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April 30, 2020

Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
Mary Mast
Dan Gordon
100 S Street, NE
Washington, DC 20549-0213

VIA EDGAR

Re: Generex Biotechnology Corp. (the "Company")
Form 10-K for the Fiscal Year Ended July 31, 2019
Filed November 12, 2019
File No. 000-25169

Ms. Nast and Mr. Gordon:

The Company is in receipt of your correspondence dated March 25, 2020, posing comments and requesting information regarding the Form 10-K referenced above.

Please find the issuer's respective responses below, restating the Staff's comments in bold, and the Company's response in plain text. In some cases, the Staff's comments were in multiple parts, and we have responded to individual parts separately.

Form 10-K for the Fiscal Year Ended July 31, 2019
Management's Discussion and Analysis
Financial Condition, Liquidity and Resources Sources of Liquidity, page 70

1. You state that your July 31, 2019 cash position was not sufficient for 12 months of operations and that anticipated revenues associated with the Veneto acquisition are expected to dramatically alter the cash flow landscape. Given the litigation with Veneto and the uncertainty relating to the assets acquired, tell us the basis for the company's assertions.

Response: On July 31, 2019, the end of the fiscal year, the Company continued to believe that it could reorganize and rehabilitate the Veneto business so that it would provide positive cash flow. Although the acquisition included pharmacy assets and operations which ceased and reported during the measurement period as part of the amended purchase and debt restructuring, the MSO operation and anticipated cashflows are expected to be realized and increase within Generex and benefit from subsequent acquisitions and services integrated in the MSO model.

Management's Discussion and Analysis Results of Operations, page 70

2. For each significant key research and development project, provide the following to be included in future filings:

-

the costs incurred during each period presented, reconciled to your research and development on your Statements of Operations

Response:

Please see the following table of research and development costs summarized by quarter and annually:

RECONCILIATION of RESEARCH AND DEVELOPMENT COSTS	3 Months Ending 10/31/2018	3 Months Ending 1/31/2019	3 Months Ending 4/30/2019	3 Months Ending 7/31/2019	12 Months Ending 7/31/2019
NGIO (Antigen)	$ 39,000	$ 342,000	$ —	$ 30	$ 381,030
Regentys	—	306,800	331,711	131,486	769,997
NGDx (HDS)	141,067	162,138	140,299	154,351	597,855
TOTAL	$ 180,067	$ 810,938	$ 472,010	$ 285,867	$ 1,748,882

The Company undertakes to provide additional information in its future filings, beginning with its quarterly report on Form 10-Q for the quarter ending April 30, 2020 that will summarize and reflect the information below.

NGIO

- **the nature of efforts and steps necessary to complete the project,**

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.

NGIO is also sponsoring the NSABP FB-14 clinical trial protocol. Merck is contributing pembrolizumab (Keytruda) for use in combination with AE37 for the treatment of triple negative breast cancer.

Based on the results from this trial, NGIO 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 began enrolling patients in September during 2019.

In addition to the breast cancer program, NGIO 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.

- **reasons for significant increases or decreases in research and development from period to period,**

The primary increase incurred by NGIO during the year ending July 31, 2019 was related the initial payment of $340,000 to NSABP Foundation Inc. (“NSABP”) for the Clinical Trial Agreement for the start-up activities of the Phase II Study, paid during the quarter ending January 31, 2020.

- **expected future increases or decreases in research and development,**

As the clinical trial continues, NGIO will be obligated to pay NSABP, pursuant to the Clinical Trial Agreement, additional amounts during each completed phase in the increments and at the times set forth in the agreement in four primary phases: Start-Up Activities, Accrual and Treatment Period, Follow-up Period and Primary Endpoint.

In addition, Generex and through NGIO have been working to develop a peptide vaccine against the new coronavirus SARS-CoV-2 using the company's proprietary and patented Ii-Key immune system activation technology. We have built our technology to assist third party groups and government agencies in their evaluation of potential vaccines against this pandemic SARS-CoV-2 virus.

