,000	162	-	-
Issuance of warrants issued in exchange for services rendered, May 1998, \$.60	-	-	-	-	-	-
Issuance of common stock for cash, June 1998, \$2.50	-	-	286,000	286	-	-
Exercise of warrants for cash, June 1998, \$0.0667	-	-	234,000	234	-	-
Issuance of common stock in exchange for services rendered, June 1998, \$2.50	-	-	24,729	24	-	-
<b>Comprehensive Income (Loss):</b>						
Net loss						
<b>Other comprehensive income (loss)</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)						
Balance, July 31, 1998	1,000	\$ 1	11,971,272	\$ 11,971	-	\$ -

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 1997	\$ 5,512,782	\$ -	(\$2,072,472)	(\$474)	\$ 3,448,836
Issuance of warrants issued in exchange for services rendered, October 1997, \$.50	234,000	-	-	-	234,000
Issuance of common stock in exchange for services rendered, December 1997, \$.05	10,698	-	-	-	10,932
Issuance of SVR Preferred Stock in exchange for services rendered, January 1998, \$.001	99	-	-	-	100
Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation	(1,105)	-	-	-	-
Issuance of common stock for cash, March 1998, \$2.50	176,812	-	-	-	176,883
Issuance of common stock for cash, April 1998, \$2.50	149,940	-	-	-	150,000
Issuance of common stock in exchange for services rendered, April 1998, \$2.50	95,392	-	-	-	95,430
Issuance of common stock for cash, May 1998, \$2.50	1,890,493	-	-	-	1,891,250
Issuance of common stock in exchange for services rendered, May 1998, \$2.50	404,838	-	-	-	405,000
Issuance of warrants issued in exchange for services rendered, May 1998, \$.60	300,000	-	-	-	300,000
Issuance of common stock for cash, June 1998, \$2.50	714,714	-	-	-	715,000
Exercise of warrants for cash, June 1998, \$0.0667	15,374	-	-	-	15,608
Issuance of common stock in exchange for services rendered, June 1998, \$2.50	61,799	-	-	-	61,823
<b>Comprehensive Income (Loss):</b>					
Net loss	-	-	(4,663,604)	-	(4,663,604)
<b>Other comprehensive income (loss)</b>					
Currency translation adjustment	-	-	-	(198,959)	(198,959)
Total Comprehensive Income (Loss)	-	-	(4,663,604)	(198,959)	(4,862,563)
<b>Balance, July 31, 1998</b>	<b>\$ 9,565,836</b>	<b>\$ -</b>	<b>(\$6,736,076)</b>	<b>(\$199,433)</b>	<b>\$ 2,642,299</b>

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 1998	1,000	\$ 1.00	11,971,272	\$ 11,971	-	\$ -
Issuance of common stock for cash, August 1998, \$3.00	-	-	100,000	100	-	-
Issuance of common stock for cash, August 1998, \$3.50	-	-	19,482	19	-	-
Redemption of common stock for cash, September 1998, \$7.75	-	-	(15,357)	(15)	-	-
Issuance of common stock for cash, September - October 1998, \$3.00	-	-	220,297	220	-	-
Issuance of common stock for cash, August - October 1998, \$4.10	-	-	210,818	211	-	-
Issuance of common stock in exchange for services rendered, August - October 1998, \$2.50	-	-	21,439	21	-	-
Issuance of common stock in exchange for services rendered, August - October 1998, \$4.10	-	-	18,065	18	-	-
Issuance of Common Stock in exchange for services rendered, September 1998, 4.10	-	-	180,000	180	-	-
Issuance of warrants in exchange for services rendered, October 1998, \$0.26	-	-	-	-	-	-
Issuance of stock options in exchange for services rendered, November 1998, \$1.85	-	-	-	-	-	-
Issuance of warrants in exchange for services rendered, November 1998, \$1.64	-	-	-	-	-	-
Issuance of common stock for cash, November 1998 - January 1999, \$3.50	-	-	180,000	180	-	-
Issuance of common stock for cash, November 1998 - January 1999, \$4.00	-	-	275,000	275	-	-
Issuance of common stock for cash, November 1998 - January 1999, \$4.10	-	-	96,852	97	-	-
Issuance of common stock in exchange for services rendered, November 1998 - January 1999, \$4.10	-	-	28,718	29	-	-
Issuance of common stock for cash, November 1998 - January 1999, \$5.00	-	-	20,000	20	-	-
Issuance of common stock for cash, November 1998 - January 1999, \$5.50	-	-	15,000	15	-	-
Issuance of common stock in exchange for services rendered, January 1999, \$5.00	-	-	392	-	-	-
Issuance of common stock for cash, February 1999, \$5.00	-	-	6,000	6	-	-
Issuance of common stock in exchange for services rendered, February 1999, \$6.00	-	-	5,000	5	-	-
Issuance of common stock for cash, March 1999, \$6.00	-	-	11,000	11	-	-
Issuance of common stock for cash, April 1999, \$5.50	-	-	363,637	364	-	-
Issuance of warrants in exchange for services rendered, April 1999, \$3.21	-	-	-	-	-	-

