Generex Biotechnology Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

98-0178636
(I.R.S. Employer Identification Number)

10102 USA Today Way, Miramar, Florida 33025
(Address of principal executive office)

Registrant's telephone number: (416) 364-2551

Title of each class Trading Symbol Name of each exchange on which traded
Common voting shares GNBT OTC

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 not required to file reports pursuant to Section 13 or Section 15 (d) of the 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 website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 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 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:

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☒
Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13 (a) of the Exchange Act.

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

☐ YES ☒ NO

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter.

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<th>Non Affiliate Float</th>
<th>Closing price as of Second Quarter January 31, 2019</th>
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Indicate the number of the number of shares outstanding of each of the registrant’s classes of common stock, as of the latest practicable date.
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<th>As of Date</th>
<th>Outstanding</th>
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</thead>
<tbody>
<tr>
<td>October 18, 2019</td>
<td>44,177,973</td>
</tr>
</tbody>
</table>
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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 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 of future revenues, expenditures, capital or other funding requirements,
- the adequacy of our cash and working capital to fund present and planned operations and growth,
- the timing of our expansion plans,
- 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;
- the effect of governmental regulations generally,
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- 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;
- economic and industry conditions generally and in our specific markets.
- 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.
PART I

Item 1. Business

Corporate History

Generex Biotechnology Corporation (the “Company,” “Generex,” “we,” “us” or “our”) is based in Miramar, Florida, with offices in Dallas, Texas, Toronto, Canada and Wellesley, Massachusetts. The Company was originally incorporated in the state of Delaware on September 4, 1997, for the purpose of acquiring Generex Pharmaceuticals Inc., a Canadian (Province of Ontario) corporation formed in November 1995 to engage in pharmaceutical and biotechnological research and development and other activities. The Company’s acquisition of Generex Pharmaceuticals Inc. was completed in October 1997 in a transaction in which the holders of all outstanding shares of Generex Pharmaceuticals Inc. exchanged their shares for shares of Generex common stock.

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

In April 1999, we completed a reorganization in which GBC - Delaware, Inc. merged with Generex Idaho. In this transaction, all outstanding shares of Generex Idaho were converted into shares of GBC - Delaware, Inc.; Generex Idaho ceased to exist as a separate entity, and we, GBC - Delaware, Inc., 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.

Following our reorganization in 1999, Generex Pharmaceuticals Inc., which was incorporated in Ontario, Canada, remained as our wholly-owned subsidiary. All of our Canadian operations are performed by Generex Pharmaceuticals Inc.; Generex Pharmaceuticals Inc. is the 100% owner of 1097346 Ontario Inc., which was also incorporated in Ontario, Canada. In August 2003, we acquired Antigen Express, Inc. (“Antigen”), 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 name NuGenerex Immuno-Oncology. On February 28, 2019 Generex issued a dividend of Antigen to Generex shareholders in the amount of 1 share of Antigen for every 4 shares of Generex common stock. Generex still maintains majority control of Antigen.

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, (“Elan”) 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), Inc.; Generex (Bermuda), Inc. 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.
On January 18, 2017, we acquired a majority of the equity interests in Hema Diagnostic Systems, LLC ("HDS"). In December 2018, we acquired the remaining interest in HDS. The company, now a wholly-owned subsidiary of Generex, has been renamed NuGenerex Diagnostics, LLC (NGDx), and is managed by President Harold Haines, PhD.

On October 3, 2018, our wholly owned subsidiary, NuGenerex Distribution Solutions, LLC ("NuGenerex"), entered into an asset purchase agreement (the “Veneto Asset Purchase Agreement”) with Veneto Holdings, L.L.C. ("Veneto"), pursuant to which NuGenerex purchased certain assets of Veneto and its subsidiaries (the “Assets”). The Veneto Asset Purchase Agreement contains provisions regarding payment terms, confidentiality and indemnification, as well as other customary provisions.

Effective as at October 3, 2018, NuGenerex assigned the Veneto Asset Purchase Agreement to NuGenerex Distribution Solutions 2, LLC. The sole member of NuGenerex Distribution Solutions 2, LLC is NuGenerex Management Services, Inc., a wholly-owned subsidiary of Generex Biotechnology Corporation.

On October 3, 2018, we acquired certain assets from Veneto (the “First Closing Assets”), primarily consisting of the operating assets of (a) system dispensing pharmacies, (b) a central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory.

On November 1, 2018, we consummated the acquisition of Veneto assets (the “Second Closing Assets”), consisting primarily of Veneto’s management services organization business and other assets. The aggregate price for the First Closing Assets and the Second Closing Assets was $30,000,000. We issued a promissory note in the principal amount of $35,000,000 (the “New Note”) consisting of the $30,000,000 purchase price and a $5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. On January 15, 2019, the parties entered into an amendment to the Asset Purchase Agreement (the “Amendment”) restructuring payment of the New Note.

On March 28, 2019, the Company entered into an amendment, a “Restructuring Agreement” with Veneto and the equity owners of Veneto to restructure the payment of the New Note that provided, in lieu of any cash payments, the Company delivered on May 23, 2019 8,400,000 shares of our common stock; plus an aggregate 5,500,000 shares of the common stock of our subsidiary, Antigen. The Veneto assets acquired by Generex included management services operations, systems, facilities, and other services.

On January 7, 2019, we acquired a majority interest in Regentys Corporation (“Regentys”) for an aggregate of $15,000,000, among which $400,000 was paid in cash and the remainder was paid by the issuance of a promissory note with a fair value of $14,342,414 for a total net purchase price of $14,742,414. The total fair value of the assets acquired totaled $907,883 and goodwill of $13,834,581. Installments payable under the note were tied to specific business development objectives and dates. As of October 26, 2019, an additional $850,000 was paid for a total of $1,250,000 against the note. Regentys is developing a non-surgical treatment for inflammatory bowel diseases such as ulcerative colitis and Crohn’s disease.

On January 7, 2019, we acquired a majority interest in Olaregen Therapeutix Inc. (“Olaregen”) for an aggregate of $12,000,000, among which $400,000 was paid in cash and the remainder was paid by the issuance of a promissory note with a fair value of $11,472,334 for a total net purchase price of $11,872,663. The total fair value of the assets acquired totaled $2,461,439 and goodwill of $9,411,224. $1,291,500 principal was paid against the note as of July 31, 2019 and an additional $500,000 was paid subsequently for a total aggregate of $1,791,500 of principal payments in addition to the $400,000 initial payment. Olaregen is launching an FDA-510(k) cleared wound care product.

On May 10, 2019, we acquired from a third party the outstanding Series A Preferred Stock in Olaregen in exchange for 4 million shares of the Company’s common stock, plus the issuance of a $2 million promissory note increasing our interest in Olaregen to approximately 62% of the Olaregen’s outstanding voting shares.
**Business Overview**

Our management team has embarked upon a complete strategic reorganization and transformation of the entire corporate structure, leveraging our legacy assets which have applied over $400 million dollars in developmental activities over the years, providing the Company with net operating loss (“NOL”) carryforwards from both United States and Canadian sources. As of July 31, 2019, the Company has significant NOL carryforwards that are described in detail in the Notes to our Financial Statements included in this 10-K. We have also formulated an acquisition strategy and identified targets to build a specialized healthcare platform with both scalability and the ability to leverage across the organization in an effort to achieve higher profit margins.

Since the new management team has taken over in January 2017, Generex has been reorganized as a strategic, diversified life science holding company that is actively involved in building a modern organizational platform for the financing, development, commercialization, and distribution of promising devices, biologics, therapeutic, and diagnostic products to improve human health and return value to its investors. As the foundation for the reorganization, we are acquiring operating companies that provide multiple and significant revenue streams through delivery of patient-focused healthcare products and services, including specialty pharmacy, orthopedic implants, surgical supplies, biologics, medical devices, and regenerative medicines. These foundational acquisitions service unique market channels that provide end-to-end healthcare solutions in partnerships with patients, physicians, health systems, and payors. The synergistic business models of the combined organization offer cross channel sales opportunities for rapid growth, with significant revenues and profits projected going forward.

Details of the Generex business strategy are provided following the discussion of the Generex historical business and our legacy assets.

**Historical Business**

Historically, we have been a research and development company focused on the commercialization of Oral-lyn buccal insulin spray for diabetes. Additionally, through our wholly-owned subsidiary Antigen Express, we have a deep intellectual property portfolio of immunotherapy assets relating to the “Ii-Key” technology that activates the immune response for the treatment of cancer and infectious diseases. We have completed a Phase IIb clinical trial of AE37 immunotherapeutic peptide vaccine with the Ii-Key technology in over 300 women with breast cancer.

In 2017, we acquired HDS (now NuGenerex Diagnostics) and their diagnostic product portfolio of rapid point-of-care EXPRESS test kits and cassettes for infectious disease testing.

We believe that these legacy diagnostics, diabetes and cancer assets are may have significant value which is not being recognized due to missteps in the clinical development process by previous management, resulting inability to raise capital necessary to fund further development. We think the products and IP portfolio retain significant value. A recently signed co-development deal with a major pharmaceutical company for AE37 in triple negative breast cancer, and a licensing deal in China for AE37 in prostate cancer illustrate the potential for AE37 immunotherapeutic vaccine. Additionally, Oral-lyn has been reformulated to enter clinical trials for Type II diabetes. The HDS EXPRESS diagnostic technology has been expanded with the new, patent-pending EXPRESS II technology and a new product pipeline. We filled our first international commercial order for 40,000 units of its NGDx-Malaria PF/PV Cassette Test Kit to Imres, BV, a Netherlands-based medical distribution company, and was recently granted a CE Mark Certification under the European Medical Devices Directive (MDD) for its The Express II Syphilis Treponemal Assay, a rapid point-of-care diagnostic assay for the detection of syphilis antibodies in primary and secondary syphilis. As part of the reorganization plan, we placed our legacy assets into separate subsidiaries under the NuGenerex family of companies, including NuGenerex Diagnostics, NuGenerex Immuno-Oncology (Antigen Express), and NuGenerex Therapeutics (Oral-Lyn and RapidMist buccal delivery technology). Our strategy is to spin out NuGenerex Immuno-Oncology as a separately traded public company, to reignite the Oral-Lyn development program with a reformulated buccal insulin spray, and to build out the diagnostics business, as detailed in the following paragraphs, however there are no assurances that we will be able to accomplish our strategic objectives.
**Treatment of Legacy Assets**

Generex and its subsidiary companies have extensive patent portfolios, with intellectual property for composition of matter, formulation, design, and use in a number of therapeutic areas, across multiple indications. As described, we plan to build our legacy assets with the ultimate goal to spin-out such assets at the appropriate time, which have been incorporated into NuGenerex subsidiary companies in an effort to unlock the potential unrealized value of the intellectual property and commercial opportunities for these development companies in major markets for immuno-oncology, diabetes, and infectious disease testing:

- **NuGenerex Therapeutics**: Oral-lyn (Buccal Insulin) and RaidMist Buccal delivery technology
- **NuGenerex Immuno-Oncology**: Phase II AE37 + Keytruda in TNBC; Antigen Express (Ii-Key), Licensing, Partnerships, investor dividend paid (1:4) for spin-out
- **NuGenerex Diagnostics**: NGDx Express II rapid diagnostic tests for infectious disease

**NuGenerex Therapeutics**

NuGenerex Therapeutics houses the legacy diabetes assets, Oral-Lyn and RapidMist buccal delivery technology. We believe that our buccal delivery technology is a platform technology that has application to many large molecule drugs and designed to provide 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 cannabinoid medicines. To that end we have entered into a licensing agreement with Scientus Pharmaceuticals for the use of the RapidMist technology for the administration of cannabinoids.

**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 U.S. Food and Drug Administration (“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 facts 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.
According to the Centers for Disease Control (CDC), 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 (CDC). 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.

According to the American Diabetes Association, 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, according to the American Diabetes Association. 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 2017 Diabetes Atlas Update, published by the International Diabetes Federation (IDF), approximately 40 million people in the United States and more than 425 million people worldwide 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.

There is no known cure for diabetes. The IDF estimates that there are currently approximately 382 million diabetics worldwide per their 2017 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 proven drug delivery system for the delivery of large molecules directly into the blood stream with the attendant advantages.

**Oral-lyn History**

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 Investigational New Drug (“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 IND 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 metaanalysis 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. We believe that the 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™.

**Future Plans**

We have reformulated the original Oral-Lyn buccal insulin as a new patentable Oral-Lyn 2 that requires only 2 - 3 pre-prandial (before meal) sprays for the treatment of Type II diabetes. The reformulated Oral-lyn 2 was made possible by new techniques in protein chemistry and pharmaceutical formulation science, that with minimal changes in the production process and content of the components, allow the development of a new and improved, concentrated insulin formulation for improved diabetes management.

NuGenerex has engaged the University of Toronto’s Center for Molecular Design and Pre-formulations (CMDP) through the University Health Network with the goal of enhancing the Oral-lyn™ 2 formulation to make it more attractive to patients and prospective commercialization partners by increasing the bioavailability of insulin in the product and reducing the number of sprays required to achieve effective prandial metabolic control for patients with diabetes. Under the supervision of NuGenerex consultant Dr. Lakshmi P. Kotra, B.Pharm. (Hons), Ph.D., of CMDP, preliminary efforts succeeded in increasing the insulin concentration in the product by approximately 400 - 500% as confirmed by a variety of *in vitro* testing procedures, while preserving the solubility, stability, biologic activity, and potency of the insulin in the formulation.

NuGenerex subsequently entered into a Research Services Agreement with the University of Guelph pursuant to which Dr. Dana Allen, DVM, MSc. and Dr. Ron Johnson, DVM, Ph.D. of the Ontario Veterinary College of the University of Guelph conducted a study of the relative bioavailability of the enhanced formulation in dogs in the University’s Comparative Clinical Research Facility. The University had previously conducted the studies of the original formulation of Generex Oral-lyn™ for proof of concept, safety, and toxicity.
In the new studies, the enhanced NuGenerex Oral-lyn™ 2 formulation was compared with the original formulation in a blinded, parallel controlled study involving fasted, awake, healthy mature beagle dogs. Each dog received three sprays of either the enhanced formulation or the original formulation. Each dog was observed with assessments of serum insulin and glucose measured over a two-hour period. There were no adverse events observed in any of the animals.

In the dogs given the enhanced Generex Oral-lyn™ formulation (5X), there was a greater than 20-fold increase in serum insulin at 15 minutes (excluding one dog who had little response at any time point; (with dog included it was greater than 5-fold)) and almost 500% greater absorption of insulin over the two-hour test period compared to dogs given the original formulation (1X). There was a 33% decrease in serum glucose at 30 minutes in dogs treated with the enhanced Generex Oral-lyn™ formulation, compared to a 12% increase in serum glucose in dogs treated with the original formulation.

The results of the dog studies coupled with the positive findings from the in vitro work provide support and confidence to move forward with the remaining clinical and regulatory work necessary to achieve FDA approval of the enhanced NuGenerex Oral-lyn™ formulation through a 505(b)2 NDA.

The combined results provide evidence that the enhanced NuGenerex Oral-lyn™ 2 will be able to be used by people with either type 1 or type 2 diabetes mellitus as a safe, simple, fast, flexible, and effective alternative to pre-prandial insulin injections with dosing of only two to four sprays required before meals.

The Oral-lyn Safety Database contains information on 1,496 subjects. Eight hundred sixty-nine (869) subjects were exposed to Oral-lyn, while 627 served as Control subjects and were exposed to commercially available oral antihyperglycemics, injected insulin, or Oral-lyn placebo. There were 695 subjects in pK/pD studies (368, Oral-lyn; 327, Control) and 801 subjects in efficacy trials (501, Oral-lyn; 300, Control).

Two hundred seventy-two (272) Oral-lyn subjects reported at least one adverse event (132 in pK/pD studies; 140 in efficacy studies) while 278 Control subjects reported at least one adverse event (111 in pK/pD studies; 167 in efficacy studies). With respect to adverse events by Maximum Severity there appeared to be no significant differences between Oral-lyn and the Control groups in either the Efficacy or the pK studies.

In summary, there appear to be no indications of any significant unexpected adverse events. The expected events of hypoesthesia oral, throat irritation, dry throat, and cough were for the most part mild and could be consistent with the Oral-lyn therapy especially during the learning phase of administration. There was an indication of overlap of some of these events with multiple event terms in the constellation of upper respiratory tract infection that appeared to be balanced across therapy groups.

Our strategy is to revitalize our diabetes program by advancing the reformulated buccal spray Oral-lyn 2 for the treatment of Type II diabetes, and to integrate Oral-Lyn 2 therapy into our end-to-end solution for disease management through our MSO model.

Beyond Oral-lyn 2 for Type II diabetes, NuGenerex Drug Delivery Solutions will advance the RapidMist buccal delivery technology with additional small and large molecule drugs which will benefit from an alternative route of administration.

NuGenerex Immuno-Oncology (NGIO, formerly Antigen Express)

NuGenerex Immuno-Oncology is developing immunotherapeutic products and vaccines based on our proprietary, patented platform technology, li-Key. The li-Key is a peptide derived from the major histocompatibility complex (MHC) Class II associated invariant chain (li) that regulates the formation, trafficking, and antigen-presenting functions of MHC class II complexes, essential for the activation of T cells in the immune response. T cells recognize antigenic epitopes when they are 'presented' to them by specific molecules, termed (MHC) on the surface of infected or malignant cells. This interaction activates the T cells, stimulating a multicellular cascade of actions that eliminates the diseased cell and protects against future disease recurrence.
When the Ii-Key peptide is linked to an antigenic epitope, it can bind to MHC Class II molecules, displacing resident antigens from the antigen binding groove, essentially 'hijacking' the MHC class II complex to present the Ii-Key epitope to selectively activate T-Cell Th1 responses, thereby increasing the intensity and duration of the immune response.

NuGenerex Immuno-Oncology has developed a number of Ii-Key Hybrid peptides for the immunotherapeutic targeting of tumor associated antigens (TAAs) in cancer and for vaccines against infectious diseases.

Ii-Key hybrid peptides can also be used to selectively activate Th2 responses and thereby induce tolerance to antigens involved in harmful immune reactions, e.g. autoimmunity, allergy, and transplant rejection.

**AE37 – Ii-Key/HER2/neu Hybrid Immunotherapeutic Vaccine**

Our most advanced immunotherapy vaccine is AE37, an **Ii-Key-Hybrid molecule** that contains the HER2/neu antigenic peptide linked to the Ii-Key to enhance immune stimulation against HER2, which is expressed in numerous cancers, including breast, prostate, and bladder cancers. We have completed a Phase I clinical trial of AE37 in breast cancer: A phase Ib safety and immunology study of AE37 and GM-CSF in 16 breast cancer patients who had completed all first-line therapies and who were disease-free at the time of enrollment to the study (Holmes et al. Results of the first phase I clinical trial of the novel Ii-Key hybrid preventive HER-2/neu peptide (AE37) vaccine. J Clin Oncol 2008;26:3426-33). Furthermore, we completed a Phase IIb trial of AE37 in the prevention of cancer recurrence in women who were at high risk of recurrence after undergoing successful primary standard of care breast cancer therapies and were disease free at time of enrollment. Though the study enrolled 300 subjects, the results were not statistically significant due to a complete lack of recurrence in the 160 women with HER2-3+ positive tumors who were treated with Herceptin during primary therapy. Though the trial was not powered to evaluate the prevention of recurrence in subgroups, the trial indicated efficacy in the subset of patients diagnosed with HER2 1+, 2+, and triple negative breast cancer.

Based on the results from this trial, NuGenerex has entered into a collaborative agreement with Merck Sharpe & Dohme B.V. (Merck) and the National Surgical Adjuvant Breast and Prostate Program (NSABP) to conduct a Phase II trial to evaluate the safety and efficacy of AE37 in combination with the anti-PD-1 therapy, KEYTRUDA (pembrolizumab) in patients with metastatic triple-negative breast cancer. The trial is scheduled to begin enrolling patients in the second quarter of 2019.

In addition to the breast cancer program, NuGenerex has conducted a Phase I clinical trial in prostate cancer, enrolling thirty-two HER-2/neu+, castrate-sensitive, and castrate-resistant prostate cancer patients to demonstrate safety and strong immunological response to AE37. We are advancing AE37 for the treatment of prostate cancer through a licensing and research agreement with Shenzhen BioScien Pharmaceuticals Co., Ltd., for which NuGenerex has received a $700,000 upfront payment, with additional future milestone and royalty payments.

In exchange for exclusive rights to AE37 for prostate cancer in China, Shenzhen is financing and conducting the Phase II trials in the European Union and Phase III trials globally under International Commission on Harmonisation (“ICH”) guidelines, with NuGenerex retaining the rights to all clinical data for regulatory submissions and commercialization in the rest of the world outside China.

**Future Plans**

NuGenerex Immuno-Oncology has been established to not only to advance the NuGenerex Immuno-Oncology core technology, but also to expand our portfolio in the field of immunotherapy and personalized medicine through partnerships and acquisitions. As part of our strategy, we are planning to spin-out NuGenerex Immuno-Oncology as a separate, publicly traded entity to unlock the true value of the Ii-Key technology for our stockholders as it creates a pure play in immunotherapy, which will foster investment and collaboration.
As an initial step in accomplishing the spin-out of NGIO, on February 25, 2019, we issued a stock dividend to our shareholders, whereby our shareholders received 1 share of NGIO for every 4 shares of our stock held on the dividend date. The stock dividends will enable our stockholders to directly participate in the potentially promising future of NGIO, while creating a large shareholder base with the potential for substantial liquidity immediately upon spin-out to a national exchange, which will provide NGIO with ready access to the capital markets to finance its on-going clinical and regulatory initiatives.

Additionally, we are in discussions with multiple academic institutions and biotechnology development companies to acquire products and technologies to augment the NGIO development pipeline and product portfolio.

We plan to finalize our corporate acquisition strategy and to initiate the spin-out process for NGIO in the second quarter of 2020.

NuGenerex Diagnostics (formerly Hema Diagnostic Systems LLC)

Our wholly-owned subsidiary, NuGenerex Diagnostics (formerly Hema Diagnostic Systems LLC or HDS) is in the business of developing, manufacturing, and distributing rapid point-of-care in-vitro medical diagnostics for infectious diseases. These are commonly referred as rapid diagnostic tests (“RDTs”). We manufacture and sell RDTs based upon our own proprietary EXPRESS platforms as well as standard “cassette” devices.

Since its founding, NuGenerex Diagnostics has been developing and continues to develop an expanding line of RDTs for infectious disease diagnosis. These include products for human immunodeficiency virus (HIV), tuberculosis, malaria, hepatitis B, hepatitis C, syphilis, and others. These assays are all qualitative in nature and provide a simple positive or negative result directly at the clinical site. They can be used for definitive diagnosis, triage or in combination with other assays depending on which disease is being considered.

Each device incorporates a test strip containing reagent lines (stripes) that have been impregnated with specific antigens or antibodies that detect the target molecules specific to an infectious disease. The test strips are incorporated into our proprietary EXPRESS platforms which are easy-to-use and user-friendly diagnostic devices. There are two EXPRESS platforms: the EXPRESS and the EXPRESS II. The EXPRESS II is an upgraded version of the original EXPRESS and its use involves fewer operator steps, making it of higher clinical utility value. The Express II platform is designed to be used in a broad range of clinical and laboratory medical settings and for direct use by consumers in the home. It is simple to use, with fewer steps of operation than other rapid point-of-care tests. A single drop of blood taken by a simple finger stick is added directly to the device and the assay is activated by placing a pod of buffer solution onto the device. Results can be read in as early as 5 minutes, and no longer than 30 minutes. The accuracy of the Express II Syphilis Treponemal Assay is equal to or better than standard laboratory assays for syphilis antibodies with sensitivities and specificities of over 99%.

We believe that each system delivers its own advantages which enhance the use, application and performance of each diagnostic. This ease of use in the EXPRESS delivery systems is designed to ensure that our RDTs perform efficiently and effectively providing the most accurate and repeatable test results available while, at the same time, minimizing the transference of a potentially infected blood sample. The EXPRESS and cassette diagnostic kits for infectious disease testing are designed for use in resource-poor countries throughout the world, especially in sub-Saharan Africa, where the World Health Organization coordinates population screening for infectious diseases. We recently filled our first international commercial order for 40,000 units of its NGDx -Malaria PF/PV Cassette Test Kit to Imres, BV, a Netherlands-based medical distribution company.

NuGenerex Diagnostics was recently granted a CE Mark Certification under the European Medical Devices Directive (MDD) for its The Express II Syphilis Treponemal Assay, a rapid point-of-care diagnostic assay for the detection of syphilis antibodies in primary and secondary syphilis. The assay is based upon NuGenerex Diagnostic’s innovative patent pending point-of-care diagnostic platform, the Express II. The accuracy of the Express II Syphilis Treponemal Assay is equal to or better than standard laboratory assays for syphilis antibodies with sensitivities and specificities of over 99%.
With the receipt of the CE Mark Certification for its rapid point-of-care Express II Syphilis Treponemal Assay, we believe NuGenerex Diagnostics is well situated to enter into this growing syphilis testing market and will now pursue marketing efforts in Europe and, in parallel, begin plans for the filing of a 510k application with the United States FDA for marketing clearance in the United States. To this end, NuGenerex Diagnostics is fully qualified as a diagnostic test developer and manufacturer under FDA Good Manufacturing Procedures (GMP) and is certified by the International Standards Organization for the manufacture of medical devices under ISO 13485-2016 regulations.

NuGenerex Diagnostics has just begun a new initiative which revolves around the development of quantitative rapid diagnostic assays. These assays allow laboratory personnel and clinicians to assess the absolute amount of specific target molecules in blood or serum samples as opposed to “yes” or “no” results of qualitative RDTs. The first assay to be developed is a multiplex biomarker test for the diagnosis of sepsis and the potential differentiation of infectious sepsis from systemic immune response syndrome (SIRS).

We maintain an FDA registered facility in Miramar, Florida and are certified under both ISO9001 and ISO13485 for the Design, Development, Production and Distribution of the in-vitro devices. Approval of our HIV rapid test has been issued by the United States Agency for International Development (USAID). Additionally, some of our products qualified for and carry the European Union “CE” Mark, which allows us to enter into CE Member countries subject to individual country requirements. Currently, we have two malaria rapid tests approved under World Health Organization (WHO) guidelines. This process allows expedited approval of rapid tests, reducing the current 24 -30-month process down to approximately 6-9 months. WHO approval is necessary for our products to be used in those countries which rely upon the expertise of the WHO, as well as for non-governmental organizations (“NGO”) funding for the purchase of diagnostic products.

We maintain current U.S. Certificates of Exportability that are issued by two FDA divisions-CBER and CDRH. CBER (Center for Biologics Evaluation and Research) is the FDA regulatory division that oversees infectious disease diagnostic devices, including our HIV, Hepatitis B and Hepatitis C EXPRESS and EXPRESS II kits. The other division, Center for Devices and Radiological Health (CDRH), is responsible for the oversight of other HDS devices which include Tuberculosis, Syphilis, and the remaining product line. Our HDS facility maintains FDA Establishment Registration status and is in accord with GMP (Good Manufacturing Practice) as confirmed by the FDA.

We do not currently have FDA clearance to sell our products in the United States. We intend to submit selected devices to the FDA under a Pre-Market Approval Application (PMA) or through the 510K process. The 510K would require the appropriate regulatory administrative submissions as well as a limited scientific review by the FDA to determine completeness (acceptance and filing reviews); in-depth scientific, regulatory, and Quality System review by appropriate FDA personnel (substantive review); review and recommendation by the appropriate advisory committee (panel review); and final deliberations, documentation, and notification of the FDA decision. The PMA process is more extensive, requiring clinical trials to support the application. We expect to apply to the FDA for clearance of our first RDT (Express II Syphilis Treponemal Assay) for FDA 510K approval in early 2020. We anticipate the FDA process will be completed within 9 months after submission. During this timeline, we will be preparing documentation for additional rapid tests to undergo either the FDA PMA or 510k process.

Future Plans

Generex plans to use the NuGenerex Diagnostics subsidiary to build a multi-faceted diagnostics business focused on personalized medicine. To that end, we are exploring opportunities in multiplex assays for point-of-care infectious disease testing, pharmacogenomic testing for medication management, and biomarker analysis for personalized cancer treatment, including immunotherapy.
The “New” Generex & The NuGenerex Family of Subsidiary Companies

Through reorganization and acquisition, we are building the family of NuGenerex subsidiary companies to provide end-to-end solutions for physicians and patients. To that end, our subsidiary NuGenerex Distribution Solutions (NDS) has established a network of physicians, ancillary service providers, and patients through a Management Services Organization (MSO). As the MSO network currently consists of orthopedic surgeons and podiatrists, we have acquired and/or have agreements to acquire a number of revenue-generating companies that manufacture, market and distribute surgical and wound healing products. The acquisitions include Olaregen Therapeutix, a regenerative medicine company that has recently launched Excellagen wound conforming gel, which is FDA-cleared for the management of 17 wound healing indications, and Regentys, a clinical-stage development company with regenerative medicine technology for the treatment of inflammatory bowel diseases; Pantheon Medical, a manufacturer of patented, FDA-cleared foot & ankle kits with surgical plates, screws, and tools; and MediSource Partners, a licensed distributor of surgical supplies, orthopedic implants, and biologics, including human placental derived tissue products for regenerative medicine applications. Additionally, NDS will be launching a new software as a service (SaaS) business called DME-IQ that enables orthopedic surgeons to manage in-house programs for orthopedic durable medical equipment, including inventory controls, insurance adjudication, and patient billing. Together, under the banner of these subsidiary companies offer a range of products and services to meet the needs of our proprietary distribution channels. Cross selling of products and services will enhance the revenue opportunities for the entire family of NuGenerex subsidiaries.

Our corporate mission is to provide end-to-end solutions for physicians and patients through geographic expansion of our MSO model, diversification of management services offerings, the establishment of an HMO in partnership with Dr. Kiran Patel, and the proposed acquisition of an Accountable Care Organization for complex care.

The NuGenerex family of subsidiary companies offer a broad range of products and services to meet the needs of physicians and patients, including:

- **NuGenerex Distribution Solutions**: MSO, Ancillary Services, DME-IQ, and Surgical Products.
- **NuGenerex Regenerative Medicine**: Olaregen Therapeutix, Regentys.
- **NuGenerex Surgical Products**: Pantheon Medical – Foot & Ankle, LLC and MediSource Partners, LLC.
- **NuGenerex Health**: MSO/HMO with Dr. Kiran Patel: Ancillary health management services for chronic conditions – 65,000+ Patient population with Diabetes; Ophthalmology, Podiatry, Chronic Care Management (CCM).

**Services and Products**

**NuGenerex Distribution Solutions**

Generex Biotechnology established NuGenerex Distribution Solutions (NDS) in 2018 as the foundational piece in the transformation of the Company into an integrated healthcare holding company that provides end-to-end solutions for physicians and patients. Part of the NDS model includes a physician-owned MSO which is positioned to procure our new products and services as made available. NDS will also continue to provide inventory selection and management, as well as management services for legal and regulatory compliance, accounting, HR, IT and customer support services through the MSO networks.

We serve as the General Partner of the MSO which is 99% owned by over 50 entities. The entities included orthopedic and podiatric surgery centers with over 100 Physicians in 5 states and this MSO structure creates the foundation of our future alternative distribution channel with an open sales channel for products and services. The company plans to expand its geographic footprint nationally where appropriate.
NuGenerex Distribution Solutions Corporate Mission NDS benefits the medical community by providing cost effective ancillary services that ultimately deliver better outcomes and enhance the doctor-patient relationship. NDS will make available numerous best of class products and services using a patient centric approach that enables ancillary service providers, physicians, and patients to better coordinate healthcare services from diagnosis through treatment and follow-up.

NDS Expansion

The NuGenerex MSO network has operated in five states and is configuring a roll out which will be compliant and take costs out of healthcare through better outcomes. Those organizations which invest in our new MSO model will be aligned solely with our GNBT shareholders and will receive discount codes to procure our products such as Excellagen.

DME-IQ

NuGenerex Distribution Solutions is planning a launch DME-IQ, a novel software as a service (SaaS) solution for physicians to manage in-office distribution of durable medical equipment (DME). DME-IQ supports the development and management of compliant and profitable in-office DME programs. DME-IQ focuses on several key areas which include negotiating on behalf of the physicians with key vendors to decrease the COGS (Cost of Goods Sold), increasing insurance collections by providing oversight of the coding during the billing process, providing the necessary personnel to manage the appeals processes, and ensuring compliance with state and federal regulations.

DME-IQ will automate and provide the orthopedic practices with a proprietary, tablet-based software package that immediately verifies patient benefits and eligibility. This unique system manages DME inventory, collects patient copays and deductibles, and links patient information with the DME products and necessary patient forms all in one easy to use platform.

The DME Market

The US market for DME is large and growing, a result of several factors including the rising prevalence of chronic diseases requiring long-term care, the rapidly growing geriatric population, and the trend toward home healthcare services. Chronic disorders such as diabetes, diabetic foot & pressure ulcers, chronic pain, and cancer that require long-term patient care and postoperative recovery are driving demand for DME. According to a 2018 market report by Grand View Research, Inc., the US DME market is expected to reach $70.8 billion by 2025, growing at a 6.0% CAGR during the forecast period.

DME-IQ tracks and maintains DME inventory to ensure an adequate supply and product mix for orthopedic patient populations, and the system facilitates insurance claim submissions and adjudication to help achieve optimal reimbursements. With the DME-IQ system, the practice gains control of their DME program from an operations and financial perspective, while patients gain access to a wider variety of DME products that are custom fitted for their needs.

The explosion of high deductible insurance plans has resulted in a dramatic increase of patient out-of-pocket payments for care, and the subsequent requirement that physicians spend more time as collection agents rather than doctors. DME-IQ provides practice workflow solutions for DME with custom, tablet-based software that removes the administrative burden from the practice, facilitating patient eligibility review, collection of patient co-pay and deductibles, centralized insurance adjudication, DME product procurement, and other support services that allow physician practices to increase revenue and service quality. The launch of DME-IQ advances the mission of NDS to provide physicians with end-to-end solutions for patient centric care.”
Our majority-owned subsidiary, Olaregen Therapeutix, Inc. is a regenerative medicine company focused on the development, manufacturing and commercialization of products that fill unmet needs in the current wound care market. We aim to provide advanced healing solutions that substantially improve medical outcomes while lowering the overall cost of care. Olaregen’s first product, Excellagen® (wound conforming matrix) is a topically applied product for dermal wounds and other indications. Excellagen is a FDA 510(k) cleared device for a broad array of dermal wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds, enabling Olaregen to market Excellagen in multiple vertical markets.

The Wound Care Market

Total Global Wound Care Industry is expected to reach $22.01 billion by 2022, according to Markets and Markets; Bioactive Wound Care Market (i.e. skin substitute) is valued at $7.8 billion; In the U.S. There are 6.5 million patients in the U.S. with chronic wounds (NIH estimate).

Olaregen Highlights

- Received FDA 510(k) clearance on October 3, 2013, for 17 indications;
- Obtained Intellectual properties and global rights of Excellagen® except China, Russia and CIS.
- Received Patent on October 10, 2017;
- Has a unique Healthcare Common Procedure Coding System (HCPCS) Code - Q4149
- Clinical data show significant tissue growth and positive wound closure (PDGF)
- Ease of use – No grafting
- Low cost provider with High profit margins;
- Low execution risk (seasoned management team with product launch experience);
- No development risk (over $20 million invested and completed);
- No regulatory risk (FDA cleared).
Excellagen is an advanced, wound care management platform:

- Formulated fibrillar Type I bovine collagen (2.6%)
- High molecular weight
- Viscosity optimized for dripless wound coverage
- Flowable with no staples or sutures required
- Pre-filled, ready to use syringes
- One syringe covers up to 5.0 cm² wound
- Refrigerated storage only with no thawing or mixing
- Treatment at only one-week intervals
- Activates human platelets
- Triggers the release of Platelet-Derived Growth Factor (PDGF)
- Accelerates granulation tissue growth in “non-healing wounds”

Additionally, Excellagen can serve as an Enabling Delivery Platform for pluripotent stem cells, antimicrobial agents, small molecule drugs, DNA-Based Biologics, conditioned cell media and peptides. Olaregen's initial focus will be in advanced wound care including diabetic foot ulcers (DFU), venous leg ulcers and pressure ulcers. Future products focusing on innovative therapies in bone and joint regeneration comprise the current pipeline.

Excellagen® History

Olaregen Therapeutix Inc. acquired the intellectual properties and global rights of Excellagen® except in China, Russia and CIS, from Taxus Cardium, Inc. (OTC: CRXM), and its wholly owned subsidiaries Activation Therapeutics, Inc. and Gene Biotherapeutics, Inc.

On August 2018, Olaregen acquired the IP for a total consideration is $4,200,000 and is broken down as follows: 1) $650,000 upfront payment, 2) $200,000 sales credit for collagen solution, and 3) $3,350,000 payable at 10% of net sales, which is defined as total sales less allowances, including hub fees, sales concessions, co-promote fees, cost of goods sold and other charges.

Regentys Corporation

Our majority-owned subsidiary, Regentys Corporation (formerly Asana Medical, Inc.) is a regenerative medicine company developing a tissue engineered therapy for the treatment of Ulcerative Colitis.

Overview

In January 2019, we acquired a majority interest in Regentys Corporation, a Florida corporation, a development-stage regenerative medicine company. Since its formation in May 2013 as Asana Medical Inc., Regentys has been developing a first-in-class tissue engineered therapies for the treatment of Ulcerative Colitis (UC) and other inflammatory bowel diseases.
**Ulcerative Colitis**

According to an article that was published in The Lancet on December 23, 2018 named *worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies* (2018 Dec 23;390(10114):2769-2778), Ulcerative Colitis affects an estimated 3.2 million patients in Europe, the United States and Japan. It is a chronic, inflammatory disease that causes sores or ulcers in the lining of the large intestine (the colon). Immunological in nature, UC is thought to be facilitated by a variety of hereditary, genetic and environmental factors and it is increasingly being diagnosed in more urbanized areas. Symptoms, including urgency, bleeding, and diarrhea, that substantially affect quality of life.

**Regentys™ Extracellular Matrix Hydrogel (“ECMH”)**

Regentys’ initial product, ECMH™ Rectal Solution, is a first-in-class, non-pharmacologic, non-surgical treatment option for millions of patients suffering from mild to moderate Ulcerative Colitis. Its product candidate is a powder that is reconstituted with saline and delivered as a liquid via enema. As ECMH reaches body temperature, it gels and coats the mucosal lining of the GI tract.

The core technology is derived from ECM, a safe and effective FDA-approved base now extensively used for surgical applications and wound treatment. ECMH acts as a bio-scaffold, separating the damaged tissue from waste flow, covering ulcerations to limit the inflammatory response, and facilitating a healing environment using endogenous (the body’s own) stem cells.

**Pre-Clinical Results**

Published pre-clinical results in the *Journal of Crohn’s and Colitis* highlight the promise of Regentys technology. Animal data show the ECMH therapy can both alleviate clinical symptoms and facilitate healing in UC patients. Previous pre-clinical ECM animal data for approved products has been shown to have a high correlation with human data.

**Competition**

Currently four biologics are FDA-approved, including top-selling antibody medicines Humira® (adalimumab), Simponi® (golimumab), Remicade® (infliximab) and Entyvio® (vedolizumab), all of which act to suppress the pro-inflammatory protein, TNF-a (Tumor Necrosis Factor Alpha), a leading cause of the proliferation of ulcerative colitis and other forms of IDB. However, even with these options, more than half of all UC patients do not achieve long-term remission. Moreover, 20-30% of non-responsive patients will undergo colon removal surgery in an attempt to remediate the disease.

**Regentys Advantages**

We expect our product to offer a true alternative to patients non-responsive to first line therapies such as 5-ASA.Unresponsive patients will then need to choose among therapies that alter the body’s immune system or pose long term health risks or perhaps both. Regentys’ technology is expected to enable targeted tissue healing but pose none of the health risks of more expensive market-leading biologics that generally suppress the immune system. We expect to provide our therapy at a cost less than other therapies.