The patented NuGenerex Immuno-Oncology (Formerly Antigen Express) Ii-Key technology uses synthetic peptides that mimic essential protein regions from a virus that are chemically linked to the 4-amino acid Ii-Key to ensure robust immune system activation. In particular, the Ii-Key ensures potent activation of CD4+ T cells, which in turn facilitates antibody production to ward off infection. This Ii-Key modification can be applied to any protein fragment of any pathogen to increase the potency of immune stimulation.

Generex is working with our partners at EpiVax who have identified such protein fragments or epitopes to generate Ii-Key-SARS 2 peptide vaccines in collaboration with our peptide manufacturing partners. The peptides and Ii-Key are made from naturally occurring amino acids, ensuring an excellent safety profile for Ii-Key peptide vaccines.

- **the risks and uncertainties associated with completing development,**

There is always uncertainty and risk associated with the development of any vaccine, medical treatment or therapy, but the continued development depends upon the completing the trials under various collaboration agreements and associated potential commercialization of the product, FDA approval and/or licensing agreements. 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. During the pandemic COVID-19, it is anticipated that delays will occur, but the full impact of any slow down due to COVID-19 has not been determined.

- **the extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project, and**

With respect to the NSABP FB-14 clinical trial, Merck is not contributing financial support; NGIO is funding the conduct of the trial through NSABP and a collaboration and licensing agreement with Shenzhen Bioscien Pharmaceuticals Co. Ltd. ("Shenzhen") for the rights to China. This trial is expected to continue without further funding by Generex. All the funding for trial is being contributed by Shenzhen. All Clinical Data shall be jointly owned by NGIO and Merck.

In exchange for exclusive rights to AE37 for prostate cancer in China, Shenzen 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 NGIO retaining the rights to all clinical data for regulatory submissions and commercialization in the rest of the world outside China. This trial continue for the duration of the Phase II combination trial of AE37 plus pembrolizumab in patients with triple negative breast cancer. NGIO has also sign a Pharmacovigilance Agreement among Merck, NSABP and NGIO to ensure the clinical monitoring of the trial.

The funding for the development of a vaccine of SARS-CoV-2 virus is in advanced discussions and currently expected that the development costs will be borne by the U.S. and foreign government agencies and without additional external funding, Generex will not pursue these projects.

- **your estimate of the date of completion of any future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency.**

Except for the development of a vaccine of SARS-CoV-2 virus, the other trials being conducted with NSABP and Merck with Shenzhen are multi-year studies. The FDA approved our Ii-Key peptide vaccine, AE37 (Ii-Key-HER2/neu) for Phase 1 and Phase II clinical trials without requiring additional animal studies.

With respect to the SARS-CoV-2 vaccine, our plan to make a targeted vaccine that produces a complete immune response that neutralizes the virus. We will work with the FDA to approve an IND for the Ii-Key-SARS-COV-2 vaccine candidate to quickly enter clinical trials with a rapid assessment of safety and immunogenicity with the first trial starting as early as July 2020. Based on the results of this initial safety and immunogenicity study, we propose a pivotal healthcare worker clinical trial in the fall of 2020 as well as trials in special populations to continue assessing the safety and efficacy data required for licensure. Manufacturing is major advantage for the Ii-Key-SARS-CoV-2 vaccine, because is a synthetic peptide that can be readily scaled. Generex and our commercial manufacturing partners will be positioned to begin delivery of up to 100 million doses (100 Kg) of vaccine starting in the fall of 2020.

Regentys

- **the nature of efforts and steps necessary to complete the project,**

Regentys is developing ECMH™ Rectal Solution, an extracellular matrix (“ECM”) hydrogel, to facilitate tissue healing in patients with inflammatory bowel diseases. Initially, the company is targeting patients with Ulcerative Colitis and thereafter, it plans to modify its products and delivery system to address patients with Crohn’s Disease, Rectal Mucositis and other similar indications.

