GENEREX BIOTECHNOLOGY CORP
Form 10-K
January 13, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended July 31, 2016

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-25169

GENEREX BIOTECHNOLOGY CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	98-0178636
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4145 North Service Road, Suite 200

Burlington, Ontario, Canada L7L 6A3

(Address of principal executive offices) (Zip Code)

(416) 364-2551

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.001 par value per share	None

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes No

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	
	Smaller reporting company
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of July 31, 2016 , the aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was $3,854,750 based on the average bid and asked price at which such stock was last sold as of such date. Generex Biotechnology Corporation has no non-voting common equity. At December 29, 2016 there were 908,541,475 shares of common stock outstanding.

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As used herein, the terms the "Company," "Generex," "we," "us," or "our" refer to Generex Biotechnology Corporation, a Delaware corporation.

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Forward-Looking Statements

Certain matters in this Annual Report on Form 10-K, including, without limitation, certain matters discussed under *Item 1 - Business*, *Item 1A - Risk Factors*, and *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations*, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, included in this Annual Report that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "expects," "anticipates," "plans," "intends," "believes," "will," "estimates," "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

- our expectations concerning product candidates for our technologies;
- our expectations concerning existing or potential development and license agreements for third-party collaborations and joint ventures;
- our expectations of when different phases of clinical activity may commence and conclude;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received; and
- our expectations of when commercial sales of our products may commence and when actual revenue from the product sales may be received.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates;
- the inherent uncertainties associated with commercialization of products that have received regulatory approval;
- the volatility of, and decline in, our stock price; and
- our current lack of financing for operations and our ability to obtain the necessary financing to fund our operations and effect our strategic development plan.

Additional factors that could affect future results are set forth below under *Item 1A. Risk Factors.* We caution investors that the forward-looking statements contained in this Annual Report must be interpreted and understood in

light of conditions and circumstances that exist as of the date of this Annual Report. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements made in this Annual Report to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based.

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Part I

Item 1. Business.

Preliminary Note

As of October, 2015, (the first quarter of fiscal 2016), we laid off all of our employees, and ceased compensating our officers, and suspended substantially all of our operations due to lack of funds. The description below related to our historical business. If we do not receive substantial financing, we will need to completely shut down our operations.

Corporate History and Structure

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 development 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., an 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 GB 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.

Subsidiaries

Following our reorganization in 1999, Generex Pharmaceuticals Inc., which is incorporated in Ontario, Canada, remained as our wholly-owned subsidiary. All of our Canadian operations are performed by Generex Pharmaceuticals. Generex Pharmaceuticals is the 100% owner of 1097346 Ontario Inc., which is also incorporated in Ontario, Canada. In August 2003, we acquired Antigen Express, Inc., a Delaware incorporated company. Antigen is engaged in the research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. Antigen also does business under the names Generex Oncology and Generex Infectious Diseases.

We formed Generex (Bermuda), Inc., which is organized in Bermuda, in January 2001 in connection with a joint venture with Elan International Services, Ltd., a wholly-owned subsidiary of Elan Corporation, plc, to pursue the application of certain of our and Elan's drug delivery technologies, including our platform technology for the buccal delivery of pharmaceutical products. In December 2004, we and Elan agreed to terminate the joint venture. Under the termination agreement, we retained all of our intellectual property rights and obtained full ownership of Generex (Bermuda). Generex (Bermuda) does not currently conduct any business activities. We have additional subsidiaries incorporated in the U.S. and Canada which are dormant and do not carry on any business activities.

Overview of Business

We are engaged primarily in the research and development of drug delivery systems and 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. Through our wholly-owned subsidiary, Antigen, we have expanded our focus to include immunomedicines incorporating proprietary vaccine formulations.

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, including estrogen, heparin, monoclonal antibodies, human growth hormone and fertility hormones, but to date have focused our development efforts primarily on one pharmaceutical product, Generex Oral-lyn™, an insulin formulation administered as a fine spray into the oral cavity using our proprietary hand-held aerosol spray applicator known as RapidMist™.

Our wholly-owned subsidiary, Antigen, concentrates on developing proprietary vaccine formulations that work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). Our immunomedicine products are based on two platform technologies and are in the early stages of development. We continue clinical development of Antigen's synthetic peptide vaccines designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene for patients with HER-2/neu positive breast cancer in a Phase II clinical trial and patients with prostate cancer and against avian influenza in two Phase I clinical trials. We also initiated an additional Phase I clinical trial in patients with either breast or ovarian cancer. The synthetic vaccine technology has certain advantages for pandemic or potentially pandemic viruses, such as the H5N1 avian and H1N1 swine flu. In addition to developing vaccines for pandemic influenza viruses, we have vaccine development efforts underway for seasonal influenza virus, HIV, HPV, melanoma, ovarian cancer, allergy and Type I diabetes mellitus. We have established collaborations with clinical investigators at academic centers to advance these technologies.

To date, we have received regulatory approval in Ecuador, India (subject to regulatory approval of a 2012 in-country study), Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. We have previously submitted regulatory dossiers for Generex Oral-lyn™ in a number of other countries, including Bangladesh, Kenya, Jordan and Armenia. While we believe these countries will ultimately approve our product for commercial sale, we do not anticipate recognizing revenues in any of these jurisdictions in the next twelve months. No dossier related activities or product shipments have taken place during fiscal 2014 or 2015, nor are any expected to these countries during the remainder of calendar year 2015. In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas in April 2008. Approximately 450 patients were enrolled at approximately 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia, Ukraine and Ecuador. The final subjects completed the trial in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. . We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure sufficient additional financing. However, we have initiated a project with the University Health Network of the University of Toronto, and the University of Guelph, Ontario to enhance the formulation of Generex Oral-lyn™ in order to reduce the number of puffs required for prandial use. Early results in an animal study have been encouraging and we expect to release the final results in the third quarter of 2015.

In November 2008 we, together with our marketing partner Shreya Life Sciences Pvt. Ltd., officially launched Generex Oral-lyn™ in India under marketing name of Oral Recosulin™. Each package of Oral Recosulin™ contains two canisters of our product along with one actuator. The product received regulatory price approval in India in January 2009. Per the requirements of the regulatory approval in India, an in-country clinical study must be completed in India with Oral Recosulin™ before commercial sales can commence. The field portion of the study was completed in the third calendar quarter of 2012. Shreya has advised Generex that the dossier was submitted in December of 2012 to the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Generex has provided additional, detailed scientific data to support the Shreya submission. We have not recognized any revenues from the sale of Generex Oral-lyn™ in India through fiscal year ended July 31, 2016 and do not expect any revenues to be recognized in India in

the next twelve months.

In December 2008, we, together with our marketing partner Benta S.A., received an approval to market Generex Oral-lyn™ in Lebanon. The official product launch in Lebanon took place in May 2009. In May 2009, the Algerian health authorities granted us permission to import and sell Generex Oral-lyn™ for the treatment of diabetes in Algeria. The official product launch in Algeria took place in October 2009. To date, we have not recognized any revenue from the sales of Generex Oral-lyn™ in Algeria and very minimal revenues in Lebanon. We do not anticipate any revenues to be recognized from these jurisdictions in the next twelve months.

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have discontinued development and/or sale of their inhalable forms of insulin. MannKind introduced a new pulmonary insulin which was approved by the FDA in 2014, and MannKind subsequently partnered with sanofi-aventis to market the product under the tradename of Afrezza.

Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally absorbed formulation with no pulmonary deposition. We believe that our buccal delivery technology offers several advantages, including the ease of use, portability, avoidance of pulmonary inhalation and safety profile. Furthermore, insulin administered through the Generex Oral-lyn™ RapidMist™ technology is absorbed directly into the blood stream and not only acts rapidly, but returns to baseline quickly, thereby minimizing the chance of developing hypoglycemia.

Large pharmaceutical companies, such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., MedImmune Inc. (a subsidiary of Astra-Zeneca, Inc.) and others, also compete against us in the oncology, immunomedicine and vaccine markets. These companies have competing experience and expertise in securing government contracts and grants to support research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, as well as manufacturing and marketing approved products. As such, they are also considered significant competitors in these fields of pharmaceutical products and therapies. There are also many smaller companies which are pursuing similar technologies in these fields who are considered to be competitors of Generex.

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. To date, we have not been profitable and our accumulated net loss available to shareholders was $375,704,372 at July 31, 2016. As of July 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months. To continue operations, we will require additional funds to support our working capital requirements and any development activities, or will need to suspend operations. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. We have sold non-essential real estate assets which were classified as Assets Held for Investment to augment our cash position. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

We operate in only one segment: the research and development of drug delivery systems and technologies for metabolic and immunological diseases.

Our Business Strategy

Our business model focuses on the research and development of diabetes, oncology and infectious diseases drugs. This business model leverages the expertise of our management team, scientific advisory board and the history of our company. Our goal is to develop next generation drugs for diabetes, oncology and infectious disease by leveraging our buccal delivery technology to administer large and small molecule drugs, including insulin, and proprietary vaccine formulations based upon two Antigen platform technologies to provide innovative biopharmaceutical products that offer the potential for superior efficacy and safety over existing products. To achieve these goals, the key elements of our strategy include:

- Completing any additional studies or clinical trials of Generex Oral-lyn™, which may be required in order to obtain regulatory approval in major and other jurisdictions;

- Enhancing the formulation for Generex Oral-lyn™ to increase effectiveness and to improve the potential for new financing for additional clinical trials.

- Developing a proprietary portfolio of products for the treatment of diabetes through strategic partnerships licensing and acquisitions;

- A keystone of Generex's strategy, announced at the annual meeting of stockholders in June 2011 is the proposed spin-out of Antigen Express as a separate company from Generex. Management believes that this action would allow Antigen to establish value for its immunotherapeutic vaccine technologies separate from the Generex buccal drug delivery platform technologies. The spin-out would be accomplished by the issuance of one or more dividends of Antigen Express stock to Generex stockholders;

- Completing the ongoing Phase II clinical trials of Antigen's synthetic peptide vaccines designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene for patients with HER-2/neu positive breast cancer, conducting a Phase II prostate cancer trial and a Phase I trial in patients with breast or ovarian cancer;

- Conducting further clinical trials of Antigen's synthetic peptide vaccines against avian (H5N1) influenza and initiating clinical trial of such vaccines against swine (H1N1) influenza; and

- Exploring other applications for our RapidMist platform buccal technology; morphine, LWH, fentanyl (all of which have undergone Phase I clinical studies), as well as cell therapy for late stage diabetes.

Buccal Delivery Technology and Products

Our buccal delivery technology involves the preparation of proprietary formulations in which an active pharmaceutical agent is placed in a solution with a combination of absorption enhancers and other excipients classified "generally recognized as safe" ("GRAS") by the United States Food and Drug Administration (the "FDA") when used in accordance with specified quantities and other limitations. The resulting formulations are aerosolized with a pharmaceutical grade chemical propellant and are administered to patients using our proprietary RapidMist™ brand metered dose inhaler. 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, patients self-administer the formulations by spraying them 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 flagship oral insulin product Generex Oral-lyn™, insulin absorption in the buccal cavity has been shown to be efficacious and safe.

Buccal Insulin Product – Generex Oral-Lyn™

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

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

In Type 2 diabetes (adult onset or non-insulin dependent diabetes mellitus), the body does not produce enough insulin, or cannot properly use the insulin produced. Type 2 diabetes is the most common form of the disease and accounts for 90-95 percent of diabetes cases. In addition to insulin therapy, Type 2 diabetics may take oral drugs that stimulate the production of insulin by the pancreas or that help the body to more effectively use insulin. Generex Oral-lyn™ provides a simple means of delivering needed insulin to this major cohort of individuals.

Studies in diabetes have identified a condition closely related to and preceding diabetes, called impaired glucose tolerance (IGT). People with IGT do not usually meet the criteria for the diagnosis of diabetes mellitus. They have normal fasting glucose levels but two hours after a meal their blood glucose level is far above normal. With the increase use of glucose tolerance tests the number of people diagnosed with this pre-diabetic condition is expanding exponentially. Per the 2013 Diabetes Atlas Update, published by the International Diabetes Federation (IDF), approximately 40 million people in the United States and more than 316 million people world-wide suffer from IGT. Generex Oral-lyn™ is an ideal solution to providing meal-time insulin to the millions of IGT sufferers. This therapeutic area is currently being investigated.

If not treated, diabetes can lead to blindness, kidney disease, nerve disease, amputations, heart disease and stroke. Each year, between 12,000 and 24,000 people suffer vision impairment or complete blindness because of diabetes. Diabetes is also the leading cause of end-stage renal disease (kidney failure), accounting for about 40 percent 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 two to four times more likely to have heart disease, which is present in 75 percent of diabetes-related deaths, and are two to four times more likely to suffer a stroke.

There is no known cure for diabetes. The IDF estimates that there are currently approximately 382 million diabetics worldwide per their 2013 Diabetes Atlas Update and is expected to affect over 592 million people by the year 2035. There are estimated to be over 37 million people suffering from diabetes in North America alone and diabetes is the second largest cause of death by disease in North America.

A substantial number of large molecule drugs (*i.e.*, drugs composed of molecules with a high molecular weight and fairly complex and large spatial orientation) 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 inefficient or ineffective. The RapidMist technology provides a recognized and proved drug delivery system for the delivery of large molecules directly into the blood stream with the attendant advantages.

In May 2005, we received approval from the Ecuadorian Ministry of Public Health for the commercial marketing and sale of Generex Oral-lyn™ for treatment of Type 1 and Type 2 diabetes. We have successfully completed the delivery and installation of a turnkey Generex Oral-lyn™ production operation at the facilities of PharmaBrand in Quito, Ecuador. The first commercial production run of Generex Oral-lyn™ in Ecuador was completed in May, 2006. While Ecuador production capability may be sufficient to meet the needs of South America, it is believed to be insufficient for worldwide production for future commercial sales and clinical trials.

On the basis of the test results in Ecuador and other pre-clinical data, we made an IND submission to Health Canada (Canada's equivalent to the FDA) 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 FDA 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 subjects with Type 1 and Type 2 diabetes and healthy volunteers. The study protocols in most trials involved administration of two different doses of our insulin formulation following either a liquid Sustacal meal or a standard meal challenge. The objective of these studies was to evaluate our insulin formulation's efficacy in controlling post-prandial (meal related) glucose levels. These trials demonstrated that our insulin formulation controlled post-prandial hyperglycemia in a manner comparable to injected insulin. In April 2003, a Phase II-B clinical trial protocol was approved in Canada. In September 2006, a Clinical Trial Application relating to our Generex Oral-lyn™ protocol for late-stage trials was approved by Health Canada. The FDA’s review period for the protocol lapsed without objection in July 2007.

In late April 2008, we initiated Phase III clinical trials in North America for Generex Oral-lyn™ with the first subject screening in Texas. Other clinical sites participating in the study were located in the United States (Texas, Maryland, Minnesota and California), Canada (Alberta), European Union (Romania, Poland and Bulgaria), Eastern Europe (Russia and Ukraine),) and Ecuador. Approximately 450 subjects were enrolled in the program at approximately 70 clinical sites around the world. The Phase III protocol called for a six-month trial with a six-month follow-up with the primary objective to compare the efficacy of Generex Oral-lyn™ and the RapidMist™ Diabetes Management System with that of standard regular injectable human insulin therapy as measured by HbA1c, in patients with Type-1 diabetes mellitus. The final subjects completed the trial in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure additional financing. However we have undertaken a formulation enhancement project with the University Health Network at the University of Toronto and the University of Guelph, Ontario to increase the amount of insulin reaching the blood stream. Preliminary results from an animal study are encouraging,

In the past, we engaged a global clinical research organization to provide many study related site services, including initiation, communication with sites, project management and documentation; a global central lab service company to arrange for the logistics of kits and blood samples shipment and testing; an Internet-based clinical electronic data management company to assist us with global data entry, project management and data storage/processing of the Phase III clinical trial and regulatory processes. In the past, we have contracted with third-party manufacturers to produce sufficient quantities of the RapidMist™ components, the insulin, and the raw material excipients required for the production of clinical trial batches of Generex Oral-lyn™.

As described above, we have obtained regulatory approval for the commercial marketing and sale of Generex Oral-lyn™ in Ecuador, India (subject to regulatory approval of a 2012 in-country study), Lebanon and Algeria.

Other Potential Buccal Products

We have currently ongoing discussions regarding possible research collaborations with various pharmaceutical companies concerning use of our large molecule drug delivery technology with other compounds Memorandums of Understanding have been signed with two companies for the testing of RapidMist technology with both Leuprolide and medical marijuana and clinical work is expected to commence in the latter half of 2015.

Immunomedicine Technology and Products

Our wholly-owned subsidiary Antigen Express is developing proprietary vaccine formulations based upon two platform technologies that were discovered by its founder, the Ii-Key hybrid peptides and Ii-Suppression. These technologies are applicable for either antigen-specific immune stimulation or suppression, depending upon the dosing and formulation of its products. Using active stimulation, we are focusing on major diseases such as breast, prostate and ovarian cancer, melanoma, influenza (including H5N1 avian and H1N1 swine flu) and HIV. Autoimmune diseases such as diabetes and multiple sclerosis are the focus of our antigen-specific immune suppression work.

Antigen’s immunotherapeutic vaccine was in Phase II clinical trials for patients with HER-2/neu positive breast cancer when we had financial resources. The trial is being conducted with the United States Military Cancer Institute's (USMCI) Clinical Trials Group and will examine the rate of relapse in patients with node-positive or high-risk node-negative breast cancer after two years. The study is randomized and will compare patients treated with AE37 plus the adjuvant GM-CSF versus GM-CSF alone. The Phase II trial follows a Phase I trial that demonstrated safety, tolerability, and immune stimulation of the AE37 vaccine in breast cancer patients.

Based on positive results in trials of the AE37 vaccine in breast cancer patients, we entered into an agreement in August 2006 with the Euroclinic, a private center in Athens, Greece, to commence clinical trials with the same compound as an immunotherapeutic vaccine for prostate cancer. A Phase I trial involving 29 patients was completed in August 2009, which similarly showed safety, tolerability and induction of a specific immune response. Agreements, as well as a protocol, are in place for initiation of a Phase II clinical trial once additional funding is available.

The same technology used to enhance immunogenicity is being applied in the development of a synthetic peptide vaccine for H5N1 avian influenza and the 2009 H1N1 swine flu. In April 2007, a Phase I clinical trial of Antigen's proprietary peptides derived from the hemagglutinin protein of the H5N1 avian influenza virus was initiated in healthy volunteers in the Lebanese-Canadian Hospital in Beirut, Lebanon. We have completed the first portion of the Phase I trial. Modified peptide vaccines for avian influenza offer several advantages over traditional egg-based or cell-culture based vaccines. Modified peptide vaccines can be manufactured by an entirely synthetic process which reduces cost and increases both the speed and quantity of vaccine relative to egg- or cell-culture based vaccines. Another advantage is that the peptides are derived from regions of the virus that are similar enough in all H5N1 and H1N1 virus strains such that they would not have to be newly designed for the specific strain to emerge in a pandemic.

A Physician's Investigational New Drug ("IND") application for the Phase I and Phase II trials in patients with stage II HER-2/neu positive breast cancer has been filed with the FDA. The Phase I trial was completed at the Walter Reed Army Medical Center in Washington, D.C., and the Phase II trial were taking place before our resources were exhausted. A Physician's Investigational New Drug application for a Phase I trial in patients with breast or ovarian cancer also has been filed with the FDA and this Phase I trial is being conducted in Dallas, Texas at the Mary Crowley Cancer Center. Applications were filed and approvals obtained for a Phase I prostate cancer trial using AE37 in Athens, Greece from the Hellenic Organization of Drugs, and this Phase I trial was completed in August 2009. The Ministry of Health in Lebanon gave approval for Phase I trial of our experimental H5N1 prophylactic vaccine in Beirut, Lebanon following submission of an application. All other immunomedicine products are in the pre-clinical stage of development.

Government Regulation

Our research and development activities and the manufacturing and marketing of our pharmaceutical products are subject to extensive regulation by the FDA in the United States, Health Canada in Canada and comparable designated regulatory authorities in other countries. Among other things, extensive regulations require us to satisfy numerous conditions before we can bring products to market. While these regulations apply to all competitors in our industry, having a technology that is unique and novel extends the requisite review period by the various divisions within the FDA and other regulators. Also, other companies in our industry are not limited primarily to products which still need to be approved by government regulators, as we are now.

If requisite regulatory approvals are not obtained and maintained, our business will be substantially harmed. In many cases, we expect that extant and prospective development partners will participate in the regulatory approval process. 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 relating to pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States. United States federal and state statutes and regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of pharmaceutical products. The regulatory approval process, including clinical trials, usually takes several years and requires the expenditure of substantial resources. If regulatory approval of a product is granted, the approval may include significant limitations on the uses for which the product may be marketed.

The steps required before a pharmaceutical product may be marketed in the United States include:

- Conducting appropriate pre-clinical laboratory evaluations, including animal studies, in compliance with the FDA's Good Laboratory Practice ("GLP") requirements, to assess the potential safety and efficacy of the product, and to characterize and document the product's chemistry, manufacturing controls, formulation and stability;

- Submitting the results of these evaluations and tests to the FDA, along with manufacturing information, analytical data, and protocols for clinical studies, in an IND Application, and receiving approval from the FDA that the clinical studies proposed under the IND are allowed to proceed;

- Obtaining approval of Institutional Review Boards ("IRBs") to administer the product to humans in clinical studies; conducting adequate and well-controlled human clinical trials in compliance with the FDA's Good Clinical Practice ("GCP") requirements that establish the safety and efficacy of the product candidate for the intended use;

- Developing manufacturing processes which conform to the FDA's current Good Manufacturing Practices, or cGMPs, as confirmed by FDA inspection;

- Submitting to the FDA the results of pre-clinical studies, clinical studies, and adequate data on chemistry, manufacturing and control information to ensure reproducible product quality batch after batch, in an NDA or Biologics License Application ("BLA"); and

- Obtaining FDA approval of the NDA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent.

Quality and pre-clinical tests and studies include: laboratory evaluation of Drug Substance and Drug Product chemistry, formulation/manufacturing, and stability profiling, as well as a large number of animal studies to assess the potential safety and efficacy of each product. Typically, the pre-clinical studies consist of the following:

Pharmacology

- Primary and Secondary Pharmacodynamics
- Safety Pharmacology
- Other Pharmacodynamics

Pharmacokinetics ("PK")

- Single and Multiple Dose Kinetics
- Tissue Distribution
- Metabolism
- PK Drug Interactions
- Other PK studies

Toxicology

- Single and Multiple Dose Toxicity
- Genotoxicity
- Carcinogenicity
- Reproduction Toxicity
- Other Toxicity

The results of the quality and pre-clinical tests/studies, in addition to any non-clinical pharmacology, are submitted to the FDA along with the initial clinical study protocol (see descriptive of process below) as part of the initial IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to it, the IND becomes effective 30 days following its receipt by the FDA. The FDA reviews all protocols, protocol amendments, adverse event reports, study reports, and annual reports in connection with a new pharmacological product.

The IND for our oral insulin formulation became effective in November 1998. Amendments are also subsequently filed as new Clinical Studies and their corresponding Study Protocols are proposed. In July 2007, we received a no

objection clearance to initiate our Phase III study protocol for our oral insulin product. The Physician's Investigational New Drug Application for the Phase 1 and Phase II trial of AE37, Antigen's synthetic peptide vaccine designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene, in patients with stage II HER-2/neu positive breast cancer became effective in March 2006.

Clinical trials involve the administration of a new drug to humans under the supervision of qualified investigators. The protocols for the trials must be submitted to the FDA as part of the IND. Also, each clinical trial must be approved and conducted under the auspices of an IRB, 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 usually 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 and confirm clinical efficacy and to test for safety in an expanded patient population at clinical trial sites in different geographical locations. The 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 (known as "Pivotal Trials"). The successful completion of Phase III clinical trials is a mandatory step in the approval process for the manufacturing, marketing, and sale of products.

In the United States, the results of quality, pre-clinical studies and clinical trials, if successful, are submitted to the FDA in an NDA to seek approval to market and commercialize the drug product for a specified use. The NDA is far more specific than the IND and must also include proposed labeling and detailed technical sections based on the data collected. The FDA is governed by the Prescription Drug User Fee Act ("PDUFA") regarding response time to the application, which is generally 12 months (and shorter for a priority application). It may deny a NDA if it believes that applicable regulatory criteria are not satisfied. The FDA also may require additional clarifications on the existing application or even additional testing for safety and efficacy of the drug. We cannot be sure that any of our proposed products will receive FDA approval. The multi-tiered approval process means that our products could fail to advance to subsequent steps without the requisite data, studies, and FDA approval along the way. Even if approved by the FDA, our products and the facilities used to manufacture our products will remain subject to review and periodic inspection by the FDA.

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

One final hurdle that is closely associated with the cGMP inspections is the pre-approval inspection that the FDA carries out prior to the issuance of a marketing license. FDA inspectors combine cGMP compliance with a review of research and development documents that were used in the formal NDA. A close inspection of historic data is reviewed to confirm data and to demonstrate that a company has carried out the activities as presented in the NDA. This is generally a long inspection and requires a team of individuals from the company to “host” the FDA inspector(s).

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 the 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 submitted by a sponsor and approved by the regulatory authorities in that country. Again, similar to the FDA, each country will mandate a specific financial consideration for the Marketing Application dossiers being submitted. Although an important consideration, 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. To date, we have received the following foreign regulatory approval for our product candidates:

- We obtained regulatory approval to begin clinical trials of our oral insulin formulation in Canada in November 1998. In April 2003, we received approval of an Oral-lyn™ Phase II-B clinical trial protocol in Canada. In September 2006 Health Canada approved our Clinical Trial Application in respect of our proposed Generex Oral-lyn™ protocol for late-stage trials.

- We obtained regulatory approval in Canada to begin clinical trials of our buccal morphine product in March 2002 and our fentanyl product in October 2002.

- In May 2005, we received approval from the Ecuadorian Ministry of Public Health for the commercial marketing and sale of Generex Oral-lyn™ for treatment of Type 1 and Type 2 diabetes. To date we have not recognized any revenue from the sale of Generex Oral-lyn™ in Ecuador and we are not currently expending any resources to further commercialization in this country.

- In November 2007, we obtained approval for the importation and commercial marketing and sale in India of Generex Oral-lyn™ under the marketing name of Oral Recosulin™ from the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India, which is responsible for authorizing marketing approval of all new pharmaceutical products in India. Per the requirements of the approval, an in-country clinical study must be completed in India with Oral Recosulin™ before commercial sales can commence. The field portion of the study was completed in the third calendar quarter of 2012. Shreya has advised Generex that the dossier was submitted in December of 2012 to the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Generex has provided additional, detailed scientific data to support the Shreya submission. • Applications were filed and approvals obtained in May 2007 for a Phase I prostate cancer trial using AE37 in Athens, Greece from the Hellenic Organization of Drugs. This Phase I trial was completed in August 2009.

- The Ministry of Health in Lebanon gave approval for the Phase I trial of our experimental H5N1 prophylactic vaccine in Beirut, Lebanon following submission of an application. In December 2008, we, together with our marketing partner Benta SA., received an approval to market Generex Oral-lyn™ in Lebanon. The official product launch in Lebanon took place in May 2009. We are not currently expending any resources to further commercialization in this country.

- In May 2009, the Algerian health authorities granted us permission to import and sell Generex Oral-lyn™ for the treatment of diabetes in Algeria. To date we have not recognized any revenue from the sale of Generex Oral-lyn™ in Algeria and we are not currently expending any resources to further commercialization in this country.

Marketing and Distribution

Our strategy is to market our products through collaborative arrangements with companies that have well-established pharmaceutical marketing and distribution capabilities, including expertise in the regulatory approval processes in their respective jurisdictions.