**Market**
In 2023, when we expect to receive approval, the projected drug costs for UC alone are expected to exceed $7.5B globally according to a 2017 report by Allied Market Research; including other inflammatory bowel disease indications, the global market is expected to be double the UC market. Based upon the nature of IBD, and the characteristics of Regentys’ technology, management believes variations of Regentys’ core technology will also be effective in treating IBD diseases such as Crohn’s, rectal mucositis, proctitis and anal fissures.

Intellectual Property

Regentys in-licensed patents and co-developed its technology platform with the University of Pittsburgh. It now holds patent rights in US and foreign jurisdictions, and has other global filings pending; as well, it has patent applications pending for similar indications predicated on its existing technology in other major global markets.

Regulatory Path

The FDA has affirmed our approach to file a 510(k) de novo application on its ECM hydrogel. We have developed a protocol and has engaged a clinical research organization to manage the conduct of its first-in-human clinical trials expected to start in Q2/Q3 2020 in Australia. Additionally, we have engaged consultants to assist in managing the trials and regulatory approval process in Australia, the US and Europe, jurisdictions in which we initially expect to undertake clinical trials and, among other markets, where it will first seek governmental approval to promote and sell medical devices.

Product Development

Since 2013, we have maintained a research and development agreement with the University of Pittsburgh supplemented with personnel from the affiliated McGowan Institute of Regenerative Medicine. In February 2018, Regentys entered into a development agreement with (and has received a co-investment by) Cook Biotech, Inc., a global leader in ECM manufacturing technology (CookBio). Product batches now on hand are expected to be sufficient for additional development and testing. A larger clinical batch with finalized specifications will be generated in the coming months for use in clinical trials. There are alternate providers of development services who can assist with product development activities. Notwithstanding these options, management believes that because of the nature of ongoing development activities, and the reliance upon certain bench and manufacturing processes and ECM product expertise and technology, any interruption in the development relationship with CookBio would subject the Company to substantial expenditures of time and cost to duplicate the product.

Manufacturing

Regentys has an exclusive manufacturing agreement with CookBio for the production of biomaterial and use of its proprietary technology conditioned upon the completion of final product development work. Management has negotiated an agreement with a third-party manufacturer for product components and kitting. We believe that there are alternate sources of these manufacturing and supply services. However, because of the nature of regulation in the medical device industry, and the reliance upon the collection, reporting and management of medical device manufacturing data, a change of manufacturer would substantially impact the time and cost required for clinical product production and regulatory compliance.

Financing

In January 2019, Regentys was acquired by Generex for an aggregate purchase price of $15,000,000, with $400,000 paid in upfront cash up-front and a promissory note of $14,600,000. Installments payable under the note were tied to specific business development objectives and dates. As October 3, 2019, an additional $850,000 was paid for a total of $1,250,000 against the note. Regentys entered into an accommodation agreement dated March 14, 2019 with Generex to provide longer time to pay. While Generex has not timely made the required payments as of the date this 10-K is filed, Management believes that payments now due will provide sufficient and timely funding to undertake and finalize its first-in-human clinical trials and to acquire one or more regulatory approvals to market and sell our products in Australia, the US and/or the EU.
Operations

Currently, Regentys employs four full-time contract employees and several part-time consultants. We supplement our business operations by engaging external legal (intellectual property, corporate and health care), accounting and tax professionals. We also have contracted with information services, regulatory and clinical trial companies who make available professionals to manage the information services, regulatory, clinical, and compliance aspects of the business. Upon payment of the interim note, Regentys will formally add two contract employees, additional administrative staff and a third-party provider to assist with employee payroll and benefits as well as undertake clinical trial activities suiting external support.

NuGenerex Surgical Products

Pantheon Medical – Foot & Ankle, LLC and MediSource Partners, LLC

Pantheon Medical is a manufacturer of orthopedic foot & ankle surgery kits that offer physician friendly “all-in-one,” integrated surgical kits that include plates, screws, and tools required for orthopedic surgeons and podiatrists conducting foot and ankle surgeries.

MediSource Partners is a 10-year old private company that is an FDA registered distributor of surgical, medical, and biologic supplies, with over 25 vendor contracts for nationwide distribution of implants and devices for spine, hips, knees, foot, ankle, hand, and wrist surgeries. Additional product lines include biologics (blood, bone, tissue, stem cells), durable medical equipment, and soft goods. We maintain partnerships and contracts with hospital systems for ordering, billing and inventory management.

The acquisitions of Pantheon and MediSource were finalized on August 1, 2019, immediately subsequent to the end of our 2019 fiscal year. MediSource Partners has contracts with over 25 vendors (including Pantheon Medical) for distribution of:

- Implants and devices
- Biologics (blood, bone, tissue, and stem cells)
- Durable medical equipment
- Soft Goods
- Kits to process bone marrow aspirates and platelet rich plasma biologics

Historical Background

MediSource Partners was founded in 2009 and designed to be unique amongst its competitors by operating as a service-focused, “one stop shop” for the healthcare professionals it serves. With over 25,000 products in its catalogue, including thirteen (13) lines dedicated to spine, MediSource prides itself on its ability to service everything from small private practices across several disciplines, to entire hospital systems. The large and broad-based inventory allows our client physicians to “customize” their operating environment by selecting and implementing the hardware, biologics, soft goods and ancillary tools they feel most confident in and comfortable with. In addition, the “one stop shop” model reduces the burden placed on support staff tasked with managing multiple reps from multiple vendors and shortens the distribution chain to reduce costs and potential redundancies. The success of this model is demonstrated in MediSource’s ability to offer this client-focused, low-impact service at a pricing matrix often below even standard GPO pricing, thus increasing client profitability and productivity.

Pantheon Medical was founded in 2014 to build a manufacturing company with proprietary product lines that offer convenience and cost effectiveness to physicians. Pantheon is contracted with MediSource Partners for nationwide distribution of its proprietary “All-in-One” Foot & Ankle Surgery Kit.
Product Development

Pantheon Medical – Foot & Ankle, LLC is developing proprietary surgical systems to expand the product line. Over the next three years Pantheon will be developing three new product lines for submission to the FDA for 510K clearance, including Cannulated Screws, a Hammertoe System and Surgical Staples. Additionally, MediSource Partners will distribute a line of regenerative medicine products under development by an affiliated organization licensed for the production of biologics, including umbilical cord blood and Wharton’s Jelly (rich sources of stem cells), mesenchymal stem cells, and human placental derived tissue factors, primarily exosomes.

The acquisitions of Pantheon and MediSource Partners expands the commercial product portfolio of Generex into the surgical field, adding revenues and profits with their current product line and significant upside opportunities for new FDA-approved product introductions over the next several years. The MSO partners in NuGenerex Distribution Solutions, many of whom are orthopedic surgeons and podiatrists, will immediately benefit from Pantheon’s Foot & Ankle surgery kit.

NuGenerex Health, LLC

In addition to our efforts in orthopedic medicine, we are currently in the process of setting up NuGenerex Health MSO to provide ancillary health services in partnership with Arizona Endocrinology Center and Paradise Valley Family Medicine, two major physician practices that care for a population of ~65,000 patients, approximately 25,000 of whom are insulin dependent diabetics with chronic care needs. With an initial focus on the management of complex diabetes patients, NuGenerex Health will offer ophthalmology, podiatry, chronic care management (CCM) services to provide patients with integrated, concierge care to improve outcomes and reduce costs. NuGenerex Health will employ ophthalmologists, podiatrists, and medical staff to provide ancillary health services for chronic care diabetes patients in support of the endocrinology and family medicine practices. By bringing the specialty ancillary care directly to the patients who regularly visit the clinic, NuGenerex Health provides an integrated, collaborative care model to not only enhance patient wellbeing, but also to comply with CMS guidelines for diabetes and chronic care management that can lead to 5-star ratings and increased reimbursements.

Ophthalmology

Regular eye exams for persons diagnosed with diabetes mellitus are important for detecting potentially treatable vision loss. Monitoring, surveillance, and evaluation of visual health are widely recognized as prerequisites for effective, accessible, and high-quality individual and population-based health services.

Medicare Part B (Medical Insurance) covers preventive and diagnostic eye exams as part of a comprehensive diabetes care plan, with reimbursements averaging $215 per patient for standard eye exam with accompanying tests for glaucoma and macular degeneration.

Podiatry

According to an article that was published in Therapeutics Advances Endocrinology & Metabolism, Financial burden of diabetic foot ulcers to world: a progressive topic to discuss always(2018 Jan; 9(1): 29–31.), as diabetic foot ulcers (DFUs) are the leading cause of non-traumatic lower extremity amputation costing an estimated $13 billion annually, CMS promotes preventive and diagnostic foot exams by a podiatrist, with reimbursement rates averaging $175 for a new patient evaluation, and $150 for follow up. Under the CMS guidelines, patients are eligible for diabetic foot exams every six months.

Chronic Care Management (CCM)

According to the CDC an estimated 117 million adults have one or more chronic health conditions, and 2/3 of Medicare patients have 2 or more chronic conditions. The Centers for Medicare & Medicaid Services (CMS) made benefit payments of $583 billion in 2018, with chronic care patients accounting for 99% of expenditures. Recognizing chronic care management (CCM) as a critical component of health care, CMS has established reimbursement codes to promote adoption in the marketplace, including significant improvements in 2017 that increased payment amounts and introduced new billing codes. NuGenerex Health is designed to provide comprehensive ancillary services to fill the current gaps in care that lead to significant morbidity and astronomical costs of diabetes.
Once the model is established for the diabetes population in Arizona, NuGenerex Health plans to expand to other states.

**NuGenerex Health HMO**

Generex is in the process of building the final link in our corporate mission to provide physicians, hospitals, and all healthcare providers with an end-to-end solution for patient-centric care from rapid diagnosis through delivery of personalized therapies, streamlining care processes, minimizing expenses, and delivering transparency for payers.

Generex intends to establish NuGenerex Health a multi-specialty Management Services Organization (MSO) that will serve as in-network providers for a health maintenance organization (HMO) that provides healthcare services and disease management solutions for patients living with chronic medical conditions. NuGenerex Health will serve patients with Chronic Special Needs Plans (C-SNP) and Dual-Eligible Special Needs Plans under Medicare Advantage and Medicare Part B and Part D. In doing this, Generex intends to partner with an experienced HMO developer. Following the roadmap established by this partner in building some of the most successful HMO companies in recent history, NuGenerex plans to generate significant membership growth by developing patient-centric engagement programs and building on our strong provider relationships. The HMO infrastructure will be managed by Beacon Health Solutions, which has provided back-end services for HMOs since 2009.

**Contemplated Product Positioning and Plan Design**

**Medicare Advantage Prescription Drug Plan (MAPD) HMO** for individuals who have both Medicare Part A and Part B. This plan caters to individuals that prefer an all-inclusive product that covers Part C, Part D, and additional supplemental benefits at a low plan premium amount.

**Chronic Special Needs Plan (CSNP) HMO** for individuals in addition to having Medicare Part A and Part B are faced with the burden of living with diabetes or a cardiovascular disorder. This plan is offered to individuals that prefer an all-inclusive product that covers Part C, Part D, and additional supplemental benefits at a low plan premium amount.

**Dual Eligible Special Needs Plan (DSNP) HMO** for individuals that have both Medicare Part A and Part B and medical assistance through their state of residence. This plan is offered to individuals that prefer an all-inclusive product that covers Part C, Part D, and additional supplemental benefits with no monthly plan premium.

**NuGenerex Health D-SNP HMO** Full will cover all Medicare-covered benefits at zero cost-sharing. In addition to the base supplemental products, the plan also offers routine foot care, and transportation.

**GOVERNMENT REGULATION**

**Regulatory Considerations for Generex**

Our research and development activities and the manufacturing and marketing of our medical device, biologic, and pharmaceutical products are subject to extensive regulation by the FDA in the United States, Health Canada in Canada, the EMEA in Europe, 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 medical device, biologic, and 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 medical device, biologic or 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, a 510(k), PMA or Biologics License Application (“BLA”); and
- Obtaining FDA approval of the NDA, BLA, PMA, or 510(k) 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.
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 I 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.

The Investigational New Drug Application for the Phase II trial of AE37 in combination with pembrolizumab (Merck’s Keytruda) for treatment of triple negative breast cancer became effective in December 2018, and the trial is expected to begin enrolling patients in the second quarter of 2019.

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. We have received a number of foreign regulatory approval for the first generation Oral-lyn buccal insulin and over-the-counter products in the past, however, Oral-Lyn was never launched, and we are not manufacturing, marketing, nor distributing products in these regions based upon these approvals.

In May 2019, NuGenerex Diagnostics (formerly HDS) filled an international order for 40,000 units of its malarial diagnostic product, The NGDx-Malaria PF/PV Cassette Test Kit to Imres, BV, a Netherlands-based medical distribution company. The kits were part of a World Health Organization contract. That contract is fulfilled, and the contract has expired.

We have relocated our headquarters from Canada to the United States, but we maintain our Canadian entity, Generex Pharmaceuticals, Inc. This entity contains all the intellectual property (IP) for the entire history of our Oral-Lyn diabetic products and patents for buccal delivery. There are no live operations in Canada, but we continue with an office. Also, temporarily, as we continue to transition GNBT into a major company again, our Banking Operations are housed at the Royal Bank of Canada (RBC) and will be replaced by a USA based public company treasury platform with JP Morgan Chase. This entity also holds a significant Canadian NOL of value to be used upon the reactivation of operations once funded.

We have a few international initiatives that we continue to pursue in regard to development of new drugs, however, no international clinical trials are currently being conducted. Moving forward, we will pursue international development of promising drug candidates, with the goal of out-licensing those products to local companies or to international pharmaceutical companies for marketing and distribution in those countries, particularly in the European Union and Japan represent major markets for pharmaceutical and diagnostic products. To that end, we are in frequent contact with international countries with interests in licensing agreements with us on some of our products. Currently we have a licensing agreement with Shen Zhen BioScien for the rights to our cancer vaccine AE37 for the treatment of prostate cancer in China.
NuGenerex Diagnostics Regulatory Considerations

The manufacturing and marketing of our existing and proposed diagnostic products are regulated by the FDA and comparable regulatory bodies in other countries. Our products are also regulated by, subject to approval by, or must meet standards set by, of certain non-governmental organizations involved in the purchase and distribution of products like ours. These regulations and standards govern almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and record keeping.

Commercialization of medical devices in the European Union requires meeting the regulatory guidelines of the European Medical Devices Directive (MDD) and fulfillment of those requirements allows a device to carry the “CE-Mark” as verification of its diagnostic authenticity.

FDA regulated products require some form of action by that agency before they can be marketed in the United States, and, after approval or clearance, we must continue to comply with other FDA requirements applicable to marketed products, e.g. Quality Systems (for medical devices). Failure to comply with the FDA’s requirements can lead to significant penalties, both before and after approval or clearance.

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA’s implementing regulations have an approved application), the FDA must approve a Pre-Marketing Application (“PMA”) before marketing can begin. PMA’s must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA application is typically a complex submission, including the results of non-clinical and clinical studies. Preparing a PMA application is a much more expensive, detailed and time-consuming process as compared with a 510(k) pre-market notification.

In addition, the FDA regulates the export of medical devices that have not been cleared for marketing in the United States. The Federal Food, Drug and Cosmetic Act contains general requirements for any medical device that may not be sold in the United States and is intended for export. Specifically, a medical device intended for export is not deemed to be adulterated or misbranded if the product: (1) complies with the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is prominently labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. However, the Federal Food, Drug and Cosmetic Act does permit the export of devices to any country in the world, if the device complies with the laws of the importing country and has valid marketing authorization in one of several "listed" countries under the theory that these listed countries have sophisticated mechanisms for the review of medical devices for safety and effectiveness.

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We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval or evaluations by international public health agencies, such as the World Health Organization, in order to sell diagnostic products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for United States governmental approvals. On the other hand, the fact that our HIV diagnostic tests are of value in the AIDS epidemic may lead to some government process being expedited. The extent of potentially adverse governmental regulation affecting HDS that might arise from future legislative or administrative action cannot be predicted.

Our products may rely on international regulatory approvals for sale into markets outside of the USA, and, domestically, our devices would require US FDA clearance and, in some cases, WHO Listings.

It is our intent to focus on both the domestic and international regulatory approvals.

Domestically, we intend on submitting our devices to the FDA under a Pre-Market Approval Application (PMA) or through the 510K process. The 510K would require the appropriate regulatory administrative submissions as well as a limited scientific review by the FDA to determine completeness (acceptance and filing reviews); in-depth scientific, regulatory, and Quality System review by appropriate FDA personnel (substantive review); review and recommendation by the appropriate advisory committee (panel review); and final deliberations, documentation, and notification of the FDA decision. The PMA process is more extensive, requiring clinical trials to support the application. We expect to apply to FDA for approval of our first Rapid Diagnostic Test (RDT) to be submitted to the FDA for 510K approval within the next 3 months. We anticipate the FDA process will be completed within 12-18 months after submission.

Internationally, we intend on submitting our EXPRESS devices and cassettes to the WHO procurement listing process which requires a full regulatory and quality documentation dossier, produced and compiled by the Company. WHO process requires laboratory testing and evaluation and then may require clinical trials for public deployment and documentation throughout the whole process.

Once the WHO process is complete and documented, there is a submission into the Global Fund, which is a partnership between governments, civil society, the private sector and people affected by infectious diseases specifically HIV/AIDS, tuberculosis, and malaria.

The Global Fund raises and invests nearly $4 billion a year to support programs run by local experts in countries that are most in need.

It is our intent to submit selected cassettes and EXPRESS RTDs to the FDA, WHO and the Global Fund for regulatory review.

Currently, both our cassette malaria pF and malaria pF/pV have been listed under the WHO procurement process.

**Regulatory considerations for the NuGenerex Family of Companies**

Our business is subject to highly complex United States federal and state regulations that may impact our ability to fully implement our strategic plans and initiatives. We are required to obtain and hold licenses and permits and to comply with the regulatory requirements of various governmental agencies. If we fail to comply with such regulatory requirements or if allegations are made that we fail to comply with such regulations, the economic viability of our Company may be adversely affected.
FDA Regulations

The manufacturers and suppliers of the products we market are subject to extensive regulation by the FDA, other federal governmental agencies, and state authorities. These laws and regulations govern the approval of, clearance of, or license to commercialize medical devices (such as Orthopedic Implants), Biologics, and drugs. This includes compliance with the standards and requirements related to the design, testing, manufacture, labeling, promotion, and sales of the products, record keeping requirements, tracking of devices, reporting of potential product defects and adverse events, conduct of corrections, and recalls and other matters. As a distributor, marketer, and now, an FDA-registered medical device specification developer and repackager/relabeler of such FDA-regulated products, we are subject to independent requirements to register and list certain products. We may be required to obtain state licensure or certifications and we may be subject to inspections, in addition to complying with requirements that apply to the manufacturers of the products we market. Failure to comply with those applicable requirements could result in a wide variety of enforcement actions, ranging from warning letters to more severe sanctions such as fines, civil penalties, operating restrictions, injunctions, and criminal prosecutions. To support our Biologics product lines, we are a registered establishment with the FDA for the storage and distribution of human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Healthcare Laws and Regulations

We are required to comply with federal and state healthcare laws and regulations. Such healthcare fraud and abuse laws apply to the relationships that we and our distributors have with healthcare professionals and entities, such as physicians and hospitals. U.S. federal health care laws including laws related to false claims, health care fraud and abuse, physician self-referrals, and anti-kickbacks apply when we or are customers submit claims for items or services that are reimbursed under federally-funded health care programs (such as Medicare or Medicaid). In comparable fashion, state health care laws of a similar nature apply to state-funded health care programs and may also apply with private third-party payors. The requirements of these laws are complex and subject to varying interpretations. If we fail to comply with these laws, we could be subject to federal or state government investigations, substantial fines, exclusion from future participation in government healthcare programs, and civil or criminal sanctions. Such sanctions and damages could adversely affect the economic viability of our Company.

We instituted a company-wide compliance program for all employees, vendors, and contractors. During 2018, we hired a compliance officer who is responsible for developing compliance programs, reviewing our policies, overseeing adherence to those policies, and advising management on possible risks. Our policies related to this realm include general ethical business practices as well as specific operating policies and training to ensure compliance with relevant and applicable healthcare laws and regulations that include the laws referenced above in addition to other applicable laws, such as Health Insurance Portability and Accountability Act of 1996, as amended (“HIPPA”) and the Physician Payments Sunshine Act.

NuGenerex Distribution Solutions and MSO Regulatory Considerations

NuGenerex Distribution Solutions has operated under strict federal and state guidelines across several of the product and service lines offered by the Company. In particular, the NuGenerex MSO is regulated at the state level, where the physician-owned management services organization (MSO) has been deemed by our healthcare attorneys to be legally compliant in 27 states. The NuGenerex MSO operates in compliance with all laws and regulations as detailed below:

We believe that the following statements support an assertion that the ownership structure of the Company and the proposed arrangement as a whole is structured to comply with some of the recommendations set forth by the OIG in the Bulletin, the Special Fraud Alert and other guidance:

• Each investor will have made a financial investment in a bona fide business venture organized for the primary purpose of performing certain contracted services for the benefit of a Contracted Ancillary Provider;

• If an investor receives any distributions, such distributions will be made solely on the basis of such investor’s proportionate ownership of the Company, and not on the basis of referrals by any individual or class of investors or the revenues generated by referrals from such investor;

• Subscriptions for ownership of the Company will not be accepted or rejected on the basis of expected volume of referrals or amount of business otherwise generated for the Company or indirectly a Contracted Ancillary Provider by the subscriber; and

• There is no requirement that an investor make referrals to, or otherwise generate business for, a Contracted Ancillary Provider, NuGenerex or the Company as a condition of participation in the Company.
Some of the most applicable health care related laws, rules, and regulations to the company are, including but not limited to, the following:

**Stark Laws**

The types of financial arrangements between a physician and an entity that trigger the self-referral prohibitions of the Stark Law are broad and include direct and indirect ownership and investment interests and direct and indirect compensation arrangements. We do not believe that the Stark Law will be applicable to the Company or any Physician Member because neither we nor any Physician Member intends to make any referral to a Contracted Ancillary Provider (as hereinafter defined) for the furnishing of any ancillary healthcare services for which payment may be made under the Medicare or Medicaid programs.

We do not believe the Subcontracted Services Agreement creates a direct financial relationship between the Physician Members (or their professional organizations) and a Contracted Ancillary Provider because (i) the Vendor Services Agreement is between NuGenerex on the one hand, and a Contracted Ancillary Provider on the other and (ii) the Subcontracted Services Agreement is between the Company on the one hand and NuGenerex on the other. Further, we believe that the Subcontracted Services Agreement, as structured, complies with the Stark Law exception for personal services should any enforcement authorities or agencies take the position that the Physician Members have a direct financial relationship with a Contracted Ancillary Provider. Further, we believe the arrangements meet the Stark Law exception for personal services.

**The Anti-Kickback Statue**

The federal anti-kickback statute, (the “Anti-Kickback Statute”), makes it a felony to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, to induce, or in exchange for, referrals of business reimbursed under federal health care programs, including Medicare and Medicaid.

We do not believe that the Anti-Kickback Statute will be applicable to the Company or any Physician Member because neither we nor any Physician Member intends to make any referral of business to a Contracted Ancillary Provider reimbursed under any federal healthcare programs, including Medicare and Medicaid.

**False Claims Act**

The False Claims Act is a civil statute used as a primary tool for recovering monies from health care entities who have committed fraud against the federal government.

We do not intend to receive any compensation that is related to the referral of patients covered by any federal healthcare program, including Medicare and Medicaid. We also plan to take precautions to avoid any activity that could be considered civil or criminal false claims.

**Civil Monetary Penalty Statute**

The Civil Monetary Penalty Statute prohibits a health care provider from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to Medicare or Medicaid patients under the physician’s direct care. We do not believe that the Civil Monetary Penalty Statute will be applicable to the Company or any Physician Member because neither we nor any Physician Member intends to make any referral of business to a Contracted Ancillary Provider reimbursed under the Medicare or Medicaid programs.

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Each state has its own statutes and regulation governing relationships among healthcare providers, including ant-kickback, limitations on referral fees and similar issues. Other states may have more restrictive laws which would make pursuing our business plan more difficult. Given that we started in Texas the following are examples of the types of state by state regulations which will govern us.

**Texas Patient Non-Solicitation Act**

The Texas Patient Non-Solicitation Act prohibits anyone from intentionally or knowingly offering to pay or agreeing to accept any remuneration (directly or indirectly, overtly or covertly, or in cash or in kind) to or from anyone else for securing or soliciting patients for or from a person licensed, certified or registered by a Texas healthcare regulatory agency. Unlike the Stark Law and the Anti-Kickback Statute that only apply to payments by federal government programs, the Texas Patient Non-Solicitation Act applies to all payers, including private insurance companies. As a means of balancing this broad application, however, the Texas Patient Non-Solicitation Act provides that compliance with the Anti-Kickback Statute constitutes compliance with the Texas Patient Non-Solicitation Act.

Because the Texas statute provides that compliance with the Anti-Kickback Statute constitutes compliance with the Texas Patient Non-Solicitation Act, the analysis of the Company under the Texas Patient Non-Solicitation Act is essentially the same as the analysis under the Anti-Kickback Statute.

**Texas Fee Splitting**

The Texas Medical Practice Act prohibits fee-splitting and other unprofessional conduct. Any physician who is found to have violated the Texas Medical Practice Act may be subject to criminal sanctions or loss of such physician’s license to practice medicine. Prospective physician investors are advised to consult their personal counsel regarding the potential impact of this statute on their individual circumstances.

**Texas Commercial Bribery Statute**

The Texas Commercial Bribery Statute makes it a criminal violation for anyone, including a physician, acting without the consent of their patient, to accept any benefit from another person or entity to influence such physician’s conduct toward the patient. A violation of the commercial bribery law could result in a physician’s loss of license to practice medicine in Texas.

The risk of violation of both the commercial bribery and the non-solicitation of patient’s statutes will be significantly reduced if the patient of a Physician Member, prior to receiving services from a Contracted Ancillary Provider, is informed of the Physician Member’s ownership in the Company and its indirect financial relationship with a Contracted Ancillary Provider.

**MARKETING AND DISTRIBUTION**

**Generex Historical Business Marketing & Distribution**

Historically, Generex had marketing agreements with international distribution companies for distribution of Oral-Lyn in approved territories. Those agreements are no longer in effect.

Currently, as clinical stage development companies, neither NuGenerex Immuno-Oncology (formerly Antigen Express) nor NuGenerex Therapeutics (Oral-Lyn and RapidMist buccal delivery system) markets or distributes any products.
**NuGenerex Diagnostics Marketing & Distribution**

Sales of the NuGenerex Diagnostics EXPRESS line of diagnostic kits for infectious diseases is dependent on regulatory approvals issued by such agencies as the WHO, FDA and registration with the Global Fund. These approvals are a key element in the sales and marketing effort on an international basis. We will work with these organizations as well as governmental agencies in target countries and commercial companies.

**WHO-Listed**

Following the successful fulfillment of previous PFSCM (Partnership for Supply Chain Management) and WHO shipments, HDS continues to participate in requests for proposals from PFSCM for our currently WHO-approved HDS Malaria test. All of the HDS Malaria RDT’s are on the WHO procurement list.

We will also participate in the newly designed and recently announced WHO Pre-Qualification Program for Malaria RDTs. It is our intention to present the new Malaria EXPRESS II devices for Pf, Pf/Pv and Pf/Pan for this Pre-Qualification Program.

**NGDx EXPRESS II - Syphilis**

In January 2019, NuGenerex Diagnostics received CE Marking Certification for its rapid point-of-care Express II Syphilis Treponemal Assay from the European Union. We are currently seeking a distribution partner to launch the test in Europe in the fourth quarter of 2019.

**Olaregen Marketing & Distribution**

Olaregen has established a team of internal sales and marketing professionals who oversee the marketing, sales & distribution for Excellagen. Currently the product is sold and marketed in the United States. Olaregen Therapeutix Inc. plans to focus its efforts on selling to the Veterans Affairs (VA) system, surgeons, dermatologists, and in phase II to wound care centers and nursing homes. These are important market segments since approximately ~80-90% of patients that qualify for using Excellagen are treated in these centers and nursing homes. Excellagen can be used for nearly all wound indications but management plans to focus on difficult to manage wounds including Diabetic, Venous and Arterial ulcers initially as well as Post Moth’s surgery, Operating Rooms (OR) and Ambulatory Care Surgeries with all these indications being extremely prevalent, most significantly amongst the elderly.

Olaregen is signing intra-company agreements with partner companies in the NuGenerex family of companies for distribution of Excellagen through both our proprietary market channels, and through our national distribution footprint.

**Manufacturing**

**Generex Historical Business**

**NuGenerex Immuno-Oncology (formerly Antigen Express) Manufacturing**

NuGenerex Immuno-Oncology manufactures AE37 immunotherapeutic vaccine, a nineteen amino-acid peptide referred to as AE37 (Ii-Key/HER2 776-790 hybrid) under contract with PolyPeptide Laboratories, San Diego, CA. The suspended substance (lyophilized peptide suspended in sterile, normal saline) is formulated into 2 mL glass vials containing 500 micrograms of peptide in 0.5 mL of 0.45% saline. All manufacturing of AE37 is conducted under FDA cGMP compliance.
We have produced, packaged and shipped AE37 for the upcoming clinical trial of AE37 in combination with pembrolizumab (Merck’s Keytruda) for the treatment of triple negative breast cancer.

The Company will require additional manufacturing for future trials with AE37 or any other Ii-Key hybrid immunotherapeutic peptide for the treatment of cancer, and plans to use PolyPeptide Laboratories for future production work. In the event that PolyPeptide Laboratories is unable to meet the manufacturing requirements of NuGenerex Immuno-Oncology, there are multiple contract manufacturers that can provide cGMP peptide synthesis, purification, and packaging services.

**NGDx Diagnostic Manufacturing**

NGDx manufactures its RTD devices in our Miramar, Florida facility. Based on order size, delivery requirements and current orders in process, the Miramar facility can manufacture up to 1 million RTD devices, all of which are currently hand assembled. We have long-standing relationships with subcontractors to handle additional production requirements.

Cassette production is conducted through subcontractors in India and China. Each site operates under GMP (Good Manufacturing Practice) as well as being compliant with ISO 9001 and ISO13485. All HDS cassettes are included in our U.S. Certificate of Exportability and European Union CE Mark registrations. All of our cassette malaria tests are approved by the WHO.

We have established Quality and Assembly Agreements as well as confidentiality agreements with our subcontractors. All are subject to our inspection at a moment’s notice.

The quality of final assembly of each of our products is maintained under the strict guidelines of our internal Quality System, which forms the basis for our ISO13485 rating.

Full quality oversight is mandatory and final batch release testing is conducted on each lot of products assembled prior to shipment release.

With full automation, we anticipate producing up to 10 million EXPRESS devices annually. Expanded production would allow for additional expansion beyond this volume. Additionally, it is anticipated that subcontractors would provide approximately 60 million cassette tests per year.

**Olaregen Manufacturing**

Olaregen contracts with a third-party specialty manufacturer in the United Kingdom to manufacture Excellagen. Excellagen is an aseptically manufactured, flowable dermal matrix consisting of a stabilized formulation of renatured atelopeptide bovine fibrillar tropocollagen supplied in prefilled, ready to use syringes. Excellagen is manufactured according to Current Good Manufacturing Practices (cGMP) and requires controlled temperature storage (2-8°C) to maintain structural integrity and bioactivity.

During manufacture, the collagen component of Excellagen is purified using a specialized, validated aseptic process that effectively inactivates potential contaminating viruses, eliminates impurities, and removes denatured molecules and collagen fragments. Excellagen consists almost exclusively of high molecular weight, intact, fibrillar collagen and is formulated at a concentration of 2.6% (26 mg/mL) in a physiologic buffer with protein stabilizing agents.
Regentys Manufacturing

Regentys has contracted with Cook Biotech Incorporated (CBI), West Lafayette, IN on the development and manufacture of the Regentys ECMH™ (Extracellular Matrix Hydrogel) Rectal Solution, an extracellular matrix hydrogel derived from small intestinal submucosa (SIS) of pigs. All manufacturing is conducted according to FDA cGMP standards.

Pantheon Medical Manufacturing

Pantheon manufacturers foot & ankle surgical kits including plates and screws under contract with a third-party contract manufacturer. The FDA has granted 510(k) clearance (“510(k) Approval”) to the Pantheon plates and screws, authorizing Pantheon to commercially distribute the foot & ankle surgical kit. The 510(k) Approval process, also known as pre-market notification, requires demonstrating that the new medical device is substantially equivalent to a legally U.S. marketed medical device. Once a device receives a 510(k) Approval, maintaining that status is based on compliance with annual requirements set by the FDA. All manufacturing is conducted under FDA GMP compliance.

RAW MATERIAL SUPPLIES

Generex Historical Business Raw Materials

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 believe 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.

AE37 and other Ii-Key hybrid immunotherapeutic peptides are produced via standard peptide synthesis and purification methods requiring readily available amino acids and standard chemicals.

NuGenerex Diagnostics Raw Materials

A number of our components and critical raw materials are provided by third-party suppliers. Some of our supplies, including antigens and antibodies may be available from only one or a limited number of sources. This may impact our ability to manufacture or sell product if our suppliers cannot or will not deliver those materials in a timely fashion, or at all, due to an interruption in their supply, quality or technical issues, or any other reason. The absence of any one or more of these supplies could prevent us from being able to commercially produce and market the affected product or products.
**Olaregen Raw Materials**

Excellagen collagen is derived from bovine hides that are sourced from animals continuously reared and slaughtered in Australia, a country recognized by the World Organization for Animal Health as having a negligible BSE risk. The cattle are declared fit for human consumption by Australian Quarantine and Inspection Service, and the starting material is EDQM certified. As of 2010, the World Health Organization (WHO) categorizes skin as a “lower-infectivity tissue” (Category IB). BSE has never been detected in cattle in Australia. Each lot of Excellagen undergoes rigorous release testing according to validated test methods and product specifications, including sterility.

**Regentys Raw Materials**

Extracellular matrix hydrogel is derived from porcine small intestinal submucosa, which is primarily Types I, III, IV and VI collagen. The natural composition of SIS also includes fibronectin and laminin. The general function of these extracellular matrix (ECM) components are well-established. Porcine intestines are sourced from domestic animals in compliance with ISO 22442.

**Intellectual Property**

**Generex Historical Business**

Oral-Lyn & RapidMist

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 2017 to 2022. The expiration dates of the patents issued in Canada range from 2017 to 2021. The expiration dates of the patents issued in other jurisdictions range from 2017 to 2028. We plan to submit new patent applications for the reformulated Oral-Lyn II for Type II diabetes upon funding.

We possess the worldwide manufacturing and marketing rights to our oral insulin product.
Immunotherapy Intellectual Property Portfolio

Platform Patents

The foundational “Platform Patents” for Ii-Key technology focus on methods of increasing the antigen-specific activation of CD4+ T cells. This cell type is a critical component of the immune system, involved both in the recognition of new pathogenic agents as well as in autoimmune syndromes. The first technology platform (Ii-Key hybrid) relates to a means for increasing the vaccine potency of virtually any protein and while the second (Ii-suppression) relates to generation of an effective cell-based vaccine (REH-2007, REH-2014, REH-2015, REH-2017).

Oncology Patents

This group of patents relate more specifically to the use of the platform technologies for generating anti-cancer vaccines. We have generated Ii-Key hybrid compounds specifically for patients with breast, prostate, bladder, melanoma and HPV-related cancers (AEX-2001, AEX-2006, AEX-2007, REH-2005).

NuGenerex Immuno-Oncology holds 9 U.S. patents and 1 worldwide patent covering:

- Compositions and Methods Related to Ii Technology
- Ii hybrid peptides used for the enhancement of antigen presentation
- Constructs for the expression of Ii-Key/antigen epitope fusion peptides
- Hybrid Ii-Key/antigen epitope fusion peptides
- Methods for inhibiting Ii expression

Although some U.S. patents on the Ii-Key technology have expired, we are in discussions with third parties to extend the patent coverage of the Ii-Key technology for cancer immunotherapy. The expiration dates of the immune-oncology applications of the Ii-Key hybrid technologies extend to 2031.

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.

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.

NuGenerex Diagnostics (NGDx) Intellectual Property

NGDx holds a U.S. Patent for its sample delivery system which expires in 2026, US Patent # 7,749,771, titled “Device and methods for detecting analyte in a sample.” This is the basis for our EXPRESS system platform.
On June 2018, we filed for patent protection for the Express II format with the US Patent and Trademark Office. This patent is still pending.

We believe NGDx’s 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 future patents will be granted, or that any patents which we now own or obtain in the future will fully protect our position. Our patent rights and the patent rights of medical device companies in general, are uncertain and can 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.

**Olaregen Intellectual Property**

Olaregen has the exclusive license to Excellagen in all regions of the world except Russia, China, and the other countries with Commonwealth of Independent States (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan).

The U.S. patent on Excellagen has been issued as of October 10, 2017 and now has 17 years of additional exclusivity.

**Regentys Intellectual Property**

Regentys has licensed the exclusive, world-wide intellectual property rights for Regentys ECMHÔ from the University of Pittsburgh in exchange for future royalties. The Intellectual property subject to the license is entitled "Extracellular Matrix Derived Gels" and "Methods for Preparation of A Terminally Sterilized Hydrogel Derived From Extracellular Matrix" developed by Stephen Badylak et.al. of University faculty.

Additionally, Regentys and the University of Pittsburgh are co-owners by assignment of certain intellectual property rights pertaining to "Method and Composition for Treating Inflammatory Bowel Disease Without Colectomy" developed by Stephen Badylak and Timothy Keane of University and by Marc Ramer of the Regentys.

We continue to develop intellectual property for its current and future products.

**NuGenerex Surgical Supply Subsidiaries Intellectual Property**

We pursue strategic alliances and partnerships through intellectual property license agreements, and secure key purchase agreements from suppliers to build upon our portfolio of licensed IP.

We also maintain stocking distribution agreements providing for exclusive distribution rights in certain geographic areas and use of associated trademarks, service marks, and tradenames for the sale and promotion of the products we offer, which generally have durations of one (1) to three (3) years, subject to renewal terms. Furthermore, we require leased employees, independent contractors, consultants, and advisors to execute agreements, with varying terms of one (1) to three (3) years, that assign to us the IP existing and generated from their work. We believe our IP and exclusive distribution agreements provide us with important competitive advantages by (i) increasing our brand awareness and the brand awareness of the products we distribute; and (ii) ensuring that we use the latest design and manufacturing technology for our products that are perceived to be important to our customers.
**Seasonality**

The products and services provided by the organization are not subject to seasonality.

**Competition**

**Generex Historical Business 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.

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 our competitors.

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.
In addition, 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., Cellidex 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.

NuGenerex Diagnostics Competition

The diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing and marketing resources. Industry competition in general is based on the following:

- Scientific and technological Capability;
- Proprietary know-how and intellectual protection;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other regulatory clearances;
- The ability to manufacture products that meet applicable governmental and NGO requirements;
- The ability to manufacture products cost-effectively;
- Access to adequate capital; and
- The ability to find and retain qualified personnel.

We believe our scientific and technological capabilities as well as our proprietary technology and know-how relating to our rapid tests, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases are, indeed, very strong and will allow us to compete in this market.

Main Competitors

In the diagnostic space, Alere Inc., which was acquired by Abbott Laboratories in 2017, is our main competitor and one of the major players in RTDs for infectious diseases. Standard Diagnostics is a strong competitor on an international basis, incorporating a cassette design into each of their products. Our competitors also include Chembio Diagnostic Systems Inc., a publicly traded diagnostic company that develops, manufactures and commercializes diagnostic solutions. There are a number of point-of-care strip manufacturers in China which serve the market in that country. As of yet most of these companies have not made a significant impact on the overall global market but could be considered as a future source of competition. As infectious diseases are epidemic and in the minds of the public, there will be more competitors coming into the marketplace. However, competition will be based upon the implementation of a cassette or a “dipstick” format.