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of warrants in exchange for services rendered, April 1999, \$3.17	-	-	-	-	-	-
Issuance of warrants in exchange for services rendered, April 1999, \$2.89	-	-	-	-	-	-
Issuance of warrants in exchange for services rendered, April 1999, \$3.27	-	-	-	-	-	-
Stock adjustment	-	-	714	1	-	-
Issuance of common stock for cash, May 1999, \$5.50	-	-	272,728	273	-	-
Issuance of common stock in exchange for services rendered, May - June 1999, \$5.50	-	-	60,874	61	-	-
Exercise of warrants for cash, June 1999, \$5.50	-	-	388,375	389	-	-
Exercise of warrants in exchange for note receivable, June 1999, \$5.00	-	-	94,776	95	-	-
Exercise of warrants in exchange for services rendered, June 1999, \$5.00	-	-	13,396	3	-	-
Reduction of note receivable in exchange for services rendered	-	-	-	-	-	-
Shares tendered in conjunction with warrant exercise, June 1999, \$7.8125	-	-	(323,920)	(324)	-	-
Exercise of warrants for shares tendered, June 1999, \$5.00	-	-	506,125	506	-	-
Cost of warrants redeemed for cash	-	-	-	-	-	-
Cost related to warrant redemption, June 1999	-	-	-	-	-	-
Costs related to issuance of common stock	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net Loss	-	-	-	-	-	-
<b>Other comprehensive income (loss):</b>						
Currency translation adjustment	-	-	-	-	-	-
<b>Total Comprehensive Income (Loss)</b>						
<b>Balance, July 31, 1999</b>	<b>1,000</b>	<b>\$ 1</b>	<b>14,740,683</b>	<b>\$ 14,741</b>	<b>-</b>	<b>\$ -</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 1998	\$ 9,565,836	-	(\$6,736,076)	[\$199,433]	\$ 2,642,299
Issuance of common stock for cash, August 1998, \$3.00	299,900	-	-	-	300,000
Issuance of common stock for cash, August 1998, \$3.50	68,168	-	-	-	68,167
Redemption of common stock for cash, September 1998, \$7.75	(119,051)	-	-	-	(119,066)
Issuance of common stock for cash, September - October 1998, \$3.00	660,671	-	-	-	660,891
Issuance of common stock for cash, August - October 1998, \$4.10	864,142	-	-	-	864,353
Issuance of common stock in exchange for services rendered, August - October 1998, -\$2.50	53,577	-	-	-	53,598
Issuance of common stock in exchange for services rendered, August - October 1998, -\$4.10	74,048	-	-	-	74,066
Issuance of Common Stock in exchange for services rendered, September 1998, 4.10	737,820	-	-	-	738,000
Issuance of warrants in exchange for services rendered, October 1998, \$2.6	2,064	-	-	-	2,064
Issuance of stock options in exchange for services rendered, November 1998, \$1.85	92,500	-	-	-	92,500
Issuance of warrants in exchange for services rendered, November 1998, \$1.64	246,000	-	-	-	246,000
Issuance of common stock for cash, November 1998 - January 1999, \$3.50	629,820	-	-	-	630,000
Issuance of common stock for cash, November 1998 - January 1999, \$4.00	1,099,725	-	-	-	1,100,000
Issuance of common stock for cash, November 1998 - January 1999, \$4.10	397,003	-	-	-	397,100
Issuance of common stock in exchange for services rendered, November 1998 - January 1999, \$4.10	117,715	-	-	-	117,744
Issuance of common stock for cash, November 1998 - January 1999, \$5.00	99,980	-	-	-	100,000
Issuance of common stock for cash, November 1998 - January 1999, \$5.50	82,485	-	-	-	82,500
Issuance of common stock in exchange for services rendered, January 1999, \$5.00	1,960	-	-	-	1,960
Issuance of common stock for cash, February 1999, \$5.00	29,994	-	-	-	30,000
Issuance of common stock in exchange for services rendered, February 1999, \$6.00	29,995	-	-	-	30,000
Issuance of common stock for cash, March 1999, \$6.00	65,989	-	-	-	66,000
Issuance of common stock for cash, April 1999, \$5.50	1,999,640	-	-	-	2,000,004
Issuance of warrants in exchange for services rendered, April 1999, \$3.21	160,500	-	-	-	160,500
Issuance of warrants in exchange for services rendered, April 1999, \$3.17	317,000	-	-	-	317,000

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	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, \$2.89	144,500	-	-	-	144,500
Issuance of warrants in exchange for services rendered, April 1999, \$3.27	184,310	-	-	-	184,310
Stock adjustment	(1)	-	-	-	-
Issuance of common stock for cash, May 1999, \$5.50	1,499,731	-	-	-	1,500,004
Issuance of common stock in exchange for services rendered, May - June 1999, \$5.50	334,746	-	-	-	334,807
Exercise of warrants for cash, June 1999, \$5.50	1,941,484	-	-	-	1,941,873
Exercise of warrants in exchange for note receivable, June 1999, \$5.00	473,787	(473,882)	-	-	-
Exercise of warrants in exchange for services rendered, June 1999, \$5.00	66,967	-	-	-	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	(2,530,301)	-	-	-	(2,530,625)
Exercise of warrants for shares tendered, June 1999, \$5.00	2,530,119	-	-	-	2,530,625
Cost of warrants redeemed for cash	(3,769)	-	-	-	(3,769)
Cost related to warrant redemption, June 1999	(135,431)	-	-	-	(135,431)
Costs related to issuance of common stock	(1,179,895)	-	-	-	(1,179,895)
<b>Comprehensive Income (Loss):</b>					
Net Loss	-	-	(6,239,602)	-	(6,239,602)
<b>Other comprehensive income (loss):</b>					
Currency translation adjustment	-	-	-	1,393	1,393
Total Comprehensive Income (Loss)			(6,239,602)	1,393	(6,238,209)
<b>Balance, July 31, 1999</b>	<b>\$ 20,903,728</b>	<b>(\$434,903)</b>	<b>(\$12,975,678)</b>	<b>(\$198,040)</b>	<b>\$ 7,309,849</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 1999	1,000	\$ 1	14,740,683	\$ 14,741	-	\$ -
Adjustment for exercise of warrants recorded June 1999, \$5.00	-	-	(2300)	(2)	-	-
Issuance of common stock for cash, September 1999, \$6.00	-	-	2,500	2	-	-
Issuance of common stock for cash pursuant to private placement, January 2000, \$4.25	-	-	470,590	471	-	-
Financing costs associated with private placement, January, 2000	-	-	-	-	-	-
Issuance of stock in exchange for services rendered, January 2000, \$5.00	-	-	8,100	8	-	-
Granting of stock options for services rendered, January 2000	-	-	-	-	-	-
Granting of 150,000 stock warrants for services rendered, January 2000	-	-	-	-	-	-
Exercise of stock warrants for cash, February 2000, \$5.50	-	-	2,000	2	-	-
Exercise of stock warrants for cash, March 2000, \$5.50	-	-	29,091	29	-	-
Exercise of stock warrants for cash, March 2000, \$6.00	-	-	2,000	2	-	-
Exercise of stock warrants for cash, March 2000, \$7.50	-	-	8,000	8	-	-
Issuance of common stock for cash pursuant to private placement, June 2000, \$6.00	-	-	1,041,669	1,042	-	-
Financing costs associated with private placement, June 2000	-	-	-	-	-	-
Issuance of common stock for services, June 2000, \$6.00	-	-	4,300	4	-	-
Exercise of warrants for cash, July 2000, \$6.00	-	-	3,000	3	-	-
Exercise of warrants for cash, July 2000, \$7.50	-	-	16,700	17	-	-
Granting of stock options for services rendered, July 2000	-	-	-	-	-	-
Reduction of note receivable in exchange for services rendered	-	-	-	-	-	-
Accrued interest on note receivable	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net Loss	-	-	-	-	-	-
<b>Other comprehensive income (loss):</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)	-	-	-	-	-	-
<b>Balance, July 31, 2000</b>	<b>1,000</b>	<b>\$ 1</b>	<b>16,326,333</b>	<b>\$ 16,327</b>	<b>-</b>	<b>\$ -</b>



