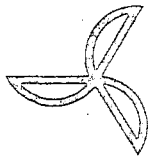
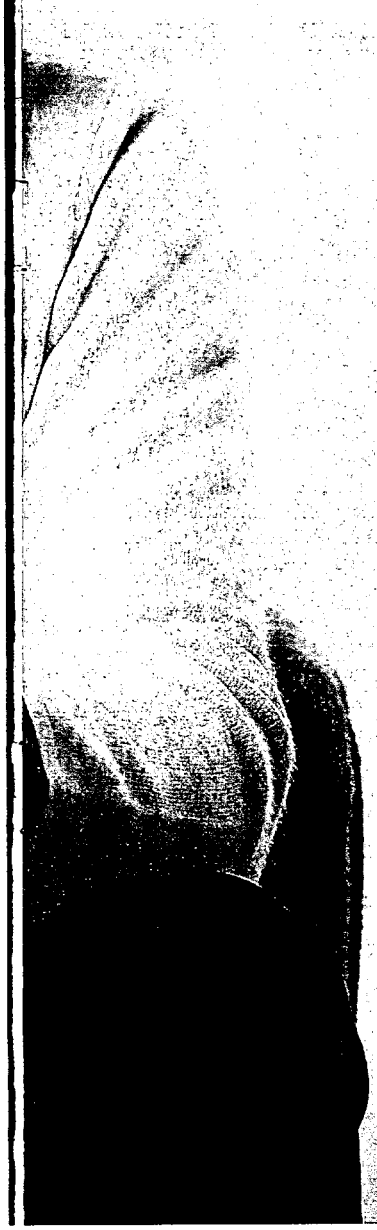
2001 | ANNUAL REPORT



Generex Biotechnology

looking forward

Generex is developing new methods for pain-free drug delivery

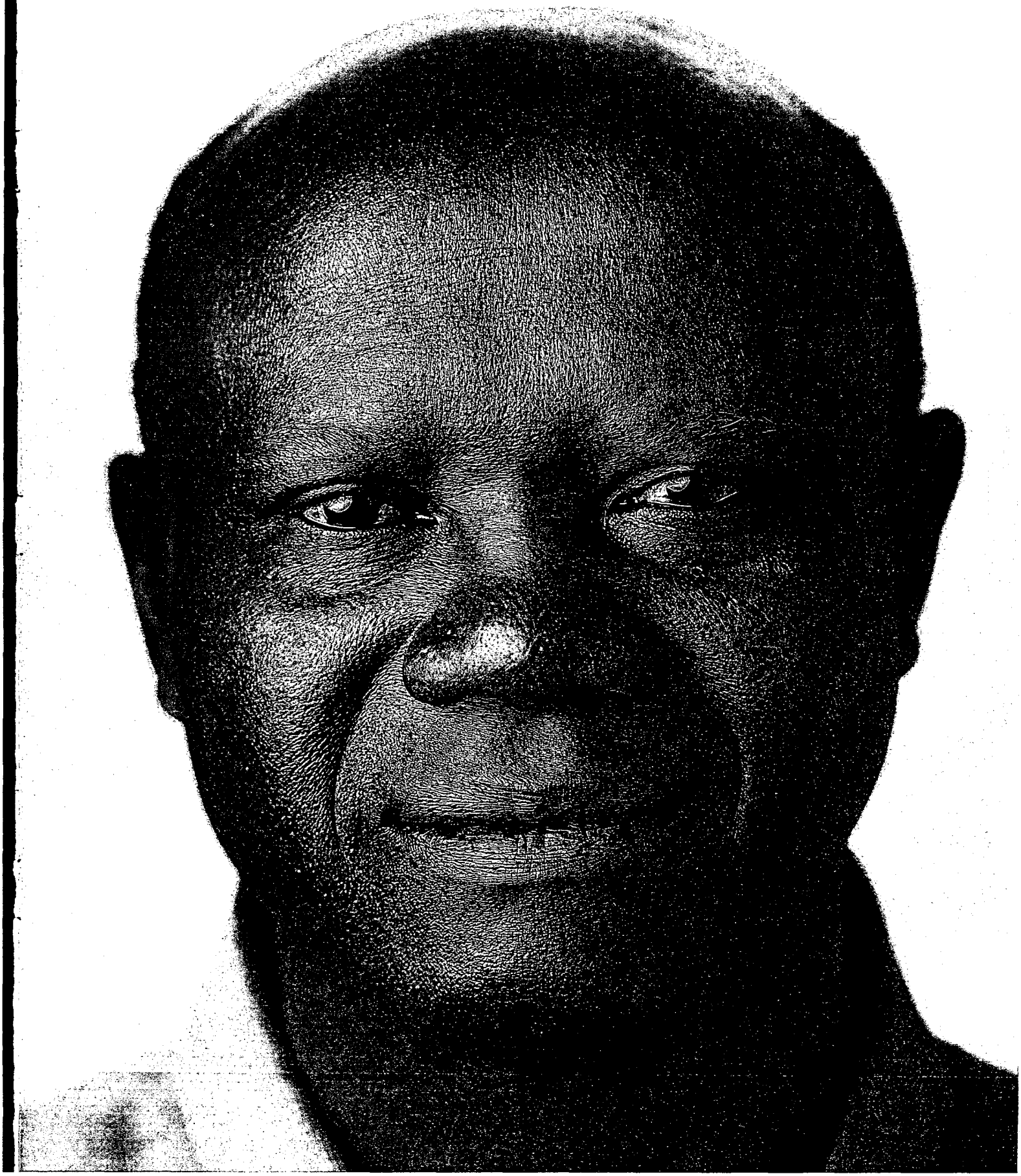


Our goal—improved quality of life for people who currently depend on regular, painful injections to maintain their health.

We've developed a platform technology that we believe has the potential to revolutionize the way many large-molecule drugs are delivered. Now we're in the process of testing and refining that technology. As a first application, we're developing Oralin™, a unique oral insulin formulation for the treatment of diabetes.

diabetes: the medical context

Currently there are about 150 million people worldwide with some form of diabetes. That number will probably double by 2025. According to the World Health Organization (WHO), those are conservative estimates.



"DIABETES IS NOW EMERGING AS THE NEW PANDEMIC OF THE 21ST CENTURY."—WORLD HEALTH ORGANIZATION, 2001

diabetes statistics

- 2,200 Americans are diagnosed with diabetes every day
- An estimated 15.7 million people have diabetes in the U.S.A., 10.3 million cases are currently diagnosed
- Diabetes is the 7th leading cause of death in the U.S.A.
- 2 million Canadians have diabetes
- The medical costs incurred by a person with diabetes are two to five times higher than those of a person without diabetes
- The financial burden of diabetes will double in ten years
- Diabetes management can delay or prevent the long-term complications of diabetes: blindness, kidney failure, heart disease, nerve damage, and amputation
- All type 1 diabetics and up to 30 percent of type 2 diabetics use insulin to help control their condition

The increasing incidence of diabetes poses an enormous challenge for society, and for the medical community in particular. Though there's a widespread public perception that diabetes is a straightforward condition that can be well controlled, the reality is more problematic.

Diabetes often leads to serious, sometimes deadly, complications. These complications put a significant strain on health care systems. Statistics gathered by the WHO indicate that treatment of diabetes-related illnesses accounts for four to five percent of health budgets. That's $9 billion annually in Canada. In the US, the direct cost of diabetes treatment is $44 billion a year, with an additional $54 billion in indirect costs, for a total economic impact of $98 billion.

Research has shown that the complications of diabetes are significantly diminished when blood sugar levels are carefully controlled. Unfortunately, achieving that control is proving to be a formidable goal. Why is diabetes so difficult to manage? How can we do better?

It's the doctor's role to establish guidelines for diabetes control that are appropriate for each patient, but the day-to-day management of diabetes rests in the hands of the person who has the disease, and it can be difficult to maintain the high levels of attentiveness and discipline required. In fact, non-compliance with treatment recommendations is a major issue in diabetes management.

Insulin injections are a necessity for all people with type 1 diabetes, and for many people with type 2 diabetes. These injections, required as often as five times a day, can be intrusive. People who dislike needles have a built-in deterrent against taking their insulin. Others skip injections in inconvenient situations or when they are forced to acknowledge their diabetes publicly. For some young children and seniors, insulin injections are traumatic.

Today, health care professionals are emphasizing the importance of education and support in diabetes management. We know, for instance, that diabetics who can count on supportive family members are more likely to follow recommendations about diet, exercise, and medication.

At Generex, we're doing our part by pursuing the development of a convenient, painless alternative to the injection of insulin. We've created a technology that delivers insulin in the form of an oral spray. Our RapidMist™ device administers a proprietary formulation of insulin called Oralin, which can be quickly absorbed through the walls of the cheeks and into the bloodstream.

By eliminating the pain of injections and making it easier to take insulin, our technology could remove one obstacle to successful diabetes management.

diabetes: the human context

Behind the facts and statistics, the demographics and trends, there are real people with diabetes, who live with the disease every day. Their experience of diabetes is very different from the clinical perspective of doctors and researchers.

Al Baudner learned he had type 1 diabetes when he was twelve years old. His mother, a nurse, recognized the telltale symptoms, thereby ensuring a timely diagnosis. Thirty-five years later, Al understands diabetes as well as anyone, and by necessity has become an expert in the practicalities of diabetes management.

"New technology such as Generex's oral insulin spray and RapidMist device could eliminate or dramatically reduce the need for injections."

There's a genetic component to diabetes—Al's condition, for example, can be traced back to his father's aunt. Even knowing this, Al was still taken by surprise when, three years ago, within the space of a week, two of his three children were also diagnosed with type 1 diabetes. Sarah was 10 at the time, Jordan 7. "It's a big shock in the beginning, but it gets better," Sarah explains. "A girl in our school just got diagnosed. She came to me and said, 'It's horrible! All those needles! Do your fingers hurt? Are you sore?' I find that you are, but you kind of get used to it."

"Getting used to it" means incorporating insulin injections into the routines of daily life, as Al has. Three or four times a day, Al "cocktails" a mixture of rapid acting and slow acting insulin into a disposable syringe. Then it's simply a matter of doing the injection—for Al, the abdomen and legs are favourite sites. "Yes, there's some discomfort to it," he says, "but it's not such a big deal."

Al, Sarah, and Jordan share a matter-of-fact attitude about diabetes management, and a healthy sense of humour. For example, like many parents, Al occasionally has to "encourage" his children to get up in the morning. But in the Baudner household, there's an extra twist—the first blood sugar level check of the day, administered by Dad. "Sometimes even that isn't enough to wake them up," Al says. Though he and his wife Sylvia help the kids interpret their blood sugar levels, both Sarah and Jordan do their own injections now. Most often they use an insulin pen, an injection device that makes it easy to adjust insulin dosages.

Monitoring blood sugar levels at school has proved to be problematic. At first, Sarah and Jordan would check their blood sugar before lunch in the company of an adult from the school. Unfortunately, these caregivers would become alarmed when readings fell slightly outside normal parameters. "They would see a blood sugar level and they wouldn't know what it meant. It wasn't accomplishing anything—it just made Sarah and Jordan feel isolated and different." So now the second check of the day comes at 3:15 p.m., and is followed by other checks at dinner and bedtime. As a way of underscoring the importance of good diabetes management, Al, Sarah, and Jordan often take their final insulin shot of the day together.

Diet and exercise are important aspects of diabetes management. Jordan's a hockey player, Sarah does figure skating and dance, and Al golfs and walks as much as he can. As Sarah points out, being busy makes it hard to stick to a regimented diet. "If you're in a hurry, you don't have time to figure out the number of grapes you can have. You just grab them and go."

SARAH, JORDAN & AL BAUDNER

Listening to the Baudners talk about their condition, it becomes clear that there's an essential paradox to coping with diabetes. Diabetes is both a very small and a very big part of their life. As Jordan says, "There's just a couple of things extra to your day. I mean, how much time does it take, maybe two minutes?" All the same, the three of them realize that failing to control blood sugar levels can have negative effects. Al puts it this way: "We know those consequences can happen. It's not something we like to talk about or think about, but it's something we're definitely aware of."

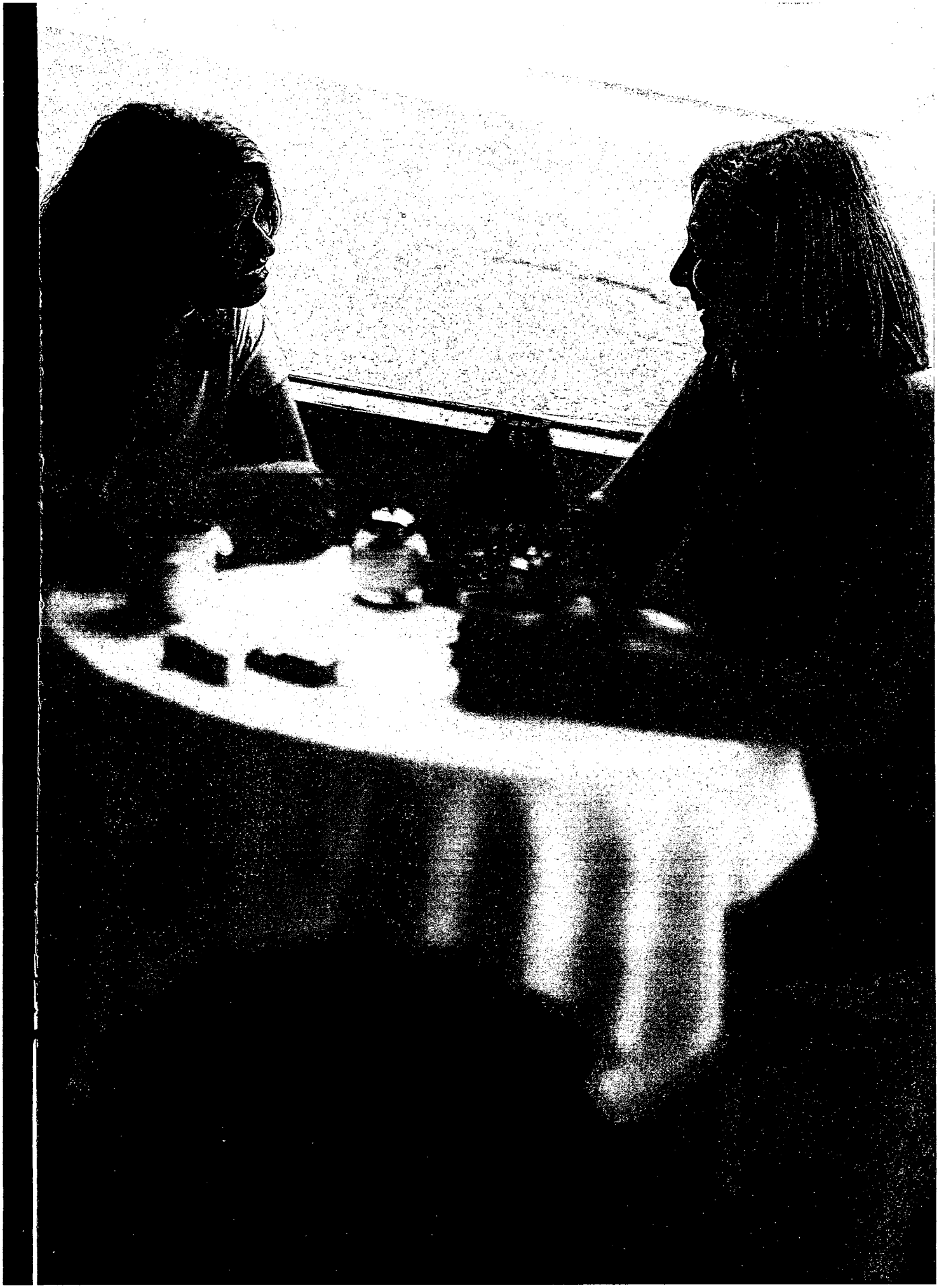
Al's awareness of the necessity of keeping blood sugar levels in range is a crucial factor in his continuing good health. Advances in the technology of diabetes management are also important. "When I was diagnosed, it was glass syringes. There weren't any disposable syringes available. You had to boil them and keep them in alcohol. There was no blood monitoring system available. It was strictly through your urine. You'd pee on a stick and the stick would change colour—it was very inaccurate."

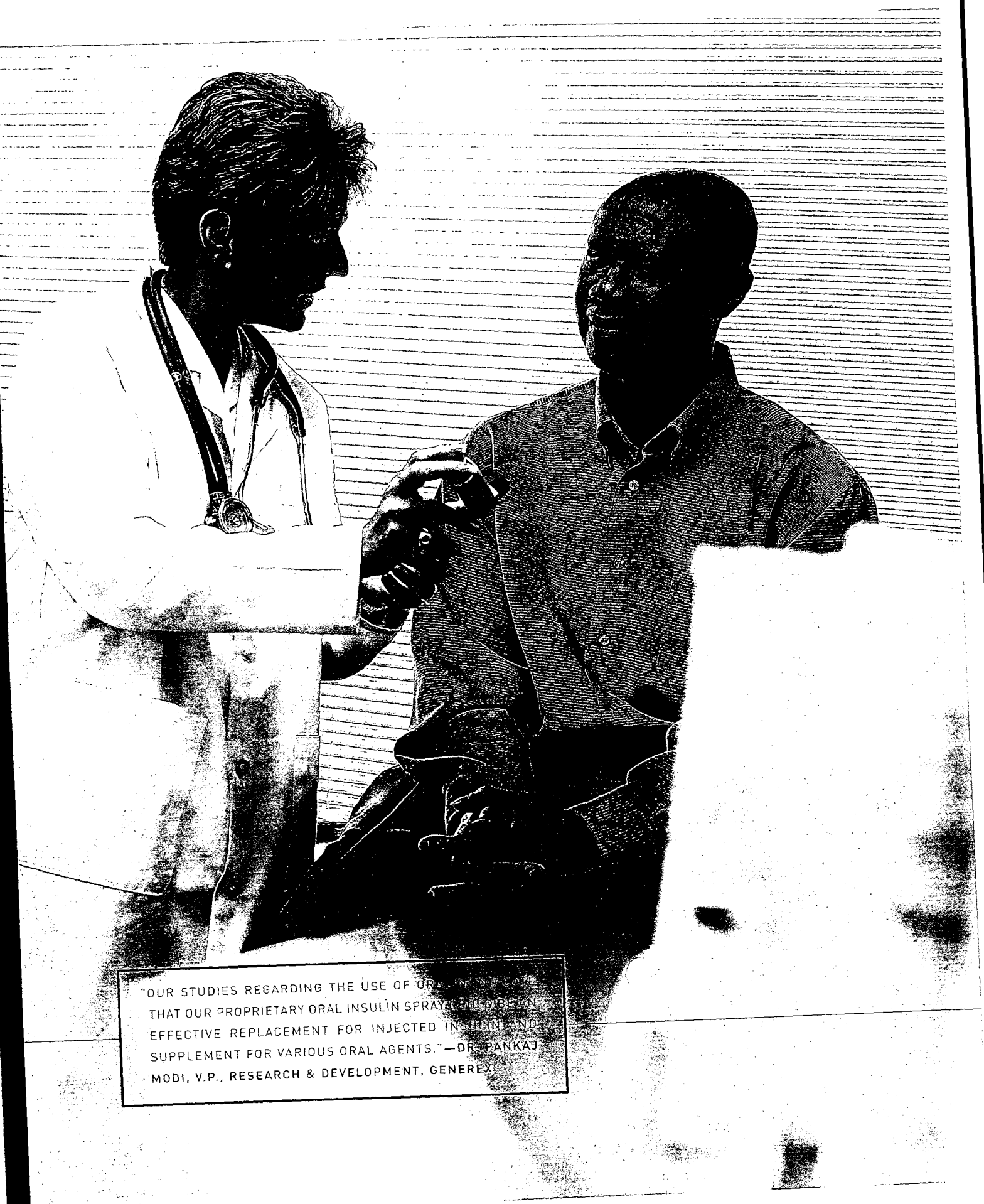
Al, Sarah, and Jordan have clear ideas about changes that would make it easier to live with diabetes. Not surprisingly, a cure for the disease is first on their list. They'd also appreciate increased awareness and fewer misconceptions about what diabetes is and what people with diabetes can eat. And they're looking forward to improvements in the way that insulin is administered. New technology such as Generex's oral insulin spray and RapidMist device could eliminate or dramatically reduce the need for injections. At work, Al would no longer have to head to the washroom to administer his insulin; he could take it in his office at the same time that he checks his blood sugar. And Sarah is quick to see the advantages from a teenager's viewpoint: "It would be a lot more convenient. Even if you were at a movie, you could just do it there. You can't really pull out your syringe in public like that." None of them would miss the discomfort of injections, either.

In the end, what's it like to live with diabetes? "Not to make light of it," Al says, "but to me, it's like brushing my teeth. I'll just continue to brush and do the best I can to keep my blood sugar in range. I guess there's more I could do, but there's a lot more everyone can do to stay healthy, not just people with diabetes. I've lived an absolutely normal life, I think. Diabetes hasn't changed anything I did or wanted to do. It just hasn't. All the same, having an easier way to take insulin would make a real difference."

innovation: oral insulin spray

Obviously the primary goal of diabetes research is to find a cure. While there are some promising new directions, an outright cure for diabetes appears to be many years away. At Generex, we're focusing our research on another important goal—making diabetes management easier.





"OUR STUDIES REGARDING THE USE OF ORAL INSULIN [illegible] THAT OUR PROPRIETARY ORAL INSULIN SPRAY COULD BE AN EFFECTIVE REPLACEMENT FOR INJECTED INSULIN AND A SUPPLEMENT FOR VARIOUS ORAL AGENTS."—DR. PANKAJ MODI, V.P., RESEARCH & DEVELOPMENT, GENEREX

Improving the efficacy of diabetes management is good for all of us. The Diabetes Control and Complications Trial (DCCT) conclusively demonstrated the benefits of intensive blood sugar management. If we can make it easier for people with diabetes to control their blood sugar levels, they'll be less likely to develop debilitating health complications. That in turn will mean a significant reduction in the costs associated with diabetes, helping us to avert a looming health care emergency.

More importantly, making diabetes management easier is a way of helping people improve their quality of life. Studies indicate that the majority of people with diabetes are not achieving recommended therapy levels. Research that's successful in finding a better way of administering insulin could have an immediate and direct impact on millions of lives. In the short term, there would be less inconvenience, less anxiety, less pain associated with the taking of insulin. In the long term, people with diabetes would be less likely to face extreme interventions such as eye surgery, dialysis, and amputation.

The Oralin Advantage:
A New Way To Take Insulin

Through our research, we're pursuing an innovative approach to the delivery of insulin. We are developing Oralin, a proprietary insulin formulation specially engineered to be delivered directly into the mouth via our RapidMist device. On contact with the buccal mucosa (the mucous membranes that line the inner walls of the cheek), Oralin is rapidly absorbed into the bloodstream and our studies indicate that it has the same effect as insulin that's injected.

Oralin is designed for the treatment of both type 1 and type 2 diabetes. Using Oralin, it is our hope that people with diabetes can continue to self-administer the insulin doses they need to manage their blood sugar levels—but without needles and without pain.

Generex's oral insulin formulation, by making it more convenient and less stressful for people with diabetes to take the insulin they need, could have a significant impact on the success of diabetes management.

Until there's a cure, we'll continue to seek the most convenient and pain-free methods for insulin delivery that research can provide.

Research Pays Dividends

We've been conducting research on buccally absorbed insulin formulations since 1998. Our studies to date have followed a standard clinical path, and have included animal trials, trials in healthy volunteers, and trials in people with type 1 and type 2 diabetes. The results have been strongly positive.

In 2001, we took these results to a broader audience. Generex has made several key presentations of clinical data this year, including appearances at the annual meetings of the American Diabetes Association (June), the European Association for the Study of Diabetes (September), and the Canadian Diabetes Association (October).

Our studies have indicated that Oralin may be used safely and effectively in place of injected insulin to treat Type-1 and Type-2 diabetes. Here are some of the main findings:

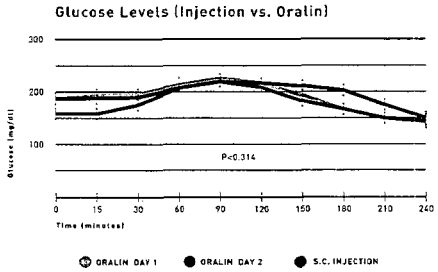
- There are no statistically significant differences between Oralin and subcutaneous insulin injections in terms of post-prandial glucose control, rise in plasma insulin levels and the suppression of C-peptide levels after a standard Sustacal meal challenge

- Oralin can be safely used in combination with metformin to control meal-related glucose levels

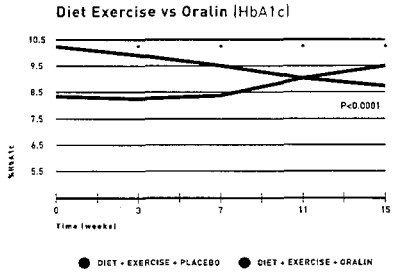
- Oralin can be safely used in combination with pioglitazone to significantly improve HbA1c levels compared to the baseline group receiving pioglitazone alone

- Oralin can be used in diet and exercise failure patients to improve HbA1c levels and achieve better control of glucose levels

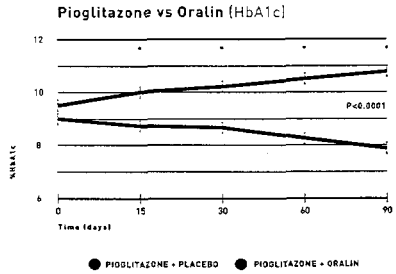
- Oralin can be used effectively with failing oral agents as an add-on therapy to achieve better control on meal-related in glucose levels



ORALIN EFFECTIVELY LOWERS BLOOD GLUCOSE LEVELS AFTER MEALS



ORALIN CAN BE USED IN DIET AND EXERCISE FAILURE PATIENTS TO IMPROVE HbA1c LEVELS



ORALIN CAN BE USED IN COMBINATION WITH PIOGLITAZONE TO SIGNIFICANTLY IMPROVE HbA1c LEVELS

Research and innovation pay dividends—dividends such as recognition and opportunity. Our achievements in the past year are a perfect example. Thanks to the early successes we've enjoyed in our development of alternative methods of drug delivery, we've been able to establish alliances with two world leaders in the pharmaceutical sector—Eli Lilly and Company and Elan Corporation, plc.