Competitive Advantage

We believe our unique and simple EXPRESS product design delivers significant advantages over our competition.

Due to the potential infectious character of the whole blood test sample, our EXPRESS series of RDTs are designed to perform and deliver test results while sealed within the EXPRESS housing, carefully controlling the potentially infectious test sample. This design helps to increase our ability to control the possibility of cross-contamination. Most of our competitors’ products, while inexpensive, are not as user-friendly, require substantially more training and have greater risk of cross-contamination. And, the simplicity of use of our EXPRESS platforms fits directly into the necessities of World Health Organization Rapid Disease Testing Algorithms and individual country disease reduction goals and priorities.
Our products are more intuitive and self-explanatory than our competitors making it easier and safer to use. Our products require less training and education. Each EXPRESS is configured to operate in the same way regardless of the type of disease being tested.

With ease of use, simple design and faster results, our products allow for more tests administered at the patient point of care level.

We will compete on the basis these advantages. Most of our competitors’ products, while inexpensive, are not as user-friendly, require substantially more training and have greater risk of cross-contamination.

**NuGenerex Immuno-Oncology Competition**

The cancer immunotherapy space is crowded as the scientific mechanisms of cancer and immunity become better understood. According to the Cancer Research Institute, there are 3,394 immuno-oncology therapies in the current global development pipeline, with 1,287 of them in clinical studies. The major pharmaceutical companies, including Novartis, Bristol-Myers Squibb, Merck, Sanofi, and Pfizer, among others have significant research and development efforts in the immune-oncology field.

Neon Therapeutics is a leading immune-oncology biotechnology company. TapImmune and Marker Therapeutics recently merged to advance innovative neoantigen and immunotherapy products.

**NuGenerex Surgical Products Competition**

As a national distributor, we primarily compete with other distributors, as well as large, vertically-integrated medical device manufacturers that enjoy well-established distribution channels, national sales networks, direct sales models, and participation in large group purchasing organizations contracted with major hospitals and surgery centers.

We believe that our status as the manufacturer and distributor of FDA-approved Maxim X-Treme System, sets us apart from other distributors and gives us a competitive advantage against distributors who are not able to manufacture their own products.

Generally, we view Stryker Corporation, Smith & Nephew, and Orthofix International, N.V., as examples of our vertically-integrated competitors. We believe those competitors, and companies like them, only distribute products they manufacture and have significant costs related to research and development and organizational support. Conversely, we sell a broad portfolio of specialized third-party manufacturers’ products and have no costs related to research and development for such third-party products, nor do we have similar costs for organizational support since we are not vertically-integrated. Thus, we believe our competitive advantage lies primarily with our single-source fulfillment sales model, allowing us to offer a broader assortment of several manufacturers’ products. Furthermore, as a manufacturer for some medical devices, we do not have significant costs associated with research and development or organizational support. Thus, we generally see immediate increases in revenues because of the increased gross margins afforded by the lower costs associated with being a manufacturer. Accordingly, the compensation packages we offer to our employed sales team have higher-earning potentials than the compensation packages our competitors offer, allowing us to attract and retain talented and experienced employees.

We contract primarily with small- and medium-sized manufacturers of Orthopedic Implants that are subject to FDA compliance and approval standards. These manufacturers are highly innovative and cost effective because of their streamlined sales infrastructures. Because of our organizational structure, large distribution footprint, and our sales model, we tend to align well with our specialized suppliers’ competitive strategies, which we believe results in more partnerships with such suppliers than our competitors, because we can purchase large quantities of their product as a wholesale customer.
We believe the competition in our industry is primarily caused by continued mergers and acquisitions of smaller distributors by larger, vertically-integrated companies that produce, market and distribute medical devices, Orthopedic Implants, and Biologics. Our vertically-integrated competitors benefit from their ability to control costs for the devices they manufacture and distribute. Moreover, the market in which we operate is sensitive to changes in third-party and government reimbursements and, to a lesser degree, competitive discount pricing. We believe that our industry will continue to see increased mergers and acquisitions because the market is significantly fragmented with numerous medical device distributors and specialized suppliers offering similar product portfolios throughout the United States.

**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**

**NuGenerex Diagnostics Research & Development Expenditures**

A substantial portion of our activities to date have been in research and development. Generex expended $381,030 in the fiscal year ended July 31, 2019 and $315,318 in the fiscal year ended July 31, 2018 on research and development related to its buccal delivery products and Antigen’s immunotherapy products.

NGDx research and development expenditures were $598,000 in the 12 months ended July 31, 2019 and $524,000 in the 12 months ended July 31, 2018. NGDx research and development is primarily related to development of the EXPRESS II and testing of existing products for stability and accuracy and development of new test parameters.

**NuGenerex Immuno-Oncology (formerly Antigen Express) Research & Development Expenditures**

NuGenerex Immuno-Oncology is engaged in a clinical trial to evaluate the use of AE37 immunotherapeutic peptide vaccine in combination with pembrolizumab (Merck’s Keytruda) for the treatment of triple negative breast cancer. We have expended roughly $450,000 to date to finance the trial, including the cost of clinical supplies and packaging. The trial will require additional funding estimated at roughly $1.5 million over the next three years.

Regentys research and development expenditures were $770,000 from January 8, 2019 through July 31, 2019.

**Employees**

The Generex management team has been working without contracts or employment agreements since taking over the Company in January 2017. Upon financing, we expect to engage the management team as employees with terms to be determined by the Compensation Committee of the Generex Board of Directors.
The historical Generex businesses have no employees. Other than our officers, we have no employees in Generex Biotechnology Corporation. Dr. Eric von Hofe is the President of NuGenerex Immuno-Oncology, overseeing the development of AE37; we have hired a consultant to help manage the AE37 clinical development program. Dr. James Anderson, a Generex Director oversees the Oral-Lyn development program, and has outsourced development activities to third-party academic researchers for Ora-Lyn II reformulation.

**NuGenerex Distribution Solutions Employees**

NDS has retained a staff of four departmental leaders to kick off the restart of our MSO including HR, IT, Legal, and Sales.

NDS intends to restart its MSO and launch sales initiatives of its new products and services. We will continue to augment our staff with third-party contractors to expand our portfolio of ancillary services with a large focus on sales in targeted key markets.

**NuGenerex Diagnostics Employees**

We had one officer who is engaged as an independent contractor. We engage consultants from time to time to assist with financial recordkeeping and other tasks. As of July 31, 2019, NGDx had four full time employees and two part-time regulatory consultants. Of these, three were engaged in development, regulatory compliance, laboratory validation and manufacturing, one in sales and one in professional or administrative activities.

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.

**Olaregen Employees**

Olaregen employs a staff of 5 full-time executives and administrative personnel, including the CEO, COO, Medical Director, and Vice Presidents of Sales and Business Development. Additionally, the company contracts with distributors and contract sales forces in target market sectors.

Following the commercial launch of Excellagen in April 2019, the company plans to manage growth through a combination of hiring operations, finance & accounting, marketing, and sales professionals, with support staff on an as needed basis. We will continue to augment our staff with third-party contractors for manufacturing, distribution, and sales in target markets.

**Regentys Employees**

Regentys employs a staff of 4 full-time executives and administrative personnel, including the CEO, COO and Vice President of finance.

**Item 1A. Risk Factors.**

**Risks Related to Our Financial Condition**

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

Our operations to date have consumed substantial amounts of cash and we have sustained negative cash flows from our operations for the last several years. We will require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to continue the development of our product candidates. However, there can be no assurances that we will complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. Any additional equity financing will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition and results of operations.
We have a history of losses and will incur additional losses.

Historically, we have been a clinical development company with a limited line of commercial products in international markets. In 2018, we began to recognize revenues resulting from the acquisition of the Veneto assets and operations. In 2019, we launched our first commercial product Excellagen, which we expect to generate ongoing revenues going forward. While we have begun to generate revenues, we are still operating at a loss, and there is no guarantee that we will be able to grow the revenues enough to offset our costs to realize profitability.

To date, we have not been profitable and our accumulated net loss available to shareholders was $416 million at July 31, 2019. 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. In order to commercialize our historical assets and our recently acquired product pipeline, 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 any new product candidates we discover, in-license, or acquire. 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. We may never achieve profitability.

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. 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, 2019, 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 Securities Exchange Act of 1934, as amended (the “Exchange Act”) and concluded that, subject to the inherent limitations, our disclosure controls and procedures were not effective due to the existence of several significant deficiencies culminating in 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. We have not made a formal determination that our disclosure control and procedures are effective since that date.

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 Exchange Act 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. 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 entered into a collaborative development program with Merck to evaluate our immunotherapeutic peptide vaccine AE37 in combination with Merck’s Keytruda for the treatment of triple negative breast cancer in a phase II clinical trial, however, this collaboration only involves the donation of Keytruda for the clinical trial, and any future financial commitment from Merck for a co-development deal is dependent on the successful completion of the trial. There is no guarantee that the results of the trial will be positive, or that Merck will continue the collaboration with financial support.

Additionally, we have out-licensed AE37 for the immunotherapeutic treatment of prostate cancer to Shenzhen Bioscien (“Shenzhen”), a Chinese biopharmaceutical company that has agreed to fund the development of AE37 for prostate cancer through a clinical development program conducted under ICH guidelines that would allow global registration of the AE37 product in the prostate cancer indication. The development deal includes upfront and milestone payments to Generex, together with a double-digit royalty on sales of AE37 in China in exchange for the rights to AE37 for prostate cancer treatment in China, with the ex-China global rights remaining with us. Though Shenzhen has made an upfront payment of $700,000 to us, there is no guarantee that they will continue to fulfill their contractual obligations to advance the clinical development of AE37 for prostate cancer. Further, there is no guarantee that AE37 will prove to be safe and efficacious for the treatment of prostate cancer, or that the product will be approved by regulatory authorities.

Moving forward, we will need to expand current collaborations and develop new collaborations to advance new products that Generex and its subsidiaries may wish to commercialize. We will continue to seek research collaborations, co-development and marketing agreements, and licensing deals for its products in development, however, there is no guarantee that we will be successful in our efforts.

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 Business

We have reorganized our business model to transform us from a research & development biotechnology company to an integrated life science and healthcare holding company that generates revenues through its subsidiary companies. There is no guarantee that this business transformation will be successful.

Since our new management team took control in January 2017, we have focused our efforts on making strategic acquisitions that will form the foundation for building an end-to-end business model for the delivery of products and services through proprietary market channels to physicians and patients. The initial step in the process was the acquisition of the Veneto group of assets that provided an operating MSO with revenues, a network of physician partners (primarily orthopedic surgeons and podiatrists), contracts with ancillary health services companies, including pharmacies and laboratories, and infrastructure, personnel, and IT systems that are scalable to meet the demands of growth. With the goal of adding new products and services that can be utilized by the MSO physicians in our proprietary network, we have acquired, and are in the process of acquiring revenue-generating companies in the fields of wound care, surgical supplies, orthopedic implants, artificial joints, biologics, medical devices, and regenerative medicine products. There are a number of risks associated with this end-to-end healthcare model, and there is no guarantee that the model will deliver the expected revenues and profits going forward.
As we evolve from being a company that was primarily involved in clinical development to a company that is also involved in commercialization of novel products, including manufacturing, distribution, and utilization, we may encounter difficulties in expanding our operations successfully.

We have been reorganized as a life science and healthcare holding company, with wholly-owned and majority-owned subsidiaries that operate independently. Our operating subsidiaries are led by management teams who are responsible for operating the businesses and achieving corporate revenue and profit targets. Our corporate strategy is to unite the subsidiary companies, together with the NuGenerex family of companies, through shared client access, cross-selling opportunities, share services, and joint development programs. If the subsidiary companies do not work together to build the organization as envisioned, we may not realize the revenue and profit expectations that are based on the synergies among our subsidiaries to drive intra-company sales.

As we pursue our plans to reorganize the historical Generex clinical stage assets into separate operating subsidiaries that can more effectively advance the clinical development and commercial value of our product pipeline, we may encounter difficulties in obtaining the financing necessary to support our clinical development programs.

Through the corporate restructuring, we have formed three subsidiaries to house the historical Generex assets, including NuGenerex Immuno-Oncology, NuGenerex Diagnostics (NGDx), and NuGenerex Therapeutics (housing the Oral-Lyn oral insulin product and the RapidMist buccal delivery technology). Each of these subsidiaries require significant funds and commercialization partners to advance their products and technologies through the clinical development and regulatory processes necessary to achieve product commercialization. We may not be able to obtain the necessary funds or find corporate partners to commercialize our historical assets, which will negatively affect the value of these assets.

We may not be able to unlock the intrinsic value of our historical development pipeline, because we may encounter difficulties in financing and operating our commercial development programs successfully.

As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities, and may need to further contract with third parties to provide these capabilities. As our operations expand, we likely will need to manage additional relationships with such third parties, as well as additional collaborators, distributors, marketers, and suppliers.

Maintaining third party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to: manage our development efforts effectively; recruit and train sales and marketing personnel; manage our participation in the clinical trials in which our product candidates are involved effectively; and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing, or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.
Future business combinations or acquisitions may be difficult to integrate, which could cause us to shift our attention away from our primary business and its operations. We may pursue future business combinations with other companies or strategic acquisitions of complementary businesses, product lines, or technologies. There can be no assurance that such acquisitions will be available at all, nor on terms acceptable to us. These transactions may require additional capital, which may increase our indebtedness or outstanding shares, resulting in a dilution to our stockholders or a reduction in working capital. The inability to obtain such future capital may inhibit our growth and operating results. Integration of acquisitions or additional products can be costly, time-consuming, and complicated which could significantly impact operating results. Furthermore, the integration of any acquisition may disproportionately divert our executive team’s time and resources from our primary business and its operations. We may sell some or all of our product lines to other companies or we may agree to merge with another company. There can be no assurance that future transactions will ultimately benefit us. If we face difficulty integrating future acquisitions or if our executive team’s attention is diverted, our future results of operations may negatively impact our business, results of operations, and financial condition.

The MSO acquired in the Veneto transaction may not continue to participate in the business following the acquisition.

The MSO acquired from Veneto is named Rapport Services, LLC (“Rapport”), which is a physician-owned limited liability company (or LLC) requiring an at-risk equity investment from physicians or physician groups that wish to participate in the network. The Rapport physician investors own 99% of Rapport, and Generex (through its wholly-owned subsidiary NuGenerex Distribution Solutions 2) owns 1% and serves as the managing director of the LLC. The MSO was built through relationships between physicians and the previous Veneto administration. There is no guarantee that the current network of physician partners will remain with Rapport. There is no guarantee that the physicians will continue to utilize the ancillary healthcare services that Rapport provides the MSO through contractual relationships with pharmacies, labs, or other providers of ancillary services.

Regulatory actions may affect our ability to operate.

Our MSO and pharmaceutical distribution businesses operate in fields that are very highly regulated by both the federal government and state pharmacy licensing agencies. Adverse decisions by the DEA or state pharmacy regulators could materially and adversely affect our ability to maintain and grow our distributions business. The MSOs we manage are primarily owned by physicians and serve pharmacy and other healthcare organizations. We believe that our MSO business is structured to comply with laws and regulations governing economic relationships between physicians and other health care providers, such as fraud and abuse laws. If regulators or courts determine our activities did not comply, we may be required to restructure our business in a manner that would reduce or eliminate its profitability.

The MSO model may not be profitable without the right product mix and reimbursements from payors.

The Rapport MSO operates as a limited liability company, and therefore distributes profits to the members based upon their equity interest. Profitability is determined based the revenues generated by reimbursements, the cost of goods sold, and the cost of services. The success of the MSO model is predicated on several factors, including: 1) the ability to obtain competitive and specialty pricing from ancillary providers of pharmaceuticals, medical devices, surgical supplies, and biologics used by the physicians in the MSO for the optimal care of their patients; 2) the reimbursements for pharmaceuticals, medical devices, surgical supplies, and biologics that are established and paid by third-party payors, including insurance companies, pharmacy benefits managers (or PBMs), distributors, and employers; 3) the cost for delivering ancillary services, including personnel, facilities, licenses, insurances, and administrative expenses, among others, and 4) the ability to grow the business with new partners, clients, products and services that provide new and increased revenue streams. We may not obtain pricing for goods and services that provide enough margin to maintain profitability. Reimbursements from third-party payors for pharmaceuticals, medical devices, surgical supplies, and biologics are under cost pressure, and subject to change on a quarterly basis, with the threat of reduced reimbursements an ongoing concern. We may not be able to maintain the flexibility required or have the financing to support the appropriate level of personnel, lease the correct number and type of facilities, secure the requisite licenses, and grow the business as projected due to the variability of business cycles, the uncertainty in cost of goods and services, and the ongoing threat of declining reimbursements.
Based on the opinion of counsel, we believe that the Rapport MSO model is currently legal in 22 states, however, state laws and regulations often change.

To our knowledge, Rapport, a physician-owned limited liability company is operated in full compliance with all state and federal regulations. Although we have obtained third-party legal guidance, there is no guarantee that the legal guidance is correct, nor that the Rapport model is in full compliance with all regulations, nor that regulations will change rendering the model noncompliant.

The regulations pertaining to the physician-owned MSO model may change such that the Rapport model is no longer compliant with state laws, requiring changes to the MSO model.

Changes to federal and state regulations may have significant adverse effect on the business. If the regulations change such that the Rapport MSO model is no longer allowed, we will need to change our business model to maintain compliance. Despite the fact that we are currently planning to institute additional service models under the NuGenerex subsidiary, there is no guarantee that we will be able to maintain a profitable business that is in compliance with laws and regulations.

If the statutes and regulations in our industry change, our business could be adversely affected.

The U.S. healthcare industry has undergone significant changes designed to improve patient safety, improve clinical outcomes, and increase access to medical care. These changes include enactments and repeals of various healthcare related laws and regulation. Our operations and economic viability may be adversely affected by the changes in such regulations, including: (i) federal and state fraud and abuse laws; (ii) federal and state anti-kickback statutes; (iii) federal and state false claims laws; (iv) federal and state self-referral laws; (v) state restrictions on fee splitting; (vi) laws regarding the privacy and confidentiality of patient information; and (vii) other laws and government regulations.

If there are changes in laws, regulations, or administrative or judicial interpretations, we may have to change our business practices, or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition, and results of operations.

We are expanding our product and service offerings to offset risk associated with the cost of goods and regulatory concerns, however, there is no guarantee that the new products and services will be successful in the marketplace.

We launched DMEiq, LLC (“DME-IQ”), a tablet-based software and service business designed to help orthopedic practices manage and operate an in-house program for orthopedic durable medical equipment (or DME). While we are beginning to generate revenues with the first implementation of DME-IQ, the return on investment for us is still to be proven. The sales cycle for contracting with new orthopedic practices to implement the DME-IQ program is long, and requires multiple meetings, financial and practice analysis, and legal/regulatory review. There is no guarantee that we will be able to achieve our sales goals.

We are in the process of acquiring manufacturers and suppliers of orthopedic implants, surgical supplies and tools, and biologics that can be utilized by the MSO network. There is no guarantee that these acquisitions will be completed, or if completed, that the products will be chosen by the MSO physicians in the surgical and medical practices.

Our subsidiary Olaregen is offering our newly launched product for wound management, Excellagen to the MSO network of orthopedic surgeons and podiatrists. There is no guarantee that we will get Excellagen on hospital and insurance formularies for reimbursement. Therefore, there is a risk that the product may not be utilized as expected.

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We have non-binding letters of intent to acquire companies that manufacture and distribute orthopedic implants, surgical supplies and equipment, and biologics. If we complete the target acquisitions, our operating earnings will be dependent on certain significant suppliers.

The target acquisitions use original equipment manufacturers & suppliers to support their operations. They distribute products from dozens of suppliers and are dependent on these suppliers for the continuing supply of products. The companies rely on suppliers to provide agreeable purchasing and delivery terms and performance incentives. Our ability to sustain adequate operating earnings will be dependent upon our ability to obtain favorable terms and incentives from suppliers, as well as suppliers’ continuing use of third-party distributors to sell and deliver their products. An unforeseen delay in raw material supplies, a change in terms by a significant supplier, or a decision of such a supplier to distribute its products directly to healthcare providers rather than through third-party distributors could have a material adverse effect on our results of operations and financial condition.

We may encounter difficulties in managing our growth, and the nature of our business and rapid changes in the healthcare industry makes it difficult to reliably predict future growth and operating results.

We may not be able to successfully grow and expand. Successful implementation of our business plan will require management of growth, including potentially rapid and substantial growth, which could result in an increase in the level of responsibility for management personnel and strain on our human and capital resources. To manage growth effectively, we will be required, among other things, to continue to implement and improve our operating and financial systems, procedures and controls and to expand, train and manage our employee base. If we are unable to implement and scale improvements to our existing systems and controls in an efficient and timely manner or if we encounter deficiencies, we will not be able to successfully execute our business plans.

Failure to attract and retain sufficient numbers of qualified personnel could also impede our growth.

If we are unable to manage our growth effectively, it will have a material adverse effect on our business, results of operations and financial condition. The evolving nature of our business and rapid changes in the healthcare industry make it difficult to anticipate the nature and amount of medical reimbursements, third-party private payments, and participation in certain government programs and thus to reliably predict our future growth and operating results. Our growth strategy may incur significant costs, which could adversely affect our financial condition. Our growth by strategic transactions strategy involves significant costs, including financial advisory, legal and accounting fees, and may include additional costs for items such as fairness opinions and severance payments. These costs could put a strain on our cash flows, which in turn could adversely affect our overall financial condition.

We are regulated by federal Anti-Kickback Statutes

The federal Anti-Kickback Statute is a provision of the Social Security Act of 1972 that prohibits as a felony offense the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (1) the referral of a patient for items or services for which payment may be made in whole or part under Medicare, Medicaid, or other federal healthcare programs, (2) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid, or other federal healthcare programs or (3) the purchase, lease, or order or arranging or recommending the purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Patient Protection and Affordable Care Act (“ACA”) amended section 1128B of the Social Security Act to make it clear that a person need not have actual knowledge of the statute, or specific intent to violate the statute, as a predicate for a violation. The OIG, which has the authority to impose administrative sanctions for violation of the statute, has adopted as its standard for review a judicial interpretation which concludes that the statute prohibits any arrangement where even one purpose of the remuneration is to induce or reward referrals. A violation of the Anti-Kickback Statute is a felony punishable by imprisonment, criminal fines of up to $25,000, civil fines of up to $50,000 per violation, and three times the amount of the unlawful remuneration. A violation also can result in exclusion from Medicare, Medicaid or other federal healthcare programs. In addition, pursuant to the changes of the Affordable Care Act (“ACA”), a claim that includes items or services resulting from a violation of the Anti-Kickback Statute is a false claim for purposes of the False Claims Act.
We cannot assure that the applicable regulatory authorities will not determine that some of our arrangements with physicians violate the federal Anti-Kickback Statute or other applicable laws. An adverse determination could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We are regulated by federal Stark Laws

The federal Stark Law, 42 U.S.C. 1395nn, also known as the physician self-referral law, generally prohibits a physician from referring Medicare and Medicaid patients to an entity (including hospitals) providing “designated health services,” if the physician or a member of the physician’s immediate family has a “financial relationship” with the entity, unless a specific exception applies. Designated health services include, among other services, inpatient hospital services, outpatient prescription drug services, clinical laboratory services, certain imaging services (e.g., MRI, CT, ultrasound), and other services that our affiliated physicians may order for their patients. The prohibition applies regardless of the reasons for the financial relationship and the referral; and therefore, unlike the federal Anti-Kickback Statute, intent to violate the law is not required. Like the Anti-Kickback Statute, the Stark Law contains statutory and regulatory exceptions intended to protect certain types of transactions and arrangements. Unlike safe harbors under the Anti-Kickback Statute with which compliance is voluntary, an arrangement must comply with every requirement of a Stark Law exception or the arrangement is in violation of the Stark Law.

Because the Stark Law and implementing regulations continue to evolve and are detailed and complex, while we attempt to structure its relationships to meet an exception to the Stark Law, there can be no assurance that the arrangements entered into by us with affiliated physicians and facilities will be found to be in compliance with the Stark Law, as it ultimately may be implemented or interpreted. The penalties for violating the Stark Law can include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, and civil penalties of up to $15,000 for each violation, double damages, and possible exclusion from future participation in the governmental healthcare programs. A person who engages in a scheme to circumvent the Stark Law’s prohibitions may be fined up to $100,000 for each applicable arrangement or scheme.

Some states have enacted statutes and regulations against self-referral arrangements similar to the federal Stark Law, but which may be applicable to the referral of patients regardless of their payor source and which may apply to different types of services. These state laws may contain statutory and regulatory exceptions that are different from those of the federal law and that may vary from state to state. An adverse determination under these state laws and/or the federal Stark Law could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We must comply with Health Information Privacy and Security Standards

The privacy regulations Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended, contain detailed requirements concerning the use and disclosure of individually identifiable patient health information (“PHI”) by entities like our MSOs and affiliated IPAs and medical groups. HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health information received, maintained, or transmitted. HIPAA also implemented standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including billing and claim collection activities. Violations of the HIPAA privacy and security rules may result in civil and criminal penalties, including a tiered system of civil money penalties that range from $100 to $50,000 per violation, with a cap of $1.5 million per year for identical violations. A HIPAA covered entity must also promptly notify affected individuals where a breach affects more than 500 individuals and report breaches affecting fewer than 500 individuals annually. State attorneys general may bring civil actions on behalf of state residents for violations of the HIPAA privacy and security rules, obtain damages on behalf of state residents, and enjoin further violations.
Many states also have laws that protect the privacy and security of confidential, personal information, which may be similar to or even more stringent than HIPAA. Some of these state laws may impose fines and penalties on violators and may afford private rights of action to individuals who believe their personal information has been misused. We expect increased federal and state privacy and security enforcement efforts.

A cyber security incident could cause a violation of HIPAA, breach of customer and patient privacy, or other negative impacts.

We rely extensively on our information technology (or IT) systems to manage scheduling and financial data, communicate with customers and their patients, vendors, and other third parties, and summarize and analyze operating results. In addition, we have made significant investments in technology, including the engagement of a third-party IT provider. A cyber-attack that bypasses our IT security systems could cause an IT security breach, a loss of protected health information, or other data subject to privacy laws, a loss of proprietary business information, or a material disruption of our IT business systems. This in turn could have a material adverse impact on our business and result of operations. In addition, our future results of operations, as well as our reputation, could be adversely impacted by theft, destruction, loss, or misappropriation of public health information, other confidential data, or proprietary business information.

Computer malware, viruses, and hacking and phishing attacks by third parties have become more prevalent in our industry, have occurred on our systems in the past, and may occur on our systems in the future. Because techniques used to obtain unauthorized access to or sabotage systems change frequently and generally are not recognized until successfully launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. As cyber-security threats develop and grow, it may be necessary to make significant further investments to protect data and infrastructure. If an actual or perceived breach of our security occurs, (i) we could suffer severe reputational damage adversely affecting customer or investor confidence, (ii) the market perception of the effectiveness of our security measures could be harmed, (iii) we could lose potential sales and existing customers, our ability to deliver our services or operate our business may be impaired, (iv) we may be subject to litigation or regulatory investigations or orders, and (v) we may incur significant liabilities. Our insurance coverage may not be adequate to cover the potentially significant losses that may result from security breaches. Additionally, while we currently do not have cybersecurity coverage, we plan to evaluate options for this type of coverage in late 2019, or early 2020.

We must comply with Environmental and Occupational Safety and Health Administration Regulations

We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. In the event of an accident, we could be held liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance coverage, which we may not be able to maintain on acceptable terms, or at all. We could incur significant costs and attention of our management could be diverted to comply with current or future environmental laws and regulations. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood-borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject as those regulations are being implemented, which could adversely affect our operations.

We must comply with a range of other Federal and State Healthcare Laws.

We are also subject to other federal and state healthcare laws that could have a material adverse effect on our business, financial condition or results of operations. The Health Care Fraud Statute prohibits any person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, which can be either a government or private payor plan. Violation of this statute, even in the absence of actual knowledge of or specific intent to violate the statute, may be charged as a felony offense and may result in fines, imprisonment, or both. The Health Care False Statement Statute prohibits, in any matter involving a federal health care program, anyone from knowingly and willfully falsifying, concealing or covering up, by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statement or representation, or making or using any materially false writing or document knowing that it contains a materially false or fraudulent statement. A violation of this statute may be charged as a felony offense and may result in fines, imprisonment or both. Under the Civil Monetary Penalties Law of the Social Security Act, a person (including an organization) is prohibited from knowingly presenting or causing to be presented to any United States officer, employee, agent, or department, or any state agency, a claim for payment for medical or other items or services where the person knows or should know (a) the items or services were not provided as described in the coding of the claim, (b) the claim is a false or fraudulent claim, (c) the claim is for a service furnished by an unlicensed physician, (d) the claim is for medical or other items or service furnished by a person or an entity that is in a period of exclusion from the program, or (e) the items or services are medically unnecessary items or services. Violations of the law may result in penalties of up to $10,000 per claim, treble damages, and exclusion from federal healthcare programs.
In addition, the office of inspector general ("OIG") may impose civil monetary penalties against any physician who knowingly accepts payment from a hospital (as well as against the hospital making the payment) as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid program beneficiaries. Further, except as permitted under the Civil Monetary Penalties Law, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider of Medicare or Medicaid payable items or services may be liable for civil money penalties of up to $10,000 for each wrongful act.

In addition to the state laws previously described, we may also be subject to other state fraud and abuse statutes and regulations if we expand our operations nationally. Many states have adopted a form of anti-kickback law, self-referral prohibition, and false claims and insurance fraud prohibition. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Generally, state laws reach to all healthcare services and not just those covered under a governmental healthcare program. A determination of liability under any of these laws could result in fines and penalties and restrictions on our ability to operate in these states. We cannot assure that our arrangements or business practices will not be subject to government scrutiny or be found to violate applicable fraud and abuse laws.

Changes in healthcare laws could create an uncertain environment and materially impact us.

We cannot predict the effect that the ACA (also known as Obamacare) and its implementation, amendment, or repeal and replacement, may have on our business, results of operations or financial condition. Any changes in healthcare laws or regulations that reduce, curtail or eliminate payments, government-subsidized programs, government-sponsored programs, and/or the expansion of Medicare or Medicaid, among other actions, could have a material adverse effect on our business, results of operations and financial condition. For example, the ACA dramatically changed how healthcare services are covered, delivered, and reimbursed. The ACA requires insurers to accept all applicants, regardless of pre-existing conditions, cover an extensive list of conditions and treatments, and charge the same rates, regardless of pre-existing condition or gender.

The ACA and the Health Care and Education Reconciliation Act of 2010 (collectively, the “Health Care Reform Acts”) also mandated changes specific to home health and hospice benefits under Medicare. In 2012, the U.S. Supreme Court upheld the constitutionality of the ACA, including the “individual mandate” provisions of the ACA that generally require all individuals to obtain healthcare insurance or pay a penalty. However, the U.S. Supreme Court also held that the provision of the ACA that authorized the Secretary of the U.S. Department of Health and Human Services ("HHS") to penalize states that choose not to participate in the expansion of the Medicaid program by removing all of its existing Medicaid funding was unconstitutional. In response to the ruling, a number of state governors opposed its state’s participation in the expanded Medicaid program, which resulted in the ACA not providing coverage to some low-income persons in those states. In addition, several bills have been, and are continuing to be, introduced in U.S. Congress to amend all or significant provisions of the ACA, or repeal and replace the ACA with another law. In December 2017, the individual mandate was repealed via the Tax Cuts and Jobs Act of 2017. Afterwards, legal and political challenges as to the constitutionality of the remaining provisions of the ACA resumed.
Our operations are subject to the nation’s healthcare laws, as amended, repealed, or replaced from time to time.

The net effect of the ACA on our business is subject to numerous variables, including the law’s complexity, lack of complete implementing regulations and interpretive guidance, gradual and potentially delayed implementation or possible amendment, as well as the uncertainty as to the extent to which states will choose to participate in the expanded Medicaid program. The continued implementation of provisions of the ACA, the adoption of new regulations thereunder and ongoing challenges thereto, also added uncertainty about the current state of U.S. healthcare laws and could negatively impact our business, results of operations and financial condition. Healthcare providers could be subject to federal and state investigations and payor audits.

Due to our and our affiliates’ participation in government and private healthcare programs, we are from time to time involved in inquiries, reviews, audits, and investigations by governmental agencies and private payors of our business practices, including assessments of our compliance with coding, billing and documentation requirements. Federal and state government agencies have active civil and criminal enforcement efforts against healthcare companies, and their executives and managers. The Deficit Reduction Act (“DRA”), which provides a financial incentive to states to enact their own false claims acts, and similar laws encourage investigations against healthcare companies by different agencies. These investigations could also be initiated by private whistleblowers.

Responding to audit and investigative activities are costly and disruptive to our business operations, even when the allegations are without merit. If we are subject to an audit or investigation, a finding could be made that we or our affiliates erroneously billed or were incorrectly reimbursed, and we may be required to repay such agencies or payors, be subjected to pre-payment reviews, which can be time-consuming and result in non-payment or delayed payments for the services we or our affiliates provide, and may be subject to financial sanctions or required to modify our operations.

Product pricing is subject to regulatory control.

Routinely, the pricing and profitability of the products we sell are subject to control by third-party payors. The continuing efforts of governmental and other third-party payors to contain or reduce the cost of healthcare through various means may adversely affect our ability to successfully commercialize our products. We anticipate that there will continue to be federal and state proposals to implement similar governmental control, although it is unclear which proposals will ultimately become law, if any. Direct or indirect changes in prices, including any mandated pricing, could impact our revenues, profitability, and financial performance.

Our revenues will depend on our customers’ continued receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.

Political, economic, and regulatory influences continue to change the healthcare industry in the United States. The ability of hospitals to pay fees for our products partially depends on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third-party payors do not provide adequate coverage and reimbursement to hospitals.

Major third-party payors of hospitals, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in stricter standards for reimbursement of hospital charges for certain specified products, potentially adversely impacting our business, results of operations, and financial conditions.
The FDA regulates the manufacturers and suppliers of the products that we sell, market, manufacture, and distribute, and regulatory compliance is costly and could contribute to delays in the availability of our products.

Under FDA regulations, we are subject to the same FDA regulation as the manufacturers and suppliers to whom we distribute. These regulations govern (i) the manufacturing and processing of cellular and tissue products; (ii) the introduction of new medical devices; (iii) the observance of certain standards with respect to the design, manufacturing, testing, labeling, promotion, and sales of the devices; (iv) the maintenance of certain records; (v) the ability to track devices; (vi) the reporting of potential product defects; (vii) the importing and exporting of devices; and (viii) various other matters. Furthermore, manufacturers that create the products we market face an increasing amount of scrutiny and compliance costs as more states implement regulations governing medical devices and Biologics. In addition, we are subject to ongoing compliance concerning our 510(k) Approvals, as well as potential on-site inspections by the FDA. Being found in violation and failing to correct an FDA compliance issue could potentially result in product recall, product seizure, or the de-listing of our products with 510(k) Approval. These types of FDA regulations could affect many of the products we market, impacting our revenues and profitability, results of operations, and working capital. Future regulatory action remains uncertain.

We operate in a highly regulated and evolving environment with rigorous regulatory enforcement. Any legal or regulatory action could be time-consuming and costly. If we or the manufacturers or distributors that supply our products fail to comply with all applicable laws, standards, and regulations, action by the FDA or other regulatory agencies could result in significant restrictions, including restrictions on the marketing or use of the products we sell or the withdrawal of the products we sell from the market. Any such restrictions or withdrawals could materially affect our reputation, business and operations.

U.S. federal and state governmental regulation could restrict our ability to sell our products.

Our business is subject to highly complex and evolving regulatory and licensing requirements that are subject to uncertainty, rapid change, differing interpretations, and rigorous regulatory enforcement. Failure to comply with such regulatory requirements may result in civil or criminal penalties, including the loss of licenses or the exclusion from future participation in government healthcare programs. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will affect our Company on a going-forward basis only. Any investigation or challenge could have a material adverse effect on our reputation, business, financial condition, and results of operations.

The FDA and similar state authorities require us to list and register certain products, because we are a distributor, marketer, specification developer and repackager/relabeler and manufacturer for FDA-regulated products.

If we are successful in executing our business plan, we will be a distributor, marketer, and specification developer and repackager/relabeler of FDA-regulated products, and as such we may be subject to independent requirements to register and list certain products. We may be required to obtain state licensure or certifications and may be subject to inspections, in addition to complying with derivative requirements applicable to the manufacturers of the products we market. Failure to comply with such applicable requirements could result in a wide variety of enforcement actions, ranging from warning letters to more severe sanctions, such as significant costly fines and civil penalties, operating restrictions, injunctions, and criminal prosecutions, all of which could adversely impact our business.

Our product candidates will remain subject to ongoing regulatory review even after they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any of our approved commercial products could be suspended.

Even as we receive regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to the product will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities or discover any previously unknown problems with any approved product, manufacturer, or manufacturing process, we could be subject to administrative or judicially imposed sanctions, including:
• restrictions on the products, manufacturers, or manufacturing processes;
• warning letters;
• civil or criminal penalties;
• fines;
• injunctions;
• product seizures or detentions;
• pressure to initiate voluntary product recalls;
• suspension or withdrawal of regulatory approvals; and
• refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even when any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Physicians may decide not to recommend our treatments for a variety of reasons including:

• timing of market introduction of competitive products;
• demonstration of clinical safety and efficacy compared to other products;
• cost-effectiveness;
• limited or no coverage by third-party payers;
• convenience and ease of administration;
• prevalence and severity of adverse side effects;
• restrictions in the label of the drug;
• other potential advantages of alternative treatment methods; and
• ineffective marketing and distribution support of its products.

If any of our product candidates are approved, but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products.

The medical device and pharmaceutical industries are characterized by extensive intellectual property litigation and, from time to time, we may become the subject of claims of infringement or misappropriation. Regardless of outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.
We depend extensively on our patents and proprietary technology and the patents and proprietary technology we license from others, and we must protect those assets in order to preserve our business.

Although we expect to seek patent protection for any compounds, devices, biologics, systems, and processes we discover and/or for any specific use we discover for new or previously known compounds, devices, biologics, systems, or processes, any or all of which may not be subject to effective patent protection. In addition, our issued patents may be declared invalid or our competitors may find ways to avoid the claims in the patents.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We are the exclusive licensee, sole assignee or co-assignee of numerous granted United States patents, pending United States patent applications and international patents. The patent position of pharmaceutical and biotechnology firms like us are generally highly uncertain and involves complex legal and factual questions, resulting in both an apparent inconsistency regarding the breadth of claims allowed in United States patents and general uncertainty as to their legal interpretation and enforceability. Accordingly, patent applications assigned or exclusively licensed to us may not result in patents being issued, any issued patents assigned or exclusively licensed to us may not provide us with competitive protection or may be challenged by others, and the current or future granted patents of others may have an adverse effect on our ability to do business and achieve profitability.

Moreover, because some of the basic research relating to one or more of our patent applications and/or patents were performed at various universities and/or funded by grants, one or more universities, employees of such universities and/or grantors could assert that they have certain rights in such research and any resulting products. Further, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, as a result of the assertion of rights by a third-party or otherwise, we may be required to obtain licenses to patents or other proprietary rights of others in or outside of the United States. Any licenses required under any such patents or proprietary rights may not be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product market introductions during our attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. In addition, we could incur substantial costs in defending suits brought against us or in connection with patents to which we hold licenses or in bringing suit to protect our own patents against infringement.

We depend on license agreements with third-parties for certain intellectual property rights relating to our products and product candidates. In general, our license agreements require us to make payments and satisfy performance obligations in order to keep these agreements in effect and retain our rights under them. These payment obligations can include upfront fees, maintenance fees, milestones, royalties, patent prosecution expenses, and other fees. These performance obligations typically include diligence obligations. If we fail to pay, be diligent or otherwise perform as required under our license agreements, we could lose the rights under the patents and other intellectual property rights covered by these agreements. If disputes arise under any of our in-licenses, we could lose our rights under these agreements. Any such dispute may not be resolvable on favorable terms, or at all. Whether or not any disputes of this kind are favorably resolved, our management’s time and attention and our other resources could be consumed by the need to attend to these disputes and our business could be harmed by the emergence of such a dispute.