The company’s product is categorized by the US Food and Drug Administration (“FDA”) as a medical device. This requires approval by the FDA prior to marketing or sale in the United States and by other governmental regulatory authorities in different foreign jurisdictions. Most simplistically, the process to obtain approval for similar products in the US is as follows: undertake preclinical and animal studies; assess and validate study results; draft regulatory filings to prepare for clinical trials; make manufacturing batches of the product; validate the effectiveness of the manufacturing process; scale up manufacturing for clinical trial batches, file clinical trial documentation, solicit patients, undertake a first-in-man (FIM) pilot study, adjust the product/study and protocol if required, and undertake additional pivotal studies, gather and present data and submit final regulatory applications with all the required product, manufacturing and clinical data. Thereafter, once all elements are met, permission to market and sell is granted by the regulatory authority. For FDA medical device applications that are 510(k) de novo, there is a great likelihood of approval.

In 2016 and 2017, Regentys completed promising pre-clinical and animal studies under a research and development agreement with the University of Pittsburgh. In 2018, Regentys engaged HPA, a Boston, MA-based consulting firm, to provide the company with guidance in its US FDA filing activities. In 2018, Regentys received guidance from the FDA regarding its need to file a 510(k) de novo application to position its product for clinical evaluation, commercialization and market approval the US. The clinical program Regentys is undertaking is being designed to meet FDA standards which are recognized by major industrialized countries globally with statutory regulatory clinical trial and filing adjustments to be made to account for the distinctions imposed by each country. The company expects to conduct a 20-person study and a 50-person study prior to filing its application with the US FDA.

In 2018, Regentys entered into a development agreement with Cook Biotech, Inc. (“CookBio”) a recognized global leader in the development and manufacture of extracellular matrix products. CookBio is helping Regentys to facilitate a final production version of the ECMH product, and upon completion, CookBio has agreed to manufacture the product in North America. As well, CookBio is collecting relevant product data and

building the product and manufacturing data portfolio required for submission to the FDA and other governmental entities. In 2018, the Company also entered into an agreement with Natureplex, a finished goods maker is the second largest enema manufacturer behind Fleet. The Natureplex diluent and bottles along with the Cook Bio ECM biomaterial is expected to comprise the final product kit.

During 2019, Regentys' development activities focused on scaling-up batch sizes of the product and evaluating key indicators to demonstrate conformity with the original formulae plus certain enhancements. The company achieved an almost identical version of the original formula in a scaled-up production run, but it seeks to improve on two commercial specifications. To facilitate this process, Regentys engaged Dr. Steven Badylak, DVD, MD and the McGowan Institute at the University of Pittsburgh to help with this work. Should improvements not meet all the desired commercialization parameters, Regentys has an established back-up version of its formula that will meet all indicators without the commercial enhancements.

- **reasons for significant increases or decreases in research and development from period to period,**

In 2019, Regentys contracted with Brandwood CKC, a Sydney, Australia-based global regulatory firm to assist the company with all necessary regulatory filings to conduct clinical trials and gain product approvals in jurisdictions outside of the US. The company intends to undertake a clinical trial in Australia within months of the completion of the final product. Brandwood representatives will help Regentys establish the process for the pilot clinical trial in Australia. Currently, the United States, Canada, Europe and Israel are proposed pivotal trial venues.

In 2019, Regentys finalized its clinical protocol and developed an advanced version of the Investigators Brochure. Dr. Thomas Borody, MD, a Sydney, Australia based physician with the Center for Digestive Diseases and recognized expert in GI matters, has agreed to be our principal investigator in Australia. Along with Brandwood, Dr. Borody's team will undertake a coordinated effort to manage human clinical trials and regulatory activities in Australia.

- **expected future increases or decreases in research and development,**

Our pre-2020 business plan forecasted the initiation of our first-in-human pilot clinical trial in Australia to generate data that will be used to focus later human trials and support regulatory filings. In the future, over the next several years, the development, clinical and regulatory activities and to secure approval to market and sell the initial product candidate for ulcerative colitis in the US, with approximately $7 million allocated to development activities and $8 million for clinical trial and regulatory approvals. In addition, about $15 million is also likely to be needed to develop the asset to treat Crohn's Disease and each other indication.