We have entered into licensing and distribution agreements with a number of multinational distributors to assist us with the process of gaining regulatory approval for the registration and subsequent marketing, distribution, and sale of Generex Oral-lyn™ in countries throughout the world, including:

- Shreya Life Sciences Pvt. Ltd. for India, Pakistan, Bangladesh, Nepal, Bhutan, Sri Lanka, and Myanmar;
- Adcock Ingram Limited and Adcock Ingram Healthcare (Pty) Ltd. for South Africa, Lesotho, Swaziland, Botswana; Namibia, Mozambique and Zimbabwe;
- E&V Alca Distribution Corp. for Albania, Montenegro, and Kosovo;
- SciGen, Ltd. for China, Hong Kong, Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam;
- Pharmaris Perus S.A.C. for Peru;
- MediPharma SA for Argentina;
- PMG S.A. for Chile;
- Dong Sung Pharm. Co. Ltd. for South Korea; and
- Benta S.A. for Lebanon.

Under these licensing and distribution agreements excluding the one with Dong Sung Pharm Co., we will not receive an upfront license fee, but the distributor will bear any and all costs associated with the procurement of governmental approvals for the sale of Generex Oral-Lyn™, including any clinical and regulatory costs. We possess the worldwide marketing rights to our oral insulin product. We do not currently plan to expend significant resources on additional clinical trials or to further the commercialization of Generex Oral-lyn™ until after such time that we secure additional financing.

Manufacturing

In December 2000, we completed a pilot manufacturing facility for Generex Oral-lyn™ in Toronto, Canada in the same commercial complex in which our laboratories were located. In the first quarter of fiscal year 2006, we initiated a scale-up commercial production run of several thousand canisters of Generex Oral-lyn™ at this facility. In July 2012, we sold the property which housed the manufacturing and laboratory facility. We would engage contract manufacturers in order to manufacture any product in significant quantities for any future commercial sales and clinical trials.

In March 2006, we successfully completed the delivery and installation of a turnkey Generex Oral-lyn™ filling operation at the facilities of PharmaBrand, in Quito, Ecuador for the purposes of commercial supply and sales in Ecuador and potentially other countries. We do not currently have a manufacturing agreement with PharmaBrand and are not currently manufacturing product at this facility.

In anticipation of undertaking late-stage clinical trials of Generex Oral-lyn™ in Canada, we entered into an agreement with Cardinal Health PTS, LLC, now known as Catalent Pharma Solutions (Catalent), in June 2006, pursuant to which Catalent manufactured clinical trial batches of Generex Oral-lyn™. Pursuant to pre-extant supply arrangements, our third-party suppliers had been manufacturing the quantities of the RapidMist™ brand metered dose inhaler components (valves, canisters, actuators, and dust caps), the insulin, and the formulary excipients that were required for the Catalent production. In addition, our Regulatory Affairs, Quality Control and R&D personnel have worked with Catalent to prepare and validate the Catalent production processes. We are not currently manufacturing product under this agreement and we expect that any agreements regarding the manufacturing of Generex Oral-lyn™ for any future trials or commercial sales will need to be renegotiated at such time.

Our subsidiary Antigen leases office space in Worcester, Massachusetts, which is sufficient for its present needs.

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 guaranteed commercial supply of any such products. Components suitable for our RapidMist™ brand metered dose inhaler are available from a limited number of potential suppliers, as is the chemical propellant used in the device. The components which now comprise the device are expected to be used in the commercial version of our insulin product in countries where the product has been approved. We do not currently have supply arrangements for commercial quantities with manufacturers for the components and the propellant that we presently use in our RapidMist™ brand metered dose. Reputable and reliable suppliers for these components exist and we believes that we can enter into arrangements for commercial supply with these suppliers when we are ready to commence commercial production.

Insulin is available worldwide from multiple sources. We do not currently have any agreements for the long-term supply of insulin, but we expect that we will be readily able to negotiate such an agreement before further clinical trials or commercial sales commence.

Intellectual Property

We hold a number of patents in the United States and foreign countries covering our buccal and other delivery technologies. We also have developed brand names and trademarks for products in appropriate areas. We consider the overall protection of our patent, trademark and other intellectual property rights to be of material value and acts to protect these rights from infringement.

Patents are a key determinant of market exclusivity for most branded pharmaceutical products. Protection for individual products or technologies extends for varying periods, in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

We currently have five issued U.S. patents and one pending U.S. patent applications pertaining to various aspects of drug delivery technology, including oral administration of macromolecular formulations (such as insulin) as well as pain relief medications such as morphine and fentanyl. We currently hold eleven issued Canadian patents and one pending Canadian patent applications also relating to various aspects of drug delivery technology. We also hold eleven issued patents and one pending patent applications covering our drug delivery technology in jurisdictions other than the U.S. and Canada, including Brazil, Argentina, Israel, Australia and Europe.

The expiration dates of the U.S. issued patents range from 2016 to 2022. The expiration dates of the patents issued in Canada range from 2015 to 2021. The expiration dates of the patents issued in other jurisdictions range from 2015 to 2028.

Our subsidiary Antigen Express currently holds nine issued U.S. patents and twenty-two other foreign patents. There are also four pending patent applications worldwide concerning technology for modulating the immune system via activation of antigen-specific helper T lymphocytes. Dr. Robert Humphreys, a retired officer of Antigen, is the listed inventor or co-inventor on many of these patents and patent applications.

The expiration dates of the Antigen U.S. issued patents range from 2016 to 2031. The expiration dates of the patents issued in other jurisdictions range from 2017 to 2023.

We possess the worldwide manufacturing and marketing rights to our oral insulin product.

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 for which we have applied do not infringe anyone 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 the discussion under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under the heading “Legal Proceedings” in this annual report on Form 10-K.

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 other pharmaceutical and biotechnology companies, universities, government agencies and public and private research organizations.

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

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

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

Large pharmaceutical companies, such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., MedImmune Inc. (a subsidiary of Astra-Zeneca, Inc.) and others, also compete in the oncology, immunomedicine and vaccine markets. These companies have greater experience and expertise in securing government contracts and grants to support research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, as well as manufacturing and marketing approved products. As such, they are also considered significant competitors in these fields of pharmaceutical products and therapies. There are also many smaller companies which are pursuing similar technologies in these fields and are considered to be competitors of Generex.

The following descriptions of our competitors and their products were obtained from their filings with the Securities and Exchange Commission, information available on their web sites and industry research reports.

Buccal Insulin Product

- MannKind Corporation’s product candidates include AFREZZA®, a mealtime insulin therapy being studied for use in adult patients with type 1 and type 2 diabetes. It is a drug-device combination product which administers insulin through inhalation to the lungs. MannKind submitted an NDA to the FDA requesting approval to market AFREZZA® in May 2009. In January 2011, MannKind announced that it had received a complete response letter from the FDA for AFREZZA®. In August 2011, MannKind announced that it has confirmed with the FDA the design of the two additional Phase III studies which are required for AFREZZA®. In August 2013, MannKind announced positive late-stage data on its inhaled insulin AFREZZA® from the two additional Phase III studies on Type 1 and Type 2diabetes and has resubmitted a new drug application to the FDA in October 2013 seeking approval for the marketing of AFREZZA®. MannKind received FDA approval in June 2014 and the product is now commercially available in the United States.

Amylin Pharmaceuticals, Inc. received FDA approval in January 2012 for Bydureon, an extended-release injectable formulation, which is the first once-a-week therapy for the treatment of type 2 diabetes.

- There are several companies that are working on developing products which involve the oral delivery of analogs of insulin. Oramed Pharmaceuticals is developing an orally ingestible insulin capsule which is currently in Phase II clinical trials. Biocon Limited has developed IN-105, a tablet for the oral delivery of insulin, which is currently in phase II trials. Diabetology has developed Capsulin IR, an insulin capsule which is currently in Phase II clinical trials. Access Pharmaceuticals has developed Cobalamin, an oral insulin which is currently in pre-clinical trials. Dance Pharmaceuticals is developing an inhaled insulin product based on Aerogen's proprietary OnQ Aerosol Generator technology.

There are also a number of companies developing alternative means of delivering insulin in the form of oral pills, transdermal patches, and intranasal methods, which are at early stages of development. In addition to other delivery systems for insulin, there are numerous products, such as sulfonylureas (Amaryl®and Glynase®), biguanides (branded and generic metformin products), thiazolidinediones (Avandia®and Actos®), glucagon-like peptide 1 (Byetta®and Victoza®), and dipeptidyl peptidase IV inhibitors (Januvia® and Onglyza™), which have been approved for use in the treatment of Type 2 diabetics in substitution of, or in addition to, insulin therapy. These products may also be considered to compete with insulin products.

Immunomedicine Technology and Products

- Bavarian Nordic, Inc. employs a DNA vector-based technology platform to design and develop immunotherapeutic vaccines for different cancers. Their most advanced compound, PROSTVAC, is in a pivotal Phase III trial in patients with prostate cancer. Additionally they have a HER2 vaccine in a Phase I/II trial in patients with breast cancer. They have recently presented data on studies combining their MVA-BN-HER2 cancer vaccine with different immune checkpoint inhibitors.

- Advaxis, Inc. uses a proprietary technique to bioengineer Listeria bacteria to create a specific antigen that can stimulate an immune response after recognition by the recipient's immune system. Advaxis' most advanced product candidate is ADXS-HPV, which is in Phase II trials for HPV-associated CIN (cervical intraepithelial neoplasia) and recurrent cervical cancer. The company has recently partnered with MedImmune to initiate combination studies utilizing their most advanced ADXS-HPV with MedImmune's anti-PD-L1 immune checkpoint inhibitor in patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical or head and neck cancer.

- Amgen Inc.'s BiTE® technology uses the body's cell destroying T cells to attack tumor cells. Amgen's lead product candidate blinatumomab (MT103) has completed a Phase II clinical trial in patients with minimal residual disease positive acute lymphoblastic leukemia.

- Sanofi Pasteur Inc., the vaccine division of sanofi-aventis and one of the largest vaccines companies in the world, has product candidates including inoculations against 20 varieties of infectious diseases. It received FDA approval for an H5N1 avian influenza vaccine in April 2007 and for an H1N1 vaccine in September 2009.

- Galena Biopharma's (formerly Rxi Pharmaceuticals Corporation) NeuVax™, is currently in Phase III clinical trials to evaluate NeuVax™ for the treatment of early stage, HER2-positive breast cancer. Clinical trials are currently underway to test NeuVax™ as a treatment for prostate cancer, and to use NeuVax™ in combination with Herceptin® to target breast cancer.

- Cell Genesys, Inc. was developing products for the treatment of prostate cancer using the GVAX™ cancer treatments, which are composed of tumor cells that are genetically modified to secrete an immune-stimulating cytokine and are irradiated for safety. Cell Genesys and Takeda Pharmaceutical Co. entered into an exclusive licensing agreement for GVAX in March 2008. In late 2008, Cell Genesys announced it was terminating the Phase III trials for the GVAX™ prostate cancer products. In May 2010, BioSante Pharmaceuticals, Inc. announced that development of the GVAX vaccine for the treatment of prostate cancer has been reinitiated and is in Phase II human clinical trials. In addition to GVAX prostate product, BioSante has several other cancer vaccines which are in Phase II clinical development including vaccines for leukemia, breast cancer and pancreatic cancer and has vaccines in Phase I clinical development including vaccines for colorectal cancer and melanoma.

CEL-SCI Corporation’s main product is Multikine® an immunotherapeutic agent being developed as a cancer treatment. Multikine®’s goal is to harness the body's natural ability to fight tumors. Multikine® has been cleared in the U.S. and Canada for study in a global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients.

In addition to the companies listed above, there are a number of companies which are pursuing cancer treatments using immunotherapy technologies which have products in various clinical trial stages. Some of these companies are Argos Therapeutics Inc., Celldex Therapeutics Inc., Northwest Therapeutics Inc., Immatics Biotechnology GmbH, Immunocellular Therapeutics Ltd., TVAX Biomedical Inc. and Newlink Genetics Corporation. These companies can also be considered to be competitors.

Environmental Compliance

Our research and development activities have involved 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 applicable 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. We expended $407,382 in the fiscal year ended July 31, 2016 and $1,185,384 in the fiscal year ended July 31, 2015 on research and development. Research and development activities decreased in 2016 from 2015, as we have not initiated any new trials after the completion of the global Phase III clinical trial of our oral insulin product due to lack of available funding. We have not conducted any material research and development since October, 2015 due to lack of funds.

Financial Information About Geographic Areas

The regions in which we had identifiable assets and revenues and the amounts of such identifiable assets and revenues for each of the last three fiscal years are presented in Note 13 in the *Notes to Consolidated Financial Statements* in this annual report on Form 10-K. Identifiable assets are those that can be directly associated with a geographic area.

Employees

At July 31, 2016, we had no employees. All of our previous employees have been laid off due to our inability to pay. We engage consultants from time to time to assist with financial recordkeeping and other tasks.

We will continue to need qualified scientific personnel and personnel with experience in clinical testing and government regulation. We may have difficulty in obtaining qualified scientific and technical personnel as there is strong competition for such personnel 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 have fixed-term agreements with only certain members of our key management and scientific staff, Mark Fletcher, President and CEO of Generex, and Eric von Hofe, President of Antigen.

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

Available Information

We were incorporated in the State of Delaware in 1997. Our principal executive offices are located at (4145 North Service Road, Suite 200, Burlington, Ontario, Canada, and our telephone number at that address is (416) 364-2551. We maintain an Internet website at www.generex.com. However, information found on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K. We make available free of charge on or through our website our filings with the Securities and Exchange Commission, or SEC, including this annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, a copy of this annual report is located at the SEC's Public Reference Room at 100 F Street N. E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors

Our business and results of operations are subject to numerous risks, uncertainties and other factors that you should be aware of, some of which are described below. The risks, uncertainties and other factors described below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

Any of the risks, uncertainties and other factors could have a materially adverse effect on our business, financial condition or results of operations and could cause the trading price of our common stock to decline substantially.

Risks Related to Our Financial Condition

We will require additional financing to continue our operations.

As of July 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months. To continue operations, we will require additional funds to support our working capital requirements and any expansion or other activities. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. The securities purchase agreement that we entered into on June 24, 2015 with certain

investors limits the financing activities that we may undertake in the near future as it prohibits us from (i) issuing additional equity securities until 60 days after the effective date of a registration statement covering the resale of the common stock issuable upon exercise of the warrants and conversion of the preferred stock sold in each transaction and (ii) issuing additional debt or equity securities with a variable conversion or exercise price until June 24, 2016. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. Management has sold non-essential real estate assets which were classified as Assets Held for Investment to augment its cash position.

We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations completely.

We have a history of losses and will incur additional losses.

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. We do not expect to receive significant revenues in Ecuador, Algeria and Lebanon where we have been approved for commercial sale in the next twelve months. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate recognizing revenue from sales of Generex Oral-lyn™ in India in 2017, as our partner has to receive approval from the Indian regulatory authority before the product can be offered for commercial sale in India.

To date, we have not been profitable and our accumulated net loss available to shareholders was $375,704,372 at July 31, 2016. 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.

With the exception of Generex Oral-lyn™, which has received regulatory approval in Ecuador, India (subject to regulatory approval of a 2012 in-country study), Lebanon and Algeria, our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We must also complete further clinical trials and seek regulatory approvals for Generex Oral-lyn™ in countries outside of Ecuador, India, Lebanon and Algeria. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern as of July 31, 2016.

To date, we have not been profitable and our accumulated net loss available to shareholders was $375,704,372 at July 31, 2016, and our consolidated balance sheet reflected a stockholders' deficiency of $11,216,850 at that date. We received a report from our independent auditors for the year ended July 31, 2016 that includes an explanatory paragraph describing an uncertainty as to Generex's ability to continue as a going concern. We must secure financing to continue our operations.

Due to material weaknesses in our internal controls over financial reporting, our internal controls were determined not to be effective for the prior fiscal year ended July 31, 2012. Our disclosure controls and procedures and internal controls over financial reporting may not be effective in future periods as a result of existing or newly identified material weaknesses in internal controls.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports and to effectively prevent fraud. If we cannot provide reasonable assurance with respect to our financial reports and effectively prevent fraud, our reputation and operating results could be harmed. Pursuant to the Sarbanes-Oxley Act of 2002, we are required to furnish a report by management on internal control over financial reporting, including management's assessment of the effectiveness of such control. Internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, our business and operating results could be adversely impacted, we could fail to meet our reporting obligations, and our business and stock price could be adversely affected.

At July 31, 2012, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and concluded that, subject to the inherent limitations identified in Item 9A of Part II of the Form 10-K filed on October 15, 2012, our disclosure controls and procedures were not effective due to the existence of material weaknesses in our internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Our independent auditors issued an adverse attestation report regarding the effectiveness of the Company's internal control over financial reporting at July 31, 2012.

We believe we have taken appropriate and reasonable steps to make the necessary improvements to remediate these deficiencies, however we cannot be certain that our remediation efforts will ensure that our management designs, implements and maintains adequate controls over our financial processes and reporting in the future or that the changes made will be sufficient to address and eliminate the material weaknesses previously identified. Our inability to remedy any additional deficiencies or material weaknesses that may be identified in the future could, among other things, have a material adverse effect on our business, results of operations and financial condition, as well as impair our ability to meet our quarterly, annual and other reporting requirements under the Securities Exchange Act of 1934 in a timely manner, and require us to incur additional costs or to divert management resources.

Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators.

Because we have limited resources, we have sought to enter into collaboration agreements with other pharmaceutical companies that will assist us in developing, testing, obtaining governmental approval for and commercializing products using our buccal delivery and immunomedicine technologies. We may be unable to achieve commercialization of any of our products until we obtain a large pharmaceutical partner to assist us in such commercialization efforts. To date, we have not entered into any such collaborative arrangements. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our program may compete for time, attention and resources with such collaborator's internal programs. Therefore, these collaborators may not commit sufficient resources to our program to move it forward effectively, or that the program will advance as rapidly as it might if we had retained complete control of all research, development, regulatory and commercialization decisions.

Risks Related to Our Technologies

With the exception of Generex Oral-lyn™, our technologies and products are at an early stage of development and we cannot expect significant revenues in respect thereof in the foreseeable future.

We have no products approved for commercial sale at the present time with the exception of Generex Oral-lyn™ in Ecuador, Lebanon, Algeria and India (subject to regulatory approval of a 2012 in-country study). To be profitable, we must not only successfully research, develop and obtain regulatory approval for our products under development, but also manufacture, introduce, market and distribute them once development is completed or find a partner that can perform these activities on our behalf. We have yet to manufacture, market and distribute these products on a large-scale commercial basis, and we do not expect to receive revenues from product sales in the next twelve months. We may not be successful in one or more of these stages of the development or commercialization of our products, and/or any of the products we develop may not be commercially viable. Until we can establish that they are commercially viable products, we will not receive significant revenues from ongoing operations.

Until we receive regulatory approval to sell our pharmaceutical products in additional countries, our ability to generate revenues from operations may be limited and those revenues may be insufficient to sustain operations. Many factors impact our ability to obtain approvals for commercially viable products.

Our only pharmaceutical product that has been approved for commercial sale by drug regulatory authorities is our oral insulin spray formulation, and that approval was obtained in Ecuador, Lebanon, Algeria and India (subject to regulatory approval of a 2012 in-country study). We have initiated late stage clinical trials of Generex Oral-lyn™ at clinical trial sites in North America and other countries according to the initial Phase III clinical plan. The final subjects completed the trial in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure additional financing.

Our immunomedicine products are in the pre-clinical stage of development, with the exception of a Phase II trial in human patients with stage II HER-2/neu positive breast cancer (U.S.), a Phase I trial in human patients with prostate cancer (Athens, Greece) completed in August 2009, a Phase I trial in human patients with breast or ovarian cancer (U.S.) and a Phase I trial in human volunteers of a peptide vaccine for use against the H5N1 avian influenza virus (Beirut, Lebanon). Preliminary results from the Phase II breast cancer trial suggest a 46% reduction in breast cancer recurrence in low HER2 expressing tumors, together with an excellent safety profile. While preliminary results are promising, they are not statistically significant and final results could deviate. .

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technologies, are subject to extensive, costly and rigorous regulation by governmental authorities in the United States, Canada and other countries. The process of obtaining required regulatory approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the product candidates. For these reasons, it is possible we will not receive regulatory approval for any prescription pharmaceutical product candidate in any countries other than Ecuador, Lebanon, Algeria and India.

In addition, we cannot be sure when or if we will be permitted by regulatory agencies to undertake additional clinical trials or to commence any particular phase of clinical trials. Because of this, statements in this Annual Report on Form 10-K or our reports filed with the SEC regarding the expected timing of clinical trials cannot be regarded as actual predictions of when we will obtain regulatory approval for any "phase" of clinical trials.

Delays in obtaining United States or other foreign approvals for our oral insulin product could result in substantial additional costs to us, and, therefore, could adversely affect our ability to continue operations. If regulatory approval is ultimately granted in any countries other than Ecuador, Lebanon, Algeria and India, the approval may place limitations on the intended use of the product we wish to commercialize, and may restrict the way in which we are permitted to market the product.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

Because a substantial number of patents have been issued in the field of alternative drug delivery and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subject to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Several of our currently issued patents have expired or will expire in the next twelve months.

Also because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the United States and other countries, even after reasonable investigation we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. For example, we are aware of certain patents owned by third parties that such parties could attempt to use in the future in efforts to affect our freedom to practice some of the patents that we own or have applied for. Based upon the science and scope of these third-party patents, we believe that the patents that we own or

have applied for do not infringe any such third-party patents; however, we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend our intellectual property in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

Risks Related to Marketing of Our Potential Products

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

Even if we obtain regulatory approval to market our oral insulin product outside of Ecuador, India, Lebanon and Algeria or to market any other prescription pharmaceutical product candidate, many factors may prevent the product from ever being sold in commercial quantities. Some of these factors are beyond our control, such as:

- acceptance of the formulation or treatment by health care professionals and diabetic patients;
- the availability, effectiveness and relative cost of alternative diabetes or immunomedicine treatments that may be developed by competitors; and
- the availability of third-party (i.e. insurer and governmental agency) reimbursements.

We will not receive significant revenues from Generex Oral-lyn™ or any of our other pharmaceuticals products that may receive regulatory approval until we can successfully manufacture, market and distribute them in the relevant markets.

We have to depend upon others for marketing and distribution of our products, and we may be forced to enter into contracts limiting the benefits we may receive and the control we have over our products. We intend to rely on collaborative arrangements with one or more other companies that possess strong marketing and distribution resources to perform these functions for us. We may not be able to enter into beneficial contracts, and we may be forced to enter into contracts for the marketing and distribution of our products that substantially limit the potential benefits to us from commercializing these products. In addition, we will not have the same control over marketing and distribution that we would have if we conducted these functions ourselves.

We may not be able to compete with treatments now being marketed and developed, or which may be developed and marketed in the future by other companies.

Our products will compete with existing and new therapies and treatments. We are aware of a number of companies currently seeking to develop alternative means of delivering insulin, as well as new drugs intended to replace insulin therapy at least in part. We are also aware of a number of companies currently seeking to develop alternative means of enhancing and suppressing peptides. In the longer term, we also face competition from companies that seek to develop cures for diabetes and other malignant, infectious, autoimmune and allergic diseases through techniques for correcting the genetic deficiencies that underlie some of these diseases.

Numerous pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations are engaged in the development of alternatives to our technologies. Some of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Collaborations or mergers between large pharmaceutical or biotechnology companies with competing drug delivery technologies could enhance our competitors' financial, marketing and other resources. Developments by other drug delivery companies could make our products or technologies uncompetitive or obsolete. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have discontinued development and/or sale of their inhalable forms of insulin. Unlike inhaled insulin formulations, Generex Oral-lyn™ is a buccally absorbed formulation with no residual pulmonary deposition.

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

Sales of our oral insulin formulation in Ecuador, Lebanon, Algeria and India and our other potential pharmaceutical products in other markets will depend in part on the availability of reimbursement by third-party payers such as government health administration authorities, private health insurers and other organizations. Third-party payers often challenge the price and cost-effectiveness of medical products and services. Governmental approval of health care products does not guarantee that these third-party payers will pay for the products. Even if third-party payers do accept our product, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement.

Risks Related to Potential Liabilities

We face significant product liability risks, which may have a negative effect on our financial condition.

The administration of drugs or treatments to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs or treatments are actually at fault for causing an injury. Furthermore, our pharmaceutical products may cause, or may appear to have caused, serious adverse side effects (including death) or potentially dangerous drug interactions that we may not learn about or understand fully until the drug or treatment has been administered to patients for some time. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a severe negative effect on our financial condition. We previously maintained product liability insurance in amounts we believe to be commercially reasonable for our levels of activity and exposure. We no longer carry this insurance due to lack of activities and funds. , .

Risks Related to the Market for Our Common Stock

Our stock price is below $5.00 per share and is treated as a "penny stock", which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, and the rules promulgated thereunder. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

- broker-dealers must deliver, prior to the transaction a disclosure schedule prepared by the SEC relating to the penny stock market;
- broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
- broker-dealers must disclose current quotations for the securities;

if a broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealers presumed control over the market; and

- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Because we were delinquent in our SEC filings, we have been removed from the OTCQB.

We did not timely file this Annual Report or our Quarterly Report for the quarter ended October 31, 2016, and therefore our common stock is no longer quoted on the OTCQB. Since being removed from the OTCQB, quotes for our common stock have only appeared on the OTCPINK, with a notation that we have not provided current information. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares, and the liquidity of the market for our shares may be greatly reduced.

The price of our common stock may be affected by a limited trading volume, may fluctuate significantly and may not reflect the actual value of our business.

There may be a limited public market for our common stock on the OTCPINK, which may continue even if we are able to again have our common stock quoted on the OTCQB market, and there can be no assurance that an active trading market will continue. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock in short time periods, or at all. Our common stock has experienced, and is likely to experience in the future, significant price and volume fluctuations that could adversely affect the market price of our common stock without regard to our operating performance. In addition, we believe that factors, such as our sale of securities in connection with capital raising activities, could cause the price of our common stock to fluctuate substantially. Thus, the price at which shares of our common stock may trade from time to time may not reflect the actual value of our business or the actual value of our common stock.

From time to time, we may hire companies to assist us in pursuing investor relations strategies to generate increased volumes of investment in our common stock. Such activities may result, among other things, in causing the price of our common stock to increase on a short-term basis.

Furthermore, the stock market generally and the market for stocks of companies with lower market capitalizations and small biopharmaceutical companies, like us, have from time to time experienced, and likely will again experience significant price and volume fluctuations that are unrelated to the operating performance of a particular company.

Risks Related to Ownership of Our Common Stock

If an exemption under state securities laws is not available for resales of shares of common stock, state securities regulators have the authority to seek rescission of such resales and, in some instances, may seek restitution or disgorgement of amounts received on such resales.

Because the shares of common stock registered under our S-1 registration statements have not been registered or qualified for resale under the securities laws of any state, an exemption from registration or qualification under state law is necessary for compliance with state securities laws. Generex has taken no steps to register or qualify, nor seek an exemption for, the resale of the shares of common stock under the securities laws of any state. The availability of exemptions will depend on the laws of the particular state in which a holder of the shares resides and the circumstances under which such holder seeks to sell the shares. If an exemption is not available but a resale of the shares is effected, state securities laws give state securities regulators authority to seek rescission (or cancellation) of transactions involving sales of securities that are not registered, qualified or exempted and, in some instances, authority to require restitution or disgorgement of profits from the sales of such securities and to impose statutory interest or penalties on disgorged amounts. While we are not aware of any state securities regulator taking action with respect to the resales of shares of our common stock, we cannot provide any assurance that regulators will refrain from taking such action in the future.

Provisions of our Restated Certificate of Incorporation could delay or prevent the acquisition or sale of our business.

Our Restated 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 our stockholders. 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 stockholder approval for an acquisition of our business or increase the cost of any such acquisition.

Provisions of the Delaware General Corporation Law may prohibit us from making required payments with respect to our Series G 9% Convertible Preferred Stock, which default may constitute a violation of our certificate of incorporation or a breach of our contractual obligations to the holders of our preferred stock.