If we lose our rights under these agreements, we might not be able to develop any related product candidates further, or following regulatory approval, if any, we might be prohibited from marketing or commercializing these product candidates. In particular, patents previously licensed to us might, after termination of an agreement, be used to stop us from conducting these activities.

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.

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 several 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 several 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.
Our industry is highly competitive, and our product candidates may become obsolete.

The healthcare industry is highly competitive and fragmented. We compete with other health care management companies for customers across all our services, including MSOs and healthcare providers, such as local, regional, and national networks of physicians, medical groups and hospitals, many of which are substantially larger than us and have significantly greater financial and other resources, including personnel, than what we have.

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies, and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical, and human resources than we do. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. We are aware of potential competitors developing products similar to our sarcoma vaccine, ovarian cancer vaccine and pancreatic cancer antibodies product candidates. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than we do, which could materially adversely affect our business.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates or those that are in-licensed, and/or we may be unable to pursue the clinical trials that we would like to pursue.

We have limited technical, managerial, and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. Due to our limited available financial resources, we may have curtailed clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes.

We may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. Furthermore, we cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all the objectives that we otherwise would seek to accomplish. Our decisions to allocate our research, management, and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate drug development programs may also cause us to miss valuable opportunities.

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We use independent clinical investigators and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates, and expect to continue to do so for the foreseeable future. We rely heavily on these parties for successful execution of our clinical trials. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the FDA’s requirements and our general investigational plan and protocol.

The FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement action against us.
**Risks Related to Manufacturing & Distribution**

We have limited manufacturing capacity and have relied on, and expect to continue to rely on, third-party contract manufacturers to produce our products and clinical development candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our products and candidates, and we currently lack the resources and the capabilities to build our own manufacturing facilities. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party contract manufacturers to supply our products and clinical trial supplies. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates or products ourselves, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current FDA Good Manufacturing Procedures (“cGMP”). Contract manufacturers may face manufacturing or quality control problems, leading to drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

**Interuption of manufacturing operations could adversely affect our business.**

Our suppliers have manufacturing facilities for certain product lines that may be concentrated in one (1) or more plants. Damage to these facilities or issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to quality systems regulations, equipment breakdown or malfunction, among other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing of certain products, we may be unable to quickly shift to alternate means of production to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production of affected products due to the need for regulatory approvals. We may experience loss of market share, additional expense, or harm to our reputation.

Additionally, we contract with a limited amount of suppliers for the raw materials that we use to produce certain products. While we have not experienced a shortage of raw materials in the past and believe that it is unlikely that there will be one in the future, if there were a shortage of raw materials, it could either increase the cost of production or prevent us from being able to produce some of our products, which could adversely affect future results of our operations and financial condition.
We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements.

We are exposed to potential product liability risks inherent in the design, manufacturing, and marketing of pharmaceuticals and medical devices, many of which are administered to or implanted in the human body for long periods of time or indefinitely. These matters are subject to many uncertainties and outcomes are not predictable. In addition, we may incur significant legal expenses regardless of whether we are found to be liable.

While we maintain product liability insurance, there can be no assurance that such coverage is sufficient to cover all product liabilities that we may incur. We are not currently subject to any product liability proceedings, and we have no reserves for product liability disbursements. However, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage and delivery of our products. Should we incur product-related liabilities exceeding our insurance coverage, we would be required to use available cash or raise additional cash to cover such liabilities.

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.

Because we may not be able to obtain or maintain the necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business. Our existing products as well as our manufacturing facility must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies.

All our proposed and existing products are subject to regulation in the U.S. by the FDA, the U.S. Department of Agriculture ("USDA") and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacturing, labeling, distribution, and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for that product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time required to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes in government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.
Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the USDA, as well as non-governmental organizations such as the International Organization for Standardization (“ISO”) and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA quality system regulation and that also require meeting certain documentary requirements regarding the approval of the product in export markets. Although we believe that we meet the regulatory standards required for the export of our products, these regulations could change in a manner that could adversely impact our ability to export our products.

*We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results.*

Introducing and achieving market acceptance for our products will require substantial marketing efforts and will require us and/or our contract partners, sales agents, and/or distributors to make significant expenditures of time and money. In some instances, we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, and/or distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

In addition to the market success of our products, the success of our business depends on our ability to raise additional capital through the sale of debt or equity or through borrowing, and we may not be able to raise capital or borrow funds on attractive terms and/or in amounts necessary to continue our business, or at all.

**General Risks**

*General economic conditions may adversely affect demand for our products and services.*

Poor or deteriorating economic conditions in the U.S. could adversely affect the demand for healthcare services and consequently, the demand for our products and services. Poor economic conditions also could lead our suppliers to offer less favorable terms of purchase, which would negatively affect our cash flows and profitability. These and other possible consequences of financial and economic decline could have material adverse effect on our business, results of operations, and financial condition. We operate our business in regions subject to natural disasters and other catastrophic events, and any disruption to our business resulting from natural disasters would adversely affect our revenue and results of operations.

We operate our business in regions subject to severe weather and natural disasters, including hurricanes, floods, fires, earthquakes, and other catastrophic events. Any natural disaster could adversely affect our ability to conduct business and provide products and services to our customers, and the insurance we maintain may not be adequate to cover our losses resulting from any business interruption resulting from a natural disaster or other catastrophic event.
Although we have an ethics and anti-corruption policy in place, and have no knowledge or reason to know of any practices by our employees, agents, or distributors that could be construed as in violation of such policies, our business includes sales of products to countries where there is or may be widespread corruption.

We have a policy in place prohibiting employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act. Nevertheless, because we work through independent sales agents and distributors outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we may sell our products, there is significant oversight from the President’s Emergency Plan for AIDS Relief, or PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations including five active collaborations and manufacturer’s quality systems, as well as price and delivery.

We depend heavily on our executive officers, directors, and principal consultants and the loss of their services would materially harm our business.

We believe that our success depends, and will likely continue to depend, upon our ability to retain the services of our current executive officers, directors, principal consultants and others. In addition, we have established relationships with universities, hospitals and research institutions, which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. The loss of the services of any of these individuals or institutions would have a material adverse effect on our business.

Risks Related to Our Common Stock

Our common stock is “penny stock”, which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as “penny stock” under 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-dealer’s 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. 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 make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

There is a limited trading market for our common stock.

Our common stock is not listed on any national securities exchange. Accordingly, investors may find it more difficult to buy and sell our shares than if our common stock was traded on an exchange. Although our common stock is quoted on the OTCQB, it is an unorganized, inter-dealer, over-the-counter market which provides significantly less liquidity than the Nasdaq Capital Market or other national securities exchange. These factors may have an adverse impact on the trading and price of our common stock.
**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.

**We do not intend to pay cash dividends on our common stock for the foreseeable future.**

We have paid no cash dividends on our common stock to date and we do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, we currently anticipate that we will retain any earnings to finance our future expansion and for the implementation of our business plan. Investors should take note of the fact that a lack of a cash dividend can further affect the market value of our common stock and could significantly affect the value of any investment in the Company.

**Our issuance of common stock upon exercise of warrants or options or conversion of convertible notes may depress the price of our common stock.**

As of July 31, 2019, we have 62,290,940 shares of common stock issued and outstanding, outstanding warrants to purchase 15,399,681 shares of common stock, outstanding options to purchase 7,988,675 shares of common stock, and outstanding convertible notes in the amount of $3,944,972, convertible into 2,087,286 shares of common stock. The issuance of shares of common stock upon exercise of outstanding warrants or conversion of convertible notes could result in substantial dilution to our stockholders, which may have a negative effect on the price of our common stock.

**Item 1B. Unresolved Staff Comments.**

There are no current unresolved staff comments.

**Item 2. Properties.**

We employ executives, employees and consultants who work in various locations in and outside of Florida. Our office in Miramar, Florida serves as the headquarters for the Company. This space is sufficient to accommodate the expected amount of employees working in the metro Miami area. The existing lease provides substantial flexibility in the event we require additional space. Technology affords us the luxury of collaboration among staff from varying locations.

NGDx’s corporate offices, product development facilities, regulatory affairs offices, and laboratory and assembly facilities are contained in a 5,627 square foot facility in Miramar, Florida. The facility is leased through July 31, 2020 with a current monthly base rent of $7,325 including taxes and expenses. Our facility is an FDA Registered Facility. Based on order size, delivery requirements and current orders in process, our Miramar facility can handle up to one million RTD devices, all of which are currently hand assembled. We have relationships with subcontractors to handle additional production requirements.
Generex currently uses spaces in NGDx’s facility as its principal executive office. We also use a small space in Burlington, Ontario, Canada for an executive office. The rent is immaterial.

We do not expect to need manufacturing capabilities related to our insulin or immunotherapy products, 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.**

On August 22, 2017, Generex received a letter from counsel for Three Brothers Trading LLC, d/b/a Alternative Execution Group (“AEXG”), claiming breach of a Memorandum of Understanding (“MOU”) between Generex and AEXG. The MOU related to AEXG referring potential financing candidate to Generex. The letter from AEXG counsel claimed that Generex’s acceptance of $3,000,000 in financing from Pharma Trials, LLC, in March 2017, violated the provisions of the MOU prohibiting Generex from seeking other financing, with certain exceptions, for a period of 60 days after execution of the MOU. AEXG has demanded at least $210,000 in cash and 84,000 warrants for Generex stock convertible at $2.50 per share, for attorney’s fees and costs. AEXG filed a demand for arbitration and on September 25, 2018 an arbitration hearing was held with an arbitrator from the American Arbitration Association’s International Centre for Dispute Resolution. On December 2, 2018, an arbitrator awarded AEXG an aggregate of $315,695 in damages, costs and fees as well as warrants exercisable for 84,000 shares of Generex Common Stock at an exercise price of $2.50 per share. AEXG filed a petition to confirm the arbitrator’s award in the United States District Court for the Southern District of New York. The petition includes a demand of $3,300,360 as the value of the Warrants. The arbitrator did not award the specific amount of $3.5 million, but only liquidated damages in the amount of $220,000 and the value of 84,000 warrants “as of today” (the date of the award) plus attorney’s fees, certain costs, prejudgment and post-judgment interest (which continues to run on a daily basis) and arbitration fees. Generex has responded that the value of the warrants on the date of the award is $0 or some figure far less than the value calculated by AEXG. The petition to confirm the arbitrator’s award and Generex’s opposition were remanded by the Court to the arbitrator and returned for clarification. The arbitrator stated that he was unable to add any clarification, as he did not take evidence on the issue of warrant valuation. The parties are awaiting the court’s response to the Arbitrator’s statement.

On October 26, 2018, Generex entered into a Securities Purchase Agreement with Alpha Capital Anstalt (“Alpha”) pursuant to which we agreed to sell and sold its note due October 26, 2019 in the principal amount of $682,000. The purchase price of the note was $550,000. The remaining $122,000 of principal amount represents original issue discount. On January 25, 2018, Generex received a letter from Alpha’s counsel stating that the note was in default because Generex’s common stock was not listed on NASDAQ within 90 days after the issuance of the note. The letter demanded repayment in full. The Company filed a motion for summary judgement in lieu of complaint in the Supreme Court demanding the aggregate principal amount, default interest and costs. Counsel for Generex and Alpha have engaged in settlement discussions.

On March 21, 2019 Compass Bank filed suit against NuGenerex Distributions Solutions 2, L.L.C. in the District Court of Dallas County, Texas requesting damages of $3,413,000. In connection with the closing of the Veneto acquisition, Compass Bank had a lien on certain assets that were supposed to be transferred into the ownership of NuGenerex, a subsidiary of Generex. Those assets were never transferred due to regulatory impositions. Generex had listed Compass Bank as an intended third party beneficiary to the transaction in relation to the assets liened and Veneto ceased payments upon the loan which the lien generated from. Compass bank filed suit against 6 parties involved in the transaction to collect on the loan, including NuGenerex. NuGenerex’s position is the contract was frustrated by the assets that were liened were never transferred, NuGenerex did not receive any benefit from the agreement, and thus NuGenerex is not responsible to Compass Bank for repayment of a loan on assets not transferred. Generex intends to impale Brooks Houghton for indemnification who was retained to perform due diligence on the transaction.

On December 2011, a vendor of us commenced an action against us and our 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. We 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 we have 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 we fail 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.
On June 28, 2018, the Company was named in respect of a claim by Burrard Pharmaceutical Enterprises Ltd. and Moa'yeri Kayhan for unspecified damages and other remedies issued by the Supreme Court of British Columbia. The claim is made in connection with one advanced against Burrard and Kayhan by Middle East Pharmaceutical Factory L.L.C., a foreign corporation, for fraudulent or negligent misrepresentation. Middle East alleges that it was misled by Burrard and Kayhan into believing that Burrard had rights to distribute Generex product in the Middle East. Burrard and Kayhan allege that they did have rights in that regard, which the Company denies. The matter remains at the pleadings stage and we are investigating the facts.

In May 2019 Brooks Houghton initiated a FINRA Dispute Resolution. Brooks Houghton, who the managing representative is Mr. Centonfanti a prior board member, was under contract to perform due diligence on the Veneto transaction, assist in raising capital, as well as other unrelated items. The Veneto transaction closed three times, each time with a reduction in price due to material negative circumstances. Brook Houghton, who was under contract to perform due diligence, claims their fee should be paid on the initial closing price not the ultimate resolution of the matter. The company offered to compensate Brooks Houghton pursuant to agreement, 3% on the most recent closing price for Veneto for which Brooks Houghton may have performed some level of work, payable in kind, and Brooks Houghton declined the offer. Brooks Houghton is claiming $450,000 for the first closing of Veneto, $714,000 for the second closing of Veneto, $882,353 for the Regentys acquisition, and $705,882 for Olaregen.

On September 9, 2019 Generex and its subsidiary NuGenerex Distribution Solutions, LLC, and NuGenerex Distributions Solutions 2, LLC (jointly “NDS”) filed a litigation against Veneto, and the constituent entities, for fraud, breach of contract, and a motion for a temporary restraining order restraining the shares contemplated in the Asset Purchase Agreement (“APA”) (supra) for hiding their involvement in a massive healthcare fraud scheme, which is currently being prosecuted civilly by the federal government and filing to transfer assets specified in the APA. The litigation is pending the Court of Chancery in the State of Delaware. Our motion for a temporary restraining order on transfer of shares we issued in connection with the acquisition of Veneto assets was denied by the Court of Chancery. Generex intends to continue to pursue claims against Veneto and its principals in a separate action. In a related action, our transfer agent has been sued for failure to process a transfer of the shares issued pursuant to the APA. This suit was brought in the United States District Court for the Eastern District of New York. Generex is not named in the suit, but our transfer agent has notified us of our obligation to indemnify them pursuant to our agreement with the transfer agent.

**Item 4. Mine Safety Disclosures.**

This item is not applicable.
PART II

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

Market Information

Our common stock is quoted on the OTCQB, a tiered marketplace of the OTC Markets Group. Previously, our common stock was quoted on the OTC Pink market, a lower tier marketplace of the OTC Markets Group, under the symbol "GNBT". Our common stock was previously removed from the OTCQB due to our failure to file SEC reports.

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 reflected for the aggregate inter-quarter highest high and lowest low. 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, 2018, and July 31, 2019. 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.

Please take notice that the below table and chart are split, and stock dividend adjusted. Specifically, in October 2018 Generex issued a 20:1 stock dividend, twenty shares issued for each share held by holders which served as a significant dilution to the stock.

<table>
<thead>
<tr>
<th>Sales/Bid Price</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fiscal 2019</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fourth Quarter</td>
<td>$3.28</td>
<td>$0.88</td>
</tr>
<tr>
<td>Third Quarter</td>
<td>$2.42</td>
<td>$1.08</td>
</tr>
<tr>
<td>Second Quarter</td>
<td>$3.10</td>
<td>$0.40</td>
</tr>
<tr>
<td>First Quarter</td>
<td>$0.60</td>
<td>$0.09</td>
</tr>
<tr>
<td><strong>Fiscal 2018</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fourth Quarter</td>
<td>$0.16</td>
<td>$0.10</td>
</tr>
<tr>
<td>Third Quarter</td>
<td>$0.20</td>
<td>$0.14</td>
</tr>
<tr>
<td>Second Quarter</td>
<td>$0.23</td>
<td>$0.11</td>
</tr>
<tr>
<td>First Quarter</td>
<td>$0.25</td>
<td>$0.13</td>
</tr>
</tbody>
</table>
Holders

As of October 19, 2019, Generex had 99 holders of record.

Dividends

We have not paid cash dividends on our common stock in the past and have no present intention of paying cash dividends on our common stock in the foreseeable future. We have issued stock dividends and a dividend of shares of our subsidiary, Antigen Express, Inc.

Equity Compensation Plan Information

<table>
<thead>
<tr>
<th>Plan category</th>
<th>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</th>
<th>Weighted-average exercise price of outstanding options, warrants and rights (b)</th>
<th>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity compensation plans approved by security holders</td>
<td>7,988,675</td>
<td>$0.84</td>
<td>234,846,325</td>
</tr>
<tr>
<td>Equity compensation plans not approved by security holders</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Recent sales of unregistered securities; use of proceeds from registered securities

<table>
<thead>
<tr>
<th>Date of Issuance</th>
<th>Shares</th>
<th>Consideration</th>
<th>Exemption from Registration</th>
<th>Terms of Conversion or Exercise</th>
<th>Use of Proceeds</th>
<th>Underwriter of other Purchaser</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/1/2019</td>
<td>560,000</td>
<td>Stock Purchase Agreement $1,400,000</td>
<td>Section 4(2)</td>
<td>Accepted Rate of $2.50/share</td>
<td>Acquisition of Pantheon Medical - Foot &amp; Ankle, LLC</td>
<td>Shaleholders of Pantheon</td>
</tr>
<tr>
<td>8/1/2019</td>
<td>400,000</td>
<td>Stock Purchase Agreement $1,000,000</td>
<td>Section 4(2)</td>
<td>Accepted Rate of $2.50/share</td>
<td>Acquisition of Medisource Partners, LLC</td>
<td>Shareholders of Medisource</td>
</tr>
<tr>
<td>8/8/2019</td>
<td>384,000</td>
<td>Convertible Debt: $649,851 (principal)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.69232/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>8/12/2019</td>
<td>30,666</td>
<td>Convertible Debt: $45,000 (principal) and $2,500 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.54896/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>8/15/2019</td>
<td>230,351</td>
<td>Convertible Debt: $350,000 (principal)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.51942/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>8/19/2019</td>
<td>46,110</td>
<td>Convertible Debt: $60,000 (principal) and $3,450 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.37606/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>8/21/2019</td>
<td>94,373</td>
<td>Convertible Debt: $100,000 (principal) and $5,699 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.1197/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>9/10/2019</td>
<td>75,737</td>
<td>Convertible Debt: $100,000 (principal) and $6,361 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.40434/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>9/17/2019</td>
<td>95,130</td>
<td>Convertible Debt: $130,000 (principal) and $8,522 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.45614/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
<tr>
<td>9/18/2019</td>
<td>112,941</td>
<td>Convertible Debt: $150,000 (principal) and $9,699 (interest)</td>
<td>Section 4(2)</td>
<td>Conversion Rate of $1.414/share</td>
<td>Conversion of Debt</td>
<td>Hedge Fund</td>
</tr>
</tbody>
</table>
Purchases of equity securities by the issuer and affiliated purchasers.

Neither Generex nor any of its affiliates made any material purchases of the stock during the fiscal 2019.


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 year ended July 31, 2019 and 2018. We engaged in certain acquisition transactions during the twelve months ended July 31, 2019, with effectives as follows:

- Effective August 1, 2019 we purchased the assets of Pantheon and MediSource Partners. Our balance sheet at July 31, 2019 does not include our interest in Pantheon and MediSource Partners assets as our interest commenced after period ended July 31, 2019.

- Effective October 3, 2018, we purchased certain assets of Veneto Holdings, L.L.C. (“Veneto”), and its subsidiaries (the “First Closing Assets”). We acquired additional assets of Veneto effective November 1, 2018 (the “Second Closing Assets” and together with the First Closing Assets, the “Acquired Veneto Assets.”). The transaction was subsequently renegotiated, culminating in an amendment, a “Restructuring Agreement” March 28, 2019, but that did not affect our interest in the assets, or production thereof, and only effected the transaction price. Subsequent to the Restructuring Agreement, we entered into litigation with Veneto and their constituent parties which may affect the future of those assets but does not currently affect the accounting for the Acquired Veneto Assets and recently filed a motion for Arbitration on September 10, 2019. Our balance sheet at July 31, 2019 includes our interest in the Acquired Veneto Assets, the obligations issued in connection with the purchase of the Acquired Veneto Assets. Our interest in the results of operations of the First Closing Assets since October 3, 2018 and the Second Closing Assets since November 1, 2018 is included in our Consolidated Statement of Operations and Comprehensive Loss for the year ended July 31, 2019. We are currently in litigation with Veneto and its affiliates regarding the assets and business transferred. Many of the contractual arrangement we assumed from Veneto have been terminated, and we have had to rebuild the business relationships and the structure of the contractual relationships we took over from Veneto.

- Effective January 7, 2019, we purchased a majority interest in the capital stock of Regentys Corporation. (“Regentys”). Our balance sheet at July 31, 2019 includes our interest in Regentys and our interest in the results of operations of Regentys for the period ended July 31, 2019 is included in our Consolidated Statement of Operations and Comprehensive Loss for the year ended July 31, 2019.

- Effective January 7, 2019, we purchased a majority interest in the capital stock of Olaregen Therapeutix Inc. (“Olaregen”). Our balance sheet at July 31, 2019 includes our interest in Olaregen and our interest in the results of operations of Olaregen for the period ended July 31, 2019 is included in our Consolidated Statement of Operations and Comprehensive Loss for the year ended July 31, 2019.

Executive Summary

Preliminary Note

On January 17, 2017, we acquired a 51% interest in Hema Diagnostic Systems, LLC (“Hema” or “HDS”).
On December 1, 2018, we acquired the remaining equity of HDS, and HDS became a wholly owned subsidiary; we have renamed HDS as NuGenerex Diagnostics (NGDx). We intend to focus resources on NGDx’s business as well as other potential acquisition candidates going forward, but do not intend to discontinue our pre-Acquisition activities.

On October 3, 2018, we acquired the First Closing Assets from Veneto, primarily consisting of the operating assets of (a) system dispensing pharmacies, (b) a central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory.

On November 1, 2018 we consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto’s management services organization business and two additional ancillary services. The aggregate price for the First Closing Assets and the Second Closing Assets was $30,000,000. We issued a promissory note in the principal amount of $35,000,000 consisting of the $30,000,000 purchase price and a $5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. In addition, we agreed to assume approximately $3.8 million in outstanding institutional debt of Veneto subsidiaries, but will have use of Veneto cash and the collateral of the underlying assets outlined in the note, which would otherwise have been applied to paying down the debt, or securing by the assets.

On January 15, 2019, we entered into an Amendment Agreement (the “Amendment”) with Veneto and the equity owners of Veneto entered into restructuring payment of the note as follows:

- Payment of $15,750,000 by delivery of Generex common stock, initially valued at $2.50 per share.

- If, on the first to occur of (i) the ninetieth (90th) day after closing under the Amendment and (ii) the effective date of a registration statement filed with the SEC including the Generex shares pursuant to the Amendment, the average volume weighted average price (“VWAP”) of Generex common stock for the preceding five (5) trading days is less than $2.50 share, Generex will deliver additional Generex Shares such that the aggregate number of shares delivered under this Agreement equals $15,750,000 ÷ such average VWAP.

- The remainder of the principal and interest under the Note shall be payable on April 15, 2019; provided that on that maturity date, Veneto shall have the option of (i) payment of principal and interest in cash and (ii) payment of principal and interest by Generex’s delivery of Generex Shares valued at $2.50 per share.

- All Generex shares issued pursuant to the Amendment will be delivered pro rata to the six equity owners of Veneto as distributions from Veneto.

On March 28, 2019 we entered into an amendment, the Restructuring Agreement with Veneto with respect to the payment terms of the January 15, 2019 promissory note. The parties agreed to restructure the terms as follows:

- In lieu of any payments under the agreement or the note, we will deliver shares of its common stock and the common stock of its subsidiary, Antigen;

- All shares of our common stock delivered pursuant to the foregoing sentence will be outstanding shares held by existing shareholders;

- 8.4 million of our shares have been placed in escrow as of May 6, 2019, and delivered to the transfer agent on May 9, 2019 for transfer;

- 5.5 million of Antigen’s common stock; and

- Limited “downside protection” to ensure the value of our common stock to be delivered.

On January 7, 2019, we acquired a majority interest in Regentyx Corporation for an aggregate of $15,000,000. $400,000 was paid in cash and the remainder was paid by the issuance of a promissory note. Installments payable under the note were tied to specific business development objectives and dates. As October 3, 2019, an additional $850,000 was paid, for a total of $1,250,000 against the note. Regentyx is developing a non-surgical treatment for inflammatory bowel diseases such as ulcerative colitis and Crohn’s disease.
On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of guaranteed payments amounting to $2,800,000 on or before April 1, 2019. The extension of this due date has no impact on the existing schedule of future payments or any additional terms within the note. We did not furnish payments due on April 1, 2019, or a $2,000,000 payment due on or before May 1, 2019. On October 31, 2019, Regentys and the Company entered into an Amendment Agreement extending the payment date of approximately $7,000,000 in overdue Payments to November 30, 2019.

On January 7, 2019, we acquired a majority interest in Olaregen for an aggregate of $12,000,000. $400,000 was paid in cash and the remainder was paid by the issuance of a promissory note. An aggregate of $1,291,500 has been paid in addition to the $400,000 initial payment. Olaregen is launching an FDA-510(k) cleared wound care product.

On March 14, 2019, the Company and Olaregen amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the second tranche of guaranteed payments amounting to $600,000 on or before April 1, 2019. The extension of this due date has no impact on the existing schedule of future payments or any additional terms within the note. We did not furnish the required payments on April 1, 2019. Olaregen has not filed any notice of default as of the date of publication, and we continue to provide Olaregen with business opportunities continuing the relationship. Olaregen launched Excellagen, an FDA 510(k) cleared product for the management of wounds.

We intend to focus resources on NGDx’s business, and on the businesses of Regentys, Olaregen and the MSO business acquired from Veneto, as well as additional acquisition targets, but do not intend to discontinue our historical activities. However, we will not pursue our historical business if we do not receive substantial financing for that purpose.

Subsequent Events

On August 1, 2019 Generex finalized the acquisition of Pantheon Medical – Foot & Ankle, LLC through a stock purchase agreement.

On August 1, 2019 Generex finalized the acquisition of MediSource Partners, LLC through a stock purchase agreement.

On August 8, 2019, the Company converted $649,851 of debt into 384,000 shares of common stock.

On August 12, 2019, the Company converted $45,000 of principal and $2,500 of interest into 30,666 shares of common stock.

On August 12, 2019, the Company retained a consultant to provide financial advisory services in connection with and support of the various financing options and other services for the Company to raise up to Seven Million Dollars ($7,000,000) in debt capital for the Company payable upon funding equal to five (5%) of the principal amount funded by investors introduced by the Consultant.

On August 13, 2019, the Company entered into a Public Secured Financing Facility Agreement with an investor pursuant to which the Company will receive a $5,000,000 financing facility bearing 13.50% interest per annum. The Company may receive subsequent financing in addition to the initial amount of $5,000,000 but shall not exceed a total of $7,000,000. The financing facility matures on August 13, 2021.

On August 14, 2019, the Company entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 10% per annum in the principal amount of $1,100,000. Pursuant to the Securities Purchase Agreements, the Company also sold to the Investor warrants to purchase up to an aggregate 62,857 shares of common stock with the fair value of the warrants as of the date of issuance in excess of the Notes resulting in full discount of the Notes.

On August 15, 2019, the Company entered an agreement to pay an investor $900,000 for the prepayment of $666,667 owed under the note. Pursuant to the agreement, the Company converted $350,000 owed under the note into 230,351 shares of the Company’s common stock based upon a conversion price of $1.51942 per share.
On August 16, 2019, the Company entered into a Share Exchange Agreement to purchase an additional 900,000 shares in Olaregen Therapeutix Inc. from Olaregen Therapeutix LLC representing increasing Generex’s ownership from approximately 62% to 76%.

On August 19, 2019, the Company repaid a convertible note in cash $100,149 in principal and $37,411 of interest.

On August 19, 2019, the Company converted $60,000 of debt and $3,450 of interest into 46,110 shares of common stock.

On August 21, 2019, the Company converted $100,000 of principal and $5,699 of interest into 94,373 shares of common stock.

On August 28, 2019, the Company issued 12,444 shares of common stock to an investor pursuant to the Asset Purchase Agreement dated July 11, 2019.

On August 29, 2019, the Company entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 9% per annum in the principal amount of $250,000.

On September 1, 2019, the Company retained a consultant to provide consulting services directly or through affiliated entities, certain management, administrative, marketing and/or clinical services to various ancillary healthcare for providers for a fee of $2,000,000; $250,000 payable in shares of common stock; and $1,750,000 payable in 18 equal installments of $97,222.22 per month payable in cash as is available from the operations of newly acquired subsidiaries Pantheon and MediSource, or shares of common stock issued monthly.

On September 2, 2019 Generex signed a Memorandum of Understanding with Paradise Valley Family Medicine to form a partnership under NuGenerex Health, LLC for the provision of ancillary health services.

On September 3, 2019, the Company declared a stock dividend on our outstanding Common Stock for stockholders of record date August 30, 2019 (the “Record Date”). As a result, all stockholders on the Record Date who hold their shares through the pay date of November 29, 2019 (as extended) will receive one new share of Common Stock for each share of Common Stock owned by them as of that date.

On September 6, Generex signed a binding Letter of Intent with ALTuCELL, Inc (“ALTuCELL”), a clinical-stage development company with a broad intellectual property portfolio focused on cell encapsulation technology for the treatment of diabetes, autoimmune diseases, and inflammatory conditions to purchase 51% of ALTuCELL’s equity in exchange for $2,000,000 in cash, $8,000,000 in the Company’s common stock price at $2.50/share, and commitment to fund $5,000,000 towards ALTuCELL’s development costs pursuant to a mutually agreed upon clinical development plan based upon a valuation of ALTuCELL equal to $29,500,000. On September 20, 2019, Generex paid ALTuCELL a preliminary payment of $50,000 to bind the agreement.

On September 10, 2019, the Company converted $100,000 of debt and $6,361 of interest into 75,737 shares of common stock.

On September 10, 2019, Generex and its subsidiaries, NuGenerex Distribution Solutions, LLC and NuGenerex Distributions Solutions 2, LLC (jointly “NDS”) filed an arbitration action against Veneto Holdings, LLC and certain affiliated entities holding shares of our common stock issued in connection with our acquisition of Veneto’s assets, alleging, among other things, that Veneto never transferred the ownership rights in at least one pharmacy to NDS. This pharmacy was a necessary element in the operation of other assets transferred by Veneto. The ownership rights in this pharmacy was a substantial portion of the consideration for shares issued to Veneto and its affiliates, and, as a result, Generex contends the shares issued to Veneto and its affiliates were never fully paid for. The arbitration is pending before the American Arbitration Association in Delaware.

On September 12, 2019, 20,375,900 shares of common stock held in trust for the benefit of the Company were cancelled by the Company.

On September 13, 2019, the Company converted 592,683 Preferred Shares of Olaregen Therapeutics, Inc. Series A Preferred Stock into Common Stock.

On September 17, 2019, the Company converted $130,000 of debt and $8,522 of interest into 95,130 shares of common stock.

On September 26, 2019, the Company converted $150,000 of debt and $9,699 of interest into 112,941 shares of common stock.

On October 1, 2019, the Company retained a consultant to provide consulting services in support of the Company’s mission to raise capital, identify potential mergers, as well as other strategic advice to increase the value of the Company for a monthly fee of $5,000 for each calendar month commencing October 2019 and continuing through the termination date of September 30, 2024. The consultant received options to purchase 1,000,000 shares of common stock, vesting in equal increments of 200,000 shares on October 1 of each year commencing on October 1, 2019 at an exercise price of $2.09 per share. The consultant is to be paid a 2.0% transaction fee payable on all transactions consummated during the term. The transaction fee is based on the amount of all proceeds and other consideration paid or received, to be paid or received, or retained by the Company.
Results of Operations

Year ended July 31, 2019 Compared to Year ended July 31, 2018

We had a net loss for the year ended July 31, 2019 in the amount ($11,006,794) versus net income of $35,948,698 in the prior fiscal year. The decrease in net income was primarily attributable to the increase in general and administrative expenses, interest expense and change in value of contingent purchase consideration. Our operating loss for the year ended July 31, 2019 increased to $24,345,441 compared to $2,495,609 in the fiscal year 2018. The rise in operating loss resulted from an increase in stock compensation expense to $3,003,380 from $0, an increase in professional services to $7,255,262 from $714,963, an increase in salary and wages to $5,114,311 from $1,555,955, an increase in financial services to $899,682 from $103,809, an increase in travel expenses to $459,232 from $48,060, an increase in other general and administrative expenses to $4,216,692 from $662,310, research and development costs to $1,748,882 from $839,147 and an increase in bad debt expense in the current fiscal year was $3,252,439 compared to the previous fiscal year $0. Revenue in years ended July 31, 2019 and 2018 was $6,203,761 and $703,244, respectively.

The bad debt expense in the current fiscal year was $3,252,439 compared to the previous fiscal year $0 due the impairment of accounts receivables and note receivables derived from Veneto Holdings, L.L.C. which was acquired during fiscal year 2019.

The increase in revenue was generated from Veneto which was acquired during fiscal year 2019.

Interest expense in the current fiscal year was $7,087,502 compared to the previous fiscal year $583,594. Change in fair value of derivative liabilities was $2,125,449 in the 2019 fiscal year compared to $0 in the previous 2018 fiscal year. Change in value of contingent purchase consideration in the current fiscal year was $18,587,782 compared to the previous fiscal year $39,027,901 (Note 9).

The increase in research and development expenses in the year ended July 31, 2019 versus the comparative previous fiscal year is primarily due the expenses incurred by Regentys Corporation.

Financial Condition, Liquidity and Resources

Sources of Liquidity

To date we have financed our activities primarily through private placements of our common stock, securities convertible into our common stock, and investor loans. We will require additional funds to support our working capital requirements and any development or other activities. NGDx will require additional funds to support its working capital requirements and any development or other activities or will need to curtail its research and development and other planned activities or suspend operations. NGDx will no longer be able to rely on its former primary owner for necessary financing. Going forward, NGDx will rely on Generex financing activities to fund NGDx operations, development and other activities

Our July 31, 2019 cash position was not sufficient for 12 months of operations. Anticipated revenues associated with the Veneto acquisition are expected to dramatically alter the cash flow landscape.

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, as well as investor notes, and raised approximately $6.5 million during fiscal 2019 (including proceeds from issuance of convertible notes), our cash balances have been low throughout fiscal 2019.
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.

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 our 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.

**Financings**

Following is a summary of the financing activities that we have completed since the end of fiscal 2018.

*Financing – January 18, 2019*
*Investor Note convertible into stock*

On January 18, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $530,000. The Note accrues at 10% per annum and has a maturity date of January 18, 2020 and is convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, the investor has converted 205,897 shares and has a principal balance remaining of $250,000.

*Financing – January 18, 2019*
*Investor Note convertible into stock*

On January 18, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $750,000. The Note accrues at 10% per annum and has a maturity date of January 18, 2020 and is convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.

*Financing – January 21, 2019*
*Investor Note convertible into stock*

On January 21, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $530,000. The Note accrues at 10% per annum and has a maturity date of January 21, 2020 and is convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, $28,136 has been converted into common shares and $435,000 remains outstanding.

*Financing – January 22, 2019*
*Investor Note convertible into stock*

On January 22, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $1,050,000. The Note accrues at 10% per annum and had a maturity date of January 22, 2020 and was convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, the investor has converted the entire note, principal and accrued interest, into 806,516 shares.
Financing – February 4, 2019  
Investor Note convertible into stock

On February 4, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $750,000. The Note accrues at 10% per annum and had a maturity date of February 4, 2020 and was convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.

Financing – April 23, 2019  
Investor Note convertible into stock

On April 23, 2019, we entered into Convertible Notes and Securities Purchase Agreements with two investors in the principal amount of $530,000. The Notes accrue at 10% per annum and have a maturity date of April 23, 2020 and is convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.

Financing – April 8, 2019  
Investor Note convertible into stock

On April 8, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $530,000. The Note accrues at 10% per annum and had a maturity date of April 8, 2020 and was convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.

Financing – May 10, 2019  
Investor Note Payable

On May 24, 2019, we entered into a Promissory Note with a lender in the principal amount of $2,000,000. The Note accrues at 7% per annum and had a maturity date of August 1, 2019. The note remains active and interest has continued to accrue while new terms of the note are in process of being negotiated.

Financing – May 24, 2019  
Investor Note convertible into stock

On May 24, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $278,300. The Note accrues at 9% per annum and had a maturity date of May 24, 2020 and was convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.

Financing – July 8, 2019  
Investor Note convertible into stock

On July 8, 2019, we entered into a Convertible Note and Securities Purchase Agreement with an investor in the principal amount of $168,300. The Note accrues at 9% per annum and had a maturity date of July 8, 2020 and was convertible into common voting shares at a variable rate determined in the instrument. As of July 31, 2019, there have been no conversions and the full balance remains outstanding.
On October 26, 2018, we entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its note due October 26, 2019 in the principal amount of $682,000. The purchase price of the note was $550,000 from which we were required to pay the $15,000 fee of the investor’s counsel. The remaining $122,000 of principal amount represents original issue discount. The note does not bear any stated interest in addition to the original issue discount.

Joseph Moscato, our President & Chief Executive Officer, has guaranteed our obligations under the note. In addition, Mr. Moscato has pledged as collateral for the guaranty 156,400 shares of our common stock.

The note provided it would become due and payable prior to maturity if our common stock is not listed for trading on a NASDAQ market on or before ninety (90) days after the date of the note. The listing has not occurred. In January 2019, the note holder demanded repayment on this basis and in March 2019, filed suit to recover the principal amount of the Note plus interest. The company has answered the claim and the matter is currently in litigation.

On November 25, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its note due November 26, 2019 in the principal amount of $1,060,000. The purchase price of the note was $1,000,000. The remaining $60,000 of principal amount represents original issue discount. The note does not bear any stated interest in addition to the original issue discount.

Joseph Moscato, our President & Chief Executive Officer, has guaranteed our obligations under the note. In addition, Mr. Moscato has pledged as collateral for the guaranty 400,000 shares of our post-stock dividend Common Stock owned by him. At the option of either the investor or Mr. Moscato, all or any party of the loan can be paid with shares of the pledged stock valued at $2.50 per share, without default.

In July 2019, the Note was converted in full to shares of our Common Stock, pursuant to the option contained in Mr. Moscato’s guarantee.

Cash Flows for the Year ended July 31, 2019

For the year ended July 31, 2019, we used $9.6 million in cash to fund our operating activities. The use for operating activities included a net loss of $11 million, changes in fair value of contingent purchase consideration of $18.6 million, and $2.1 million for changes in fair value of derivatives.

The use of cash was offset by non-cash expenses of $0.4 million related to depreciation and amortization, $3 million related to the issuance of stock options as compensation, $3.1 million related to amortization of debt discount, $3.3 million related to bad debt expense and $11.1 million related to changes in working capital. Changes to working capital including an increase of $9.3 million related to accounts payable and accrued expenses, a decrease of $0.8 million in accounts receivable and a decrease of $1.1 million in inventory.