**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 1999	\$ 20,903,728	(\$434,903)	(12,975,678)	(\$198,040)	\$ 7,309,849
Adjustment for exercise of warrants recorded June 1999, \$5.00	2	-	-	-	-
Issuance of common stock for cash, September 1999, \$6.00	14,998	-	-	-	15,000
Issuance of common stock for cash pursuant to private placement, January 2000, \$4.25	1,999,537	-	-	-	2,000,008
Financing costs associated with private placement, January, 2000	(220,192)	-	-	-	(220,192)
Issuance of stock in exchange for services rendered, January 2000, \$5.00	40,492	-	-	-	40,500
Granting of stock options for services rendered, January 2000	568,850	-	-	-	568,850
Granting of 150,000 stock warrants for services rendered, January 2000	355,500	-	-	-	355,500
Exercise of stock warrants for cash, February 2000, \$5.50	10,998	-	-	-	11,000
Exercise of stock warrants for cash, March 2000, \$5.50	159,972	-	-	-	160,001
Exercise of stock warrants for cash, March 2000, \$6.00	11,998	-	-	-	12,000
Exercise of stock warrants for cash, March 2000, \$7.50	59,992	-	-	-	60,000
Issuance of common stock for cash pursuant to private placement, June 2000, \$6.00	6,248,972	-	-	-	6,250,014
Financing costs associated with private placement, June 2000	(385,607)	-	-	-	(385,607)
Issuance of common stock for services, June 2000, \$6.00	25,796	-	-	-	25,800
Exercise of warrants for cash, July 2000, \$6.00	17,997	-	-	-	18,000
Exercise of warrants for cash, July 2000, \$7.50	125,233	-	-	-	125,250
Granting of stock options for services rendered, July 2000	496,800	-	-	-	496,800
Reduction of note receivable in exchange for services rendered	-	384,903	-	-	384,903
Accrued interest on note receivable	-	(4,118)	-	-	(4,118)
<b>Comprehensive Income (Loss):</b>					
Net Loss	-	-	(8,841,047)	-	(8,841,047)
<b>Other comprehensive income (loss):</b>					
Currency translation adjustment	-	-	-	32,514	32,514
<b>Total Comprehensive Income (Loss)</b>			(8,841,047)	32,514	(8,808,533)
<b>Balance, July 31, 2000</b>	<b>\$ 30,435,066</b>	<b>(\$54,118)</b>	<b>(\$21,816,725)</b>	<b>(\$165,526)</b>	<b>\$ 8,415,025</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 2000	1,000	\$ 1	16,326,333	\$ 16,327	-	\$ -
Exercise of stock warrants for cash, August 2000, \$6.00	-	-	2,000	2	-	-
Issuance of common stock for services rendered August 2000	-	-	35,000	35	-	-
Issuance of stock warrants in exchange for equity line agreement, August 2000	-	-	-	-	-	-
Exercise of stock warrants for cash, August 2000, \$7.50	-	-	30,300	30	-	-
Exercise of stock warrants for cash, August 2000, \$8.6625	-	-	30,000	30	-	-
Cashless exercise of stock warrants, August 2000	-	-	8,600	9	-	-
Exercise of stock warrants for cash, August 2000, \$10.00	-	-	10,000	10	-	-
Exercise of stock warrants for cash, September 2000, \$8.6625	-	-	63,335	63	-	-
Exercise of stock warrants for cash, September 2000, \$5.50	-	-	16,182	16	-	-
Exercise of stock warrants for cash, September 2000, \$6.00	-	-	53,087	53	-	-
Exercise of stock warrants for cash, September 2000, \$10.00	-	-	9,584	10	-	-
Exercise of stock warrants for cash, September 2000, \$7.50	-	-	32,416	32	-	-
Issuance of common stock for cash pursuant to private placement, October 2000, \$11.00	-	-	2,151,093	2,151	-	-
Exercise of stock warrants for cash, Oct. 2000, \$6.00	-	-	1,000	1	-	-
Financing costs associated with private placement, October 2000	-	-	-	-	-	-
Exercise of stock warrants for cash, November - December 2000, \$4.25	-	-	23,528	23	-	-
Cashless exercise of stock warrants, December 2000	-	-	3,118	3	-	-
Exercise of stock warrants for cash, November - December 2000, \$6.00	-	-	22,913	23	-	-
Exercise of stock warrants for cash, December 2000, \$7.00	-	-	8,823	9	-	-
Issuance of common stock as employee compensation, December 2000	-	-	8,650	8	-	-
Exercise of stock warrants for cash, January 2001, \$6.00	-	-	3,000	3	-	-
Issuance of common stock for cash pursuant to private placement, January 2001, \$14.53	-	-	344,116	344	-	-
Financing costs associated with private placement, January 2001	-	-	-	-	-	-

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common stock pursuant to litigation settlement, January 2001	-	-	2,832	2	-	-
Granting of stock options in exchange for services rendered, January 2001	-	-	-	-	-	-
Granting of stock options in exchange for services rendered, February 2001	-	-	-	-	-	-
Exercise of stock options for cash, February 2001, \$5.00	-	-	50,000	50	-	-
Exercise of stock warrants for cash, March 2001, \$6.00	-	-	500	1	-	-
Exercise of stock options in exchange for note receivable, March 2001	-	-	50,000	50	-	-
Issuance of common stock in exchange for services rendered, March 2001, \$5.50	-	-	8,000	8	-	-
Granting of stock options in exchange for services rendered, May 2001	-	-	-	-	-	-
Exercise of stock options for cash, June 2001- \$5.00	-	-	75,000	75	-	-
Exercise of stock options for cash, June 2001- \$5.50	-	-	12,500	12	-	-
Exercise of warrants for cash, June 2001, \$6.00	-	-	4,000	4	-	-
Exercise of stock options for cash, July 2001- \$5.00	-	-	7,500	8	-	-
Exercise of stock options for cash, July 2001- \$5.50	-	-	2,500	3	-	-
Exercise of warrants for cash, July 2001, \$6.00	-	-	2,000	2	-	-
Issuance of common stock for cash pursuant to private placement, July 2001, \$9.25	-	-	1,254,053	1,254	-	-
Financing costs associated with private placement, July 2001	-	-	-	-	-	-
Shares issued in exchange for services rendered, July 2001, \$9.25	-	-	23,784	24	-	-
Shares issued for Anti-Dilution Provisions, July 2001	-	-	5,779	6	-	-
Issuance of stock warrants in exchange for services rendered, July 2001	-	-	-	-	-	-
Accrued interest on note receivable	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net Loss	-	-	-	-	-	-
<b>Other comprehensive income (loss):</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)	-	-	-	-	-	-
<b>Balance at July 31, 2001 as restated (see Note 17)</b>	<b>1,000</b>	<b>\$ 1</b>	<b>20,681,526</b>	<b>\$ 20,681</b>	<b>-</b>	<b>\$ -</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 1 OF 2**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2000