We are incorporated in the State of Delaware and are subject to the provisions of the Delaware General Corporation Law (the "DGCL"). Section 170 of the DGCL provides, among other things, that a Delaware corporation may declare and pay dividends upon shares of its capital stock out of its surplus, as defined in and computed in accordance with Sections 154 and 244 of the DGCL. As of the date hereof, we have 500 shares of our Series G 9% Convertible Preferred Stock outstanding. As of the date hereof, we have sufficient surplus to make dividend payments with respect to our outstanding Series G 9% Convertible Preferred Stock, as well as sufficient surplus to make the make-whole payments that may be due to the holders of our Series G 9% Convertible Preferred Stock, should such make-whole payments be deemed a dividend under the DGCL. However, our surplus will decrease as we spend our capital on operational activities, unless our spending is offset by capital-raising transactions. If our surplus is less than then-due dividend payments, including make-whole payments if they are deemed a dividend under the DGCL, we will be prohibited by the DGCL from making the dividend or make-whole payment, which may constitute a violation of our certificate of incorporation or a breach of our contractual obligations to the holders of our Series G 9% Convertible Preferred Stock.

Our equity financing will dilute current stockholders and could prevent the acquisition or sale of our business.

The equity financing transactions into which we have entered into in the prior 2 fiscal years have and will dilute current stockholders. At July 31, 2016, there were 383,877,521 shares of common stock issuable upon exercise of the warrants that we issued in and in the registered direct offerings in February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015. In addition, in connection with the private placements that closed on June 17, 2013, March 27, 2014 and June 24, 2015, an additional 33,333,333 shares of common stock are issuable upon conversion of the remaining Series F and G 9% Convertible Preferred Stock at July 31, 2016. Together the shares of common stock issuable upon exercise or conversion of the above-mentioned warrants and preferred stock represent approximately 46% of the shares of common stock outstanding at July 31, 2016. Assuming the holders of the warrants convert and exercise all of the warrants into shares of common stock, the number of shares of issued and outstanding common stock will increase significantly, and current stockholders will own a smaller percentage of the outstanding common stock of Generex. The issuance of shares of common stock pursuant to the warrants will also have a dilutive effect on earnings per share and may adversely affect the market price of the common stock.

In addition, the issuance of shares of common stock upon exercise of the above warrants, could have an anti-takeover effect because such issuance will make it more difficult for, or discourage an attempt by, a party to obtain control of Generex by tender offer or other means. The issuance of common stock upon the exercise of the warrants or conversion of convertible preferred stock will increase the number of shares entitled to vote, increase the number of votes required to approve a change of control of the company, and dilute the interest of a party attempting to obtain control of the company.

If we raise funds through one or more additional equity financings in the future, it will have a further dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares may be sold at a time when the market price is low because we are in need of the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price. Most of our outstanding warrants have price protection provisions, which decrease the exercise price of the warrant and increase the number of shares which may be purchased upon exercise of the warrants, if we sell additional equity at an effective price per common share less than the current exercise price of the warrant. Therefore, equity financings at a low price per share will result in even more dilution to existing shareholders.

Item 1B. Unresolved Staff Comments.

Generex is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 2. Properties.

We use a small space in Burlington, Ontario, Canada for our principal executive office. The rent is immaterial.

We lease approximately 546 square feet of office space in Worcester, Massachusetts which we rent under a lease agreement which runs on a month-to-month basis, which Antigen uses for its research and development activities at an annual rent of approximately $18,000. This space is sufficient for Antigen’s present activities.

We do not expect to need manufacturing capabilities related to our insulin product, as it is likely that we will contract out the manufacturing of product requirements for any future clinical trials and commercial sales.

Item 3. Legal Proceedings.

Subash Chandarana et al. v. Generex Biotechnology Corporation. In February 2001, a former business associate of Pankaj Modi ("Modi") (a former officer of Generex) and an entity called Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against us and Modi seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate 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 CTI. The three patents are entitled Liquid Formulations for Proteinic Pharmaceuticals, Vaccine Delivery System for Immunization, Using Biodegradable Polymer Microspheres, and Controlled Releases of Drugs or Hormones in Biodegradable Polymer Microspheres. It is our position that the buccal drug delivery technologies which are the subject matter of our research, development, and commercialization efforts, including Generex Oral-lyn™ and the RapidMist™ Diabetes Management System, do not make use of, are not derivative of, do not infringe upon, and are entirely different from the intellectual property identified in the plaintiffs' statement of claim. On July 20, 2001, we filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by us. Consequently, the shareholders of CBI are in a deadlock. The court granted our motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in the name of or on behalf of CBI. The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against Modi and us. We opposed the application. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against Modi and us. A statement of claim was served in July 2004. Since that time, the plaintiffs have not taken any steps in furtherance of the proceeding. We are not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

In December 2011, a vendor of the Company commenced an action against the Company and its subsidiary, Generex Pharmaceuticals, Inc., in the Ontario Superior Court of Justice claiming damages for unpaid invoices including interest in the amount of $429,000, in addition to costs and further interest. The Company responded to this statement of claim and also asserted a counterclaim in the proceeding for $200,000 arising from the vendor's breach of contract and detinue, together with interest and costs. On November 16, 2012, the parties agreed to settle this action and the Company has agreed to pay the plaintiff $125,000, following the spinout of its subsidiary Antigen, from the proceeds of any public or private financing related to Antigen subsequent to such spinout. Each party agreed to execute mutual releases to the claim and counterclaim to be held in trust by each party's counsel until payment of the settlement amount. Following payment to the plaintiff, the parties agree that a Consent Dismissal Order without costs will be filed with the court. If the Company fails to make the payment following completion of any post-spinout financing related to Antigen or any other subsidiaries, the plaintiffs may take out a judgment in the amount of the claim plus interest of 3% per annum and costs fixed at $25,000.

Disputes with Former Officer

On May 20, 2011, our former Chief Financial Officer, Rose Perri filed a statement of claim (subsequently amended) in the Ontario Superior Court of Justice, naming as defendants the Company and certain directors of the Company, Mr. Barratt, Ms. Masterson, Mr. McGee, and Mr. Fletcher. In this action, Ms. Perri has alleged that defendants engaged in discrimination, harassment, bad faith and infliction of mental distress in connection with the termination of her employment with the Company. Ms. Perri is seeking damages in this action in excess of $7,000,000 for, among other things, breach of contract, breach of fiduciary duty, violations of the Ontario Human Rights Code and aggravated and punitive damages. On September 20, 2011, the defendants filed a statement of defense and counterclaim, also naming Time Release Corp., Khazak Group Consulting Corp., and David Khazak, C.A. as defendants by counterclaim, and seeking damages of approximately $2.3 million in funds that the defendants allege Ms. Perri wrongly caused the Company to pay to third parties in varying amounts over several years and an accounting of certain third-party payments, plus interests and costs. The factual basis for the counterclaim involves payments made by the Company to third parties believed to be related to Ms. Perri. The Company intends to defend this action and pursue its counterclaim vigorously and 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.

On June 1, 2011, Golden Bull Estates Ltd. filed a claim (subsequently amended) in the Ontario Superior Court of Justice, naming the Company, 1097346 Ontario, Inc. and Generex Pharmaceuticals, Inc. as defendants. The plaintiff, Golden Bull Estates, is controlled by Ms. Perri. The plaintiff alleges damages in the amount of $550,000 for breach of contract, $50,000 for punitive damages, plus interest and costs. The plaintiff’s claims relate to an alleged contract between the plaintiff and the Company for property management services for certain Ontario properties owned by the Company. The Company terminated the plaintiff’s property management services in April 2011. Following the close of pleadings, the Company served a motion for summary judgment. The plaintiff responded by amending its statement of claim to include a claim to the Company’s interest in certain of its real estate holdings. The plaintiff moved for leave to issue and register a Certificate of Pending Litigation in respect of this real estate. The motion was not successful in respect of any current real estate holdings of the Company. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

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

With respect to all litigation matters, as additional information concerning the estimates used by us becomes known, we reassess each matter's position both with respect to accrued liabilities and other potential exposures.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

)Our common stock is been quoted on the OTC Pink market, a tiered marketplace of the OTC Markets Group under the symbol "GNBT". Previously, our common stock was quoted on a higher tier of the OTC Markets Group, the OTCQB. Our common stock was removed from the OTCQB due to our failure to file SEC reports. Our common stock was listed on the NASDAQ Capital Market (formerly the NASDAQ SmallCap Market) on June 5, 2003. On October 21, 2010, our common stock was delisted due to our failure to regain compliance with the $1.00 bid price requirement for continued listing set forth in NASDAQ Listing Rule 5550(a)(2). From May 5, 2000 to June 4, 2003, our common stock was listed on the NASDAQ National Market. From February 1998 to May 2000, the "bid" and "asked" prices for our common stock were quoted on the OTC Bulletin Board operated by the National Association of Securities Dealers. Prior to February 1998, there was no public market for our common stock.

The table below sets forth prices for our common stock for the last eight fiscal quarters. The prices below reflect the high and low bid information. The over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions. The table below sets forth prices for our common stock for each fiscal quarter in the prior two years ended July 31, 2016. The prices below reflect the high and low bid information. The over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

	Sales/Bid Prices	
	High	**Low**
Fiscal 2015		
First Quarter	$0.04	$0.02
Second Quarter	$0.02	$0.01
Third Quarter	$0.02	$0.01
Fourth Quarter	$0.02	$0.01
Fiscal 2016		
First Quarter	$0.01	$0.08
Second Quarter	$0008	$0.006
Third Quarter	$0.007	$0.005
Fourth Quarter	$0.008	$0.006

As of December 29, 2016, there were approximately 345 holders of record of our common stock. Record holders do not include owners whose shares are held in street name by a broker or other nominee.

Dividends

We have not paid dividends on our common stock in the past and have no present intention of paying dividends on our common stock in the foreseeable future. The Certificate of Designations pertaining to our Series G 9% Convertible Preferred Stock imposes certain restrictions on our ability to pay dividends on our common stock. For information about these restrictions and the dividends that we paid on our Series G 9% Convertible Preferred Stock, see the discussion under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under the heading “Financial Condition, Liquidity and Resources” and the subheadings “Financing – June 2015”, “Financing – March 2014” and “Financing – January 2014” in this Annual Report on Form 10-K.

Sales of Unregistered Securities

We did not issue any securities in reliance upon Section 4(2) of the Securities Act in the fiscal quarter ended July 31, 2016.

Issuer Purchases of Equity Securities

Neither we nor any affiliated purchaser (as defined in Rule 10 b-18(a)(3) promulgated under the Exchange Act) purchased any of our equity securities during the fourth quarter of the fiscal year ending July 31, 2016.

Item 6. Selected Financial Data.

Generex is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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

The following discussion and analysis by management provides information with respect to our financial condition and results of operations for the fiscal years ended July 31, 2016 and 2015. This discussion should be read in conjunction with the information in the consolidated financial statements and the notes pertaining thereto contained in *Item 8 - Financial Statements and Supplementary Data* of this Annual Report on Form 10-K for the year ended July 31, 2016 and the information discussed in *Part I, Item 1A - Risk Factors*.

Overview of Business

We are engaged primarily in the research and development of drug delivery systems and 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. Through our wholly-owned subsidiary, Antigen, we have expanded our focus to include immunomedicines incorporating proprietary vaccine formulations.

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, including estrogen, heparin, monoclonal antibodies, human growth hormone and fertility hormones, but to date have focused our development efforts primarily on one pharmaceutical product, Generex Oral-lyn™, an insulin formulation administered as a fine spray into the oral cavity using our proprietary hand-held aerosol spray applicator known as RapidMist™.

Our wholly-owned subsidiary, Antigen, concentrates on developing proprietary vaccine formulations that work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). Our immunomedicine products are based on two platform technologies and are in the early stages of development. Prior to exhausting our funds, we continued clinical development of Antigen's synthetic peptide vaccines designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene for patients with HER-2/neu positive breast cancer in a Phase II clinical trial and patients with prostate cancer and against avian influenza in two Phase I clinical trials. We also initiated an additional Phase I clinical trial in patients with either breast or ovarian cancer. The synthetic vaccine technology has certain advantages for pandemic or potentially pandemic viruses, such as the H5N1 avian and H1N1 swine flu. We have established collaborations with clinical investigators at academic centers to advance these technologies.

To date, we have received regulatory approval in Ecuador, India (subject to regulatory approval of a 2012 in-country study), Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. We have previously submitted regulatory dossiers for Generex Oral-lyn™ in a number of other countries, including Bangladesh, Kenya, Jordan and Armenia. While we believe these countries will ultimately approve our product for commercial sale, we do not anticipate recognizing revenues in any of these jurisdictions in the next twelve months. No dossier related activities or product shipments have taken place during fiscal 2015 or 2016, nor are any expected to these countries during the remainder of calendar year 2016 or in calendar year 2017.

In March 2008, we initiated Phase III clinical trials for Generex Oral-lyn™ in the U.S. with the first patient screening for such trials at a clinical study site in Texas in April 2008. Approximately 450 patients were enrolled at approximately 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia, Ukraine and Ecuador. The final subjects completed the trial in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure sufficient additional financing. However, we have initiated a project with the University Health Network of the University of Toronto, and the University of Guelph, Ontario to enhance the formulation of Generex Oral-lyn™ in order to reduce the number of puffs required for prandial use.

In November 2008 we, together with our marketing partner Shreya Life Sciences Pvt. Ltd., officially launched Generex Oral-lyn™ in India under marketing name of Oral Recosulin™. Each package of Oral Recosulin™ contains two canisters of our product along with one actuator. The product received regulatory price approval in India in January 2009. Per the requirements of the regulatory approval in India, an in-country clinical study must be completed in India

with Oral Recosulin™ before commercial sales can commence. The field portion of the study was completed in the third calendar quarter of 2012. Shreya has advised Generex that the dossier was submitted in December of 2012 to the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Generex has provided additional, detailed scientific data to support the Shreya submission. We have not recognized any revenues from the sale of Generex Oral-lyn™ in India through fiscal year ended July 31, 2016.

In December 2008, we, together with our marketing partner Benta S.A., received an approval to market Generex Oral-lyn™ in Lebanon. The official product launch in Lebanon took place in May 2009. In May 2009, the Algerian health authorities granted us permission to import and sell Generex Oral-lyn™ for the treatment of diabetes in Algeria. The official product launch in Algeria took place in October 2009. To date, we have not recognized any revenue from the sales of Generex Oral-lyn™ in Algeria and very minimal revenues in Lebanon. We do not anticipate any revenues to be recognized from these jurisdictions in the next twelve months.

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have discontinued development and/or sale of their inhalable forms of insulin. MannKind introduced a new pulmonary insulin which was approved by the FDA in 2014, and MannKind subsequently partnered with sanofi-aventis for a period of time to market the product under the tradename of Afrezza.

Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally absorbed formulation with no pulmonary deposition. We believe that our buccal delivery technology offers several advantages, including the ease of use, portability, avoidance of pulmonary inhalation and safety profile. Furthermore, insulin administered through the Generex Oral-lyn™ RapidMist™ technology is absorbed directly into the blood stream and not only acts rapidly, but returns to baseline quickly, thereby minimizing the chance of developing hypoglycemia.

Large pharmaceutical companies, such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., MedImmune Inc. (a subsidiary of Astra-Zeneca, Inc.) and others, also compete against us in the oncology, immunomedicine and vaccine markets. These companies have competing experience and expertise in securing government contracts and grants to support research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, as well as manufacturing and marketing approved products. As such, they are also considered significant competitors in these fields of pharmaceutical products and therapies. There are also many smaller companies which are pursuing similar technologies in these fields who are considered to be competitors of Generex.

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. To date, we have not been profitable and our accumulated net loss available to shareholders was $375,704,372 at July 31, 2016. As of July 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months. To continue operations, we will require additional funds to support our working capital requirements and any development activities, or will need to suspend operations completely. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. We have sold non-essential real estate assets which were classified as Assets Held for Investment to augment our cash position. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material

adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

We operate in only one segment: the research and development of drug delivery systems and technologies for metabolic and immunological diseases.

Accounting for Research and Development Projects

Our major research and development projects are the refinement of our platform buccal delivery technology, our buccal insulin project (Generex Oral-lyn™) and Antigen's peptide immunotherapeutic vaccines.

During the fiscal years ended July 31, 2016 and 2015, we expended resources on the clinical testing of our buccal insulin product, Generex Oral-lyn™. The completion of further late-stage trials in Canada and the United States may require significantly greater funds than we currently have on hand.

During the fiscal years ended July 31, 2016 and 2015, we expended resources on research and development relating to Antigen's peptide immunotherapeutic vaccines and related technologies. One Antigen vaccine is currently in Phase II clinical trials in the United States involving patients with HER-2/neu positive breast cancer, and we have completed a Phase I clinical trial for an Antigen vaccine for H5N1 avian influenza which was conducted at the Lebanese-Canadian Hospital in Beirut. Antigen's prostate cancer vaccine based on AE37 has been tested in a completed (August 2009) Phase I clinical trial in Greece.

Because of various uncertainties, we cannot predict the timing of completion and commercialization of our buccal insulin or Antigen's peptide immunotherapeutic vaccines or related technologies. These uncertainties include the success of current studies, our ability to obtain the required financing and the time required to obtain regulatory approval even if our research and development efforts are completed and successful, our ability to enter into collaborative marketing and distribution agreements with third-parties, and the success of such marketing and distribution arrangements. For the same reasons, we cannot predict when any products may begin to produce net cash inflows.

Most of our buccal delivery research and development activities to date have involved developing our platform technology for use with insulin. As a result, we have not made significant distinctions in the accounting for research and development expenses among products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all of our potential buccal products. During the fiscal year ended July 31, 2016, approximately 47%% of our $467,302 in research and development expenses was attributable to insulin and platform technology development. During the fiscal year ended July 31, 2015, approximately 46% of our $1,185,384 in research and development expenses was attributable to insulin and platform technology development.

During the fiscal year ended July 31, 2016, approximately 53% of our $358,314 in research and development expenses was attributable to Antigen's immunomedicine products. During the fiscal year ended July 31, 2015, approximately 54% of our $1,185,384 in research and development expenses was attributable to Antigen's immunomedicine products.

We ceased all material research and development activities in the first quarter of fiscal 2016 due to lack of funds.

Because these products are in initial phases of clinical trials or early, pre-clinical stage of development (with the exception of the Phase II clinical trials of Antigen HER-2/neu positive breast cancer vaccine that are underway), all of the expenses were accounted for as basic research and no distinctions were made as to particular products. Due to the early stage of development, we cannot predict the timing of completion of any products arising from this technology, or when products from this technology might begin producing revenues.

Critical Accounting Policies

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

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

Going Concern . As shown in the accompanying consolidated financial statements, we have not been profitable and have reported recurring losses from operations. These factors raise substantial doubt about our ability to continue to operate in the normal course of business. The accompanying consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Impairment of Long-Lived Assets. Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Consolidated Statement of Operations. As of July 31, 2016, there were no indications of any impairment of our long-lived assets.

Intangible Assets. We have intangible assets related to patents. The determination of the related estimated useful lives and whether or not these assets are impaired involves significant judgments. In assessing the recoverability of these intangible assets, we use an estimate of undiscounted operating income and related cash flows over the remaining useful life, market conditions and other factors to determine the recoverability of the asset. If these estimates or their related assumptions change in the future, we may be required to record impairment charges against these assets. All of the Company’s patents were written down in the fiscal year ended July 31, 2016. There were patent write downs of $320,160 in the fiscal year ended July 31, 2015.

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

Share-based compensation. Management determines value of stock-based compensation to employees in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, Compensation – Stock Compensation. Management determines value of stock-based compensation to non-employees and consultants in accordance with and ASC 505, Equity-Based Payments to Non-Employees.

Derivative warrant liability. FASB ASC 815, Derivatives and Hedging, requires all derivatives to be recorded on the consolidated balance sheet at fair value for fiscal years beginning after December 15, 2008. As a result, certain derivative warrant liabilities (namely those with a price protection feature) are now separately valued as of August 1, 2009 and accounted for on our balance sheet, with any changes in fair value recorded in earnings. On our consolidated balance sheets as of July 31, 2016 and July 31, 2015, we used the binomial lattice model to estimate the fair value of these warrants. Key assumptions of the binomial lattice option-pricing model include the market price of our stock, the exercise price of the warrants, applicable volatility rates, risk-free interest rates, expected dividends and the instrument's remaining term. These assumptions require significant management judgment. In addition, changes in any of these variables during a period can result in material changes in the fair value (and resultant gains or losses) of this derivative instrument.

Results of Operations

Year ended July 31, 2016 Compares to Year ended July 31, 2015

We had a net loss for the fiscal year ended July 31, 2016 of $3,223,109 versus a net loss in the prior fiscal year (fiscal 2015) of $2,193,358. The loss this year was caused primarily by operating expenses of $1,902,568 and an impairment loss on patents of $1,165,364 offset by a gain due to the change in fair value of the derivative liabilities of $263,823, while in the prior year operating expenses were $3,562,914 with a gain due to the change in fair value of the derivative liabilities of $1,448,237 and a gain on extinguishment of debt of $551,501. The decrease in operating loss resulted from a decrease in research and development expenses (to $467,382 from $1,185,384) and a decrease in general and administrative expenses (to $1,435,186 from $2,377530). We did not have any revenues in either fiscal 2016 or 2015.

The decrease in research and development expenses in the current fiscal year versus the comparative period in the previous fiscal year is primarily due lack of resources to pursue clinical trials. Our efforts to significantly reduce expenses in all categories also contributed to the decrease in this category. The decrease in general and administrative expenses is related to a decrease in compensation expenses of approximately $1,730,000, offset by a forbearance fee on one of our key accounts payable in the amount of $459,000. We also incurred reductions of expenses in most other categories due to our efforts to conserve cash pending further strategic developments.

Our interest expense in fiscal 2016 was $418,500 compared to the previous year's interest expense of $350,028. Change in fair value of derivative liabilities contributed a gain of $263,823 in fiscal 2016 as compared to a gain of $1,488,237 in fiscal 2015.

Our net loss available to common stockholders increased to ($3,223,107) in fiscal 2016 from ($2,532,941) in fiscal 2015. The increase was due primarily to the write-down in the value of our patents of approximately $1,165,864, as further described in Note 4 to the *Notes to Consolidated Financial Statements* included elsewhere in this Annual Report.

Financial Condition, Liquidity and Resources

Sources of Liquidity

To date we have financed our development stage activities primarily through private placements of our common stock and securities convertible into our common stock.

As of July 31, 2016 and the date of this Annual Report on Form 10-K, our current cash position is not sufficient to meet our working capital needs for the next twelve months. We have been required to lay-off all of our employees, and our officers have ceased receiving compensation. We will require additional funds to support our working capital requirements and any development or other activities.

While we have financed our development stage activities to date primarily through private placements of our common stock and securities convertible into our common stock and raised approximately $534,000 million during fiscal 2016 and 2015 (including proceeds from warrant exercises, short term loans and the issuance of preferred stock), our cash balances have been low throughout fiscal 2016.

On March 30, 2011, our realigned management team announced its strategic development plan for Generex's future growth. The plan included the proposed spin-out of Antigen Express, a reverse stock split for Generex and a rights offering to Generex stockholders. As proposed, we would spin out Antigen Express as a separate DTC-eligible company, register its shares with the Securities and Exchange Commission (the "SEC"), and seek to list its shares on a national securities exchange. Management believes that the spin-out would increase value for stockholders and provide Antigen Express with ready access to capital markets to finance its on-going clinical and regulatory initiatives. Management further believes that the spin-out would benefit Generex, by allowing Generex to hold a controlling interest in a publicly-traded company while continuing to focus on maximizing opportunities for its buccal drug delivery platform. The spin-out would be accomplished by the issuance of one or more dividends of Antigen Express stock to Generex stockholders. No determination has been made as to the timing of the proposed spin-out. This plan does not constitute an offer of any securities for sale or a solicitation of an offer to buy any securities.

Our stockholders approved a reverse split proposal at our annual general meeting held on August 19, 2015, which approval allows the Board to implement a reverse split in its discretion at any time prior to December 31, 2016 and is not contingent upon listing our common stock on a national stock exchange. However, the terms of the securities purchase agreements that we entered into on January 14, 2014, March 27, 2014 and June 24, 2015 prohibit us from undertaking a reverse or forward stock split or reclassification of our common stock except for a reverse stock split made in conjunction with a listing of the common stock on a national securities exchange.

Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities.

Upon the filing of our Annual Report on Form 10-K on October 14, 2011, we were no longer eligible to use Form S-3 to register shares sold to investors, as the aggregate market value of our outstanding voting and non-voting common equity held by non-affiliates was less than $75 million. As we are required under the registration rights agreements that we entered into on January 31, 2012, August 8, 2012, December 10, 2012, June 17, 2013, January 14, 2014, March 27, 2014 and June 24, 2015 with certain investors to register shares of our common stock issuable upon conversion or exercise of the securities purchased by the investors, we filed the respective registration statements on Form S-1. We incurred additional legal and accounting fees in connection with the preparation of these Form S-1 registration statements.

In addition, management is actively pursuing financial and strategic alternatives, including strategic investments and divestitures, industry collaboration activities, and potential strategic partners. Management has sold non-essential real estate assets which are classified as Assets Held for Investment to augment the company’s cash position and reduce its long-term debt.

We will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of our product candidates, further clinical trials for Oral-lyn™ and to commence sales and marketing efforts if the FDA or other regulatory approvals are obtained.

Unforeseen problems with the conduct or results of Phase III clinical trials for Oral-lyn™ or further negative developments in general economic conditions could interfere with our ability to raise additional capital as needed, or materially adversely affect the terms upon which such capital is available. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

Equity Financings

Following is a summary of the equity financing activities that we have completed since the beginning of the 2014 calendar year.

Financing – June 2015

Series G 9% Convertible Preferred Stock and Warrants

On June 24, 2015, we entered into a securities purchase agreement with certain investors, pursuant to which we agreed to sell an aggregate of 500 shares of our newly designated non-voting Series G 9% Convertible Preferred Stock and warrants to purchase up to an aggregate of 100% of the shares of our common stock issuable upon conversion of the convertible preferred stock. The purchase closed on June 25, 2015. We sold the convertible preferred stock and warrants in units, with each unit consisting of one share of convertible preferred stock and a warrant to purchase 100% of the shares of our common stock issuable upon conversion of such share of convertible preferred stock. Each unit was sold at a negotiated price of $1,000, for an aggregate purchase price of $500,000. An aggregate of 33,333,333 shares of our common stock are issuable upon conversion of, or exercise of, the convertible preferred stock and warrants. We received net proceeds of approximately $475,000 from this transaction.

Subject to certain ownership limitations, the Series G convertible preferred stock will be convertible at the option of the holder at any time into shares of our common stock at an effective conversion price of $0.015 per share, and will accrue a 9% dividend until June 24, 2018 and, beginning on June 24, 2018 and on each one year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend will be payable quarterly on September 30, December 31, March 31 and June 30, beginning on the first such date after the original issue date and on each conversion date in cash, or at our option, in shares of common stock. In the event that the convertible preferred stock is converted prior to June 24, 2018, we will pay the holder of the converted preferred stock an amount equal to $270 per $1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such “make-whole payment” may be made in cash or, at our option, in shares of our common stock. In addition, beginning June 24, 2018, we will pay dividends on shares of the convertible preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. We will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the Series G convertible preferred stock will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of our common stock pursuant to the fundamental transaction.

We may become obligated to redeem the Series G convertible preferred stock in cash upon the occurrence of certain triggering events, including, material breach of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of Generex, the occurrence of certain insolvency events relating to Generex, or the failure of our common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or regulated quotation service. Upon the occurrence of certain triggering events, each holder of convertible preferred stock will have the option to redeem such holder’s shares of convertible preferred stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 18% on all of such holder’s outstanding convertible preferred stock. Late fees will apply on all redemption amounts not paid within five trading days of the payment date.

Subject to certain ownership limitations, the warrants will be exercisable at any time after their date of issuance and on or before the fifth-year anniversary thereafter at an exercise price of $0.015 per share of common stock. The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock

issuable upon exercise will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of common stock pursuant to the fundamental transaction.