For Generex, these are landmark agreements that point the way to an exciting period of growth. Our partnership with Lilly ensures the best possible foundation for the development and future commercialization of our oral insulin formulation. And working with Elan holds the promise of new directions in our research—pursuit of additional buccally delivered formulations of large-molecule drugs.

Partnering

Eli Lilly and Company

In September 2000, Generex Biotechnology and Eli Lilly and Company announced an agreement to develop a buccal formulation of insulin that is administered as a fine spray into the oral cavity using Generex proprietary technology. Under the terms of the agreement, Lilly is responsible for conducting further clinical trials, securing regulatory approvals, and subsequent worldwide marketing of the product. Research and development is actively proceeding under the agreement.

Lilly has been a leader in diabetes care for more than 80 years. In fact, Lilly's know-how led to a breakthrough in the mass production of insulin in the early 1920s, helping to make the drug available to millions of people with diabetes. The company continues to aggressively pursue the goal of being a complete diabetes-care company and intends to provide innovative products to treat all types, stages, and complications of the disease.

Elan Corporation, plc

In January 2001, Generex and Elan, agreed to collaborate on the application of their proprietary drug delivery technologies to pharmaceutical products for the treatment of a variety of conditions.

Elan Corporation, plc is a leading worldwide, fully integrated biopharmaceutical company headquartered in Ireland, with its principal research, development, manufacturing and marketing facilities located in Ireland, the United States and the United Kingdom. Elan is focused on the marketing of therapeutic products and services in neurology, pain management, oncology, infectious disease and dermatology and on the development and commercialization of products using its extensive range of proprietary drug delivery technologies.

"We believe buccal delivery of drugs represents a tremendous opportunity as it will, in our opinion, enhance patient compliance and offer less potential side effects than other drug delivery systems."
— Ivan Lieberburg, Chief Scientific and Medical Officer, Elan

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turning possibility into reality

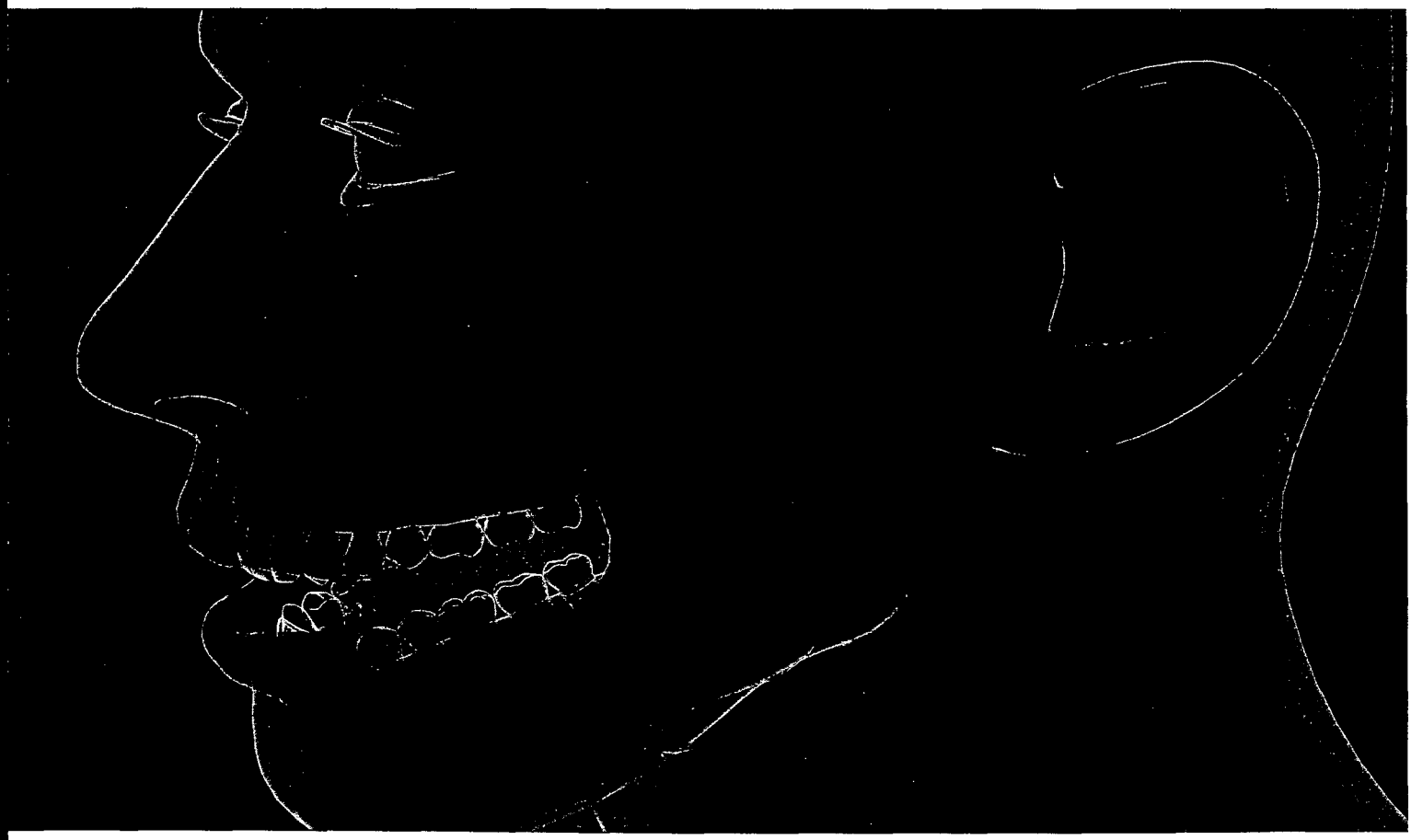
Oralin is just the first application of our innovative research. Our mission as a company goes beyond one disease and one medication. We're aiming to find pain-free, accurate, and safe alternatives for the delivery of large-molecule drugs of all kinds.

A New Approach

We're focusing on an alternative drug delivery approach that is both medically effective and competitively advantageous: buccal delivery.

The mucous membranes on the inside of the cheeks (called the buccal mucosa) offer a near ideal, noninvasive portal through which large-molecule drugs might enter the body. The large surface area of the buccal mucosa provides direct access to a rich network of blood vessels, offering the potential of rapid absorption of medications into the circulatory system. Using this route, drugs avoid the gastrointestinal system and other hostile environments.

Typically, large molecules cannot travel through the buccal mucosa. But using our innovative platform technology, we're unlocking the secret of buccal delivery.



A New Technology

Generex's platform technology consists of pharmaceutical agents, a unique proprietary liquid formulation, and the compact RapidMist device, which administers the formulation as a metered-dose spray.

The pharmaceutical agents are the large-molecule medications targeted for delivery. Insulin is the first pharmaceutical agent in our product pipeline. Our proprietary formulation is a liquid that contains the pharmaceutical agent plus a number of enhancers. The enhancers are the key. Enhancers are surface-active compounds, called surfactants. Under certain conditions, a surfactant assumes a micelle structure—a protective shell that can be used to surround a large molecule. The micelle carries the target molecule through cell membranes and even through cell walls.

A relatively small concentration of surfactant not only allows a drug to traverse mucous membranes rapidly, but it also increases both the solubility and the stability of the drug, which makes it possible to achieve therapeutic levels of the drug in blood plasma.

Our unique combination of enhancers allows us to deliver insulin as an oral spray that's absorbed through the buccal mucosa—a breakthrough that no other drug-delivery company has attained.

Common Drug Delivery Routes

1. Drugs administered buccally are absorbed through the mucous membranes lining the inside of the cheeks.

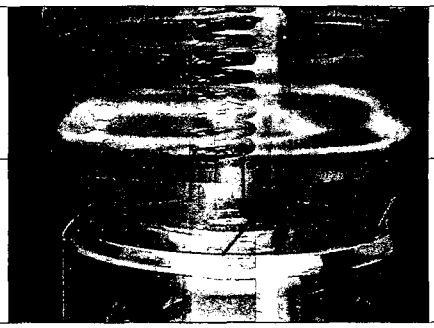
2. Drugs administered orally are taken as a tablet or capsule and absorbed from the gastrointestinal tract.

3. Drugs administered by injection (also called parenteral administration) are absorbed through subcutaneous or muscular tissue, or are delivered directly into the bloodstream.

4. Drugs administered by inhalation are absorbed from the alveoli within the lungs.

5. Drugs administered transdermally are absorbed through the skin.

THE ACTUATOR OF THE RAPIDMIST DEVICE



What is a large-molecule drug?

A large-molecule drug has a polymeric chain structure, giving it a comparatively large molecular weight.

Why are large-molecule drugs important?

Medications based on large molecules are increasingly crucial to the treatment of many diseases and conditions. In fact, large-molecule biopharmaceutical products—including proteins, peptides, hormones, vaccines, and nucleic acids—are sometimes referred to as "next generation" medicines.

How are large-molecule drugs typically administered?

Large-molecule drugs are poorly absorbed through the epithelial membranes, easily destroyed by gastrointestinal acids and enzymes, and relatively insoluble. They are therefore usually introduced into the body via injection.

Why seek alternative delivery methods for large-molecule drugs?

Finding new ways of administering large-molecule drugs, such as Generex's buccal delivery technology, will improve the quality of life for people who require frequent injections. There's an excellent business opportunity, as well. In 1998, the world-wide market for recombinant large-molecule drugs was US$14.1 billion; growth was pegged at 27% in 1997–98.

Generex's RapidMist device is specially engineered to propel metered doses of our formulation into the oral cavity as a fast-moving, aqueous spray. The device is compact, discreet, and easy to use. Most importantly, it delivers medications accurately and reliably. Though our RapidMist device looks like a typical metered-dose inhaler, there's an important difference. An inhaler delivers drugs into the lungs. Our RapidMist device targets the mouth, not the lungs. The modified actuator optimizes the dispersal pattern of the spray for maximum impact with the oral cavity. The spray strikes the buccal mucosa at high velocity (approximately 100 mph) to encourage absorption. Additionally, the actuator creates droplets that are the ideal size for absorption through the buccal mucosa, but too large for entry into the lungs.

Buccal Delivery vs. Inhalation

Although our approach utilizes an aerosol spray that's propelled into the mouth by an inhaler-like device, buccal delivery is not the same as inhalation.

With inhalation techniques, insulin is delivered as a fine powder that is inhaled into the small airways in the deep lung. The powder then dissolves in the fluid layer of the lung and is absorbed into the circulatory system.

Buccal delivery involves the absorption of medication through the mucous membranes that line the inner walls of the cheeks. The medication is not inhaled and never reaches the lungs. This is an important distinction, because some research has linked the inhalation of insulin with potentially dangerous side effects. This could lead to significant long-term risks for patients who need insulin every day.

In the development of any new pharmaceutical product, patient safety is paramount.

- We have worked to ensure that our buccal drug delivery technology avoids the lungs without damaging the buccal mucosa.

- A gamma-scintigraphy study indicates that there is no lung deposition associated with buccal administration of Oralin. The study illustrates that the droplet-size distribution of the formulation is too large to enter the deep lung region, and that the deposition of the formulation is located in the mouth, oropharynx, and the GI areas.

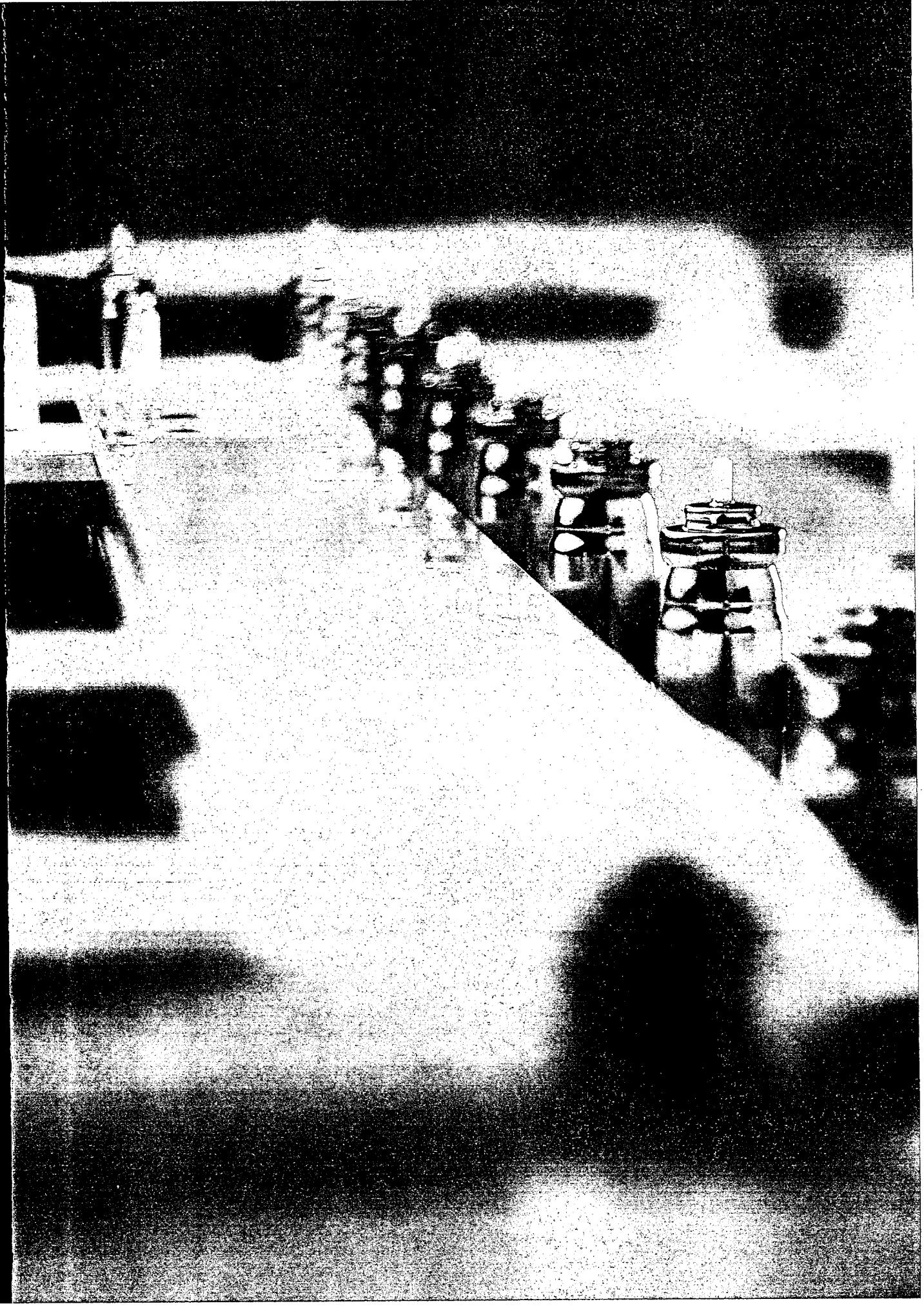
- A long-term toxicology study (sixteen months) of forty dogs indicates that buccal delivery of Oralin is safe. There was no damage to the tissues inside the dogs' mouths, and all blood counts and biochemical profiles revealed no significant changes to the parameters measured.

Looking Beyond

We're working to identify the best target molecules for our product pipeline. We'll be focusing on the therapeutic agents (either proven or late-stage) for which there are the greatest need and fit with our technology. And we'll continue with our strategy of exploring collaborative opportunities for undertaking the development and commercialization of new products.

positioning for growth

We're enhancing our ability to explore the potential of our platform technology through timely research and development. We're readying ourselves to meet anticipated production needs. And we're positioning ourselves for growth so we'll be able to pursue new applications aggressively as they arise.



clinical studies

Long-Term Safety and Toxicology Study of Oralin

- 16-month double blind study involving 40 dogs
- conducted by Dr. Dana Allen, DVM, MSc., Diplomate ACVIM (Internal Medicine), Professor at the University of Guelph, Ontario Veterinary College in Guelph, Ontario, Canada
- designed to examine and report on oral cavity epithelial cell cytology (changes in buccal cavity membrane), and hematological and biochemical changes
- tests included regular (every two months) cylogical examinations of the oral cavity; plus a blood count, biochemical profile (including serum electrolytes), urine analysis, electrocadiogram, and arterial blood pressure at months 6 and 12
- no changes in the epithelial cells of the mouth; no evidence of toxic injury

"All of the dogs accepted the daily administration of the oral spray readily without evidence of aversion or adverse effects. The dogs are bright and alert, eating well, and are maintaining a good body weight." – Dr. Dana Allen

Deposition of Oralin

- in-vitro and in-vivo study using radio-labeled Oralin and gamma-scintigraphy
- conducted by Pharmaceutical Profiles, Ltd. of the United Kingdom
- designed to establish quantitative mouth deposition and the area of deposition for the Oralin spray formulation
- tests included in-vitro experiments using an artificial lung simulator (Anderson 8-stage Cascade Impactor), plus in-vivo human experiments using a radio-labeled Oralin spray formulation
- the in-vitro study determined that the droplets of the Oralin spray formulation were too large (greater than 7 microns) to enter the deep lung regions
- the in-vivo study determined that deposition was located in the mouth, oropharynx, and the GI areas; no lung deposition was observed

"These studies provide further confirmation that our unique buccal delivery technology will offer a safe way to administer drugs, without the risk to the lungs posed by competing delivery technologies." – Anna Gluskin, President and CEO, Generex

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Scientific Presentations

Generex has presented its research at the most prestigious Diabetes Meetings and Conferences globally

- Seven Research Studies at the American Diabetes Association 61st Scientific Sessions
- Four Research Studies at 37th Annual Meeting of European Association for The Study of Diabetes (EASD)
- Six Research Studies at the 5th Annual Canadian Diabetes Association/Canadian Society of Endocrinology and Metabolism Professional Conference

The Frost & Sullivan Market Engineering Product Differentiation Innovation Award

In May 2001, we were honored to receive Frost & Sullivan's prestigious 2001 Product Differentiation Innovation Award for our platform technology. This award is bestowed to companies that demonstrate the ability to develop or advance products that are more innovative than those of their competitors. Award recipients must meet specific criteria, such as degree of differentiation innovation and benefit to end users.

In granting the award, Frost & Sullivan made these important observations: "The alternate routes of insulin delivery are associated with substantial scope. Taking into account the potential, as many as three companies are developing inhalable insulin. The competition is expected to be fierce among these companies. Generex, however, has taken an alternate route (buccal delivery) in order to differentiate its product from inhalable insulin. This approach is innovative and has shown good results in clinical trials. Their innovative delivery method is expected to lead to fast acceptance of Generex's insulin."

"GENEREX IS ADVANCING A CREATIVE ALTERNATIVE TO INJECTION OF PROTEIN-BASED MEDICINES THROUGH THEIR PROPRIETARY BUCCAL DELIVERY TECHNOLOGY. INITIAL CLINICAL STUDIES WITH INSULIN ARE ENCOURAGING AND FORM A FOUNDATION FOR ADDRESSING TECHNICAL ISSUES PERTINENT TO COMMERCIALIZATION. IN THE LAST YEAR, APPRECIABLE PROGRESS HAS BEEN MADE IN THE DEVELOPMENT OF A ROBUST PHARMACEUTICAL FORMULATION SUITABLE FOR LARGER CLINICAL STUDIES"—RICHARD DIMARCHI, GROUP VICE PRESIDENT, RESEARCH TECHNOLOGIES AND PRODUCT DEVELOPMENT, LILLY

Collaborations

Generex is collaborating with leading global organizations in the pharmaceutical sector.

Generex + Lilly: development of a buccal formulation of insulin, with the option to develop a number of additional products

Lilly

Generex + Elan: application of certain proprietary drug delivery technologies to a number of pharmaceutical products

élan

Supplier Agreements

Our RapidMist device represents years of advancements in aerosol drug delivery technology. We've gone to great lengths to source components that can deliver medications accurately and cost effectively.

PRESSPART: AEROSOL CAN BESPAK: ACTUATOR VALOIS: VALVE SOLVAY: PROPELLANT

New Patents

During 2001, Generex was granted five U.S. patents related to aspects of buccal delivery technology. In addition, one more of our U.S. patent applications was allowed. As a result, the company now holds a total of nine U.S. patents and one allowed U.S. patent application related to aspects of buccal delivery technology. Generex has six more U.S. patent applications pending, including patent applications that, if granted, would cover our core insulin formulation and delivery technology.

New Private Placements

In July 2001, Generex closed two separate private placement transactions that generated gross proceeds of over $11 million. The terms of the two transactions were similar and consisted of the sale of shares of Generex common stock to accredited investors at a price of $9.25 per share. For each share of common stock, investors received a three-year warrant to purchase 0.25 shares of Generex common stock at an exercise price of $10.175 per share.

The company has continued to maintain its customary strong cash position – as of October 31 2001, Generex's balance sheet showed $33 million in cash, cash equivalents and short-term investments.

New Appointments

Ivan Lieberburg, Ph.D., M.D., to Generex's Board of Directors

Dr. Lieberburg is an Executive Vice President and the Chief Scientific and Medical Officer for Elan Corporation, plc, a worldwide pharmaceutical and biotechnology company focused on the development and commercialization of drugs and drug delivery technologies.

Prior to joining Elan in 1987, Dr. Lieberburg held faculty positions at Albert Einstein College of Medicine and Mt. Sinai School of Medicine in New York. Dr. Lieberburg has been an active biomedical researcher for over 25 years, having authored over 100 research publications, and has been awarded a number of honors, including Rockefeller University Fellow, Public Health Corps Scholar, National Research Service Award, Hartford Foundation Scholar, and McKnight Fellow. He received an A.B. in biology from Cornell University, a Ph.D. from the Rockefeller University and an M.D. from the University of Miami. He completed post-doctoral training at the Rockefeller University and the University of California, San Francisco. He carried on with his clinical training also at UCSF, where he presently holds an appointment as Clinical Professor of Medicine. He is board certified by the American College of Physicians in internal medicine and in endocrinology and metabolism.

Gerald Bernstein, M.D., F.A.C.P., as Generex's Vice President, Medical Affairs

Dr. Bernstein is a past president of the American Diabetes Association, and a former member of the ADA's Board of Directors and its Executive Committee.

As Vice President, Medical Affairs, Dr. Bernstein will act as a key liaison for the company on medical and scientific affairs to the medical, scientific, and financial communities. He will consult with the company on its research and development studies and activities, particularly in the area of buccal delivery of insulin. Dr. Bernstein has previously acted as a consultant for a number of pharmaceutical companies, including Bristol Myers Squibb, Janssen Pharmaceuticals, Alza, Aventis, and Eli Lilly and Company.

Dr. Bernstein graduated from Dartmouth College and Tufts University School of Medicine. He is board certified in internal medicine and endocrinology and metabolism. 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."

DESIGN: COMPASSION [www.compassion.com]

innovations in drug delivery

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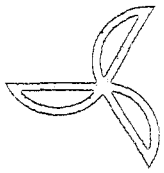

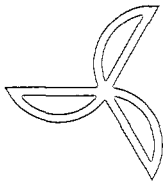

Generex BIOTECHNOLOGY

To Our Stockholders:

I think most people would agree that good news is particularly welcome as we begin 2002. I have excellent news to report regarding Generex's successes in 2001 and our expectations for continued growth in the coming year.

As you read the accompanying report, you will see that there have been many significant developments for Generex recently. Most of you will know that in September 2000, the beginning of our last fiscal year, we announced a landmark agreement between ourselves and Eli Lilly and Company for the further development of Generex's proprietary oral insulin formulation. We are proceeding actively with the research and development that we are required to perform under the terms of that agreement, and we are continuing to make significant and ongoing progress in this regard.

We have been extremely pleased with the results of research studies that we ourselves have conducted or sponsored, and have been invited to present at prestigious scientific conferences. Our first presentation in 2001 occurred in June at the annual conference of the American Diabetes Association in Philadelphia, where we announced positive findings from several Generex studies. Our studies indicate that the buccal delivery of our oral insulin formulation is viable—in fact, its effectiveness appears comparable to that of insulin administered by injection. In the latter half of 2001, we carried this news to the key diabetes-related conferences in Europe and Canada. It's equally gratifying to report that no adverse events or side effects have been observed in any of our animal or human studies.

This past year, we also turned our attention to bringing other large-molecule drugs into our product pipeline. To that end, in January 2001 we agreed to form a joint venture with Elan Corporation, plc, a leader in the pharmaceutical sector, to pursue some of these potential opportunities. With the successful completion recently of a proof-of-concept, Phase 1 clinical study of the buccal delivery of morphine using our proprietary technology, we have now expanded our agreement with Elan to include this application and have agreed with Elan to pursue this application as our initial product for joint development. The study indicates that the bioavailability of buccally delivered morphine is comparable to injected morphine, and that buccally delivered morphine provides significantly faster onset of action than the immediate-release oral morphine tablets commonly used for pain management.

For biotechnology research and development, having access to adequate cash reserves is obviously an important issue. Stockholders will be glad to see from the accompanying annual report that we are in an excellent financial position to achieve both our short-term and long-term objectives. We raised an additional $11 million in July 2001 and we expect our current cash reserves to be more than adequate to sustain the research and development that lies immediately ahead.

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TOLL FREE 1-800-391-6755
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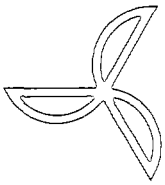


Generex

In terms of our patent portfolio, we were granted five patents last year and one additional patent application was allowed, which means we have moved significantly closer to our goal of completely covering the main aspects of our formulation and delivery technologies.

Our organization also grew stronger thanks to two recent appointments - with Dr. Ivan Lieberburg, Executive Vice President and Chief Scientific and Medical Officer for Elan Corporation, plc, joining Generex's Board of Directors; and Dr. Gerald Bernstein, a past president of the American Diabetes Association and a former member of the ADA's Board of Directors and Executive Committee, becoming Generex's Vice President, Medical Affairs.