In the year ended July 31, 2019, we had net cash provided by investing activities of $2.3 million primarily relating to cash received in the acquisition of Veneto.

We had cash provided by financing activities in the fiscal year ended July 31, 2019 of $6.5 million, which pertained to proceeds from notes payable of $6.3 million offset by repayments on notes payable of $0.2 million.

Our net working capital July 31, 2019 declined to deficiency of $28 million from a deficiency of $24 million at July 31, 2018, which was attributed primarily to an increase in notes payable of $8 million, an increase in accounts payable and accrued expenses of $8 million, an increase of deferred tax liability of $1.5 million, and a decrease in cash of $0.7 million. These were partially offset by a decrease of loans from related parties of $13.8 million and an increase of inventory and other current assets of $0.4 million.
In addition to our commitments under the financings described above, we have the following obligations:

**Veneto Acquisition Related Debt**

On November 1, 2018, in connection with the completion of the acquisition of the pharmacy, management service organization and other assets of Veneto, our subsidiary, NuGenerex Distribution Solutions 2, LLC (“NuGenerex”), issued Veneto a promissory note in the principal amount of $35,000,000. The note calls for payment in full on or before January 15, 2019 with interest at an annual rate of 12% on the $30,000,000 portion of the New Note representing the purchase price of the Assets. The note is guaranteed by Generex and Joseph Moscato and secured by a first priority security interest in all of Generex’s assets. Mr. Moscato’s guaranty is limited to the principal amount of $15,000,000.

On January 15, 2019, we entered into an Amendment Agreement with Veneto and the equity owners of Veneto entered into restructuring payment of the Note as follows:

- Payment of $15,750,000 by delivery of Generex common stock, initially valued at $2.50 per share.
- If, on the first to occur of (i) the ninety (90th) day after closing under the Amendment and (ii) the effective date of a registration statement filed with the SEC including the Generex shares pursuant to the Amendment, the average volume weighted average price (“VWAP”) of Generex common stock for the preceding five (5) trading days is less than $2.50 share, Generex will deliver additional Generex Shares such that the aggregate number of shares delivered under this Agreement equals $15,750,000 ÷ such average VWAP.
- The remainder of the principal and interest under the Note shall be payable on April 15, 2019; provided that on that maturity date, Veneto shall have the option of (i) payment of principal and interest in cash and (ii) payment of principal and interest by Generex’s delivery of Generex Shares valued at $2.50 per share.
- All Generex shares issued pursuant to the Amendment will be delivered pro rata to the six equity owners of Veneto as distributions from Veneto

As of the date hereof, we had delivered the shares of Generex Common Stock to the transfer agent for distribution to the Veneto equity owners, and the transaction is finalized.

On March 28, 2019, we entered into an amendment Restructuring Agreement with Veneto with respect to the payment terms of the January 15, 2019 promissory note. The parties agreed to restructure the terms as follows:

- In lieu of any payments under the agreement or the note, we will deliver shares of its common stock and the common stock of its subsidiary, Antigen;
- All shares of our common stock delivered pursuant to the foregoing sentence will be outstanding shares held by existing shareholders;
- 8.4 million of our shares have been placed in escrow as of May 6, 2019, and delivered to the transfer agent on May 9, 2019 for transfer;
- 5.5 million of Antigen’s common stock as the original agreement was pre dividend and the restructuring was ex-dividend, and the company honored the intent of the prior agreements; and
- Limited “downside protection” to ensure the value of our common stock to be delivered.
Olaregen and Regentys Acquisitions

Olaregen

As of January 7, 2019, we completed a definitive Stock Purchase Agreement and related documents relating to our purchase of 3,282,632 newly issued shares of the Olaregen common stock representing 51% percent of the issued and outstanding capital stock of Olaregen for an aggregate $12,000,000.

In addition to $400,000 paid to Olaregen upon signing of the LOI, the purchase price for the Olaregen Shares will consist of the following cash payments:

- $800,000 on or before January 15, 2019. The Company has paid this installment.
- $800,000 on or before January 31, 2019. As of the date this report was filed, the Company has paid $491,500 of this installment and remaining balance of $308,500 is payable on or before June 30, 2019 per extension in amended agreement.
- $3,000,000 on or before April 1, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $3,000,000 is payable on or before June 30, 2019 per extension in amended agreement.
- $1,000,000 on or before May 31, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $1,000,000 is payable on or before June 30, 2019 per extension in amended agreement.
- $6,000,000 on or before November 30, 2019.

Generex issued its Promissory Note in the amount of $11,600,000 representing its obligation to pay the above amounts. The Note is secured by a pledge of the Olaregen Shares pursuant to a Pledge and Security Agreement.

On March 14, 2019, the Company and Olaregen amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of guaranteed payments amounting to $600,000 on or before April 1, 2019 and the second payment of $1,000,000 on or before April 1, 2019. The extension of this due date has no impact on the existing schedule of future payments or any additional terms within the note. We did not furnish the required payments due on April 1, 2019. Olaregen has not filed any notice of default as of the date of publication, and we continue to provide Olaregen with business opportunities continuing the relationship. In the event we do not make any other payments, our share ownership of Olaregen will be proportionately reduced. We have a limited anti-dilution right under the Stock Purchase Agreement, to ensure that we will retain 51% ownership in Olaregen for a period of time.

On May 10, 2019, the Company acquired Olaregen’s outstanding Series A Preferred Stock in exchange for 4 million shares of the Company’s common stock, plus the issuance of a $2 million promissory note increasing our interest in Olaregen to approximately 62% of the Olaregen’s outstanding voting shares.
On January 7, 2019 the Company completed a definitive Stock Purchase Agreement and related documents relating to our purchase of 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys (“Regentys Shares”).

In addition to $400,000 paid to Regentys upon signing of the LOI, the purchase price for the Regentys Shares consists of the following cash payments, with the proceeds intended to be used for specific purposes, as noted:

- $3,450,000 to initiate pre-clinical activities on or before January 15, 2019. As of the date this report was filed, the Company has paid $650,000 and the remaining balance of $2,800,000 is payable on or before November 30, 2019 per extension in amended agreement.
- $2,000,000 to initiate patient recruitment activities on or before May 1, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $2,000,000 is payable on or before November 30, 2019 per extension in amended agreement.
- $3,000,000 to initiate a first-in-human pilot study on or before November, 2019 per extension in the amended agreement
- $5,000,000 to initiate a human pivotal study on or before February 1, 2020.
- $1,150,000 to submit a 510(k) de novo submission to the FDA on or about February 1, 2021.

We issued a Promissory Note in the amount of $14,600,000 representing its obligation to pay the above amounts. The note is secured by a pledge of the Regentys pursuant to a Pledge and Security Agreement.

We have paid a total of $1,250,000 of principal on this Note. On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of guaranteed payments amounting to $2,800,000 on or before April 1, 2019. The extension of this due date has no impact on the existing schedule of future payments or any additional terms within the note. On October 3, 2019, Regentys and the Company entered into an Amendment Agreement extending the payment date of approximately $7,000,000 in overdue Payments to November 30, 2019.

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

In addition to the 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.

Accounting for Research and Development Projects

Our major research and development projects are focused on the clinical development of our peptide immunotherapeutic AE37. Additionally, we have developed the NGDx EXPRESS II Syphilis Treponema Assay.

We did not extend any material resources on our buccal insulin (Generex Oral-lyn™) or other oral delivery products in the last two fiscal years due to lack of funds. 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 year ended July 31, 2019 and 2018, we paid $354,000 and $234,000, respectively, to NSABP for clinical trials for additional research and development relating to Antigen’s peptide immune therapeutic vaccines. 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 HSN1 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.

During the fiscal year ended July 31, 2019, NGDx expended $598,000 resources on research and development relating to its rapid diagnostic tests. NGDx expects to expend resources on its rapid diagnostic test during the fiscal year ending July 31, 2020.

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.
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 financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities. Critical accounting policies are those that require application of management’s most subjective or complex judgments, often as a result of matters that are inherently uncertain and may change in subsequent periods. Our critical accounting policies include those related to revenue recognition, allowance for doubtful accounts, acquisitions, income taxes and valuation of investments, derivatives and long-lived assets. Management bases its estimates and judgments on historical experience and other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. See Note 2 to the Consolidated Financial Statements in this Annual Report for a complete discussion of our significant accounting policies.

**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.
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Generex Biotechnology Corporation and Subsidiaries.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Generex Biotechnology Corporation and subsidiaries (the “Company”) as of July 31, 2019, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ deficit, and cash flows for the fiscal year then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of July 31, 2019, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant operating losses and negative cash flows from operations since inception. The Company also had an accumulated deficit of $418,727,875 at July 31, 2019. The Company is dependent on obtaining necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue their operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management’s plans regarding those matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Mazars USA LLP

We have served as the Company’s auditor since 2019.

Edison, New Jersey
November 12, 2019
To the Board of Directors and
Stockholders of Generex Biotechnology Corporation

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Generex Biotechnology Corporation and its subsidiaries (the Company) as of July 31, 2018, and the related consolidated statements of operations and comprehensive income (loss), change in stockholders' deficiency, and cash flows for the year then ended, and the related notes, comprising a summary of significant accounting policies and other explanatory information (collectively referred to as the consolidated financial statements).

In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of July 31, 2018, and its consolidated financial performance and its consolidated cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Material Uncertainty Related to Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1, the Company’s experience of negative cashflow from operations since inception and its dependency upon future financing, which is uncertain due to the limitations imposed by previous financings on future financings, raise substantial doubt about its ability to continue as a going concern. Management’s plans regarding these matters are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ MNP LLP

We have served as the Company’s auditor since 2013.

Mississauga, Canada

October 26, 2018
## GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
### CONSOLIDATED BALANCE SHEETS

**July 31,**  
**2019**  

| ASSETS                        |  |  
|-------------------------------|---|---|
| **Current Assets**            |  |  
| Cash and cash equivalents     | $ 298,485 | $ 1,046,365 |
| Accounts receivable, net      | 36,311  | 33,555  |
| Inventory, net                | 363,008 | 12,075  |
| Other current assets          | 275,731 | 96,251  |
| **Total current assets**      | $ 973,535 | $ 1,188,246 |
| **Property and equipment**    | 499,993 | 31,536  |
| Call option (Note 9)          | 0     | 2,168,211 |
| Goodwill (Note 12)            | 38,297,573 | 0 |
| Intangible assets             | 9,834,269 | 3,211,037 |
| Other assets, net             | 30,621 | 7,824  |
| **TOTAL ASSETS**              | $ 49,635,991 | $ 6,606,854 |

| LIABILITIES AND STOCKHOLDERS’ DEFICIENCY |  |  
|-----------------------------------------|---|---|
| **Current Liabilities**                 |  |  
| Accounts payable and accrued expenses   | $ 19,055,822 | $ 11,044,774 |
| Notes payable, current (Note 9 and 13) | 8,368,379 | 320,000  |
| Loans from related parties (Note 3)    | 19,700 | 13,864,241 |
| Deferred tax liability (Note 9)        | 1,502,122 | 0 |
| **Total Current Liabilities**          | $ 28,946,023 | $ 25,229,015 |
| Derivative liability (Note 14)         | 7,820,283 | 0 |
| Common stock payable                   | 1,123,188 | 0 |
| Warrants to be issued (Note 9)         | 0     | 24,962,507 |
| **Total Liabilities**                  | $ 37,889,494 | $ 50,191,522 |
| Redeemable non-controlling interest (Note 7) | 4,073,898 | 0 |
| Stockholders’ Equity (Deficiency) (Note 6) |  |  
| Series H Convertible Preferred Stock, $.001 par value; authorized 109,000 shares, 0 and 63,000 issued shares at July 31, 2019 and 2018, respectively | 0 | 3 |
| Series I Convertible Preferred Stock, $.001 par value; authorized 6,000 shares, 0 and 16,590 issued shares at July 31, 2019 and 2018, respectively | 0 | 1 |
| Common stock, $.001 par value; authorized 750,000,000 shares; 62,290,940 and 22,430,121 issued and outstanding at July 31, 2019 and 2018, respectively | 62,290 | 22,430 |
| Common stock payable                 | 0     | 2,168,951 |
| Additional paid-in capital           | 408,566,529 | 368,388,265 |
| Accumulated deficit                  | (418,727,875) | (409,386,468) |
| Accumulated other comprehensive income | 797,216 | 798,422 |
| Non-controlling interest (Note 6)    | 16,974,439 | (5,576,272) |
| **Total Stockholders’ Equity (Deficiency)** | 7,672,599 | (43,584,668) |

**TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIENCY)**  

|  |  |  
|-------------------------------|---|---|
| **$ 49,635,991**              | **$ 6,606,854** |  

The accompanying notes are an integral part of these consolidated financial statements
<table>
<thead>
<tr>
<th></th>
<th>Year Ended July 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue, net</td>
<td>$ 6,203,761</td>
<td>$ 3,244</td>
</tr>
<tr>
<td>Licensing income</td>
<td>—</td>
<td>700,000</td>
</tr>
<tr>
<td>Total Revenue</td>
<td>6,203,761</td>
<td>703,244</td>
</tr>
<tr>
<td>Cost of Goods Sold</td>
<td>4,138,453</td>
<td>—</td>
</tr>
<tr>
<td>Gross Profit</td>
<td>2,065,308</td>
<td>703,244</td>
</tr>
<tr>
<td>Operating expenses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>1,748,882</td>
<td>839,147</td>
</tr>
<tr>
<td>Bad debt expense</td>
<td>3,252,439</td>
<td>—</td>
</tr>
<tr>
<td>General and administrative</td>
<td>21,409,428</td>
<td>2,359,706</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>26,410,749</td>
<td>3,198,853</td>
</tr>
<tr>
<td>Operating Loss</td>
<td>(24,345,441)</td>
<td>(2,495,609)</td>
</tr>
<tr>
<td>Other Income (Expense):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense</td>
<td>(7,087,502)</td>
<td>(583,594)</td>
</tr>
<tr>
<td>Interest income</td>
<td>47,961</td>
<td>—</td>
</tr>
<tr>
<td>Changes in fair value of contingent purchase consideration (Note 9)</td>
<td>18,587,782</td>
<td>39,027,901</td>
</tr>
<tr>
<td>Change in fair value of derivative liability (Note 14)</td>
<td>2,125,449</td>
<td>—</td>
</tr>
<tr>
<td>Gain on extinguishment of debt</td>
<td>(16,000)</td>
<td>—</td>
</tr>
<tr>
<td>Impairment of long-lived assets (Note 9)</td>
<td>(287,587)</td>
<td>—</td>
</tr>
<tr>
<td>Other income, net</td>
<td>(31,456)</td>
<td>—</td>
</tr>
<tr>
<td>Net (Loss) Income</td>
<td>(11,006,794)</td>
<td>35,948,698</td>
</tr>
<tr>
<td>Net loss attributable to noncontrolling interests (Note 13)</td>
<td>(1,665,387)</td>
<td>(385,400)</td>
</tr>
<tr>
<td>Net Income (Loss) Available to Common Stockholders</td>
<td>$ (9,341,407)</td>
<td>$ 36,334,098</td>
</tr>
<tr>
<td>Net Income (Loss) per Common Share</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>$ (0.19)</td>
<td>$ 34.02</td>
</tr>
<tr>
<td>Diluted</td>
<td>$ (0.19)</td>
<td>$ 14.02</td>
</tr>
<tr>
<td>Shares Used to Compute Income per Share (Note 5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic</td>
<td>48,360,127</td>
<td>1,068,101</td>
</tr>
<tr>
<td>Diluted</td>
<td>48,360,127</td>
<td>2,591,129</td>
</tr>
<tr>
<td>Comprehensive Income:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net Income (Loss)</td>
<td>$ (9,341,407)</td>
<td>$ 36,334,098</td>
</tr>
<tr>
<td>Change in foreign currency translation adjustments</td>
<td>(1,206)</td>
<td>15,272</td>
</tr>
<tr>
<td>Comprehensive Income Available to Common Stockholders</td>
<td>$ (9,342,613)</td>
<td>$ 36,349,370</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements
<table>
<thead>
<tr>
<th>Description</th>
<th>Preferred Stock</th>
<th>Common Stock</th>
<th>Common Stock Payable</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Accumulated Other Comprehensive Income</th>
<th>Sub Total</th>
<th>Non-controlling Interest</th>
<th>Total Stockholders’ Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investment in subsidiary by noncontrolling interest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>327,593</td>
</tr>
<tr>
<td>Currency translation adjustment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>327,593</td>
</tr>
<tr>
<td>Net Income (Loss)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15,272</td>
<td>15,272</td>
<td></td>
<td>15,272</td>
</tr>
<tr>
<td>Balance at July 31, 2018</td>
<td>79,590</td>
<td>4</td>
<td>22,430,121</td>
<td>22,430</td>
<td>2,168,951</td>
<td>$368,388,265</td>
<td>(409,386,468)</td>
<td>(38,008,396)</td>
<td>$(5,576,272)</td>
</tr>
<tr>
<td>Investment in subsidiary by noncontrolling interest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>227,245</td>
</tr>
<tr>
<td>Conversion of preferred series H</td>
<td>(63,000)</td>
<td>(3)</td>
<td>25,200,000</td>
<td>25,200</td>
<td></td>
<td>(25,197)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conversion of preferred series I</td>
<td>(16,590)</td>
<td>(1)</td>
<td>6,639,045</td>
<td>6,639</td>
<td></td>
<td>(6,638)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise of call option to acquire noncontrolling interest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(6,951,015)</td>
<td></td>
<td></td>
<td>(6,951,015)</td>
</tr>
<tr>
<td>Issuance of common stock payable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(6,951,015)</td>
<td></td>
<td></td>
<td>5,565,285</td>
</tr>
<tr>
<td>Issuance of common stock for conversion of debt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(1,953,257)</td>
<td></td>
<td></td>
<td>18,406,684</td>
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<tr>
<td>Conversion of debt to equity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15,176,629</td>
<td></td>
<td></td>
<td>15,176,629</td>
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<tr>
<td>Antigen dividend</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(1,070,456)</td>
<td></td>
<td></td>
<td>(1,070,456)</td>
</tr>
<tr>
<td>Issuance of warrants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5,592,244</td>
<td></td>
<td></td>
<td>5,592,244</td>
</tr>
<tr>
<td>Acquisition of NCI of Regentys</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9,873,553</td>
</tr>
<tr>
<td>Acquisition of NCI of Olaregen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11,999,559</td>
</tr>
<tr>
<td>Acquisition of Olaregen Series A Preferred Stock</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reclassification of equity to liability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(201,294)</td>
<td></td>
<td></td>
<td>(201,294)</td>
</tr>
<tr>
<td>Extinguishment of derivative liability associated with</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Convertible Notes

| Currency translation adjustment | — | — | — | — | — | — | — | — | — | 1,570,174 | — | — | 1,570,174 | — | 1,570,174 |
| Net Income (Loss) | — | — | — | — | — | — | — | — | — | (1,206) | (1,206) | — | (1,206) |
| **Balance at July 31, 2019** | — | $62,290,940 | $62,290 | — | $408,566,529 | $(418,727,875) | $797,216 | $9,301,840 | $(16,974,439) | $7,672,599 |

The accompanying notes are an integral part of these consolidated financial statements.
## GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

### CONSOLIDATED STATEMENTS OF CASH FLOWS

#### Year Ended July 31,

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASH FLOWS FROM OPERATING ACTIVITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (Loss) Income</td>
<td>$(11,006,794)</td>
<td>$35,948,698</td>
</tr>
<tr>
<td>Adjustments to reconcile net (loss) income to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>426,440</td>
<td>23,780</td>
</tr>
<tr>
<td>Impairment of long-lived assets</td>
<td>99,519</td>
<td>—</td>
</tr>
<tr>
<td>Impairment of goodwill</td>
<td>188,069</td>
<td>—</td>
</tr>
<tr>
<td>Stock compensation expense</td>
<td>3,006,203</td>
<td>—</td>
</tr>
<tr>
<td>Loss on extinguishment of debt</td>
<td>16,000</td>
<td>—</td>
</tr>
<tr>
<td>Changes in fair value of contingent purchase consideration</td>
<td>(18,587,782)</td>
<td>(39,027,901)</td>
</tr>
<tr>
<td>Amortization of debt discount</td>
<td>3,121,569</td>
<td>—</td>
</tr>
<tr>
<td>Non-cash interest expense from issuance on debt (derivative)</td>
<td>988,267</td>
<td>—</td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities - convertible notes</td>
<td>988,267</td>
<td>—</td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities - convertible warrants</td>
<td>(28,215)</td>
<td>—</td>
</tr>
<tr>
<td>Change in fair value of derivative liabilities - downside protection</td>
<td>(3,085,502)</td>
<td>—</td>
</tr>
<tr>
<td>Bad debt expense</td>
<td>3,252,439</td>
<td>—</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities, net of effect of acquisitions:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(750,241)</td>
<td>(3,555)</td>
</tr>
<tr>
<td>Inventory</td>
<td>1,126,424</td>
<td>(2,040)</td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>9,285,221</td>
<td>872,164</td>
</tr>
<tr>
<td>Accrued interest on notes receivable</td>
<td>1,387,763</td>
<td>—</td>
</tr>
<tr>
<td>Other current assets</td>
<td>49,248</td>
<td>(74,360)</td>
</tr>
<tr>
<td>Other assets, net</td>
<td>(22,797)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash used in operating activities</strong></td>
<td>(9,574,193)</td>
<td>(2,293,214)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM INVESTING ACTIVITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase of property and equipment</td>
<td>(289,917)</td>
<td>(8,552)</td>
</tr>
<tr>
<td>Purchase of intangible assets</td>
<td>(26,487)</td>
<td>—</td>
</tr>
<tr>
<td>Disposal of property and equipment</td>
<td>292,681</td>
<td>—</td>
</tr>
<tr>
<td>Disposal of intangible assets</td>
<td>62,091</td>
<td>—</td>
</tr>
<tr>
<td>Cash received in acquisition of a business, net of cash paid (Note 9)</td>
<td>2,280,425</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash provided by (used in) investing activities</strong></td>
<td>2,318,793</td>
<td>(8,552)</td>
</tr>
<tr>
<td><strong>CASH FLOWS FROM FINANCING ACTIVITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loan proceeds from related party</td>
<td>230,441</td>
<td>126,101</td>
</tr>
<tr>
<td>Payment of notes payable</td>
<td>(51,625)</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from note payable</td>
<td>6,329,910</td>
<td>—</td>
</tr>
<tr>
<td>Investment in subsidiary by noncontrolling interest</td>
<td>—</td>
<td>327,593</td>
</tr>
<tr>
<td><strong>Net cash provided by financing activities</strong></td>
<td>6,508,726</td>
<td>453,694</td>
</tr>
<tr>
<td><strong>Effects of currency translation on cash and cash equivalents</strong></td>
<td>(1,206)</td>
<td>15,272</td>
</tr>
<tr>
<td><strong>Net increase (decrease) in cash and cash equivalents</strong></td>
<td>(747,880)</td>
<td>(1,832,800)</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents, beginning of period</strong></td>
<td>1,046,365</td>
<td>2,879,165</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents, end of period</strong></td>
<td>$298,485</td>
<td>$1,046,365</td>
</tr>
</tbody>
</table>

**Supplemental Disclosure of Cash Flow Information**

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen dividend</td>
<td>$ —</td>
<td>$320,000</td>
</tr>
<tr>
<td>Conversion of HDS debt and issuance of call option (Note 9)</td>
<td>$14,056,113</td>
<td>$ —</td>
</tr>
<tr>
<td>Conversion of debt to equity</td>
<td>$8,257,918</td>
<td>—</td>
</tr>
<tr>
<td>Exercise of call option</td>
<td>$1,385,730</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of warrants</td>
<td>$5,592,244</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition of Olaregen stock through issuance of common stock</td>
<td>$2,000,000</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition of Veneto through issuance of debt (Note 9)</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>Acquisition of Regentys through issuance of debt (Note 9)</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>Acquisition of Olaregen through issuance of debt (Note 9)</td>
<td>$ —</td>
<td>$ —</td>
</tr>
</tbody>
</table>
The accompanying notes are an integral part of these consolidated financial statements.
Generex Biotechnology Corporation and Subsidiaries
Notes to the Consolidated Financial Statements

Note 1 – Organization of Business and Going Concern:

Generex Biotechnology Corporation (“Generex” or the “Company”), was formed in the State of Delaware on September 4, 1997 and its year-end is July 31. It is engaged primarily in the research and development of drug delivery systems and the use of the Company’s proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator; and through the Company’s wholly-owned subsidiary, Antigen Express, Inc. (“Antigen”), has undertaken work on immunomedicines incorporating proprietary vaccine formulations.

On January 18, 2017, the Company closed an Acquisition Agreement pursuant to which the Company acquired a 51% interest in NuGenerex Diagnostics LLC (“NGDx,” formerly known as Hema Diagnostic Systems, LLC, a Florida limited liability company established in December 2000 to market and distribute rapid test devices including infectious diseases. Since 2002, NGDx has been developing an expanding line of rapid diagnostic tests (RDTs) including such diseases as Human Immunodeficiency Virus (HIV) – 1/2, tuberculosis, malaria, hepatitis, syphilis, typhoid and dengue as well as other infectious diseases. Subsequently, on December 1, 2018, the Company exercised its call option and closed the acquisition of the remaining 49% interest in NGDx to become a wholly owned subsidiary of the Company.

On October 3, 2018, the Company entered into an Asset Purchase Agreement with Veneto Holdings, L.L.C. (“Veneto”) to purchase certain assets of Veneto and its subsidiaries. The Agreement bifurcated the closing. On October 3, 2018 (the “First Closing”), the Company purchased substantially all the operating assets of Veneto including (a) system of dispensing pharmacies, (b) one central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory. On November 1, 2018 the Company consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto’s management services organization business and two additional ancillary services.

In March 2019, the Company changed its business model to no longer utilize their existing pharmacies. This shift resulted in breaking their existing lease agreements with their pharmacies, lab and lab related equipment which resulted in a liability of $744,958 as of July 31, 2019 and disposing of the applicable leasehold improvements, reduction of employees and no longer holding and selling inventory. Going forward Veneto will conduct business exclusively through their management services organization and by entering into more ancillary provider service agreements with third party pharmacies as an effort to reduce fixed costs and salaries. This was made practicable due to the decrease in overall script volume coupled with delays in the Company being able to receive operating licenses from various government agencies.

On January 7, 2019, the Company closed two separate Acquisition Agreements pursuant to which the Company acquired a 51% interest in both Regents Corporation (“Regents”) and Olaregen Therapeutix Inc. (“Olaregen”). Regents is a regenerative medicine company focused on developing novel treatments for patients with gastrointestinal (GI) disorders. Olaregen is a New York based regenerative medicine company that is preparing to launch its proprietary, patented, wound conforming gel matrix, Excellagen, an FDA 510K cleared wound healing product.

Going Concern

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“US GAAP”), which contemplate continuation of the Company as a going concern. The Company has experienced recurring net losses and negative cash flows from operations since inception and has an accumulated deficit of approximately $418.7 million and a working capital deficiency of approximately $28 million at July 31, 2019. The Company has funded its activities to date almost exclusively from debt and equity financings.

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, and 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 conditions raise substantial doubt about the Company’s ability to continue as a going concern for a period of twelve months from the balance sheet date. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The unaudited condensed interim 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.

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Note 2 – Summary of Significant Accounting Policies:

Basis of Presentation

These financial statements include all of the Company’s subsidiaries, including those operating outside the United States and are prepared in accordance with US GAAP. The consolidated financial statements include the accounts of the Company and all of its wholly-owned and majority-owned subsidiaries. All intercompany transactions and balances have been eliminated. The subsidiaries included in the Company’s consolidated financial statements are: Generex Pharmaceuticals, Inc.; Generex (Bermuda), Inc.(dormant); Antigen Express, Inc.; 1097346 Ontario, Inc.(inactive); NuGenerex Diagnostics LLC “NGDx,” formerly known as Hema Diagnostic Systems, LLC; Hema Diagnostics Systems Panama S.A.(dissolved); Rapid Medical Diagnostics Corporation; NuGenerex Distribution Solutions, LLC; Grainland Pharmacy Inc.(inactive); Empire State Pharmacy Inc (inactive); NuGenerex Medical Marketing (inactive); Regentys Corporation (51%); and Olaregen Therapeutics Inc. (51%).

Business Combinations

Business combinations are accounted for using the acquisition method of accounting. Acquisition cost is measured as the aggregate of the fair value at the date of acquisition of the assets given, equity instruments issued, or liabilities incurred or assumed. Acquisition related costs are expensed as incurred (except for those costs arising on the issue of equity instruments which are recognized directly in equity). Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured at fair value on the acquisition date. Goodwill is measured as the excess of the acquisition cost and the amount of any non-controlling interest, over the fair value of the identifiable net assets acquired.

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.

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 and the acquisition of NGDx in January 2017. 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.

Revenue Recognition

It is the Company’s policy that revenues from product sales is recognized in accordance with ASC 606 “Revenue Recognition.” Five basic steps must be followed before revenue can be recognized; (1) Identifying the contract(s) with a customer that creates enforceable rights and obligations; (2) Identifying the performance obligations in the contract, such as promising to transfer goods or services to a customer; (3) Determining the transaction price, meaning the amount of consideration in a contract to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer; (4) Allocating the transaction price to the performance obligations in the contract, which requires the company to allocate the transaction price to each performance obligation on the basis of the relative standalone selling prices of each distinct good or services promised in the contract; and (5) Recognizing revenue when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer. The amount of revenue recognized is the amount allocated to the satisfied performance obligation. Adoption of ASC 606 has not changed the timing and nature of the Company’s revenue recognition and there has been no material effect on the Company’s financial statements.

Revenue from the pharmacy services is recognized when the prescription is dispensed (picked up by the patient or shipped to the patient using common carrier or delivered by the pharmacies own personnel). At the time of dispensing each pharmacy has a contract with the insurance payor (item (i)); the insurance payor has accepted the claim for reimbursement from the pharmacy (item ii) and informed the pharmacy how much will be paid for the prescription (item (iii)); the insurance payor is now legally obligated to make payment on the accepted claim within a given period proscribed by statute (item (iv)); and, the prescription has been taken from the pharmacy inventory, placed into an individually labeled container specific to the patient, and the patient is able to take possession of the prescription (item (v)). Shipment to or pick up by the patient is the first time that all criteria for revenue recognition have been met.

Revenue from the laboratory services is recognized upon the completion of accessions (the requested laboratory test has been performed and the report has been issued to the requesting physician). After the test has been performed and reported, the insurance company and/or patient has an obligation to pay for medically necessary laboratory tests (items (i) and (ii)). Unlike the pharmacy services model, laboratory services are provided prior to insurance company approval; as a result, the seller’s price to buyer is not known until payment is provided (items (iii) and (iv)). Based on historical collections, the Company estimates the expected revenues associated with similar tests and recognizes the revenue when testing results have been provided (v).

Revenue from Olaregen and NGDx is recognized upon payment at the time the product(s) is released (shipment delivered using a common carrier), and the control is transferred which is simultaneous to when payment received and accepted.
Revenue from the provision of management services is recognized in accordance with the contractual terms of the relationship (item i); however, the current agreements in place typically specify that a percentage of the gross margin associated with the third-parties’ sales that the Company facilitates is to be remitted (iii), and as such, the revenue is considered earned upon completion of the third parties’ sales of such products (iv). Like pharmacy services described above, revenue is recognized when the prescription is dispensed (picked up by the patient or shipped to the patient using common carrier or delivered by the pharmacies own personnel) (v).

Provisions for estimated sales returns and uncollectible accounts are recorded in the period in which the related sales are recognized based on historical and anticipated rates.

The Company determines whether it is the principal or agent for its retail pharmacy contract services on a contract by contract basis. In the majority of its contracts, the Company has determined it is the principal due to: (i) being the primary obligor in the arrangement, (ii) having discretion in supplier selection, (iv) having involvement in the determination of product or service specifications, and (v) having credit risk. The Company’s obligations under its client contracts for which revenues are reported using the gross method are separate and distinct from its obligations to the third-party pharmacies included in its retail pharmacy network contracts. Pursuant to these contracts, the Company is contractually required to pay the third-party pharmacies in its retail pharmacy network for products sold, regardless of whether the Company is paid by its clients. The Company’s responsibilities under its client contracts typically include validating eligibility and coverage levels, communicating the prescription price and the co-payments due to the third-party retail pharmacy, identifying possible adverse drug interactions for the pharmacist to address with the prescriber prior to dispensing, suggesting generic alternatives where clinically appropriate, and approving the prescription for dispensing. Although the Company does not have credit risk with respect to Retail Co-Payments or inventory risk related to retail network claims, management believes that all of the other applicable indicators of gross revenue reporting are present. For contracts under which the Company acts as an agent, revenue is recognized using the net method.

In March 2019, the Company changed its business model to no longer utilize their existing pharmacies. This shift resulted in breaking their existing lease agreements with their pharmacies, lab and lab related equipment leases which resulted in a liability of $784,999 as of July 31, 2019 and disposing the majority of applicable leasehold improvements, reduction of employees and no longer holding and selling inventory. Going forward Veneto will conduct business exclusively through their management services organization and by entering into more ancillary provider service agreements with third party pharmacies as an effort to reduce fixed costs and salaries. This was made practicable due to the decrease in overall script volume coupled with delays in the Company being able to receive operating licenses from various government agencies.

**Intangible Assets**

The costs of in-process research and development (“IPR&D”), related to the Company’s business combination with NGDx, were recorded at fair value on the acquisition date. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized, but is reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. The Company also acquired licenses to operate pharmacies which were recorded at cost. They are evaluated annually for possible impairment. Management determined that as of July 31, 2019, the IPR&D and licenses are not impaired.

**Impairment or Disposal of Long-Lived Assets and Intangibles**

The Company accounts for the impairment or disposal of long-lived assets according to FASB ASC Topic 360, *Property, Plant and Equipment* (“ASC 360”). ASC 360 clarifies the accounting for the impairment of long-lived assets and for long-lived assets to be disposed of, including the disposal of business segments and major lines of business. Long-lived assets are reviewed when facts and circumstances indicate that the carrying value of the asset may not be recoverable. When necessary, impaired assets are written down to estimated fair value based on the best information available. Estimated fair value is generally based on either appraised value or measured by discounting estimated future cash flows. Considerable management judgment is necessary to estimate discounted future cash flows. Accordingly, actual results could vary significantly from such estimates.

At July 31, 2019, we recorded an asset impairment charge of $287,587 for an intangible assets acquired in 2018, comprised of $188,069 and $99,519 for the Empire State Pharmacy and Grainland Pharmacy assets, respectively.

**Derivative Liability**

The Company’s derivative financial instruments are measured at fair value using the Monte Carlo, Black Scholes and multinomial lattice models 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 instrument. 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 liabilities.”

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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.

Inventories

Inventories, which consist of both raw materials and finished goods, is valued at the lower of cost or net realizable value. Inventory costs are comprised primarily of product, labor, freight and duty. The Company writes down inventory for estimated obsolescence equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. For the year ending July 31, 2019, the Company had a write down of inventory for $645,351 related to obsolescence which is classified as cost of goods sold.

Property and Equipment

Property, equipment and improvements to leased premises are depreciated using the straight-line method over the estimated useful lives of the assets, or when applicable, the term of the lease, whichever is shorter. Major renewals or replacements that substantially extend the useful life of an asset are capitalized and depreciated. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which are generally as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>Useful Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leasehold improvements</td>
<td>The shorter of the expected useful life of the improvement or the lease term</td>
</tr>
<tr>
<td>Computers and technological assets</td>
<td>3-5 years</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>3-5 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>3-7 years</td>
</tr>
</tbody>
</table>

Assets acquired through finance lease arrangements or long-term rental arrangements that transfer substantially all the risks and rewards associated with ownership of the asset to the Company (as lessee) are capitalized.

Goodwill

The Company accounts for purchased goodwill and intangible assets with indefinite lives in accordance with FASB Accounting Standards Codification 350-10, “Intangibles—Goodwill and Other,” (“ASC 350-10”) goodwill and intangible assets with indefinite lives are reviewed by us at least annually for impairment. For purposes of these analyses, the estimate of fair value is based on the income approach, which estimates the fair value based on future discounted cash flows. The estimate of future discounted cash flows is based on assumptions and projections that are believed to be currently reasonable and supportable. If it is determined the carrying value of goodwill or other intangible assets to be impaired, the carrying value is reduced.

The purchase price of acquisitions is allocated to the assets acquired and liabilities assumed based upon their respective fair values and are subject to change during the twelve month period subsequent to the acquisition date. We engage independent third-party valuation firms to assist us in determining the fair values of assets acquired and liabilities assumed at the time of acquisition. Such valuations require us to make significant estimates and assumptions, including projections of future events and operating performance. Fair value estimates are derived from established market values of comparable assets, or internal calculations of estimated future net cash flows. Our estimate of future cash flows is based on assumptions and projections we believe to be currently reasonable and supportable.
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 consolidated financial statements based on their fair value at the grant date and recognized as compensation expense over their vesting periods, which typically conform to the performance period. 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 Income (Loss) per Common Share

Net earnings per share is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the year. Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the year. 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. Diluted earnings per share is calculated using the treasury stock method.

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.

Foreign Currency Transactions andTranslations

The functional and reporting currency of the Company and most of its subsidiaries is the United States Dollar. One subsidiary, Generex Pharmaceuticals, Inc., has a functional currency of the Canadian Dollar. 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. Revenue and expense accounts are translated at an average of exchange rates which were in effect during the period. Translation adjustments that arise from translating the foreign subsidiary’s financial statements from its functional currency to the Company’s reporting currency are recorded in the other comprehensive loss component of stockholders’ equity. Gains and losses resulting from foreign currency transactions are included in the consolidated statement of operations and comprehensive loss.

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, trade receivables, other receivables, payables, and short term and long term debt. The carrying values of cash and cash equivalents, trade receivables, other receivables, and payables approximate their fair value due to their short maturities. The carrying value of long term debt approximates the fair value of debt of similar terms and remaining maturities available to the company.

At July 31, 2019, the Company did not have any assets measured at fair value on a recurring basis. The following is a listing of the Company’s liabilities required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of July 31, 2018:

<table>
<thead>
<tr>
<th>July 31, 2018</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call option</td>
<td>$ —</td>
<td>$ 2,168,211</td>
<td>$ —</td>
<td>$ 2,168,211</td>
</tr>
<tr>
<td>Total</td>
<td>$ —</td>
<td>$ 2,168,211</td>
<td>$ —</td>
<td>$ 2,168,211</td>
</tr>
</tbody>
</table>

The following is a listing of the Company’s liabilities required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of July 31, 2019 and July 31, 2018:

<table>
<thead>
<tr>
<th>July 31, 2019</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Derivative liability</td>
<td>$ —</td>
<td>$ —</td>
<td>$ 7,820,282</td>
<td>$ 7,820,282</td>
</tr>
<tr>
<td>Total</td>
<td>$ —</td>
<td>$ —</td>
<td>$ 7,820,282</td>
<td>$ 7,820,282</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>July 31, 2018</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warrants to be issued</td>
<td>$ —</td>
<td>$ 24,962,507</td>
<td>$ —</td>
<td>$ 24,962,507</td>
</tr>
<tr>
<td>Total</td>
<td>$ —</td>
<td>$ 24,962,507</td>
<td>$ —</td>
<td>$ 24,962,507</td>
</tr>
</tbody>
</table>

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP 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 consolidated 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.

Redeemable Non-Controlling Interest

As a result of the acquisition of Regentys, which had redeemable convertible preferred stock classified as a mezzanine instrument outside of its equity accounts, such amounts are reclassified as redeemable non-controlling interest as the carrying value determined by the purchase price allocation at the time of the acquisition of Regentys.

Derivative Financial Instruments

As a result of the early adoption of ASU 2017-11 in the second quarter of the fiscal year 2019, the Company has no derivative financials instruments with down round features classified as a liability at July 31, 2019.
Adoption of New Accounting Standards

We have reviewed the FASB issued Accounting Standards Update (“ASU”) accounting pronouncements and interpretations thereof that have effective dates during the periods reported and in future periods. The Company does not believe that any new or modified principles will have a material impact on the Company’s reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of our financial management and certain standards are under consideration.

- ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”
- ASC 815-40 (formerly SFAS No. 133 “Accounting for derivative instruments and hedging activities”), requires that embedded derivative instruments be bifurcated and assessed, along with free-standing derivative instruments such as warrants, on their issuance date and in accordance with ASC 815-40-15 (formerly EITF-00-19 “Accounting for derivative financial instruments indexed to, and potentially settled in, a company’s own stock”) to determine whether they should be considered a derivative liability and measured at their fair value for accounting purposes. In determining the appropriate fair value, the Company uses the Black-Scholes option pricing formula and present value pricing.

- ASU 2016-08 “Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net).”
- ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.”
- ASU 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients.”
- ASU 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers.”
- ASU 2017-13, “Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840) and Leases (Topic 842). Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments.”
The standards provide companies with a single model for use in accounting for revenue arising from contracts with customers that supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The guidance was adopted as of August 1, 2018. The Company found that the adoption did not have a material effect on the Company’s consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). This standard affects the accounting for equity instruments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. In February 2018, the FASB issued ASU 2018-03, “Technical Corrections and Improvements to Financial Instruments (Subtopic 825-10) – Recognition and Measurement of Financial Assets and Financial Liabilities”. This update was issued to clarify certain narrow aspects of guidance concerning the recognition of financial assets and liabilities established in ASU No. 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities”. This includes an amendment to clarify that an entity measuring an equity security using the measurement alternative may change its measurement approach to a fair valuation method in accordance with Topic 820, Fair Value Measurement, through an irrevocable election that would apply to that security and all identical or similar investments of the same issued. The update is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years beginning after June 15, 2018. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing diversity in practice regarding how certain cash receipts and cash payments are presented in the statement of cash flows. The standard provides guidance on the classification of the following items: (1) debt prepayment or debt extinguishment costs, (2) settlement of zero-coupon debt instruments, (3) contingent consideration payments made after a business combination, (4) proceeds from the settlement of insurance claims, (5) proceeds from the settlement of corporate-owned life insurance policies, (6) distributions received from equity method investments, (7) beneficial interests in securitization transactions, and (8) separately identifiable cash flows. The Company is required to adopt ASU 2016-15 for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017 on a retrospective basis. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which requires that a statement of cash flows should include the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The update is effective for fiscal years beginning after December 15, 2017. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-01, “Business Combinations (Topic 805): Clarifying the Definition of a Business.” These amendments clarify the definition of a business. The amendments affect all companies and other reporting organizations that must determine whether they have acquired or sold a business. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The amendments are intended to help companies and other organizations evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, “Compensation—Stock Compensation” (Topic 718): Scope of Modification Accounting. The amendments provide guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718 Compensation-Stock Compensation. An entity should account for the effects of a modification unless all the following are met: 1. The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. 2. The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. 3. The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The ASU is effective for all entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.
Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). In January 2018, the FASB issued ASU 2018-01, which provides additional implementation guidance on the previously issued ASU 2016-02. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The Company is required to adopt ASU 2016-02 for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. This ASU will be effective for us in the first quarter of 2019 which begins with interim period ending October 31, 2019. We do not anticipate the adoption of this ASU to have a material impact to our financial statements.

In January 2017, the FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment* (Topic 350), which eliminates Step 2 from the goodwill impairment test. Instead, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company will adopt the standard effective August 1, 2020. The Company is evaluating the effect that ASU 2017-04 will have on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable non-controlling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. The Company early adopted the ASU 2017-11 in the second quarter as of January 31, 2019.

In February 2018, the FASB issued ASU 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which was issued to address the income tax accounting treatment of the stranded tax effects within other comprehensive income due to the prohibition of backward tracing due to an income tax rate change that was initially recorded in other comprehensive income. This issue came about from the enactment of the TCJA on December 22, 2017 that changed the Company's federal income tax rate from 35% to 21% effective January 1, 2018 and the establishment of a territorial-style system for taxing foreign-source income of domestic multinational corporations. In December 2017, the SEC issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Act* ("SAB118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment. The Company remeasured its deferred tax assets and liabilities as of July 31, 2018, applying the reduced corporate income tax rate and recorded a provisional decrease to the deferred tax assets of $31,876,520, with a corresponding adjustment to the valuation allowance. In the fourth quarter of fiscal year ended July 31, 2019, we completed our analysis to determine the effect of the Tax Act and there were no material adjustments as of July 31, 2019.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company is evaluating the effect that ASU 2018-13 will have on consolidated financial statements.

**Note 3 - Loans from Related Parties**

NGDx received substantially all of its funding from a shareholder, who owned 98.9% of NGDx prior to the acquisition of NGDx by the Company. The loan is unsecured, matures on December 31, 2019 and bears interest at 0.75% per annum through January 19, 2017, and bears no interest thereafter. Upon acquisition of NGDx by the Company (see Note 9), the outstanding principal balance was $13,239,837 and total accrued interest of $191,869. This loan was subject to a call option (Note 9) which, if exercised, the principal and accrued interest through January 18, 2017 would be eliminated.

Pursuant to the January 18, 2017 Acquisition, Mr. Berkman, previous owner of NGDx and debt holder, agreed, under certain conditions to transfer the remaining 49% of the NGDx equity to the Company for a consideration of $1.00. On December 1, 2018, the Company and Mr. Berkman entered into an Agreement, Assignment and Release, pursuant to which Mr. Berkman transferred the remaining NGDx equity interests to the Company, waiving and releasing any conditions to such transfer. NGDx is now a wholly owned subsidiary of the Company. In addition to the assignment of the NGDx interests, Mr. Berkman released these loans in exchange for shares of the Company's common stock valued at the aggregate of such amount using the closing price for the common stock on November 30, 2018. The closing price was $18.99, resulting in 32,881 shares issuable to Mr. Berkman. This transaction resulted in Mr. Berkman's advances of $624,404 plus the loan and call option which resulted in additional paid in capital of $13,431,705 which was reclassified to the Company's stockholders' equity as an extinguishment of debt for $14,056,109.

Pursuant to the January 7, 2019 acquisition of Regentys, the Company assumed $16,505 of loans payable to Regentys shareholders. During the year ended July 31, 2019, the Company repaid $3,305 of the principal balance and borrowed an additional $6,500. The outstanding balance as of July 31, 2019 was $19,700.
Note 4 - Commitments and Contingencies:

Pending Litigation

The Company is a defendant in one legal proceeding relating to alleged breach of contract and claims against certain of the Company’s original buccal delivery patents. The Company is also a defendant in two legal proceedings brought by a former executive officer and her affiliate. These legal proceedings have been reported in the Company’s prior periodic reports. No activity has occurred in these cases in several years, and the Company now considers them dormant.

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 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. This has been accrued in the consolidated financial statements.

On August 22, 2017, Generex received a letter from counsel for Three Brothers Trading LLC, d/b/a Alternative Execution Group (“AEXG”), claiming breach of a Memorandum of Understanding (“MOU”) between Generex and AEXG. The MOU related to AEXG referring potential financing candidate to Generex. The letter from AEXG counsel claimed that Generex’s acceptance of $3,000,000 in financing from Pharma Trials, LLC, in March 2017, violated the provisions of the MOU prohibiting Generex from seeking other financing, with certain exceptions, for a period of 60 days after execution of the MOU. AEXG has demanded at least $210,000 in cash and 84,000 warrants for Generex stock convertible at $2.50 per share, for attorney’s fees and costs. On December 2, 2018, an arbitrator awarded Three Brothers Trading LLC, d/b/a Alternative Execution Group (“AEXG”) an aggregate of $315,695 in damages, costs and fees as well as warrants exercisable for 84,000 shares of Generex Common Stock at an exercise price of $2.50 per share. The awards were made pursuant to claims under a Memorandum of Understanding (“MOU”) between Generex and AEXG related to AEXG referring potential financing candidate to Generex. AEXG filed a petition to confirm the arbitrator’s award in the United States District Court for the Southern District of New York. The petition includes a demand of $3,300,360 as the value of the Warrants. The arbitrator did not award the specific amount of $3.3 million, but only liquidated damages in the amount of $220,000 and the value of 84,000 warrants “as of today” (the date of the award) plus attorney’s fees, certain costs, prejudgment and post-judgment interest (which continues to run on a daily basis) and arbitration fees. As of July 31, 2019, the value of the warrants have a market value of $232,283. Between the warrants and the $220,000 of liquidated damages, the Company has accrued $452,283 related to this matter.

On June 28, 2018, the Company was named in respect of a claim by Burrard Pharmaceutical Enterprises Ltd. and Mo’yeri Kayhan for unspecified damages and other remedies issued by the Supreme Court of British Columbia. The claim is made in connection with one advanced against Burrard and Kayhan by Middle East Pharmaceutical Factory L.L.C., a foreign corporation, for fraudulent or negligent misrepresentation. Middle East alleges that it was misled by Burrard and Kayhan into believing that Burrard had rights to distribute Generex product in the Middle East. Burrard and Kayhan allege that they did have rights in that regard, which the Company denies. The matter remains at the pleadings stage and the Company is investigating the facts.

On October 26, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 (“Note”) in the principal amount of $682,000. On January 25, 2019, Generex received a letter from the purchaser’s counsel stating that the Note was in default because Generex’s common stock was not listed on NASDAQ within 90 days after the issuance of the Note. The letter demanded repayment in full. On February 12, 2019, the Purchaser filed a Motion for Summary Judgment in lieu of complaint in the Supreme Court of New York, demanding the aggregate principal amount, default interest and costs. Counsel for Generex and Alpha have engaged in settlement discussions.

On March 21, 2019 Compass Bank filed suit against NuGenerex Distributions Solutions 2, L.L.C. in the District Court of Dallas County, Texas requesting damages of $3,413,000. In connection with the closing of the Veneto acquisition, Compass Bank had a lien on certain assets that were supposed to be transferred into the ownership of NuGenerex, a subsidiary of Generex. Those assets were never transferred due to regulatory impositions. Generex had listed Compass Bank as an intended third-party beneficiary to the transaction in relation to the assets lien and Veneto ceased payments upon the loan which the lien generated from. Compass bank filed suit against 6 parties involved in the transaction to collect on the loan, including NuGenerex. NuGenerex’s position is the contract was frustrated by the assets that were lien and never transferred, NuGenerex did not receive any benefit from the agreement, and thus NuGenerex is not responsible to Compass Bank for repayment of a loan on assets not transferred. Generex intends to implead Brooks Houghton for indemnification who was retained to perform due diligence on the transaction.
In May 2019 Brooks Houghton threatened litigation by way of a FINRA Dispute Resolution. Brooks Houghton, who the managing representative is Mr. Centonfanti a prior board member, was under contract to perform due diligence on the Veneto transaction, as well as other unrelated items. The Veneto transaction closed three times, each time with a reduction in price due to material negative circumstances. Brook Houghton, who was under contract to perform due diligence, claims their fee should be paid on the initial closing price not the ultimate resolution of the matter. The company offered to compensate Brooks Houghton pursuant to agreement, 3% on the most recent closing price for Veneto for which Brooks Houghton may have performed some level of work on, payable in kind, and Brooks Houghton declined the offer. Brooks Houghton is claiming $450,000 for the first closing of Veneto, $714,000 for the second closing of Veneto, $882,353 for the Regentys acquisition, and $705,882 for Olaregen. The company is awaiting service. As of July 31, 2019, the Company has accrued for the full $2,752,235 balance.

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.

**Commitments**

**Lease Agreements**

There are rental agreements in effect at Hema Diagnostics Systems, Empire State Pharmacy Inc. and Regentys Corporation which have the following commitments as of July 31, 2019: $112,801 in fiscal year 2020 and $39,879 in fiscal year 2021.

**Intellectual Property**

In connection with the Company’s acquisition of Olaregen, intellectual property was acquired that had a valuation of $650,000 prior to being acquired and revalued. This initial $650,000 valuation represented the initial payment remitted by Olaregen in accordance with the $4 million signed commitment agreement entered into with Activation Therapeutics, Inc. The remaining $3.35 million balance is to be paid in quarterly installments equal to 10% of quarterly net sales generated by Activation Therapeutics assuming the Exellagen average selling price per unit exceeds $800. In the event that the average selling price per unit is less than $800 per unit, cost of goods sold shall be excluded from the computation of net sales.

**Note 5 – Property and Equipment**

Property and equipment, net consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computers and technological assets</td>
<td>$163,168</td>
<td>$11,365</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>386,929</td>
<td>—</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>73,227</td>
<td>19,879</td>
</tr>
<tr>
<td>Leasehold Improvements</td>
<td>16,596</td>
<td>21,501</td>
</tr>
<tr>
<td></td>
<td>639,920</td>
<td>52,745</td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(132,927)</td>
<td>(21,209)</td>
</tr>
<tr>
<td></td>
<td>499,993</td>
<td>31,536</td>
</tr>
</tbody>
</table>

Depreciation expense related to property and equipment amounted to $170,605 and $21,782 for the years ended July 31, 2019 and 2018, respectively.

For the year ended July 31, 2019, the Company had $292,681 of disposals and $11,208 of impairment of long-lived assets. The $292,681 of disposals pertains to Veneto and was mostly the result of their shift in business operations during March 2019 described in Notes 1 and 2. The $11,208 impairment of long-lived assets pertains to Grainland Pharmacies Holdings, LLC which ceased to operate – see Note 13.

**Note 6 - Stockholders’ Equity:**

**Common Stock**

On November 13, 2018, the Company declared a stock dividend on its outstanding Common Stock for stockholders of record date to be determined (the “Record Date”). As a result, all stockholders on the Record Date received twenty new shares of Common Stock for each share of Common Stock owned by them as of that date. Proportional adjustments for the reverse stock split were made to the Company’s outstanding stock options, and warrants including all share and per-share data, for all amounts and periods presented in the condensed interim consolidated financial statements.
On January 18, 2017, the Company issued 1,117,431 shares of common stock for the acquisition of 51% of NGDx and is obligated to issue 4,830,000 shares of common stock upon the conclusion of the Company’s reverse stock split which were issued on October 26, 2018.

On January 30, 2019, the Company declared a dividend to holders of Generex common shares of its subsidiary Antigen Express, Inc., d/b/a NuGenerex Immuno-Oncology. On February 25, 2019, Generex shareholders received a dividend of one share of Antigen Express, Inc. for every four shares of Generex common stock which amounted to an issuance of 15,076,849 shares, representing approximately 3.77% ownership of Antigen. The fair value of the shares issued amounted to $1,070,456 and was recorded as a dividend with a corresponding increase to noncontrolling interest.

In May 2019, the Company issued 4,000,000 shares of common stock and a $2 million note payable for the acquisition of 592,682 shares of Series A Preferred Stock of Olaregen pursuant to a Stock Purchase Agreement entered into January 14, 2019 subject to the approval of the Board of Directors of Olaregen and consummated on May 10, 2019.

In July 2019, the Company issued 1,920,376 shares of common stock for the conversion debt in the amount of $4,350,571.

During the fourth quarter of 2019, the Company converted a note payable of $53,000 for 30,000 shares of common stock with a fair value of $69,000. The difference between the fair value of the common stock and the outstanding balance of the note payable was recorded as a loss on extinguishment of debt. As of July 31, 2019, the shares were yet to be issued by the Company.

As of July 31, 2018, 302,614 shares remained to be issued resulting in common stock payable of $2,168,951. During the year ended July 31, 2019, 1,238,517 shares of common stock payable were issued. As of July 31, 2019, 588,658 shares remain to be issued resulting in common stock payable of $1,123,188.

**Series H and Series I Convertible Preferred Stock**

The Company has authorized 109,000 shares of designated non-voting Series H Convertible Preferred Stock with a stated value of $1,000 per share and authorized 6,000 shares of designated non-voting Series I Convertible Preferred Stock with a stated value of $47.61 per share pursuant to the Purchase Agreement dated March 27, 2017. The Series H Preferred Stock was scheduled to be sold in four tranches to the Purchaser. Under the Securities Purchase Agreement, in the event the Purchaser failed to purchase 100% of the shares of Preferred Stock at any given Closing, the Company can decline to sell any further securities to the Purchaser (the “Purchase Agreement”).

The Series H and Series I Convertible Preferred Stock are convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price of $0.12 per share.

Neither Series H nor Series I Convertible Preferred Stock have special dividend rights. If the Company pays dividends on its common stock, the holders of the preferred stock will receive dividends in the amount they would have received had they converted the preferred stock to common stock.

At closing of the first tranche on March 28, 2017, the Company issued 63,000 shares of Series H Preferred Stock for a purchase price of $3,000,000. The proceeds of this sale were paid directly on the Company’s behalf to Emmaus as an additional deposit under the Company’s Emmaus LOI. The full amount of such proceeds was repaid to the Company in July 2017 upon termination of the Emmaus LOI. On December 1, 2018, after payment of the dividend, B-H Sanford, LLC, converted all of its holding of the Company’ Series H Convertible Preferred Stock owned by it into 25,200,000 shares of common stock.

Prior to payment of Generex’s 20 for 1 common stock dividend, on November 30, 2018, Joseph Moscato, the Company’s President and Chief Executive Officer, and Lawrence Salvo, a member of the Company’s Board of Directors, converted all shares of the Company’ Series I Convertible Preferred Stock owned by them. Mr. Moscato received 3,276,000 shares of the Company’s Common Stock upon conversion. Mr. Salvo received 3,354,645 shares of the Company’s Common Stock upon conversion.

**Non-controlling Interest**

Mr. Berkman agreed, under certain conditions to transfer the remaining 49% of the NGDx equity to the Company for a consideration of $1.00. On December 1, 2018, the Company and Mr. Berkman entered into an Agreement, Assignment and Release, pursuant to which Mr. Berkman transferred the remaining NGDx equity interests to the Company, waiving and releasing any conditions to such transfer. As of December 1, 2018, NGDx is a wholly owned subsidiary of the Company. During the year ended in July 31, 2019, there was a net loss attributable to the non-controlling interest (49%) in NGDx of $122,692 and contributions made of $133,679. As of July 31, 2019, and 2018, the non-controlling interest in NGDx was $0 and $5,576,272, respectively.

Pursuant to the Company’s acquisition of Regentys on January 7, 2019 to acquire a 51% interest, the Company was issued 12,048,161 shares of Regentys common stock. As of July 31, 2019, Regentys had a total of 18,623,278 shares of common stock and 2,793,192 Series A voting preferred stock for a total of 21,416,470 total voting shares outstanding. As such, there are 9,368,309 of shares that belong to non-controlling interest shareholders which represents a 43.74% non-controlling interest.
Pursuant to the Company’s acquisition of Olaregen on January 7, 2019 to acquire a 51% interest, the Company was issued 3,282,632 shares of Olaregen common stock. As of July 31, 2019, Olaregen had a total of 5,648,819 shares of common stock and 592,683 Series A voting preferred stock for a total of 6,241,502 total voting shares outstanding. As such, there are 2,958,870 of shares that belong to non-controlling interest shareholders which represents a 47.41% non-controlling interest.

On November 1, 2018, the Company completed its second closing of Veneto Holdings, L.L.C. (“Veneto”) which granted the Company Rapport Services, LLC (“Rapport”) through the ownership of the units of Class B membership interests providing control of Rapport as only the Class B Member is entitled to elect the nominees to the Board of Managers, which constitute a one percent (1%) ownership in Rapport. The remaining interests represent a 99% non-controlling interest.

Note 7 – Redeemable Non-Controlling Interest:

Pursuant to the Company’s acquisition of 51% of the outstanding capital stock of Regentys, Regentys had authorized 7,500,000 shares of redeemable Series A Convertible Preferred Stock (“Preferred Stock A”), with a par value of $0.0001 and redemption value of $1.46 per share of which 2,793,192 Preferred Stock A was outstanding as of the date of acquisition and as of July 31, 2019. Preferred Stock may be converted into common stock at the initial conversion ratio of 1:1 which ratio shall be adjusted in accordance with stock dividends, splits, combinations and other similar events, including the sale of additional shares of common or preferred stock and the holders of Preferred Stock A are entitled to vote, together with the holders of Regentys common stock, on all matters submitted to stockholders of Regentys for a vote. At any time after November 1, 2026, the holders of the Company’s Series A Preferred Stock will have the right to require the Company to redeem all or a portion of their shares for cash at a redemption price equal to its liquidation value. Accordingly, this Preferred Stock A was valued to be $4,073,898 at the time of acquisition of Regentys and reclassified as Redeemable Non-Controlling Interest outside of stockholders’ deficit on the condensed interim consolidated balance sheets.

Note 8 – Inventory

Inventory consists of the following components:

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw materials</td>
<td>$77,782</td>
<td>—</td>
</tr>
<tr>
<td>Finished goods</td>
<td>285,226</td>
<td>12,075</td>
</tr>
<tr>
<td><strong>Total Inventory</strong></td>
<td><strong>$363,008</strong></td>
<td><strong>$12,075</strong></td>
</tr>
</tbody>
</table>

Note 9 – Notes Payable

On October 26, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 (“Note”) in the principal amount of $682,000. The purchase price of the Note was $550,000 from which Generex was required to pay the $15,000 fee of the investor’s counsel. The remaining $147,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount. The effective interest is 27.5%.

On November 25, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note due November 26, 2019 (“Note”) in the principal amount of $1,060,000. The purchase price of the Note was $1,000,000. The remaining $60,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount. In May 2019, the Company issued 400,000 shares of common stock for full satisfaction of this Note.

On January 24, 2019, Generex entered into Securities Purchase Agreements with three investors pursuant to which the Company agreed to sell and sold convertible notes bearing interest at 10% per annum (the “Notes”) in the aggregate principal amount of $2,110,000. The purchase price of the Notes was $2,010,000 and the remaining $100,000 of principal amount represents original issue discount. Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of a price determined as of the date of closing; and 70% of the lowest trading price of the common stock on the ten days prior to conversion. The embedded conversion feature of these Notes was deemed to require bifurcation and liability classification, at fair value. Pursuant to the Securities Purchase Agreements, Generex also sold warrants to the investors to purchase up to an aggregate 120,570 shares of common stock. The fair value of the derivative liability and warrants as of the date of issuance was in excess of the Notes (Note 14) resulting in full discount of the Notes. In July 2019, the Company issued 1,065,826 shares of common stock for the conversion of $1,425,000 of principal and $76,976 of accrued interest. Out of the 1,065,826 shares, 266,793 were recorded as common stock payable until the shares were delivered in August 2019.
In February 2019, Generex entered into Securities Purchase Agreements with two investors pursuant to which the Company agreed to sell and sold convertible notes bearing interest at 10% per annum (the “Notes”) in the aggregate principal amount of $1,500,000. The purchase price of the Notes was $1,425,000 and the remaining $75,000 of principal amount represents original issue discount. Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of a price determined as of the date of closing; and 70% of the lowest trading price of the common stock on the ten days prior to conversion. The embedded conversion feature of these Notes was deemed to require bifurcation and liability classification, at fair value. Pursuant to the Securities Purchase Agreements, Generex also sold warrants to the investors to purchase up to an aggregate 102,143 shares of common stock. The fair value of the derivative liability and warrants as of the date of issuance was in excess of the Notes (Note 14) resulting in full discount of the Notes.

In April 2019, Generex entered into Securities Purchase Agreements with two investors pursuant to which the Company agreed to sell and sold convertible notes bearing interest at 10% per annum (the “Notes”) in the aggregate principal amount of $1,060,000. The purchase price of the Notes was $1,010,000 and the remaining $50,000 of principal amount represents original issue discount. Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of a price determined as of the date of closing; and 70% of the lowest trading price of the common stock on the ten days prior to conversion. The embedded conversion feature of these Notes was deemed to require bifurcation and liability classification, at fair value. Pursuant to the Securities Purchase Agreements, Generex also sold warrants to the investors to purchase up to an aggregate 176,968 shares of common stock. The fair value of the derivative liability and warrants as of the date of issuance was in excess of the Notes (Note 14) resulting in full discount of the Notes.

In May 2019, the Company consummated a Stock Purchase Agreement entered into January 14, 2019 to which the Company agreed to sell and sold $2,000,000 Promissory Note bearing interest at 7% per annum (the “Notes”) originally due and payable on August 1, 2019. The note remains active and interest has continued to accrue while new terms of the note are in process of being negotiated.

In July 2019, Generex entered into Securities Purchase Agreements with two investors pursuant to which the Company agreed to sell and sold convertible notes bearing interest at 9% per annum (the “Notes”) in the aggregate principal amount of $446,600. The purchase price of the Notes was $400,000 and the remaining $46,600 of principal amount represents original issue discount. Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of a price determined as of the date of closing; and 80% of the lowest volume weighted average trading price of the common stock on the ten days prior to conversion. The embedded conversion feature of these Notes was deemed to require bifurcation and liability classification, at fair value. The fair value of the derivative liability as of the date of issuance was $206,548 and was recorded as a discount of the Notes.

For the year ending July 31, 2019, amortization of debt discount was $3,008,849 leaving a remaining debt discount balance as of July 31, 2019 of $1,938,994.

On December 28, 2017, the Company through its wholly owned subsidiary NuGenerex, completed the acquisition of the assets and 100% of the membership interests of two pre-operational pharmacies, Empire State Pharmacy Holdings, LLC and Grainland Pharmacy Holdings, LLC, pursuant to the bills of sale for a consideration of $320,000 Promissory Note due and payable on June 28, 2018 bearing an annual interest rate of 3%. The note was extended by six months and set to mature with the same terms on December 28, 2018. The note remains active and interest has continued to accrue while new terms of the note are in process of being negotiated.

Pursuant to the second closing of the acquisition of certain operating assets of Veneto Holdings, L.L.C. and its affiliates, Generex’s wholly owned subsidiary agreed to assume outstanding debt of Veneto subsidiaries to Compass Bank, including obligations under a term loan and a revolving line of credit. Claiming three separate types of default, Compass Bank has demanded payment in full of amounts due under the term loan and revolving line of credit, in an aggregate amount of approximately $3,413,000. Generex believes it has defenses to such demand, including that the bank was not an intended beneficiary of the subsidiary’s agreement to assume the debt.

Pursuant to its acquisition of Regentys, the Company inherited convertible notes with several investors which collectively held a principal plus of $615,000 as of the date of acquisition. During the year ended July 31, 2019, $187,500 was converted into common stock of Regentys and $51,625 was repaid in cash. As of July 31, 2019, the remaining principal balance was $353,375 with an unamortized debt discount balance of $3,719. These notes have an accrued interest balance of $24,940 as of July 31, 2019.
Deferred Tax Liability

As a result of the acquisition of Regentys and Olaregen, the purchase price allocation attributed to deferred tax liability was $889,782 and $1,040,173, respectively. The Company has deferred tax assets of over $68 million with a full allowance equally to the to the amount of the deferred tax asset. Although the Company deferred tax assets are in excess of deferred tax liabilities totaling $1,502,122, the Company cannot offset the deferred tax liabilities against its deferred tax assets since the Company acquired less than the 80% of both Regentys and Olaregen preventing the Company to consolidate its income tax returns with Regentys and Olaregen for tax purposes. Therefore, the deferred tax liabilities will be reported separately until such time that the Company determines otherwise. In addition, the Company acquired approximately 51% of each of Regentys and Olaregen, less than the 80% required to permit the Company to consolidate with Regentys and Olaregen for tax purposes. Therefore, the deferred tax liabilities will be reported separately until such time that the Company determines otherwise.

Note 10 – 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 gain or (loss) arising from domestic operations (United States) were ($11,006,793) and $35,948,698 for the years ended July 31, 2019 and 2018, respectively. Pre-tax (losses) arising from foreign operations (Canada) were $(326,461) and $(150,394) for the years ended July 31, 2019 and 2018, respectively.

As of July 31, 2019, the Company has NOL carryforwards in Generex Biotechnology Corporation of approximately $196.2 million, which expire in 2020 through 2038, and $13.7 million will not expire. The non-expiring portion is limited to 80% of the current year taxable income of the respective entity. Generex Pharmaceuticals Inc. has NOL carryforwards of approximately $34.4 million, which expire in 2024 through 2039. Antigen Express, Inc. has NOL carryforwards of approximately $36.2 million which expire in 2020 through 2038. Regentys Corporation has NOL carryforwards of approximately $6.0 million of which $5.0 million will expire 2033 through 2039. Olaregen Therapeutics, Inc. has NOL carryforwards of $1.1 million of which $1.1 million will not expire. Veneto has NOL carryforwards of $8.4 million which will not expire. Some of these loss carryforwards are subject to limitation due to the acquisition of Regentys, Olaregen and 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, 2019 and 2018, 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:

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net operating loss carryforwards</td>
<td>$64,308,679</td>
<td>$59,296,530</td>
</tr>
<tr>
<td>Other temporary differences</td>
<td>1,812,190</td>
<td>(102,273)</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>2,173,419</td>
<td>2,518,572</td>
</tr>
<tr>
<td>Total Deferred Tax Assets</td>
<td>68,294,288</td>
<td>61,712,829</td>
</tr>
<tr>
<td>Valuation Allowance</td>
<td>(68,294,288)</td>
<td>(61,712,829)</td>
</tr>
<tr>
<td>Deferred Tax Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>(—)</td>
<td>(—)</td>
</tr>
<tr>
<td>Other temporary differences</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total Deferred Tax Liabilities</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net Deferred Income Taxes</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

$ —  $ —
A reconciliation of the United States Federal Statutory rate to the Company’s effective tax rate for the years ended July 31, 2019 and 2018 is as follows:

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal statutory rate</td>
<td>(21.0)%</td>
<td>(26.5)%</td>
</tr>
<tr>
<td>Increase (decrease) in income taxes resulting from:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of purchase consideration</td>
<td>(40.2)</td>
<td>28.5</td>
</tr>
<tr>
<td>Expiration of net operating loss carryforward</td>
<td>9.9</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>2.4</td>
<td>0.9</td>
</tr>
<tr>
<td>Tax rate change</td>
<td>—</td>
<td>(88.7)</td>
</tr>
<tr>
<td>Change in valuation allowance</td>
<td>48.9</td>
<td>85.8</td>
</tr>
<tr>
<td>Effective tax rate</td>
<td>—%</td>
<td>—%</td>
</tr>
</tbody>
</table>

On December 22, 2017, the Tax Cuts and Jobs Act (“The Act”), was signed into law by President Trump. The Act includes a number of provisions, including the lowering of the U.S. corporate tax rate from 34 percent to 21 percent, effective January 1, 2018 and the establishment of a territorial-style system for taxing foreign-source income of domestic multinational corporations. In December 2017, the SEC issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Act (“SAB118”), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment. The Company remeasured its deferred tax assets and liabilities as of July 31, 2018, applying the reduced corporate income tax rate and recorded a provisional decrease to the deferred tax assets of $31,876,520, with a corresponding adjustment to the valuation allowance. In the fourth quarter of fiscal year ended July 31, 2019, we completed our analysis to determine the effect of the Tax Act and there were no material adjustments as of July 31, 2019.

As of July 31, 2019, 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 years presented. Generally, tax years 2016 to 2019 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 2011 to 2019 remain open to examination by the Canada Revenue Agency or other tax jurisdictions to which the Company is subject.

**Note 11 - Net Income Per Share (“EPS”):**

Basic net income or loss per share is calculated using the weighted average number of common shares outstanding during the period. Diluted net income per share is calculated by dividing income available to common shareholders by the weighted average number of common shares outstanding for the period and, when dilutive, potential shares from stock options and warrants to purchase common stock, using the treasury stock method. Common stock equivalents are included in the diluted income per share calculation only when option exercise prices are lower than the average market price of the common shares for the period presented.

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted average number of common shares outstanding - Basic</td>
<td>48,360,127</td>
<td>1,068,100</td>
</tr>
<tr>
<td>Potentially dilutive common stock equivalents</td>
<td>5,157,374</td>
<td>1,523,028</td>
</tr>
<tr>
<td>Weighted average number of common and equivalent shares outstanding-Diluted</td>
<td>53,517,501</td>
<td>2,591,129</td>
</tr>
</tbody>
</table>

The following table provides weighted average number of common stock equivalents not included in diluted income per share, because the effects are anti-dilutive, for the years ended July 31, 2019 and 2018, respectively.

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock options</td>
<td>2,831,301</td>
<td>17,850</td>
</tr>
<tr>
<td>Warrants</td>
<td>15,599,681</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>18,230,982</td>
<td>17,850</td>
</tr>
</tbody>
</table>

**Note 12 – Goodwill and Intangible Assets**

Intangible assets consist of the following at July 31:

<table>
<thead>
<tr>
<th></th>
<th>July 31, 2019</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Process Research &amp; Development</td>
<td>$8,761,427</td>
<td>$2,911,377</td>
</tr>
<tr>
<td>Non-compete agreements</td>
<td>1,210,000</td>
<td>—</td>
</tr>
<tr>
<td>Developed Software/Technology</td>
<td>131,000</td>
<td>327,654</td>
</tr>
<tr>
<td>Other Intangibles</td>
<td>51,274</td>
<td>10,153,701</td>
</tr>
<tr>
<td>Less accumulated amortization</td>
<td>(319,432)</td>
<td>(27,994)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td>$</td>
<td>9,834,269</td>
<td>$</td>
</tr>
<tr>
<td></td>
<td>3,211,037</td>
<td></td>
</tr>
</tbody>
</table>

100
Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets. The Company is currently not amortizing the in-process research and development until it becomes commercially viable and placed in service. At the time when the intangible assets are placed in service the Company will determine a useful life.

Amortization expense amounted to $255,835 and 2,571 for the years ended July 31, 2019 and 2018, respectively.

Estimated amortization expense (in thousands) for the next five years and thereafter is as follows:

<table>
<thead>
<tr>
<th>Year Ending July 31,</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>$434,117</td>
</tr>
<tr>
<td>2021</td>
<td>434,118</td>
</tr>
<tr>
<td>2022</td>
<td>164,895</td>
</tr>
<tr>
<td>2023</td>
<td>30,787</td>
</tr>
<tr>
<td>2024</td>
<td>11,138</td>
</tr>
<tr>
<td>Thereafter</td>
<td>7,898</td>
</tr>
<tr>
<td></td>
<td>$1,082,952</td>
</tr>
</tbody>
</table>

Changes in the value of goodwill:

<table>
<thead>
<tr>
<th></th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of July 31, 2018</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition of Veneto (revaluation)</td>
<td>15,051,768</td>
</tr>
<tr>
<td>Acquisition of Regentys (revaluation)</td>
<td>13,834,581</td>
</tr>
<tr>
<td>Acquisition of Olaregen (revaluation)</td>
<td>9,411,224</td>
</tr>
<tr>
<td>Balance as of July 31, 2019</td>
<td>$38,297,573</td>
</tr>
</tbody>
</table>

Note 13 – Acquisitions:

**NuGenerex Diagnostics LLC:**

On January 18, 2017, the Company acquired a 51% interest in NuGenerex Diagnostics LLC (“NGDx”), formerly Hema Diagnostic Systems, LLC, pursuant to the Acquisition Agreement. At closing, the Company acquired 4,950 of NGDx’s 10,000 previously outstanding limited liability company units in exchange for 1,117,011 shares of Generex common stock valued at $253,721, plus 420 shares of Generex common stock issued to NGDx in exchange for 300 new limited liability company units. The Acquisition Agreement also provides the Company with a call option to acquire the remaining 49% of NGDx and a retirement of NGDx shareholder loans in the amount of $13,431,706 (including interest) (the “Call Option”) for the aggregate purchase price of $1. On November 30, 2018, the call option was exercised, and the Company acquired the remaining 49% of NGDx.

Following the closing and the completion of Company’s reverse stock split, the Company was required to issue an additional 4,830,000 shares of common stock and issue a warrant to a former shareholder of NGDx to acquire 15,000,000 additional shares of Generex common stock for $2.50 per share. The issue of this warrant is contingent upon the Company obtaining approval from its shareholders for an increase in its authorized share capital. The total consideration was valued at $1,350,916 on the date of the acquisition. As of July 31, 2019, all warrants relating to this acquisition have been issued which resulted in additional paid in capital of $9,032,435.
Fair Value of the NGDx Assets

The intangible assets acquired includes In–Process Research & Development (“IPR&D”). The Fair Value of the IPR&D intangible asset using an Asset Cost Accumulation methodology as of January 18, 2017 (the “Valuation Date”) was determined to be $2,911,377. Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets. The Company is currently not amortizing the in-process research and development until it becomes commercially viable and placed in service. At the time when the intangible assets are placed in service the Company will determine a useful life.

The net purchase price of NGDx was determined to be as follows:

<table>
<thead>
<tr>
<th>Purchase price:</th>
<th>Stock Price at Closing</th>
<th>Shares</th>
<th>Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Stock at closing</td>
<td>$ 0.23</td>
<td>1,117,011</td>
<td>$253,721</td>
</tr>
<tr>
<td>Common Stock after closing</td>
<td>$ 0.23</td>
<td>420</td>
<td>95</td>
</tr>
<tr>
<td>Common Stock post reverse stock split</td>
<td>$ 0.23</td>
<td>4,830,000</td>
<td>1,097,100</td>
</tr>
<tr>
<td>Total purchase price</td>
<td></td>
<td>5,947,431</td>
<td>$1,350,916</td>
</tr>
</tbody>
</table>

As of January 18, 2017, the issue of the warrant to acquire 15,000,000 additional common shares of Generex was contingent upon shareholder approval of an increase in the Company’s authorized capital stock. No warrant could be issued by the Company until such time that an increase in authorized capital has been approved. At the time of closing, management was not of the opinion that it is more likely than not that the warrant will be issued, and the Call Option will be exercised, accordingly no values have been attributed to the warrant and Call Option at closing. During 2017, management made a redetermination and estimated that it was more likely than not that the shareholder approval to increase authorized share capital would be obtained and the Call Option would be exercised.

On December 1, 2018, pursuant to the Acquisition Agreement the Company issued the warrant to 15,000,000 additional common shares of Generex to Stephen L. Berkman. The Warrant is exercisable until December 1, 2019 at an exercise price of $2.50 per share. The Warrant contains a provision prohibiting the exercise of the Warrant to the extent that, after exercise, Mr. Berkman would own more than 9.99% of the Company’s common stock. The Warrant was issued pursuant to the January 18, 2017 Acquisition Agreement among the Company, NGDx, Stephen L. Berkman and the other equity owners of NGDx.

Simultaneously, on December 1, 2018, Company exercised the Call Option and acquired the remaining 49% non-controlling interest in NGDx. Accordingly, the fair values of the warrants and call option was updated through the issuance and exercise date and the change in the fair value of the contingent purchase consideration of a loss of $4,397,507 and a gain of $15,147,591 was recorded and included in the condensed interim consolidated statements of operations and comprehensive income for the year ending July 31, 2019. The Company adopted a sequencing policy and determined that the warrants with fixed exercise price were excluded from derivative consideration.

The remaining fair value of the call option and the warrant payable remaining at the time of exercise of the call option and issuance of the warrant was charged against additional paid-in capital as an elimination of non-controlling interest for a loss of $6,951,015.

Fair Value Assumptions Used in Accounting for the Warrant

The Company used the Black-Scholes option-pricing model to calculate the fair value of the warrant. The Black-Scholes option-pricing 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. The key inputs used in the fair value calculations were as follows:

<table>
<thead>
<tr>
<th></th>
<th>December 1, 2018</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise price</td>
<td>2.50</td>
<td>2.50</td>
</tr>
<tr>
<td>Time to expiration</td>
<td>3.14 years</td>
<td>3.47 years</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>3.01%</td>
<td>2.77%</td>
</tr>
<tr>
<td>Estimated volatility</td>
<td>138.61%</td>
<td>143.97%</td>
</tr>
<tr>
<td>Dividend</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stock price at valuation date</td>
<td>$ 0.9</td>
<td>$ 0.1</td>
</tr>
</tbody>
</table>
The Company used the Monte Carlo model to calculate the fair value of the call option. The valuations are based on assumptions as of the valuation date with regard to the value of the asset acquired net of impairment, the risk-free interest rate, the estimated volatility of the stock price in the future, the time to expiration and the stock price at the date of valuation.