The securities purchase agreement and the certificate of designation authorizing the Series G convertible preferred stock include certain agreements and covenants for the benefit of the holders of the convertible preferred stock, including restrictions on our ability to amend the certificate of incorporation and bylaws, pay cash dividends or distributions with respect to our common stock or other junior securities, repurchase more than a *de minimis* number of shares of our common stock or other junior securities.

With very limited exceptions, the investors will have a pro rata right of first refusal in respect of participation in any private debt or equity financings undertaken by us during the 12 months following the closing of the transaction.

We offered these securities privately pursuant to Rule 506(b) of Regulation D under the Securities Act of 1933. We entered into a registration rights agreement with the investors pursuant to which we agreed to file a registration statement with the SEC covering the public resale of the common stock issuable upon conversion of the preferred stock, issuable as dividends on the preferred stock, issuable upon exercise of the warrants and issued as a finders' fee.

We agreed to file the registration statement within 25 days of the closing of the transaction and to use our best efforts to have the registration statement declared effective within 75 days after the filing date. The registration statement was declared effective by the SEC on July 31, 2015.

In addition, until the first anniversary date of the securities purchase agreement, each investor could, in its sole determination, elect to purchase, severally and not jointly with the other investors, in one or more purchases, in the ratio of such investor's original subscription amount to the original aggregate subscription amount of all investors, additional units consisting of convertible preferred stock and warrants at a purchase price of $1,000 per unit with an aggregate subscription amount thereof of up to $500,000, which units would be identical to the units of convertible preferred stock and warrants issued in connection with the June 2015 closing. To ensure that we have sufficient authorized shares of common stock to reserve for issuance if the investors exercise this right in full, we sought stockholder approval of an amendment to our Certificate of Incorporation at our annual meeting on August 19, 2015 to increase our authorized shares of common stock, and the amendment was approved. On September 15, 2015, we filed the amendment increasing our authorized common stock from 1,500,000,000 shares to 2,450,000,000 shares.

In addition, if, during the six-month period after the issuance of the warrants and continuing until such time that all of the securities may be sold without our compliance with the current public information requirement under Securities Act rule 144(c)(1), we fail to meet such requirement, we will pay liquidate damages equal to 2.0% of the purchase price paid by each investor, payable in cash every 30 days until current public information for Generex is available or is no longer required for the investors to rely on Rule 144 to transfer the securities (including underlying securities) acquired under the securities purchase agreement.

Financing – March 2014

Series F 9% Convertible Preferred Stock and Warrants

On March 27, 2014, we entered into a securities purchase agreement with certain investors, pursuant to which we agreed to sell an aggregate of 2,075 shares of our newly designated non-voting Series F 9% Convertible Preferred Stock and warrants to purchase up to an aggregate of 100% of the shares of our common stock issuable upon conversion of the convertible preferred stock. The purchase closed on March 28, 2014. We sold the convertible preferred stock and warrants in units, with each unit consisting of one share of convertible preferred stock and a warrant to purchase 100% of the shares of our common stock issuable upon conversion of such share of convertible preferred stock. Each unit was sold at a negotiated price of $1,000, for an aggregate purchase price of $2,075,000. An aggregate of 138,333,334 shares of our common stock are issuable upon conversion of, or exercise of, the convertible preferred stock and warrants. We received net proceeds of approximately $2,020,000 from this transaction.

Subject to certain ownership limitations, the Series F convertible preferred stock will be convertible at the option of the holder at any time into shares of our common stock at an effective conversion price of $0.03 per share, and will accrue a 9% dividend until March 27, 2017 and, beginning on March 27, 2017 and on each one year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend will be payable quarterly on September 30, December 31, March 31 and June 30, beginning on the first such date after the original issue date and on each conversion date in cash, or at our option, in shares of common stock. In the event that the convertible preferred stock is converted prior to March 27, 2017, we will pay the holder of the converted preferred stock an amount equal to $270

per $1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such “make-whole payment” may be made in cash or, at our option, in shares of our common stock. In addition, beginning March 27, 2016, we will pay dividends on shares of the Series F convertible preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. We will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the Series F convertible preferred stock will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of our common stock pursuant to the fundamental transaction.

We may become obligated to redeem the Series F convertible preferred stock in cash upon the occurrence of certain triggering events, including, material breach of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of Generex, the occurrence of certain insolvency events relating to Generex, or the failure of our common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or regulated quotation service. Upon the occurrence of certain triggering events, each holder of convertible preferred stock will have the option to redeem such holder’s shares of convertible preferred stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 18% on all of such holder’s outstanding convertible preferred stock. Late fees will apply on all redemption amounts not paid within five trading days of the payment date.

Subject to certain ownership limitations, the warrants will be exercisable at any time after their date of issuance and on or before the fifth-year anniversary thereafter at an exercise price of $0.03 per share of common stock. The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of common stock pursuant to the fundamental transaction.

The securities purchase agreement and the certificate of designation authorizing the Series F convertible preferred stock include certain agreements and covenants for the benefit of the holders of the convertible preferred stock, including restrictions on our ability to amend the certificate of incorporation and bylaws, pay cash dividends or distributions with respect to our common stock or other junior securities, repurchase more than a *de minimis* number of shares of our common stock or other junior securities.

The investors' pro rata right of first refusal in respect of participation in any private debt or equity financings undertaken by us during the 12 months following the closing of the transaction has expired.

We offered these securities privately pursuant to Rule 506(b) of Regulation D under the Securities Act of 1933. We entered into a registration rights agreement with the investors pursuant to which we agreed to file a registration statement with the SEC covering the public resale of the common stock issuable upon conversion of the preferred stock, issuable as dividends on the preferred stock, issuable upon exercise of the warrants and issued as a finders' fee. The registration statement was declared effective by the SEC on April 16, 2014.

In addition, until the first anniversary date of the securities purchase agreement, each investor could, in its sole determination, elect to purchase, severally and not jointly with the other investors, in one or more purchases, in the ratio of such investor's original subscription amount to the original aggregate subscription amount of all investors, additional units consisting of convertible preferred stock and warrants at a purchase price of $1,000 per unit with an aggregate subscription amount thereof of up to $2,075,000, which units would be identical to the units of convertible preferred stock and warrants issued in connection with the March 2014 closing. These additional exercise rights expired without being exercised in March 2015.

In addition, if, during the six-month period after the issuance of the warrants and continuing until such time that all of the securities may be sold without our meeting the current public information requirement under Securities Act rule 144(c)(1), we fail to meet such requirement, we will pay liquidate damages equal to 2.0% of the purchase price paid by each investor, payable in cash every 30 days until current public information for Generex is available or is no longer required for the investors to rely on Rule 144 to transfer the securities (including underlying securities) acquired under the securities purchase agreement.

Financing – January 2014

Series E 9% Convertible Preferred Stock and Warrants" Greenshoe"

On June 17, 2013, we entered into a securities purchase agreement with certain investors, pursuant to which we agreed to sell an aggregate of 1,225 shares of our newly designated non-voting Series E 9% Convertible Preferred Stock and warrants to purchase up to an aggregate of 100% of the shares of our common stock issuable upon conversion of the convertible preferred stock. Under the June 17, 2013 securities purchase agreement, for a period of up to one year, each investor could, in its sole determination, elect to purchase, in one or more purchases, additional units consisting of convertible preferred stock and warrants at a purchase price in the amount originally purchased by such investor (the "Greenshoe"). The units purchased in the Greenshoe would be identical to the units of convertible preferred stock and warrants originally issued pursuant to the securities purchase agreement.

On January 14, 2014, in connection with the exercise of the Greenshoe by certain investors, we entered into a separate securities purchase agreement, pursuant to which we agreed to sell an aggregate of 800 shares of our Series E 9% Convertible Preferred Stock and warrants to purchase up to an aggregate of 100% of the shares of our common stock issuable upon conversion of the convertible preferred stock. The purchase closed on January 15, 2014. Each unit was sold at a negotiated price of $1,000, for an aggregate purchase price of $800,000. An aggregate of 53,333,336 shares of our common stock were initially issuable upon conversion of, or exercise of, the convertible preferred stock and warrants covered by this securities purchase agreement.

The investors' pro rata right of first refusal in respect of participation in any private debt or equity financings undertaken by us during the 12 months following the closing of the transaction has expired.

We offered these securities privately pursuant to Rule 506(b) of Regulation D under the Securities Act of 1933. This offering was subject to the registration rights agreement dated June 17, 2013 with the investors pursuant to which we agreed to file a registration statement with the SEC covering the public resale of the common stock issuable upon conversion of the preferred stock, issuable as dividends on the preferred stock, issuable upon exercise of the warrants and issued as a finders' fee. The registration statement was declared effective by the SEC on February 7, 2014.

In addition, if, during the six-month period after the issuance of the warrants and continuing until such time that all of the securities may be sold without our meeting the current public information requirement under Securities Act rule 144(c)(1), we fail to meet such requirement, we will pay liquidate damages equal to 2.0% of the purchase price paid by each investor, payable in cash every 30 days until current public information for Generex is available or is no longer required for the investors to rely on Rule 144 to transfer the securities (including underlying securities) acquired under the securities purchase agreement.

Proceeds from Warrant Exercises

In the fiscal years ended July 31, 2016 and 2015, we received no proceeds from the exercise of outstanding warrants.

We may receive additional proceeds from the exercise of warrants issued in February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015 in connection with the issuance of the Series C 9% Convertible Preferred Stock, Series D 9% Convertible Preferred Stock, Series E 9% Convertible Preferred Stock, Series F 9% Convertible Preferred Stock and Series G 9% Convertible Preferred Stock, although some of the warrants include a cashless exercise feature.

- In connection with the securities purchase agreement dated August 8, 2012, we sold an aggregate of 750 shares of our Series C 9% Convertible Preferred Stock and issued warrants exercisable for up to 9,375,000 shares of our common stock to investors.

- In connection with the securities purchase agreement dated December 10, 2012, we sold an aggregate of 750 shares of our Series D 9% Convertible Preferred Stock and issued warrants exercisable for up to 24,999,999 shares of our common stock to investors.

- In connection with the securities purchase agreement dated June 17, 2013, we sold an aggregate of 1,225 shares of our Series E 9% Convertible Preferred Stock and issued warrants exercisable for up to 40,833,335 shares of our common stock to investors.

- In connection with the securities purchase agreement dated January 14, 2014, we sold an aggregate of 800 shares of our Series E 9% Convertible Preferred Stock and issued warrants exercisable for up to 26,666,668 shares of our common stock to investors.

- In connection with the securities purchase agreement dated March 27, 2014, we sold an aggregate of 2,075 shares of our Series F 9% Convertible Preferred Stock and issued warrants exercisable for up to 33,333,333 shares of our common stock to investors.

In connection with the securities purchase agreement dated June 24, 2015, we sold an aggregate of 500 shares of our Series G 9% Convertible Preferred Stock and issued warrants exercisable for up to 33,333,333 shares of our common stock to investors.

As of July 31, 2016, all of the warrants issued in the aforementioned registered direct offerings were exercisable. At July 15, 2016, outstanding warrants issued in connection with the February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015 private placements were as follows (after adjustment for anti-dilution provisions and subsequent exercises):

Date Issued	***Aggregate No. of Shares Unexercised***	***Exercise Price***	Expiration Date
March 31, 2008*	54,545,440	$ 0.015	September 30, 2016
February 1, 2012*	11,350,454	0.015	February 1, 2017
August 10, 2012*	9,999,998	0.015	August 10, 2017
December 10, 2012*	16,648,288	0.015	December 12, 2017
June 17, 2013*	68,333,338	0.015	June 17, 2018
January 15, 2014*	51,333,336	0.015	January 15, 2019
March 27, 2014*	138,333,334	0.015	March 27, 2019
June 25, 2015*	33,333,333	0.015	June 25, 2020

**Upon issuance of securities at a price per share of common stock less than the then applicable exercise price, the warrants are subject to anti-dilution adjustment of the exercise price and to the number of shares of common stock that may be purchased upon exercise of each warrant such that the aggregate exercise price payable upon exercise of the warrant will be the same as the aggregate exercise price in effect immediately prior to such adjustment. Due to the anti-dilution adjustment provision of these warrants, they have been reclassified on Generex's balance sheet as a liability under the caption "Derivative Warrant Liability" with any changes in fair value at each reporting period recorded in earnings in accordance with ASC 815.*

Cash Flows for the Year ended July 31, 2016

For the fiscal year ended July 31, 2016, we used $775,483 in cash to fund our operating activities. The use for operating activities included a net loss of $3,223,109, changes to working capital including an increase of $1,056,955 related to accounts payable and accrued expenses, and an increase related to other current assets of $43,076.

The use of cash was offset by non-cash expenses of $265,210 related to depreciation and amortization, $1,165,864 related to the write-off of patents, stock-based compensation and common stock issued for interest on our convertible preferred stock of $148,500. There was also a year-to-date non-cash gain of $263,823related to the fair valuation of the derivative liabilities at July 31, 2016.

We had no net cash used in or provided by investing activities in the fiscal year ended July 31, 2016. In the prior year, we had net cash used in investing activities of $90,982, representing costs incurred for patents. We did not pay maintenance fees or other costs for patents in fiscal 2016.

We had cash provided by financing activities in the fiscal year ended July 31, 2016 of $52,952, which pertained primarily to proceeds from issuance of long terms debt in the amount of $50,000.

Our net working capital at July 31, 2016 worsened to negative $8,975,894 from negative $7,217,128 at July 31, 2015, which was attributed primarily to cash used in operations for fiscal 2016.

Conversion of Outstanding Series A, Series B, Series C, Series D, Series E, Series F and Series G 9% Convertible Preferred Stock

As of July 31, 2016, all of the 2,575 shares of our Series A 9% Convertible Preferred Stock had been converted into shares of our common stock. A total of 17,166,666 shares of common stock have been issued upon the conversion of 2,575 shares of Series A convertible preferred stock. Upon conversion, we paid the holders of the Series A convertible preferred stock a “make whole” payment equal to $270 per $1,000 of stated value of the Series A convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. We issued 6,129,666 additional shares of common stock on such conversions of the Series A convertible preferred stock as “make-whole payments”.

As of July 31, 2016, all of the 2,000 shares of our Series B 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 38,520,832 shares of common stock upon the conversion of the Series B convertible preferred stock and an additional 14,819,679 shares of common stock were issued as “make-whole payments” on such conversions.

As of July 31, 2016, all of the 750 shares of our Series C 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 22,916,665 shares of common stock upon the conversion of the Series C convertible preferred stock and an additional 6,664,863 shares of common stock were issued as “make-whole payments” on such conversions.

As of July 31, 2016, all of the 750 shares of our Series D 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 24,999,999 shares of common stock upon the conversion of the Series D convertible preferred stock and an additional 7,825,191 shares of common stock were issued as “make-whole payments” on such conversions.

As of July 31, 2016, all of the 2,025 shares of our Series E 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 68,333,333 shares of common stock upon the conversion of the Series E convertible preferred stock and an additional 19,035,193 shares of common stock were issued as “make-whole payments” on such conversions.

As of July 31, 2016, 1,955 shares of our Series F 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 89,108,331 shares of common stock upon the conversion of the Series F convertible preferred stock and an additional 36,533,875 shares of common stock were issued as “make-whole payments” on such conversions.

As of July 31, 2016, none of the 500 shares of our Series G 9% Convertible Preferred Stock had been converted into shares of our common stock.

Funding Requirements and Commitments

If we obtain necessary financing, we expect to expend resources towards regulatory approval and commercialization of Generex Oral-lyn™ and further clinical development of our immunotherapeutic vaccines.

Our future funding requirements and commitments and our ability to raise additional capital will depend on factors that include:

- the timing and amount of expense incurred to complete our clinical trials;
- the costs and timing of the regulatory process as we seek approval of our products in development;
- the advancement of our products in development;
- our ability to generate new relationships with industry partners throughout the world that will provide us with regulatory assistance and long-term commercialization opportunities;
- the timing, receipt and amount of sales, if any, from Generex Oral-lyn™ in India, Lebanon, Algeria and Ecuador;
- the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;
- the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;
- our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development;
- our ability to obtain the necessary financing to fund our operations and effect our strategic development plan; and
- the receptivity of the financial market to biopharmaceutical companies.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, and we do not have any non-consolidated special purpose entities.

Tabular Disclosure of Contractual Obligations

Generex is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Recently Adopted Accounting Pronouncements

In June 2014, the FASB issued guidance regarding the elimination of the reporting requirement for development stage entities and removed the definition of development stage entity from the Accounting Standards Codification. We adopted this guidance effective for the Company's annual fiscal year ended July 31, 2014. The adoption of this new accounting guidance resulted in the elimination of the inception-to-date financial information in the consolidated statements of operations, statements of changes in stockholders' deficiency and statements of cash flows, as well as the removal of the subheading "A Development Stage Company" from the consolidated financial statements and the notes to the consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2014, the FASB issued guidance regarding *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity.* The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

In August 2014, the FASB issued guidance regarding disclosure of uncertainties about an entity's ability to continue as a going concern. The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Generex is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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Item 8. Financial Statements and Supplementary Data

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	July 31, 2016	July 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$16,899	$749,965
Other current assets	8,077	51,240
Total Current Assets	24,976	801,205
Property and Equipment (Note 3)	1,298	2,869
Patents (Note 4)	—	1,430,016
TOTAL ASSETS	$26,274	$2,234,090
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable and accrued expenses (Note 6)	$8,950,870	$8,018,333
Loan payable (Note 6)	50,000	—
Total Current Liabilities	9,000,870	8,018,333
Derivative Warrant Liability (Note 8 and 9)	2,048,846	2,363,415
Derivative Additional Investment Rights Liability (Note 8 and 9)	193,408	142,662
Total Liabilities	11,243,124	10,524,410
Commitments and Contingencies (Note 7)		
Stockholders' Deficiency (Note 10):		
Series A 9% Convertible Preferred Stock, $1,000 par value; authorized 5,500 shares, -0- issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Series B 9% Convertible Preferred Stock, $1,000 par value; authorized 2,000 shares, -0- issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Series C 9% Convertible Preferred Stock, $1,000 par value; authorized 750 shares, -0- issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Series D 9% Convertible Preferred Stock, $1,000 par value; authorized 750 shares, -0- issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Series E 9% Convertible Preferred Stock, $1,000 par value; authorized 2,450 shares, -0- issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Series F 9% Convertible Preferred Stock, $1,000 par value; authorized 4,150 shares, 120 and 670 issued shares at July 31, 2016 and July 31, 2015, respectively	—	—

Series G 9% Convertible Preferred Stock, $1,000 par value; authorized 1,000 shares, 500 issued shares at July 31, 2016 and July 31, 2015, respectively	—	—
Common stock, $.001 par value; authorized 2,450,000,000 shares and 1,500,000,000 shares at July 31, 2016 and July 31, 2015, respectively; 908,541,475 and 825,496,238 issued and outstanding at July 31, 2016 and July 31, 2015, respectively	908,542	825,496
Additional paid-in capital	362,780,108	362,556,710
Accumulated deficit	(375,704,372)	(372,481,263)
Accumulated other comprehensive income	798,872	808,737
Total Stockholders' Deficiency	(11,216,850)	(8,290,320)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$26,274	$2,234,090

The accompanying notes are an Integral part of the financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended July 31,	
	2016	2015
Operating Expenses:		
Research and development	$467,382	$1,185,384
General and administrative	1,435,186	2,377,530
Total Operating Expenses	1,902,568	3,562,914
Operating Loss	(1,902,568)	(3,562,914)
Other Income (Expense):		
Impairment of patents (Note 4)	(1,165,864)	(320,160)
Interest income	—	6
Interest expense	(418,500)	(350,028)
Change in fair value of derivative liabilities (Note 9)	263,823	1,488,237
Gain on extinguishment of debt (Note 6)	—	551,501
Net Loss	(3,223,109)	(2,193,358)
Preferred Stock Dividend (Note 8)	—	339,583
Net Loss Available to Common Stockholders	$(3,223,109)	$(2,532,941)
Basic and Diluted Net Loss Per Common Share (Note 12)	$(.004)	$(.003)
Weighted Average Number of Shares of Common Stock Outstanding - basic and diluted (Note 12)	880,941,375	793,346,901
Other Comprehensive Income:		
Net Loss	(3,223,109)	(2,193,358)
Change in foreign currency translation adjustments	(9,865)	36,663
Comprehensive (Loss)	(3,232,974)	(2,156,695)
Preferred Stock Dividend (Note 8)	—	339,583
Comprehensive Loss Available to Common Stockholders	$(3,232,974)	$(2,496,278)

The accompanying notes are an Integral part of the financial statements.

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GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	To Sto Def
Balance at July 31, 2014	1,250	$—	778,512,092	$778,512	$362,307,678	$(369,948,322)	$772,074	$(6,0
Issuance of common stock in exchange for services	—	—	5,809,780	5,810	127,190	—	—	133
Issuance of preferred stock in financing	500	—	—	—	—	—	—	—
Issuance of common stock upon conversion of preferred stock	(580)	—	25,775,002	25,775	(25,775)	—	—	—
Issuance of common stock for preferred stock make whole payments	—	—	8,983,048	8,983	147,617	—	—	156
Exercise of stock options for cash	—	—	6,416,316	6,416	—	—	—	6,4
Net loss	—	—	—	—	—	(2,193,358)	—	(2,1
Preferred stock dividend	—	—	—	—	—	(339,583)	—	(33
Currency translation adjustment	—	—	—	—	—	—	36,663	36,6
Balance at July 31, 2015	1,170	$—	825,496,238	$825,496	$362,556,710	$(372,481,263)	$808,737	$(8,2
Issuance of common stock in exchange for services	—		300,000	300	4,200	—	—	4,5
Issuance of common stock	(550)		36,666,665	36,667	(36,667)	—	—	—

upon conversion of preferred stock								
Issuance of common stock for preferred stock make whole payments			20,139,207	20,139	128,361	—	—	148
Exercise of stock options for cash	—		25,939,365	25,940	(25,940)	—	—	—
Issuance of stock options for compensation liabilities	—		—	—	123,147	—	—	123
Issuance of stock options as compensation	—		—	—	30,297	—	—	30,2
Net loss	—		—	—	—	(3,223,109)	—	(3,2
Currency translation adjustment	—		—	—	—	—	(9,865)	(9,8
Balance at July 31, 2016	620	$—	908,541,475	$908,542	$362,780,108	$(375,704,372)	$798,872	$(11

The accompanying notes are an Integral part of the financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Twelve Months Ended July 31,	
	2016	2015
Cash Flows From Operating Activities:		
Net loss	$(3,223,109)	$(2,193,358)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	265,210	380,680
Common stock issued for services rendered	4,500	133,000
Write-off of patents	1,165,864	320,160
Issuance of stock options as compensation	27,344	
Common stock issued for interest on convertible debentures and preferred stock	148,500	156,600
Change in fair value of derivative liabilities	(263,823)	(1,488,237)
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,056,955	(117,739)
Deferred revenue	—	(223,662)
Other current assets	43,076	147,820
Net Cash Used in Operating Activities	(775,483)	(2,884,736)
Cash Flows From Investing Activities:		
Costs incurred for patents	—	(90,982)
Net Cash Used In Investing Activities	—	(90,982)
Cash Flows From Financing Activities:		
Proceeds from issuance of long-term debt	50,000	—
Proceeds from exercise of stock options	2,952	6,416
Proceeds from issuance of preferred stock, net	—	475,000
Net Cash Provided by Financing Activities	52,952	481,416
Effect of Exchange Rates on Cash	(10,535)	(25,222)
Net Decrease in Cash and Cash Equivalents	(733,066)	(2,519,524)
Cash and Cash Equivalents, Beginning of Year	749,965	3,269,489
Cash and Cash Equivalents, End of Year	$16,899	$749,965
Supplemental Disclosure of Cash Flow Information:		
Interest paid in cash	$—	$—
Issuance of stock options to satisfy compensation liabilities	$123,147	$—

The accompanying notes are an Integral part of the financial statements.

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Note 1 - Organization of Business and Going Concern:

Generex Biotechnology Corporation (the Company) and its wholly-owned subsidiary Generex Pharmaceuticals, Inc. has been 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's wholly-owned subsidiary, Antigen Express, Inc. (Antigen), has been engaged in research and development of technologies and immunomedicines for the treatment of malignant, infectious, autoimmune and allergic diseases. The Company's immunomedicine products work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). The immunomedicine products are based on two platform technologies that were discovered by an executive officer of Antigen, the Ii-Key hybrid peptides and Ii-Suppression. These technologies are expected to greatly boost immune cell responses which diagnose and treat the ailments and conditions.

The Company has a limited history of operations and limited revenue to date. Although the Company has had several product candidates that are in various research or early stages of pre-clinical and clinical development, due to its lack of funding the Company has effectively ceased these operations and is now seeking new investment opportunities (see Note 15). There can be no assurance that the Company will be successful in completing these investment opportunities and maintaining its position as a going concern.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has experienced negative cash flows from operations since inception and has an accumulated deficit of approximately $376 million and a working capital deficiency of approximately $9.0 million at July 31, 2016. The Company has funded its activities to date almost exclusively from debt and equity financings, as well as the sale of real estate assets.

The Company will continue to require substantial funds to implement its new investment acquisition plans. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments. Management is also actively pursuing financial and strategic alternatives, including strategic investments and divestitures, industry collaboration activities and strategic partners.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations.

Note 2 - Summary of Significant Accounting Policies:

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all of its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Cash and Cash Equivalents

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

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 and comprehensive loss in the year of disposal. Repairs and maintenance expenditures are expensed as incurred.

Patents

Capitalized patent costs represent legal costs incurred to establish patents and a portion of the acquisition price paid attributed to patents upon the acquisition of Antigen in August 2003. When patents reach a mature stage, any associated legal costs are comprised mostly of maintenance fees and costs of national applications and are expensed as incurred. Capitalized patent costs are amortized on a straight line basis over the remaining life of the patent. As patents are abandoned, the net book value of the patent is written off. In the fiscal year ended July 31, 2016, the Company recorded a write down of $1,165,864 (2015 - $320,160) on the Company's patents.

Impairment or Disposal of Long-Lived Assets and Intangibles

The Company assesses the impairment of long-lived assets under FASB ASC Topic 360 whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable and exceeds its fair value. The carrying amount of the long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposal of the asset. All patents were written off in the fiscal year ended July 31, 2016.

Derivative Warrant Liability

The Company's derivative warrant instruments are measured at fair value using the binomial valuation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk-free interest rate for the term of the warrant. The liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss under the caption "Change in fair value of derivative warrant liability." See *Note 9 – Derivative Liabilities*.

Revenue Recognition and Deferred Revenue

Revenues from the sale of commercial products are recognized at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership. Sales are reported net of estimated returns and allowances, discounts, mail-in rebate redemptions and credit card chargebacks. If actual sales returns, allowances, discounts,

mail-in rebate redemptions or credit card chargebacks are greater than estimated by management, additional expense may be incurred.

Research and Development Costs

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

Income Taxes

Income taxes are accounted for under the asset and liability method prescribed by FASB ASC Topic 740. These standards require a company to determine whether it is more likely than not that a tax position will be sustained upon examination based upon the technical merits of the position. If the more likely than not threshold is met, a company must measure the tax position to determine the amount to recognize in the financial statements. 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. At July 31, 2016 and 2015, the Company had a full valuation allowance equal to the amount of the net deferred tax asset.

The Company adopted the FASB guidance concerning accounting for uncertainty in income taxes, which clarifies the accounting and disclosure for uncertainty in tax positions, as of August 1, 2007. The guidance requires that the Company determine whether it is more likely than not that a tax position will not be sustained upon examination by the appropriate taxing authority. If a tax position does not meet the more likely than not recognition criterion, the guidance requires that the tax position be measured at the largest amount of benefit greater than 50 percent not likely of being sustained upon ultimate settlement. Based on the Company's evaluation, management has concluded that there are no significant uncertain tax positions requiring recognition in the consolidated financial statements.

Stock-Based Compensation

The Company follows FASB ASC Topic 718 which requires that new, modified and unvested share-based payment transactions with employees, such as grants of stock options and restricted stock, be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over their vesting periods. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock based on the quoted market price or the value of the services provided, whichever is more readily determinable. The Company also follows the guidance in FASB ASC Topic 505 for equity based payments to non-employees for equity instruments issued to consultants and other non-employees.