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 2000	\$ 30,435,066	(\$54,118)	(\$21,816,725)	(\$165,526)	\$ 8,415,025
Exercise of stock warrants for cash, August 2000, \$6.00	11,998	-	-	-	12,000
Issuance of common stock for services rendered August 2000	411,215	-	-	-	411,250
Issuance of stock warrants in exchange for equity line agreement, August 2000	3,406,196	-	-	-	3,406,196
Exercise of stock warrants for cash, August 2000, \$7.50	227,220	-	-	-	227,250
Exercise of stock warrants for cash, August 2000, \$8.6625	259,845	-	-	-	259,875
Cashless exercise of stock warrants, August 2000	(9)	-	-	-	-
Exercise of stock warrants for cash, August 2000, \$10.00	99,990	-	-	-	100,000
Exercise of stock warrants for cash, September 2000, \$8.6625	548,576	-	-	-	548,639
Exercise of stock warrants for cash, September 2000, \$5.50	88,986	-	-	-	89,002
Exercise of stock warrants for cash, September 2000, \$6.00	318,470	-	-	-	318,523
Exercise of stock warrants for cash, September 2000, \$10.00	95,830	-	-	-	95,840
Exercise of stock warrants for cash, September 2000, \$7.50	243,088	-	-	-	243,120
Issuance of common stock for cash pursuant to private placement, October 2000, \$11.00	23,659,872	-	-	-	23,662,023
Exercise of stock warrants for cash, Oct. 2000, \$6.00	5,999	-	-	-	6,000
Financing costs associated with private placement, October 2000	(1,956,340)	-	-	-	(1,956,340)
Exercise of stock warrants for cash, November - December 2000, \$4.25	99,971	-	-	-	99,994
Cashless exercise of stock warrants, December 2000	(3)	-	-	-	-
Exercise of stock warrants for cash, November - December 2000, \$6.00	137,455	-	-	-	137,478
Exercise of stock warrants for cash, December 2000, \$7.00	61,752	-	-	-	61,761
Issuance of common stock as employee compensation, December 2000	100,548	-	-	-	100,556
Exercise of stock warrants for cash, January 2001, \$6.00	17,997	-	-	-	18,000
Issuance of common stock for cash pursuant to private placement, January 2001, \$14.53	4,999,656	-	-	-	5,000,000
Financing costs associated with private placement, January 2001	(200,000)	-	-	-	(200,000)

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Issuance of common stock pursuant to litigation settlement, January 2001	21,096	-	-	-	21,098
Granting of stock options in exchange for services rendered, January 2001	745,000	-	-	-	745,000
Granting of stock options in exchange for services rendered, February 2001	129,600	-	-	-	129,600
Exercise of stock options for cash, February 2001, \$5.00	249,950	-	-	-	250,000
Exercise of stock warrants for cash, March 2001, \$6.00	2,999	-	-	-	3,000
Exercise of stock options in exchange for note receivable, March 2001	249,950	(250,000)	-	-	-
Issuance of common stock in exchange for services rendered, March 2001, \$5.5	43,992	-	-	-	44,000
Granting of stock options in exchange for services rendered, May 2001	592,300	-	-	-	592,300
Exercise of stock options for cash, June 2001- \$5.00	374,925	-	-	-	375,000
Exercise of stock options for cash, June 2001- \$5.50	68,738	-	-	-	68,750
Exercise of warrants for cash, June 2001, \$6.00	23,996	-	-	-	24,000
Exercise of stock options for cash, July 2001- \$5.00	37,492	-	-	-	37,500
Exercise of stock options for cash, July 2001- \$5.50	13,747	-	-	-	13,750
Exercise of warrants for cash, July 2001, \$6.00	11,998	-	-	-	12,000
Issuance of common stock for cash pursuant to private placement, July 2001, \$9.25	11,598,736	-	-	-	11,599,990
Financing costs associated with private placement, July 2001	(768,599)	-	-	-	(768,599)
Shares issued in exchange for services rendered, July 2001, \$9.25	219,978	-	-	-	220,002
Shares issued for Anti-Dilution Provisions, July 2001	53,450	-	-	-	53,456
Issuance of stock warrants in exchange for services rendered, July 2001	19,134	-	-	-	19,134
Accrued interest on note receivable	-	(10,182)	-	-	(10,182)
<b>Comprehensive Income (Loss):</b>					
Net Loss	-	-	(27,097,210)	-	(27,097,210)
<b>Other comprehensive income (loss):</b>					
Currency translation adjustment	-	-	-	(81,341)	(81,341)
<b>Total Comprehensive Income (Loss)</b>			(27,097,210)	(81,341)	(27,178,551)
<b>Balance at July 31, 2001 as restated (see Note 17)</b>	<b>\$ 76,761,861</b>	<b>(\$314,300)</b>	<b>(\$48,913,935)</b>	<b>(\$246,867)</b>	<b>\$ 27,307,440</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	SVR Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance, August 1, 2001 as restated (see Note 17)	1,000	\$ 1	20,681,526	\$ 20,681	-	\$ -
Exercise of stock options for cash, August 2001, \$5.50	-	-	5,000	5	-	-
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	-	-	-	-	-	-
Issuance of common stock as employee compensation, January 2002	-	-	10,800	11	-	-
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	-	-	-	-	-	-
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	-	-	-	-	-	-
Purchase of Treasury Stock for cash July 2002, \$4.025	-	-	-	-	(34,600)	(116,703)
Accrued interest on note receivable	-	-	-	-	-	-
<b>Comprehensive Income (Loss):</b>						
Net Loss	-	-	-	-	-	-
<b>Other comprehensive income (loss):</b>						
Currency translation adjustment	-	-	-	-	-	-
Total Comprehensive Income (Loss)	-	-	-	-	-	-
<b>Balance at July 31, 2002</b>	<b>1,000</b>	<b>\$ 1</b>	<b>20,697,326</b>	<b>\$ 20,697</b>	<b>(96,500)</b>	<b>\$ (395,531)</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
 FOR THE PERIOD NOVEMBER 2, 1995 (DATE OF INCEPTION) TO JULY 31, 2002