The following assumptions were used in estimating the value of the Call Option:

<table>
<thead>
<tr>
<th>Assumption</th>
<th>December 1, 2018</th>
<th>July 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>2.52%</td>
<td>2.44%</td>
</tr>
<tr>
<td>Estimated volatility</td>
<td>164.43%</td>
<td>129.95%</td>
</tr>
<tr>
<td>Remaining Term</td>
<td>1.13 years</td>
<td>1.47 years</td>
</tr>
<tr>
<td>Stock price at valuation date</td>
<td>$0.9043</td>
<td>$0.0976</td>
</tr>
</tbody>
</table>

**Grainland and Empire Pharmacies:**

On December 28, 2017, the Company through its wholly owned subsidiary NuGenerex, completed the acquisition of the assets and 100% of the membership interests of two pre-operational pharmacies, Empire State Pharmacy Holdings, LLC and Grainland Pharmacy Holdings, LLC, pursuant to the bills of sale for a consideration of $320,000 Promissory Note due and payable in full on June 28, 2018 bearing an annual interest rate of 3%. The note was extended by six months and set to mature with the same terms on December 28, 2018. The note remains active and interest has continued to accrue while new terms of the note are in process of being negotiated.

We finalized our allocation of the purchase price as of December 28, 2018. The final allocation of the purchase price as of January 31, 2019, is as follows:

<table>
<thead>
<tr>
<th>Preliminary Allocation as of December 28, 2017</th>
<th>Allocation Adjustments</th>
<th>Final Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intangible assets (licenses)</td>
<td>$276,380</td>
<td>$276,380</td>
</tr>
<tr>
<td>Property and equipment</td>
<td>19,879</td>
<td>19,879</td>
</tr>
<tr>
<td>Computer software acquired</td>
<td>5,980</td>
<td>5,980</td>
</tr>
<tr>
<td>Leasehold Improvements</td>
<td>17,761</td>
<td>17,761</td>
</tr>
<tr>
<td>Total assets acquired</td>
<td>320,000</td>
<td>320,000</td>
</tr>
<tr>
<td>Consideration:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note Payable</td>
<td>320,000</td>
<td>320,000</td>
</tr>
<tr>
<td>Goodwill</td>
<td>$ —</td>
<td>$ —</td>
</tr>
</tbody>
</table>

The entire value of the intangible assets represents the licenses obtained to operate a pharmacy in the respective state of each of the acquired pharmacies. Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets. The Company is currently not amortizing the pharmacy license until the pharmacies becomes commercially viable and operations begin in the acquired pharmacies. At the time, when the licenses are placed in service, the Company will determine a useful life.

Since acquisition, Grainland Pharmacy Holdings, LLC ceased to operate. Accordingly, the value allocated to its tangible assets, leasehold improvements and licenses acquired for $99,519 was charged to impairment of long-lived assets.

Since acquisition, Empire State Pharmacy Holdings, LLC ceased to operate. Accordingly, the value allocated to its Intangible Assets Arising on Acquisition acquired for $188,068 was charged to impairment of long-lived assets.
On October 3, 2018, the Company entered into an Asset Purchase Agreement (the “Agreement”) with Veneto Holdings, L.L.C. (“Veneto”) to purchase certain assets of Veneto.

Effective as at October 3, 2018, NuGenerex Distribution Solutions, LLC assigned the Veneto Asset Purchase Agreement to NuGenerex Distribution Solutions 2, LLC. The sole member of that LLC is NuGenerex Management Services, Inc., a wholly-owned subsidiary of Generex Biotechnology Corporation.

The aggregate purchase price for the Assets is $35,000,000 including the Promissory Note. At the Second Closing, the Company will pay the principal of the Promissory Note plus interest to Veneto, (i) $9,000,000 will be paid by the Company into a trust or other fiduciary account acceptable to Veneto to be used exclusively for satisfaction of certain contingent liabilities of Veneto and subsidiaries of Veneto not being acquired by the Company, (ii) $3,000,000 will be paid by the Company into an escrow account to secure potential obligations of Veneto in respect of the Second Closing date working capital and under the indemnification provisions of the Agreement and (iii) the balance will be payable directly to Veneto in cash.

The Company had also entered into a temporary fee-for-service arrangement with Veneto and one of its subsidiaries for Veneto to provide management, personnel, operational, administrative and other services with respect to the First Closing Assets pending the Second Closing. At the Second Closing, all of Veneto personnel providing these services became employees or consultants of the Company, and, therefore, Veneto no longer provides these services.

At the First Closing, the Promissory Note issued to Veneto in the original principal amount of $15,000,000 with interest at an annual rate of 5.0% and guaranteed by Generex and Joseph Moscato, and secured by a first priority security interest in the Company’s assets other than the First Closing Assets was subsequently cancelled upon the issuance of the new promissory note on the Second Closing in the principal amount of $35,000,000 with an annual of 12.0% and guaranteed by Generex and Joseph Moscato.

On November 1, 2018 the Company consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto’s management services organization business and two additional ancillary services. The aggregate price for the First Closing Assets and the Second Closing Assets was $30,000,000. The Company issued a promissory note in the principal amount of $35,000,000 (the “New Note”) consisting of the $30,000,000 purchase price and a $5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. In addition, we agreed to assume approximately $3.8 million in outstanding institutional debt of Veneto subsidiaries, but will have the use of Veneto cash which would otherwise have been applied to paying down the debt.

There was $62,500 of accrued interest on the first closing $15,000,000 note and an additional $1,716,129 of accrued interest on the second closing $35,000,000 promissory note for a total of $1,778,629 accrued interest through March 28, 2019 when the Company entered into an Amendment Agreement (the “Amendment”). This Amendment between with Veneto and the equity owners of Veneto (the “Veneto Members”) to restructure the payment of the obligation that in satisfaction of all obligations the Company would cause to be delivered 8,400,000 shares of the Company’s common stock (the “Generex Shares”) to be delivered on or before April 22, 2019; plus an aggregate 5,500,000 shares of the Company’s subsidiary, common stock of Antigen Express, Inc (“Antigen Shares”). The Company and the Veneto Members further agreed to certain downside protection between $2.50 per share and $1.50 per share subject to terms and conditions contained in the agreement. The Generex Shares were delivered on May 23, 2019, but due to the current and ongoing litigation with the Veneto Members, the Antigen Shares have not been delivered.

As a result of the Amended Agreement entered into on March 28, 2019 (“the Amendment”) with Veneto and the equity owners of Veneto (the “Veneto Members”) to restructure the Promissory Note, the Company was evaluated for downside protection associated with the 8,400,000 issued shares in lieu of cash payments against the Promissory Note. Based on the valuation as of the date of agreement on March 28, 2019, an allocation of $6,424,338 was allocated to derivative liability for downside protection. As of July 31, 2019, the downside protection had a market change of $3,085,502 and held a value of $3,338,836.
Fair Value of the Veneto Acquisition

The following table summarizes the allocation of the preliminary purchase price as of the Veneto acquisition as of the First Closing and the Second Closing:

<table>
<thead>
<tr>
<th></th>
<th>“First Closing” completed on October 3, 2018</th>
<th>“Second Closing” completed on November 1, 2018</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$2,410,150</td>
<td>$2,410,150</td>
<td>$2,410,150</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>1,935,078</td>
<td>1,935,078</td>
<td>1,935,078</td>
</tr>
<tr>
<td>Inventory, net</td>
<td>1,068,856</td>
<td>1,068,856</td>
<td>1,068,856</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>95,804</td>
<td>95,804</td>
<td>95,804</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>652,590</td>
<td>652,590</td>
<td>652,590</td>
</tr>
<tr>
<td>Other receivables</td>
<td>1,014,316</td>
<td>1,014,316</td>
<td>1,014,316</td>
</tr>
<tr>
<td>Notes receivable - LT</td>
<td>1,387,763</td>
<td>1,387,763</td>
<td>1,387,763</td>
</tr>
<tr>
<td>Other assets, net</td>
<td>25,745</td>
<td>25,745</td>
<td>25,745</td>
</tr>
<tr>
<td>Intangible assets, net</td>
<td>35,603</td>
<td>7,110,000</td>
<td>7,145,603</td>
</tr>
<tr>
<td><strong>Total assets acquired</strong></td>
<td><strong>8,625,905</strong></td>
<td><strong>16,140,000</strong></td>
<td><strong>15,735,905</strong></td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>2,509,887</td>
<td>2,509,887</td>
<td>2,509,887</td>
</tr>
<tr>
<td>Notes payable</td>
<td>3,403,948</td>
<td>3,403,948</td>
<td>3,403,948</td>
</tr>
<tr>
<td><strong>Total liabilities assumed</strong></td>
<td><strong>2,509,887</strong></td>
<td><strong>3,403,948</strong></td>
<td><strong>5,913,835</strong></td>
</tr>
<tr>
<td>Net identifiable assets acquired</td>
<td>6,116,018</td>
<td>9,822,070</td>
<td>9,822,070</td>
</tr>
<tr>
<td>Goodwill</td>
<td>8,883,982</td>
<td>16,293,948</td>
<td>23,177,930</td>
</tr>
<tr>
<td><strong>Total consideration transferred</strong></td>
<td><strong>$15,000,000</strong></td>
<td><strong>$20,000,000</strong></td>
<td><strong>$35,000,000</strong></td>
</tr>
</tbody>
</table>

The following table summarizes the allocation of the revalued purchase price as of the Veneto acquisition as of the First Closing and the Second Closing during the year ending July 31, 2019:

<table>
<thead>
<tr>
<th></th>
<th>“First Closing” completed on October 3, 2018</th>
<th>“Second Closing” completed on November 1, 2018</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$2,410,150</td>
<td>$2,410,150</td>
<td>$2,410,150</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>1,935,078</td>
<td>1,935,078</td>
<td>1,935,078</td>
</tr>
<tr>
<td>Inventory, net</td>
<td>1,068,856</td>
<td>1,068,856</td>
<td>1,068,856</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>95,804</td>
<td>95,804</td>
<td>95,804</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>652,590</td>
<td>652,590</td>
<td>652,590</td>
</tr>
<tr>
<td>Other receivables</td>
<td>1,014,316</td>
<td>1,014,316</td>
<td>1,014,316</td>
</tr>
<tr>
<td>Notes receivable - LT</td>
<td>1,387,763</td>
<td>1,387,763</td>
<td>1,387,763</td>
</tr>
<tr>
<td>Other assets, net</td>
<td>25,745</td>
<td>25,745</td>
<td>25,745</td>
</tr>
<tr>
<td>Intangible assets, net</td>
<td>35,603</td>
<td>811,000</td>
<td>846,603</td>
</tr>
<tr>
<td><strong>Total assets acquired</strong></td>
<td><strong>8,181,465</strong></td>
<td><strong>811,000</strong></td>
<td><strong>8,992,465</strong></td>
</tr>
<tr>
<td>Total current liabilities</td>
<td>2,065,448</td>
<td>2,065,448</td>
<td>2,065,448</td>
</tr>
<tr>
<td>Notes payable</td>
<td>3,403,948</td>
<td>3,403,948</td>
<td>3,403,948</td>
</tr>
<tr>
<td><strong>Total liabilities assumed</strong></td>
<td><strong>2,065,448</strong></td>
<td><strong>3,403,948</strong></td>
<td><strong>5,469,396</strong></td>
</tr>
<tr>
<td>Net identifiable assets acquired</td>
<td>6,116,017</td>
<td>9,822,070</td>
<td>9,822,070</td>
</tr>
<tr>
<td>Goodwill</td>
<td>8,883,982</td>
<td>16,293,948</td>
<td>25,177,930</td>
</tr>
<tr>
<td><strong>Total consideration transferred</strong></td>
<td><strong>$15,000,000</strong></td>
<td><strong>$20,000,000</strong></td>
<td><strong>$35,000,000</strong></td>
</tr>
</tbody>
</table>

In accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification® (“ASC”) Topic 310, “Receivables”, this agreement is classified as a note receivable and carried at their net realizable value net of allowance of credit losses when management determines that it is probable a loss has been incurred. Notes receivable are charged off against the allowance for credit losses when management determines that the notes receivable are uncollectible and the Company ceases collection efforts. The Company recognizes a portion of the note as interest income in the accompanying consolidated financial statements.

The note receivable for $1,387,763 acquired during the first closing of Veneto on October 3, 2018 was to be automatically converted per the purchase agreement into 6% ownership of a third-party company. Due to the ongoing litigation with Veneto, management has not been able to obtain evidence that this note was converted into 6% ownership of the third-party company. In July 2019, Management reviewed all aspects of this transactions and concluded that it has no reason to believe that this amount will be recovered, as such they deem the note receivable of $1,387,763 to be fully impaired.

As of July 31, 2019, the note receivable balance had increased to $1,443,083 due to $55,300 of additional accrued interest. The Company has elected to record an allowance for credit loss of $1,387,763 as of July 31, 2019 to fully reserve for the principal portion of the note receivable. The remaining $55,300 of accrued interest was written off and netted against interest income in the consolidated financial statements.
The significant intangible assets identified in the purchase price allocation discussed above include developed software and technology, referral base (recurring revenue from the MSO investments and their use of Company owned pharmacies) and non-compete agreements with continued employment of key employees. Tradenames and trademarks were not valued as tradenames and trademarks will not be maintained going forward. To value the developed software and technology, the Company utilized the relief from royalty method, a form of the income approach to value the developed software and technology which assumes a limited technology life and market share adjusted by assumed obsolescence with a terminal value. The referral base was valued using a multi-period excess earnings method, a form of the income approach. The Company utilized the with and without method, a form of the income approach to value non-compete agreements with Generex.

The preliminary amounts assigned to the identifiable intangible assets, the estimated useful lives, and the estimated amortization expense related to these identifiable intangible assets are as follows:

<table>
<thead>
<tr>
<th>Intangible Asset</th>
<th>Preliminary Fair Value</th>
<th>Average Estimated Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed Software/Technology</td>
<td>$131,000</td>
<td>5</td>
</tr>
<tr>
<td>Referral Base</td>
<td>—</td>
<td>15</td>
</tr>
<tr>
<td>Non-compete agreements</td>
<td>$680,000</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$811,000</strong></td>
<td></td>
</tr>
</tbody>
</table>

Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets.

Goodwill initially represented the excess of the purchase price over the fair market value of net assets acquired. Goodwill for Veneto Acquisition was $8.9 million as of the date of the First Closing and $16.3 million as of the date of the Second Closing. Based on the Amended Agreement (the “Amendment”) entered into on March 28, 2019 referred to above which stipulated that in lieu any cash payments, the Company would deliver shares of the Company’s common stock (the “Generex Shares”). Additionally, in pursuant to ASC 805 and specifically, ASC 805-10-25-14, the Company recognized the change in assets and liabilities as a result of facts and circumstances that existed as of the acquisition date that would have resulted in the recognition of the assets and liabilities with the corresponding decrease of goodwill from $24.2 million to $13.6 million.

During the year ending July 31, 2019, the amounts assigned to the identifiable intangible assets, the estimated useful lives, and the estimated amortization expense related to these identifiable intangible assets were revalued as follows:

<table>
<thead>
<tr>
<th>Intangible Asset</th>
<th>Preliminary Fair Value</th>
<th>Average Estimated Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed Software/Technology</td>
<td>$397,000</td>
<td>5</td>
</tr>
<tr>
<td>Referral Base</td>
<td>10,000</td>
<td>15</td>
</tr>
<tr>
<td>Non-compete agreements</td>
<td>1,870,000</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,277,000</strong></td>
<td></td>
</tr>
</tbody>
</table>

_Regentys and Olaregen:_

On January 7, 2019, the Company closed two separate Acquisition Agreements pursuant to which the Company acquired a 51% interest in both Regentys Corporation (“Regentys”) and Olaregen Therapeutix Inc. (“Olaregen”).

The Company accounted for the acquisitions of both Regentys and Olaregen as business combinations using the purchase method of accounting as prescribed in Accounting Standards Codification 805, Business Combinations (“ASC 805”) and ASC 820 – Fair Value Measurements and Disclosures (“ASC 820”). In accordance with ASC 805 and ASC 820, the Company used its best estimates and assumptions to accurately assign fair value to the tangible assets acquired, identifiable intangible assets and liabilities assumed as of the acquisition dates. Goodwill as of the acquisition date is measured as the excess of purchase consideration over the fair value of tangible and identifiable intangible assets acquired and liabilities assumed.

The fair values assigned to Regentys’ and Olaregen’s tangible and identifiable intangible assets acquired, and liabilities assumed are based on management’s estimates and assumptions. The estimated fair values of these assets acquired, and liabilities assumed are considered preliminary and are based on the information that was available as of the date of the acquisition. The preliminary estimated fair values of assets acquired, and liabilities assumed, and identifiable intangible assets may be subject to change as additional information is received. Thus, the provisional measurements of fair value are subject to change. The Company expects to finalize the valuations as soon as practicable, but not later than one year from the closing date.
Regentys:

On November 28, 2018, Generex and Regentys entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital stock of Regentys for a total consideration of $15,000,000. On January 7, 2019 the Company completed a definitive Stock Purchase Agreement and related documents effecting the transactions contemplated by the LOI.

Pursuant to a Stock Purchase Agreement between the Company and Regentys (the “Purchase Agreement”) the Company acquired 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys (“Regentys Shares”).

In addition to $400,000 paid to Regentys upon signing of the LOI, the purchase price for the Regentys Shares will consist of the following cash payments, with the proceeds intended to be used for specific purposes, as noted:

- $3,450,000 to initiate pre-clinical activities on or before January 15, 2019. As of the date this report was filed, the Company has paid $650,000 and the remaining balance of $2,800,000 is payable on or before November 30, 2019 per extension in amended agreement.
- $2,000,000 to initiate patient recruitment activities on or before May 1, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $2,000,000 is payable on or before November 30, 2019 per extension in amended agreement.
- $3,000,000 to initiate a first-in-human pilot study on or before September 1, 2019.
- $5,000,000 to initiate a human pivotal study on or before February 1, 2020.
- $1,150,000 to submit a 510(k) de novo submission to the FDA on or about February 1, 2021.

The Company issued its Promissory Note in the amount of $14,600,000 (the “Note”) representing its obligation to pay the above amounts. The Note is secured by a pledge of the Regentys shares pursuant to a Pledge and Security Agreement. In the event that Generex does not make any of the first three payments listed above, at Regentys’ option either:

- Generex will forfeit all of the Regentys shares issued with no refund of amounts paid; or
- Generex will issue shares of its common stock to Regentys equivalent to 110% of the value of the missing payment, which shares will be registered for resale.

In the event Generex does not make either or both of the fourth and fifth payments, its share ownership of Regentys will be proportionately reduced.

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of Guaranteed Payments amounting to $2,800,000 on or before April 1, 2019. On October 31, 2019, the Company and Regentys signed an extension to extend the due date on or before November 30, 2019. The extensions of the due date have no impact on the existing schedule of future payments or any additional terms within the Note. Regentys has not filed any notice of default as of the date of publication, and Generex continues to provide Regentys with business opportunities continuing the relationship.
## Fair Value of the Regentys Acquisition

The following table summarizes the allocation of the preliminary purchase price as of the Regentys acquisition:

<table>
<thead>
<tr>
<th></th>
<th>Preliminary Allocations as of January 7, 2019</th>
<th>Allocation Adjustments</th>
<th>Revised Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$61,857</td>
<td>$0</td>
<td>$61,857</td>
</tr>
<tr>
<td>Other current assets</td>
<td>13,138</td>
<td>20,543</td>
<td>33,591</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>444</td>
<td>$0</td>
<td>444</td>
</tr>
<tr>
<td>Accounts payable and accrued liabilities</td>
<td>(1,181,920)</td>
<td>(307,495)</td>
<td>(1,488,870)</td>
</tr>
<tr>
<td>Notes payable</td>
<td>(639,009)</td>
<td>29,685</td>
<td>(609,324)</td>
</tr>
<tr>
<td>Loans form related parties</td>
<td>(16,506)</td>
<td>(399,999)</td>
<td>(416,505)</td>
</tr>
<tr>
<td>Deferred tax liability</td>
<td>(889,782)</td>
<td>30,320</td>
<td>(859,462)</td>
</tr>
<tr>
<td>In-Process research &amp; development</td>
<td>3,510,680</td>
<td>(119,630)</td>
<td>3,391,050</td>
</tr>
<tr>
<td><strong>Total Fair Value of Assets Acquired</strong></td>
<td><strong>1,259,447</strong></td>
<td><strong>(751,613)</strong></td>
<td><strong>907,833</strong></td>
</tr>
</tbody>
</table>

### Non-Controlling interest, net of proceeds:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Note receivable from Generex</td>
<td>14,345,205</td>
<td>(2,791)</td>
</tr>
<tr>
<td>Redeemable non-controlling interest</td>
<td>(4,073,898)</td>
<td></td>
</tr>
<tr>
<td>Non-controlling interest</td>
<td>(9,870,762)</td>
<td>(2,791)</td>
</tr>
<tr>
<td>Cash paid prior to the time of closing</td>
<td>—</td>
<td>400,000</td>
</tr>
<tr>
<td><strong>Total Fair Value of Assets Acquired</strong></td>
<td><strong>1,259,447</strong></td>
<td><strong>(751,613)</strong></td>
</tr>
</tbody>
</table>

### Consideration:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid prior to the time of closing</td>
<td>400,000</td>
<td></td>
</tr>
<tr>
<td>Note receivable from Generex</td>
<td>14,345,205</td>
<td>(2,791)</td>
</tr>
<tr>
<td><strong>Goodwill</strong></td>
<td>$13,485,758</td>
<td>$748,823</td>
</tr>
</tbody>
</table>

The redeemable non-controlling interest of $4,073,898, representing the Series Stock A, was determined by deducting the total consideration paid of $14,745,205 from the total purchase value totaling $28,689,865 based on a convergence method in an Option Pricing Model using the Regentys capital structure with 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys. See Note 7 – Redeemable Non-Controlling Interest.

### Olaregen:

On November 27, 2018, Generex and Olaregen entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital stock of Olaregen for a total consideration of twelve million dollars ($12,000,000).

As of January 7, 2019, the Company completed a definitive Stock Purchase Agreement (“Purchase Agreement”) and related documents effecting the transactions contemplated by the LOI.

The Company acquired 3,282,632 newly issued shares of the Olaregen common stock representing 51% percent of the issued and outstanding capital stock of Olaregen (“Olaregen Shares”).

In addition to $400,000 paid to Olaregen upon signing of the LOI, the purchase price for the Olaregen Shares will consist of the following cash payments:

- **$800,000** on or before January 15, 2019. The Company has paid this installment.
- **$800,000** on or before January 31, 2019. As of the date this report was filed, the Company has paid $491,500 of this installment and remaining balance of $308,500 is payable on or before November 30, 2019 per extension in amended agreement.
- **$3,000,000** on or before April 1, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $3,000,000 is payable on or before November 31, 2019 in amended agreement.
- **$1,000,000** on or before May 31, 2019. As of the date this report was filed, the Company has not yet paid this installment and the full balance of $1,000,000 is payable on or before November 30, 2019 per extension in amended agreement.
- **$6,000,000** on or before September 30, 2019.
In addition, during May 2019, Generex pursuant to a Stock Purchase Agreement purchased 592,682 shares of Series A Preferred Stock of Olaregen in exchange for 4,000,000 shares of the Company’s common stock and a $2,000,000 Promissory Note bearing interest at 7% per annum (the “Notes”) originally due and payable on August 1, 2019. As of the date this report was filed, the Company has not yet paid the balance due of this Note.

The Company issued its Promissory Note in the amount of $11,600,000 (the “Note”) representing its obligation to pay the above amounts. The Note is secured by a pledge of the Olaregen shares pursuant to a Pledge and Security Agreement. In the event that Generex fails to pay the installment due on November 30, 2019, Generex will forfeit the shares allocated to that installment (1,600,000 Olaregen shares) and Olaregen will be entitled to “claw back” fifty percent (50%) of any and all shares paid for by the prior payments.

On March 14, 2019, the Company and Olaregen amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the second tranche of Guaranteed Payments amounting to $600,000 on or before April 1, 2019. The Company remitted additional payments of $200,000 on April 30, 2019 and $38,500 on May 17, 2019. On May 22, 2019, the Company and Olaregen amended the agreement to extend the due date of the remaining balance of the second tranche of Guaranteed Payments amounting to $361,500, the full balance of the third tranche amounting to $3,000,000 and the full balance of the fourth tranche amounting to $1,000,000 (total of $4,361,500) on or before June 30, 2019. The extensions of the due date have no impact on the existing schedule of future payments or any additional terms within the Note. Olaregen has not filed any notice of default as of the date of publication, and Generex continues to provide Olaregen with business opportunities continuing the relationship.

In the event Generex does not make any other payments, its share ownership of Olaregen will be proportionately reduced.

Based on the Note, in the event any incremental payment is not paid when due, Olaregen has the option to increase the per share purchase price for all remaining purchased shares to $4.00 per share. Based on $1,400,000 of remitted payments and a Promissory Note balance of $10,400,000 prior to the first extension agreement on March 14, 2019, Olaregen elected the option to proportionally increase the per share purchase price to $4.00 for the remaining 2,899,658 of the total 3,282,632 shares to be acquired. The resulting penalty amounts to an additional $998,633 which has been accrued for the Company to remit to Olaregen pursuant to the acquisition.

Generex has a limited anti-dilution right under the Purchase Agreement, to ensure that Generex will retain 51% ownership in Olaregen for a period of time.

**Fair Value of the Olaregen Acquisition**

The following table summarizes the allocation of the preliminary purchase price as of the Olaregen acquisition:

<table>
<thead>
<tr>
<th>Preliminary Allocations as of January 7, 2019</th>
<th>Allocation Adjustments</th>
<th>Revised Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$608,419</td>
<td>$208,419</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>20,488</td>
<td></td>
</tr>
<tr>
<td>Inventory</td>
<td>408,501</td>
<td></td>
</tr>
<tr>
<td>Other current assets</td>
<td>37,950</td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(216,670)</td>
<td>(216,670)</td>
</tr>
<tr>
<td>Accrued liabilities</td>
<td>(216,694)</td>
<td>(216,694)</td>
</tr>
<tr>
<td>Deferred tax liability</td>
<td>(1,040,173)</td>
<td>(642,660)</td>
</tr>
<tr>
<td>In-Process research &amp; development</td>
<td>3,980,000</td>
<td>2,459,000</td>
</tr>
<tr>
<td>Non-compete agreements</td>
<td>790,000</td>
<td>530,000</td>
</tr>
</tbody>
</table>

**Non-Controlling interest, net of proceeds:**

| Note receivable from Generex               | 11,472,663             | 11,472,663        |
| Non-controlling interest                  | (11,999,559)           | (11,999,559)      |
| Cash paid prior to the time of closing    | —                      | 400,000           |
| Total Fair Value of Assets Acquired       | 3,844,925              | 2,461,440         |

**Consideration:**

| Cash paid prior to the time of closing    | 400,000                | 400,000           |
| Note receivable from Generex              | 11,472,663             | 11,472,664        |
| Goodwill                                  | $8,027,738             | $9,411,224        |

<table>
<thead>
<tr>
<th>Preliminary Allocations as of January 7, 2019</th>
<th>Allocation Adjustments</th>
<th>Revised Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$608,419</td>
<td>$208,419</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>20,488</td>
<td></td>
</tr>
<tr>
<td>Inventory</td>
<td>408,501</td>
<td></td>
</tr>
<tr>
<td>Other current assets</td>
<td>37,950</td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(216,670)</td>
<td>(216,670)</td>
</tr>
<tr>
<td>Accrued liabilities</td>
<td>(216,694)</td>
<td>(216,694)</td>
</tr>
<tr>
<td>Deferred tax liability</td>
<td>(1,040,173)</td>
<td>(642,660)</td>
</tr>
<tr>
<td>In-Process research &amp; development</td>
<td>3,980,000</td>
<td>2,459,000</td>
</tr>
<tr>
<td>Non-compete agreements</td>
<td>790,000</td>
<td>530,000</td>
</tr>
</tbody>
</table>

**Non-Controlling interest, net of proceeds:**

| Note receivable from Generex               | 11,472,663             | 11,472,663        |
| Non-controlling interest                  | (11,999,559)           | (11,999,559)      |
| Cash paid prior to the time of closing    | —                      | 400,000           |
| Total Fair Value of Assets Acquired       | 3,844,925              | 2,461,440         |

**Consideration:**

| Cash paid prior to the time of closing    | 400,000                | 400,000           |
| Note receivable from Generex              | 11,472,663             | 11,472,664        |
| Goodwill                                  | $8,027,738             | $9,411,224        |
The components of the acquired intangible assets were as follows:

<table>
<thead>
<tr>
<th>In-process research and development</th>
<th>Preliminary Fair Value $3,980,000</th>
<th>Average Estimated Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-compete agreement</td>
<td>790,000</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>$4,770,000</td>
<td></td>
</tr>
</tbody>
</table>

**Unaudited Supplemental Pro Forma Data**

Unaudited pro forma results of operations for the year ended July 31, 2019 and 2018 as though the Company acquired Veneto, Olaregen and Regentys (the “Acquired Companies”) on the first day of each fiscal year are set forth below.

<table>
<thead>
<tr>
<th>Year Ended</th>
<th>July 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>Revenues</td>
<td>$11,217,169</td>
</tr>
<tr>
<td>Cost of revenues</td>
<td>4,143,586</td>
</tr>
<tr>
<td>Gross profit</td>
<td>7,073,583</td>
</tr>
<tr>
<td>Operating expenses</td>
<td>13,338,328</td>
</tr>
<tr>
<td>Operating loss</td>
<td>(6,264,744)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>1,469,732</td>
</tr>
<tr>
<td>Net loss</td>
<td>(4,795,012)</td>
</tr>
<tr>
<td>Net loss attributable to noncontrolling interests</td>
<td>(1,606,316)</td>
</tr>
<tr>
<td>Net Income (loss) Available to Common Stockholders</td>
<td>(3,188,696)</td>
</tr>
<tr>
<td>Comprehensive net loss</td>
<td>$ (3,188,696)</td>
</tr>
<tr>
<td>Basic and diluted earnings per share</td>
<td>$ (0.05)</td>
</tr>
</tbody>
</table>
Note 14 – Derivative Liability

The Company issued debts that consist of the issuance of convertible notes with variable conversion provisions. The conversion terms of the convertible notes are variable based on certain factors, such as the future price of the Company’s common stock. The number of shares of common stock to be issued is based on the future price of the Company’s common stock. The number of shares of common stock issuable upon conversion of the promissory note is indeterminate. Due to the fact that the number of shares of common stock issuable could exceed the Company’s authorized share limit, the equity environment is tainted and all additional convertible debentures and warrants are included in the value of the derivative. Pursuant to ASC 815-15 Embedded Derivatives, the fair values of the variable conversion option and warrants and shares to be issued were recorded as derivative liabilities on the issuance date. The Company’s estimate of fair value used quoted market prices of the underlying financial instrument and valued the warrants using a multinomial lattice models.

The following table presents the activity for derivative liabilities measured at estimated fair value:

<table>
<thead>
<tr>
<th>Derivative Liability – Convertible Notes</th>
<th>Derivative Liability – Warrants</th>
<th>Derivative Liability – Downside Protection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of August 1, 2017</td>
<td>$—</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Balance as of July 31, 2018</td>
<td>$5,178,241</td>
<td>$353,464</td>
<td>$6,424,338</td>
</tr>
<tr>
<td>Change in fair value</td>
<td>$988,267</td>
<td>$(28,214)</td>
<td>$(3,085,502)</td>
</tr>
<tr>
<td>Change due to exercise / redemptions</td>
<td>$(2,010,312)</td>
<td>$—</td>
<td>$(2,010,312)</td>
</tr>
<tr>
<td>Balance as of July 31, 2019</td>
<td>$4,156,196</td>
<td>$325,250</td>
<td>$3,338,836</td>
</tr>
</tbody>
</table>

Note 15 - Warrants:

A summary of the Company’s warrant activities is as follows:

<table>
<thead>
<tr>
<th>Number of Warrants</th>
<th>Weighted Average Exercise Price per Share</th>
<th>Weighted Average Remaining Life (Years)</th>
<th>Aggregate Intrinsic Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding – August 1, 2018</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Outstanding - July 31, 2018</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Issued</td>
<td>15,399,681</td>
<td>2.53</td>
<td>0.40</td>
</tr>
<tr>
<td>Outstanding - July 31, 2019</td>
<td>15,399,681</td>
<td>2.53</td>
<td>0.40</td>
</tr>
</tbody>
</table>

For the year ended July 31, 2019, the Company issued 15,399,681 warrants which consisted of 399,681 issued to investors of convertible notes and 15,000,000 issued to a former shareholder of NGDx upon acquisition of the remaining 49% interest of the entity (Note 9). All the warrants issued vested immediately upon issuance. Additionally, 84,000 warrants are to be issued to AEXG in connection with an arbitrator’s award (Note 4).

Note 16 - Stock-Based Compensation:

Stock Option Plans

As of July 31, 2019, the Company had three 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 2,835,000 shares of common stock are reserved for issuance under the 2006 Stock Plan as amended (the 2006 Plan) and 240,000,000 shares of common stock reserved for issuance under the 2017 Stock Option Plan (the 2017 Plan) and 1,200,000 shares of common stock reserved for issuance under the 2019 Stock Option Plan (the 2019 Plan). At July 31, 2019, there were 2,823,450, 232,022,875, 1,200,000 shares of common stock reserved for future awards under the 2006 Plan, 2017 Plan and 2019 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 2006, 2017 and 2019 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.

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

<table>
<thead>
<tr>
<th>Options</th>
<th>Weighted Average Exercise Price per Share</th>
<th>Weighted Average Remaining Life (Years)</th>
<th>Aggregate Intrinsic Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding – August 1, 2018</td>
<td>379,998</td>
<td>$1.48</td>
<td>1.11</td>
</tr>
<tr>
<td>Granted</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Forfeited or expired</td>
<td>(147,777)</td>
<td>(0.05)</td>
<td>—</td>
</tr>
<tr>
<td>Exercised</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Outstanding - July 31, 2018</td>
<td>232,221</td>
<td>$1.00</td>
<td>0.25</td>
</tr>
<tr>
<td>Granted</td>
<td>9,976,125</td>
<td>0.71</td>
<td>7.59</td>
</tr>
<tr>
<td>Forfeited or expired</td>
<td>(2,219,671)</td>
<td>(0.43)</td>
<td>8.18</td>
</tr>
<tr>
<td>Exercised</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Outstanding - July 31, 2019</td>
<td>7,988,675</td>
<td>$0.84</td>
<td>7.21</td>
</tr>
</tbody>
</table>

The intrinsic value is calculated as the difference between the market value and the exercise price of the shares on July 31, 2019. The market values as of July 31, 2019 was $2.80 based on the closing bid price for July 31, 2019.

There were 3,369,842 vested common stock options under the Plan as of July 31, 2019. The compensation expense was $3,000,974 for the year ended July 31, 2019. There was additional compensation expense pertaining to the Regentys acquisition of $11,472 for the year ended July 31, 2019 for total compensation expense of $3,012,446. The Company had $3,263,569 of unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the Plan at July 31, 2019 to be recognized over an average of 2.49 years.

The Company estimated the fair value of each stock option on the grant date using a Black-Scholes option-pricing model. Black-Scholes option-pricing models requires the Company to make predictive assumptions regarding future stock price volatility, recipient exercise behavior, and dividend yield. The Company estimated the future stock price volatility using the historical volatility over the expected term of the option. The following assumptions were used in the Black-Scholes option-pricing model:

<table>
<thead>
<tr>
<th>Year Ended July 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise price</td>
</tr>
<tr>
<td>Expected term</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
</tr>
<tr>
<td>Estimated volatility</td>
</tr>
<tr>
<td>Expected dividend</td>
</tr>
<tr>
<td>Stock price at valuation date</td>
</tr>
</tbody>
</table>
Note 17 - Subsequent Events:

The Company has evaluated subsequent events occurring after the balance sheet date through the date the audited annual consolidated financial statements were issued in the unaudited condensed interim consolidated financial statements were issued.

On August 1, 2019, Generex finalized the acquisition of Pantheon Medical – Foot & Ankle, LLC (“Pantheon”) through a stock purchase agreement and issued 560,000 shares of common stock.

On August 1, 2019, Generex finalized the acquisition of MediSource Partners, LLC through a stock purchase agreement and issued 400,000 shares of common stock.

On August 8, 2019, the Company converted $649,851 of principal into 384,000 shares of common stock.

On August 12, 2019, the Company converted $45,000 of principal and $2,500 of interest into 30,666 shares of common stock.

On August 12, 2019, the Company retained a consultant to provide financial advisory services in connection with and support of the various financing options and other services for the Company to raise up to Seven Million Dollars ($7,000,000) in debt capital for the Company payable upon funding equal to five (5%) of the principal amount funded by investors introduced by the Consultant.

On August 13, 2019, the Company entered into a Public Secured Financing Facility Agreement with an investor pursuant to which the Company will receive a $5,000,000 financing facility bearing 13.50% interest per annum. The Company may receive subsequent financing in addition to the initial amount of $5,000,000 but shall not exceed a total of $7,000,000. The financing facility matures on August 13, 2021.

On August 14, 2019, the Company entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 10% per annum (the “Note”) in the principal amount of $1,100,000. Pursuant to the Securities Purchase Agreements, the Company also sold to the Investor warrants to purchase up to an aggregate 62,857 shares of common stock with the fair value of the warrants as of the date of issuance in excess of the Notes resulting in full discount of the Notes.

On August 15, 2019, the Company entered an agreement to pay an investor $900,000 for the prepayment of $666,667 owed under the note. Pursuant to the agreement, the Company converted $350,000 owed under the note into 230,351 shares of the Company’s common stock based upon a conversion price of $1.51942 per share.

On August 16, 2019, the Company entered into a Share Exchange Agreement to purchase an additional 900,000 shares in Olaregen Therapeutix Inc. from Olaregen Therapeutix LLC representing increasing Generex’s ownership from approximately 62% to 76%.

On August 19, 2019, the Company converted $60,000 of principal and $3,450 of interest into 46,110 shares of common stock.

On August 21, 2019, the Company converted $100,000 of principal and $5,699 of interest into 46,110 shares of common stock.

On August 29, 2019, the Company entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 9% per annum (the “Note”) in the principal amount of $250,000.

On September 1, 2019, the Company retained a consultant to provide consulting services directly or through affiliated entities, certain management, administrative, marketing and/or clinical services to various ancillary healthcare for providers for a fee of $2,000,000; $250,000 payable in shares of common stock; and $1,750,000 payable in 18 equal installments of $97,222.22 per month payable in cash as is available from the operations of newly acquired subsidiaries Pantheon and MediSource, or shares of common stock issued monthly. On September 2, 2019 Generex signed a Memorandum of Understanding with Paradise Valley Family Medicine to form a partnership under NuGenerex Health, LLC for the provision of ancillary health services.

On September 2, 2019 Generex signed a Memorandum of Understanding with Arizona Endocrinology Center to form a partnership under NuGenerex Health, LLC for the provision of ancillary health services.

On September 3, 2019, we declared a stock dividend on our outstanding Common Stock for stockholders of record date August 30, 2019 (the “Record Date”). As a result, all stockholders on the Record Date who hold their shares through the pay date of November 29, 2019 will receive one new share of Common Stock for each share of Common Stock owned by them as of that date.

On September 2, 2019 Generex signed a Memorandum of Understanding with Arizona Endocrinology Center to form a partnership under NuGenerex Health, LLC for the provision of ancillary health services.

On September 6, Generex signed a binding Letter of Intent with ALTuCELL, Inc (“ALTuCELL”), a clinical-stage development company with a broad intellectual property portfolio focused on cell encapsulation technology for the treatment of diabetes, autoimmune diseases, and inflammatory conditions to purchase 51% of ALTuCELL’s equity in exchange for $2,000,000 in cash, $8,000,000 in the Company’s common stock price at $2.50/share, and commitment to fund $5,000,000 towards ALTuCELL’s development costs pursuant to a mutually agreed upon clinical development plan based upon a valuation of ALTuCELL equal to $29,500,000. On September 20, 2019, Generex paid ALTuCELL a preliminary payment of $50,000 to bind the agreement.