As you turn through the pages of our annual report, you'll learn more about the good news I've touched on in this letter. You'll also see, that we at Generex have a view beyond the innovative technologies we're developing. We understand that the benefits that result from our work are ultimately measured in human terms, through the reduction of inconvenience, anxiety, and pain. And those are benefits truly worth striving for.

E. Mark Perri
Chairman and Chief Financial Officer

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

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS TO BE HELD MARCH 18, 2002

Dear Stockholder:

You are cordially invited to attend the annual meeting of stockholders of Generex Biotechnology Corporation ("Generex") that will be held on Monday, March 18, 2002, at 10:00 a.m. (local time), at St. Lawrence Hall, 157 King Street East, Toronto, Ontario, Canada M5E 1C4, for the following purposes, as set forth in the accompanying proxy statement:

1. To elect seven directors;
2. To approve the Generex 2001 Stock Option Plan;
3. To ratify the appointment of Deloitte & Touche, LLP as independent public accountants for Generex for the fiscal year ending July 31, 2002; and
4. To transact such other business as may properly come before the meeting and any adjournments or postponements thereof.

The Board of Directors has established the close of business on February 4, 2002 as the record date for the determination of stockholders entitled to receive notice of, and to vote at, the annual meeting and any adjournment or postponement thereof.

YOU ARE URGED TO REVIEW CAREFULLY THE ACCOMPANYING PROXY STATEMENT AND TO COMPLETE, SIGN, DATE AND RETURN THE ENCLOSED PROXY CARD AS PROMPTLY AS POSSIBLE WHETHER OR NOT YOU PLAN TO ATTEND THE MEETING.

You may revoke your proxy at any time before it has been voted. You are cordially invited to attend the annual meeting in person if it is convenient for you to do so.

By order of the Board of Directors,

Rose C. Perri
Secretary

February 8, 2002

GENEREX BIOTECHNOLOGY CORPORATION

PROXY STATEMENT

General Information

This proxy statement is provided to the stockholders of Generex Biotechnology Corporation ("Generex") in connection with the solicitation by the Board of Directors of Generex of proxies for use at the annual meeting of stockholders of Generex to be held on Monday, March 18, 2002, at 10:00 a.m. (local time), at St. Lawrence Hall, 157 King Street East, Toronto, Ontario, Canada M5E 1C4, and any adjournments or postponements thereof. A form of proxy is enclosed for use at the annual meeting. Proxies properly executed and returned in a timely manner will be voted at the annual meeting in accordance with the directions specified therein. If no direction is indicated, they will be voted for the election of the nominees named herein as directors, for the approval of the Generex 2001 Stock Option Plan, for the appointment of Deloitte & Touche, LLP as Generex's independent public accountants and on other matters presented for a vote, in accordance with the judgment of the persons acting under the proxies. The persons named as proxies were selected by the Board of Directors and are present members of the executive management of Generex.

Any stockholder voting by proxy may revoke that proxy at any time before it is voted at the annual meeting by delivering written notice to the Secretary of Generex, by delivering a proxy bearing a later date or by attending the annual meeting in person and casting a ballot.

Generex's principal executive offices are located at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2, and its telephone number is (416) 364-2551. Proxy materials are first being mailed to stockholders beginning on or about February 8, 2002.

Shares Outstanding, Voting Rights and Vote Required

Only stockholders of record at the close of business on February 4, 2002 are entitled to vote at the annual meeting. The only voting stock of Generex outstanding and entitled to vote at the annual meeting is its common stock, $.001 par value per share (the "Common Stock"). As of the close of business on January 15, 2002, 20,682,634 shares of Common Stock were outstanding. Each share of Common Stock issued and outstanding is entitled to one vote on matters properly submitted at the annual meeting. Cumulative voting is not permitted under Generex's Restated Certificate of Incorporation.

The presence, in person or by proxy, of the holders of a majority of the total issued and outstanding shares of Common Stock entitled to vote at the annual meeting is necessary to constitute a quorum for the transaction of business at the annual meeting. Abstentions and broker non-votes will be counted for purposes of determining the presence or absence of a quorum. A broker non-vote occurs when a nominee holding shares for a beneficial owner does not vote on a particular proposal because the nominee does not have discretionary voting power with respect to that item and has not received instructions from the beneficial owner. Abstentions will be counted in tabulating votes cast on the proposals presented to stockholders and will have the same effect as negative votes. Broker non-votes will not be counted in tabulating votes cast on the proposals presented to stockholders. Votes cast in person or by proxy at the annual meeting will be tabulated by the election inspectors appointed for the meeting.

Directors will be elected by a plurality of the votes of the shares present or represented by proxy at the annual meeting and entitled to vote on the election of directors. The proposals to approve the Generex 2001 Stock Option Plan and to ratify the appointment of Deloitte & Touche, LLP as Generex's independent public accountants require the affirmative vote of a majority of the votes of the shares present or represented by proxy at the annual meeting and cast on such proposals. The Board of Directors recommends voting (1) FOR the election of the nominees named herein for directors, (2) FOR the approval of the Generex 2001 Stock Option Plan and (3) FOR the appointment of Deloitte & Touche, LLP as Generex's independent public accountants for fiscal 2002.

ELECTION OF DIRECTORS
(Proposal 1)

Seven directors are to be elected at the annual meeting of stockholders. All directors will be elected to hold office until the next annual meeting of stockholders following election and until their successors are duly elected and qualified.

The persons named below have been designated by the Board of Directors as nominees for election as directors. All nominees currently serve as directors of Generex. The individuals named in the enclosed proxy intend to vote all proxies received by them for the nominees listed below unless otherwise instructed. If you do not wish your shares to be voted for any of the nominees, you may so indicate on the proxy. If, for any reason, any of the nominees shall become unavailable for election, the individuals named in the enclosed proxy may exercise their discretion to vote for any substitutes proposed by the Board of Directors. At this time, the Board of Directors knows of no reason why any of the nominees might be unavailable to serve.

Name	Age	Position Held with Generex
Anna E. Gluskin	50	President, Chief Executive Officer and Director
Michael Hawke, M.D.	60	Director
Ivan M. Lieberburg, Ph.D., M.D.	52	Director
Pankaj Modi, Ph.D.	47	Vice President, Research and Development and Director
E. Mark Perri	41	Chairman, Chief Financial Officer and Director
Rose C. Perri	34	Chief Operating Officer, Treasurer, Secretary and Director
Jan Michael Rosen	50	Director

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.

Ivan M. Lieberburg Ph.D., M.D. — Director since May 2001. Dr. Lieberburg has been employed by Elan Corporation, plc (worldwide pharmaceutical and biotechnology company) since 1987. Dr. Lieberburg served as Senior Vice President of Research from 1994 to 1997 and as Executive Vice President and Chief Scientific and Medical Officer for Elan from 1997 to the present. Prior to joining Elan in 1987, Dr. Lieberburg held faculty positions at Albert Einstein College of Medicine and Mt. Sinai School of Medicine in New York. He currently holds an appointment as Clinical Professor of Medicine at the University of California, San Francisco.

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.

E. Mark Perri — Director since September 1997. Mr. Perri has served as the Chairman and Chief Financial Officer of Generex since October 1997. He held comparable positions with Generex Pharmaceuticals, Inc. from its formation in 1995 until its acquisition by Generex in October 1997.

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.

Jan 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 is the nominee of EIS thereunder. 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. See "Certain Relationships and Related Transactions" for a description of the Generex securities owned by, or that may be acquired by, Elan or its affiliates.

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 further amended and supplemented as of December 31, 2000. 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. See "Director Compensation; Other Compensation" for information relating to Dr. Modi's consulting agreement.

Mr. Perri and Ms. Perri are siblings. There are no other family relationships among our officers and directors.

The Board of Directors Recommends a Vote FOR the Election of the Above-Named Nominees

PROPOSAL TO APPROVE THE GENEREX BIOTECHNOLOGY CORPORATION 2001 STOCK OPTION PLAN
(Proposal 2)

The Board of Directors has adopted, subject to stockholder approval, the Generex Biotechnology Corporation 2001 Stock Option Plan (the "2001 Plan"). The Board of Directors believes that the 2001 Plan will provide an additional incentive to employees and directors to enter into and remain in the service or employ of Generex by providing such individuals with an opportunity to receive grants of options. In addition, the Board of Directors believes that the receipt of such options will encourage the recipients to contribute materially to the growth of Generex and further align the interests of such recipients with the interests of stockholders.

A copy of the 2001 Plan is attached to this proxy statement as Exhibit A. A summary of the principal features of the 2001 Plan follows.

Summary Description of the 2001 Plan

The 2001 Plan will be administered by the Compensation Committee of the Board of Directors (the "Committee"). The Committee has the authority to determine: (i) the individuals to whom Options shall be granted; (ii) the type, size and terms of the Options to be made to each individual and (iii) the time when the Options will be granted and the duration of any applicable exercise period, including the criteria for exercisability and the acceleration of exercisability. The Committee also has the authority to amend the terms of a previously issued Option and deal with any other matters arising under the 2001 Plan.

Awards under the 2001 Plan may be in the form of incentive stock options ("ISOs") within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), and options that are not incentive stock options ("Non-ISOs") (collectively, "Options").

Options may be granted to employees and non-employee directors as well as certain consultants and advisors of Generex and its subsidiary corporations; provided, however, that ISOs may only be granted to employees. Twenty-eight employees and non-employee directors were eligible to participate in the 2001 Plan as of January 15, 2002. A total of 4,000,000 shares of Common Stock are available for issuance under the 2001 Plan. If an Option granted under the 2001 Plan expires, lapses or is terminated for any reason, the underlying shares again become available for issuance under the 2001 Plan, unless otherwise provided by the Committee. The maximum number of Options that may be granted to any individual during any calendar year is 400,000.

Options granted under the Plan may include terms that permit a participant to use shares of Common Stock to exercise the Options. The terms of any such Options may provide for the grant of additional Options (or the Committee may grant additional Options) to purchase a number of shares of Common Stock equal to the number of whole shares used to exercise the Option and the number of whole shares, if any, withheld in payment of any taxes. Any Options so granted will be granted with an exercise price equal to the fair market value of the Common Stock on the date of grant, or at such other exercise price as the Committee may establish, for a term not longer than the unexpired term of the exercised Option and on such other terms as the Committee may determine.

The exercise price of ISOs granted under the 2001 Plan must be equal to the fair market value of the Common Stock on the date the ISO is granted (110 percent of the fair market value in the case of an ISO granted to an individual who at the time of the grant owns ten percent or more of the combined voting power of Generex capital stock (a "Ten Percent Owner")). The fair market value of the Common Stock will be determined by the Committee.

In the event a participant's employment with Generex or its subsidiary corporations is terminated for any reason, a participant may exercise an Option only to the extent it was exercisable on the participant's date of termination. An Option must be exercised prior to the earlier of (i) the expiration of ninety days or such other period as the Committee may select (one year in the case of disability or death) after the termination date or (ii) the expiration date of the Option, which may not exceed ten years from the date of grant (five years in the case of an ISO granted to a Ten Percent Owner). However, in the event of a participant's termination for cause or the participant's engaging in conduct after termination that constitutes cause (as defined in the 2001 Plan and

determined by the Committee), the participant's Option will terminate immediately and the participant automatically will forfeit all Common Stock for which Generex has not yet delivered share certificates, upon refund of the exercise price.

The Committee may adjust the number of shares covered by outstanding options, the kind of shares issued under the 2001 Plan and the price per share of Common Stock available for issuance under the 2001 Plan, at any time to reflect any change in the capital structure of Generex affecting outstanding shares of Common Stock, whether through merger, consolidation, reorganization, recapitalization, stock dividend, stock split, combination of shares, exchange of shares or other similar change in the capital structure of Generex.

In the event of a "Change of Control" (as defined in the 2001 Plan), unless the Committee determines otherwise, outstanding Options will become exercisable immediately. In addition, the Committee may take whatever action it deems necessary with respect to any or all outstanding Options, including requiring that Optionees surrender their outstanding options in exchange for a payment by Generex or terminating any or all unexercised options after giving Optionees an opportunity to exercise their outstanding Options. If a Change of Control occurs in which Generex is not the surviving corporation, or survives only as a subsidiary of another corporation, unless the Committee determines otherwise, all outstanding Options that have not been exercised will be assumed by, or replaced with comparable options or rights by the surviving corporation.

No Option may be transferred, except by will or the laws of descent and distribution, and in the case of a Non-ISO, as permitted by the Committee.

The Committee may amend or terminate the 2001 Plan at any time; provided, however, that the Committee will not increase the aggregate number of shares that may be issued or transferred under the 2001 Plan or upon which awards under the 2001 Plan may be granted, or otherwise materially amend the 2001 Plan, without stockholder approval to the extent such approval is required in order to comply with the Internal Revenue Code or applicable laws, or to comply with applicable stock exchange requirements.

Federal Income Tax Consequences

The following description of federal income tax consequences is based on current law and interpretations.

ISOs. In general, the value of an ISO is not included in the participant's income at the time of grant, and the participant does not recognize income on exercise of an ISO for the purpose of computing regular federal income tax. However, when calculating income for alternative minimum tax purposes, the excess, if any, of the fair market value of the shares acquired over the exercise price (the "Spread") generally will be considered part of income. At the subsequent sale of Common Stock received through the exercise of an ISO, all gain on the sale of the Common Stock (as long as the Common Stock has been held for one year after exercise and two years after grant) will be characterized as capital gain or loss, and Generex will not be entitled to any federal income tax deduction with respect to such gain. If the Common Stock has been held for at least one year, the capital gain or loss will be taxed as long-term capital gain or loss. If a participant disposes of ISO Common Stock before the holding period has expired (a "Disqualifying Disposition"), the Spread (up to the amount of the gain on disposition) will be ordinary income at the time of such Disqualifying Disposition, and Generex will be entitled to a federal income tax deduction. A participant must recognize as ordinary income the gain on the disposition.

Non-ISOs. In general, the value of a Non-ISO is not included in the participant's income at the time of grant, unless the Non-ISO Common Stock has a "readily ascertainable fair market value" at the date of grant. It is not anticipated that any Non-ISO will have a "readily ascertainable fair market value" at the date of grant. On exercise, the difference between the exercise price of a Non-ISO and the fair market value of the Common Stock received generally will be recognized as ordinary income, subject to federal income tax withholding, and will be allowed as a deduction to Generex. At the subsequent sale of Common Stock received through the exercise of a Non-ISO, all gain on the sale of the Common Stock will be characterized as capital gain or loss. If the Common Stock has been held for at least one year, the capital gain or loss will be taxed as long-term capital gain or loss.

Awards under the 2001 Plan

Subject to stockholder approval of the 2001 Plan, the Board of Directors has granted options under the 2001 Plan as follows (through January 15, 2002) to the named executives, all executives as a group, all non-executive

directors as a group and all non-executive officer employees as a group. The exercise prices of the options were fixed at the fair market value of the underlying shares of Common Stock on the date of grant and range from $5.19 per share to $8.70 per share.

Awards Granted Under Generex's 2001 Stock Option Plan

Name	Dollar Value(1)	Number of Options
Anna E. Gluskin, President and Chief Executive Officer	0	0
E. Mark Perri, Chairman and Chief Financial Officer	0	0
Rose C. Perri, Chief Operating Officer, Treasurer and Secretary	0	0
Pankaj Modi, Ph.D., Vice President, Research and Development	0	150,000
All executives, as a group (4 persons)	0	150,000
Non-executive directors, as a group (3 persons)	214,500	150,000
All non-executive officer employees, As a group (21 persons)	1,592,000	800,000

(1) The dollar value is the closing price of the Common Stock at January 15, 2002 ($7.18) less the exercise price. For purposes of calculating the dollar value, all of the options were assumed to be exercisable as of January 15, 2002, notwithstanding the specific vesting schedule associated with any of the grants.

Pursuant to the consulting agreement under which Dr. Modi is compensated for his services to Generex, Generex has agreed to grant to Dr. Modi options to purchase 150,000 shares of Common Stock over ten consecutive fiscal years, which started with the fiscal year ended July 31, 2001. Generex has granted 150,000 options to Dr. Modi under the 2001 Plan with effect as of July 31, 2001, subject to stockholder approval of the 2001 Plan. Generex intends to continue to use the 2001 Plan in the future to satisfy its obligations to grant options under the agreement with Dr. Modi. Approval of the 2001 Plan at this year's annual meeting will constitute approval as well to use the 2001 Plan to satisfy Generex's obligations to grant options to Dr. Modi for so long as Options remain available for issuance under the 2001 Plan. (For more details concerning Dr. Modi's consulting agreement, see "Director Compensation; Other Compensation".)

The Board of Directors Recommends a Vote FOR the Proposal to Approve the 2001 Stock Option Plan

PROPOSAL TO RATIFY THE APPOINTMENT OF DELOITTE & TOUCHE, LLP AS GENEREX'S INDEPENDENT PUBLIC ACCOUNTANTS (Proposal 3)

The Board of Directors of Generex has selected Deloitte & Touche, LLP ("Deloitte & Touche") to serve as the independent public accountants to audit the financial statements of Generex and its subsidiaries for the fiscal year ending July 31, 2002. Deloitte & Touche served as Generex's independent public accountants for the audit of Generex's financial statements for the fiscal year ended July 31, 2001. Representatives of Deloitte & Touche will attend the annual meeting and will be available to answer appropriate questions. They will have the opportunity to make a statement at the annual meeting if they desire.

The decision to appoint Deloitte & Touche as Generex's independent public accountants beginning with the fiscal year ended July 31, 2001, replacing WithumSmith+Brown, was approved by the Audit Committee of the Board of Directors and ratified by the stockholders at last year's annual meeting. WithumSmith+Brown did not decline to stand for re-election and WithumSmith+Brown's reports on financial statements for the two fiscal years preceding their replacement did not contain an adverse opinion, disclaimer of opinion or qualification as to uncertainty, audit scope or accounting principles. There had been no disagreements with WithumSmith+Brown in the two fiscal years preceding their replacement on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure.

During the two fiscal years preceding their replacement, WithumSmith+Brown did NOT advise Generex that:

- The internal controls necessary for Generex to develop reliable financial statements did not exist;
- Information had come to their attention that led them to believe that they could no longer rely on management's representations or that made them unwilling to be associated with the financial statements prepared by management;
- They needed to expand the scope of their audit or that information existed, that had come to their attention during the last two fiscal years, that if further investigated may (i) materially impact the fairness or reliability of either a previously issued audit report or the underlying financial statements, or the financial statements issued or to be issued covering the fiscal period(s) subsequent to the date of the most recent financial statements covered by an audit report (including information that may prevent them from rendering any unqualified audit report on those financial statements) or (ii) cause them to be unwilling to rely on management's representations or be associated with our financial statements; and that due to their replacement or for any other reason, they did not so expand the scope of their audit or conduct further investigation; or
- Information has come to their attention that they have concluded materially impacts the fairness or reliability of either (i) a previously issued audit report or the underlying financial statements, or (ii) the financial statements issued or to be issued covering the fiscal period(s) subsequent to the date of the most recent financial statements covered by an audit report (including information that, unless resolved to their satisfaction, would prevent them from rendering an unqualified audit report on those financial statements); and due to their replacement, or for any other reason, the issue has not been resolved to their satisfaction prior to their replacement.

If the stockholders do not ratify the appointment of Deloitte & Touche as independent public accountants, the Audit Committee of the Board of Directors will investigate the reasons for the rejection by the stockholders and the Board of Directors will reconsider the appointment.

The Board of Directors Recommends a Vote FOR the Appointment of Deloitte & Touche As Generex's Independent Public Accountants for the Fiscal Year Ending July 31, 2002.

Fees Paid to Generex's Independent Public Accountants

The following table sets forth the aggregate fees paid by Generex for the fiscal year ended July 31, 2001 to Deloitte & Touche:

Audit Fees(1)	$ 68,695
Financial Information Systems Design and Implementation Fees(2)	$ 0
All Other Fees(3)	$ 0

(1) Includes the aggregate fees billed for professional services rendered by Deloitte & Touche for the audit of Generex's annual financial statements for the fiscal year ended July 31, 2001 and the reviews of financial statements included in Generex's Quarterly Reports on Form 10-Q for the 2001 fiscal year. This amount is shown in U.S. dollars and was converted from Canadian dollars to U.S. dollars based on the exchange rate on January 15, 2002.

(2) No amounts were billed by Deloitte & Touche in fiscal 2001 for financial information systems design and implementation services.

(3) No amounts were billed by Deloitte & Touche in fiscal 2001 for any other services.

MEETINGS AND COMMITTEES OF THE BOARD OF DIRECTORS

The business affairs of Generex are managed under the direction of the Board of Directors. During the fiscal year ended July 31, 2001, Generex's Board of Directors held 4 meetings. During the fiscal year ended July 31, 2001, all of the directors attended all of the Board of Directors meetings that were held.

The Board of Directors has established two committees, the Audit Committee and the Compensation Committee.

The Audit Committee was established on March 1, 2000, and met 3 times during the fiscal year ended July 31, 2001. All of the members of the Audit Committee attended all of the meetings that they were eligible to attend. The Audit Committee is currently composed of Mr. Rosen, who is the Chairman of the Committee, Dr. Lieberburg and Dr. Hawke. The Board of Directors has adopted an Audit Committee charter that specifies the duties of the Audit Committee.

The Common Stock is listed on the Nasdaq National Market and, therefore, Generex is governed by the applicable rules of the Nasdaq Stock Market. The listing requirements for Nasdaq National Market issuers require that each issuer's audit committee be comprised of at least two – and preferably three – independent directors. Mr. Rosen and Dr. Hawke meet the definition of independence under Rule 4200(a)(15) of the listing requirements. Dr. Lieberburg does not currently meet the definition of independence due to the fact that Generex (Bermuda) Ltd., the subsidiary of Generex that was formed to conduct Generex's joint venture with Elan, was deemed to have paid an up-front $15 million license fee to an affiliate of Elan in connection with the formation of the joint venture in January 2001. Dr. Lieberburg is nevertheless eligible pursuant to Rule 4350(d)(2) of the listing requirements to continue to serve as a member of the Audit Committee because the Board of Directors has determined that Dr. Lieberburg's membership on the Audit Committee is required by the best interests of Generex and its stockholders. Dr. Lieberburg served as Senior Vice President of Research for Elan from 1994 to 1997 and since 1997 has served as Executive Vice President and Chief Scientific and Medical Officer of Elan. As a result, Dr. Lieberburg has acquired substantial knowledge and understanding of the biotechnology industry and financial operations of biotechnology companies as well as the accounting issues faced by companies whose operations primarily involve research and development activities.

Nevertheless, the Board of Directors intends to commence a search for one or more additional directors who meet the definition of independence under the Nasdaq Stock Market listing requirements and intends to add at least one such additional director to the Board of Directors and the Audit Committee by the next annual meeting of stockholders.

The Compensation Committee was formed on July 30, 2001 and met one time during the fiscal year ended July 31, 2001. All of the members of the Compensation Committee attended that meeting. The Compensation Committee is currently composed of Dr. Hawke, who is the Chairman of the Committee, Dr. Lieberburg and Mr. Rosen.

Report of the Audit Committee

The Audit Committee reviewed and discussed Generex's audited financial statements for the fiscal year ended July 31, 2001 with management. The Audit Committee discussed with Deloitte & Touche, LLP, Generex's independent public accountants for the fiscal year ended July 31, 2001, the matters required to be discussed by Statement on Auditing Standards No. 61. The Audit Committee received the written disclosures and the letter from Deloitte & Touche, LLP required by Independence Standards Board Standard No. 1 (Independence Discussions with Audit Committees), and discussed with Deloitte & Touche, LLP its independence. Based on the review and discussions described above, among other things, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in Generex's Annual Report on Form 10-K for the fiscal year ended July 31, 2001.

Submitted by the Audit Committee

Jan Michael Rosen (Chairman)
Michael Hawke, M.D.
Ivan M. Lieberburg, Ph.D., M.D.

The foregoing Report of the Audit Committee shall not be deemed to be soliciting material, to be filed with the Securities and Exchange Commission (the "SEC") or to be incorporated by reference into any of Generex's previous or future filings with the SEC, except as otherwise explicitly specified by Generex in any such filing.

Report of the Board of Directors and the Compensation Committee on Executive Compensation

During the majority of the fiscal year ended July 31, 2001, the Board of Directors was responsible for overseeing the compensation to be paid to the executive officers of Generex. Ms. Gluskin, Dr. Modi, Mr. Perri and Ms. Perri, all of whom are both directors and executive officers of Generex, participated in some of the discussions and decisions of the Board of Directors concerning compensation to be paid to the executive officers of Generex. Effective July 30, 2001, all decisions regarding executive compensation are being made by the Compensation Committee of the Board of Directors. Dr. Hawke is chairman of the Compensation Committee and Dr. Lieberburg and Mr. Rosen are the other members of the Compensation Committee.

Compensation Philosophy. The goals of Generex's compensation program are to attract and retain talented executives, to motivate these executives to achieve Generex's business goals, to align executive and stockholder interests and to recognize individual contributions as well as overall business results.

The key elements of Generex's executive compensation are base salary, cash bonuses and stock options. While the elements of compensation are considered separately, the Compensation Committee ultimately looks to the value of the total compensation package provided by Generex to the individual executive. At the end of the fiscal year ended July 31, 2001, the Compensation Committee conducted a review of Generex's executive compensation program. This review included a comprehensive report from an independent executive compensation consultant and compared Generex's total executive compensation, including base salaries, cash bonuses and stock options, to a peer group of publicly traded biotechnology companies. For the fiscal year ended July 31, 2001, the Compensation Committee targeted total cash compensation for Generex executives to the median of the peer group.