- **the risks and uncertainties associated with completing development,**

As will all trials, there is always uncertainty and risk associated with the development of any medical treatment or therapy, but the continued development of the trials financing and the lack of such financing is central risk to the development of a final product formulation, the conduct of human clinical trials and the receipt of regulatory approval for marketing its ECMH™ Rectal Solution.

As a condition of its licensing agreement with the University of Pittsburgh, Regentys has specific milestones to meet in its development program in 2020 or its exclusive license can be terminated. Funding is required to retain this license. Should this license be lost, Regentys would have options to develop its co-developed technology with Pittsburgh, but the company would likely have to repeat research to use a new form of hydrogel process to make its product without infringing the University of Pittsburgh's patent. This would be a substantial additional cost to Regentys and create a competitive advantage to any new holder in due course of such rights. In addition, Regentys has additional patents in process that could serve as the basis of additional regenerative medicine products in the urogenital space, but additional research and development is required. Any delay in funding could substantial delay these projects in time and increase costs.

- **the extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project, and**

In addition to the funding requirements noted above, additional funding is expected by Generex by the end of Q3 2020 to meet Regentys' present stage of development of the product, and the milestones required to successfully meet all regulatory, clinical, and manufacturing requirements to acquire regulatory approval to market and sell products.

In addition to financial capital, Regentys will require additional human resources to get its product approved and to market. More specifically, the company expects that commercial success will more readily occur with a proven strategic partner with established global and or regional sales and distribution channels. Management has made identifying and engaging an entity (or multiple entities) with a global sales and distribution footprint to facilitate its product introduction and market expected Q4 2022. Should this strategic partnering not occur, Regentys would be required to raise substantial additional monies to develop the company's resources to enable it to undertake the marketing and sale of the developed assets.

- **your estimate of the date of completion of any future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency.**

We anticipate the earliest we may expect development to be finalized is Q4 2020 and first-in-human trials to begin in Q1 2021. Accordingly, we may expect to commence sales in the US no earlier than in Q1 2023 contingent on FDA acceptance of our proposed clinical and regulatory strategy and our ability to execute this strategy. Product commercialization with a CE mark in the EU and Australia is anticipated simultaneously, or soon thereafter, contingent upon applicable approvals to market by jurisdiction and a partnering arrangement with an established European life sciences partner that has not yet been identified.

Prior to licensing products from the University of Pittsburgh, management conducted extensive due diligence on the then market trends, competitive landscape, government regulatory and compliance matters for ECM regenerative products. Management continues this monitoring activity. To date, no similar technologies to ECMH™ addressing Ulcerative Colitis and Crohn's Disease have surfaced. In fact, the market is in greater need to fill the void between current first-line therapies, like 5-ASA, steroids, and biologics, such as Humira™, and other monoclonal antibody technologies principally because ECM has shown the ability to facilitate tissue healing as opposed to simply suppressing inflammation as many other competitive products do.

The market continues to be dominated by pharmaceutical therapies for IBD treatment. While recent regulatory trends, including the FDA's effort to reform the 510(k) process, tend to raise the regulatory bar and add additional costs, therapies that show promise in treating chronic diseases such as UC and Crohn's Disease, especially those therapies providing a regenerative approach to treating the disease will be viewed favorably. Stem cell-based therapies continue to be developed, however, we are not aware of any clinical trial applications for IBD.

We are closely monitoring the use of emerging technologies to enhance the healing aspects of ECM products like ours and look to support our existing product with variations that might enhance the benefits of our products. The likelihood is that any adjustment to our initial product candidate with any such advance will only occur in the second generation of the product candidate.

NGDx (formerly HDS)

NuGenerex Diagnostics is the development of the HDS EXPRESS diagnostic technology which has been expanded with the new, patent-pending EXPRESS II technology that will create a new product pipeline.

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%.