On September 10, 2019, Generex and its subsidiaries, NuGenerex Distribution Solutions, LLC and NuGenerex Distributions Solutions 2, LLC (jointly “NDS”) filed an arbitration action against Veneto Holdings, LLC and certain affiliated entities holding shares of our common stock issued in connection with our acquisition of Veneto’s assets, alleging, among other things, that Veneto never transferred the ownership rights in at least one pharmacy to NDS. This pharmacy was a necessary element in the operation of other assets transferred by Veneto. The ownership rights in this pharmacy was a substantial portion of the consideration for shares issued to Veneto and its affiliates, and, as a result, Generex contends the shares issued to Veneto and its affiliates were never fully paid for. The arbitration is pending before the American Arbitration Association in Delaware.
On September 10, 2019, the Company converted $100,000 of principal and $6,361 of interest into 75,737 shares of common stock.

On September 12, 2019, 20,375,900 shares of common stock held in trust for the benefit of the Company were cancelled by the Company.

On September 13, 2019, the Company converted 592,683 Preferred Shares of Olaregen Therapeutics, Inc. Series A Preferred Stock into Common Stock.

On September 17, 2019, the Company converted $130,000 of principal and $8,522 of interest into 95,130 shares of common stock.

On September 18, 2019, the Company converted $150,000 of principal and $9,699 of interest into 112,941 shares of common stock.

On October 1, 2019, the Company retained a consultant to provide consulting services in support of the Company’s mission to raise capital, identify potential mergers, as well as other strategic advice to increase the value of the Company for a monthly fee of $5,000 for each calendar month commencing October 2019 and continuing through the termination date of September 30, 2024. The consultant received options to purchase 1,000,000 shares of common stock, vesting in equal increments of 200,000 shares on October 1st of each year commencing on October 1, 2019 at an exercise price of $2.09 per share. The consultant is to be paid a 2.0% transaction fee payable on all transactions consummated during the term. The transaction fee is based on the amount of all proceeds and other consideration paid or received, to be paid or received, or retained by the Company.

On October 10, 2019 Generex amended the acquisition agreement for the purchase of Pantheon effective on August 1, 2019 to provide a performance incentive up to $500,000 of GNBT Stock for exceeding annual EBIDTA targets of Pantheon of $1,000,000, 1,500,000 and $2,000,000 for the years ending July 31, 2020, 2021 and 2022, respectively, plus an additional $50,000 of GENBT Stock for each additional $100,000 of EBIDTA achieved by Pantheon.
On September 13, 2019, the Company converted 592,683 Preferred Shares of Olaregen Therapeutics, Inc. Series A Preferred Stock into Common Stock.

On September 17, 2019, the Company converted $130,000 of principal and $8,522 of interest into 95,130 shares of common stock.

On September 26, 2019, the Company converted $150,000 of principal and $9,699 of interest into 112,941 shares of common stock.

On October 1, 2019, the Company retained a consultant to provide consulting services in support of the Company’s mission to raise capital, identify potential mergers, as well as other strategic advice to increase the value of the Company for a monthly fee of $5,000 for each calendar month commencing October 2019 and continuing through the termination date of September 30, 2024. The consultant received options to purchase 1,000,000 shares of common stock, vesting in equal increments of 200,000 shares on October 1st of each year commencing on October 1, 2019 at an exercise price of $2.09 per share. The consultant is to be paid a 2.0% transaction fee payable on all transactions consummated during the term. The transaction fee is based on the amount of all proceeds and other consideration paid or received, to be paid or received, or retained by the Company.

On October 10, 2019 Generex amended the acquisition agreement for the purchase of Pantheon effective on August 1, 2019 to provide a performance incentive up to $500,000 of GNB Stock for exceeding annual EBDITA targets of Pantheon of $1,000,000, $1,500,000 and $2,000,000 for the years ending July 31, 2020, 2021 and 2022, respectively, plus an additional $50,000 of GNB Stock for each additional $100,000 of EBDITA achieved by Pantheon.


On May 6, 2019, MNP LLP ("MNP") resigned as the auditor for Generex Biotechnology Corporation. Effective May 31, 2019, we engaged Mazars USA LLP ("Mazars") to serve as the independent public accountants to audit our financial statements for the fiscal year ending July 31, 2019.

MNP’s reports on our financial statements for the fiscal years ended July 31, 2018 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles, except that MNP’s reports on our financial statements for the fiscal years ended July 31, 2018 and July 31, 2017 did contain an explanatory paragraph regarding their substantial doubt as to our ability to continue as a going concern, and the lack of any adjustments to the financial statements that might result from that circumstance.

During our past two fiscal years and the interim period through May 6, 2019, we had no disagreements with MNP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to MNP’s satisfaction, would have caused MNP to make reference to the subject matter of the disagreement in connection with its report.

During our past two fiscal years and the interim period through May 6, 2019 MNP did not advise us of any of the matters specified in Item 304(a)(v) of Regulation S-K, except as follows:

MNP advised management of material weaknesses in internal controls during its review of our financial statements for the second quarter ended January 31, 2019. The internal control deficiencies were disclosed and detailed in Part 1, Item 4 of our 10-Q/A for that period, filed April 16, 2019. MNP discussed these issues with the Chairman of our Audit Committee. Generex has authorized MNP to respond fully to the inquiries of any successor accountant retained by Generex regarding these issues.

Item 9A. Controls and Procedures.

Preliminary Note

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.
We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

**Evaluation of Disclosure Controls and Procedures**

Regulations under the Securities Exchange Act of 1934 (the “Exchange Act”) require public companies to maintain “disclosure controls and procedures,” which are defined as controls and other procedures that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

**MANAGEMENT’S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Management of the Company is responsible for the preparation of the financial statements and related financial information appearing in this Annual Report on Form 10-K. The financial statements and notes have been prepared in conformity with U.S. GAAP. The management of the Company is also responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. A company’s internal control over financial reporting is defined as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

During the period ended January 31, 2019, the Company issued a restatement of the form 10-Q for that period. After investigation and inquiry, the company implemented new procedures designed to prevent the circumstances from arising in the future, which was previously disclosed and publicity available on EDGAR. The company believes that the primary increase in acquisition activities which resulted in a temporary gap of accounting resources. Immediately following this occurrence, the Company implemented additional procedures designed to accelerate the tempo of upwardly reporting subsidiaries and the visibility of receipt of reports by the parent company, plus recently hired of a corporate controller and increased its outsourced financial reporting accounting services to enhance the controls and financial reporting process.

As of July 31, 2019, 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, our disclosure controls and procedures were not effective due to the existence of several significant deficiencies culminating in material weaknesses in our internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, lack of a centralized accounting system, as well as the financial reporting of such transactions.

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We have been working and are currently working to remediate the material weaknesses described above, including assessing the need for additional remediation steps and implementing additional measures to remediate the underlying causes that gave rise to the material weaknesses by (i) adding additional personnel in the future when working capital permits; (ii) implementing a new centralized accounting system to provide cohesion across the enterprise and standardize the close process across all subsidiaries; (iii) working with our independent registered public accounting firm to refine our internal procedures; and (iv) performing a complete review of its internal controls during 2020.

We believe we have taken appropriate and reasonable steps to make the necessary improvements to remediate these internal control 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.

To address these internal control deficiencies, management performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to the rules of the Commission that permit us to provide only management’s report in this Annual Report on Form 10-K.

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 10. Directors, Executive Officers and Corporate Governance.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joseph Moscato</td>
<td>CEO, President and Chairman of the Board</td>
<td>56</td>
</tr>
<tr>
<td>Andrew Ro</td>
<td>Chief Investment Officer, Director</td>
<td>49</td>
</tr>
<tr>
<td>Mark Corrao</td>
<td>Chief Financial Officer, Treasurer</td>
<td>61</td>
</tr>
<tr>
<td>Terry Thompson</td>
<td>Chief Operating Officer</td>
<td>61</td>
</tr>
<tr>
<td>Anthony Crisci, Esq., CPA</td>
<td>Chief Legal Officer</td>
<td>49</td>
</tr>
<tr>
<td>Richard Purcell</td>
<td>Executive Vice President of Research &amp; Drug Development</td>
<td>59</td>
</tr>
<tr>
<td>Dr. Jason Terrell, MD</td>
<td>Chief Scientific Officer</td>
<td>38</td>
</tr>
<tr>
<td>Dr. Craig Eagle, MD</td>
<td>Independent Director</td>
<td>57</td>
</tr>
<tr>
<td>Brian T. McGee</td>
<td>Independent Director</td>
<td>58</td>
</tr>
<tr>
<td>Dr. James H. Anderson Jr., MD</td>
<td>Independent Director</td>
<td>69</td>
</tr>
<tr>
<td>Lawrence Salvo</td>
<td>Director</td>
<td>67</td>
</tr>
<tr>
<td>Omar Gzouli</td>
<td>Independent Director</td>
<td>45</td>
</tr>
<tr>
<td>Mark Prieletti</td>
<td>Interim Independent Director</td>
<td>68</td>
</tr>
</tbody>
</table>

Directors are currently appointed for a one-year term, which will be ratified to a three year term at the upcoming annual meeting.

**Joseph Moscato.** Mr. Moscato, 59, has served as our Chief Executive Officer, President, and Chairman of the Board since January 2017.

Mr. Moscato has over 30 years of experience in healthcare, sales and marketing, distribution management, and finance. Mr. Moscato brings his marketing and advertising acumen to drug discovery and diagnostic & treatment development and commercialization. Since 2009, Mr. Moscato has been working as an exclusive consultant to the Company. Mr. Moscato has originated and negotiated several licensing deals with the top biopharmaceutical companies; has advised on equity financings totaling over $300 million, and has implemented the broad strategic vision for the Company. Mr. Moscato has worked and consulted for Pfizer in several capacities from sales and marketing to new drug discovery & development for licensing. He has worked with other biopharmaceutical companies such as GlaxoSmithKline, Johnson & Johnson, Parke-Davis, Amgen and others. Mr. Moscato has consulted for several healthcare focused private equity, hedge funds and family offices.

Mr. Moscato also owned several advertising and marketing agencies focused on media, entertainment, and healthcare with clients ranging from Motorola, Chadmoore Wireless, Nextel, Cannon, Sharp, GlaxoSmithKline, Pfizer, and other biopharmaceutical companies. Mr. Moscato’s agency was acquired by William Douglas McAdams, one of the largest independent healthcare advertising and marketing agencies.

**Terry Thompson.** Mr. Thompson, 61, has been serving as our Chief Operating Officer from January 2018.

From December 2018, he also has been serving as President of NuGenerex Distribution Solutions. Prior to this, Mr. Thompson served as a private consultant to his private equity partners and investors providing analysis, strategic business development, and due diligence on targeted companies primarily but not limited to health care. Mr. Thompson spent a long career in significant positions for companies including start-up Federal Express Corporation, National Pharmacies, Medco Containment Services, Synetic, Inc., Merck- Medco, Inc., Merit Behavioral Care Corporation, Medical Logistics, Inc., Treasure Coast Ventures, LLC, Closer Healthcare, Inc. Mr. Thompson graduated from the University of Memphis.
Anthony S. Crisci, Esq., C.P.A. Mr. Crisci, 49, has served as our Chief Legal Officer since August 2019.

Anthony S. Crisci, Esq., C.P.A. is an attorney and certified public accountant with over twenty (20) years of experience in tax, accounting, finance, corporate, health care and employee benefit matters. Mr. Crisci has built a stellar career as a business legal executive across a number of regulated industries.

Mr. Crisci has served as our Chief Legal Officer since August 2019; prior he was Corporate Counsel for Generex and remains as the Chief Administrative Officer and Chief Legal Counsel for Generex’s wholly owned subsidiary, NuGenerex Distribution Solutions, where he oversees business, accounting, and legal matters for NuGenerex’s distribution enterprise. Most recently, Mr. Crisci was General Counsel, COO, CFO, and Controller for a publicly traded holding company, specializing in financial services and technology software companies. Previously, he served as Corporate Counsel for a major health system with $1 Billion in annual revenues, and General Counsel for a National Pharmacy Benefit Management Company that includes mail and specialty drug dispensing.

Mr. Crisci brings a broad range of capabilities with his legal, business, financial, and regulatory background, and his expertise is instrumental in the execution of Generex’s strategic objectives, including mergers & acquisitions, joint venture and development agreements, in-licensing and out-licensing agreements, and most importantly, long term supply and distributorship agreements for nation-wide pharmacy, laboratory, and medical management services. Mr. Crisci holds a Bachelor of Business Administration degree in Accounting from Hofstra University and a Juris Doctor degree, with distinction, from Hofstra University School of Law. He is a licensed CPA and a Member of the New York State and New Jersey State Bar Associations.

Andrew Ro. Mr. Ro has served as our Chief Investment Officer and a Director since January 2017.

Mr. Ro has over 25 years of experience in the financial markets ranging from trading global futures and equity markets, senior secured debt, convertible securities, private investments in public equities (PIPEs) and investing. From 2012 to 2017, Mr. Ro was a consultant and advisor involved in developing strategies in specialty finance for healthcare, technology, real estate, media, entertainment, energy and project financing. From 2008 to 2012, Mr. Ro was a consultant and registered representative with boutique investment and merchant banks where he consulted and advised US and international companies on capital markets, operational, and regulatory issues as well as being involved in capital raising, mergers & acquisitions, and strategic implementation. From 2002 to 2008, Mr. Ro was a Partner with an active Investment Fund where he was involved in originating, structuring, negotiating and closing financing transactions providing growth capital, acquisition financing, recapitalization, restructuring and general working capital to late-stage venture, distressed and middle market companies across all industries and sectors. Mr. Ro originated and structured over $2 billion in total commitments and managed a portfolio of over $650 million in investments. Previously, Mr. Ro was a trader involved in trading financial and non-financial derivatives where he eventually developed a FinTech platform for trading futures and commodities. Mr. Ro graduated from George Mason University with a Bachelor of Science in Economics. He also held Series 3, Series 7, and Series 63 licenses.

Mark Corrao. Mr. Corrao has served as our Chief Financial Officer, Treasurer since January 2017.

Mr. Corrao has experience in financial management with a proven track record of raising capital and extraordinary bottom line management. He has been involved in the initial registration of numerous public companies and subsequent SEC quarterly and annual reporting and has developed, authored and presented numerous business plans and models inclusive of budgets, forecasts, cash flow, cash management and investment strategies. From 2012 to present he has affiliated with The Mariner Group LLC, which merged with the CFO Squad, creating a much larger and diverse multi-talented organization. The CFO Squad is a financial and business advisory firm providing outsourced and part-time CFO services for emerging to midsized companies (both private and public) in a wide range of businesses and industries. He is the Chief Financial Officer for a pharmaceutical company specializing in the research and development of novel and new therapeutic agents designed to reduce oxidative stress and act as immune modulators and Neuroprotectants. From 2010-12, he served as Chief Financial Officer of New York Business Efficiency Experts, Inc. which provides professional services in the financial areas of accounting, taxation, auditing, venture capital and SEC registrations (reporting). He served as a Director and Chief Financial Officer for a manufacturer of proprietary software for the prevention of identity theft and the protection of computer systems from unauthorized access. Additionally, Mr. Corrao is currently the CFO for a software company.
Richard Purcell. Mr. Purcell has served as our Executive Vice-President of Research & Drug Development since January 2017.

Since 2005, Mr. Purcell has managed a consulting practice, DNA Healthlink, Inc. advising emerging biopharmaceutical and technology companies on new business strategy, operations management, and clinical development of novel compounds. Since January 2017, he has served as the Senior Vice President of Research and Drug Development for Generex, active in strategic planning, business development, clinical operations, R&D, and M&A. Through DNA Healthlink, Mr. Purcell has been the SVP of R&D for RespireRx Pharmaceuticals since 2014. From 2011 to 2017, Mr. Purcell was the President and founder of a Healthcare IT startup, IntelliSanté. Mr. Purcell graduated with a degree in Biochemical Sciences from Princeton University, and attended Rutgers Graduate School of Management majoring in marketing and finance. He is also an Adjunct Professor of Biology at Monmouth University.

Dr. Jason B. Terrell, MD. Dr. Terrell has served as the Company’s Chief Scientific Officer and Chief Medical Officer since January 2017.

Dr. Terrell is the Chief Scientific Officer and Chief Medical Officer of Generex, providing scientific and medical due diligence for partnerships and mergers/acquisitions, and providing clinical oversight for subsidiary operations and product development strategies. Since 2017, he has also served as Assistant Clinical Professor of Oncology, University of Texas at Austin Dell Medical School as an industry and clinical expert advisor to researchers, innovators, and entrepreneurs for accelerating the translation of innovations to health products for Texas Health Catalyst. Since 2017, he has also been Lead Independent Director and Non-Executive Chairman of Kiromatic Biopharma Inc, providing guidance for corporate formation, business development, product development and commercialization strategies. Since 2016, Dr. Terrell has served as CEO and Chief Medical Officer for Volition America Inc. From 2010 to 2015 he was Corporate Medical Director for AnyLabTestNow, Dr. Terrell is a summa cum laude graduate from Hardin-Simmons University with a degree in Biochemistry. He graduated as recipient of the Holland Medal of Honor for the top graduate in the School of Science and Mathematics. Dr. Terrell was honored with the Hardin-Simmons University Outstanding Young Alumni Award and currently serves on the University’s Board of Development. Dr. Terrell attended The University of Texas School of Medicine in Houston and received General Medicine Internship and Pathology Residency training at the Texas Tech University Health Sciences Center.

Dr. Craig Eagle, MD. Dr. Eagle serves as an independent Director.

Dr. Eagle is currently the Vice President of Medical Affairs Oncology, Genentech where he oversees the medical programs across the oncology portfolio. Prior to his current role, Dr Eagle worked at Pfizer in several positions including as the oncology business lead in United Kingdom and Canada delivering significant business growth. Previously, Dr Eagle was the global lead for Oncology Strategic Alliances and Partnerships based in New York at Pfizer Inc. and was involved in multiple deals on both the sell and buy side. Dr Eagle started work in Pfizer New York as the global head of the Oncology Therapeutic Area Global Medical and Outcomes Group for Pfizer, including the US oncology business, in this role he oversaw an extensive oncology clinical trial program, health outcomes assessments and scientific collaborations with key global research organizations like the National Cancer Institute (NCI), and EORTC. As part of this role Dr Eagle lead the worldwide development of several compounds including celecoxib, aromasin, irinotecan, dalteparin and ozagomicin, Concurrently Dr. Eagle has been a Member of Scientific Advisory Board at Generex Biotechnology Corp. since August 2010. He has served on the scientific advisory committee and board of directors for several start up biotechnology companies.

Dr. 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, Dr. Eagle performed basic research at the Royal Prince of Wales hospital to develop a new monoclonal antibody to inhibit platelets.
Mr. Gzouli serves as an interim independent Director.

Mr. Gzouli was appointed as the Company’s new independent interim director on April 3, 2019. Mr. Gzouli is a global finance executive with a distinguished investment banking career in New York and London. Currently, he is a Partner and Portfolio Manager at Rokos Capital Management, London, UK where he has built the global equity and equity derivatives platform and manages an equity-focused portfolio. Previously, Mr. Gzouli was Managing Director, Equity Derivatives at Barclays Investment Bank, London, UK where he was Global Head of Trading for the Equity and Funds Structured markets unit (EFS), an £800mm a year global business. In his time at Barclays, he was also Head of Equity Financing for Europe and Asia. Mr. Gzouli started his investment banking career at Lehman Brothers/Barclays Investment Bank in New York, NY where he became Managing Director of Equity Derivatives after heading the U.S. Structured Product Trading Desk. Mr. Gzouli earned a Diplome d'Ingénieur in Applied Mathematics from Ecole Centrale Paris, where he was awarded the Moroccan Merit Scholarship. He received his Master of Science degree in Operations Research from the MIT Sloan School of Management. Mr. Gzouli provides the Generex board with broad expertise in finance and global markets.

Dr. James H. Anderson, Jr., MD. Dr. Anderson serves as an independent Director.

Dr. Anderson has served as Director of the Company since June 2011. Dr. Anderson has previously served as Chairman of the Corporate Governance and Nominating Committee and a member of the Generex Compensation and Audit Committees 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 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.

Mr. McGee serves as an independent Director.

Dr. Anderson has served as Director of the Company since June 2011. Dr. Anderson has previously served as Chairman of the Corporate Governance and Nominating Committee and a member of the Generex Compensation and Audit Committees 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 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.

Brian T. McGee. Mr. McGee serves as an independent Director.

Mr. McGee has served as director of Generex since 2004. Mr. McGee has served as Chairman of the Generex Audit Committee and a member of the Generex Compensation and Corporate Governance and Nominating Committees. 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.
Lawrence Salvo. Mr. Salvo served as Director. Previously he was Generex Executive VP of Diagnostics and President of Hema Diagnostic Systems until March 2017, and therefore is not independent.

Mr. Salvo is the founder of Hema Diagnostic Systems which grew out of the predecessor company, International Diagnostics and Medical Supply. In his role at NGDx (formerly “HDS”), he was directly responsible for all international negotiations, applications, and approvals from the World Health Organization (WHO). Since selling HDS to Generex, Mr. Salvo has been an active member of the Generex board, and has engaged in external consulting activities, primarily in international development. He is a graduate from St. Vincent de Paul Major Seminary, Boynton Beach, Florida.

Mark Prioletti. Mr. Prioletti serves as an interim independent Director.

Mr. Prioletti was appointed as the Company’s new independent interim director on April 3, 2019. Mr. Prioletti is a highly experienced marketing and business professional with over 35 years of success in the wireless communications industry for government, enterprise, and consumer segments in both the US and International markets. Mr. Prioletti had a distinguished career at Motorola, leading Channel Marketing & Sales, New Program Development, Partnership and Alliance Development to vastly expand the Motorola sales operations, which continually generated profitable revenue and growth for both emerging markets and mature businesses. Mr. Prioletti graduated with a BA in Marketing Communications and a minor in Journalism from the University of Detroit. Mr. Prioletti served on the board for the International Wireless Communications Association from 2000-2011.

Family Relationships

There are no family relationships among the officers and directors, nor are there any arrangements or understanding between any of the Directors or Officers of our Company or any other person pursuant to which any Officer or Director was or is to be selected as an officer or director.

Involvement in Certain Legal Proceedings

During the past ten years, none of our directors, executive officers, promoters, control persons, or nominees has been:

- the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or any Federal or State authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law;
- the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of (a) any Federal or State securities or commodities law or regulation; (b) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or (c) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a) (26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.
Delinquent §16 (a) Reports
The Friends of Generex Biotechnology Investment Trust did not report a beneficial ownership on Form 3 upon the creation of the Trust in April 2019, and three Form 4s. The trustee of the Trust is the CEO of the Company and is statutorily a beneficiary 17 CFR §240.16a-8. The Trust is scheduled to retire the shares shortly.

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.

Corporate Governance

Nominating Committee
We do not have a standing Nominating Committee. Nominating functions are performed by the full Board of Directors. No material changes to the procedures by which the security holders may recommend nominations to the company’s board have taken place during fiscal 2019.

Compensation Committee
Our Compensation Committee was dormant for a number of years due to our financial inability to provide compensation. We have recently reconstituted our Compensation Committee with Dr. Anderson and Mr. McGee as its members.

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. 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.
Generex has a separately designated standing audit committee consisting of Messrs. McGee, as chairman, and Ro. 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.

**Item 11. Executive Compensation.**

*Compensation, Discussion & Analysis*

**Compensation Philosophy**

In fiscal 2018 and fiscal 2019, due to limited resources, we only paid a small amount of cash bonus compensation to certain executive officers, in no way reflective of market rates or value of services. The following discussion of our philosophy assumes we have the resources to follow that philosophy.

The Company focuses on research, development, and commercialization of our medical services and administration. In addition to our existing businesses, our strategic plan is to acquire full ownership, or controlling interests, in companies with promising pharmaceutical and related products in development.

Our future depends on the ability of our executives to obtain necessary regulatory approvals to launch products in key markets such as the United States, Canada, and Europe, as well as furthering the development of products in our pipeline through the clinical trial and regulatory processes. Attracting, retaining, and motivating key executives who can lead Generex through these processes 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 policy making executives. We refer herein to these executives as the “named executives.” In prior years, before our recent change in management, we identified our President and Chief Executive Officer, Chief Operating Officer and Chief Financial Officer as our named executives. We expect to reassess this when our Compensation Committee is fully reconstituted.

In addition to the compensation of our named executives, the Compensation Committee also reviews and approves the compensation of members of our senior management.

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 with limited revenues to a fully 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 2019, the Compensation Committee did not implement any changes to base salaries for any of the named executives.

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, 2019, 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 financial position of the Company, the Committee did not follow such a schedule in fiscal 2019, as there were no salary changes. One set of equity options was awarded but not reviewed by the Compensation Committee. Because of the Company’s financial position, no increases were made to base salary and no salaries were paid, with only small bonuses being paid to certain officers in fiscal 2017, 2018 and fiscal 2019.

**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.
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 whether any bonuses are paid to the named executives, the amounts of any such bonuses, and the form of any such bonuses. Due to lack of capital resources, the company has not made long term commitments to any of our key personnel and has used bonuses to retain and motivate key personnel, except for two employment agreements with executive personnel.

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, the Amended and Restated 2006 Stock Plan, and a 2017 Stock Compensation Plan, which allows grants of stock. We account for Stock-Based Compensation under ASC 718 “Compensation – Stock Compensation”, which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services, with a primary focus on transactions in which an entity obtains employee services in share-based payment transactions. ASC 718 requires measurement of the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. Incremental compensation costs arising from subsequent modifications of awards after the grant date must be recognized.

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 2019, 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 2019, no employment agreements, plans or arrangements were effective, with any of our named executives whether written or unwritten, relating to compensation, termination of employment or a change in control. There are no benefits currently made available to our named executives which are in addition to benefits available generally to salaried employees.

Subsequent to the end of fiscal 2019, we entered into employment agreements with certain officers which provide for cash compensation as well as significant equity awards and incentives.
**Other Benefit Plans**

We have no defined benefit or actuarial pension plans.

Certain officers held options at the end of fiscal 2019 under the 2017 stock compensation plan, as noted in the accompanying tables. 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.

Under the 2017 Plan, in the event a plan participant is terminated without cause, or the participant terminates his or her employment for good reason, options and restricted stock that is still outstanding following a change in control shall become fully vested and exercisable with all restrictions lapsed.

**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.

**Summary Compensation Table**

<table>
<thead>
<tr>
<th>Name &amp; Principal Position</th>
<th>Year</th>
<th>Salary</th>
<th>Bonus</th>
<th>Stock Awards</th>
<th>Option Awards</th>
<th>Non-Equity Incentive Plan Compensation</th>
<th>Non-Qualified Deferred Compensation Earnings</th>
<th>All Other Compensation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joseph Moscato, CEO, President and Chairman of the Board</td>
<td>2016-2017</td>
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<td>Terry Thompson, COO</td>
<td>2016-2017</td>
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<td>2019</td>
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<td>Anthony S. Crisci, CLO</td>
<td>2016-2017</td>
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<td>2018-2019</td>
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<td>$822,039</td>
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<td>Mark Corrao</td>
<td>2016-2017</td>
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<td>$10,000</td>
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<td></td>
<td>2018</td>
<td>—</td>
<td>$40,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>$40,000</td>
</tr>
<tr>
<td></td>
<td>2018-2019</td>
<td>—</td>
<td>$27,540</td>
<td>—</td>
<td>$9,892</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>$37,432</td>
</tr>
<tr>
<td>Anthony J. Dolisi, Chief Commercial Officer</td>
<td>2016-2017</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>2017</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>2018</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>2018-2019</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>$819,825</td>
</tr>
</tbody>
</table>

126
### OUTSTANDING EQUITY AWARDS AT JULY 31, 2019

#### OPTION AWARDS

<table>
<thead>
<tr>
<th>Name</th>
<th>Number of Securities Underlying Unexercised Options (#)</th>
<th>Exercisable</th>
<th>Unexercisable</th>
<th>Option Exercise Price ($)</th>
<th>Option Expiration Date</th>
<th>Number of Shares or Units of Stock Underlying Unexercised Options (#)</th>
<th>Number of Shares or Units of Stock That Have Not Vested</th>
<th>Market Value of Shares, Units or Other Rights That Have Not Vested ($)</th>
<th>Number of Shares, Units or Other Rights That Have Not Vested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joseph Moscato</td>
<td>140,000</td>
<td>280,000</td>
<td>-</td>
<td>$0.11</td>
<td>10/03/2028</td>
<td>250,000</td>
<td>500,000</td>
<td>$0.64</td>
<td>1/1/2028</td>
</tr>
<tr>
<td>Terry Thompson</td>
<td>859,375</td>
<td>-</td>
<td>-</td>
<td>$0.64</td>
<td>11/01/2028</td>
<td>350,000</td>
<td>-</td>
<td>$0.78</td>
<td>12/12/2028</td>
</tr>
<tr>
<td>Anthony S. Crisci</td>
<td>24,500</td>
<td>49,000</td>
<td>-</td>
<td>$0.11</td>
<td>10/03/2028</td>
<td>468,750</td>
<td>-</td>
<td>$0.64</td>
<td>11/01/2028</td>
</tr>
<tr>
<td></td>
<td>100,000</td>
<td>200,000</td>
<td>-</td>
<td>$0.78</td>
<td>12/12/2028</td>
<td>262,500</td>
<td>-</td>
<td>$1.02</td>
<td>12/12/2028</td>
</tr>
<tr>
<td>Mark Corrao</td>
<td>31,500</td>
<td>63,000</td>
<td>-</td>
<td>$0.11</td>
<td>10/03/2028</td>
<td>-</td>
<td>-</td>
<td>$0.11</td>
<td>10/03/2028</td>
</tr>
<tr>
<td>Anthony J. Dolisi</td>
<td>315,000</td>
<td>-</td>
<td>-</td>
<td>$1.02</td>
<td>05/30/2024</td>
<td>500,000</td>
<td>-</td>
<td>$1.02</td>
<td>05/30/2024</td>
</tr>
</tbody>
</table>

None of our officers exercised options in the fiscal year ended July 31, 2019

### DIRECTOR COMPENSATION

<table>
<thead>
<tr>
<th>Name</th>
<th>Fees Earned or Paid in Cash ($)</th>
<th>Option Awards ($)</th>
<th>Non-Equity Incentive Plan Compensation ($)</th>
<th>Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)</th>
<th>All Other Compensation ($)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrew Ro</td>
<td>$22,000</td>
<td>$2,198</td>
<td></td>
<td></td>
<td></td>
<td>$24,198</td>
</tr>
<tr>
<td>Dr. Gary Lyman*</td>
<td></td>
<td>$2,198</td>
<td></td>
<td></td>
<td></td>
<td>$2,198</td>
</tr>
<tr>
<td>Dr. Craig Eagle*</td>
<td></td>
<td>$2,198</td>
<td></td>
<td></td>
<td></td>
<td>$2,198</td>
</tr>
<tr>
<td>Brian McGee*</td>
<td></td>
<td>$2,198</td>
<td></td>
<td></td>
<td></td>
<td>$2,198</td>
</tr>
<tr>
<td>Joseph Moscato</td>
<td>$103,144</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$103,144</td>
</tr>
<tr>
<td>Lawrence Salvo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark Prioletti*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omar Gzouli*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Indicates Independent Director

1 Indicates interim appointment
In Fiscal 2019, the Compensation Committee, whose members are Independent Directors Brian McGee, CPA, and Dr. James Anderson, and is assisted by executive personnel to compile the respective data upon which to base decisions, and then bring the results and recommendations to the Board at large, did not meet.


Security Ownership of Certain Beneficial Holders and Management

The table on the following pages sets forth information regarding the beneficial ownership of the common stock by (i) our directors and named executive officers (including persons who served as principal executive officer and principal financial officer during a portion of the fiscal year ended July 31, 2019) and all the named executives and directors as a group and (ii) any other person or group that to our knowledge beneficially owns more than five percent of our outstanding shares of common stock.

The information contained in this table is as of September 20, 2019. At that date, we had 44,065,032 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.

<table>
<thead>
<tr>
<th>Name of Beneficial Owner</th>
<th>Number of Shares</th>
<th>Percent of Class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Named Executives, Directors and Nominees</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joseph Moscato</td>
<td>3,432,000</td>
<td>5.38%</td>
</tr>
<tr>
<td>Brian T. McGee (1)</td>
<td>28,820</td>
<td>*</td>
</tr>
<tr>
<td>James Anderson (2)</td>
<td>21,000</td>
<td>*</td>
</tr>
<tr>
<td>Lawrence Salvo</td>
<td>3,354,645</td>
<td>5.6%</td>
</tr>
<tr>
<td>Andrew Ro (3)</td>
<td>94,500</td>
<td>*</td>
</tr>
<tr>
<td>Richard Purcell (4)</td>
<td>169,000</td>
<td>*</td>
</tr>
<tr>
<td>Jason Terrell (5)</td>
<td>169,000</td>
<td>*</td>
</tr>
<tr>
<td>Mark Corrao (6)</td>
<td>94,500</td>
<td>*</td>
</tr>
<tr>
<td>Craig Eagle (7)</td>
<td>21,000</td>
<td>*</td>
</tr>
<tr>
<td>Terry Thompson (8)</td>
<td>2,029,375</td>
<td>3.4%</td>
</tr>
<tr>
<td><strong>Named Executives and Directors as a group 9 persons</strong></td>
<td>9,323,840</td>
<td>15.5%</td>
</tr>
<tr>
<td><strong>Other Holders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BH-Sanford, LLC</td>
<td>25,200,000</td>
<td>41.8%</td>
</tr>
<tr>
<td>Stephen Berkman (9)</td>
<td>20,979,882</td>
<td>27.9%</td>
</tr>
</tbody>
</table>

(1) Includes options for 23,100 shares issued under various Company stock option and equity plans.
(2) Consists of options for 21,000 shares issued under various Company stock option and equity plans.
(3) Consists of options for 94,500 shares issued under various Company stock option and equity plans.
(4) Consists of options for 169,000 shares issued under various Company stock option and equity plans.
(5) Consists of options for 169,000 shares issued under various Company stock option and equity plans.
(6) Consists of options for 94,500 shares issued under various Company stock option and equity plans.
(7) Consists of options for 21,000 shares issued under various Company stock option and equity plans.
(8) Consists of options for 2,029,375 shares issued under various Company stock option and equity plans.
(9) Includes a warrant exercisable for 15,000,000 shares.
Item 13. Certain Relationships and Related Transactions, and Director Independence.

**CFO Squad**

The CFO Squad, LLC, provides accounting and financial services to the Company. Our CFO, Mark Corrao, is an advisor to CFO Squad. CFO Squad was paid $174,000 for accounting and financial services provided to the Company in Fiscal 2019.

**Director Independence**

The Board of Directors currently consists of eight members, five of whom are “independent” as defined under applicable rules of the SEC and The NASDAQ Stock Market LLC.

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 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, with the exception of the Audit Committee who performed maintenance activities on extraordinary items such as the restatement of the 10-Q for the period ended January 31, 2019.
Item 14. Principal Accounting Fees and Services.

Mazars USA LLP ("Mazars") has served as our independent auditors since May 31, 2019. The appointment of Mazars as our independent public accountants was unanimously approved by the Audit Committee and our Board of Directors. Mazars is the successor to our former independent auditors, MNP LLP ("MNP"). MNP served as our independent auditors from June 1, 2013 until May 6, 2019.

The following table sets forth the aggregate fees paid by Generex for the fiscal years ended July 31, 2018, 2017 and 2016 to our independent auditors:

<table>
<thead>
<tr>
<th>Auditors</th>
<th>Years</th>
<th>Audit Fees</th>
<th>Audit Related Fees</th>
<th>Tax Fees</th>
<th>All Other Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mazars USA LLP</td>
<td>2018-2019</td>
<td>$255,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MNP, LLP</td>
<td>2018-2019</td>
<td>—</td>
<td>127,573</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>2017-2018</td>
<td>$161,175</td>
<td>—</td>
<td>$11,390</td>
<td>—</td>
</tr>
</tbody>
</table>

PART IV

Item 15 Exhibits and Financial Statements and Schedules.


The Consolidated financial statements include the following:
Consolidated Balance Sheets as of July 31, 2019 and 2018
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended July 31, 2019 and 2018
Consolidated Statements of Changes in Stockholders’ Deficiency for the for the Years Ended July 31, 2019 and 2018
Consolidated Statements of Cash Flows for the Years Ended July 31, 2019 and 2018

2. Financial Statement Schedule and Auditors’ Report

Schedule I - Condensed financial information of registrant

This schedule is not applicable.

Schedule II - Valuation and qualifying accounts

<table>
<thead>
<tr>
<th></th>
<th>Balance at Beginning Of Period</th>
<th>Additions Charged To Expenses</th>
<th>Other Additions</th>
<th>Deductions</th>
<th>Balance at End of Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year ended July 31, 2019 Valuation Allowance on Deferred Tax Asset</td>
<td>$61,712,829</td>
<td>$5,537,182</td>
<td>$1,044,277</td>
<td>—</td>
<td>$68,294,288</td>
</tr>
<tr>
<td>Year ended July 31, 2018 Valuation Allowance on Deferred Tax Asset</td>
<td>$92,560,537</td>
<td>$1,452,823</td>
<td>—</td>
<td>$(32,300,531)</td>
<td>$61,712,829</td>
</tr>
</tbody>
</table>

The auditors’ report of Mazars USA LLP with respect to the Financial Statement Schedule information for the year ended July 31, 2019 is included with its report on our financial statements located at page 79.

The auditors’ report of MNP LLP with respect to the Financial Statement Schedule information for the year ended July 31, 2018 is included with its report on our financial statements located at page 80.

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 105 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.

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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 26 day of October 2018.

GENEREX BIOTECHNOLOGY CORPORATION

By:  /s/ Joseph Moscato
Name:Joseph Moscato
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity in Which Signed</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ Joseph Moscato</td>
<td>President and Chief Executive Officer</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Joseph Moscato</td>
<td>(Principal Executive Officer)</td>
<td></td>
</tr>
<tr>
<td>/s/ Brian T. McGee</td>
<td>Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Brian T. McGee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Andrew Ro</td>
<td>Chief Investment Officer, Senior VP of Investments, Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Andrew Ro</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Mark Prioletti</td>
<td>Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Mark Prioletti</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Craig Eagle</td>
<td>Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Craig Eagle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Lawrence Salvo</td>
<td>Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>Lawrence Salvo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ James T Anderson</td>
<td>Director</td>
<td>November 12, 2019</td>
</tr>
<tr>
<td>James T. Anderson</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CERTIFICATION

I, Joseph Moscato, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended July 31, 2019 of Generex Biotechnology Corporation;

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

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

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, 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;

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

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

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

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

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

DATE: November 12, 2019

By:/s/ Joseph Moscato
Joseph Moscato
President & Chief Executive Officer
(Principal Executive Officer)
CERTIFICATION

I, Mark Corrao, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended July 31, 2019 of Generex Biotechnology Corporation;

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

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

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, 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;

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

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

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

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

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

DATE: November 12, 2019

By: /s/ Mark Corrao
Mark Corrao
Principal Financial Officer
CERTIFICATIONS

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. ss. 1350, as adopted), Mark A. Fletcher, Chief Executive Officer, President and Principal Financial Officer of Generex Biotechnology Corporation (the "Company"), hereby certifies that, to the best of their knowledge:

1. The Company's 10-K for the fiscal year ended July 31, 2019 to which this Certification is attached as Exhibit 32 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of the period covered by the Report.

DATE: November 12, 2019

By: /s/ Joseph Moscato
Joseph Moscato
President & Chief Executive Officer
(Principal Executive Officer)

DATE: November 12, 2019

By: /s/ Mark Corrao
Mark Corrao
Chief Financial Officer
(Principal Financial Officer)