Base Salaries. Generex historically has paid very modest base salaries to its executive officers, relying on option grants to supplement the low base salaries. That practice continued for the fiscal year ended July 31, 2001, as is evident from the base salaries set forth in the Compensation Table. The Compensation Committee believes that the base salaries of Generex's executive officers are low in comparison to base salaries for comparable positions at other biotechnology companies and intends to implement increases for fiscal 2002 to bring the base salaries of Generex's executives in line with base salaries of Generex's principal competitors.

Cash Bonuses. Cash bonuses were introduced for fiscal 2001 in order to recognize and reward the executives of Generex for their strong performance and for the accomplishments achieved by Generex during fiscal 2001. The Compensation Committee determined the executive officer bonuses that were awarded for the fiscal year ended July 31, 2001. Executive officer bonuses were based on the individual's position within Generex as well as individual contribution to Generex's accomplishments, and took into account the levels of cash bonus and total cash compensation (base salary plus bonus) paid by the median of the peer group of biotechnology companies. The Compensation Committee judged that the executive officer bonus awards for fiscal 2001 were consistent with each executive's level of accomplishment and appropriately reflected Generex's overall performance.

Stock Options. The purpose of stock option grants is to provide an additional incentive to Generex employees, including executive officers, to contribute materially to the growth of Generex. Stock options are granted to align the interests of the recipients with the interests of stockholders. The Compensation Committee did not grant any options to executive officers during the fiscal year ended July 31, 2001, other than the options that were required to be granted to Dr. Modi under the terms of his consulting agreement. The executives all own substantial numbers of shares of Common Stock and the Compensation Committee does not intend to use option grants regularly to compensate the current group of executives other than the grants required to be made to Dr. Modi under the terms of his consulting agreement.

Chief Executive Officer Compensation. Ms. Gluskin's compensation for the fiscal year ended July 31, 2001, was determined in accordance with the compensation policies described above. Ms. Gluskin was paid a modest cash salary of approximately $127,240 and was granted a bonus of $250,000. This compensation package was considered fair and reasonable in view of Generex's significant accomplishments during the fiscal year and Ms. Gluskin's substantial contributions to those accomplishments. The compensation paid to Ms. Gluskin for fiscal 2001 was considered to give appropriate incentives to Ms. Gluskin to continue to promote the strategic objectives of Generex and to enhance stockholder value.

Deductibility of Compensation. Section 162(m) of the Internal Revenue Code does not allow public companies to take a Federal income tax deduction for compensation paid to certain executive officers, to the extent that compensation exceeds $1 million for any such officer in any fiscal year. This limitation does not apply to compensation that qualifies as "performance-based compensation" under the Code. The Board of Directors believes that at the present time it is quite unlikely that the compensation paid to any executive officer will exceed $1 million in any fiscal year. Therefore, the Board of Directors has not taken any measures to date specifically to qualify any of the compensation paid to its executive officers as "performance-based compensation" under the Code.

Submitted by the Board of Directors
and the Compensation Committee

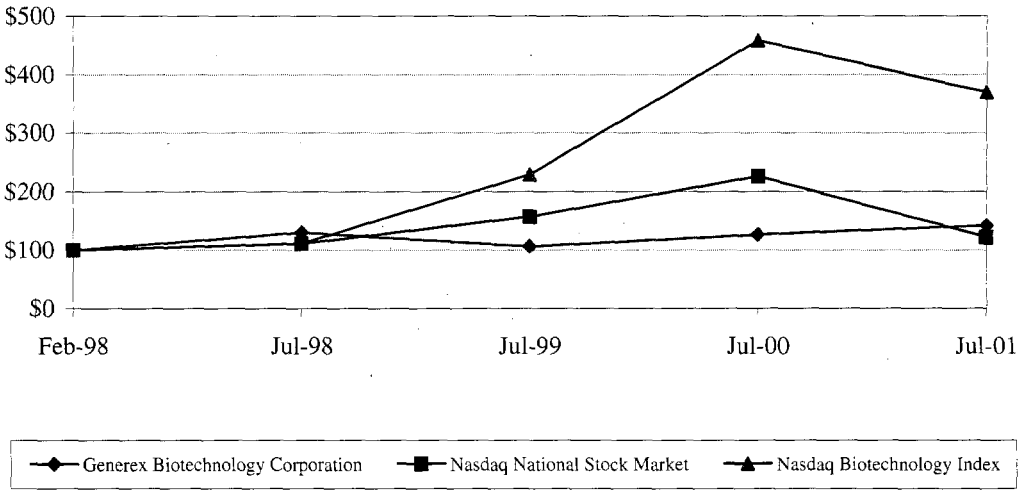
Anna E. Gluskin
Michael Hawke, M.D.*
Ivan M. Lieberburg, Ph.D., M.D.**
Pankaj Modi, Ph.D.
E. Mark Perri
Rose C. Perri
Jan Michael Rosen**

* Chairman of Compensation Committee
** Member of Compensation Committee

The foregoing Report of the Board of Directors and the Compensation Committee on Executive Compensation and the following Performance Graph shall not be deemed to be soliciting material, to be filed with the SEC or to be incorporated by reference into any of Generex's previous or future filings with the SEC, except as otherwise explicitly specified by Generex in any such filing.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total return on Generex's Common Stock with cumulative total returns of the Nasdaq National Market (U.S. Companies) and the Nasdaq Biotechnology Index for the period commencing February 5, 1998 (the date Generex's Common Stock was first listed for trading on the Nasdaq over-the-counter market) and ending on July 31, 2001. The graph assumes that $100 was invested on February 5, 1998, in Generex's Common Stock, the stocks in the Nasdaq National Market (U.S. Companies) and the stocks comprising the Nasdaq Biotechnology Index, and that all dividends were reinvested. Generex's Common Stock has been trading on the Nasdaq National Market since May 5, 2000.



	February 5 1998	July 31 1998	July 31 1999	July 31 2000	July 31 2001
Generex Biotechnology Corporation	$100	130.21	106.25	126.05	141.67
The Nasdaq National Stock Market	$100	111.27	157.00	226.46	121.55
Nasdaq Biotechnology Index	$100	111.25	229.28	458.31	369.61

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") requires that Generex's directors and executive officers, and any persons who own more than ten percent of the Common Stock, file with the SEC initial reports of ownership and reports of changes in ownership of the Common Stock and other equity securities of Generex. Such persons are required by SEC regulations to furnish Generex with copies of all such reports that they file. To the knowledge of Generex, based upon its review of these reports, all Section 16 reports required to be filed by our directors and executive officers during the fiscal year ended July 31, 2001 were filed on a timely basis.

COMPENSATION OF EXECUTIVE OFFICERS AND DIRECTORS

Compensation of Executive Officers

The following table sets forth, for Generex's last three fiscal years, all compensation awarded to, earned by or paid to the chief executive officer ("CEO") and the three most highly compensated executive officers of Generex other than the CEO whose salary and bonus payments exceeded $100,000 for the fiscal year ended July 31, 2001.

Summary Compensation Table

		Annual Compensation		Long-Term Compensation	
				Awards	
Name and Principal Position	Year Ended July 31	Salary ($) (3)	Bonus ($)	Other Annual Compensation	Options (#)
Anna E. Gluskin (1),	2001	127,240	250,000	*	0
President and	2000	105,385	0	*	300,000
Chief Executive	1999	136,483	0	*	0
Officer					
E. Mark Perri (1),	2001	95,081	180,000	*	0
Chairman and	2000	103,249	0	*	250,000
Chief Financial	1999	120,777	0	*	0
Officer					
Rose C. Perri (1),	2001	81,068	100,000	*	0
Chief Operating,	2000	97,147	0	*	250,000
Officer, Treasurer	1999	120,777	0	*	0
and Secretary					
Pankaj Modi (2),	2001	250,000	300,000	*	150,000(4)
Vice President,	2000	89,723	5,302	*	300,000
Research and	1999	87,472	4,374	*	0
Development					

* Perquisites and other personal benefits, securities or other property received by each executive officer did not exceed the lesser of $50,000 or 10% of such executive officer's salary and bonus.

(1) Portions of the cash compensation paid to Ms. Gluskin, Mr. Perri and Ms. Perri are attributable to amounts paid indirectly through a management services agreement with a corporation of which Ms. Gluskin, Mr. Perri and Ms. Perri are equal owners.

(2) All of the cash compensation paid to Dr. Modi is paid indirectly to him through a corporation owned 100% by him.

(3) Cash compensation is stated in the table in U.S. dollars. To the extent any cash compensation was paid in Canadian dollars, it has been converted into U.S. dollars based on the weighted average Canadian/U.S. dollar exchange rate for the years ended July 31, 2001, 2000 and 1999, respectively.

(4) Granted on October 23, 2001 with effect as of July 31, 2001 pursuant to the terms of Dr. Modi's consulting agreement. These options were granted under the Generex 2001 Stock Option Plan, which is subject to stockholder approval.

Option Grants during the 2001 Fiscal Year

The following tables set forth information related to options to purchase Common Stock granted to the CEO and the named executive officers during the fiscal year ended July 31, 2001.

	Individual grants				Potential realizable value at assumed annual rates of stock appreciation for option term	
Name	Number of Securities Underlying options granted (#)	Percent of total options granted to employees in fiscal year (%)	Exercise price ($/Sh)	Expiration date	5% ($)	10%
Anna E. Gluskin	0	—	—	—	—	—
E. Mark Perri	0	—	—	—	—	—
Rose C. Perri	0	—	—	—	—	—
Pankaj Modi	150,000(1)	11.5	8.70	9/24/06	360,000	796,500

(1) Granted on October 23, 2001 with effect as of July 31, 2001 pursuant to the terms of Dr. Modi's consulting agreement. These options were granted under the Generex 2001 Stock Option Plan, which is subject to stockholder approval.

Fiscal Year End Option Values

No options were exercised by the CEO or the named executive officers during the fiscal year ended July 31, 2001. The following table provides information relating to the number and value of options held by the CEO and the named executive officers at fiscal year end.

Name	Shares acquired on exercise (#)	Value realized ($)	Number of securities underlying exercised options at July 31, 2001 (#) Exerciseable/Unexercisable	Value of unexercised options at January 15, 2002 ($) Exerciseable(1)/Unexercisable
Anna E. Gluskin	-0-	-0-	300,000/0	218,000/0
E. Mark Perri	-0-	-0-	250,000/0	218,000/0
Rose C. Perri	-0-	-0-	250,000/0	218,000/0
Pankaj Modi	-0-	-0-	300,000/150,000	327,000/0

(1) Based on the closing price of Common Stock ($7.18) at January 15, 2002.

Other Benefit Plans

We have no long-term incentive plans or defined benefit or actuarial pension plans, and have not repriced any options previously granted to the above named officers.

Directors' Compensation; Other Compensation

None of our directors received any cash compensation for their services as directors during the fiscal year ended July 31, 2001. Dr. Hawke was granted options on May 18, 2001 under the Generex 2001 Stock Option Plan to purchase 20,000 shares of Common Stock in recognition of his service as a director. Mr. Rosen was granted options on August 18, 2000 under the Generex 2000 Stock Option Plan to purchase 20,000 shares of Common Stock and options on May 18, 2001 under the 2001 Plan to purchase 20,000 shares of Common Stock in

recognition of his service as a director. The options under the 2001 Plan were granted subject to stockholder approval of the 2001 Plan.

Dr. Modi is compensated through 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 further amended and supplemented as of December 31, 2000. The parties to the agreement are Dr. Modi, Generex and Generex Pharmaceuticals, Inc., a wholly-owned subsidiary of Generex. All references to the consulting agreement in the following discussion relate to the agreement, as amended and supplemented.

Pursuant to the terms of the consulting agreement, Dr. Modi holds the position of Vice President, Research and Development of Generex and Generex Pharmaceuticals, and both Generex and Generex Pharmaceuticals are jointly and severally responsible for the payment to Dr. Modi of all amounts due under the agreement. The agreement provides for Dr. Modi's term of service to extend through July 31, 2010, subject to termination without cause by Dr. Modi or Generex at any time after January 1, 2003 upon 12 months' prior written notice.

The consulting agreement provides for an annual base compensation of $250,000 a year, effective as of August 1, 2000, subject to certain cost-of-living increases. In addition, Dr. Modi is entitled to receive certain bonus compensation during the term of the agreement. During the first calendar quarter of 2001, a $300,000 bonus was paid to Dr. Modi in respect of Dr Modi's services in securing the development and license agreement between Generex and Eli Lilly and Company ("Lilly"). Dr. Modi will also receive certain additional bonus payments based upon the Lilly agreement or any similar agreements entered into by Generex for rights granted to third parties to develop, manufacture and/or market products based upon ideas, improvements, designs or discoveries made or conceived by Dr. Modi.

The consulting agreement provides for Dr. Modi to be granted options to purchase 150,000 shares of Common Stock in each of the next ten fiscal years, starting with the fiscal year ending July 31, 2001. The options may be granted only under option plans of Generex that have been approved by the stockholders.

In connection with amending and supplementing the consulting agreement in January 1998, Generex issued 1,000 shares of Special Voting Rights Preferred Stock ("Special Preferred Stock") to Dr. Modi, comprising all of the outstanding shares of Special Preferred Stock. Special Preferred Stock does not generally carry the right to vote, but does have the following special voting rights:

- the holders of Special Preferred Stock have the right to elect a majority of Generex's Board of Directors if a change of control occurs; and
- the holders of Special Preferred Stock have the right to approve any transaction that would result in a change of control.

A "change of control" is deemed to occur if Generex's founders (namely, Ms. Gluskin, Dr. Modi, Mr. Perri or Ms. Perri), or directors appointed or nominated with the approval of Generex's founders, should cease to constitute at least 60% of Generex's directors, or if any person becomes either Chairman of the Board of Directors or Chief Executive Officer of Generex without the prior approval of the founders. If a change of control were to occur, Dr. Modi would thereafter be able to elect a majority of the directors. No change of control has occurred to date.

Compensation Committee Interlocks and Insider Participation

Ms. Gluskin, Dr. Modi, Mr. Perri and Ms. Perri, all of whom are both directors and executive officers of Generex, participated during the fiscal year ended July 31, 2001 in some discussions and decisions of the Board of Directors concerning compensation to be paid to the executive officers of the Company. Effective July 30, 2001, all decisions regarding executive compensation are made by the Compensation Committee of the Board of Directors. Dr. Hawke is chairman of the Compensation Committee and Dr. Lieberburg and Mr. Rosen are the other members of the Compensation Committee.

No executive officer of Generex has served on the board of directors or compensation committee of any other entity that has or has had one or more executive officers serving as a director of Generex (excluding entities that are wholly owned by one or more of the executive officers).

Security Ownership Of Certain Beneficial Owners And Management

The tables on the following pages sets forth information regarding the beneficial ownership of the Common Stock by:

- Our executive officers and directors;
- All directors and executive officers as a group; and
- Each person known to us to beneficially own more than five percent (5%) of our outstanding shares of Common Stock.

The information contained in these tables is as of January 15, 2002. At that date, Generex had 20,682,634 shares of Common Stock outstanding. In addition to Common Stock, Generex has outstanding 1,000 shares of Special Voting Rights Preferred Stock. All of the shares of Special Voting Rights Preferred Stock are owned by Dr. Pankaj Modi. In connection with Generex's joint venture with Elan, Generex issued 1,000 shares of Series A Preferred Stock, all of which are presently held of record by an affiliate of Elan.

A person is deemed to be a beneficial owner of shares if he has the power to vote or dispose of the shares. This power can be exclusive or shared, direct or indirect. In addition, a person is considered by SEC rules to beneficially own shares underlying options or warrants that are presently exercisable or that will become exercisable within sixty (60) days.

Name of Beneficial Owner	Beneficial Ownership	
	Number of Shares	Percent of Class
(i) Directors and Executive Officers		
Anna E. Gluskin	1,488,127(1)	7.2%
Michael Hawke, M.D.	71,000(2)	*
Ivan M. Lieberburg, Ph.D., M.D.	10,000(3)	*
Pankaj Modi, Ph.D.	1,400,200(4)	6.8%
E. Mark Perri	4,542,792(5)	22.0%
Rose C. Perri	1,438,026(6)	7.0%
Jan Michael Rosen	98,730(7)	*
Officers and directors as a group	6,672,875(8)	32.3%
(ii) Other Beneficial Owners (and their addresses)		
Protius Overseas Limited P.O. Box 17512-14 Finch Road Douglas Isle of Man, IM99	1,405,526(9)	6.8%
Cranshire Capital, L.P. 666 Dundee Road, Suite 1901 Northbrook, IL 60062	(9)	(9)
Downsview Capital, Inc. 666 Dundee Road, Suite 1901 Northbrook, IL 60062	(9)	(9)
JMJ Capital, Inc. 666 Dundee Road, Suite 1901 Northbrook, IL 60062	(9)	(9)
EURAM Cap Strat. "A" Fund Limited 666 Dundee Road, Suite 1901 Northbrook, IL 60062	(9)	(9)
Mitchell P. Kopin 666 Dundee Road, Suite 1901 Northbrook, IL 60062	(9)	(9)
EBI, Inc. In Trust c/o Miller & Simons First Floor, Butterfield Square P.O. Box 260 Providencials Turks and Caicos Islands British West Indies	1,441,496(10)	7.0%
GHI, Inc. In Trust c/o Miller & Simons First Floor, Butterfield Square P.O. Box 260 Providencials Turks and Caicos Islands British West Indies	2,500,050(11)	12.1%
Smallcap World Fund, Inc. c/o Capital Research and Management Company 333 South Hope Street Los Angeles, CA 90071	1,243,467(12)	6.0%

* Less than one percent.

(1) Includes 1,188,000 shares owned of record by GHI, Inc. that are beneficially owned by Ms. Gluskin, 100,000 shares issuable upon the exercise of an option granted under Generex's 1998 Stock Option Plan (the "1998 Plan") and 200,000 shares issuable upon the exercise of an option granted under Generex's 2000 Stock Option Plan (the "2000 Plan").

(2) Includes 50,000 shares issuable upon the exercise of an option granted under the 1998 Plan and 20,000 shares issuable upon the exercise of an option granted under the 2000 Plan, but does not include 50,000 shares issuable upon the exercise of options granted under the 2001 Plan (20,000 of which were granted during fiscal 2001 and 30,000 of which were granted after fiscal 2001), which are not presently exercisable but will become exercisable if the 2001 Plan is approved by the stockholders.

(3) Does not include 50,000 shares issuable upon the exercise of an option granted under the 2001 Plan (after fiscal 2001), which is not presently exercisable but will become exercisable if the 2001 Plan is approved by the stockholders. Also does not include any shares that are owned by, or that may be acquired by, Elan or its affiliates. See "Certain Relationships and Related Transactions" for a description of the shares of Common Stock that are owned by, or that may be acquired by, Elan or its affiliates.

(4) Includes 150,000 shares issuable upon the exercise of an option granted under the 1998 Plan and 150,000 shares issuable upon the exercise of an option granted under the 2000 Plan. Does not include 150,000 shares issuable upon the exercise of an option granted under the 2001 Plan which is not presently exercisable but will become exercisable if the 2001 Plan is approved by the stockholders. The options granted under the 2001 Plan were granted on October 23, 2001 with effect as of July 31, 2001 pursuant to the terms of Dr. Modi's consulting agreement. Dr. Modi also owns all the outstanding shares of Generex's Special Voting Rights Preferred Stock. This stock is not convertible into Common Stock.

(5) Includes 45,914 shares owned of record by Mr. Perri, and a total of 1,529,382 shares beneficially owned by Mr. Perri but owned of record by EBI, Inc. (1,100,000 shares), GHI, Inc. (124,050 shares) and Union Securities Ltd. (305,332 shares). Also includes: (a) 100,000 shares issuable upon the exercise of an option granted under the 1998 Plan and 150,000 shares issuable upon the exercise of an option granted under the 2000 Plan, (b) 2,376,000 shares owned of record by GHI, Inc., which Mr. Perri may be deemed to beneficially own because of his power to vote the shares but which are beneficially owned by Ms. Gluskin or Ms. Perri; and (c) 341,496 shares owned of record by EBI, Inc., which Mr. Perri may be deemed to beneficially own because of his power to vote the shares but which are beneficially owned by other stockholders because they are entitled to the economic benefits of the shares.

(6) Includes 1,188,000 shares owned of record by GHI, Inc. that are beneficially owned by Ms. Perri, 100,000 shares issuable upon the exercise of an option granted under the 1998 Plan and 150,000 shares issuable upon the exercise of an option granted under the 2000 Plan.

(7) Includes 20,000 shares issuable upon the exercise of an option granted under the 2000 Plan, but does not include 50,000 shares issuable upon exercise of options granted under the 2001 Plan (20,000 of which were granted during fiscal 2001 and 30,000 of which were granted after fiscal 2001), which are not presently exercisable but will become exercisable if the 2001 Plan is approved by the stockholders. Also includes 7,943 shares owned by a company of which Mr. Rosen is an officer and indirect 25% owner; Mr. Rosen may be deemed to beneficially own these shares because he shares voting power and investment power with respect to such shares.

(8) Includes 500,000 shares issuable upon the exercise of options granted under the 1998 Plan, and 690,000 shares issuable upon the exercise of options granted under the 2000 Plan. Does not include any shares issuable upon the exercise of options granted under the 2001 Plan, all of which are subject to stockholder approval of the 2001 Plan. Includes 1,441,496 shares owned of record by EBI, Inc. but beneficially owned or deemed to be beneficially owned by Mr. Perri. Includes 2,500,050 shares owned of record by GHI, Inc. but beneficially owned by Ms. Gluskin, Mr. Perri or Ms. Perri (but eliminates any doublecounting of shares that are beneficially owned by Ms. Gluskin and Ms. Perri but also deemed to be beneficially owned by Mr. Perri).

(9) Based solely on Schedule 13G filed with the SEC under the Exchange Act on January 18, 2002. The Schedule 13G was filed for Protius Overseas Limited; Cranshire Capital, L.P.; Downsview Capital, Inc.; JMJ Capital, Inc.; EURAM Cap Strat. "A" Fund Limited; and Mitchell P. Kopin as a group. The members of the group hold shared voting power and shared dispositive power with respect to these shares. Does not include any warrants exercisable for Common Stock that are held by any of the members of the group.

(10) All these shares also are deemed to be beneficially owned by Mr. Perri because he has the sole power to vote the shares. With respect to 1,100,000 of the shares owned of record by EBI, Inc., Mr. Perri also has investment power and otherwise is entitled to the economic benefits of ownership.

(11) Mr. Perri beneficially owns 124,050 of the shares owned of record by GHI, Inc. by reason of his ownership of investment power and other economic benefits associated with such shares and his sole power to vote the shares. Ms. Gluskin and Ms. Perri each own beneficially 1,188,000 of the shares owned of record by GHI, Inc. by reason of their ownership of investment power and other economic benefits associated with such shares. The shares beneficially owned by Ms. Gluskin and Ms. Perri also are deemed to be beneficially owned by Mr. Perri because he has the sole power to vote the shares.

(12) Includes warrants to purchase a total of 164,467 shares of the Common Stock.

Certain Relationships and Related Transactions

Generex acquired Generex Pharmaceuticals, Inc. in October 1997. Prior to Generex's acquisition of Generex Pharmaceuticals, it was a private Canadian corporation majority-owned and controlled by Mr. Perri, Ms. Perri and Ms. Gluskin. Unless otherwise indicated, the transactions described below occurred prior to the acquisition of Generex Pharmaceuticals or pursuant to contractual arrangements entered into prior to that time. Generex presently has a policy requiring approval by stockholders or by a majority of disinterested directors of transactions in which one of our directors has a material interest apart from such director's interest in Generex.

Real Estate Financing Transactions: In May 1997, EBI, Inc., a company controlled by Mr. Perri, acquired shares of common stock of Generex Pharmaceuticals for $3 million (CAD) which, based on the exchange rate then in effect, represented approximately $2.1 million (US). Generex Pharmaceutical's use of those funds was restricted to acquiring an insulin research facility. Subsequently this restriction was eased to permit use of the funds to acquire properties used for manufacturing Generex's oral insulin product and other proprietary drug delivery products, and related testing, laboratory and administrative services. Under the terms of the investment, Generex Pharmaceuticals was required to lend these funds back to EBI until they were needed for the purposes specified. The entire amount was loaned back to EBI and was outstanding at July 31, 1997. During the period ended July 31, 1998, a total of $2,491,835 (CAD) was repaid by EBI. There were no repayments made in the years ended July 31, 2001, 2000 and 1999. The balance due from EBI at July 31, 2001, was $508,165 (CAD) (approximately $332,289 (US) based on the exchange rate then in effect). These funds are due on demand by Generex Pharmaceuticals, provided they are used for the purchase and/or construction or equipping of oral insulin manufacturing and testing facilities. The amounts repaid by EBI were used primarily to purchase and improve certain of the real estate and buildings owned by Generex.

Related Party Transactions: Between November 1995 and July 31, 1998, companies owned and controlled by Mr. Perri, Ms. Perri and Ms. Gluskin incurred a net indebtedness of $629,234 to Generex Pharmaceuticals, excluding the indebtedness of EBI described in the preceding paragraph. This indebtedness arose from cash advances and the payment by Generex Pharmaceuticals of expenses incurred by these companies, net of repayments and payment of expenses on behalf of Generex Pharmaceuticals. At July 31, 1999, these companies' net indebtedness to Generex Pharmaceuticals, exclusive of the EBI indebtedness described above, was $284,315. At July 31, 2000, this balance had been reduced to zero. The transactions between Generex Pharmaceuticals and entities owned and controlled by Mr. Perri, Ms. Perri and Ms. Gluskin were not negotiated at arms-length, and were not on normal commercial terms. No interest was charged on any of the advances, and the transactions were of far greater financial benefit and convenience to Mr. Perri, Ms. Perri and Ms. Gluskin than to Generex Pharmaceuticals. These transactions and financing arrangements were mostly initiated prior to the transaction in which Generex acquired Generex Pharmaceuticals, and no such transactions have taken place since January 1, 1999. Generex presently has a policy requiring the approval of the Board of Directors, including a majority of

disinterested directors, for any transactions in which a director has a material interest apart from such director's interest in Generex.