Net Loss per Common Share

Basic earnings per share is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period. The computation of diluted earnings per share does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings. Refer to Note 12 for methodology for determining net loss per share.

Comprehensive Income/(Loss)

Other comprehensive income/(loss), which includes only foreign currency translation adjustments, is shown in the consolidated statements of operations and comprehensive loss and in the consolidated statements of changes in stockholders' deficiency.

Concentration of Credit Risk

The Company maintains cash balances, at times, with financial institutions in excess of amounts insured by the Canada Deposit Insurance Corporation and the U.S. Federal Deposit Insurance Corporation. Management monitors the soundness of these institutions and has not experienced any collection losses with these financial institutions.

Foreign Currency Translation

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

Fair Value of Financial Instruments

Fair value is defined under FASB ASC Topic 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for an asset or liability in an orderly transaction between participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. The levels are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities

- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data for substantially the full term of the assets or liabilities

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities

The Company's financial instruments consist of cash and cash equivalents, other current assets, accounts payable and accrued expenses, loan payable as well as derivative warrant liabilities and derivative additional investment rights. All of these items, except for the derivative warrant liabilities and derivative additional investment rights, were determined to be Level 1 fair value measurements. The carrying amounts of cash and cash equivalents, other current assets, accounts payable and accrued expenses and the loan payable approximate their respective fair values because of the short maturities of these instruments.

The Company has determined its derivative warrant liability and its derivative additional investment rights liability to be Level 2 fair value measurements and has used the binomial lattice model valuation method to calculate the fair value of the derivative warrant liability and the derivative additional investment rights liability at July 31, 2016 and 2015. See *Note 9 – Derivative Liabilities*.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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.

The Company evaluates its estimates, including those related to long lived assets (including patents) impairment valuations, derivatives and contingencies and litigation, on an ongoing basis. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting estimates are reviewed and discussed with the Board of Directors. The Company considers an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made, if changes in the estimate or if different estimates that could have been selected would have a material impact on our results of operations or financial condition.

Effects of Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements

In November 2014, the FASB issued guidance regarding *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity.* The guidance will be effective for the Company's first quarter of the fiscal year ended July 31, 2017. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

In August 2014, the FASB issued guidance regarding disclosure of uncertainties about an entity's ability to continue as a going concern. The guidance will be effective for the Company's fiscal year ended July 31, 2017 and subsequent interim periods. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

Note 3 – Property and Equipment:

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

	July 31, 2016	2015
Furniture and Fixtures	$10,900	$10,954
Less: Accumulated depreciation	9,602	8,085
Property and Equipment, net	$1,298	$2,869

Depreciation expense related to property and equipment amounted to $1,517 and $1,726 for the years ended July 31, 2016 and 2015, respectively.

Note 4 - Patents:

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

	July 31, 2016	2015
Patents	$—	$4,705,715
Less: Accumulated amortization	—	3,275,699
Patents, net	$—	$1,430,016
Weighted average life	0 years	6.6 years

Amortization expense amounted to $281,894 and $378,954 for the years ended July 31, 2016 and 2015, respectively. No amortization expense is expected for the years ended July 31, 2017 through 2022. During the year ended July 31, 2016, the Company wrote off patents with a net book value of $1,165,864 as the patents had been abandoned or were no longer being used. During the year ended July 31, 2015, the Company wrote off patents with a net book value of $320,160 as the patents had been abandoned or were no longer being used.

Note 5 - Income Taxes:

The Company has incurred losses since inception, which have generated net operating loss (“NOL”) carryforwards. The NOL carryforwards arise from both United States and Canadian sources. Pre-tax (losses) arising from domestic operations (United States) were $(1,374,725) and $(677,616) for the years ended July 31, 2016 and 2015, respectively. Pre-tax (losses) arising from foreign operations (Canada) were $(504,101) and $(1,515,741) for the years ended July 31, 2016 and 2015, respectively. As of July 31, 2016, the Company has NOL carryforwards in Generex Biotechnology Corporation of approximately $201 million, which expire in 2018 through 2036, in Generex Pharmaceuticals Inc. of approximately $32 million, which expire in 2017 through 2036, and in Antigen Express, Inc. of approximately $29 million, which expire in 2026 through 2036. These loss carryforwards are subject to limitation due to the acquisition of Antigen and may be limited in future years due to certain structural ownership changes which have occurred over the last several years related to the Company’s equity and convertible debenture financing transactions.

For the years ended July 31, 2016 and 2015, the Company’s effective tax rate differs from the federal statutory rate principally due to net operating losses and other temporary differences for which no benefit was recorded.

Deferred income taxes consist of the following:

	July 31, 2016	2015
Net operating loss carryforwards	$86,895,338	$86,370,251
Other temporary differences	150,004	338,000
Intangible assets	—	108,022
Total Deferred Tax Assets	87,045,342	86,816,273
Valuation Allowance	(86,678,987)	(86,816,273)
Deferred Tax Liabilities		
Intangible assets	(366,355)	—
Other temporary differences	—	—
Total Deferred Tax Liabilities	—	—
Net Deferred Income Taxes	$—	$—

A reconciliation of the United States Federal Statutory rate to the Company's effective tax rate for the years ended July 31, 2016 and 2015 is as follows:

	July 31, 2016	2015
Federal statutory rate	(34.0)%	(34.0)%
Increase (decrease) in income taxes resulting from:		
Imputed interest income on intercompany receivables from foreign subsidiaries	4	4
Non-deductible or non-taxable items	(3)	(24)
Other temporary differences	26	170
Change in valuation allowance	7	(116)
Effective tax rate	— %	— %

As of July 31, 2016, the Company had no tax benefits which have not been fully allowed for, and no adjustment to its financial position, results of operations or cash flows was required. The Company does not expect that unrecognized tax benefits will increase within the next twelve months. The Company records interest and penalties related to tax matters within other expense on the accompanying consolidated statement of operations. These amounts are not material to the consolidated financial statements for the periods presented. Generally, tax years 2013 to 2016 remain open to examination by the Internal Revenue Agency or other tax jurisdictions to which the Company is subject. The Company's Canadian tax returns are subject to examination by federal and provincial taxing authorities in Canada. Generally, tax years 2008 to 2016 remain open to examination by the Canada Revenue Agency or other tax jurisdictions to which the Company is subject.

Note 6 - Accounts Payable and Accrued Expenses:

Accounts payable and accrued expenses consist of the following:

	July 31, 2016	2015
Accounts Payable and Accruals - General and Administrative	$3,750,638	$3,156,951
Accounts Payable and Accruals - Research and Development	4,395,061	3,861,902
Accounts Payable and Accruals - Selling and Marketing	326,229	326,250
Accrued Make-whole Payments on Convertible Preferred Stock (See Note 8)	167,400	315,900
Executive Compensation and Directors' Fees Payable	311,542	357,330
Total	$8,950,870	$8,018,333

In the fiscal year ended July 31, 2016 the Company did not have extinguishment of debt. In the fiscal year ended July 31, 2015 the Company had a gain on extinguishment of debt of $327,839 related to the final settlement of a previously owed balance to a vendor. In addition, the Company wrote off a balance of $223,662 previously reported as deferred revenue on the consolidated balance sheets. These amounts have been reported on the Company's consolidated statements of operations and comprehensive loss under the caption "Gain on extinguishment of debt" and are included in the changes in accounts payable and accrued expenses and deferred revenue categories, respectively in the consolidated statements of cash flows.

During the year the Company received a loan in the amount of $50,000 in order to fund certain operating costs. This loan is unsecured, due on demand and bears interest at a rate of 9% per annum.

Note 7 - Commitments and Contingent Liabilities:

Leases

As at July 31, 2016 the Company does not have any outstanding operating lease agreements for the use of operating space, vehicles and office equipment.

Lease expense amounted to approximately $25,000 and $59,000 for the years ended July 31, 2016 and 2015, respectively.

Pending Litigation

In February 2001, a former business associate of the former Vice President of Research and Development ("VP") of the Company and an entity known as Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against the Company and the VP seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and the VP that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by the Company of three patents allegedly owned by CTI. The three patents are entitled *Liquid Formulations for Proteinic Pharmaceuticals*, *Vaccine Delivery System for Immunization, Using Biodegradable Polymer Microspheres*, and *Controlled Releases of Drugs or Hormones in Biodegradable Polymer Microspheres*. It is the Company's position that the buccal drug delivery technologies which are the subject matter of the Company's research, development, and commercialization efforts, including Generex Oral-lyn™ and the RapidMist™ Diabetes Management System, do not make use of, are not derivative of, do not infringe upon, and are entirely different from the intellectual property identified in the plaintiffs' statement of claim. On July 20, 2001, the Company filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by the Company. Consequently, the shareholders of CBI are in a deadlock. The court granted the Company's motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in the name of or on behalf of CBI. The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against the VP and the Company. The Company opposed the application. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against the VP and the Company. A statement of claim was served in July 2004. 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.

On May 20, 2011, Ms. Perri filed a statement of claim (subsequently amended) in the Ontario Superior Court of Justice, naming as defendants the Company and certain directors of the Company, Mr. Barratt, Ms. Masterson, Mr. McGee, and Mr. Fletcher. In this action, Ms. Perri has alleged that defendants engaged in discrimination, harassment, bad faith and infliction of mental distress in connection with the termination of her employment with the Company. Ms. Perri is seeking damages in this action in excess of $7,000,000 for, among other things, breach of contract, breach of fiduciary duty, violations of the Ontario Human Rights Code and aggravated and punitive damages. On September 20, 2011, the defendants filed a statement of defense and counterclaim, also naming Time Release Corp., Khazak Group Consulting Corp., and David Khazak, C.A. as defendants by counterclaim, and seeking damages of approximately $2.3 million in funds that the defendants allege Ms. Perri wrongly caused the Company to pay to third parties in varying amounts over several years and an accounting of certain third-party payments, plus interests and costs. The factual basis for the counterclaim involves payments made by the Company to third parties believed to be related to Ms. Perri. The Company intends to defend this action and pursue its counterclaim vigorously and 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.

On June 1, 2011, Golden Bull Estates Ltd. filed a claim (subsequently amended) in the Ontario Superior Court of Justice, naming the Company, 1097346 Ontario, Inc. and Generex Pharmaceuticals, Inc. as defendants. The plaintiff, Golden Bull Estates Ltd., is controlled by Ms. Perri. The plaintiff alleges damages in the amount of $550,000 for breach of contract, $50,000 for punitive damages, plus interest and costs. The plaintiff's claims relate to an alleged contract between the plaintiff and the Company for property management services for certain Ontario properties owned by the Company. The Company terminated the plaintiff's property management services in April 2011. Following the close of pleadings, the Company served a motion for summary judgment. The plaintiff responded by amending its statement of claim to include a claim to the Company's interest in certain of its real estate holdings. The plaintiff moved for leave to issue and register a Certificate of Pending Litigation in respect of this real estate. The motion was not successful in respect of any current real estate holdings of the Company. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

In December 2011, a vendor of the Company commenced an action against the Company and its subsidiary, Generex Pharmaceuticals, Inc., in the Ontario Superior Court of Justice claiming damages for unpaid invoices including interest in the amount of $429,000, in addition to costs and further interest. The Company responded to this statement of claim and also asserted a counterclaim in the proceeding for $200,000 arising from the vendor's breach of contract and detinue, together with interest and costs. On November 16, 2012, the parties agreed to settle this action and the Company has agreed to pay the plaintiff $125,000, following the spinout of its subsidiary Antigen, from the proceeds of any public or private financing related to Antigen subsequent to such spinout. Each party agreed to execute mutual releases to the claim and counterclaim to be held in trust by each party's counsel until payment of the settlement amount. Following payment to the plaintiff, the parties agree that a Consent Dismissal Order without costs will be filed with the court. If the Company fails to make the payment following completion of any post-spinout financing related to Antigen or any other subsidiaries, the Plaintiffs may take out a judgment in the amount of the claim plus interest of 3% per annum and costs fixed at $25,000.

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, operations or cash flows.

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

Employment Agreements

As of July 31, 2015, the Company had an employment arrangement with its President & Chief Executive Officer, whereby the Company is required to pay an annual base salary of $475,000. The term of service for this executive extended through March 16, 2008, which term had not been formally extended as of July 31, 2015. In the event the agreement is terminated, by reason other than cause, death, voluntary retirement or disability, the Company is required to pay the employee in one lump sum twelve months' base salary and the average annual bonus. During fiscal 2016 this executive resigned and the Company is no longer subject to the potential termination payment.

As of July 31, 2015, the Company has an at will employment agreement with an Antigen employee requiring the Company to pay an annual aggregate salary of $260,480 to the employee. In the event the agreement is terminated by reason other than death, disability, a voluntary termination not for good reason (as defined in the agreement) or a termination for cause, the Company is required to pay the employee severance of six months' salary ($130,240), in accordance with the terms of the individual's employment agreement. During fiscal 2016 this executive resigned and the Company is no longer subject to the potential termination payment.

Note 8 - Series A, B, C, D, E, F & G 9% Convertible Preferred Stock:

Series A 9% Convertible Preferred Stock

The Company has authorized 5,500 shares of Series A 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated July 8, 2011, the Company sold an aggregate of 2,575 shares of convertible preferred stock, as well as accompanying warrants to purchase 17,166,666 shares of common stock. An aggregate of 17,166,666 shares of the Company's common stock were issuable upon conversion of the convertible preferred stock which was issued at the initial closing. As of the end of the Company's fiscal year 2012, all of the issued Series A 9% Convertible Preferred Stock had been converted to common stock. There were 17,166,666 shares of common stock issued upon the conversion of the Series A convertible preferred stock and 6,129,666 shares of common stock issued as "make-whole payments" on such conversions.

Series B 9% Convertible Preferred Stock

The Company has authorized 2,000 shares of Series B 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated January 31, 2012, the Company sold an aggregate of 2,000 shares of Series B convertible preferred stock, as well as accompanying warrants to purchase 13,333,333 shares of common stock. An aggregate of 13,333,333 shares of the Company's common stock were issuable upon conversion of the Series B convertible preferred stock which was issued at the initial closing. On December 10, 2012, the triggering of the price protection features of the Series B convertible preferred stock resulted in a decrease of the conversion price from $0.08 to $0.03 per share and a corresponding increase in the number of common shares underlying the remaining 792 shares of Series B convertible preferred stock as of December 10, 2012 from 9,897,500 to 26,393,333. As of the end of the Company's fiscal year 2013, all of the issued Series B 9% Convertible Preferred Stock had been converted to common stock. There were 38,520,832 shares of common stock issued upon the conversion of the Series B convertible preferred stock and 14,819,679 shares of common stock issued as "make-whole payments" on such conversions.

Series C 9% Convertible Preferred Stock

The Company has authorized 750 shares of Series C 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated August 8, 2012, the Company sold an aggregate of 750 shares of Series C convertible preferred stock, as well as accompanying warrants to purchase 9,375,000 shares of common stock. An aggregate of 9,375,000 shares of the Company's common stock were issuable upon conversion of the Series C convertible preferred stock which was issued at the initial closing. On December 10, 2012, the triggering of the price protection features of the Series C convertible preferred stock resulted in a decrease of the conversion price from $0.08 to $0.03 per share and a corresponding increase in the number of common shares underlying the 650 shares of Series C convertible preferred stock as of December 10, 2012 from 8,125,000 to 21,666,666. As of the end of the Company's fiscal year 2013, all of the issued Series C 9% Convertible Preferred Stock had been converted to common stock. There were 22,916,665 shares of common stock issued upon the conversion of the Series C convertible preferred stock and 6,664,863 shares of common stock issued as "make-whole payments" on such conversions.

Series D 9% Convertible Preferred Stock

The Company has authorized 750 shares of Series D 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated December 10, 2012, the Company sold an aggregate of 750 shares of Series D convertible preferred stock, as well as accompanying warrants to purchase 24,999,999 shares of common stock. An aggregate of 24,999,999 shares of the Company's common stock were issuable upon conversion of the Series D convertible preferred stock which was issued at the initial closing. As of the end of the Company's fiscal year 2013, all of the Series D convertible preferred stock had been converted to common stock. There were 24,999,999 shares of common stock issued upon the conversion of the Series D convertible preferred stock and 7,825,191 shares of common stock issued as "make-whole payments" on such conversions.

Series E 9% Convertible Preferred Stock

The Company has authorized 2,450 shares of Series E 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated June 17, 2013, the Company sold an aggregate of 1,225 shares of Series E convertible preferred stock, as well as accompanying warrants to purchase 40,833,335 shares of common stock. An aggregate of 40,833,335 shares of the Company's common stock are issuable upon conversion of the Series E convertible preferred stock which was issued at the initial closing on June 17, 2013. Pursuant to a securities purchase agreement dated January 14, 2014, the Company sold an aggregate of 800 shares of Series E convertible preferred stock, as well as accompanying warrants to purchase 26,666,668 shares of common stocks. An aggregate of 26,666,668 shares of the Company's common stock are issuable upon conversion of the Series E convertible preferred stock which was issued at the closing on January 15, 2014. The conversion price for the Series E Convertible Preferred Stock was adjusted from $0.03 to $0.015 after the Series G Convertible Preferred Stock financing on June 24, 2015 and the number of common shares underlying the 25 Series E Convertible Preferred Stock outstanding at that date increased from 833,333 to 1,666,666. As of July 31, 2015, all of the Series E convertible preferred stock had been converted to common stock. There were 68,333,333 shares of common stock issued upon the conversion of the Series E convertible preferred stock and 19,035,193 shares of common stock issued as "make-whole payments" on such conversions.

Similar to the accounting treatment of the Series F and G 9% Convertible Preferred Stock below, as the assigned fair values of the various components of the financing were greater than the net cash proceeds from the transaction, the excess of $472,279 was treated as a "deemed dividend" for accounting purposes and was reported on the Company's consolidated statement of operations and comprehensive loss for the fiscal year ended July 31, 2014 under the caption "Preferred Stock Dividend".

Series F and G 9% Convertible Preferred Stock

The Company has authorized 4,150 shares of Series F 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated March 27, 2014, the Company sold an aggregate of 2,075 shares of Series F convertible preferred stock, as well as accompanying warrants to purchase 69,166,667 shares of common stock. An aggregate of 69,166,667 shares of the Company's common stock were issuable upon conversion of the Series F convertible preferred stock which was issued at the closing on March 27, 2014.

The Company has authorized 1,000 shares of Series G 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated June 24, 2015, the Company sold an aggregate of 500 shares of Series G convertible preferred stock, as well as accompanying warrants to purchase 33,333,333 shares of common stock. An aggregate of 33,333,333 shares of the Company's common stock are issuable upon conversion of the Series G convertible preferred stock which was issued at the closing on June 24, 2015.

Subject to certain ownership limitations, the convertible preferred stock is convertible at the option of the holder at any time into shares of the Company's common stock at an effective conversion price of $0.015 per share (Note: The conversion price for the Series F Convertible Preferred Stock was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock financing on June 24, 2015), and will accrue a 9% dividend until the third year anniversary of the issuances. On each one-year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend is payable quarterly on September 30, December 31, March 31 and June 30, beginning on June 30, 2014 and June 30, 2015, respectively, and on each conversion date in cash, or at the Company's option, in shares of common stock. In the event that the Series F and G convertible preferred stock is converted prior to March 27, 2017 and June 24, 2018, respectively, the Company will pay the holder of the converted preferred stock an amount equal to $270 per $1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such "make-whole payment" may be made in cash or, at the Company's option, in shares of its common stock. In addition, beginning on the third anniversary date of the issuances, the Company will pay dividends on shares of preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, and if such dividends are paid. The Company will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the convertible preferred stock is subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock

will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction. The conversion price for the Series F Convertible Preferred Stock was adjusted from $0.03 to $0.015 for the Series F Convertible Preferred Stock in conjunction with the Series G Convertible Preferred Stock on June 24, 2015 and the number of common shares underlying the 838 Series F Convertible Preferred Stock outstanding at that date increased from 27,941,667 to 55,883,333.

In conjunction with the issuance of the Series F convertible preferred stock in March 2014 and the issuance of the Series G convertible preferred stock in June 2015, the Company also issued 69,166,667 and 33,333,333 warrants, respectively to the investors. Subject to certain ownership limitations, the warrants will be exercisable at any time after their respective dates of issuance and on or before the fifth-year anniversary thereafter at an exercise price of $0.015 per share of common stock (Note: The conversion price for the warrants issued in the Series F Convertible Preferred Stock financing was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock financing on June 24, 2015 and the number of warrants increased from 69,166,667 to 138,333,334).

The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction. These warrants have been classified as derivative liabilities and are described further in *Note 9 – Derivative Liabilities***.**

In addition, until the first anniversary date of the March 2014 securities purchase agreement and the first anniversary of the August 19, 2015 shareholder approval of the increase in authorized stock, respectively, each investor may, in its sole determination, elect to purchase, severally and not jointly with the other investors, in one or more purchases, in the ratio of such investor's original subscription amount to the original aggregate subscription amount of all investors, additional units consisting of convertible preferred stock and warrants at a purchase price of $1,000 per unit with an aggregate subscription amount thereof of up to $2,075,000 and $500,000, respectively, which units will have terms identical to the units of convertible preferred stock and warrants issued in connection with the March 2014 and June 2015 closings. These additional investment rights of the investors have been classified as derivative liabilities and are described further in *Note 9 – Derivative Liabilities***.** The March 2014 additional investment rights expired on March 27, 2015 and none had been exercised up to that date. The June 2015 additional investment rights expire on August 19, 2016 and none have been exercised to date.

As of July 31, 2016, 1,955 of the Series F convertible preferred stock had been converted to common stock. There were 89,108,331 shares of common stock issued upon the conversion of the Series F convertible preferred stock and 36,533,878 shares of common stock issued as "make-whole payments" on such conversions. As of July 31, 2016, none of the Series G convertible preferred stock had been converted to common stock.

Accounting for proceeds from the Series F convertible preferred stock financing

The initial cash proceeds, net of issuance costs of $55,000, from the Series F convertible preferred stock financing in March 2014 were $2,020,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing, second to the additional investment rights associated with the financing and then to the make whole payments and subsequent issuance costs. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a "deemed dividend" for accounting purposes and was reported on the Company's consolidated statement of operations and comprehensive loss for the fiscal year ended July 31, 2014 under the caption "Preferred Stock Dividend". The calculation methodologies for the fair values of the derivative warrant liability and the

derivative additional investment rights liability are described in *Note 9 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds	
Net proceeds	$2,020,000
Derivative warrant liability fair value	(2,016,064)
Derivative additional investment rights fair value	(863,735)
Other issuance costs (finders' fee)	(166,000)
Make whole payments liability	(560,250)
Deemed dividend	$(1,586,050)

The initial "make-whole payments" of $560,250 on the Series F convertible preferred stock were accrued as of the date of the financing and the remaining balance of $32,400 after conversions (2015 - $180,900) is included in Accounts Payable and Accrued Expenses (see Note 6) at July 31, 2016.

Accounting for proceeds from the Series G convertible preferred stock financing

The initial cash proceeds, net of issuance costs of $25,000, from the Series G convertible preferred stock financing in June 2015 were $475,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing, second to the additional investment rights associated with the financing and then to the make whole payments and subsequent issuance costs. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a "deemed dividend" for accounting purposes and was reported on the Company's consolidated statement of operations and comprehensive loss for the fiscal year ended July 31, 2015 under the caption "Preferred Stock Dividend". The calculation methodologies for the fair values of the derivative warrant liability and the derivative additional investment rights liability are described in *Note 9 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds	
Net proceeds	$475,000
Derivative warrant liability fair value	(354,535)
Derivative additional investment rights fair value	(285,048)
Other issuance costs (finders' fee)	(40,000)
Make whole payments liability	(135,000)
Deemed dividend	$(339,583)

The initial "make-whole payments" of $135,000 on the Series G convertible preferred stock were accrued as of the date of the financing and the balance (no conversions have taken place) is included in Accounts Payable and Accrued Expenses (see Note 6) at July 31, 2016 and 2015.

Note 9 - Derivative Liabilities:

Derivative warrant liability

The Company has warrants outstanding with price protection provisions that allow for the reduction in the exercise price of the warrants in the event the Company subsequently issues stock or securities convertible into stock at a price lower than the exercise price of the warrants. Simultaneously with any reduction to the exercise price, the number of shares of common stock that may be purchased upon exercise of each of these warrants shall be increased or decreased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of warrants shall be the same as the aggregate exercise price in effect immediately prior to such adjustment.

Accounting for Derivative Warrant Liability

The Company's derivative instruments have been measured at fair value at July 31, 2016 and 2015 using the binomial lattice model. The Company recognizes all of its warrants with price protection in its consolidated balance sheets as a liability. The liability is revalued at each reporting period and changes in fair value are recognized currently in the consolidated statements of operations and comprehensive loss. The initial recognition and subsequent changes in fair value of the derivative warrant liability have no effect on the Company's consolidated cash flows.

The derivative warrants outstanding at July 31, 2016 are all currently exercisable with a weighted-average remaining life of 2.1 years.

The revaluation of the warrants at the end of the respective reporting periods resulted in the recognition of a gain of $314,569 within the Company's consolidated statements of operations and comprehensive loss for the fiscal year ended July 31, 2016 and a gain of $626,763 within the Company's consolidated statements of operations and comprehensive loss for the fiscal year ended July 31, 2015, which are included in the consolidated statement of operations and comprehensive loss under the caption "Change in fair value of derivative liabilities". The fair values of the warrants at July 31, 2016 and 2015 were $2,048,846 and $2,363,415, respectively, which are reported on the consolidated balance sheets under the caption "Derivative Warrant Liability". The following summarizes the changes in the value of the derivative warrant liability from August 1, 2014 until July 31, 2016:

	Value	No. of Warrants
Balance at August 1, 2014 – Derivative warrant liability	$2,635,643	239,788,852
Additional warrants from price protection features of existing warrants	2,111,077	239,788,852
Additional warrants issued in June 2015 financing	354,535	33,333,333
Decrease in fair value of derivative warrant liability	(2,737,840)	n/a
Balance at July 31, 2015 – Derivative warrant liability	2,363,415	512,911,037
Forfeited or expired	(455,573)	(129,033,516)
Increase in fair value of derivative warrant liability	141,004	n/a
Balance at July 31, 2016 – Derivative warrant liability	$2,048,846	383,877,521

Fair Value Assumptions Used in Accounting for Derivative Warrant Liability

The Company has determined its derivative warrant liability to be a Level 2 fair value measurement and has used the binominal lattice pricing model to calculate the fair value as of July 31, 2016 and July 31, 2015. The binomial lattice model requires six basic data inputs: the exercise or strike price, time to expiration, the risk free interest rate, the current stock price, the estimated volatility of the stock price in the future, and the dividend rate. Because the warrants contain the price protection feature, the probability that the exercise price of the warrants would decrease as the stock price decreased was incorporated into the valuation calculations. The key inputs used in the July 31, 2016 and July 31, 2015 fair value calculations were as follows:

	July 31, 2016		July 31, 2015	
Current exercise price	$0.015		$0.015	
Time to expiration	2.1 years		2.5 years	
Risk-free interest rate	0.76	%	1.08	%
Estimated volatility	101	%	82	%
Dividend	-0-		-0-	
Stock price at period end date	$0.008		$0.010	

Fair Value Assumptions Used in Accounting for Derivative Additional Investment Rights Liability

The Company has determined the derivative additional investment rights liability to be a Level 2 fair value measurement and has used the binominal lattice pricing model to measure the fair value. The additional investment rights from the March 2014 Series F financing expired in March 2015 and their value at July 31, 2016 is zero. The fair value of the derivative liability associated with the additional investment rights was determined to be $193,408 (June 2015 Series G financing) and $142,662 (June 2015 Series G financing) at July 31, 2016 and 2015, respectively.