	Additional Paid-In Capital	Notes Receivable - Common Stock	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, August 1, 2001 as restated (see Note 17)	\$ 76,761,860	\$ (314,300)	\$ (48,913,935)	\$ (246,867)	\$ 27,307,440
Exercise of stock options for cash, August 2001, \$5.50	27,495	-	-	-	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	-	-	-	25,000
Issuance of common stock as employee compensation, January 2002	71,161	-	-	-	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	-	-	-	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	-	-	-	132,387
Purchase of Treasury Stock for cash July 2002, \$4.025	-	-	-	-	(116,703)
Accrued interest on note receivable	-	(22,585)	-	-	(22,585)
<b>Comprehensive Income (Loss):</b>					
Net Loss	-	-	(13,693,034)	-	(13,693,034)
<b>Other comprehensive income (loss):</b>					
Currency translation adjustment	-	-	-	(71,185)	(71,185)
Total Comprehensive Income (Loss)	-	-	(13,693,034)	(71,185)	(13,764,219)
<b>Balance at July 31, 2002</b>	<b>\$ 77,220,231</b>	<b>(\$336,885)</b>	<b>(\$63,327,889)</b>	<b>(\$318,052)</b>	<b>\$ 12,862,592</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Years Ended July 31			Cumulative From
	2002	2001	2000	November 2, 1995 (Date of Inception) to July 31, 2002
<b>Cash Flows Used in Operating Activities:</b>				
Net loss	\$ (13,693,034)	\$ (27,097,210)	\$ (8,841,047)	\$ (62,606,969)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	431,547	230,600	86,804	872,824
Minority interest share of loss	(52,560)	(2,985,000)	--	(3,037,560)
Reduction of notes receivable - common stock in exchange for services rendered	--	--	384,903	423,882
Write-off of deferred offering costs	--	3,406,196	--	3,406,196
Common stock issued for services rendered	71,172	829,264	66,300	2,141,164
Stock options and warrants issued for services rendered	359,715	1,486,036	1,421,150	4,947,775
Preferred stock issued for services rendered	--	--	--	100
Founders' shares transferred for services rendered	--	--	--	353,506
Changes in operating assets and liabilities:				
Miscellaneous receivables	--	2,747	170,481	30,620
Other current assets	(108,610)	(14,858)	21,219	(226,216)
Accounts payable and accrued expenses	(740,319)	1,479,803	773,506	2,751,802
Other, net	--	--	--	110,317
<b>Net Cash Used in Operating Activities</b>	<b>(13,732,089)</b>	<b>(22,662,422)</b>	<b>(5,916,684)</b>	<b>(50,832,559)</b>
<b>Cash Flows From Investing Activities:</b>				
Purchase of property and equipment	(779,519)	(1,623,017)	(381,163)	(3,076,490)
Costs incurred for patents	(440,698)	(197,434)	(269,499)	(907,631)
Change in restricted cash	--	--	--	(5,595)
Change in officers' loans receivable	(90,341)	(1,023,743)	--	(1,114,084)
Increase in officers' loans receivable	14,029,972	(22,926,466)	(3,733,918)	(12,862,757)
Change in short-term investments - net	(614,464)	27,396	19,720	(584,949)
Change in deposits	(22,585)	(10,182)	(4,118)	(36,885)
Change in notes receivable - common stock	--	--	290,973	(2,255,197)
Change in due from related parties	--	--	--	89,683
Other, net				
<b>Net Cash (Used in) Provided By Investing Activities</b>	<b>12,082,365</b>	<b>(25,753,446)</b>	<b>(4,078,005)</b>	<b>(20,753,905)</b>
<b>Cash Flows From Financing Activities:</b>				
Proceeds from issuance of long-term debt	--	--	--	993,149
Repayment of long-term debt	(9,363)	(5,208)	(480,738)	(975,347)
Change in due to related parties -	--	--	--	154,541
Change in due to related parties -	--	2,256,482	--	2,256,482
Proceeds from exercise of warrants	27,500	745,000	--	772,500
Proceeds from exercise of stock options	52,560	2,985,000	--	3,037,560
Proceeds from minority interest investment	--	37,337,074	8,045,474	61,999,294
Proceeds from issuance of common stock, net	--	12,015,000	--	12,015,000
Proceeds from issuance of preferred stock	--	--	--	(119,066)
Purchase and retirement of common stock	(395,531)	--	--	(395,531)
Purchase of treasury stock				
<b>Net Cash (Used in) Provided By Financing Activities</b>	<b>(324,834)</b>	<b>55,333,348</b>	<b>7,564,736</b>	<b>79,738,582</b>
<b>Effect of Exchange Rate Changes on Cash</b>	<b>(3,538)</b>	<b>(12,826)</b>	<b>1,657</b>	<b>(20,655)</b>
<b>Net Increase (Decrease) in Cash and Cash Equivalents</b>	<b>(1,978,096)</b>	<b>6,904,654</b>	<b>(2,428,296)</b>	<b>8,131,463</b>
<b>Cash and Cash Equivalents, Beginning of Year</b>	<b>10,109,559</b>	<b>3,204,905</b>	<b>5,633,201</b>	<b>--</b>
<b>Cash and Cash Equivalents, End of Year</b>	<b>\$ 8,131,463</b>	<b>\$ 10,109,559</b>	<b>\$ 3,204,905</b>	<b>\$ 8,131,463</b>

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



GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
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 7). 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 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**

At July 31, 2002 and 2001, short-term investments consisted of short-term notes of U.S. corporations with original maturities of between three to twelve months. These short-term notes are classified as held to maturity and are valued at amortized cost. At July 31, 2002 and 2001, 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

**Impairment of Long-Lived Assets**

The Company assesses the impairment of patents under SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of" 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 Statement of Financial Accounting Standards 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**

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), the Company follows Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock option plans. Under APB 25, if the exercise price of the Company's employee stock options equals or exceeds the fair market value of the underlying stock on the date of grant, no compensation expense is recognized. Stock options and warrants issued to non employees are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

**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 13 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

**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. 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 US 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 US currency are recorded in the other comprehensive loss component of stockholders' equity.

**Financial Instruments**

The carrying values of accounts payable, accrued expenses and long-term debt approximate their fair values. It was not practical to estimate the fair value of the officers' loans receivable due to the related party nature of these items.

Effective August 1, 2000 the Company adopted 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. The Company's adoption of this statement did not have and continues not to have a significant impact on the Company's financial position or results of operations.

**Reclassifications**

Certain amounts reported in the 2001 and 2000 financial statements have been reclassified to conform to the 2002 presentation.

**Effects of Recent Accounting Pronouncements**

In June 2001, the FASB issued SFAS No. 141, "Business Combinations." SFAS No. 141 addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination, as well as requiring use of the purchase accounting method of recording transactions. SFAS No. 141 is applicable to business combinations after July 1, 2001. The adoption of this statement did not have a significant impact on the Company's financial position or results of operations.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

**Effects of Recent Accounting Pronouncements (continued):** In June 2001, the 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 will be effective for the Company's fiscal year 2003, and management does not expect the adoption of SFAS No. 142 to 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. The Company will adopt SFAS No. 143 on August 1, 2003, and does not expect that this statement will have a material impact 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. Management does not expect the adoption of SFAS No. 144 to 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 and management does not expect the adoption to have an impact on the Company's consolidated financial position or results of operations.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 3 - Property and Equipment:**

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

	July 31,	
	2002	2001
Land	\$ 285,407	\$ 293,902
Buildings and Improvements	1,936,548	1,901,907
Furniture and Fixtures	76,956	68,229
Office Equipment	93,491	60,229
Lab Equipment	2,434,409	1,814,028
Total Property and Equipment	4,826,811	4,138,295
Less: Accumulated Depreciation	793,717	410,534
<b>Property and Equipment, Net</b>	<b>\$ 4,033,094</b>	<b>\$ 3,727,761</b>

Depreciation expense amounted to \$393,655, \$209,114 and \$85,781 for the years ended 2002, 2001 and 2000, respectively.