We maintain current U.S. Certificates of Exportability that are issued by two FDA divisions-CBER and CDRH. CBER (Center for Biologicals Evaluation and Research) is the FDA regulatory division that oversees infectious disease diagnostic devices, including our HIV, Hepatitis B and Hepatitis C EXPRESS ("EXPRESS I") 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.

As a result, 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.

In addition, our HIV rapid test has been issued by the United States Agency for International Development (USAID). 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.

- **the nature of efforts and steps necessary to complete the project,**

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.

- **reasons for significant increases or decreases in research and development from period to period,**

Increases in our research and development costs for each period incurred the prior year under NGDx (HDS) was related to the development costs associated with EXPRESS I and EXPRESS II kits.

- **expected future increases or decreases in research and development,**

Additional costs and increases are expected as NGDx pursues FDA 510K approval, plus the development of additional rapid tests beyond the existing targeted infectious diseases noted above. NGDx expects to build a multi-faceted diagnostics business focused on personalized medicine. To that end, NDGx is 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 technology developed by NDGx has the potential application for many infectious diseases which will be pursued including COVID-19.

- **the risks and uncertainties associated with completing development,**

As discussed above with other products, there is always uncertainty and risk associated with the development of any medical treatment or therapy, the outcome of trials, receipt of needed FDA approvals or our ability to fund and complete the necessary research and development. During the pandemic COVID-19, it is anticipated that delays will occur, but the full impact has not been determined.

- **the extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project, and**

It is estimated that $750,000 is needed to complete clinical trials needed for the FDA 510K approval process and to develop additional Express II products for other infectious diseases.

- **your estimate of the date of completion of any future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency.**

The primary next major milestone is the FDA 510K approval which take about 18 months. This includes approximately 6 months to complete and submit the approval, plus an additional 12 months for additional clinical testing, manufacture validation to achieve final approval

Olaregen

Since acquisition, Olaregen has had no research and development costs due to the lack of additional funding necessary to conduct further R&D related to products in development.

- **the nature of efforts and steps necessary to complete the project,**

Although, Olaregen has not conducted any further research and development, since acquisition, Excellagen® became commercially viable. Excellagen possesses a FDA 510K clearance wound healing product for the treatment of 17 types of 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 became commercially viable and requires limited research and development. Olaregen's product known as Cord Products requires funding to complete additional needed research and development to remain commercially viable and competitive in order to generate future sales. Exassome requires funding to initiate research and development costs to combine Exassome and Excellagen for the development of Excellasome® to begin the initial trials.

- **reasons for significant increases or decreases in research and development from period to period,**

Due to lack of funding additional research and development related to Olaregen and its products was not conducted.

- **expected future increases or decreases in research and development,**

Additional research and development is expected for Excellagen to enhance the product to allow the product to be used in VA Hospitals that require treatments as "room temperature." Upon funding and indications from the marketplace, Olaregen's would consider further research and development on its Cord Products to enhance and create unique qualities in order to remain commercially viable and competitive combined with other marketplace indicators. Substantial research and development costs are expected for several years to develop Excellasome® as a commercially viable product beginning with its initial Phase I trial.

- **the risks and uncertainties associated with completing development,**

The product Excellagen® is complete with active sales. Without additional funding to create a viable "room temperature" product for VA Hospitals, its full potential would not realized. Excellagen has received the FDA 510K approval with 17 indications, but any additional indications and treatments will require additional funding to fully exploit Excellegen's potential including combining Excellagen with Exassome to create the viable product Excellasome®. Without additional funding, Olaregen would not be able to maintain its Cord Products as a commercially viable product needed to remain competitive and generate future sales. As discussed above with other products, there is always uncertainty and risk associated with the development of any medical treatment or therapy, the outcome of trials, receipt of needed FDA approvals or the ability to complete research with collaborators. During the pandemic COVID-19, it is anticipated that delays will occur, but the full impact has not been determined.

- **the extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project, and**

No additional resources are currently needed for Excellagen® is complete the project as has FDA 510K approval with active sales. Limited funding is required to develop the project further to create a viable "room temperature" product noted above. Excellasome® requires substantial funding and will not continue without such funding or license and collaboration agreement to conduct the needed research and development with internal funding.