The key inputs used in the fair value calculation at July 31, 2016 and 2015 were as follows:

	July 31, 2016	July 31, 2015
Underlying number of units of convertible preferred stock	500	500
Underlying number of units of warrants	33,333,333	33,333,333
Current exercise price of warrants	$0.015	$0.015
Current conversion price of preferred stock	$0.015	$0.015
Time to expiration	0.05 years	1.05 years
Risk-free interest rate	0.38 %	0.30 %
Estimated volatility	13 %	79 %
Dividend	-0-	-0-
Stock price at period end date	$0.008	$0.010

The revaluation of the additional investment rights in the fiscal year ended July 31, 2016, resulted in the recognition of a loss of $50,746 and in the fiscal year ended July 31, 2015, the revaluation resulted in the recognition of a gain of $861,474. The gains and losses are recorded within the Company’s consolidated statements of operations and comprehensive loss under the caption “Change in fair value of derivative liabilities”.

Note 10 - Stockholders' Deficiency:

Warrants

As of July 31, 2016, the Company has the following warrants to purchase common stock outstanding:

Number of Shares to be Purchased*	Warrant Exercise Price per Share	Warrant Expiration Date
54,545,440	$ 0.015	September 30, 2016
11,350,454	$ 0.015	February 1, 2017
9,999,998	$ 0.015	August 10, 2017
16,648,288	$ 0.015	December 12, 2017
68,333,338	$ 0.015	June 17, 2018
51,333,336	$ 0.015	January 15, 2019
138,333,334	$ 0.015	March 27, 2019
33,333,333	$ 0.015	June 25, 2020
383,877,521		

* All outstanding warrants are subject to price protection provisions as described below.

There are 383,877,521 warrants outstanding as of July 31, 2016. During the fiscal year ended July 31, 2016, 129,033,516 warrants, which had an exercise price of $0.015 per warrant, expired. There were no warrants exercised for the fiscal year ended July 31, 2016. The outstanding warrants at July 31, 2016 have a weighted average exercise price of $0.015 per share and have a weighted average remaining life of 2.1 years.

As of July 31, 2016, the Company has 383,877,521 warrants with a current exercise price of $0.015 which have price protection provisions that allow for the reduction in the current exercise price upon the occurrence of certain events, including the Company's issuance of common stock or securities convertible into or exercisable for common stock, such as options and warrants, at a price per share less than the exercise price then in effect. For instance, if the Company issues shares of its common stock or options exercisable for or securities convertible into common stock at an effective price per share of common stock less than the exercise price then in effect, the exercise price will be reduced to the effective price of the new issuance. Simultaneously with any reduction to the exercise price, the number of shares of common stock that may be purchased upon exercise of each of these warrants shall be increased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of warrants shall be the same as the aggregate exercise price in effect immediately prior to such adjustment. There are a limited number of permitted types of stock and equity instrument issuances for each series of warrants which will not invoke the price protection provisions of these warrants. The conversion price for all previously outstanding warrants was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock financing on June 24,

2015 and the total number of previously outstanding warrants increased from 239,788,852 to 479,577,704, in addition to the 33,333,333 warrants issued in the financing.

The Company accounts for the warrants with price protection provisions in accordance with FASB ASC Topic 815 as described in *Note 9 - Derivative Liabilities* above. As of July 31, 2016, there were a total of 383,877,521 warrants with an estimated fair value of $2,048,846, which are identified on the consolidated balance sheets under the caption "Derivative Warrant Liability".

Preferred Stock

The Company has authorized 1,000,000 shares of preferred stock with a par value of one-tenth of a cent ($.001) per share. The preferred stock may be issued in various series and shall have preference as to dividends and to liquidation of the Company. The Company's Board of Directors is authorized to establish the specific rights, preferences, voting privileges and restrictions of such preferred stock, or any series thereof. At July 31, 2016, 120 shares of the Company's non-voting Series F 9% Convertible Preferred Stock and 500 shares of the Company's non-voting Series G 9% Convertible Preferred Stock were issued and outstanding. At July 31, 2015, 670 shares of the Company's non-voting Series F 9% Convertible Preferred Stock and 500 shares of the Company's non-voting Series G 9% Convertible Preferred Stock were issued and outstanding. See *Note 8 - Series A, B, C, D, E, F and G 9% Convertible Preferred Stock*.

Equity Instruments Issued for Services Rendered

During the years ended July 31, 2016 and 2015, the Company issued stock options, warrants and shares of common stock in exchange for services rendered to the Company. The fair value of each stock option and warrant was valued using the Black Scholes pricing model which takes into account as of the grant date the exercise price and expected life of the stock option or warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk free interest rate for the term of the stock option or warrant. Shares of common stock are valued at the quoted market price on the date of grant. The fair value of each grant was charged to the related expense in the consolidated statement of operations for the services received (see Note 11).

Note 11 – Stock-Based Compensation:

Stock Option Plans

As of July 31, 2016, the Company had two stockholder-approved stock incentive plans under which shares and options exercisable for shares of common stock have been or may be granted to employees, directors, consultants and advisors. A total of 12,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the 2001 Plan) and 135,000,000 shares of common stock are reserved for issuance under the 2006 Stock Plan as amended (the 2006 Plan). At July 31, 2016, there were 4,138,916 and 64,484,808 shares of common stock reserved for future awards under the 2001 Plan and 2006 Plan, respectively. The Company issues new shares of common stock from the shares reserved under the respective Plans upon conversion or exercise of options and issuance of restricted shares.

The 2001 and 2006 Plans (the Plans) are administered by the Board of Directors (the Board). The Board 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 Board is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Board.

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 were Non-Qualified Options. In addition, the 2006 Plan also provides for restricted stock grants.

Share-based employee compensation related to stock options for the years ended July 31, 2016 and 2015 amounted to $30,297 and $0 for each year and were charged to the consolidated statements of operations and comprehensive loss. In addition, during 2016 the Company issued 15,393,364 stock options in satisfaction of deferred compensation amounts totalling $123,147 owing to executives at that time (2015 – nil). Share-based employee compensation related to common stock grants for the years ended July 31, 2016 and 2015 amounted to $0 for both fiscal years.

The fair value of each option granted is estimated on the grant date using the Black-Scholes option pricing model or the value of the services provided, whichever is more readily determinable. The Black-Scholes option pricing model 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 Black-Scholes option pricing model was not used to estimate the fair value any option grants in the fiscal years ended July 31, 2016 and 2015.

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

	Options	Weighted Average Exercise Price per Share
Outstanding - July 31, 2014	37,964,390	$ 0.06
Forfeited or expired	(1,315,000)	$ 0.69
Exercised	(6,416,316)	$ 0.001
Outstanding - July 31, 2015	30,233,074	$ 0.05
Granted	18,345,768	$ 0.001
Forfeited or expired	(3,000,000)	$ 0.28
Exercised	(25,939,365)	$ 0.001
Outstanding - July 31, 2016	19,639,477	$ 0.03
Exercisable - July 31, 2016	19,639,477	$ 0.03

The 19,639,477 outstanding options at July 31, 2016 had a weighted average remaining contractual term of 2.79 years.

There were no non-vested common stock options granted, vested or forfeited under the Plan for the fiscal year ended July 31, 2016. As of July 31, 2015, the Company did not have any unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan.

During the twelve months ended July 31, 2016, the Company granted 18,345,768 options to executives, employees and directors in full and final payment of obligations to pay such individuals deferred salary or director fees. The options were issued in lieu of cash payment of deferred compensation amounts due to such individuals. The stock options had an exercise price equal to $0.001 per share and were made pursuant to the terms of the Company's 2006 Stock Plan. The options were fully vested at the dates of the grants and expire on the fifth anniversary of the respective dates of grant. The grants were valued at the amount of deferred compensation owed to each such individual. The Company did not grant any options during the twelve months ended July 31, 2015.

The following table summarizes information on stock options outstanding at July 31, 2016:

	Options Outstanding and Options Exercisable			
Range of Exercise Price	Number Outstanding at July 31, 2016	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value

$0.001	18,789,477	$0.001	2.76	
$0.64	850,000	$0.64	3.61	
	19,639,477	$0.029	2.79	$129,647

	For the Years Ended July 31,	
	2016	2015
Aggregate Intrinsic Value of Options Exercised	$363,151	$129,908
Cash Received for Exercise of Stock Options	$2,952	$6,416

The intrinsic value is calculated as the difference between the market value as of July 31, 2016 and 2015 and the exercise price of the shares on the respective dates. The market values as of July 31, 2016 and 2015 were $0.079 and $0.010, respectively, based on the high and low bid information for July 31, 2016 and 2015.

Note 12 - Net Loss per Share:

Basic loss per share (“EPS”) and Diluted EPS for the years ended July 31, 2016 and 2015 have been computed by dividing the net loss available to common stockholders for each respective period by the weighted average shares outstanding during that period. All outstanding options, warrants, non-vested restricted stock and shares to be issued upon conversion of the outstanding convertible preferred stock, representing approximately 456,010,331 and 642,204,110 incremental shares, have been excluded from the respective 2016 and 2015 computation of diluted EPS as they are anti-dilutive.

Note 13 - Segment Information:

The Company follows FASB ASC Topic 815 which 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. This Topic also establishes standards for related disclosures about products and services, geographic areas, and major customers.

This Topic uses a management approach for determining segments. The management approach designates the internal organization that is used by management for making operating decisions and assessing performance as the source of the Company's reportable segments. The Company's management reporting structure provides for only one segment: the research, development and commercialization of drug delivery systems and technologies for metabolic and immunological diseases.

The countries in which the Company had identifiable assets are presented in the following table. Identifiable assets are those that can be directly associated with a geographic area.

	2016	2015
Identifiable Assets		
Canada	$25,930	$1,004,337
United States	344	1,229,753
Total	$26,274	$2,234,090

Note 14 – Quarterly Information (Unaudited):

The following schedule sets forth certain unaudited financial data for the preceding eight quarters ending July 31, 2016. 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, 2016:				
Revenues, net	$-0-	$-0-	$-0-	$-0-

Operating loss	$(1,317,579)	$(157,532)	$(144,298)	$(283,159)
Net income/(loss)	$(1,731,265)	$(47,390)	$918,361	$(2,362,815)
Net income/(loss) available to common stockholders	$(1,731,265)	$(47,390)	$918,361	$(2,362,815)
Net income/(loss) per share	$(0.0020)	$(0.0001)	$0.0010	$(0.0027)

Fiscal Year July 31, 2015:

Revenues, net	$-0-	$-0-	$-0-	$-0-
Operating loss	$(908,469)	$(835,147)	$(851,601)	$(967,797)
Net income/(loss)	$49,623	$(511,916)	$(1,396,157)	$(334,908)
Net income/(loss) available to common stockholders	$49,623	$(511,916)	$(1,396,157)	$(674,491)
Net loss per share	$0.0001	$(0.0006)	$(0.0018)	$(0.0008)

Note 15 - Subsequent Events:

On August 26, 2016, the Company signed a Letter of Intent to acquire 51% of Hema Diagnostic Systems, LLC ("HDS") for consideration of $250,000 worth of the Company's restricted common stock. The number of stock issued for the transaction will be calculated based on the average over-the-counter closing price of the Company's common stock for the ten trading days immediately preceding the Closing Date. The Company will also issue, in consideration for the purchase, a warrant to acquire 15,000,000 shares of Generex common stock, at a per-share strike price equal to the over-the-counter closing price of the Company's stock on the date that the restricted common stocks were issued. It is the Company's intention to initiate a reverse stock-split following the acquisition of HDS. This acquisition of HDS has not been finalized as at the date of yet, and it is expected to finalize during the fiscal year 2017.

On December 27, 2016, the Company filed a Certificate of Amendment to effect a reverse stock split. Upon approval by the Financial Industry Regulatory Authority ("FINRA"), each 1,000 shares of the Company's common stock issued and outstanding at the effective time shall automatically be combined into one issued, fully paid and non-assessable share of common stock. This potential reverse stock-split has not been reflected in the share or per share amounts disclosed in these consolidated financial statements.

The Company has evaluated subsequent events occurring after the balance sheet date through the date the consolidated financial statements were issued.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Prior to the filing of this Annual Report on Form 10-K, an evaluation was performed under the supervision of and with the participation of the Company's management, including the Chief Executive Officer who is performing the functions of the Company's principal executive officer and principal financial officer, of the effectiveness of the Company's disclosure controls and procedures. Based on the evaluation, the Chief Executive Officer has concluded that, as of July 31, 2016, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to the Company's management, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended July 31, 2016, there were no changes in the Company's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Generex Biotechnology Corporation (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

(ii)

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management did not the effectiveness of the Company's internal control over financial reporting as of July 31, 2016.

As of July 31, 2015, the Company became eligible to report as a smaller reporting company. As a smaller reporting company under the SEC rules and regulations, we are currently not subject to the requirements of independent auditor attestation of management's assessment of our internal controls over financial reporting set forth in Section 404(b) of the Sarbanes Oxley Act of 2002 because the Dodd Frank Wall Street Reform and Consumer Protection Act signed into law on July 21, 2010 permanently exempted companies that are not "accelerated filers" or "large accelerated filers" under the SEC rules from Section 404(b) requirements; therefore, this Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting.

Item 9B. Other Information.

Reference is made to the disclosure set forth under the caption *Sales of Unregistered Securities* in Item 5 of this Annual Report on Form 10-K, which is incorporated by reference herein.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

EXECUTIVE OFFICERS AND DIRECTORS OF GENEREX

Name	**Age**	Position Held with Generex	Director Since
Mark A. Fletcher	50	President/Chief Executive Officer, Principal Financial Officer, General Counsel and Director	June 2011
Brian T. Magee	54	Independent Director	March 2004
Dr. David Brusegard	72	Chief Operating Officer and Secretary	N/A
James M. Anderson, Jr.	68	Independent Director	June 2011

Mark A. Fletcher, Esq. has served as our President and Chief Executive Officer since March 2011. Since the second quarter of fiscal 2016, he has performed the functions of our principal financial officer following the layoff of Stephen Fellows, our former Chief Financial Officer. Mr. Fletcher was elected to serve as a member of the Board of Directors at our annual meeting of stockholders held on June 8, 2011. Mr. Fletcher was appointed interim President and Chief Executive Officer on September 29, 2010 to succeed Anna E. Gluskin, who was terminated as President and Chief Executive Officer on that date. On September 29, 2010, Mr. Fletcher was also appointed Secretary and served as such until June 8, 2011. He served as Executive Vice President and General Counsel since April 2003, and he continues in his role as General Counsel. From October 2001 to March 2003, Mr. Fletcher was engaged in the private practice of law as a partner at Goodman and Carr LLP, a leading Toronto law firm. From March 1993 to September 2001, Mr. Fletcher was a partner at Brans, Lehun, Baldwin LLP, a law firm in Toronto. Mr. Fletcher received his LL.B. from the University of Western Ontario in 1989 and was admitted to the Ontario Bar in 1991.

Brian T. McGee. Independent Director since March 2004. Mr. McGee has previously served as Chairman of the Generex Audit Committee and a member of the Generex Compensation Committee and the Generex Corporate Governance and Nominating Committee. Mr. McGee has been a partner of Zeifmans LLP ("Zeifmans") since 1995. Mr. McGee began working at Zeifmans shortly after receiving a B.A. degree in Commerce from the University of Toronto in 1985. Zeifmans is a Chartered Accounting firm based in Toronto, Ontario. A significant element of Zeifmans' business is public corporation accounting and auditing. Mr. McGee is a Chartered Accountant. Throughout his career, Mr. McGee has focused on, among other areas, public corporation accounting and auditing. In 1992, Mr. McGee completed courses focused on International Taxation and Corporation Reorganizations at the Canadian

Institute of Chartered Accountants and in 2003, Mr. McGee completed corporate governance courses on compensation and audit committees at Harvard Business School. In April 2004 Mr. McGee received his CPA designation from The American Institute of Certified Public Accountants. Mr. McGee has received a certificate in International Financial Reporting Standards issued by The Institute of Chartered Accountants in England and Wales in 2010. The Board believes that Mr. McGee's knowledge and understanding of accounting and finance, his education and training in accounting and corporate governance, and his extensive experience in the accounting industry

David Brusegard, Ph.D. has served as Chief Operating Officer since March 2011 and was appointed Secretary on June 8, 2011. Dr. Brusegard served as a consultant to Generex from March 2010 to March 2011. From 2007 to March 29, 2011, Dr. Brusegard held the position of President of The OSLO Group, his consulting firm. He served as Chief Executive Officer of the Pentius Group from 2004 to 2007. The Pentius Group was a five-company group which designed, sold, and marketed health insurance, and operated a managed care facility staffed with nurses supervised by physician directors. Pentius Group's company assets were sold in 2007 to Canam Insurance of Windsor, Ontario. Dr. Brusegard has a breadth of experience in several fields, including, medical record design, health informatics, health insurance, digital mapping, database design, global positioning systems applications, business management and strategic planning. He was a senior economist at Statistics Canada for a decade, an adjunct professor at the University of Toronto and taught information ethics and information law at Ryerson University. He has consulted internationally on information management for the World Bank as well as major consumer packaged goods companies, hospitals, municipalities, and all levels of government. Other recent positions of note include; Vice President, Analytics for ICOM Communication and Information, President of Geographic Decision Support Systems, and CEO, Tristar Software. Dr. Brusegard performed his graduate work at The University of North Carolina at Chapel Hill, and the University of Calgary from which he holds a Ph.D. Phil., awarded in 1976.

Dr. James H. Anderson, Jr. Independent Director since June 2011. Dr. Anderson has previously served as Chairman of the Corporate Governance and Nominating Committee and a member of the Generex Compensation Committee, and has served on the Generex Scientific Advisory Board since October 2010. Dr. Anderson is a diabetologist and endocrinologist who has been in the pharmaceutical industry for over 25 years. He is currently CEO and President of Symcopeia, a private drug discovery and development company focused on new mechanisms of action for the treatment of diabetes mellitus, and diabetes related obesity and cardiovascular diseases. Dr. Anderson also serves as medical director of PTS Diagnostics, a cardiometabolic medical device company. From 2005 to 2009, Dr. Anderson served as Senior Medical Director for Diabetes and Cardiometabolic Medicine with Eli Lilly and Company and had medical responsibility for diabetes and cardiometabolic drug development, and drove the clinical development, registration and launch of two families of diabetes care products, Humulin® and Humalog. At Eli Lilly, Dr. Anderson contributed to the inventions of the first recombinant DNA produced human insulin analog products, led multiple clinical drug development projects, was responsible for 6 US NDAs and had clinical responsibility for all insulin products worldwide. Dr. Anderson is an elected Fellow of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK, was a founding board member of the American Association of Pharmaceutical Physicians and is a Fellow of the American College of Endocrinology. Dr. Anderson has been active in the American Diabetes Association and is a member of the International Diabetes Federation, the European Association for the Study of Diabetes, and the Endocrine Society. Dr. Anderson is a founding editorial board member of two journals for diabetes, and serves on the editorial boards or as a reviewer for 5 other diabetes/endocrine journals. Dr. Anderson is a Clinical Associate Professor of Medicine for the Division of Endocrinology and Metabolism at the Indiana University School of Medicine and was awarded an M.D. from the LSU School of Medicine. Dr. Anderson attained the rank of Lieutenant Colonel in the US Army Medical Corps and during his military career, he served as the Chairman, Department of Clinical Investigation at the Army's largest healthcare center, and Chief of the Medical Division of the US Army Medical Research Institute for Infectious Diseases. The Board believes that Dr. Anderson's extensive experience in the pharmaceutical industry, his experience in the diabetes and endocrinology fields, combined with his business experience and judgment, provide our Board with valuable scientific and operational expertise.

There are no family relationships among our officers and directors.

Other Key Employees and Consultants

Eric von Hofe, Ph.D. Dr. von Hofe is currently President of Antigen Express, Inc., a wholly-owned subsidiary of Generex. He has held this position since 2005. Since 2005, he has also been a Vice President of Generex. He served as a director of Generex from June 2011 until his resignation in August 19, 2015. He has extensive experience with technology development projects, including his previous position at Millennium Pharmaceuticals as Director of Programs & Operations, Discovery Research. Prior to that, Dr. von Hofe was Director, New Targets at Hybridon, Inc., where he coordinated in-house and collaborative research that critically validated gene targets for novel antisense medicines. Dr. von Hofe also held the position of Assistant Professor of Pharmacology at the University of Massachusetts Medical School, where he received a National Cancer Institute Career Development Award for defining mechanisms by which alkylating carcinogens create cancers. He received his Ph.D. from the University of Southern California in Experimental Pathology and was a postdoctoral fellow at both the University of Zurich and Harvard School of Public Health. His work has been published in forty-eight articles in peer-reviewed journals, and he

has been an inventor on four patents.

Scientific Advisory Board

Dr. Gerald Bernstein, M.D., F.A.C.P. graduated from Dartmouth College and Tufts University School of medicine. He is board certified in internal medicine (1966) and endocrinology and metabolism (1973). He entered practice in 1966 after completing a research fellowship. Dr. Bernstein is an associate clinical professor at Albert Einstein College of Medicine in New York. He was an attending physician at Beth Israel Medical Center, Lenox Hill Hospital and Montefiore Medical Center. He served on the National Board of Directors of the American Diabetes Association, its research foundation and many national committees. Dr. Bernstein is a past president of the American Diabetes Association and was Director of the Beth Israel Health Care Systems Diabetes Management Program. He is currently Director of the Diabetes Management Program of The Friedman Diabetes Institute at Beth Israel Hospital in New York. He has served as Vice President for Medical Affairs at Generex Biotechnology Corp. since 2001 and served as a Director of Generex from October 2002 to May 2008.

Dr. Craig Eagle attended medical school at the University of New South Wales, Sydney, Australia and received his general internist training at Royal North Shore Hospital in Sydney. He completed his hemato-oncology and laboratory hematology training at Royal Prince Alfred Hospital in Sydney. He was granted Fellowship in the Royal Australasian College of Physicians (FRACP) and the Royal College of Pathologists Australasia (FRCPA). After his training he performed basic research at the Royal Prince of Wales hospital to develop a new monoclonal antibody to inhibit platelets. He joined Pfizer Australia in 2001 as part of the medical group. In Australia, his role involved leading and participating in scientific research, regulatory and pricing & re-imbursement negotiations for compounds in therapeutic areas including oncology, anti-infectives, respiratory, arthritis and pain management. In 2003, Pfizer relocated Dr. Eagle to the United States where he was appointed as the world wide lead for development of celecoxib in oncology to oversee the global research program. Since that time he has had increasing responsibility for overseeing the global research plans and teams for irinotecan and dalteparin. In 2007, he became head of the oncology therapeutic area global medical group for Pfizer, including the US oncology business. Dr. Eagle has led, or been directly involved with, teams that resulted in eight new products or indications. As part of his current role at Pfizer, he has led the integration of the Pfizer/Wyeth oncology businesses and portfolio.

Generex has adopted a code of ethics that applies to its directors and the following executive officers: the President, Chief Executive Officer, Chief Financial Officer (principal financial/accounting officer), Chief Operating Officer, any Vice-President, Controller, Secretary, Treasurer and any other personnel performing similar functions. We also expect any consultants or advisors whom we retain to abide by this code of ethics. The Generex Code of Ethics has been posted on Generex's Internet web site - *www.generex.com*.

Non-Employee Directors' Compensation

Our non-employee directors waived all compensation in our last fiscal year in light of our financial condition; thus, no cash or other compensation was paid to any of our directors in the fiscal year ended July 31, 2016.

Our policy for compensation of non-employee directors in the past was as follows.

- Non-employee directors (other than the non-executive chairman of the board) receive an annual cash based retainer of $40,000.

- The non-executive chairman of the board receives an annual cash based retainer of $100,000 per year.

- At the discretion of the full Board of Directors, nonemployee directors may receive stock options to purchase shares of our common stock or shares of restricted stock each fiscal year. The number and terms of such options or shares is within the discretion of the full Board of Directors.

- Nonemployee directors serving on committees of the Board of Directors receive additional cash compensation as follows:

Committee	***Chairperson***	***Member***
Audit Committee	$15,000	$5,000
Compensation Committee	$10,000	$5,000
Governance & Nominating Committee	$5,000	$2,000

Directors who are officers or employees of Generex or its subsidiaries do not receive separate consideration for their service on the Board of Directors. The compensation received by Mr. Fletcher as an employee of Generex is shown in the Summary Compensation Table elsewhere in this proxy statement. The compensation received by Dr. von Hofe as an employee of our subsidiary Antigen is shown in the Director Compensation Table below under “All Other

Compensation".

Fiscal Year 2016 Director Compensation Table

Name	**Fees Earned or Paid in Cash**	**Stock Awards** (1)	**Option Awards**(2)	All Other Compensation	Total
Brian T. McGee	$ 0	$ 0	$ 0	$ 0	$0
James H. Anderson	$ 0	$ 0	$ 0	$ 0	$0
Eric von Hofe	$ 0	$ 0	$ 0	$ [] (3)	$[ ]

(1) There were no restricted stock awards to directors in fiscal year 2016. As of July 31, 2016, the aggregate number of shares underlying stock awards previously granted to each non-employee director was as follows: Mr. McGee (150,000).

(2) There were no incentive stock options granted to the directors in fiscal 2016. At fiscal year-end, the total number of stock options, inclusive of the stock options related to the salary deferrals in the tables above, held by each non-employee director was as follows: Mr. McGee (3,240,417) and Dr. Anderson (3,564,341). Dr. von Hofe, who is an employee of our subsidiary Antigen, held 12,084,709 options at fiscal year-end.

(*) Includes payments received as a member of the Scientific Advisory Board of $5,000 per month for the period from August 2015 through July 2016 which was paid in cash.

(3) Represents employment income earned as president of Antigen for the fiscal year ended July 31, 2016. On October 26, 2015, the Board of Directors approved the stock option grants to certain of Company's executive officers, including Dr. von Hofe, in full and final payment of the Company's obligation to pay such individuals deferred salary as of October 15, 2015. Dr. von Hofe received options exercisable for 7,610,911 shares at $0.001 per share, in exchange for $60,887 in accrued salary. The options were fully vested upon issuance and exercisable for 5 years after issuance.

CORPORATE GOVERNANCE

Code of Ethics

Generex has adopted a code of ethics that applies to its directors and the following executive officers: the President, Chief Executive Officer, Chief Financial Officer (principal financial/accounting officer), Chief Operating Officer, any Vice-President, Controller, Secretary, Treasurer and any other personnel performing similar functions. We also expect any consultants or advisors whom we retain to abide by this code of ethics. The Generex Code of Ethics has been posted on Generex's Internet web site - *www.generex.com*.

Board Structure; Risk Oversight; Risk Assessment of Compensation Policies and Practices

The business affairs of Generex are managed under the direction of our Board of Directors. The Board is actively involved in oversight of risks that could affect Generex. In the past, this oversight was conducted primarily through the separate standing committees of the Board. In fiscal 2016, due to attrition of Board members, the separate standing committees of the Board have ceased functioning as such. Thus, the the full Board has retained responsibility for oversight of risks. The Board satisfies this responsibility through regular reports directly from officers responsible for oversight of particular risks within Generex. The Board believes its administration of its risk oversight function has not affected the Board's leadership structure.

Board Meetings; Board Committees; Annual Meeting Attendance

During the fiscal year ended July 31, 2016, the Board of Directors did not meet or take action by consent other than in connection with filing of the Company’s Annual report on From 10-K for the Fiscal Year ended July 31, 2015 and to issue woptions to executives in lieu of accrued compensation, as discussed elsewhere in this Annual report. . No Board committees held meetings meetings in Fiscal 2016..

Due to the Company’s current exceptional circumstances, including the attrition of directors over the last two fiscal years and the Company’s limited operations and diminished financial condition, the Board’s established standing Audit Committee, Compensation Committee and Corporate Governance and Nominating Committee have ceased functioning as such, and the full Board is acting in the capacity of these committees, except to the extent that

Mr.Fletcher abstains from determinations regarding executive compensation for the principal executive officer. The Board of Directors currently consists of three members. Mr. McGee and Dr. Anderson are “independent” as defined under applicable rules of the SEC and The NASDAQ Stock Market LLC. Mr. McGee and Dr. Anderson also satisfied the separate SEC independence requirement, which provides that members of the Audit Committee may not accept directly or indirectly any consulting, advisory or other compensatory fee from Generex or any of its subsidiaries other than their directors’ compensation. .Mr. Fletcher is not independent under NASDAQ Listing Rules because he serves as our President, Chief Executive Officer, General Counsel and our principal financial officer.