**Note 4 - Patents:**

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

	July 31,	
	2002	2001
Patents	\$ 890,061	\$ 456,860
Less: Accumulated Amortization	59,919	22,553
<b>Patents, Net</b>	<b>830,142</b>	<b>434,307</b>

Amortization expense amounted to \$37,892, \$21,486 and \$1,023 for the years ended July 31, 2002, 2001 and 2000, respectively.

**Note 5 - 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. As of July 31, 2002, the Company has net operating loss carryforwards in Generex Biotechnology Corporation of approximately \$27,846,057, which expire in 2013 through 2022, and in Generex Pharmaceuticals Inc. of approximately \$12,776,626, which expire in 2005 through 2009. These loss carryforwards are subject to limitation in future years should certain ownership changes occur.

For the years ended July 31, 2002, 2001 and 2000, 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 5 - Income Taxes (Continued):**

Deferred income taxes consist of the following:

	July 31,	
	2002	2001
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 16,887,905	\$ 12,513,777
Other timing differences	2,415,561	295,314
Total deferred tax assets	19,303,466	12,809,901
Valuation allowance	(19,303,466)	(12,809,091)
<b>Net deferred income taxes</b>	<b>\$ --</b>	<b>\$ --</b>

**Note 6 - Accounts Payable and Accrued Expense:**

Accounts payable and accrued expenses consist of the following:

	July 31,	
	2002	2001
Accounts Payable	\$ 778,184	\$ 896,061
Clinical	--	147,699
Accrued Legal	460,840	612,013
Executive Compensation	584,919	--
Financial Services	75,000	995,000
<b>Total</b>	<b>\$ 1,898,943</b>	<b>\$ 2,650,773</b>

**Note 7- 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 11 for description of Special Voting Rights Preferred Stock.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 7- 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, 2002 are as follows:

Year	Amount
2003	\$ 22,352
2004	14,289
2005	8,098
2006	4,646
2007	810
Thereafter	--
<b>Total Minimum Lease Payments</b>	<b>\$ 50,195</b>

Lease expense amounted to \$13,766, \$20,753 and \$20,175 for the years ended July 31, 2002, 2001 and 2000, 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, 2002:

Year	Amount
2003	\$ 32,955
2004	33,245
2005	33,535
2006	9,610
Thereafter	--
<b>Total</b>	<b>\$ 109,345</b>

**Note 7- Commitments and Contingent Liabilities (Continued):**

**Supply Agreements**

On July 19, 2000, the Company entered into 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. In August 2000, in conjunction with the execution of the exclusive supply agreement, the Company delivered 35,000 shares of its common stock to Valois and recorded an expense of \$411,250. 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, 2002 and 2001.

On August 28, 2000, the Company entered into 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.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 7- 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% 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. 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 7- Commitments and Contingent Liabilities (Continued):**

**Pending Litigation (continued):**

In February 2001, a former business associate of the Vice President of Research and Development (VP), and an entity called Centrum Technologies Inc. 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 Centrum Technologies Inc. On July 20, 2001, the Company filed a preliminary motion to dismiss the action of Centrum Technologies Inc. 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 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 plaintiff's 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. The Company intends to continue its vigorous defense of this legal proceeding. 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 is scheduled to commence in November 2002. 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 consolidated financial position of the Company.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 7- Commitments and Contingent Liabilities (Continued):**

**Pending Litigation (Continued):**

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 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.

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 consolidated financial position.

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. Estimates that are particularly sensitive to future change relate to legal matters, which are subject to change as events evolve and as additional information becomes available during the administration and litigation process.

**Note 8 - Related Party Transactions:**

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

		EBI, Inc.
Beginning Balance, August 1, 2000	\$	343,773
Effect of foreign currency translation adjustments		(11,484)
Ending Balance, July 31, 2001		332,289
Effect of foreign currency translation adjustments		(9,604)
Ending Balance, July 31, 2002	\$	322,685

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 owned in part by the Company's Chairman of the Board.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 8 - Related Party Transactions (Continued):**

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

	For the Years Ended July 31				
	2002		2001		2000
Interest Income	\$ 31,250	\$	32,209	\$	60,962
Interest Expense	--	\$	--	\$	14,938

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

For the years ended July 31, 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 \$1,075,847 and \$672,477 for the years ended July 31, 2002 and 2001, respectively.

For the year ended July 31, 2000, the Company's three senior officers, who are also shareholders of the Company were compensated indirectly by the Company through management services contracts between the Company and a management firm of which they were equal owners. The amounts paid to this management firm amounted to \$343,594 for the year ended July 31, 2000.

See Note 7 for a discussion of the consulting agreement with the Company's Vice President of Research and Development.

On May 3, 2001, the Company's three 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 have been 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 Common Stock currently owned by this related company. As of July 31, 2002, the balance outstanding on these notes, including accrued interest, was \$1,114,084. [See Note 18 for settlement of amounts outstanding].

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 9 - Long-Term Debt:**

Long-term debt consists of the following:

	July 31	
	2002	2001
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	\$ 497,281	\$ 518,095
Mortgage payable - interest at 10 percent per annum, monthly payments of principal and interest of \$1,662, final payment due November 1, 2002, secured by real property located at 11 Carlaw Avenue, Toronto, Canada	166,032	174,565
Total Debt	663,313	692,660
Less Current Maturities	172,453	9,634
<b>Long-Term Debt, Less Current Maturities</b>	<b>\$ 490,860</b>	<b>\$ 683,026</b>

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

Year	Amount
2003	\$ 172,453
2004	7,058
2005	483,802
Thereafter	--
<b>Total</b>	<b>\$ 663,313</b>

In July 2002, Generex Pharmaceuticals secured a line of credit with the Bank of Nova Scotia with an available credit line of \$762,000, at an interest rate of 5.8 percent per annum, for the purpose of acquiring additional property for investment purposes. The terms of the line of credit are such that the loan is to be fully drawn down by August 15, 2002, and fully repaid within three years, in 35 equal monthly principal installments of \$4,233 plus accrued interest, with the final balance due in the 36th month. The credit line, when utilized, is to be secured by an assigned collateral interest in the property being acquired, a guarantee by the Company and restricted funds in the amount of \$158,750 on deposit with the Bank of Nova Scotia.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 10 - 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% of the Company's equity ownership in Generex (Bermuda) Ltd. Upon exercise, the holder and the Company would each own 50% of Generex (Bermuda) Ltd. (See Note 16 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.