Loans to Executive Officers: On May 3, 2001, Generex loaned $334,300 each to Mr. Perri, Ms. Perri and Ms. Gluskin in exchange for promissory notes. These notes bear interest at 8.5 percent per annum and are payable in full on May 1, 2002. These notes are guaranteed by GHI, Inc., a related company owned by these officers and are secured by a pledge of 2,500,000 shares of Common Stock held of record by GHI, Inc. As of October 31, 2001, the balance outstanding on these notes, including accrued interest, was $1,046,215. The loans were approved by a majority of the disinterested directors.

Joint Venture with Elan: In January 2001, Generex established a joint venture with Elan International Services, Ltd. ("EIS") and Elan Corporation, plc ("Elan"). Pursuant to the Securities Purchase Agreement dated January 16, 2001, between Generex, Elan and EIS, 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 is the nominee of EIS thereunder. In connection with the transaction, EIS purchased 344,116 shares of Common Stock for $5,000,000 and was issued a warrant to acquire 75,000 shares of Common Stock at $25.15 per share. If the joint venture achieves certain milestones, Generex may require EIS to purchase an additional $1,000,000 of Common Stock at a 30% premium to the then prevailing fair market value of shares of Common Stock. EIS also purchased 1,000 shares of a new series of Generex preferred stock, designated as Series A Preferred Stock, for $12,015,000. The proceeds from the sale of the Series A Preferred Stock were applied by Generex 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 Generex initially owns 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 Generex's interest in the joint venture entity. Alternatively, the Series A Preferred Stock may be converted, under certain conditions, into shares of Common Stock at a conversion price of $25.71 per share. The shares of Common Stock and shares of Series A Preferred Stock presently are held of record by an affiliate of EIS.

OTHER INFORMATION

Annual Report

Generex has enclosed its Annual Report for the year ended July 31, 2001, with this proxy statement, which includes Generex's Annual Report to the Securities and Exchange Commission on Form 10-K for the fiscal year ended July 31, 2001, without exhibits. Stockholders are referred to the report for financial and other information about Generex, but such report is not incorporated in this proxy statement and is not a part of the proxy soliciting material.

Stockholder Proposals for the Next Annual Meeting

Any proposals of stockholders intended to be presented at the annual meeting of stockholders for the fiscal year ended July 31, 2002, must be received by Generex at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2, no later than September 1, 2002 in order to be included in the proxy materials and form of proxy relating to such meeting. It is suggested that stockholders submit any proposals by an internationally recognized overnight delivery service to the Secretary of Generex. Such proposal must meet the requirements set forth in the rules and regulations of the Securities and Exchange Commission in order to be eligible for inclusion in the proxy materials for such meeting. The annual meeting for the fiscal year ended July 31, 2002 is scheduled to take place in February 2003.

For business to be properly brought before the annual meeting by a stockholder in a form other than a stockholder proposal, any stockholder who wishes to bring such business before the annual meeting of stockholders must give notice of such business in writing to the Secretary of Generex not less than 60 nor more than 90 days prior to the annual meeting. In the event that less than 70 days notice or prior disclosure of the date of the meeting is given or made to stockholders, notice of such business to be timely must be received by the Secretary of Generex not later than the close of business on the 10th day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made. The stockholder's notice of such

business must provide information about the stockholder proposing such business and the nature the business, as required by Generex's Amended and Restated Bylaws. A copy of these Bylaw requirements will be provided upon request in writing to the Secretary at the principal offices of Generex.

If there should be any change in the foregoing submission deadlines, Generex intends to publicly disseminate information concerning the change.

Director Nominees

Any stockholder entitled to vote for the election of directors may nominate a person for election to the Board of Directors at the annual meeting. Any stockholder wishing to do so must submit a notice of such nomination in writing to the Secretary of Generex at Generex's principal offices not less than 60 nor more than 90 days prior to the annual meeting. In the event that less than 70 days notice or prior disclosure of the date of the meeting is given or made to stockholders, notice of nomination by a stockholder to be timely must be received not later than the close of business on the 10th day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made. The stockholder's notice of nomination must provide information about both the nominee and the nominating stockholder, as required by Generex's Amended and Restated Bylaws. A copy of these Bylaw requirements will be provided upon request in writing to the Secretary at the principal offices of Generex.

Other Matters

The Board does not intend to present, and does not have any reason to believe that others will present, any item of business at the annual meeting other than those specifically set forth in the notice of the meeting. However, if other matters are properly brought before the meeting, the persons named on the enclosed proxy will have discretionary authority to vote all proxies in accordance with their best judgment.

Solicitation of Proxies

All costs and expenses of this solicitation, including the cost of preparing and mailing this proxy statement will be borne by Generex. In addition to the use of the mails, certain directors, officers and regular employees of Generex may solicit proxies personally, or by mail, telephone or otherwise, but such persons will not be compensated for such services. Arrangements will be made with brokerage firms, banks, fiduciaries, voting trustees or other nominees to forward the soliciting materials to each beneficial owner of stock held of record by them, and Generex will reimburse them for their expenses in doing so.

By order of the Board of Directors

Rose C. Perri
Secretary

February 8, 2002

EXHIBIT A

GENEREX BIOTECHNOLOGY CORPORATION
2001 STOCK OPTION PLAN

The purpose of the Generex Biotechnology Corporation 2001 Stock Plan (the "Plan") is to provide (i) designated employees of Generex Biotechnology Corporation (the "Company") and its subsidiaries, (ii) certain consultants and advisors who perform services for the Company or its subsidiaries and (iii) non-employee members of the Board of Directors of the Company (the "Board") with the opportunity to receive grants of incentive stock options and nonqualified stock options (collectively, "Options"). The Company believes that the Plan will encourage the participants to contribute materially to the growth of the Company, thereby benefiting the Company's stockholders, and will align the economic interests of the participants with those of the stockholders.

1. Administration

(a) *Committee.* The Plan shall be administered and interpreted by the Compensation Committee (the "Committee") of the Board, which consists of two or more persons who are "outside directors" as defined under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), and related Treasury regulations and "non-employee directors" as defined under Rule 16b-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). However, the Board may ratify or approve any Option grants as it deems appropriate.

(b) *Committee Authority.* The Committee shall have the sole authority to (i) determine the individuals to whom Options shall be granted under the Plan, (ii) determine the type, size and terms of the Options to be made to each such individual, (iii) determine the time when the Options will be granted and the duration of any applicable exercise period, including the criteria for exercisability and the acceleration of exercisability, (iv) amend the terms of any previously issued Option and (v) deal with any other matters arising under the Plan.

(c) *Delegation.* The Committee may delegate certain of its duties to one or more of its members or to one or more agents as it may deem advisable. The Committee may employ attorneys, agents, consultants, accountants or other persons, and shall be entitled to rely upon the advice, opinions or valuations of such persons.

(d) *Committee Determinations.* The Committee shall have full power and authority to administer and interpret the Plan, to make factual determinations and to adopt or amend such rules, regulations, agreements and instruments for implementing the Plan and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Committee's interpretations of the Plan and all determinations made by the Committee pursuant to the powers vested in it hereunder shall be conclusive and binding on all persons having any interest in the Plan or in any awards granted hereunder. All powers of the Committee shall be executed in its sole discretion, in the best interest of the Company, not as a fiduciary, and in keeping with the objectives of the Plan and need not be uniform as to similarly situated individuals.

2. Shares Subject to the Plan

(a) *Shares Authorized.* Subject to adjustment as described below, the aggregate number of shares of common stock of the Company ("Company Stock") that may be issued or transferred under the Plan or upon which awards under the Plan may be granted is 4,000,000 shares. The maximum aggregate number of shares of Company Stock that shall be subject to Options granted under the Plan to any individual during any calendar year shall be 400,000 shares. The shares may be authorized but unissued shares of Company Stock or reacquired shares of Company Stock, including shares purchased by the Company on the open market for purposes of the Plan. If and to the extent Options granted under the Plan terminate, expire, or are canceled, forfeited, exchanged or surrendered without having been exercised, the shares subject to such Options shall again be available for purposes of the Plan, unless otherwise provided by the Committee.

(b) *Adjustments.* If there is any change in the number or kind of shares of Company Stock outstanding by reason of (i) stock dividend, spinoff, recapitalization, stock split or combination or exchange of shares, (ii) merger, reorganization or consolidation, (iii) reclassification or change in par value or (iv) any other extraordinary or unusual event affecting the outstanding Company Stock as a class without the Company's receipt of consideration, or if the value of outstanding shares of Company Stock is substantially reduced as a

result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the maximum number of shares of Company Stock available under the Plan, the maximum number of shares of Company Stock that any individual participating in the Plan may be granted in any year, the number of shares covered by outstanding Options, the kind of shares issued under the Plan, and the price per share or the applicable market value of such Options may be appropriately adjusted by the Committee to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of Company Stock to preclude, to the extent practicable, the enlargement or dilution of rights and benefits under such Options; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. Any adjustments determined by the Committee shall be final, binding and conclusive.

3. Eligibility for Participation

(a) *Eligible Persons.* All employees of the Company and its subsidiaries ("Employees") and members of the Board who are not Employees ("Non-Employee Directors") shall be eligible to participate in the Plan. Consultants and advisors who perform services for the Company or any of its subsidiaries ("Key Advisors") shall be eligible to participate in the Plan if the Key Advisors render bona fide services to the Company or its subsidiaries, the services are not in connection with the offer and sale of securities in a capital-raising transaction and the Key Advisors do not directly or indirectly promote or maintain a market for the Company's securities.

(b) *Selection of Optionees.* The Committee shall select the Employees, Non-Employee Directors and Key Advisors to receive Options and shall determine the number of shares of Company Stock subject to a particular Option in such manner as the Committee determines. Employees, Key Advisors and Non-Employee Directors who receive Options under this Plan shall hereinafter be referred to as "Optionees."

4. Granting of Options

(a) *Option Agreements.* All Options shall be subject to the terms and conditions set forth herein and to such other terms and conditions consistent with this Plan as the Committee deems appropriate and as are specified in writing by the Committee to the individual in a grant instrument or an amendment to the grant instrument (the "Option Agreement"). The Committee shall approve the form and provisions of each Option Agreement.

(b) *Number of Shares.* The Committee shall determine the number of shares of Company Stock that will be subject to each Option.

(c) *Type of Option and Price.*

(i) The Committee may grant Options that are intended to qualify as "incentive stock options" within the meaning of Section 422 of the Code ("Incentive Stock options") or Options that are not intended so to qualify ("Nonqualified Stock Options") or any combination of Incentive Stock Options and Nonqualified Stock Options, all in accordance with the terms and conditions set forth herein. Incentive Stock Options may be granted only to Employees of the Company or a parent or subsidiary (within the meaning of Section 424(f) of the Code). Nonqualified Stock Options may be granted to Employees, Non-Employee Directors and Key Advisors. Unless otherwise provided in the Option Agreement, any Option granted under this Plan to an Employee is intended to be an Incentive Stock Option.

(ii) The purchase price (the "Exercise Price") of Company Stock subject to an Option shall be determined by the Committee and may be equal to or less than the Fair Market Value (as defined below) of a share of Company Stock on the date the Option is granted; provided, however, that (x) the Exercise Price of an Incentive Stock Option shall be equal to the Fair Market Value of a share of Company Stock on the date the Incentive Stock Option is granted and (y) an Incentive Stock Option may not be granted to an Employee who, at the time of grant, owns stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company or any parent or subsidiary of the Company, unless the Exercise Price per share is not less than 110% of the Fair Market Value of Company Stock on the date of grant.

(iii) The Fair Market Value per share shall be the closing price of the Company Stock on the relevant date or (if there were no trades on that date) the latest preceding date upon which a sale was reported.

(d) *Option Term.* The Committee shall determine the term of each Option. The term of any Option shall not exceed ten years from the date of grant, which date of grant is determined by the Committee. However, an Incentive Stock Option that is granted to an Employee who, at the time of grant, owns stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company, or any parent or subsidiary of the Company, may not have a term that exceeds five years from the date of grant.

(e) *Exercisability of Options.* Options shall become exercisable in accordance with such terms and conditions, consistent with the Plan, as may be determined by the Committee and specified in the Option Agreement. Unless a different vesting schedule is specified by the Committee in an Option Agreement, Options granted under this Plan shall vest in one-half increments on each annual anniversary of the date of grant over a period of two years. The Committee may accelerate, and may provide in the Option Agreement for the acceleration of, the exercisability of any or all outstanding Options at any time for any reason.

(f) *Reload Options.* In the event that shares of Company Stock are used to exercise an Option, the terms of such Option may provide for the grant of additional Options, or the Committee may grant additional Options, to purchase a number of shares of Company Stock equal to the number of whole shares used to exercise the Option and the number of whole shares, if any, withheld in payment of any taxes. Such Options shall be granted with an Exercise Price equal to the Fair Market Value of the Company Stock on the date of grant of such additional Options, or at such other Exercise Price as the Committee may establish, for a term not longer than the unexpired term of the exercised Option and on such other terms as the Committee shall determine.

(g) *Limit on Incentive Stock Options.* Each Incentive Stock Option shall provide that, if the aggregate Fair Market Value of the stock on the date of the grant with respect to which Incentive Stock Options are exercisable for the first time by an Optionee during any calendar year, under the Plan or any other stock option plan of the Company or a parent or subsidiary, exceeds $100,000, then the Option, as to the excess, shall be treated as a Nonqualified Stock Option.

5. Termination of Employment, Disability or Death

(a) *General Rule.* Except as provided below, an Option may only be exercised while the Optionee is employed by, or providing service to, the Company as an Employee, Key Advisor or member of the Board. In the event that an Optionee ceases to be employed by, or provide service to, the Company for any reason other than (i) termination by the Company without Cause (as defined below), (ii) voluntary termination by the Optionee, (iii) Disability (as defined below) or (iv) death, any Option held by the Optionee shall terminate immediately (unless the Committee specifies otherwise). In addition, notwithstanding any other provision of this Plan, if the Committee determines that the Optionee has engaged in conduct that constitutes Cause at any time while the Optionee is employed by, or providing service to, the Company or after the Optionee's termination of employment or service, any Option held by the Optionee shall immediately terminate and the Optionee shall automatically forfeit all shares underlying any exercised portion of an Option for which the Company has not yet delivered the share certificates, upon refund by the Company of the Exercise Price paid by the Optionee for such shares. Upon any exercise of an Option, the Company may withhold delivery of share certificates pending resolution of an inquiry that could lead to a finding resulting in a forfeiture.

(b) *Termination Without Cause; Voluntary Termination.* In the event that an Optionee ceases to be employed by, or provide service to, the Company as a result of (i) termination by the Company without Cause (as defined below) or (ii) voluntary termination by the Optionee, any Option which is otherwise exercisable by the Optionee shall terminate unless exercised within 90 days after the date on which the Optionee ceases to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Optionee's Options that are not otherwise exercisable as of the date on which the Optionee ceases to be employed by, or provide service to, the Company shall terminate as of such date.

(c) *Termination Because Disabled.* In the event the Optionee ceases to be employed by, or provide service to, the Company because the Optionee is Disabled, any Option which is otherwise exercisable by the Optionee shall terminate unless exercised within one year after the date on which the Optionee ceases to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the

Committee, any of the Optionee's Options which are not otherwise exercisable as of the date on which the Optionee ceases to be employed by, or provide service to, the Company shall terminate as of such date.

(d) *Death.* If the Optionee dies while employed by, or providing service to, the Company or within 90 days after the date on which the Optionee ceases to be employed or provide service on account of a termination specified in Section 5(b) above (or within such other period of time as may be specified by the Committee), any Option that is otherwise exercisable by the Optionee shall terminate unless exercised within one year after the date on which the Optionee dies or otherwise ceased to be employed by, or provide service to, the Company (or within such other period of time as may be specified by the Committee), but in any event no later than the date of expiration of the Option term. Except as otherwise provided by the Committee, any of the Optionee's Options that are not otherwise exercisable as of the date on which the Optionee dies or otherwise ceased to be employed by, or provide service to, the Company shall terminate as of such date.

(e) *Definitions.*

(i) The term "Company" shall mean the Company and its parent and subsidiary corporations or other entities, as determined by the Committee.

(ii) "Employed by, or provide service to, the Company" shall mean employment or service as an Employee, Key Advisor or member of the Board (so that an Optionee shall not be considered to have terminated employment or service until the Optionee ceases to be an Employee, Key Advisor and member of the Board), unless the Committee determines otherwise.

(iii) "Disability" shall mean an Optionee's becoming disabled under the Company's long-term disability plan, or, if the Optionee is not covered under such plan or no such plan is maintained, and in the case of an Incentive Stock Option, "Disability" shall mean an Optionee's becoming disabled within the meaning of Section 22(e)(3) of the Code.

(iv) "Cause" shall mean, except to the extent specified otherwise by the Committee, a finding by the Committee that the Optionee has: (i) breached his or her employment or service contract with the Company; (ii) engaged in disloyalty to the Company, including, without limitation, fraud, embezzlement, theft, commission of a felony or proven dishonesty in the course of his or her employment or service; (iii) disclosed trade secrets or confidential information of the Company to persons not entitled to receive such information; (iv) breached any written confidentiality, non-competition or non-solicitation agreement between the Optionee and the Company; or (v) has engaged in such other behavior detrimental to the interests of the Company as the Committee determines.

6. Exercise of Options.

(a) *Notice of Exercise.* A Optionee may exercise an Option that has become exercisable, in whole or in part, by delivering a notice of exercise to the Company.

(b) *Payment of Exercise Price.* Along with the notice of exercise, the Optionee shall pay the Exercise Price for an Option as specified by the Committee (i) in cash, (ii) with the approval of the Committee, by delivering shares of Company Stock owned by the Optionee (including Company Stock acquired in connection with the exercise of an Option, subject to such restrictions as the Committee deems appropriate) valued at Fair Market Value on the date of exercise, (iii) with the approval of the Committee, by surrender of outstanding awards under the Plan or (iv) by such other method as the Committee may approve. Shares of Company Stock used to exercise an Option shall have been held by the Optionee for the requisite period of time to avoid adverse accounting consequences to the Company with respect to the Option.

(c) *Payment of Tax.* The Optionee shall pay the amount of any withholding tax due at the time of exercise.

7. Deferrals

The Committee may permit or require an Optionee to defer receipt of the delivery of shares that would otherwise be due to such Optionee in connection with any Option. If any such deferral election is permitted or required, the Committee shall, in its sole discretion, establish rules and procedures for such deferrals.

8. Withholding of Taxes

(a) *Required Withholding.* All Options under the Plan shall be subject to applicable federal (including FICA), state, local and other tax withholding requirements. The Company shall have the right to deduct from any amounts paid to the Optionee, any federal, state, local or other taxes required by law to be withheld with respect to such Options. The Company may require that the Optionee or other person receiving or exercising Options pay to the Company the amount of any federal, state, local or other taxes that the Company is required to withhold with respect to such Options, or the Company may deduct from other wages paid by the Company the amount of any withholding taxes due with respect to such Options.

(b) *Election to Withhold Shares.* If the Committee so permits, an Optionee may elect, in the form and manner prescribed by the Committee, to satisfy the Company's income tax withholding obligation with respect to Options paid in Company Stock by having shares withheld up to an amount that does not exceed the Optionee's minimum applicable withholding tax rate for federal (including FICA), state, local and other tax liabilities.

9. Transferability of Options

(a) *Nontransferability of Options.* Except as provided below, only the Optionee may exercise rights under an Option during the Optionee's lifetime. A Optionee may not transfer those rights except (i) by will or by the laws of descent and distribution or (ii) with respect to Nonqualified Stock Options, if permitted in any specific case by the Committee, pursuant to a domestic relations order or otherwise as permitted by the Committee. When an Optionee dies, the personal representative or other person entitled to succeed to the rights of the Optionee ("Successor Optionee") may exercise such rights. A Successor Optionee must furnish proof satisfactory to the Company of his or her right to receive the Option under the Optionee's will or under the applicable laws of descent and distribution.

(b) *Transfer of Nonqualified Stock Options.* Notwithstanding the foregoing, the Committee may provide that an Optionee may transfer Nonqualified Stock Options to family members, or one or more trusts or other entities for the benefit of or owned by family members, consistent with the applicable securities laws, according to such terms as the Committee may determine; provided that the Optionee receives no consideration for the transfer of an Option and the transferred Option shall continue to be subject to the same terms and conditions as were applicable to the Option immediately before the transfer.

10. Change of Control of the Company

As used herein, a "Change of Control" shall be deemed to have occurred if:

(a) Unless the Board approves such acquisition, any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, in a single transaction or series of transactions, of securities of the Company representing more than 20 percent of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a change of ownership resulting from the death of a stockholder, and a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 20 percent of all votes to which all stockholders of the parent corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote);

(b) A merger or consolidation of the Company is consummated with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 80 percent of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors (without consideration of the rights of any class of stock to elect directors by a separate class vote);

(c) A sale or other disposition of all or substantially all of the assets of the Company occurs;

(d) A liquidation or dissolution of the Company occurs; or

(e) Shares of the Company's Special Voting Rights Preferred Stock are outstanding and a "Change of Control" under the terms and conditions of such securities occurs.

11. Consequences of a Change of Control

(a) *Notice and Acceleration.* Unless the Committee determines otherwise, any outstanding Options that are not yet exercisable or vested shall become exercisable or vested as of the Change of Control. The Committee shall provide notice to Optionees of the Change of Control as soon as practicable.

(b) *Assumption of Options.* Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Committee determines otherwise, all outstanding Options that are not exercised shall be assumed by, or replaced with comparable options or rights by, the surviving corporation (or a parent or subsidiary of the surviving corporation).

(c) *Other Alternatives.* Notwithstanding the foregoing, subject to subsection (d) below, in the event of a Change of Control, the Committee may take one or both of the following actions with respect to any or all outstanding Options: (i) the Committee may require that Optionees surrender their outstanding Options in exchange for a payment by the Company, in cash or Company Stock as determined by the Committee, in an amount equal to the amount by which the then Fair Market Value of the shares of Company Stock subject to the Optionee's unexercised Options exceeds the Exercise Price of the Options; or (ii) the Committee may, after giving Optionees an opportunity to exercise their outstanding Options, terminate any or all unexercised Options at such time as the Committee deems appropriate. Such surrender or termination or settlement shall take place as of the date of the Change of Control or such other date as the Committee may specify.

(d) *Limitations.* Notwithstanding anything in the Plan to the contrary, in the event of a Change of Control, the Committee shall not have the right to take any actions described in the Plan (including without limitation actions described in subsection (c) above) that would make the Change of Control ineligible for pooling of interests accounting treatment or that would make the Change of Control ineligible for desired tax treatment if, in the absence of such right or action, the Change of Control would qualify for such treatments and the Company intends to use such treatments with respect to the Change of Control.

12. Requirements for Issuance or Transfer of Shares

(a) *Limitations on Issuance or Transfer of Shares.* No Company Stock shall be issued or transferred in connection with any Option hereunder unless and until all legal requirements applicable to the issuance or transfer of such Company Stock have been complied with to the satisfaction of the Committee. The Committee shall have the right to condition any Option made to any Optionee hereunder on such Optionee's undertaking in writing to comply with such restrictions on his or her subsequent disposition of such shares of Company Stock as the Committee shall deem necessary or advisable, and certificates representing such shares may be legended to reflect any such restrictions. Certificates representing shares of Company Stock issued or transferred under the Plan will be subject to such stop-transfer orders and other restrictions as may be required by applicable laws, regulations and interpretations, including any requirement that a legend be placed thereon.

(b) *Lock-Up Period.* If so requested by the Company or any representative of the underwriters (the "Managing Underwriter") in connection with any underwritten offering of securities of the Company under the Securities Act of 1933, as amended (the "Securities Act"), an Optionee (including any successors or assigns) shall not sell or otherwise transfer any shares or other securities of the Company during the 30-day period preceding and the 180-day period following the effective date of a registration statement of the Company filed under the Securities Act for such underwritten offering (or such shorter period as may be requested by the Managing Underwriter and agreed to by the Company) (the "Market Standoff Period"). The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

13. Cancellation and Recission of Options

(a) Unless the Option Agreement specifies otherwise, the Committee may cancel, rescind, suspend, withhold or otherwise limit or restrict any unexpired, unpaid or deferred Options at any time if the Optionee is not

in compliance with all applicable provisions of the Option Agreement and the Plan, or if the Optionee engages in any "Detrimental Activity." For purposes of this Section 16, "Detrimental Activity" shall include: (i) the rendering of services for any organization or engaging directly or indirectly in any business which is or becomes competitive with the Company, or which organization or business, or the rendering of services to such organization or business, is or becomes otherwise prejudicial to or in conflict with the interests of the Company; (ii) the disclosure to anyone outside the Company, or the use in other than the Company's business, without prior written authorization from the Company, of any confidential information or material, in violation of the Company's applicable agreement with the Optionee or of the Company's applicable policy regarding confidential information and intellectual property; (iii) the failure or refusal to disclose promptly and to assign to the Company, pursuant to the Company's applicable agreement with the Optionee or to the Company's applicable policy regarding confidential information and intellectual property, all right, title and interest in any invention or idea, patentable or not, made or conceived by the Optionee during employment by the Company, relating in any manner to the actual or anticipated business, research or development work of the Company, or the failure or refusal to do anything reasonably necessary to enable the Company to secure a patent where appropriate in the United States and in other countries; (iv) activity that results in termination of the Optionee's employment for cause; (v) a violation of any rules, policies, procedures or guidelines of the Company, including (but not limited to) the Company's business conduct guidelines; (vi) any attempt (directly or indirectly) to induce any employee of the Company to be employed or perform services elsewhere or any attempt (directly or indirectly) to solicit the trade or business of any current or prospective customer, supplier or partner of the Company; (vii) the Optionee's being convicted of, or entering a guilty plea with respect to, a crime, whether or not connected with the Company; or (viii) any other conduct or act determined to be injurious, detrimental or prejudicial to any interest of the Company.