Audit Committee

During fiscal 2016, the full Board acted as the Audit Committee.

The Audit Committee reviews and discusses with Generex's management and its independent auditors the audited and unaudited financial statements contained in Generex's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively. Although Generex's management has the primary responsibility for the financial statements and the reporting process, including the system of internal controls and disclosure controls and procedures, the Audit Committee reviews and discusses the reporting process with management on a regular basis. The Audit Committee also discusses with the independent auditors their judgments as to the quality of Generex's accounting principles, the reasonableness of significant judgments reflected in the financial statements and the clarity of disclosures in the financial statements, as well as such other matters as are required to be discussed with the Audit Committee under generally accepted auditing standards. Our Board of Directors has determined that at least one person, Mr. McGee, serving on the Audit Committee is an "audit committee financial expert" as defined under Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee has adopted a written charter, which was amended on October 30, 2003. A copy of the Audit Committee charter was attached as *Appendix A* to the proxy statement filed on April 1, 2014.

Compensation Committee

In fiscal 2016, the full Board assumed the responsibilities of the Compensation Committee except that Mr. Fletcher did not participate in determinations regarding the compensation to be paid him in his role as a named executive officer of the Company.

The Compensation Committee has responsibility for reviewing and recommending to the Board of Directors compensation programs and policies for our President and Chief Executive Officer, General Counsel, our Chief Operating Officer and Secretary and our former Chief Financial Officer and Treasurer, who comprised Generex's executive management team during fiscal 2016. The Compensation Committee has the authority to use a compensation consultant to assist the Compensation Committee in the evaluation of the compensation of our executive management team and other executive officers and to consult with other outside advisors to assist in its duties to the Company. The Compensation Committee does not have a written charter.

The Compensation Committee does not delegate its authority. Executive officers (other than Mr. Fletcher) do not attend meetings of the Compensation Committee. The Compensation Committee does not have a charter. It has the authority to use a compensation consultant to assist the Compensation Committee in the evaluation of the compensation of our executive management team and other executive officers and to consult with other outside advisors to assist in its duties to the Company, but in fiscal 2016 it did not engage any compensation consultants or engage in benchmarking activities.

Corporate Governance and Nominating Committee

In fiscal 2016, we did not have a separate standing Corporate Governance and Nominating Committee, and no action was taken by the full Board functioning as the Committee. The Corporate Governance and Nominating Committee has a charter, which was adopted on May 29, 2007. A copy of the charter was attached as *Appendix B* to the proxy statement filed on April 1, 2014.

The Corporate Governance and Nominating Committee will consider candidates whom the stockholders of Generex put forward. The name, together with the business experience and other relevant background information of a candidate, should be sent to David Brusegard, Secretary of Generex, at Generex's principal executive offices located at 4145 North Service Road, Suite 200, Burlington, Ontario, Canada L7L 6A3. Mr. Brusegard will then submit such information to the chair of the Corporate Governance and Nominating Committee for the Committee's review and consideration. The process for determining whether to nominate a director candidate put forth by a stockholder is the same as that used for reviewing candidates submitted by directors. After full consideration, the stockholder proponent will be notified of the decision of the committee.

The Corporate Governance and Nominating Committee is responsible for seeking to identify director candidates with the highest personal and professional ethics, integrity and value and diverse experience in business, finance, pharmaceutical and regulatory matters, and other matters relevant to a company such as Generex and who have sufficient time to devote to the company's affairs. The charter of the Corporate Governance and Nominating Committee sets forth the policy with regard to the consideration of diversity in identifying director nominees and calls for periodic review of director recruitment and selection protocols so that diversity remains a component of any

director search. The Corporate Governance and Nominating Committee is charged with developing a formal list of qualifications for members of the Board of Directors as mandated by its charter and criteria to assist the Board in attaining diversity of background and skills in director candidates, but the Committee has yet to develop such a list or criteria. To date, the Corporate Governance and Nominating Committee has not engaged any third party to assist it in identifying director candidates.

In accordance with our bylaws, the Board of Directors is permitted to increase the number of directors and to fill the vacancies created by the increase until the next annual meeting of stockholders.

Item 11. Executive Compensation.

Compensation, Discussion & Analysis

Compensation Philosophy

We did not had sufficient resources to pay any cash compensation to our named executive officers in fiscal 2016 or subsequently through the date of this Annual Report, and did not pay compensation of any kind to our executive officers in fiscal 2016 other than certain options issued in October, 2015, in satisfaction of accrued salary, as discussed in detail below. Due to the Company's current exceptional circumstances, including the attrition of directors over the last two fiscal years and the Company's limited operations and diminished financial condition, our full Board assumed the responsibilities of the Compensation Committee in the fiscal year ended July 31, 2016.

The following discussion of our philosophy assumes we have the resources to follow that philosophy.

We are a development stage company focused on research, development, and commercialization of our proprietary drug delivery platform for administration of large molecule drugs to the oral cavity through a hand-held aerosol spray applicator. We are in the process of developing proprietary formulations of drugs that can be delivered through an oral spray thereby eliminating the need for injections and have focused on our Oral-lyn™ insulin formulation, which is administered as a spray into the oral cavity. We also have a subsidiary, Antigen Express, which focuses on developing proprietary immunomedicines.

As a development stage company, our future depends on the ability of our executives to obtain necessary regulatory approvals to launch Oral-lyn™ in key markets such as the United States, Canada, and Europe, as well as furthering the development of other products in our pipeline through the clinical trial and regulatory process. Attracting, retaining, and motivating key executives who can lead Generex through this process is critical to our success. We have a small executive team that works together closely. Our executives perform multiple roles and need to be able to respond to changing market dynamics quickly.

For these reasons, we seek to ensure that our compensation programs are competitive with similarly sized companies with which we compete for executive talent. The goals of our executive compensation program are to attract and retain top executives, to motivate executives to achieve our business objectives, to align executive and shareholder interests, and to recognize individual contributions and overall business success.

The Compensation Committee of the Board of Directors evaluates the types and amounts of compensation that it believes are appropriate for our President and Chief Executive Officer, our Chief Operating Officer and our Chief Financial Officer, who are considered Generex's policy making executives and who are listed in the Summary Compensation Table below. We refer herein to these executives as the "named executives."

In addition to the compensation of our named executives, the Compensation Committee also reviews and approves the compensation of members of our senior management, including the President of our subsidiary, Antigen Express, Inc.

Historically, the key components of our executive compensation have been base salary, cash bonuses, and equity incentives, including stock bonuses, restricted stock, and stock options awarded at the discretion of our Compensation Committee and Board of Directors. As a development stage company, we have reviewed compensation of our named executives annually and at the discretion of the Compensation Committee as warranted by our financial condition and achievement of our business goals. While the elements of compensation are considered separately, the Compensation Committee ultimately considers the value of the total compensation package provided to the individual named executive.

The Compensation Committee believes the company's compensation program must take into account the following factors:

- past levels of compensation adjustments;
- the expected transition of the company from a development stage company to an operating company;
- the nature of the regulatory approval process for the company's products; and
- the potential for growth of the company in the event that regulatory approvals are obtained.

In fiscal 2016, the Compensation Committeedid not implement any changes to base salaries for any of the named executives and did not award any equity incentive awards or cash bonuses to the named executives during fiscal 2016 for fiscal 2015 performance and contributions. The Compensation Committee has not made any determinations as to compensation or equity awards for the named executives with respect to performance or contributions for the fiscal year ended July 31, 2016.

In administering the executive compensation program, our Compensation Committee has relied upon market data provided on a periodic basis by external consultants, as well as its own understanding and assessment of executive compensation trends. In its consideration of compensation for the named executives, the Compensation Committee has reviewed compensation data for pharmaceutical and biotechnology companies in the past, market data provided by external compensation consultants, compensation data compiled by a third-party compensation data firm and publicly available executive compensation data for publicly traded companies.

Use of Compensation Consultant and Benchmarking

In the fiscal year ended July 31, 2016, the Compensation Committee did not engage any compensation consultants or engage in benchmarking activities. The Compensation Committee last undertook a comprehensive review of compensation and engaged a compensation consultant in November 2009.

Determination of Compensation

In prior years, the Compensation Committee typically made compensation determinations, including any increases in base salary for the next calendar year and any bonuses in respect of the prior fiscal year, before or during the first calendar quarter of each year. The Compensation Committee followed such a schedule in order to eliminate the need to award retroactive salary increases. In addition, the Compensation Committee has typically reviewed compensation arrangements in the first calendar quarter to ensure that compensation levels are appropriate in light of Generex’s financial position and performance at that time. Due to the current financial position of the Company, the Committee did not follow such a schedule in fiscal 2016, as there were no salary changes or bonus awards made. The company last made changes and warded bonuses prior to the end of fiscal 2013. Because of the Company’s current financial position, no increases were made to base salary, nor were any cash bonuses or stock incentive awards granted to the named executives during fiscal 2015 or 2016.

Components of Compensation

Base Salary

Base salary provides a fixed amount of compensation necessary to retain key executives. It is guaranteed compensation to the named executives for performance of core duties. Historically, base salaries for the named executives may be adjusted upon recommendation by the Compensation Committee and ratification by the Board of Directors, and annual base salaries for the named executives have been reviewed periodically relative to the base pay levels for each executive's position based on the peer group. The Compensation Committee last undertook such a review in November 2009. Levels of base salary were generally targeted at the market's second quartile (51% – 75%), but also reflect the compensation goals adopted by the Compensation Committee, operational goals determined by management, the named executive's individual performance, contribution of the named executive to overall corporate performance, and the level of responsibility of the named executive with respect to his or her specific position. The level of base salary also reflects multiple titles and additional responsibilities of the named executives driven by the operational needs of the company.

Salary adjustments for the President and Chief Executive Officer and the Chief Financial Officer were last made to base salary compensation in September 2010 and March 2011, respectively. In determining the levels of the base salary adjustments for the named executives, the Compensation Committee primarily considered the respective executive's new positions and responsibilities.

In September 2010, our Executive Vice President and General Counsel was appointed to interim President and Chief Executive Officer. The Compensation Committee recommended, and the Board of Directors approved, a base salary adjustment of $150,000 or 46% to $475,000 effective immediately. The increase was considered appropriate in relation to the assumption of the additional duties and responsibilities of the new role, in addition to his duties as General Counsel, as well as based on the comparison to peer companies prepared by the compensation consultant in fiscal 2010. For fiscal 2014, Mr. Fletcher received only $435,115 of his base salary in cash, agreeing to defer the remainder of his salary, for which we issued options to purchase shares of our common stock in lieu of cash payment of such deferred salary.

In March 2011, the Compensation Committee recommended, and the Special Committee of the Board of Directors approved a base salary adjustment of 12.5% for our VP Finance from $200,000 to $225,000, effective retroactive to January 1, 2011, in connection with his appointment to Chief Financial Officer. The increase was considered appropriate in relation to the assumption of the additional duties and responsibilities of the new role. For fiscal 2014, Mr. Fellows received only $206,250 of his base salary in cash, agreeing to defer the remainder of his salary, for which we issued options to purchase shares of our common stock in lieu of cash payment of such deferred salary.

In March 2011, the Compensation Committee recommended, and the Special Committee of the Board of Directors approved, the hiring and appointment of our Chief Operating Officer at an annual base salary of $225,000 effective immediately. The base salary was considered appropriate in relation to the salaries of our other executives and the responsibilities of the role of Chief Operating Officer. For fiscal 2014, Mr. Brusegard received only $206,250 of his base salary in cash, agreeing to defer the remainder of his salary for which we issued options to purchase shares of our common stock in lieu of cash payment of such deferred salary.

Cash Bonuses

Historically, performance-based compensation has been a key component of our compensation philosophy. In the past, cash bonuses have been provided to attract, motivate, and retain highly qualified executives on a competitive basis and provide financial incentives that promote company success. From time to time in the past, the Compensation Committee has granted bonuses to reward achievement relative to specific performance objectives. In awarding bonuses, the Compensation Committee considers various factors, including the named executive's position within Generex, attainment of specific business objectives and performance milestones, and the named executive's individual contributions thereto. The Committee exercises discretion with respect to the weight that it gives to these and other factors in determining bonuses. The Compensation Committee also retains discretion with respect to whether any bonuses are paid to the named executives, the amounts of any such bonuses, and the form of any such bonuses.

The Compensation Committee did not grant or accrue any bonuses in fiscal 2016, with respect to the fiscal year ended July 31, 2015, in consideration of the current financial position of the Company.

Long-Term Incentives and Equity Awards

Historically, our compensation program has included long-term incentive compensation in the form of equity grants subject to a vesting schedule. We believe such incentive compensation further aligns the interests of management with those of stockholders and enhances shareholder value. Currently, we do not have any long-term cash incentive programs in place for the named executives.

Long-term equity incentive grants have been discretionary. In determining whether such grants are warranted, the Compensation Committee has considered our compensation strategy, market practice concerning long-term incentives provided to executives at peer companies and within the broader market, and the named executive's specific roles within Generex. Typically, equity incentive awards were granted subject to vesting over a period of time and were not tied to specific performance measures.

Equity grants have historically been made through stock options under our various plans, including Generex's 2001 Stock Option Plan, as amended, and the Amended and Restated 2006 Stock Plan, which also allows grants of restricted stock. We consider the costs to the Company of granting stock options under Statement of Financial Accounting Standard (SFAS) 123(R) as compared to the costs to named executives of higher income tax liabilities associated with the granting of restricted stock.

There were no discretionary awards of options to purchase shares of our common stock to our named executives in fiscal 2016, with the exception of the following. The Company granted options to purchase, in the aggregate, 15,393,363 shares of our common stock to the named executives and Dr. von Hofe in full and final payment of obligations to pay such individuals deferred salary accrued during up to October 15, 2015. The options were issued in lieu of cash payment of compensation amounts due to such individuals. The number of options granted to each individual was equal to the dollar amount of deferred salary or fees due to such individual divided by $0.015. The stock options had an exercise price equal to $0.001 per share and were made pursuant to the terms of the Company's 2006 Stock Plan. The options were fully vested at on October 26, 2015 and will expire on the fifth anniversary of the date of grant. The grants were valued at the amount of deferred compensation owed to each such individual.

The number of options that the Compensation Committee recommended, and the Board of Directors approved, in respect of the above salary deferrals to the named executives described above were as follows:

	No. of Shares
Named Executive	Underlying Options
Mr. Fletcher	4,447,111
Mr. Fellows	1,667,671
Dr. von Hofe	7,610,911
Dr. Brusegard	1,667,671

Benefits and Perquisites

Named executives may participate in benefit plans that are offered generally to salaried employees such as short and long term disability, health and welfare benefits, and paid time off**.**

We provide very limited perquisites. During fiscal 2016, we did not provide any material perquisites.

We do not offer deferred compensation plans, defined benefit plans, supplemental executive retirement plans, supplemental life insurance, benefit restoration plans, or tax gross-ups on change-in-control benefits**.**

Employment and Severance Agreements

During fiscal 2016, we had terms of employment covering our President and Chief Executive Officer, as described in "Employment Agreements and Potential Payments Upon Termination or Change-In-Control", which clarify the terms and conditions of his employment. These terms provide clarity concerning the employment relationship and provide a competitive benefit level to the executive, thus promoting stability at the President and Chief Executive Officer position.

We have agreed to provide severance benefits to the President and Chief Executive Officer as set forth in the terms of his employment. The intent of such severance is to provide the President and Chief Executive Officer with financial security in the event of a covered termination (including change in control) and to thus support executive retention. To be eligible for certain benefits, including cash payments, under these arrangements, a named executive must experience a covered termination, which may include a change in control, a material reduction in executive compensation, a material change in duties, or a material breach in the agreement by Generex, The benefits payable to our President and Chief Executive Officer upon a change in control of Generex require two conditions, or "double triggers," to be satisfied: the change in control must occur, and the named executive's employment must be terminated, voluntarily or involuntarily, as a result of such event. Under the terms of employment, our President and Chief Executive Officer would receive a benefit upon a change in control only if he terminates his employment in connection with such event.

As of the end of fiscal 2016, each of the current named executive officers held stock options or restricted stock granted pursuant to either the 2001 Stock Option Plan or the 2006 Stock Plan. The 2001 Plan provides that outstanding options will become immediately exercisable and vested upon a change in control, unless the Board of Directors or its designee determines otherwise. In the event that Generex will not be the surviving corporation, the Board or its designee has flexibility under the 2001 Plan to determine how to treat stock options. The 2001 Plan does not condition the acceleration and vesting of stock options in such an event upon an option holder's termination of employment; however, the terms of the 2001 Plan provide that, unless otherwise provided by the Board or its designee, an option holder can exercise outstanding options after the date of his or her termination of employment only if the option holder voluntarily terminated employment with Generex or was terminated without cause by Generex. Under the terms of the 2006 Plan, unvested stock options and restricted stock will become exercisable or unrestricted, as applicable, thirty days prior to the change-in-control event and such acceleration is not conditioned upon the termination of a participant's employment with Generex. The 2006 Plan further provides that if Generex is not the surviving corporation as a result of a change in control, all outstanding options that are not exercised will be assumed by, or replaced with comparable options or rights by, the surviving corporation, and outstanding grants of restricted stock will be converted to similar grants of equity in the surviving corporation.

Tax and Accounting Considerations

Historically, the Compensation Committee has considered implications of tax and accounting requirements impacting compensation programs from the perspective of the Company and the individual named executives. The Compensation Committee may also consider sections of the tax code which impact Generex or individual taxpayers. For U.S. taxpayers, the Committee structures its programs to comply with Section 409A of the Internal Revenue Code.

Given the high individual income tax liabilities which result from the awarding of restricted stock to our executives who are all tax residents of Canada, the Compensation Committee expects to grant future equity awards in the form of stock options for the foreseeable future.

Compensation Committee Report

The full Board of Directors of Generex Biotechnology Corporation performing the functions of the Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with management and, based on such review and discussions, the full Board of Directorsrecommended and determined that the Compensation Discussion and Analysis be included in Generex's Annual Report on Form 10-K for the year ended July 31, 2016 and in the proxy statement for the 2017 annual meeting.

THE BOARD OF DIRECTORS

Brian T. McGee

James H. Anderson, Jr.

Mark A. Fletcher

Executive Compensation Tables

The following executive compensation tables pertain to the fiscal year ended July 31, 2016. Therefore, the tables contain information relating to the named executives who served as of the fiscal year end and refer to the positions held by such named executives as of July 31, 2016.

Summary Compensation Table

The following table provides information concerning compensation of Generex's named executives for Generex's last two completed fiscal years ending July 31, 2016 and 2015. In respect of those fiscal years, the named executives did not receive compensation in the form of non-equity incentive plan compensation or changes in pension value or non-qualified deferred compensation earnings. Therefore, the table below does not include columns for these types of compensation.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Mark A. Fletcher, President & Chief Executive Officer	2016	$ [XX] (1)(2)	$—	$—	$70,193 (2)	$—	$70,193
	2015 (1)	465,000 (1)(2)	—	—	$[]	—	$485,000
Stephen Fellows, Chief Financial Officer	2016	$0 (3)(4)	—	—	$26,477 (2)	—	$26,477
	2015 (3)	$225,000 (3)(4)	—	—	$[]	—	$[]
David Brusegard, Chief Operating Officer	2016	$0 (3)(4)	—	—	$26,477 (2)	—	$26,477
	2015	$157,363 (3)(4)	—	—	$82,212 (2)	—	$239,575

*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 average Canadian/U.S. dollar exchange rate for the years ended July 31, 2016 and 2015**.**

(1) This amount reflects a base salary of $475,000 in 2015. The amount reflects a car allowance of approximately $10,000 USD per year paid to the executive in Canadian currency.
(2) The 2016 amounts reflect the options set forth in the table below
(2) This amount reflects a base salary of $225,000 in 2015.

The following table provides information about the option awards granted to the named executives in the fiscal year ended July 31, 2016, including: (1) the grant date; (2) the number of shares underlying stock options awarded to the named executives, (3) the exercise price of the stock options awarded or extended, and (4) the grant date fair value of each equity award computed in accordance with FASB ASC Topic 718.

Name	Number of Securities	Exercise Price or	Grant Date Fair

	Grant Date	Underlying Options (#)	Base Price of Option Awards ($/Sh)	Value of Option Awards
Mark Fletcher, President & Chief Executive Officer	October 26, 2015	4,447,111 (1)	$0.001 (2)	$0.015 (3)
Stephen Fellows, Chief Financial Officer	October 26, 2015	1,667,671 (1)	$0.001 (2)	$0.015 (3)
David Brusegard, Chief Operating Officer	October 26, 2015	1,667,671 (1)	$0.001 (2)	$0.015 (3)

(1) The options were granted on October 26, 2015 pursuant to the terms of our 2006 Stock Plan in satisfaction of unpaid compensation. The options vested on issuance.

(2) The options have an exercise price equal to the par value of the Company's stock.

(3) The options are being issued in lieu of cash payment of deferred salary amounts due to such individuals. The executives listed above previously agreed to defer a portion of their salaries in an effort to assist the Company with its cash flow requirements. The stock options have an exercise price equal to $0.001 per share. The options awarded became fully vested on October 26, 2015 and shall expire on the fifth anniversary of the date of grant, subject to earlier termination under the terms set forth in the 2001 Stock Plan or 2006 Stock Plan, as applicable.[ ]

Compensation Elements; Employment Agreements and Agreements Providing Payments Upon Retirement, Termination or Change in Control for Named Executives

Historically, the key components of our executive compensation have been base salary, cash bonuses, and equity incentives, including stock bonuses, restricted stock, and stock options awarded at the discretion of our Compensation Committee and Board of Directors. As a development stage company, we have reviewed compensation of our executive management team from time to time and at the discretion of the Compensation Committee when warranted by our financial condition and achievement of our business goals.

Set forth below are the material terms of employment for the President and Chief Executive Officer as of the end of fiscal 2016. The terms of employment provide for certain payments upon retirement, termination or change in control. Such benefits are in addition to benefits available generally to salaried employees who joined the company prior to 2013, such as distributions under the 401(k) savings plan, disability and death benefits and accrued vacation pay.

Terms of Employment for Mr. Fletcher

On March 17, 2003, our Board of Directors approved the terms and conditions of Mr. Fletcher's employment, prior to his joining Generex on or about April 21, 2003. Pursuant to the terms of his employment, Mr. Fletcher holds the position of Executive Vice President and General Counsel. Subject to termination in accordance with the terms and conditions of his employment, Mr. Fletcher's term of service extends through March 16, 2008, which term has not been formally extended to date. Mr. Fletcher is entitled to receive annual base compensation and may receive additional cash bonuses at the discretion of the Board of Directors.

On September 29, 2010, Generex and Mr. Fletcher agreed to amend the terms of Mr. Fletcher's employment to provide that the replacement of Ms. Gluskin as a director or Chief Executive Officer will not constitute a "change of control" and to provide for an increase in Mr. Fletcher's base salary (to $475,000) upon his appointment as interim Chief Executive Officer. Under the terms of his employment with Generex, Mr. Fletcher is entitled to receive annual base compensation and may receive additional cash bonuses at the discretion of the Board.

The terms of his employment provide that Mr. Fletcher will be bound by standard restrictive covenants prohibiting him from disclosing confidential information about Generex. Either party may give at least 12 months' notice of non-renewal of the term; if such notice is not given, the term of employment will be indefinite.

Generex may terminate its obligations with respect to Mr. Fletcher's employment as follows:

(i) upon 30 days written notice;
(ii) for "cause";

(iii) in the event of Mr. Fletcher's disability;
(iv) in the event of Mr. Fletcher's death; or

(v) in the event of Mr. Fletcher voluntarily resigning.

Mr. Fletcher may terminate his obligations upon 30 days written notice upon:

(a) a material change in his duties,
(b) a material reduction in compensation,
(c) a material breach or default by Generex, or
(d) a change in control of Generex.

In the event that Mr. Fletcher terminates his employment voluntarily (and not under the circumstances described in (a), (b), (c) or (d) above) or Generex terminates his employment under the circumstances described in (ii), (iii), (iv) or (v) above, Mr. Fletcher will be entitled only to that portion of his base salary due and owing as of his last day worked, less any amounts owed to Generex. Under these circumstances, he will not be entitled to any bonus or incentive compensation.

Mr. Fletcher has waived certain provisions under the Agreement which entitled to additional payments upon termination.

We do not have employment agreements, plans or arrangements, whether written or unwritten, for various scenarios involving termination of employment or a change in control governing Dr. Brusegard’s employment. Nor did we have any such agreement, plan or arrangement with Mr. Fellows. There are no benefits made available to them which are in addition to benefits available generally to salaried employees who joined the company prior to 2013.

Other Benefit Plans

We have no defined benefit or actuarial pension plans.

Outstanding Equity Awards at 2016 Fiscal Year-End

The following table provides information on the current holdings of stock options by the named executives. This table includes unexercised and unvested option awards as of July 31, 2016. Each equity grant is shown separately for each named executive. The vesting schedule for each outstanding award is set forth in the footnotes to the table. We do not have any current “stock awards” or “equity incentive plans” referred to in Regulation S-K Item 402(p)(2); thus, the columns relating to stock awards and equity incentive awards are not included in the table below.

	Option Awards				
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**
Mark E. Fletcher, President and Chief Executive Officer	3-8-2010	300,000[(1)]	0	$0.64	3-8-2020
Stephen Fellows Chief Financial Officer	3-8-2010	250,000[(1)]	0	$0.64	0 3-8-2020
David Brusegard, Chief Operating Officer					

(1) These options were granted on March 8, 2010. The grants were made pursuant to the terms of our 2006 Stock Plan. The exercise price per share is equal to the closing price of Generex common stock on March 8, 2010. The options vested as follows: 33% of the options were exercisable on the date of grant; 33% of the options became exercisable on August 1, 2010, and the remaining 33% of the options became exercisable on August 1, 2011.

Compensation Elements; Employment Agreements and Agreements Providing Payments Upon Retirement, Termination or Change in Control for Named Executives

Historically, the key components of our executive compensation have been base salary, cash bonuses, and equity incentives, including stock bonuses, restricted stock, and stock options awarded at the discretion of our Compensation Committee and Board of Directors. As a development stage company, we have reviewed compensation of our executive management team from time to time and at the discretion of the Compensation Committee when warranted by our financial condition and achievement of our business goals.

Set forth below are the material terms of employment for the President and Chief Executive Officer as of the end of fiscal 2016. The terms of employment provide for certain payments upon retirement, termination or change in control. Such benefits are in addition to benefits available generally to salaried employees who joined the company prior to 2013, such as distributions under the 401(k) savings plan, disability and death benefits and accrued vacation pay.

Other Benefit Plans

We have no defined benefit or actuarial pension plans.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security Ownership of Certain Beneficial Owners and Management

The table below sets forth information regarding the beneficial ownership of the common stock by our directors and named executive officers (including persons who served as a director or a named executive during a portion of the fiscal year ended July 31, 2016) and all the named executives and directors as a group. We are not aware of any person or group that beneficially owns more than five percent of our outstanding shares of common stock.

The information contained in this table is as of December 29, 2016. At that date, we had 908,541,475 shares of common stock outstanding.

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.

Except as otherwise indicated, the address of each person named in the table below is c/o Generex Biotechnology Corporation, 4145 North Service Road, Suite 200, Burlington, Ontario, Canada L7L 6A3..

Beneficial Ownership

Name of Beneficial Owner	**Number of Shares**	**Percent of Class**
Named Executives, Directors and Nominees		
Mark Fletcher [1]	1,231,803	0.1 %
Brian T. McGee [2]	3,526,131	0.4 %
Dr. James Anderson [3]	3,564,341	0.4 %
Eric von Hofe, Ph.D. [4]	12,094,709	1.3 %
Dr. David Brusegard [5]	31,295	*
Stephen Fellows [6]	250,010	*
Named Executives and Directors as a group (7 persons)	20,698,289	2.3 %

* Less than 1%.