**Note 11 - Stockholders' Equity:**

**Warrants**

As of July 31, 2002, 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
7,937	\$21.82	September 6, 2002
370,589	\$ 7.00	January 17, 2003
500,000	\$ 2.50	March 21, 2003
568,647	\$12.15	August 12, 2003
150,000	\$10.00	November 17, 2003
112,584	\$ 7.50	January 31, 2004
3,500	\$ 6.00	February 17, 2004
53,000	\$ 6.00	April 6, 2004
9,091	\$ 5.50	April 26, 2004
3,243	\$14.53	July 6, 2004
11,764	\$ 4.25	January 7, 2005
948,334	\$ 8.66	May 17, 2005
19,584	\$10.00	May 17, 2005
328,878	\$12.99	September 29, 2005
215,109	\$13.20	September 29, 2005
75,000	\$25.15	January 16, 2006
313,515	\$10.18	July 6, 2006
74,000	\$12.99	March 18, 2007

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 11 - Stockholders' Equity (Continued):**

**Notes Receivable - Common Stock**

Notes receivable - common stock consists 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 was \$57,720 and a new promissory note was signed. Under the terms of the new 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 new note, the principal of \$61,867, together with accrued interest at 7 percent is due July 31, 2003. 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. As of July 31, 2002 the outstanding balance on this note, including accrued interest at 7 percent was \$275,018.

**Preferred Stock**

The Company has authorized 1,000,000 shares with a par value of one-tenth of a cent (\$.001) per share of preferred stock. 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) 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 year ended July 31, 2002, the Company purchased 96,500 shares of common stock to be held in treasury at a cost of \$395,531.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 12 - 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 and the interpretation of options. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Committee.

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, 1999	50,000	8.00
Granted	3,004,500	6.35
Canceled	--	--
Exercised	--	--
Outstanding - July 31, 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
<b>Outstanding - July 31, 2002</b>	<b>\$ 5,007,159</b>	<b>\$ 6.22</b>



GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 12 - Stock Based Compensation (Continued)**

**Stock Option Plans (Continued):**

The following table summarizes information on stock options outstanding at July 31, 2002:

Range of Exercise Price	Options Outstanding			Options Exercisable		
	Number Outstanding at July 31, 2002	Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at July 31, 2002	Weighted Average Exercise Price	
\$ 2.19	150,000	5.00	\$ 2.19	150,000	\$ 2.19	
\$ 5.00 - \$ 5.50	2,602,500	3.37	\$ 5.10	2,311,000	\$ 5.09	
\$ 6.54 - \$ 8.70	2,154,659	3.01	\$ 7.67	2,254,659	\$ 7.67	
\$10.21	100,000	3.50	\$ 10.21	70,000	\$ 10.21	
	<b>5,007,159</b>			<b>4,685,659</b>		

Options exercisable at July 31 are as follows:

2000	1,162,500
2001	3,182,000
2002	4,685,659

During the years ended July 31, 2002, 2001 and 2000, no amount was charged to compensation expense with respect to options granted to employees and directors of the Company.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 12 - Stock Based Compensation (Continued):**

**Stock Option Plans (Continued):**

Had compensation cost for the Company's options granted to employees been determined consistent with SFAS 123, the Company's net loss available to common stockholders and loss per share would be affected as follows:

	For the Years Ended July 31,		
	2002	2001	2000
<b>Net Loss Available to Common Stockholders:</b>			
As reported	\$ 14,413,934	\$ 27,097,210	\$ 8,841,047
Pro forma	\$ 17,191,333	\$ 31,755,510	\$ 17,230,637
<b>Loss Per Share:</b>			
As reported	\$ (.70)	\$ (1.44)	\$ (.58)
Pro forma	\$ (.83)	\$ (1.69)	\$ (1.13)

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, 2002	1.74%	4.81	.9641	--
July 31, 2001	4.66%	4.25	.9332	--
July 31, 2000	4.85%	4.98	.6200	--

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, 2002, 2001 and 2000 was \$4.33, \$4.12 and \$3.22 per share, respectively.

**Note 13 - Net Loss Per Share:**

Basic EPS and Diluted EPS for the years ended July 31, 2002, 2001 and 2000 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, representing approximately 8,771,934 incremental shares, have been excluded from the computation of Diluted EPS as they are antidilutive due to the losses generated in each year.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 14 - Supplemental Disclosure of Cash Flow Information:**

	For the Years Ended July 31,		
	2002	2001	2000
Cash paid during the year for:			
Interest	\$ 64,310	\$ 77,230	\$ 73,687
Income taxes	--	--	--
Disclosure of non-cash investing and financing activities:			
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
Year Ended July 31, 2000			
Long-term debt was assumed in conjunction with acquisition of property			\$ 186,805
Long-term debt was refinanced with new long-term debt			\$ 541,200
Amounts due from related parties were transferred in conjunction with the assumption of amounts due to related parties			\$ 159,022

**Note 15 - Segment Information:**

The Company follows Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information: (SFAS 131). SFAS 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 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 15 - Segment Information (Continued):**

The regions in which the Company had identifiable assets and operating losses are presented in the following table. 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.

	Identifiable Assets	Operating Loss
<b>2002</b>		
General Corporate	\$ 22,575,641	\$ 6,252,134
Canada	5,585,107	8,248,622
United States	--	--
Bermuda	--	29,690
<b>Total</b>	<b>\$ 28,160,748</b>	<b>\$ 14,530,446</b>
<b>2001</b>		
General Corporate	\$ 38,227,315	\$ 11,768,696
Canada	38,227,315	19,668,843
United States	--	--
Bermuda	--	--
<b>Total</b>	<b>\$ 42,665,873</b>	<b>\$ 31,437,539</b>
<b>2000</b>		
General Corporate	\$ 7,314,834	\$ 4,741,225
Canada	3,026,436	4,302,731
United States	--	--
<b>Total</b>	<b>\$ 10,341,270</b>	<b>\$ 9,043,956</b>

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Note 16 - Collaborative Agreements:**

On January 16, 2001, the Company 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"). 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.

The Company applied the \$12,015,000 that it received from EIS for the shares of the Company's Series A Preferred Stock (see Notes 10 and 17) 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% 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% equity ownership interest in Generex Bermuda. The Series A preferred stock has an exchange feature which allows EIS to acquire an additional 30.1% equity ownership interest in Generex Bermuda. As of July 31, 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 year ended July 31, 2002, Generex Bermuda continued to incur research and development and operational expenses in conjunction with the joint venture's operations.