(b) Upon exercise, payment or delivery pursuant to an Option, the Optionee shall certify in a manner acceptable to the Company that he or she is in compliance with the terms and conditions of the Plan. In the event an Optionee fails to comply with the provisions of paragraphs (a)(i)-(viii) of this Section 13 prior to, or during the six months after, any exercise, payment or delivery pursuant to an Award, such exercise, payment or delivery may be rescinded within two years thereafter. In the event of any such rescission, the Optionee shall pay to the Company the amount of any gain realized or payment received as a result of the rescinded exercise, payment or delivery, in such manner and on such terms and conditions as may be required, and the Company shall be entitled to set-off against the amount of any such gain any amount owed to the Optionee by the Company.

(c) The Committee, in its sole discretion, may grant to an Optionee, in exchange for the surrender and cancellation of an Option previously granted to the Optionee, a new Option in the same or different form and containing such terms, including without limitation a price that is higher or lower than any price provided in the award so surrendered or cancelled.

14. Amendment and Termination of the Plan

(a) *Amendment.* The Committee may amend or terminate the Plan at any time; provided, however, that the Committee shall not increase the aggregate number of shares of Company Stock that may be issued or transferred under the Plan or upon which awards under the Plan may be granted, or otherwise materially amend the Plan, without stockholder approval if such approval is required in order to comply with the Code or applicable laws, or to comply with applicable stock exchange requirements.

(b) *Termination of Plan.* No Incentive Stock Option may be granted more than ten years from the Plan's effective date. The Plan may be terminated by the Committee at any time.

(c) *Termination and Amendment of Outstanding Options.* A termination or amendment of the Plan that occurs after an Option is made shall not materially impair the rights of an Optionee unless the Optionee consents or unless the Committee acts under Section 20(b). The termination of the Plan shall not impair the power and authority of the Committee with respect to an outstanding Option. Whether or not the Plan has terminated, an outstanding Option may be terminated or amended under Section 20(b) or may be amended by agreement of the Company and the Optionee consistent with the Plan.

(d) *Governing Document.* The Plan shall be the controlling document. No other statements, representations, explanatory materials or examples, oral or written, may amend the Plan in any manner. The Plan shall be binding upon and enforceable against the Company and its successors and assigns.

15. Funding of the Plan

This Plan shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any Options under this Plan. In no event shall interest be paid or accrued on any Option, including unpaid installments of Options.

16. Rights of Participants

Nothing in this Plan shall entitle any Employee, Key Advisor, Non-Employee Director or other person to any claim or right to be granted an Option under this Plan. Neither this Plan nor any action taken hereunder shall be construed as giving any individual any rights to be retained by or in the employ of the Company or any other employment rights.

17. No Fractional Shares

No fractional shares of Company Stock shall be issued or delivered pursuant to the Plan or any Option. The Committee shall determine whether cash, other awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

18. Headings

Section headings are for reference only. In the event of a conflict between a title and the content of a Section, the content of the Section shall control.

19. Effective Date of the Plan

Subject to approval by the Company's stockholders, the Plan shall be effective as of May 4, 2001.

20. Miscellaneous

(a) *Options in Connection with Corporate Transactions and Otherwise.* Nothing contained in this Plan shall be construed to (i) limit the right of the Committee to grant Options under this Plan in connection with the acquisition, by purchase, lease, merger, consolidation or otherwise, of the business or assets of any corporation, firm or association, including Options to employees thereof who become Employees of the Company, or for other proper corporate purposes, or (ii) limit the right of the Company to grant stock options or make other awards outside of this Plan. Without limiting the foregoing, the Committee may grant an Option to an employee of another corporation who becomes an Employee by reason of a corporate merger, consolidation, acquisition of stock or property, reorganization or liquidation involving the Company or any of its subsidiaries in substitution for a stock option or stock awards grant made by such corporation. The terms and conditions of the substitute Options may vary from the terms and conditions required by the Plan and from those of the substituted stock incentives. The Committee shall prescribe the provisions of the substitute grants.

(b) *Compliance with Law.* The Plan, the exercise of Options and the obligations of the Company to issue or transfer shares of Company Stock under Options shall be subject to all applicable laws and to approvals by any governmental or regulatory agency as may be required. The Committee may revoke any Option if it is contrary to law or modify an Option to bring it into compliance with any valid and mandatory government regulation. The Committee may also adopt rules regarding the withholding of taxes on payments to Optionees. The Committee may, in its sole discretion, agree to limit its authority under this Section.

(c) *Governing Law.* The validity, construction, interpretation and effect of the Plan and Option Agreements issued under the Plan shall be governed and construed by and determined in accordance with the laws of State of Delaware, without giving effect to the conflict of laws provisions thereof.

FORM

GENEREX BIOTECHNOLOGY

2001

10K

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

(Mark One)

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

For the fiscal year ended July 31, 2001

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

Commission File No. 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:

Title of Each Class Common Stock ($.001 par value)

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 reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] 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 15, 2001, based on the closing price as of that date, was approximately $64,625,733. At October 15, 2001, the registrant had 20,682,634 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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), the notes to our audited financial statements (Item 8) 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, 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

→ adverse developments in our collaboration with Lilly regarding oral insulin, which is currently our only product candidate that has moved beyond preliminary research and development.

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.

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. The parties intend to select at least one pharmaceutical product for research and development under the joint venture within one year's time. 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 current fiscal year had not received any revenues from operations. We have no products approved for commercial sale by drug regulatory authorities and only one product, our oral insulin formulation, for which we have begun the regulatory approval process. As noted above, however, 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. Fentanyl, morphine, 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 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, which is stable at room temperature, 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.

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 blood-stream. 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 can-not properly use the insulin produced. Type 2 diabetes is the most common form of the disease and accounts for 90-95 per-cent 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 dis-ease (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 diabet-ics worldwide. It is further estimated that this number will almost double by the year 2025. There are estimated to be 17 mil-lion 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.

As noted above, 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. We have had discussions of possible research collaborations with various pharmaceutical companies concerning use of our large molecule drug delivery technology with these compounds, which include monoclonal antibodies, human growth hormone, fertility hormone, fentanyl, morphine, 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 also raised approximately $37 million from private placements of our common stock during the last fiscal year. Based on the financial structure of the Lilly agreement and the amounts raised through private placements, we believe we now have sufficient financial resources to pursue development 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 regulations apply to all competitors in our industry, many of our competitors have extensive experience in dealing with FDA and other regulators, while we do not. Also, other companies in our industry do not depend completely on products which still need to be approved by government regulators, as we now do.

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

United States. All aspects of our research, development and foreseeable commercial activities are subject to extensive regulation by FDA and other regulatory authorities in the United States. United States federal and state statutes and regulations govern, among other things, the testing, 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.

Preclinical 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 preclinical 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.

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 preclinical 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 in Canada in November 1998. In Ecuador, regulatory authorities approved the limited non-commercial distribution of our oral insulin formulation in September 1998.

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. Except for our agreement with Lilly with respect to our oral insulin product, 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, both 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 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.

Intellectual Property

We currently have been issued five U.S. patents pertaining to aspects of buccal delivery technology, and we have eleven U.S. patent applications and one Canadian patent application pending, including applications that cover our oral insulin formulation and technology. In addition, we hold one U.S. patent and one Canadian patent and have two Canadian applications pending that pertain 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 fifty (50%) percent 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 products using different methods of administration. For example, a number of pharmaceutical and biotechnology companies are engaged in various stages of research, development and testing of alternatives to insulin therapy for the treatment of diabetes, as well as new methods of delivering insulin. These methods, including nasal, transdermal 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. Within this category, we consider Inhale Therapeutics, Inc. to be our principal competitor for our insulin product.

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

Aradigm Corporation, which has announced a joint development agreement with Novo Nordisk A/S to jointly develop a pulmonary delivery system for insulin by inhalation, also may be considered a direct competitor of ours in the insulin area. Novo Nordisk is one of the two leading manufacturers of insulin in the world, the other being Eli Lilly and Company. Aradigm began Phase II 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 Dura Pharmaceuticals, which announced a collaboration with Eli Lilly and Company in 1998 to develop a pulmonary method of administering insulin, and 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 (pills taken orally), Nobex (pills taken orally), and Nastech (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.

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, 2001, our expenditures on research and development were $26,316,114. These included $19,149,860 in the year ended July 31, 2001, which includes a one-time charge for the licensing fee in connection with the Elan transaction, $3,476,436 in the year ended July 31, 2000 and $1,853,108 in the year ended July 31, 1999. (See "Management's Discussion and Analysis of Financial Condition and Results of Operations" (Item 7) for discussion of the licensing fee in connection with the Elan transaction.)

Employees

At September 30, 2001, we had 22 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, five 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. 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.

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. We may not be successful in obtaining regulatory clearance for the sale of existing or any future products, or any of these products may not be commercially viable.

In September 2000, as noted above, 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™ 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 successfully with other large molecule drugs in addition to insulin. We have engaged in preliminary research and development work on other applications, but we have not devoted significant time or resources to this effort to date. In January 2001, as noted above, 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. However, we and Elan have not yet selected a specific product for research and development under the joint venture, and we cannot predict whether our technology can be applied successfully to any such product, when or if selected.

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 only one product, our oral insulin formulation.

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.

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 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 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, 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.

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 may, however, 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 oral 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. Unforeseen problems, including materially negative developments in our relationship with Lilly, in our clinical trials or in general economic conditions could interfere with our ability to raise additional equity capital or materially adversely affect the terms upon which such funding is available.

It is 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.

If we are not able to obtain sufficient patent protection for our buccal delivery technology, we may face competition from potential competitors who may use the unprotected aspects of our technology to our disadvantage.

Our long-term success will substantially depend upon protecting our technology from infringement, misappropriation, discovery and duplication. We currently have been issued five U.S. patents pertaining to aspects of buccal delivery technology, and we have eleven U.S. patent applications and one Canadian patent application pending, including applications that, if granted, would cover our oral insulin formulation and technology. In addition, we hold one U.S. patent and one Canadian patent and have two Canadian applications pending that pertain 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.

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 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 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 invoving intellectual property issues.) Furthermore, patent applications are 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 any technology that we currently are developing.

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.

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

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 the our common stock. The Appellate Division held that the portion of the award directing us to issue warrants to Sands is too indefinite to be enforceable and remanded the matter to the arbitration panel for a final and definite award with respect to such relief or its equivalent (including possibly an award of monetary damages). The arbitration panel commenced hearings on the matters remanded by the Appellate Division in June 2001 and is expected to conclude its consideration of such matters and render its decision during the fourth calendar quarter of 2001. 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 performance. 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.

We are focused on the development of our oral insulin product in the immediate future, and ultimately upon additional products using our platform buccal delivery technology. In pursuing these objectives, we may undertake a range of activities, which include engaging in discovery research and process development, conducting preclinical 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.

Preclinical testing and clinical trials must demonstrate that a product candidate is safe and efficacious. The results from preclinical 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. 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.

We may incur additional losses.

To date, we have not been profitable and our accumulated net loss was approximately $49 million at July 31, 2001. 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. We cannot be sure that we will obtain required regulatory approvals, or successfully develop, commercialize, manufacture and market any other product candidates.

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;

→ results of clinical trials of our products or our competitors' products; and

→ regulatory action or inaction on our products or our competitors' products.

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. Rental income is accounted for as a reduction of our occupancy costs.

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, a portion of which has been leased to third parties. 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.

We have first mortgages on our Toronto properties totaling $692,660 at July 31, 2001. Our mortgages require the payment of interest, with minimal principal reduction, prior to their due date (November 1, 2002 with respect to $174,565 and May 25, 2005 with respect to $518,095).

At this time, we do not expect to need manufacturing capabilities beyond our pilot facility before the end of the current fiscal year. We have acquired, however, 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 our common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary that we acquired in late 1997. In exchange therefor, the letter agreement purported to grant Sands the right to acquire 17% of Generex Pharmaceuticals common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals common stock applies to our common stock since outstanding shares of Generex Pharmaceuticals common stock were converted into shares of our common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and $144,000 in monthly fees allegedly due under the terms of the purported agreement.

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 the our common stock. The Appellate Division held that the portion of the award directing us to issue warrants to Sands is too indefinite to be enforceable and remanded the matter to the arbitration panel for a final and definite award with respect to such relief or its equivalent (including possibly an award of monetary damages). The arbitration panel commenced hearings on the matters remanded by the Appellate Division in June 2001 and is expected to conclude its consideration of such matters and render its decision during the fourth calendar quarter of 2001. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

MQS, Inc. v. Generex Biotechnology Corporation. In February 1999, MQS, Inc., a former consultant, commenced a civil action against us in the United States District Court for the District of New Jersey claiming that 242,168 shares of our common stock and $243,066 are due to it for services that it rendered through December 22, 1998. MQS claimed that we used proprietary technology of MQS in developing our aerosol applicator and in formulating our oral insulin formulation for aerosol application. We filed our answer to MQS's claims in May 1999, in which we denied that MQS is entitled to the relief that it was seeking and denied that any of our products or technology incorporates any proprietary technology belonging to MQS. We also filed a counterclaim against MQS for breach of contract, as well as claims based upon unauthorized use and misappropriation of our

trade secrets and technology. In January 2001, we entered into a settlement agreement with MQS whereby we paid the plaintiff certain amounts in cash and common stock that were not material to the consolidated financial position of the Company and whereby the claims of the parties were dismissed with prejudice. The settlement agreement prohibits MQS from developing, manufacturing, licensing or marketing any insulin or non-insulin product that uses our platform technology.

Subash Chandarana et al. v Generex Biotechnology Corporation et al. In February 2001, Subash Chandarana, a former business associate of Dr. Pankaj Modi, our Vice President of Research and Development, and an entity called Centrum Technologies Inc. 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 Centrum Technologies Inc. On July 20, 2001, we 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 and, in the further alternative, to dismiss such action for failure to produce documents referred to in the statement of claim. 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.

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, 2001.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of the executive officers of the Company:

Name	Age	Position Held
Anna E. Gluskin	50	President, Chief Executive Officer and Director
Pankaj Modi, Ph.D.	47	Vice President, Research and Development and Director
E. Mark Perri	40	Chairman, Chief Financial Officer and Director
Rose C. Perri	34	Chief Operating Officer, Treasurer, Secretary and Director

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.

Pankaj Modi, Ph.D. - Director since September 1997. Dr. Modi has served as Vice President, Research and Development, since October 1997. Prior to that time, Dr. Modi was Director of Insulin Research for Generex Pharmaceuticals, Inc., a position he assumed in October 1996. Prior to joining Generex Pharmaceuticals Inc., 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.

E. Mark Perri - Director since September 1997. Mr. Perri has served as the Chairman and Chief Financial Officer of Generex since October 1997. He held comparable positions with Generex Pharmaceuticals, Inc. from its formation in 1995 until its acquisition by Generex in October 1997.

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.

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 Stock Market's 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 inter-dealer bid quotations for our common stock for certain periods prior to May 5, 2000, as furnished by the Nasdaq OTC Bulletin Board. These are "inter-dealer" quotations, without retail mark-up, mark-down or commissions, and may not represent actual transactions. The table also sets forth the high and low sales prices of our common stock reported by The Nasdaq Stock Market for these periods beginning May 5, 2000.

	Interdealer Bid Quotations (not actual transactions)		**Sales Prices** (actual transactions)	
	High	**Low**	**High**	**Low**
2000				
First quarter	$9.88	$4.62	-	-
Second quarter	$13.88	$1.06	$.38	$4.78
Third quarter	$24.75	$4.00	$24.88	$7.56
Fourth quarter	$14.69	$.03	$14.75	$10.00
2001				
First quarter			$11.50	$4.25
Second quarter			$11.60	$4.58
Third quarter			$10.00	$2.91
Fourth quarter (through Oct. 15, 2001)			$4.35	$3.55

The closing sales price for our common stock reported on October 15, 2001, was $4.25.

At October 15, 2001, there were 674 holders of record of our common stock.

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, 2000 until July 31, 2001, we have offered and sold common stock and other securities in a number of transactions, including the transactions described below, in reliance upon exemptions from the registration requirements of the Securities Act of 1933. In the transactions described below, unless otherwise indicated, we relied upon the exemptions from registration provided in Section 4(2) of the Securities Act, and Rule 506 of Regulation D thereunder. No "public solicitation", as that term is defined in Rule 502(c) of Regulation D, was employed by or in connection with the sale of these securities. All purchasers were, to our reasonable belief, accredited investors who purchased for investment. All disclosures required under Rule 502(d) of Regulation D were made by us, and all other conditions to the availability of the Rule 506 exemption were, to our knowledge and belief, complied with by us.

In order to assure that resale restrictions applicable to restricted securities are complied with, we placed a legend evidencing the restrictions on all certificates representing the shares, and issued "stop transfer" instructions to our transfer agent to prevent unapproved transfers.

Transactions in the year ended July 31, 2001, and not previously reported on a Quarterly Report on Form 10-Q were as follows:

(a) On or about July 6, 2001, we completed a private placement of 1,189,189 units of securities ("Units") for cash at a price of $9.25 per Unit. Each Unit consisted of a share of common stock and a warrant to purchase .25 shares of common stock at an initial exercise price of $10.175 per share. The Units were sold without registration under the Securities Act of 1933 (the "1933 Act") in reliance upon the exemption from registration provided in Section 4(2) thereof and Rule 506 of Regulation D promulgated thereunder. Under the terms of sale, we have agreed to register the shares of common stock issued to the investors and the shares of common stock issuable upon exercise of the warrants for sale under the 1933 Act.

(b) On or about July 6, 2001, we also completed a second private placement of 64,864 units of securities ("Units") for cash at a price of $9.25 per Unit. Each Unit consisted of a share of common stock and a warrant to purchase .25 shares of common stock at an initial exercise price of $10.175 per share. The Units were sold without registration under the 1933 Act in reliance upon the exemption from registration provided in Section 4(2) thereof and Rule 506 of Regulation D promulgated thereunder. Under the terms of sale, we have agreed to register the shares of common stock issued to the investors and the shares of common stock issuable upon exercise of the warrants for sale under the 1933 Act.

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. Our financial statements as of July 31, 2001 and for the year ended July 31, 2001 have been audited by Deloitte & Touche LLP. Our financial statements for the years ended July 31, 2000 and 1999 were audited by WithumSmith+Brown.

(In thousands, except per share data)	Years Ended July 31 2001	2000	1999	1998	1997	2001*
Operating Results						
Revenue	$1,000	-	-	-	-	$1,000
Net Loss	$(27,097)	$(8,841)	$(6,240)	$(4,664)	(1,379)	$(48,914)
Cash dividends per share	-	-	-	-	-	-
Loss per common share:						
Basic and diluted net loss per common share	(1.44)	(.58)	(.47)	(.46)	(.25)	-
Financial Positions:						
Total Assets	42,666	10,341	8,890	5,456	3,673	-
Long-term Debt	693	722	996	1,324	-	-
Stockholder's Investment	39,322	8,415	7,310	2,642	3,449	-

*Cumulative from November 2, 1995 (Date of Inception) to July 31, 2001

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

General

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

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

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

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 owed 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. The parties intend to select at least one pharmaceutical product for research and development under the joint venture within one year's time. The parties will conduct the joint venture through Generex (Bermuda), Ltd., a Bermuda limited liability company.

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.

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

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

Our buccal delivery technology is a platform technology that we believe has application to a significant number of large molecule drugs in addition to insulin. In the future, we expect to undertake development of additional products based on this technology that are not covered by our agreement with Lilly.

We do not expect to receive any revenues from product sales in the current fiscal year. We received a $1,000,000 signing fee, which is included in revenues as all necessary requirements have been satisfied, under the terms of the agreement with Lilly in the first fiscal quarter of FY 2001. We expect, however, to satisfy a substantial majority of our cash needs during the current year from capital raised through prior equity financing.

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 $19,149,860 from $3,476,436) and in general and administrative expenses (to $13,287,679 from $5,567,520). Our interest and miscellaneous income 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 Thalman & 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.

Results of Operations – 2000 Compared With 1999

We had a net loss of $8,841,047 in the year ended July 31, 2000 (FY 2000) compared to a loss of $6,239,602 in the year ended July 31, 1999 (FY 1999). The increase in our FY 2000 net loss resulted from increases in research and development expenses (to $3,476,436 from $1,853,108) and in general and administrative expenses (to $5,567,520 from $4,374,523). Our net interest and miscellaneous income in FY 2000 increased to $202,909 from a net expense of $11,971 in FY 1999, primarily as a result of increased interest income in FY 2000.

The principal reasons for the increase in our research and development expense in FY 2000 were:

→ increased expenditures relating to clinical trials of our oral insulin formulation primarily attributable to the expanded scope of these trials in FY 2000 to include additional sites in the United States and Europe, and the fact that trials did not commence in FY 1999 until the second quarter; and

→ costs associated with operations of our pilot manufacturing facility in Toronto which supports our clinical program.

The principal reasons for the increase in our general and administrative expenses in FY 2000 were:

→ an increase of $684,344 in legal and accounting fees and expenses (to $1,520,726 from $836,382) 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 business activity;

→ increased personnel costs of $198,122 (to $369,007 from $170,885) related primarily to additions to our technical and administrative staff during FY 2000; and

→ increased travel and other costs of $93,298 (to $538,062 from $444,764) associated with attendance at and sponsorship of industry seminars and exhibitions and other promotional activities.

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 ($1,845,408 in FY 2001 and $1,573,604 in FY 2000) were paid primarily through the issuance of shares of common stock and/or warrants and options to purchase common stock. We believe that any similar expenses incurred in the current fiscal year will not exceed the level of such expenses in FY 2001.

Liquidity and Capital Resources

To date we have financed our development stage activities primarily through private placements of common stock. In FY 2001, we issued approximately 3.82 million shares of common stock for cash proceeds of approximately $37.4 million (net of financing costs of approximately $2.9 million). Additionally, we granted stock options, warrants and shares of common stock to consultants, advisors and employees with a value of $5,742,592 for services rendered, of which $292,592 was included in financing costs. As a result of our sales of common stock for cash and our use of stock options, warrants and shares of common stock to pay for certain services during FY 2001, our stockholders' equity increased to approximately $39.3 million at July 31, 2001, versus approximately $8.42 million at July 31, 2000, notwithstanding our net loss during the year.

At July 31, 2001, we had on hand cash and short term investments (primarily notes of U.S. corporations) of approximately $37 million versus $7.17 million at July 31, 2000. In the final quarter of FY 2001, we received additional equity capital of approximately $531,000 from the sale of 103,500 shares of common stock upon exercise of outstanding warrants. In the final quarter of FY 2001, we received additional equity capital of approximately $10.8 million (net of financing costs of approximately $.75 million) from two private placements of units of securities consisting of 1.0 shares of common stock and warrants to purchase an additional .25 shares of common stock at a price of $9.25 per unit.

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 bear interest at 8.5 percent per annum and are payable in full on May 1, 2002. These notes are 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 currently owned by this related company. As of July 31, 2001, the balance outstanding on these notes, including accrued interest, was $1,023,743.

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.

New Accounting Pronouncements

In June 1998, 1999, and 2000, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, SFAS No. 137, Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133, and SFAS No. 138, Accounting for Certain Derivative Instruments and Certain Hedging Activities, respectively. These statements require 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 adoption on August 1, 2000 of these statements did not have a significant impact on the Company's financial position or results of operations.

In December 1999, the SEC issued Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements. SAB 101 provides guidance on the recognition, presentation, and disclosure of revenues in financial statements of all public registrants. In October 2000, the SEC issued a Frequently Asked Questions document related to SAB 101 which provides interpretive guidance. The Company adopted SAB 101 in fiscal year 2001, and the adoption of SAB 101 did not have a significant impact on the Company's financial position or results of operations.

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. Goodwill and 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 2002, however management is assessing the impact that SFAS No. 142 will have on the Company's financial position and 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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Item 8. Financial Statements and Supplementary Data
Independent Auditors' Report

To the Board of Directors and Stockholders of Generex Biotechnology Corporation

We have audited the accompanying consolidated balance sheet of Generex Biotechnology Corporation and Subsidiaries (a development stage company) as at July 31, 2001 and the consolidated statement of operations, shareholders' equity and of cash flows for the year then ended. These consolidated 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 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 audit provides a reasonable basis for our opinion.

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

DELOITTE & TOUCHE LLP

DELOITTE & TOUCHE LLP
Chartered Accountants

Toronto, Ontario
October 2, 2001

INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheet of Generex Biotechnology Corporation and Subsidiaries (a development stage company) as of July 31, 2000 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years in the two-year period 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. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Generex Biotechnology Corporation and Subsidiaries as of July 31, 2000 and the consolidated results of their operations, and their cash flows for each of the years in the two-year period 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 in conformity with accounting principles generally accepted in the United States of America.