- **your estimate of the date of completion of any future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency.**

Excellagen® became a viable commercial product after acquisition with active sales. A collaboration and funding to conduct a Phase I Trial of Excellasome® The would be the first of many research and development milestones to be completed over the next several years prior to any FDA approval. Currently, we are not aware of any clinical trial applications.

Consolidated Statements of Operations and Comprehensive (Loss) Income, page 82

3. The changes in fair value of contingent purchase consideration was $18,587,782 and $39,027,901 and $0 in the years ended July 31, 2019 and 2018 and three months ended October 31, 2019, respectively. [Individual Questions under #3 are repeated and responded to below].

Introductory Response: The two components contained in the amounts reported for "Contingent Consideration" relates to the acquisition of NGDx (formerly HDS) (See Table 1). At the time of the initial acquisition the Call Option and Warrants (to be issued) were valued and revalued at the end of each quarter through the final exercise date of the option and issuance date of the warrant (See Table 2). Once the call option was exercised and 100% of NGDx was acquired, there was no longer any contingent consideration as of July 31, 2019, nor any contingent consideration related to this acquisition on a going forward basis.

TABLE 1:

BALANCE SHEET COMPONENTS	FV at the time of issuance	As of July 31, 2018	As of October 31, 2018	As of January 31, 2019	As of July 31, 2019	As of October 31, 2019
Warrants To Be Issued	(66,060,026)	(24,962,507)	(4,005,240)	(9,032,486)	—	—
Call Option	4,237,829	2,168,211	756,041	1,385,780	—	—
Total Balance of Contingent Consideration	**(61,822,197)**	**(22,794,296)**	**(3,249,198)**	**(7,646,705)**	**—**	**—**

TABLE 2:

Components in the Change in FV of Purchase Consideration:	For the year ending July 31, 2018	3 Months Ending October 31, 2018	6 Months Ending January 31, 2019	Change in FV at Time of Issuance	For the year ending July 31, 2019	3 Months Ending October 31, 2019
Warrants To Be Issued	(41,097,519)	(20,957,267)	(15,930,021)	(3,440,191)	(19,370,212)	—
Call Option	2,069,618	1,412,170	782,431	—	782,431	—
Change in FV of Purchase Consideration	**(39,027,901)**	**(19,545,098)**	**(15,147,591)**	**(3,440,191)**	**(18,587,782)**	**—**

Question: **Please tell us the amount of contingent consideration at each balance sheet date and the components thereof. Also tell us your consideration of separately presenting the contingent consideration on the face of the balance sheet**.

Response: As of July 31, 2018, the individual components of the contingent consideration were included on the Balance Sheet on separate lines as an asset on the line "Call Option (Note 13),” and as a liability on the line "Warrants to be issued (Note 13)." Since both elements has been issued and/or exercised by July 31, 2019, they no longer were reflected on the balance sheets, but the details of each were fully disclosed in Note 13 as indicated on the Balance Sheet.

Question: **Clarify to us why there was no change in the fair value in the three months ended October 31, 2019 either to the contingent consideration outstanding at July 31, 2019 or the additional contingent consideration recorded in connection with the MediSource and Pantheon acquisitions as disclosed on page 22 of your October 31, 2019 10-Q**.

Response: Per 805-30-25-5, the contingent consideration was valued as of the date of acquisition. The contingent consideration did not change materially between the date of acquisition on Aug. 1, 2019 and October 31, 2019. The contingency payments based upon future earnings beginning in August 1, 2020 cannot be determined. In a future reporting period, as the payout gets closer and the expectation and realization of the payment more likely than not, then the Company will revalue the fair value of contingency consideration in a future filing. Currently, the anticipated change in fair value is estimated to increase by approximately five 5% percent per quarter.

Consolidated Statements of Changes in Stockholders' Equity, page 83

4. You state on pages 95 and 109 that in May 2019 you issued 4 million shares of common stock in exchange for 592,682 shares of Series A preferred stock of Olaregen. You also state on page 104 that in connection with the Amendment Agreement for the Veneto acquisition you delivered 8,400,000 shares on May 23, 2019.