**Note 17 - 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 the control of the Company. 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The reclassification as of July 31, 2001, had the following effects:

	As Previously Reported	As Restated
<b>Series A Preferred stock</b>		
Stockholders' Equity:	\$ --	\$ 12,015,000
Series A Preferred stock	1	--
Special Voting Rights preferred stock	1	1
Common stock	20,681	20,681
Additional paid in capital	88,776,859	76,761,860
Notes receivable - common stock	(314,300)	(314,300)
Accumulated deficit	(48,913,935)	(48,913,935)
Accumulated other comprehensive loss	(246,867)	(246,867)
<b>Total Stockholders' Equity</b>	<b>\$ 39,322,440</b>	<b>\$ 27,307,440</b>

**Note 18 - Subsequent Events:**

On August 7, 2002, the Company purchased additional real estate property for investment purposes. The total purchase price paid was approximately \$1,525,000 US and the property is currently being leased to third parties.

Subsequent to the year-end, Promissory Notes receivable from the officers of the Company were redeemed pursuant to the Stock Pledge Agreement with the officers and a guaranteeing party. The outstanding balance of \$1,121,939 was repaid with 592,716 shares of common stock, as determined by the Compensation Committee. These shares effectively became treasury stock.

Included in Deposits is \$100,000 paid to an unrelated company for the right to exclusive negotiations for the formation of a future business relationship. An additional payment of \$50,000 was made subsequent to year-end. While the exclusivity period has subsequently expired, the negotiations are still ongoing and the structure of any future relationship is still undetermined. The deposit is non-refundable and the exact future benefit of this deposit cannot be estimated at this time.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Not applicable.

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PART III

The information required by Item 10 "Directors and Executive Officers of the Registrant"; Item 11 "Executive Compensation"; Item 12 "Security Ownership of Certain Beneficial Owners and Management"; and Item 13 "Certain Relationships and Related Transactions" will be provided in 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.

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PART IV

**Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K.**

(a) Exhibits

Exhibit No.	Description
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 herein 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.; Novelty 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.; Novelty 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.; Novelty 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.
- 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.
- 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 Report on Form 8-K dated January 16, 2002 and filed with the Commission on May 3, 2002 (May 2002 8-K) 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 May 2002 8-K 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 2002 8-K is incorporated herein by reference.
- 21 Subsidiaries of the Registrant.\*
- 23.1 Consent of Deloitte & Touche LLP, independent auditors.\*
- 23.2 Consent of WithumSmith+Brown, independent auditors.\*
- 24 Powers of Attorney, filed as Exhibit 24 to our 2001 10-K.
- 99.1 Certification 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.

(b) Reports on Form 8- K

The following Reports on Form 8-K were filed during the last quarter of the fiscal year:

- 1. Report on Form 8-K, filed with the Commission on May 3, 2002, requesting confidential treatment for the 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.; the Amended and Restated License Agreement dated January 15, 2002, between Elan Corporation, plc and Generex (Bermuda), Ltd.; and the Amended and Restated License Agreement dated January 15, 2002, between Generex Biotechnology Corporation and Generex (Bermuda), Ltd.

## 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 12th day of November, 2002.

### GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin

Anna E. Gluskin, President

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/ Gerald Bernstein</u> Gerald Bernstein	Director	November 12, 2002
<u>/s/ Anna E. Gluskin</u> Anna E. Gluskin	President and Chief Executive Officer	November 12, 2002
<u>/s/ Rose C. Perri</u> Rose C. Perri	Secretary, Treasurer Chief Operating Officer	November 12, 2002
<u>/s/ Pankaj Modi</u> Pankaj Modi	Vice President of Research and Development	November 12, 2002
<u>/s/ Michael Hawke</u> Michael Hawke	Director	November 12, 2002
<u>/s/ Peter Levitch</u> Peter Levitch	Director	November 12, 2002
<u>/s/ Jan Michael Rosen</u> Jan Michael Rosen	Director	November 12, 2002

## CERTIFICATIONS

I, Anna E. Gluskin, Chief Executive Officer and President of GenereX Biotechnology Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of GenereX Biotechnology Corporation;
2. Based on my knowledge, this annual 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 annual report; and
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report.

DATE: November 8, 2002

By: /s/ Anna E. Gluskin

**Anna E. Gluskin, Chief Executive Officer**  
(Principal Executive Officer)

I, Rose C. Perri, Chief Operating Officer (Principal Financial Officer) of GenereX Biotechnology Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of GenereX Biotechnology Corporation;
2. Based on my knowledge, this annual 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 annual report; and
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report.

DATE: November 8, 2002

By: /s/ Rose C. Perri

**Rose C. Perri, Chief Operating Officer**  
(Principal Financial and Accounting Officer)

## SUBSIDIARIES OF GENEREX BIOTECHNOLOGY CORPORATION

<u>Name</u>	<u>Place of Incorporation</u>
Generex Pharmaceuticals, Inc.	Ontario, Canada
Generex (Bermuda), Inc.	Bermuda

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

All subsidiaries conduct business only under their respective corporate names.

INDEPENDENT AUDITORS' CONSENT

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, 2002.

/s/ DELOITTE & TOUCHE LLP

DELOITTE & TOUCHE LLP

Toronto, Ontario

October 29, 2002

## CONSENT OF INDEPENDENT AUDITORS

The Annual Report of GenereX Biotechnology Corporation and Subsidiaries (the Company) for its fiscal year ended July 31, 2002, includes our report dated September 14, 2000, on the consolidated financial statements of the Company as of July 31, 2000 and for the years then ended. We consent to the incorporation by reference of our report on such consolidated financial statements in the following registration statements of the Company on Form S-3: registration numbers 333-67118, 333-51194, and 333-42452.

/s/ WithumSmith+Brown

New Brunswick, New Jersey

October 29, 2002

**CERTIFICATION (1)**

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 GenereX 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, 2002, and to which this Certification is attached as Exhibit 99.1 (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

DATE: November 13, 2002

By: /s/ Anna E. Gluskin

**Anna E. Gluskin, Chief Executive Officer**  
(Principal Executive Officer)

DATE: November 13, 2002

By: /s/ Rose C. Perri

**Rose C. Perri, Chief Operating Officer**  
(Principal Financial and Accounting Officer)

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(1) THIS CERTIFICATION ACCOMPANIES THIS REPORT PURSUANT TO SS. 906 OF THE SARBANES-OXLEY ACT OF 2002 AND SHALL NOT BE DEEMED "FILED" BY THE COMPANY FOR PURPOSES OF SECTION 18 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.



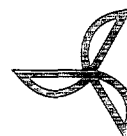


33 HARBOUR SQUARE SUITE 202 TORONTO CANADA M5J 2G2

P 416.364.2551

F 416.364.9363

[WWW.GENEREX.COM](http://WWW.GENEREX.COM)



33 Harbour Street  
Suite 202  
Toronto, Ontario, Canada, M5J 2G2  
800.391.6755

[www.generex.com](http://www.generex.com)