(1) Includes 931,803 shares, 300,000 options which were granted on March 8, 2010 under 2006 Plan, 400,000 options issued March 25, 2011 under the 2001 Stock Option Plan, 1,100,000 options issued March 25, 2011 under the 2006 Stock Option Plan, 1,457,195 options issued June 19, 2012 under the 2006 Plan, 5,143,787 options issued April 1, 2013 under the 2006 Plan, 1,587,300 options issued June 6, 2013 under the 2006 Plan and 2,254,640 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (1,854,640), 4,447,111 options issued October 26, 2015 under the 2006 Plan, 400,000 options expired from the 2001 plan, 1,100,000 options expired from the 2006 plan,, 14,490,033 options were exercised under the 2006 plan and 400,000 options were exercised under the 2001 plan during the fiscal year 2016

(2) Includes 285,714 shares, 100,000 options which were granted on March 8, 2010 under the 2006 Plan, 200,000 options issued March 25, 2011 under the 2001 Stock Option Plan, 508,197 options issued June 19, 2012 under the 2006 Plan, 1,413,374 options issued April 1, 2013 under the 2006 Plan, 328,042 options issued June 6, 2013 under the 2006 Plan and 890,804 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (490,804). 200,000 options were expired during the fiscal year 2016 from the 2001 plan.

(3) Includes 409,836 options issued June 19, 2012 under the 2006 Plan, 1,139,818 options issued April 1, 2013 under the 2006 Plan, 1,296,296 options issued June 6, 2013 under the 2006 Plan and 718,391 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (318,391).

(4) Includes 10,000 shares, 200,000 options issued March 25, 2011 under the 2001 Stock Option Plan, 626,292 options issued June 21, 2012 under the 2006 Plan, 2,177,267 options issued April 1, 2013 under the 2006 Plan, 682,210 options issued June 6, 2013 under the 2006 Plan and 988,029 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (588,029). 7,610,911 options were issued on October 26, 2015 under the 2006 plan, and 200,000 options were expired during fiscal year 2016 from the 2001 plan.

(5) Includes 31,295 shares of common stock held by Dr. Brusegard, 200,000 options issued March 25, 2011 under the 2001 Stock Option Plan, 546,448 options issued June 20, 2012 under the 2006 Plan, 1,928,925 options issued April 1, 2013 under the 2006 Plan, 595,239 options issued June 6, 2013 under the 2006 Plan and 845,492 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (445,492). 1,667,671 options were issued on October 26, 2015 under the 2006 plan, and 200,000 options were expired during fiscal year 2016 from the 2001 plan. 5,183,775 options from the 2006 plan and 400,000 options from the 2001 plan were exercised during fiscal year 2016

(6) Includes 250,000 options which were granted on March 8, 2010 under the 2006 Plan, 200,000 options issued March 25, 2011 under the 2001 Stock Option Plan and 845,492 options issued October 31, 2013 under the 2001 (400,000) and 2006 Plans (445,492). 1,667,671 options were issued on October 26, 2015 under the 2006 plan, 200,000 options were expired during the fiscal year 2016 from the 2001 plan, 2,113,153 options from the 2006 plan, and 400,000 options from the 2001 plan were exercised during the fiscal year 2016. Mr. Fellows wasl laid off . In October, 2015.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

Changes in Control

On August 26, 2016, the Company signed a Letter of Intent to acquire 51% of Hema Diagnostic Systems, LLC (“HDS”) for consideration of $250,000 worth of the Company’s restricted common stock. The number of stock issued for the transaction will be calculated based on the average over-the-counter closing price of the Company’s common stock for the ten trading days immediately preceding the Closing Date. The Company will also issue, in consideration for the purchase, a warrant to acquire 15,000,000 shares of Generex common stock, at a per-share strike price equal to the over-the-counter closing price of the Company’s stock on the date that the restricted common stocks were issued. It is the Company’s intention to initiate a reverse stock-split following the acquisition of HDS. This acquisition of HDS has not been finalized as at the date of yet, and it is expected to finalize during the fiscal year 2017.

Following closing of the HDS transaction, the Company expects to add significant members to its management team and issue a significant number of options as incentive compensation to the new members of management. The Company has no firm commitments or obligations with respect to such options as of the filing of this Annual Report.. The shares and warrants pursuant to the HDS transaction, and the options to new management personnel, if these occur, would likely in the aggregate represent a significant majority of the Company’s outstanding common stock.

We know of no arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in the change in control of Generex.

Review of Related Party Transactions

We presently have 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. We also have a policy requiring the approval by the Audit Committee for any transactions in which a director or an executive officer has a material interest apart from such director's or officer’s interest in Generex.

Related Transactions

We are not aware of any transactions or arrangements falling within the scope of the above-mentioned policy on related party transactions.

Director Independence

The Board of Directors currently consists of three members, two of whom are “independent” as defined under applicable rules of the SEC and The NASDAQ Stock Market LLC. The two independent members of the Board of Directors are Brian T. McGee and Dr. James Anderson, Jr. During the fiscal year ended July 31, 2015, the board consisted of four members, including the two independent directors identified in the preceding sentence, Mark Fletcher and Dr. Eric von Hofe. Dr. Von Hofe resigned from the Board on August 19, 2015, but remains President of Antigen Express. Mr. Fletcher and Dr. von Hofe were not independent under applicable SEC and NASDAQ rules.

For a director to be considered independent, the Board must determine that the director has no relationship which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Under NASDAQ rules, all members of the Audit Committee, the Compensation Committee and the Corporate Governance and Nominating Committee must be independent directors. Members of the Audit Committee also must satisfy a separate SEC independence requirement, which provides that they may not accept directly or indirectly any consulting, advisory or other compensatory fee from the Company or any of its subsidiaries other than their directors’ compensation. In addition, under SEC rules, an Audit Committee member who is an affiliate of the issuer (other than through service as a director) cannot be deemed to be independent. Due to the Company’s current exceptional circumstances, including the attrition of directors over the last two fiscal years and the Company’s limited operations and diminished financial condition, the Board’s established standing Audit Committee, Compensation Committee and Corporate Governance and Nominating Committee have ceased functioning as such, and during fiscal year 2016, the full Board acted in the capacity of these committees as necessary, except to the extent that Mr.Fletcher abstained from determinations regarding executive compensation for the principal executive officer.

Item 14. Principal Accounting Fees and Services.

MNP LLP ("MNP") has served as our independent auditors since June 1, 2013. The appointment of MNP as our independent public accountants was unanimously approved by the Audit Committee of our Board of Directors. MNP is the successor to our former independent auditors, MSCM LLP ("MSCM"), following MNP's merger with MSCM in June 2013. MSCM served as our independent auditors from September 5, 2008 until June 1, 2013.

The following table sets forth the aggregate fees paid by Generex for the fiscal years ended July 31, 2016 and 2015 to our independent auditors:

	Fiscal Year Ended July 31, 2016		Fiscal Year Ended July 31, 2015	
Audit Fees	$ 44,840	(1)	$ 57,760	(1)
Audit-Related Fees	$ -0-		$ -0-	
Tax Fees	$ -0-	(2)	$ -0-	(2)
All Other Fees	$	(3)	$ 3,500	(3)
TOTAL	$ 44,840		$ 61,160	

(1) Includes fees associated with quarterly reviews of financial statements included in Generex's Form 10-Q filings.
(2) MNP LLP did not provide or bill for any tax services.
(3) Represents fees associated with review of the Company's registration statements on Form S-1 and Form S-8.

PART IV

Item. 15 Exhibits and Financial Statements and Schedules.

1. Financial Statements - See *Part II - Item 8. Financial Statements and Supplementary Data* hereof on page 34.

The financial statements include the following:

Consolidated Balance Sheets as of July 31, 2016 and 2015

Consolidated Statements of Comprehensive Income for the Years Ended July 31, 2016 and 2015

Consolidated Statements of Changes in Stockholders' Deficiency for the for the Years Ended July 31, 2016 and 2015

Consolidated Statements of Cash Flows for the Years Ended July 31, 2016 and 2015

2. Financial Statement Schedule and Auditor's Report

Schedule I - Condensed financial information of registrant

This schedule is not applicable.

Schedule II - Valuation and qualifying accounts

	Balance at Beginning Of Period	Additions Charged To Expenses	Other Additions	Deductions	Balance at End of Period
Year ended July 31, 2016 Valuation Allowance on Deferred Tax Asset	$86,816,273	—	—	$137,286	$86,678.987
Year ended July 31, 2015 Valuation Allowance on Deferred Tax Asset	$91,105,273	—		$3,006,413	$86,816,273

The auditors' report of MNP LLP with respect to the Financial Statement Schedule information for the years ended July 31, 2016 and 2015 is included with its report on our financial statements located at page ??.

3. Exhibits

Exhibits are incorporated herein by reference or are filed with this Annual Report as set forth in the Exhibit Index beginning on page 77 hereof.

All other schedules and exhibits are omitted because they are not applicable, not required, or because the information required has been given as part of this report.

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 13th day of January 2017.

GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Mark A. Fletcher
Name: Mark A. Fletcher
Title: President and Chief Executive Officer

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/ Mark A. Fletcher Mark A. Fletcher	President and Chief Executive Officer and General Counsel and Secretary and Director (Principal Executive Officer and Principal Financial Officer)	January 13, 2017
/s/ Brian T. McGee Brian T. McGee	Director	January 13, 2017

EXHIBIT INDEX

Exhibit Number	Description of Exhibit[1]
1.1	Placement Agency Agreement, dated May 5, 2009, by and between Generex Biotechnology Corporation and Rodman & Renshaw (incorporated by reference to Exhibit 1.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on May 18, 2009)
1.2	Placement Agency Agreement, dated June 8, 2009, by and between Generex Biotechnology Corporation and Midtown Partners & Co., LLC and amendments dated August 5, August 18, and September 11, 2009 (incorporated by reference to Exhibit 1.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on September 15, 2009)
1.3	Amendment dated as of April 7, 2010 to Placement Agent Agreement attached as Exhibit 1.2 hereto (incorporated by reference .reference to Exhibit 1.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 8, 2010)
1.4	Placement Agency Agreement dated September 11, 2009, by and between Generex Biotechnology Corporation and Maxim Group LLC. (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on September 15, 2009)
2	Agreement and Plan of Merger among Generex Biotechnology Corporation, Antigen Express, Inc. and AGEXP Acquisition Inc. (incorporated by reference to Exhibit 2.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 15, 2003)
3(i)(a)	Restated Certificate of Incorporation of Generex Biotechnology Corporation as amended by the Certificate of Amendment dated as of September ??, 2015.
3(i)(b)	Certificate of Designation of Preferences, Rights and Limitations of Series A 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
3(i)(c)	Certificate of Designation of Preferences, Rights and Limitations of Series B 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on February 1, 2012).
3(i)(d)	Certificate of Designation of Preferences, Rights and Limitations of Series C 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 8, 2012).

3(i)(e)	Certificate of Designation of Preferences, Rights and Limitations of Series D 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on December 11, 2012)
3(i)(f)	Certificate of Amendment to Restated Certificate of Incorporation of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3(i)(f) to Generex Biotechnology Corporation's Current Report on Registration Statement on Form S-1 (File No. 333-187656) filed on April 1, 2013)
3(i)(g)	Certificate of Designation of Preferences, Rights and Limitations of Series E 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on June 17, 2013)
3(i)(h)	Certificate of Designation of Preferences, Rights and Limitations of Series F 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on March 28, 2014)
3(i)(i)	Certificate of Designation of Preferences, Rights and Limitations of Series G 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on June 25, 2015)
3(ii)	Amended and Restated By-Laws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3.2(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed December 5, 2007)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)
4.2.1	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended April 30, 2003 filed on August 13, 2003)
4.2.2	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended April 30, 2003 filed on August 13, 2003)
4.2.3	Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended April 30, 2003 filed on August 13, 2003)
4.3	

	Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003 (incorporated by reference to Exhibit 4.13.7 to Generex Biotechnology Corporation's Report on Form 10-K for the period ended July 31, 2003 filed on October 29, 2003)
4.4.1	Securities Purchase Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.2	Registration Rights Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.3	Form of Warrant issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.4	Form of Additional Investment Right issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.5.1	Securities Purchase Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.2	Registration Rights Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.3	Warrant issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.4	Additional Investment Right issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.1	Securities Purchase Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.2	Registration Rights Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.3	Warrant issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.4	Additional Investment Right issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.1	Securities Purchase Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.2	

	Registration Rights Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.10 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.3	Warrant issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.11 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.4	Additional Investment Right issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.12 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.5	Escrow Agreement, dated February 26, 2004, by and among Generex Biotechnology Corporation, Eckert Seamans Cherin & Mellott, LLC and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.13 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.1	Securities Purchase Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.14 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.2	Registration Rights Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.15 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.3	Additional Investment Right issued in connection with Exhibit 4.8.1 (incorporated by reference to Exhibit 4.17 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.1	Securities Purchase Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.18 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.2	Registration Rights Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.19 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.3	Warrant issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.4	Additional Investment Right issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.21 Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.10.1	Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.2	Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.3	Form of Warrant issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.4	

	Form of Additional Investment Right issued in connection Exhibit 4.10.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.11.1	Securities Purchase Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.2	Form of 6% Secured Convertible Debenture issued in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.3	Registration Rights Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.4	Form of Voting Agreement entered into in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.12	Warrant issued to The Aethena Group, LLC on April 28, 2005 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)
4.13.1	Amendment No. 4 to Securities Purchase Agreement and Registration Rights Agreement entered into by and between Generex Biotechnology Corporation and the Purchasers listed on the signature pages thereto on January 19, 2006 (incorporated by reference herein to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.13.2	Form of Additional AIRs issued in connection with Exhibit 4.13.1 (incorporated by reference herein to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.14	Form of Warrant issued by Generex Biotechnology Corporation on January 23, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 24, 2006)
4.15.1	Agreement to Amend Warrants between Generex Biotechnology Corporation and Cranshire Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.2	Agreement to Amend Warrants between Generex Biotechnology Corporation and Omicron Master Trust dated February 27, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006)
4.15.3	Agreement to Amend Warrants between Generex Biotechnology Corporation and Iroquois Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006)
4.15.4	Agreement to Amend Warrants between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 27, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006)
4.15.5	Form of Warrant issued by Generex Biotechnology Corporation on February 27, 2006 (incorporated by reference to Exhibit 4.26 to Generex Biotechnology Corporation's Report on Form 10-K filed on October

	16, 2006)
4.16.1	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Cranshire Capital, L.P. dated February 28, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006)
4.16.2	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Omicron Master Trust dated February 28, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006)
4.16.3	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Iroquois Capital LP dated February 28, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006)
4.16.4	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 28, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006)
4.16.5	Form of Additional AIR Debenture issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.31 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.16.6	Form of Additional AIR Warrant issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.32 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.17.1	Form of Agreement to Amend Warrants between Generex Biotechnology Corporation and the Investors dated March 6, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006)
4.17.2	Form of Warrant issued by Generex Biotechnology Corporation on March 6, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006)
4.18	Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.33 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)
4.19	Form of Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to certain employees (incorporated by reference to Exhibit 4.34 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)
4.20.1	Securities Purchase Agreement entered into by and between Generex Biotechnology Corporation and four Investors on June 1, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.20.2	Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.21.1	Form of Amendment to Outstanding Warrants (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

4.21.2	Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.22.1	Securities Purchase Agreement, dated as of March 31, 2008 among the Registrant and each of the purchasers named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.2	Form of 8% Secured Convertible Note, as amended (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Registration Statement (333-150562) on Form S-3 filed on April 30, 2008)
4.22.3	Form of Series A Warrant, as amended (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on April 30, 2008)
4.22.4	Form of Series A-1 Warrant, as amended (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on April 30, 2008)
4.22.5	Form of Series B Warrant, as amended (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on April 30, 2008)
4.22.6	Form of Series C Warrant, as amended (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on April 30, 2008)
4.22.7	Registration Rights Agreement, dated March 31, 2008, among Registrant and each of the purchasers under Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.8	Security Agreement (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.9	Form of Guaranty (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.23	Form of Securities Purchase Agreement, date May 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on May 18, 2009)
4.24.1	Form of Securities Purchase Agreement, dated June 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.2	Form of Warrant issued in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.25.1	Form of Securities Purchase Agreement, dated August 6, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)

4.25.2	Form of Warrant issued in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.28 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.26.1	Form of Securities Purchase Agreement, dated September 11, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.2	Form of Warrant issued in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.3	Form of Warrant issued to Midtown Partners & Co., LLC and Maxim Group LLC in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.27.1	Common Stock Purchase Agreement dated April 7, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
4.27.2	First Amendment to Common Stock Purchase Agreement dated April 28, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 29, 2010)
4.27.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.27.1 hereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
4.28.1	Form of Securities Purchase Agreement dated January 24, 2011 by and between Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on January 25, 2011).
4.28.2	Form of Warrant issued to the investors in connection with Exhibit 4.28.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on January 25, 2011).
4.28.3	Amendment to Purchase Agreement dated March 25, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on March 30, 2011).
4.28.4	Second Amendment to Purchase Agreement dated April 13, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 14, 2011).
4.29.1	Form of Securities Purchase Agreement, dated July 8, 2011, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).

4.29.2	Form of Common Stock Warrant issued in connection with Exhibit 4.29.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
4.30.1	Form of Securities Purchase Agreement, dated January 31, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on February 1, 2012).
4.30.2	Form of Common Stock Warrant issued in connection with Exhibit 4.30.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012).
4.30.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012)
4.31.1	Form of Securities Purchase Agreement, dated August 8, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 8, 2012).
4.31.2	Form of Common Stock Warrant issued in connection with Exhibit 4.31.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 8, 2012).
4.31.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 8, 2012)
4.32.1	Form of Securities Purchase Agreement, dated December 10, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on December 11, 2012).
4.32.2	Form of Common Stock Warrant issued in connection with Exhibit 4.32.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 11, 2012).
4.32.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 10, 2012)
4.33.1	Form of Securities Purchase Agreement, dated June 17, 2013, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on June 17, 2013).

4.33.2	Form of Common Stock Warrant issued in connection with Exhibit 4.33.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 17, 2013).
4.33.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 17, 2013)
4.34.1	Form of Securities Purchase Agreement, dated January 14, 2014, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on January 15, 2014).
4.34.2	Form of Common Stock Warrant issued in connection with Exhibit 4.34.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 15, 2014).
4.35.1	Form of Securities Purchase Agreement, dated March 27, 2014, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on March 28, 2014).
4.35.2	Form of Common Stock Warrant issued in connection with Exhibit 4.35.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 28, 2014).
4.35.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 28, 2014)
4.36.1	Form of Securities Purchase Agreement, dated June 24, 2015, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on June 25, 2015).
4.36.2	Form of Common Stock Warrant issued in connection with Exhibit 4.36.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 25, 2015).
4.36.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 25, 2015)
9	Form of Voting Agreement entered into in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on November 12, 2004)

10.1	Stock Option Agreement by and between Generex Biotechnology Corporation and Brian T. McGee to purchase 100,000 shares of Common Stock at the exercise price of $0.56 per share (incorporated by reference to Exhibit 10.5 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)*
10.2	Stock Option Agreement by and between Generex Biotechnology Corporation and Brian T. McGee to purchase 35,714 shares of Common Stock at the exercise price of $0.001 per share (incorporated by reference to Exhibit 10.7 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)*
10.3	Stock Option Agreement by and between Generex Biotechnology Corporation and Mark Fletcher to purchase 250,000 shares of Common Stock at the exercise price of $0.61 per share (incorporated by reference to Exhibit 10.9 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)*
10.4	Stock Option Agreement by and between Generex Biotechnology Corporation and Mark A. Fletcher to purchase 470,726 shares of Common Stock at the exercise price of $0.001 per share (incorporated by reference to Exhibit 10.12 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)*
10.5	1998 Stock Option Plan (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)*
10.6	2000 Stock Option Plan (incorporated by reference to Exhibit 4.3.2 to Generex Biotechnology Corporation's Annual Report on Form 10-K filed on October 30, 2000)*
10.7	Amended 2001 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 15, 2003)*
10.8	2006 Stock Plan (incorporated by reference to Annex A to Generex Biotechnology Corporation's Proxy Statement for the Annual Meeting of Stockholders held on May 30, 2006)*
10.9	Stockholders Agreement among Generex Biotechnology Corporation and the former holders of capital stock of Antigen Express, Inc. (incorporated by reference to Exhibit 10.4 to Generex Biotechnology Corporation's Annual Report on Form 10-K filed on October 29, 2003)
10.10	Form of Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to certain employees (incorporated by reference to Exhibit 4.34 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)*
10.11	Quotation for Contract Manufacturing of Oral-lyn™ entered into between Generex Biotechnology Corporation and Cardinal Health PTS, LLC on June 20, 2006 (subject to confidential treatment) (incorporated by reference to Exhibit 10.25 to Generex Biotechnology Corporation's Report on Form 10-K/A filed on February 14, 2007)
10.12	Quotation Amendment for Contract Manufacturing of Oral-lyn™ entered into between Generex Biotechnology Corporation and Cardinal Health PTS, LLC on August 18, 2006 (subject to confidential treatment) (incorporated by reference to Exhibit 10.26 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
10.13	

	Clinical Supply Agreement entered into between Generex Biotechnology Corporation and Cardinal Health PTS, LLC on September 6, 2006 (subject to confidential treatment) (incorporated by reference to Exhibit 10.27 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
10.14	Form of Restricted Stock Agreement for awards to executive officers of Generex Biotechnology Corporation under the Generex Biotechnology Corporation 2006 Stock Plan (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 23, 2007)*
10.15	Summary of Employment Terms for Mark A. Fletcher effective as of April 21, 2003 (incorporated by reference to Exhibit 10.30 to Generex Biotechnology Corporation's Report on Form 10-K/A filed on November 28, 2007)*
10.16	Form of Consent and Waiver Agreement entered into with Cranshire Capital, L.P., Portside Growth and Opportunity Fund and, Smithfield Fiduciary LLC (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 1, 2008)
10.17	Form of Consent and Waiver Agreement entered into with Rockmore Investment Master Fund Ltd. (incorporated by reference to Exhibit 10.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 1, 2008)
10.18	Form of Consent and Waiver Agreement entered into with the Iroquois Funds (incorporated by reference to Exhibit 10.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 1, 2008)
10.19	Form of separate Agreements entered into with each of Cranshire Capital, L.P., Portside Growth and Opportunity Fund, Rockmore Investment Master Fund Ltd., Smithfield Fiduciary LLC and Iroquois Capital Opportunity Fund, LP on December 22, 2008 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 23, 2008)
10.20	Form of Agreement entered into with Iroquois Master Fund Ltd. on December 22, 2008 (incorporated by reference to Exhibit 10.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 23, 2008)
10.21	Form of separate Letter Agreements dated as of February 13, 2009 and entered into by and between Generex Biotechnology Corporation and each of Cranshire Capital, L.P., Portside Growth and Opportunity Fund, Rockmore Investment Master Fund Ltd., Smithfield Fiduciary LLC, Iroquois Master Fund Ltd. and Iroquois Capital Opportunity Fund, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 17, 2009)
10.22	Form of Forbearance and Amendment Agreement dated as of February 27, 2009 and entered into by and between Generex Biotechnology Corporation and each of Cranshire Capital, L.P., Portside Growth and Opportunity Fund, Rockmore Investment Master Fund Ltd., Smithfield Fiduciary LLC, Iroquois Master Fund Ltd. and Iroquois Capital Opportunity Fund, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 2, 2009)
10.23	At Market Offering Issuance Agreement dated October 14, 2009 entered into between Generex Biotechnology Corporation and Wm Smith & Co, LLC (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on October 15, 2009)
10.24	Recombinant Human Insulin Active Ingredient Manufacturing and Supply Agreement entered into on December 7, 2009 by and between Generex Biotechnology Corporation and Sanofi-Aventis Deutschland GmbH (subject to confidential treatment) (incorporated by reference to Exhibit 10.2 to Generex

	Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 11, 2009)
10.25	Incentive Stock Option Grant Agreement dated March 9, 2010 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.4 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 11, 2010)*
10.26	Nonqualified Stock Option Grant Agreement dated March 9, 2010 by and between Generex Biotechnology Corporation and Brian McGee (incorporated by reference to Exhibit 10.5 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 11, 2010)*
10.27	Amendment to the Employment Terms for Mark A. Fletcher, dated September 29, 2010 (incorporated by reference to Exhibit 10.46 to Generex Biotechnology Corporation's Annual Report on Form 10-K filed on October 14, 2010).*
10.28	Limited Liability Company Ownership Interest Purchase Agreement by and among Generex Biotechnology Corporation, Global Medical Direct, LLC and Joseph Corso, Jr., Robert S. Shea and Mark Franz (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on October 12, 2010)
10.29	Nonqualified Stock Option Grant Agreement dated March 25, 2011 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.5 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 3, 2011).*
10.30	Nonqualified Stock Option Grant Agreement dated March 25, 2011 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.7 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 3, 2011).*
10.31	Nonqualified Stock Option Grant Agreement dated March 25, 2011 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.8 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 3, 2011).*
10.32	Nonqualified Stock Option Grant Agreement dated March 25, 2011 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.9 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 3, 2011).*
10.33	Nonqualified Stock Option Grant Agreement dated March 25, 2011 by and between Generex Biotechnology Corporation and Brian T. McGee (incorporated by reference to Exhibit 10.11 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 3, 2011).*
10.34	Nonqualified Stock Option Grant Agreement dated June 19, 2012 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.48 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.35	

	Nonqualified Stock Option Grant Agreement dated June 19, 2012 by and between Generex Biotechnology Corporation and Brian T. McGee (incorporated by reference to Exhibit 10.50 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.36	Nonqualified Stock Option Grant Agreement dated June 19, 2012 by and between Generex Biotechnology Corporation and James Anderson (incorporated by reference to Exhibit 10.52 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.37	Nonqualified Stock Option Grant Agreement dated June 19, 2012 by and between Generex Biotechnology Corporation and Eric von Hofe (incorporated by reference to Exhibit 10.53 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.38	Nonqualified Stock Option Grant Agreement dated June 20, 2012 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.54 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.39	Nonqualified Stock Option Grant Agreement dated June 20, 2012 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.55 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on September 12, 2012).*
10.4056	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.56 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.41	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and Brian T. McGee (incorporated by reference to Exhibit 10.58 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.42	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and James Anderson (incorporated by reference to Exhibit 10.59 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.43	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and Eric von Hofe (incorporated by reference to Exhibit 10.60 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.44	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.61 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.45	

	Nonqualified Stock Option Grant Agreement dated April 1, 2013 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.62 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.46	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and Mark A. Fletcher (incorporated by reference to Exhibit 10.63 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.47	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and Brian T. McGee (incorporated by reference to Exhibit 10.65 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.48	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and James Anderson (incorporated by reference to Exhibit 10.66 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.49	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and Eric von Hofe (incorporated by reference to Exhibit 10.67 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.50	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.68 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.51	Nonqualified Stock Option Grant Agreement dated June 6, 2013 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.69 to Generex Biotechnology Corporation's Registration Statement on Form S-1 filed on July 2, 2013).*
10.52	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and James Anderson (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.53	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.3 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.54	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.4 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.55	

	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Mark Fletcher (incorporated by reference to Exhibit 10.5 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.56	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Brian McGee (incorporated by reference to Exhibit 10.6 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.57	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Eric von Hofe (incorporated by reference to Exhibit 10.7 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.58	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and James Anderson (incorporated by reference to Exhibit 10.8 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.59	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and David Brusegard (incorporated by reference to Exhibit 10.10 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.60	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Stephen Fellows (incorporated by reference to Exhibit 10.11 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.61	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Mark Fletcher (incorporated by reference to Exhibit 10.12 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.62	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Brian McGee (incorporated by reference to Exhibit 10.13 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
10.63	Nonqualified Stock Option Grant Agreement dated October 31, 2013 by and between Generex Biotechnology Corporation and Eric von Hofe (incorporated by reference to Exhibit 10.14 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on December 9, 2013).*
21	Subsidiaries of the Registrant
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Management contract or management compensatory plan or arrangement.

(1) In the case of incorporation by reference to documents filed by the Registrant under the Exchange Act, the Registrant's file number under the Exchange Act is 000-25169.