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

CONSOLIDATED BALANCE SHEETS

	2001 (July 31)	2000 (July 31)
ASSETS		
Current Assets:		
Cash and cash equivalents	$10,109,559	$3,204,905
Short-term investments	26,892,729	3,966,263
Officers' loans receivable	1,023,743	-
Miscellaneous receivables	12,865	16,138
Other current assets	112,620	99,041
Total Current Assets	38,151,516	7,286,347
Property and Equipment, Net	3,727,761	2,395,867
Patents, Net	434,307	267,369
Deposits	20,000	47,914
Due From Related Parties	332,289	343,773
TOTAL ASSETS	**$42,665,873**	**$10,341,270**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$2,650,773	$1,204,282
Current maturities of long-term debt	9,634	9,404
Total Current Liabilities	2,660,407	1,213,686
Long-Term Debt, Less Current Maturities	683,026	712,559
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Series A, preferred stock, $.001 par value; (liquidation preference $12,015,000); authorized 1,000,000 shares, issued and outstanding 1,000 and -0- at July 31, 2001 and 2000, respectively	1	-
Special Voting Rights Preferred stock, $.001 par value; authorized, issued and outstanding 1,000 shares at July 31, 2001 and 2000	1	1
Common stock, $.001 par value; authorized 50,000,000 shares, issued and outstanding 20,681,526 and 16,326,333 shares at July 31, 2001 and 2000, respectively	20,681	16,327
Additional paid-in capital	88,776,859	30,435,066
Notes receivable - common stock	(314,300)	(54,118)
Deficit accumulated during the development stage	(48,913,935)	(21,816,725)
Accumulated other comprehensive loss	(246,867)	(165,526)
Total Stockholders' Equity	39,322,440	8,415,025
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$42,665,873**	**$10,341,270**

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

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended July 31			
	2001	**2000**	**1999**	**2001***
Revenues	1,000,000	$-	$-	$1,000,000
Operating Expenses:				
Research and development	19,149,860	3,476,436	1,853,108	26,095,896
Research and development - related party	-	-	-	220,218
General and administrative	13,287,679	5,567,520	4,374,523	27,751,469
General and administrative - related party	-	-	-	314,328
Total Operating Expenses	32,437,539	9,043,956	6,227,631	54,381,911
Operating Loss	(31,437,539)	(9,043,956)	(6,227,631)	(53,381,911)
Other Income (Expense):				
Miscellaneous income	10,664	7,906	-	18,570
Interest income	1,417,847	272,808	55,190	1,745,845
Interest expense	(73,182)	(77,805)	(67,161)	(281,439)
Net Loss Before the Undernoted	(30,082,210)	(8,841,047)	(6,239,602)	(51,898,935)
Minority Interest Share of Loss	2,985,000	-	-	2,985,000
Net Loss	**$(27,097,210)**	**$(8,841,047)**	**$(6,239,602)**	**$(48,913,935)**
Basic and Diluted Net Loss Per Common Share	**$(1.44)**	**$(.58)**	**$(.47)**	
Weighted Average Number of Shares of Common Stock Outstanding	**18,769,077**	**15,189,781**	**13,260,260**	

*Cumulative from November 2, 1995 (Date of Inception) to July 31, 2001

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

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, 2001

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

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED

	Notes Receivable -Common Stock	Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance November 2, 1995 (Inception)	$-	$-	$-	$-
Issuance of common stock for cash, February 1996, $.0254	-	-	-	8,159
Issuance of common stock for cash, February 1996, $.0510	-	-	-	1,792
Issuance of common stock for cash, February 1996, $.5099	-	-	-	110,358
Issuance of common stock for cash, March 1996, $10.2428	-	-	-	25,607
Issuance of common stock for cash, April 1996, $.0516-	-	-	-	25,263
Issuance of common stock for cash, May 1996, $.0512	-	-	-	5,912
Issuance of common stock for cash, May 1996, $.5115	-	-	-	218,962
Issuance of common stock for cash, May 1996, $10.2302	-	-	-	1,328,064
Issuance of common stock for cash, July 1996, $.0051-	-	-	-	13,383
Issuance of common stock for cash, July 1996, $.0255	-	-	-	3,637
Issuance of common stock for cash, July 1996, $.0513	-	-	-	1,833
Issuance of common stock for cash, July 1996, $10.1847	-	-	-	650,346
Costs related to issuance of common stock	-	-	-	(10,252)
Founders Shares transferred for services rendered	-	-	-	330,025
Comprehensive Income (Loss):				
Net loss	-	-	(693,448)	(693,448)
Other comprehensive income (Loss)				
Currency translation adjustment	-	(4,017)	-	(4,017)
Total Comprehensive Income (Loss)		(4,017)	(693,448)	(697,465)
Balance July 31, 1996	**$-**	**$(4,017)**	**$(693,448)**	**$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, 2001

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

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED

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

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, 2001

	Common Stock		Series A Preferred Stock		SVR Preferred Stock		
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-in Capital**
Balance, August 1, 1997	9,000,118	$9,000	-	$-	-	$-	$5,512,782
Issuance of warrants issued in exchange for services rendered, October 1997, $.50	-	-	-	-	-	-	234,000
Issuance of common stock in exchange for services rendered, December 1997, $0.0467	234,000	234	-	-	-	-	10,698
Issuance of SRV Preferred Sock in exchange for services rendered, January 1998, $.001	-	-	-	-	1,000	1	99
Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation	1,105,000	1,105	-	-	-	-	(1,105)
Issuance of common stock for cash, March 1998, $2.50	70,753	71	-	-	-	-	176,812
Issuance of common stock for cash, April 1998, $2.50	60,000	60	-	-	-	-	149,940
Issuance of common stock in exchange for services rendered, April 1998, $2.50	38,172	38	-	-	-	-	95,392
Issuance of common stock for cash, May 1998, $2.50	756,500	757	-	-	-	-	1,890,493
Issuance of common stock in exchange for services rendered, May 1998, $2.50	162,000	162	-	-	-	-	404,838
Issuance of warrants issued in exchange for services rendered, May 1998, $.60	-	-	-	-	-	-	300,000
Issuance of common stock for cash, June 1998, $2.50	286,000	286	-	-	-	-	714,714
Exercise of warrants for cash, June 1998, $0.0667	234,000	234	-	-	-	-	15,374
Issuance of common stock in exchange for services rendered, June 1998, $2.50	24,729	24	-	-	-	-	61,799
Comprehensive Income (Loss):							
Net loss							
Other comprehensive income (Loss)							
Currency translation adjustment	-	-	-	-	-	-	-
Total Comprehensive Income (Loss)							
Balance July 31, 1998	**11,971,272**	**$11,971**	**-**	**$-**	**1,000**	**$1**	**$9,565,836**

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED

	Notes Receivable -Common Stock	Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance, August 1, 1997	$-	$(474)	$(2,072,472)	$3,448,836
Issuance of warrants issued in exchange for services rendered, October 1997, $.50	-	-	-	234,000
Issuance of common stock in exchange for services rendered, December 1997, $0.0467	-	-	-	10,932
Issuance of SRV Preferred Sock in exchange for services rendered, January 1998, $.001	-	-	-	100
Shares issued pursuant to the January 9, 1998 reverse merger between GBC-Delaware, Inc. and Generex Biotechnology Corporation	-	-	-	-
Issuance of common stock for cash, March 1998, $2.50	-	-	-	176,883
Issuance of common stock for cash, April 1998, $2.50	-	-	-	150,000
Issuance of common stock in exchange for services rendered, April 1998, $2.50	-	-	-	95,430
Issuance of common stock for cash, May 1998, $2.50	-	-	-	1,891,250
Issuance of common stock in exchange for services rendered, May 1998, $2.50	-	-	-	405,000
Issuance of warrants issued in exchange for services rendered, May 1998, $.60	-	-	-	300,000
Issuance of common stock for cash, June 1998, $2.50	-	-	-	715,000
Exercise of warrants for cash, June 1998, $0.0667	-	-	-	15,608
Issuance of common stock in exchange for services rendered, June 1998, $2.50	-	-	-	61,823
Comprehensive Income (Loss):				
Net loss			(4,663,604)	(4,663,604)
Other comprehensive income (Loss)				
Currency translation adjustment	-	(198,959)	-	(198,959)
Total Comprehensive Income (Loss)		(198,959)	(4,663,604)	(4,862,563)
Balance July 31, 1998	**$-**	**$(199,433)**	**$(6,736,076)**	**$2,642,299**

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, 2001

	Common Stock		Series A Preferred Stock		SVR Preferred Stock		
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-in Capital**
Balance, August 1, 1998	11,971,272	$11,971	–	$–	1,000	$1	$9,565,836
Issuance of common stock for cash, August 1998, $3.00	100,000	100	–	–	–	–	299,900
Issuance of common stock for cash, August 1998, $3.50	19,482	19	–	–	–	–	68,168
Redemption of Common Stock for cash, September 1998, $7.75	(15,357)	(15)	–	–	–	–	(119,051)
Issuance of common stock for cash, September - October 1998, $3.00	220,297	220	–	–	–	–	660,671
Issuance of common stock for cash, August - October 1998, $4.10	210,818	211	–	–	–	–	864,142
Issuance of common stock in exchange for services rendered, August - October 1998, $2.50	21,439	21	–	–	–	–	53,577
Issuance of common stock in exchange for services rendered, August - October 1998, $4.10	18,065	18	–	–	–	–	74,048
Issuance of Common Stock in exchange for services rendered, September 1998, $4.10	180,000	180	–	–	–	–	737,820
Issuance of warrants in exchange for services rendered, October 1998, $.26	–	–	–	–	–	–	2,064
Issuance of stock options in exchange for services rendered, November 1998, $1.85	–	–	–	–	–	–	92,500
Issuance of warrants in exchange for services rendered, November 1998, $1.64	–	–	–	–	–	–	246,000
Issuance of common stock for cash, November 1998 - January 1999, $3.50	180,000	180	–	–	–	–	629,820
Issuance of common stock for cash, November 1998 - January 1999, $4.00	275,000	275	–	–	–	–	1,099,725
Issuance of common stock for cash, November 1998 - January 1999, $4.10	96,852	97	–	–	–	–	397,003
Issuance of common stock in exchange for services rendered, November 1998 - January 1999, $4.10	28,718	29	–	–	–	–	117,715
Issuance of common stock for cash, November 1998 - January 1999, $5.00	20,000	20	–	–	–	–	99,980
Issuance of common stock for cash, November 1998 - January 1999, $5.50	15,000	15	–	–	–	–	82,485
Issuance of common stock in exchange for services rendered, January 1999, $5.00	392	–	–	–	–	–	1,960
Issuance of common stock for cash, February 1999, $5.00	6,000	6	–	–	–	–	29,994
Issuance of common stock in exchange for services rendered, February 1999, $6.00	5,000	5	–	–	–	–	29,995
Issuance of common stock for cash, March 1999, $6.00	11,000	11	–	–	–	–	65,989

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

	Common Stock		Series A Preferred Stock		SVR Preferred Stock		
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-in Capital**
Issuance of common stock for cash, April 1999, $5.50	363,637	364	-	-	-	-	1,999,640
Issuance of warrants in exchange for services rendered, April 1999, $3.21	-	-	-	-	-	-	160,500
Issuance of warrants in exchange for services rendered, April 1999, $3.17	-	-	-	-	-	-	317,000
Issuance of warrants in exchange for services rendered, April 1999, $2.89	-	-	-	-	-	-	144,500
Issuance of warrants in exchange for services rendered, April 1999, $3.27	-	-	-	-	-	-	184,310
Stock adjustment	714	1	-	-	-	-	(1)
Issuance of common stock for cash, May 1999, $5.50	272,728	273	-	-	-	-	1,499,731
Issuance of common stock in exchange for services rendered, May - June 1999, $5.50	60,874	61	-	-	-	-	334,746
Exercise of warrants for cash, June 1999, $5.00	388,375	389	-	-	-	-	1,941,484
Exercise of warrants in exchange for note receivable, June 1999, $5.00	94,776	95	-	-	-	-	473,787
Exercise of warrants in exchange for services rendered, June 1999, $5.00	13,396	13	-	-	-	-	66,967
Reduction of note receivable in exchange for services rendered	-	-	-	-	-	-	-
Shares tendered in conjunction with warrant exercise, June 1999, $7.8125	(323,920)	(324)	-	-	-	-	(2,530,301)
Exercise of warrants for shares tendered, June 1999, $5.00	506,125	506	-	-	-	-	2,530,119
Cost of warrants redeemed for cash	-	-	-	-	-	-	(3,769)
Cost related to warrant redemption, June 1999	-	-	-	-	-	-	(135,431)
Costs related to issuance of common stock	-	-	-	-	-	-	(1,179,895)
Comprehensive Income (Loss):							
Net Loss	-	-	-	-	-	-	-
Other comprehensive income:							
Currency translation adjustment	-	-	-	-	-	-	-
Total Comprehensive Income (Loss)							
Balance, July 31, 1999	**14,740,683**	**$14,741**	**-**	**$-**	**1,000**	**$1**	**$20,903,728**

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED PART 1 OF 2

	Notes Receivable -Common Stock	Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance, August 1, 1998	$-	$(199,433)	$(6,736,076)	$2,642,299
Issuance of common stock for cash, August 1998, $3.00	-	-	-	300,000
Issuance of common stock for cash, August 1998, $3.50	-	-	-	68,187
Redemption of Common Stock for cash, September 1998, $7.75	-	-	-	(119,066)
Issuance of common stock for cash, September - October 1998, $3.00	-	-	-	660,891
Issuance of common stock for cash, August - October 1998, $4.10	-	-	-	864,353
Issuance of common stock in exchange for services rendered, August - October 1998, $2.50	-	-	-	53,598
Issuance of common stock in exchange for services rendered, August - October 1998, $4.10	-	-	-	74,066
Issuance of Common Stock in exchange for services rendered, September 1998, $4.10	-	-	-	738,000
Issuance of warrants in exchange for services rendered, October 1998, $.26	-	-	-	2,064
Issuance of stock options in exchange for services rendered, November 1998, $1.85	-	-	-	92,500
Issuance of warrants in exchange for services rendered, November 1998, $1.64	-	-	-	246,000
Issuance of common stock for cash, November 1998 - January 1999, $3.50	-	-	-	630,000
Issuance of common stock for cash, November 1998 - January 1999, $4.00	-	-	-	1,100,000
Issuance of common stock for cash, November 1998 - January 1999, $4.10	-	-	-	397,100
Issuance of common stock in exchange for services rendered, November 1998 - January 1999, $4.10	-	-	-	117,744
Issuance of common stock for cash, November 1998 - January 1999, $5.00	-	-	-	100,000
Issuance of common stock for cash, November 1998 - January 1999, $5.50	-	-	-	82,500
Issuance of common stock in exchange for services rendered, January 1999, $5.00	-	-	-	1,960
Issuance of common stock for cash, February 1999, $5.00	-	-	-	30,000
Issuance of common stock in exchange for services rendered, February 1999, $6.00	-	-	-	30,000
Issuance of common stock for cash, March 1999, $6.00	-	-	-	66,000

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED PART 2 OF 2

	Notes Receivable -Common Stock	Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Issuance of common stock for cash, April 1999, $5.50	-	-	-	2,000,004
Issuance of warrants in exchange for services rendered, April 1999, $3.21	-	-	-	160,500
Issuance of warrants in exchange for services rendered, April 1999, $3.17	-	-	-	317,000
Issuance of warrants in exchange for services rendered, April 1999, $2.89	-	-	-	144,500
Issuance of warrants in exchange for services rendered, April 1999, $3.27	-	-	-	184,310
Stock adjustment	-	-	-	-
Issuance of common stock for cash, May 1999, $5.50	-	-	-	1,500,004
Issuance of common stock in exchange for services rendered, May - June 1999, $5.50	-	-	-	334,807
Exercise of warrants for cash, June 1999, $5.00	-	-	-	1,941,873
Exercise of warrants in exchange for note receivable, June 1999, $5.00	(473,882)	-	-	-
Exercise of warrants in exchange for services rendered, June 1999, $5.00	-	-	-	66,980
Reduction of note receivable in exchange for services rendered	38,979	-	-	38,979
Shares tendered in conjunction with warrant exercise, June 1999, $7.8125	-	-	-	(2,530,625)
Exercise of warrants for shares tendered, June 1999, $5.00	-	-	-	2,530,625
Cost of warrants redeemed for cash	-	-	-	(3,769)
Cost related to warrant redemption, June 1999	-	-	-	(135,431)
Costs related to issuance of common stock	-	-	-	(1,179,895)
Comprehensive Income (Loss):				
Net Loss	-	-	(6,239,602)	(6,239,602)
Other comprehensive income (Loss):				
Currency translation adjustment	-	1,393	-	1,393
Total Comprehensive Income (Loss)		1,393	(6,239,602)	(6,238,209)
Balance, July 31, 1999	**$(434,903)**	**$(198,040)**	**$(12,975,678)**	**$7,309,849**

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, 2001

	Common Stock		Series A Preferred Stock		SVR Preferred Stock		
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-in Capital**
Balance, August 1, 1999	14,740,683	$14,741	-	$-	1,000	$1	$20,903,728
Adjustment for exercise of warrants recorded June 1999, $5.00	(2,300)	(2)	-	-	-	-	2
Issuance of common stock for cash, September 1999, $6.00	2,500	2	-	-	-	-	14,998
Issuance of common stock for cash pursuant to private placement, January 2000, $4.25	470,590	471	-	-	-	-	1,999,537
Financing costs associated with private placement, January, 2000	-	-	-	-	-	-	(220,192)
Issuance of stock in exchange for services rendered, January 2000, $5.00	8,100	8	-	-	-	-	40,492
Granting of stock options for services rendered, January 2000	-	-	-	-	-	-	568,850
Granting of 150,000 stock warrants for services rendered, January 2000	-	-	-	-	-	-	355,500
Exercise of stock warrants for cash, February 2000, $5.50	2,000	2	-	-	-	-	10,998
Exercise of stock warrants for cash, March 2000, $5.50	29,091	29	-	-	-	-	159,972
Exercise of stock warrants for cash, March 2000, $6.00	2,000	2	-	-	-	-	11,998
Exercise of stock warrants for cash, March 2000, $7.50	8,000	8	-	-	-	-	59,992
Issuance of common stock for cash pursuant to private placement, June 2000, $6.00	1,041,669	1,042	-	-	-	-	6,248,972
Financing costs associated with private placement, June 2000	-	-	-	-	-	-	(385,607)
Issuance of common stock for services, June 2000, $6.00	4,300	4	-	-	-	-	25,796
Exercise of warrants for cash, July 2000, $6.00	3,000	3	-	-	-	-	17,997
Exercise of warrants for cash, July 2000, $7.50	16,700	17	-	-	-	-	125,233
Granting of stock options for services rendered, July 2000	-	-	-	-	-	-	496,800
Reduction of note receivable in exchange for services rendered	-	-	-	-	-	-	-
Accrue interest on note receivable	-	-	-	-	-	-	-
Comprehensive Income (Loss):							
Net Loss	-	-	-	-	-	-	-
Other comprehensive income (Loss):							
Currency translation adjustment	-	-	-	-	-	-	-
Total Comprehensive Income (Loss)							
Balance July 31, 2000	**16,326,333**	**$16,327**	**-**	**$-**	**1,000**	**$1**	**$30,435,066**

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED

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

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, 2001

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

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY PART 2 OF 2

	Common Stock		Series A Preferred Stock		SVR Preferred Stock		
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-in Capital**
Financing costs associated with private placement, January 2001	-	-	-	-	-	-	(200,000)
Issuance of common stock pursuant to litigation settlement, January 2001	2,832	2	-	-	-	-	21,096
Issuance of Series A Preferred Stock, January 2001	-	-	1,000	1	-	-	12,014,999
Granting of stock options in exchange for services rendered, January 2001	-	-	-	-	-	-	745,000
Granting of stock options in exchange for services rendered, February 2001	-	-	-	-	-	-	129,600
Exercise of stock options for cash, February 2001, $5.00	50,000	50	-	-	-	-	249,950
Exercise of stock warrants for cash, March 2001, $6.00	500	1	-	-	-	-	2,999
Exercise of stock options in exchange for note receivable, March 2001	50,000	50	-	-	-	-	249,950
Issuance of common stock in exchange for services rendered, March 2001, $5.50	8,000	8	-	-	-	-	43,992
Granting of stock options in exchange for services rendered, May 2001	-	-	-	-	-	-	592,300
Exercise of stock options for cash, June 2001, $5.00	75,000	75	-	-	-	-	374,925
Exercise of stock options for cash, June 2001, $5.50	12,500	12	-	-	-	-	68,738
Exercise of warrants for cash, June 2001, $6.00	4,000	4	-	-	-	-	23,996
Exercise of stock options for cash, July 2001, $5.00	7,500	8	-	-	-	-	37,492
Exercise of stock options for cash, July 2001, $5.50	2,500	3	-	-	-	-	13,747
Exercise of warrants for cash, July 2001, $6.00	2,000	2	-	-	-	-	11,998
Issuance of common stock for cash pursuant to private placement, July 2001, $9.25	1,254,053	1,254	-	-	-	-	11,598,736
Financing costs associated with private placement, July 2001	-	-	-	-	-	-	(768,599)
Shares issued in exchange for services rendered, July 2001, 9.25	23,784	24	-	-	-	-	219,978
Shares issued for Anti-Dilution Provisions, July 2001	5,779	6	-	-	-	-	53,450
Issuance of stock warrants in exchange for services, rendered, July 2001	-	-	-	-	-	-	19,134
Accrued interest on note receivable	-	-	-	-	-	-	-
Comprehensive Income (Loss):							
Net Loss	-	-	-	-	-	-	-
Other comprehensive income (Loss):							
Currency translation adjustment	-	-	-	-	-	-	-
Total Comprehensive Income (Loss)							
Balance July 31, 2001	**20,681,526**	**$20,681**	**1,000**	**$1**	**1,000**	**$1**	**$88,776,859**

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED PART 1 OF 2

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

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY RESTUBBED PART 2 OF 2

	Notes Receivable -Common Stock	Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Issuance of common stock pursuant to litigation settlement, January 2001	-	-	-	21,098
Issuance of Series A Preferred Stock, January 2001	-	-	-	12,015,000
Granting of stock options in exchange for services rendered, January 2001	-	-	-	745,000
Granting of stock options in exchange for services rendered, February 2001	-	-	-	129,600
Exercise of stock options for cash, February 2001, $5.00	-	-	-	250,000
Exercise of stock warrants for cash, March 2001, $6.00	-	-	-	3,000
Exercise of stock options in exchange for note receivable, March 2001	(250,000)	-	-	-
Issuance of common stock in exchange for services rendered, March 2001, $5.50	-	-	-	44,000
Granting of stock options in exchange for services rendered, May 2001	-	-	-	592,300
Exercise of stock options for cash, June 2001, $5.00	-	-	-	375,000
Exercise of stock options for cash, June 2001, $5.50	-	-	-	68,750
Exercise of warrants for cash, June 2001, $6.00	-	-	-	24,000
Exercise of stock options for cash, July 2001, $5.00	-	-	-	37,500
Exercise of stock options for cash, July 2001, $5.50	-	-	-	13,750
Exercise of warrants for cash, July 2001, $6.00	-	-	-	12,000
Issuance of common stock for cash pursuant to private placement, July 2001, $9.25	-	-	-	11,599,990
Financing costs associated with private placement, July 2001	-	-	-	(768,599)
Shares issued in exchange for services rendered, July 2001, 9.25	-	-	-	220,002
Shares issued for Anti-Dilution Provisions, July 2001	-	-	-	53,456
Issuance of stock warrants in exchange for services, rendered, July 2001	-	-	-	19,134
Accrued interest on note receivable	(10,182)	-	-	(10,182)
Comprehensive Income (Loss):				
Net Loss	-	-	(27,097,210)	(27,097,210)
Other comprehensive income (Loss):				
Currency translation adjustment	-	(81,341)	-	(81,341)
Total Comprehensive Income (Loss)		(81,341)	(27,097,210)	(27,178,551)
Balance July 31, 2001	**$(314,300)**	**$(246,867)**	**$(48,913,935)**	**$39,322,440**

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES (A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS PART 1 OF 2

	Years Ended July 31			
	2001	2000	1999	2001*
Cash Flows Used in Operating Activities:				
Net loss	$(27,097,210)	$(8,841,047)	$(6,239,602)	$(48,913,935)
Adjustments to reconcile net loss to net				
Cash used in operating activities:				
Depreciation and amortization	230,600	86,804	79,784	441,277
Minority interest share of loss	(2,985,000)	-	-	(2,985,000)
Reduction of notes receivable - common stock				
in exchange for services rendered	-	384,903	38,979	423,882
Write-off of deferred offering costs	3,406,196	-	-	3,406,196
Common stock issued for services rendered	829,264	66,300	612,175	2,069,992
Stock options and warrants issued for services rendered	1,486,036	1,421,150	1,146,874	4,588,060
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	27,571	30,620
Other current assets	(14,858)	21,219	12,610	(117,606)
Accounts payable and accrued expenses	1,479,803	773,506	(87,134)	3,492,121
Other, net	-	-	-	110,317
Net Cash Used in Operating Activities	(22,662,422)	(5,916,684)	(4,408,743)	(37,100,470)
Cash Flows From Investing Activities:				
Purchase of property and equipment	(1,623,017)	(381,163)	(217,018)	(2,296,971)
Costs incurred for patents	(197,434)	(269,499)	-	(466,933)
Change in restricted cash	-	-	105,655	(5,595)
Increase in officers' loans receivable	(1,023,743)	-	-	(1,023,743)
Purchase of short-term investments	(22,926,466)	(3,733,918)	(232,345)	(26,892,729)
Change in deposits	27,396	19,720	-	29,515
Change in notes receivable - common stock	(10,182)	(4,118)	-	(14,300)
Change in due from related parties	-	290,973	428,216	(2,255,197)
Other, net	-	-	-	89,683
Net Cash (Used in) Provided By				
Investing Activities	(25,753,446)	(4,078,005)	84,508	(32,836,270)
Cash Flows From Financing Activities:				
Proceeds from issuance of long-term debt	-	-	-	993,149
Repayment of long-term debt	(5,208)	(480,738)	(416,649)	(965,984)
Change in due to related parties	-	-	(81,483)	154,541
Proceeds from exercise of warrants	2,256,482	-	-	2,256,482

CONSOLIDATED STATEMENTS OF CASH FLOWS PART 2 OF 2

	Years Ended July 31			
	2001	**2000**	**1999**	**2001***
Proceeds from exercise of stock options	*745,000*	-	-	*745,000*
Proceeds from minority interest investment	2,985,000	-	-	2,985,000
Proceeds from issuance of common stock, net	37,337,074	8,045,474	8,488,798	61,999,294
Proceeds from issuance of preferred stock	12,015,000	-	-	12,015,000
Purchase and retirement of common stock	-	-	(119,066)	(119,066)
Net Cash Provided By Financing Activities	55,333,348	7,564,736	7,871,600	80,063,416
Effect of Exchange Rates on Cash	(12,826)	1,657	(4,991)	(17,117)
Net Increase (Decrease) in Cash and Cash Equivalents	6,904,654	(2,428,296)	3,542,374	10,109,559
Cash and Cash Equivalents, Beginning of Year	3,204,905	5,633,201	2,090,827	-
Cash and Cash Equivalents, End of Year	**$10,109,559**	**$3,204,905**	**$5,633,201**	**$10,109,559**

*Cumulative from November 2, 1995 (Date of Inception) to July 31, 2001

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

Note 1 - Organization and Business:

Generex Biotechnology Corporation (the Company) was incorporated in Delaware in September 1997 for the purpose of acquiring Generex Pharmaceuticals, Inc. (Generex Pharmaceuticals), a Canadian corporation formed in November 1995 to engage in pharmaceutical and biotechnological research and other activities. The Company's 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 the Company's common stock.

In January 1998, the Company 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, the Company's shareholders (the former shareholders of Generex Pharmaceuticals) acquired a majority (approximately 90%) of the outstanding capital stock of Green Mt. P.S., Inc., the Company became a wholly-owned subsidiary of Green Mt. P. S., Inc., Green Mt. P.S., Inc. changed its corporate name to Generex Biotechnology Corporation (Generex Idaho), and the Company changed its corporate name to GBC Delaware, Inc. Because the reverse acquisition resulted in the Company's shareholders becoming the majority holders of Generex Idaho, the Company was treated as the acquiring corporation in the transaction for accounting purposes. Thus, the Company's 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, the Company completed a reorganization in which the Company merged with Generex Idaho. In this transaction, all outstanding shares of Generex Idaho were converted into the Company's shares, Generex Idaho ceased to exist as a separate entity, and the Company changed its corporate name back to Generex Biotechnology Corporation. This reorganization did not result in any material change in the Company's historical financial statements or current financial reporting.

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, 2001 and 2000, short-term investments consisted of short-term notes of U.S. corporations with original maturities of between three to twelve months. At July 31, 2001 and 2000, 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.

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 the related expenses. Included in miscellaneous receivables is $12,865 and $16,138 of such a receivable due from the Canadian government at July 31, 2001 and 2000, respectively.

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.

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

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: The Company has adopted Statement of Financial Accounting Standards No. 128, "Earnings per Share" (SFAS 128), which requires presentation of basic earnings per share (Basic EPS) and diluted earnings per share (Diluted EPS) by all entities that have publicly traded common stock or potential common stock (options, warrants, convertible securities or contingent stock arrangements).

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 12 for methodology for determining net loss per share.

Comprehensive Loss: The Company has adopted Statement of Financial Accounting Standards No. 130, "Reporting

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

Effects of Recent Accounting Pronouncements: In June 1998, 1999, and 2000, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, SFAS No. 137, Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133, and SFAS no. 138, Accounting for Certain Derivative Instruments and Certain Hedging Activities, respectively. These statements require 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 adoption of these statements on August 1, 2000 did not have a significant impact on the Company's financial position or results of operations.

In December 1999, the SEC issued Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements. SAB 101 provides guidance on the recognition, presentation, and disclosure of revenues in financial statements of all public registrants. In October 2000, the SEC issued a Frequently Asked Questions document related to SAB 101 which provides interpretive guidance. The Company adopted SAB 101 in fiscal year 2001, and the adoption of SAB 101 did not have a significant impact on the Company's financial position or results of operations.

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. Goodwill and 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 2002, however management is assessing the impact that SFAS No. 142 will have on the Company's financial position and results of operations.

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 income (loss) component of stockholders' equity.

Financial Instruments The carrying values of accounts payable and accrued expenses approximate their fair values. The fair value of the Company's long-term debt is assumed to approximate its book value.

Note 3 - Property and Equipment:

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

	July 31, 2001	July 31, 2000
Land	$293,902	$304,060
Buildings and Improvements	1,901,907	1,814,724
Furniture and Fixtures	68,229	8,190
Office Equipment	60,229	62,311
Lab Equipment	1,814,028	415,753
Total Property and Equipment	4,138,295	2,605,038
Less: Accumulated Depreciation	410,534	209,171
Property and Equipment, Net	**$3,727,761**	**$2,395,867**

Depreciation expense amounted to $209,114, $85,781 and $79,784 for the years ended 2001, 2000 and 1999, respectively.

Note 4 - Patents:

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

	July 31, 2001	July 31, 2000
Patents	$456,860	$268,392
Less: Accumulated Amortization	22,553	1,023
Patents, Net	**$434,307**	**$267,369**

Amortization expense amounted to $21,486, $1,023 and $-0- for the years ended July 31, 2001 2000 and 1999, 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, 2001, the Company has approximately

$19,730,659 and $10,270,030 in net operating loss carryforwards to offset taxable income in the United States, which expire in 2013 through 2016, and Canada, which expire in 2005 through 2008, respectively. These loss carryforwards are subject to limitation in future years should certain ownership changes occur.

For the years ended July 31, 2001, 2000 and 1999, the Company's effective tax rate differs from the federal statutory rate principally due to net operating losses and other temporary differences for which no benefit was recorded.

Deferred tax assets consist of the following:

	July 31, 2001	July 31, 2000
Net operating loss carryforwards	$12,513,777	$7,169,137
Amortization of financing fees	80,922	84,629
Amortization of reorganization costs	214,392	-
Total deferred tax assets	12,809,091	7,253,766
Valuation allowance	(12,809,091)	(7,253,766)
Net deferred tax assets	**$-**	**$-**

Note 6 - Accounts Payable and Accrued Expense:

Accounts payable and accrued expenses consist of the following:

	July 31, 2001	July 31, 2000
Accounts Payable	$896,061	$863,660
Litigation	191,653	234,504
Clinical	147,699	-
Accrued Legal Fees	420,360	106,118
Financial Services	995,000	-
Total	**$2,650,773**	**$1,204,282**

Note 7 - Commitments and Contingent Liabilities:

Consulting Services

In October 1996, the Company entered into a Consulting Agreement with its Vice President of Research and Development (the V.P.) pursuant to which, among other things, the V.P. assigned to the Company his entire right, title and interest in and to all inventions, ideas, designs and discoveries made by him during the term of such agreements which relate in any manner to the actual or demonstratably anticipated business, work, undertaking or research and development of the Company. Concurrently with execution of this Consulting Agreement, the V.P. and the Company entered into an Assignment and Assumption

Agreement pursuant to which the V.P. assigned to the Company his interests in and to specific drug delivery systems, controlled release drug delivery systems, and technology patents invented/discovered/conceived by the V.P. prior to the execution of the Agreement, including three existing patents covering insulin delivery systems, applicable to peptides and proteins; drug vaccines and hormones delivery; and controlled release of drugs and hormones (the "Existing Patents"). In addition to the Existing Patents, the V.P. assigned to the Company his interest in four US and/or Canadian patent applications and certain abstracts covering, among other things, liposomes drug delivery for vaccines, drugs, hormones, peptides and cosmetic delivery; transdermal drug delivery for proteins, peptides, hormones and small molecules; controlled release drug delivery systems for capsules, caplets, and liquid suspensions; and DNA technology relating to insulin preparation (collectively, "Other Existing Technology"). At the time of this assignment, the Existing Patents were owned of record by a Canadian corporation, which was 50 percent owned by the V.P. The Company subsequently acquired the V.P.'s interest in this corporation for no additional consideration.

The Consulting Agreement was amended and supplemented as of January 7, 1998 and further amended and supplemented as of December 31, 2000. The Consulting Agreement, 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 10 for description of Special Voting Rights Preferred Stock.

Leases

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

Aggregate minimum annual lease commitments of the Company as of July 31, 2001 are as follows:

Year	Amount
2002	$22,008
2003	18,099
2004	9,801
2005	3,431
Thereafter	-
Total Minimum Lease Payments	**$53,339**

Lease expense amounted to $20,753, $20,175 and $19,240 for the years ended July 31, 2001, 2000 and 1999, 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 to be received in years ending after July 31, 2001:

Year	Amount
2002	$36,240
2003	24,817
2004	24,817
2005	24,817
2006	4,136
Thereafter	-
Total	**$114,827**

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. If the milestone obligations are not met after a five-year period, the Company shall pay Valois an annual payment of $50,000. 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.

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, and thereafter, shall continue until terminated by either party by giving twelve months written notice.

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 and is expected to conclude its consideration of such matters and render its decision during the fourth calendar quarter of 2001. The Company is not able to estimate an amount or range of potential loss from this legal proceeding at the present time. Therefore, no provision has been recorded in the accompanying financial statements.

In February 1999, MQS, Inc., a former consultant, commenced a civil action against the Company in the United States District Court for the District of New Jersey claiming, among other things, that 242,168 shares of common stock and $243,066 were due to it for services that it rendered through December 22, 1998. In January 2001, the Company entered into a settlement agreement with MQS whereby the Company paid the plaintiff certain amounts in cash and common stock that were not material to the consolidated financial position of the Company and whereby the claims of the parties were dismissed with prejudice.

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 and, in the further alternative, to dismiss such action for failure to produce documents referred to in the statement of claim. The Company intends to defend 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.

In February 1997, 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 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 of is not material to the consolidated financial position of the Company.

In March 1999, a former consultant to the Company commenced an action in the Ontario Superior Court of Justice against the Company seeking approximately $94,000 and 1,465 shares of the Company's Common Stock for alleged breach of contract damages and additional amounts in punitive damages. In April 1999, the Company filed a counterclaim for monies the Company believes are due to the Company from this former consultant. The parties have nearly completed discovery, pending the resolution of certain outstanding motions. 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 of is not material to the consolidated financial position of the Company.

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.

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 which is included in revenues as all necessary requirements have been satisfied.

Note 8 - Related Party Transactions:

The amounts due from (to) related parties at July 31, exclusive of the officers' loans receivable, are as follows:

	The Great Tao Inc.	Angara Equities Inc.	Angara Investments Inc.	Ching Chew An Breweries	Golden Bull Estates Inc.	EBI Inc.
Beginning Balance, August 1, 1999	$(102,638)	$274,700	$(52,651)	$(94)	$164,998	$337,293
Cash advance	-	(213,871)	-	-	(30,300)	-
Company expenses paid by related parties	-	-	-	-	(46,953)	-
Other (b)	(2,457)	6,578	(1,261)	(3)	3,952	6,480
Transfer/assumption of related party liabilities (a)	105,095	(67,407)	53,912	97	(91,697)	-
Ending Balance, July 31, 2000	-	-	-	-	-	343,773
Other (b)	-	-	-	-	-	(11,484)
Ending Balance, July 31, 2001	**$-**	**$-**	**$-**	**$-**	**$-**	**$332,289**

(a) Officers of the Company are also shareholders in the related companies and have agreed to the transfer/assumption of the offsetting amounts which were due from (to) related parties.

(b) Effect of foreign currency translation adjustments.

These amounts are non-interest bearing. There are no fixed terms of repayment.

Each of the above related parties is owned in whole or in part by the Company's Chairman of the Board. In addition, EBI, Inc. and Golden Bull Estates, Inc. are shareholders of the Company.

Management feels that the related party expenses provided by such parties were transacted at terms and amounts that would have been obtained had the transactions been consummated with unrelated third parties. The exception to this is the non-recording of interest income and expense on the balances due to/from related parties. The Company estimates the following additional amounts would have been recorded if such transactions were consummated under arms length agreements:

	2001 (July 31)	2000 (July 31)	1999 (July 31)
Interest Income	$32,209	$60,962	$79,118
Interest Expense	$-	$14,938	$18,117

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

As of July 31, 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 $672,477 for the year ended July 31, 2001.

As of 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 and $388,420 for the years ended July 31, 2000 and 1999 respectively.

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 are payable in full on May 1, 2002. 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, 2001, the balance outstanding on these notes, including accrued interest, was $1,023,743.

Note 9 - Long-Term Debt:

Long-term debt consists of the following:

	July 31, 2001	July 31, 2000
Mortgage payable - interest at 9.7 percent per annum, monthly payments of principal and interest of $4,778, final payment due May 25, 2005, secured by all assets of the Company	$518,095	$541,661
Mortgage payable - interest at 10 percent per annum, monthly payments of principal and interest of $1,782, final payment due November 1, 2002, secured by real property located at 11 Carlaw Avenue, Toronto, Canada	174,565	180,302
Total Debt	692,660	721,963
Less Current Maturities	9,634	9,404
Long-Term Debt, Less Current Maturities	**$683,026**	**$712,559**

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

Year	Amount
2002	$9,634
2003	177,556
2004	7,268
2005	498,202
Thereafter	-
Total	**$692,660**

Note 10 - Stockholders' Equity:

Reverse Merger On January 9, 1998, the Company issued 9,234,118 shares of common stock to acquire GBC - Delaware, Inc.. For accounting purposes, the acquisition of GBC - Delaware, Inc. by the Company has been treated as a reverse merger. Accordingly, the 9,234,118 shares issued to acquire GBC - Delaware, Inc. have been treated as outstanding from November 2, 1995 (as adjusted for historical issuances of GBC - Delaware, Inc. and Generex Pharmaceuticals, Inc. during the period from November 2, 1995 to January 8, 1998) and the previously outstanding 1,105,000 shares have been treated as issued on the acquisition date. Since the assets and liabilities acquired on this date were immaterial, no amounts have been assigned to common stock as a result of this transaction. (See Note 1)

Warrants As of July 31, 2001, the Company has the following warrants to purchase common stock outstanding:

Number of Shares to be Purchased	Warrant Exercise Price Per Share	Number of Shares to be Purchased
7,937	$21.82	September 6, 2002
370,589	$7.00	January 17, 2003
500,000	$2.50	March 31, 2003
568,647	$12.15	August 15, 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
543,987	$12.99	September 29, 2005
75,000	$25.15	January 16, 2006
313,515	$10.18	July 6, 2006

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, is due July 31, 2002. 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 is due on March 15, 2002. As of July 31, 2001 the outstanding balance on this note, including accrued interest at 7 percent was $256,580.

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.

Series A Preferred Stock: The Company has issued 1,000 shares of Series A Preferred Stock (Series A) with a par value of $.001. 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. The Company has the right to redeem all outstanding Series A shares on January 16, 2007 for cash or shares of common stock upon written notice.

Special Voting Rights Preferred Stock: The Company has 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.

Note 11 - 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 2001 Plan was adopted in May 2001 by the Board of Directors, but is subject to stockholder approval at the next annual meeting of stockholders.

The 1998, 2000 and 2001 Plans (the Plans) have been administered by the Board of Directors, but are expected to be administered by the Compensation Committee (the Committee) in the future. References to the Committee herein include the Board of Directors so long as it continues to administer the Plans directly.

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 also is 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 thereunder 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, 1998	-	-
Granted	50,000	$8.00
Canceled	-	-
Exercised	-	-
Outstanding - July 31, 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**	$6.59

The following table summarizes information on stock options outstanding at July 31, 2001:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding at July 31, 2001	Weighted Avg. Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at July 31, 2001	Weighted Average Exercise Price
$5.00-$5.50	2,237,500	4.12	$5.09	1,217,500	$5.01
$7.56-$8.00	1,974,500	3.89	$7.60	1,924,500	$7.60
$10.21	100,000	3.50	$10.21	40,000	$10.21

Options exercisable at July 31 are as follows:

1999	50,000
2000	1,162,500

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

	2001 (July 31)	2000 (July 31)	1999 (July 31)
Net Loss:			
As reported	**$27,097,210**	**$8,841,047**	**$6,239,602**
Pro forma	**$31,755,510**	**$17,230,637**	**$6,239,602**
Loss Per Share:			
As reported	**$(1.44)**	**$(.58)**	**$(.47)**
Pro forma	**$(1.69)**	**$(1.13)**	**$(.47)**

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 Lift (Years)	Expected Volatility	Expected Dividends
July 31, 2001	4.66%	5	.9332	-
July 31, 2000	4.80%	5	.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, 2001, 2000 and 1999 was $4.12, $3.22 and $1.85 per share, respectively.

Note 12 - Net Loss Per Share:

Basic EPS and Diluted EPS for the years ended July 31, 2001, 2000 and 1999 have been computed by dividing the net loss for each respective period by the weighted average shares outstanding during that period. All outstanding warrants and options have been excluded from the computation of Diluted EPS as they are antidilutive due to the losses generated in each year.

Note 13 - Supplemental Disclosure of Cash Flow Information:

	2001 (July 31)	2000 (July 31)	1999 (July 31)
Cash paid during the year for:			
Interest	$77,230	$73,687	$67,161
Income taxes	$-	$-	$-

Disclosure of non-cash investing and financing activities:

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
Year Ended July 31, 1999	
Long-term debt was assumed in conjunction with acquisition of property	$82,968
Settlement of liability arising from the violation of financing agreement with issuance of common stock	$738,000
Deposit was utilized to acquire property and equipment	$16,740
Notes receivable were accepted in conjunction with issuance of common stock	$473,882

Note 14 - 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 superseded Statement of Financial Accounting Standards No. 14, "Financial Reporting for Segments of a Business Enterprise." 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.

	Identifiable Assets	Operating Loss
2001		
General Corporate	$38,227,315	$11,768,696
Canada	4,438,558	19,668,843
United States	-	-
Bermuda	=	=
Total	**$42,665,873**	**$31,437,539**
2000		
General Corporate	$7,314,834	$4,741,225
Canada	3,026,436	4,302,731
United States	=	=
Total	**$10,341,270**	**$9,043,956**
1999		
General Corporate	$5,427,170	$3,758,685
Canada	3,462,496	2,468,946
United States	=	=
Total	**$8,889,666**	**$6,227,631**

The regions to 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.

Note 15 - Quarterly Information (Unaudited):

The following schedule sets forth certain unaudited financial data for the preceding eight quarters ending July 31, 2001. In our opinion, the unaudited information set forth below has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the information set forth herein. The operating results for the quarter are not indicative of results for any future period.

	Q1	Q2	Q3	Q4
Fiscal Year July 31, 2001:				
Previously reported				
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)
As Restated				
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)
Fiscal Year July 31, 2000:				
Contract research revenue	$-	$-	$-	$-
Operating loss	$(1,182,342)	$(2,913,996)	$(2,323,101)	$(2,624,517)
Net loss	$(1,118,772)	$(2,878,873)	$(2,291,130)	$(2,552,272)
Net loss per share	$(0.08)	$(0.19)	$(0.15)	$(0.16)

The Company's interim financial information for Q2 has been restated to recognize additional compensation expense related to stock options issued to a consultant.

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 will 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. The parties will conduct the joint venture through Generex (Bermuda), Ltd., 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 Note 10) to form Generex (Bermuda), Ltd. The Company's interest in this company consists of 6,000 shares of Generex (Bermuda) Ltd. common stock and 3,612 shares of convertible preferred stock, representing an 80.1% equity ownership interest in Generex (Bermuda) Ltd. At the same time, EIS remitted $2,985,000 to purchase 2,388 shares of Generex (Bermuda) Ltd. convertible preferred stock, representing a 19.9% equity ownership interest in Generex (Bermuda) Ltd. As of July 31, 2001, the minority interest has been reduced to $-0- due to their share of Generex (Bermuda), Ltd.'s net loss.

The parties intend to select at least one pharmaceutical product for research and development under the joint venture by January 2002. The parties will establish a research and development plan and budget upon selection of the pharmaceutical

product that will be the initial focus of the joint venture. Generex (Bermuda), Ltd. has been 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) Ltd. paid a nonrefundable license fee of $15,000,000 to Elan in consideration for being granted rights to use the Elan drug delivery technologies. 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.

Note 17 - Subsequent Events (Unaudited):

Subsequent events occurring after July 31, 2001 consist of the following:

On August 7, 2001, the Company entered into a termination agreement with Tradersbloom, Limited, pursuant to which the parties terminated the equity draw down facility entered into August 14, 2000. Under the terms of this facility, the Company was able to sell to Tradersbloom, from time to time, shares of their common stock up to a maximum sale of $50,000,000. In conjunction with the execution of this agreement, warrants to purchase 568,647 shares of common stock were issued. The fair value of these warrants was capitalized as deferred financing costs. In conjunction with the termination of this agreement, the Company paid $245,000 to satisfy its obligations to Tradersbloom and expensed the deferred financing costs in the year ended July 31, 2001. Neither the Company nor Tradersbloom has any further rights or obligations under the equity draw down facility.

On September 25, 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.

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

Not applicable.

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.

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 June 14, 1999 is incorporated here in 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 July 12, 1999 ("1999 S-1") is incorporated herein by reference.
4.1	Form of common stock certificate filed as Exhibit 4.2 with our 1999 S-1 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 filed with the Commission on October 30, 2001, is incorporated herein by reference.
4.2.3*	2001 Stock Option Plan.
4.3	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; RAM Trading Ltd.;Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 3, 2001 filed as an exhibit to our Report on Form 8-K dated July 6, 2001 and filed on July 17, 2001 ("July 2001 8-K") is incorporated herein by reference.
4.4	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; RAM Trading Ltd.; Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 3, 2001 filed as an exhibit to our July 2001 8-K is incorporated herein by reference.

4.5	Form of Warrant granted to Cranshire Capital, L.P.; RAM Trading Ltd.; Gryphon Master Fund; Kodiak Opportunity, L.P.; Kodiak Opportunity 3C7, L.P.; Kodiak Opportunity Offshore, Ltd.; Novelly Exempt Trust; Langley Partners, L.P.; Montrose Investments, Ltd.; WEC Asset Management, LLC; ZLP Master Technology Fund, Ltd.; Alpha Capital Aktiengesellschaft; and The dotCOM Fund, LLC, dated July 6, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.6	Securities Purchase Agreement entered into with Capital Ventures International, dated July 3, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.7	Registration Rights Agreement entered into with Capital Ventures International, dated July 3, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.8	Warrant granted to Capital Ventures International, dated July 3, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.9	Form of Securities Purchase Agreement entered into with Elliott International, L.P.; and Elliott Associates, L.P., dated July 3, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.10	Form of Registration Rights Agreement entered into with Elliott International, L.P.; and Elliott Associates, L.P., dated July 3, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.11	Warrant issued to Elliott International, L.P. and Elliott Associates, L.P., dated July 5, 2001, filed as an exhibit to our July 2001 8-K, is incorporated herein by reference.
4.12	Form of Warrant issued to Ladenburg Thalmann & Co., Inc. dated July 6, 2001, filed as an exhibit to our Registration Statement on Form S-3 (File No. 333-67118) filed August 8, 2001, is incorporated herein by reference.
4.13	Registration Rights Agreement dated January 16, 2001 between Generex Biotechnology Corporation and Elan International Services, Ltd. filed as an exhibit to our Report on Form 8-K dated January 16, 2001 and filed on January 23, 2001 ("January 2001 8-K") is incorporated herein by reference.
4.14	Form of Warrant issued to Elan International Services, Ltd. filed as an exhibit to our January 2001 8-K is incorporated herein by reference.
4.15	Certificate of Designations, Preferences and Rights of Series A Preferred Stock filed as an exhibit to our January 2001 8-K is incorporated herein by reference.
4.16	Securities Purchase Agreement dated January 16, 2001, between Generex Biotechnology Corporation, Elan International Services, Ltd. and Elan Corporation, plc., filed as an exhibit to our Report on Form 8-K/A dated January 16, 2001 and filed on February 1, 2001 is incorporated herein by reference.
4.17	Form of Securities Purchase Agreement entered into with certain parties to October 2000 Private Placement filed as an exhibit 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.
4.18	Form of Registration Rights Agreement entered into with certain parties to October 2000 Private Placement filed as an exhibit to our October 2000 8-K is incorporated herein by reference.

4.19	Form of Warrant issued to certain parties to October 2000 Private Placement filed as an exhibit to our October 2000 8-K is incorporated herein by reference.
10.1.1	Consulting Agreement with Pankaj Modi filed as Exhibit 10.1.1 to our Registration Statement on Form 10 filed December 14, 1999 ("1999 Form 10") is incorporated herein by reference.
10.1.2	Assignment and Assumption Agreement with Pankaj Modi filed as Exhibit 10.1.2 to our 1999 Form 10 is incorporated herein by reference.
10.1.3*	Memorandum of Agreement dated January 7, 1998 between Generex Pharmaceuticals, Inc., GHI Inc., Generex Biotechnology Corporation, Dr. Pankaj Modi and Galaxy Technology, Canada.
10.1.4*	Supplemental Agreement dated December 31, 2000 between Generex Pharmaceuticals, Inc., Generex Biotechnology Corporation and Dr. Pankaj Modi.
21*	Subsidiaries of the Registrant
23.1.1*	Consent of Deloitte & Touche LLP, independent public accountants.
23.1	Consent of WithumSmith+Brown, independent public accountants.
24*	Powers of Attorney

* 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 22, 2001, announcing an increase in the size of Generex's Board of Directors from six to seven members, the appointment of Ivan Lieberburg, Ph.D., M.D. as a director of Generex, and the removal of Generex from the Nasdaq Biotechnology Index.

2. Report on Form 8-K, filed with the Commission on July 17, 2001, announcing two private placements completed on or about July 6, 2001 in which Generex raised $11,59,994.75 through the sale of units consisting of one share of common stock and a warrant to purchase .25 shares of common stock. The units were sold without registration under the Securities Act of 1933 in reliance upon the exemption from registration provided in Section 4(2) thereof and Rule 506 of Regulation D promulgated thereunder.

3. Report on Form 8-K, filed with the Commission on August 15, 2001, announcing that Generex had entered into a termination agreement with Tradersbloom Limited pursuant to which the equity draw down facility was terminated.

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 23rd day of October 2001.

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
/s/ Anna E. Gluskin Anna E. Gluskin	President and Chief Executive Officer	October 23, 2001
/s/ E. Mark Perri E. Mark Perri	Chairman, Chief Financial and Accounting Officer	October 23, 2001
/s/ Rose C. Perri Rose C. Perri	Secretary, Treasurer and Chief Operating Officer	October 23, 2001
/s/Pankaj Modi* Pankaj Modi	Vice President, Research and Development	October 23, 2001
/s/ Michael Hawke* Michael Hawke	Director	October 23, 2001
/s/ Ivan M. Lieberburg* Ivan M. Lieberburg	Director	October 23, 2001
/s/ Jan Michael Rosen* Jan Michael Rosen	Director	October 23, 2001

*By: /s/ E. Mark Perri
E. Mark Perri, as Attorney-in-fact

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