Question or Request: **Please tell us where the issuance of shares is presented in the Statements of Changes in Stockholders' Equity**.

Response: The amounts are only reflected in the increase of Additional Paid-In Capital. Common Stock did not increase. as the shares had already been issued and held solely for the benefit of the Company by a trust held by Joe Moscato TTEE Friends of Generex Biotechnology Investment Trust U/A/D 4/2/2019, a trust formed for the benefit of Generex and any 80% controlled subsidiary of the Company ("Generex Trust"). Several major shareholders, Joseph Moscato, Lawrence Salvo, BH-Sanford, LLC and Stephen Berkman entered into a stock control agreement and together contributed 33,175,900 shares in the aggregate into the Generex Trust. Without their contribution, it would have been difficult for Generex to attract additional capital without significant dilution. Since the shares were already outstanding and only transferred from the Generex Trust to new owners, Common Stock was not affected.

In SAB topic 5T provides guidance on the accounting for an expense settled by a shareholder transferring shares to settle a litigation. The guidance states: “the value of the shares transferred should be reflected as and expense in the company’s financial statements with a corresponding cred to contributed (paid-in) capital”. We believe the recording of the shares transferred by the Friends of Generex Trust to settle the amended purchase agreement with Veneto is analogous because the amended purchase agreement was settled by a shareholder transferring shares to settle an obligation of the Company.

You issued 1,953,257 common stock for the issuance of common stock for conversion of debt and recorded $18,404,731 of additional paid-in-capital.

Question or Request: **Please provide us an analysis of the transactions, including how the amount recorded to additional paid-in capital was determined in light of your stock price at the time of the transactions**.

Response: The transactions were valued at the time of conversion, except the shares issued for the conversion of the Veneto debt. The Friends of Generex Trust transferred the shares of the Company and share of its wholly owned subsidiary NuGenerex Immuno-Oncology, Inc. to settle the Vento debt. See Table below:

TABLE: Comment 4 b - Reconciliation of "Issuance of common stock for conversion of debt"

Name	Issue Date	Number Shares	C/S	APIC	Price per Share	Total
Common Stock						

Extinguishment of Debt (Related Party)	12/03/18	32,881	$ 33	$ 624,377	$ 18.99	$ 624,410
Conversion of debt (Note)	07/08/19	205,897	206	292,374	$ 1.42	292,580
Conversion of debt (Note)	07/16/19	1,121,343	1,121	3,149,851	$ 2.81	3,150,972
Conversion of debt (Note)	07/19/19	565,000	565	853,941	$ 1.51	854,506
Conversion of debt (Note)	07/19/19	28,136	28	52,485	$ 1.87	52,513
Conversion of debt (Veneto) **	04/30/19	**	**	13,431,703	**	13,431,703
Total		**1,953,257**	**$ 1,953**	**$18,404,731**		**$18,406,684**

** Contributed from the "Generex Trust"

Question or Request: ***Also, please reconcile the transactions to the disclosure presented on page 83 and elsewhere in the filing, as applicable***.

Response: See discussion of tracing in table below.

Tracing of Statement of Changes in Stockholder's Equity

	Line Item	Column	Amount	Note
1	**Investment in subsidiary by noncontrolling interest**	Non-controlling Interest	227,245	**Note 6**
	The total of $227,245 was not specifically reported in Note 6, but separately reported as the increase in non-controlling interest related to additional contributions of NGDx was $133,679, the remaining amount of $93,567 was related to change in contributions less distributions of Class B Membership Interests in Rapport.			
2	**Conversion of preferred series H**	Preferred Stock Shares	(63,000)	**Note 6**
		Common Stock Shares	25,200,000	
		Additional Paid-in Capital	(25,197)	
	Reported under Series H and Series I Convertible Preferred Stock reported the conversion of Series H including the decrease of ($63,000) in Series H Preferred Shares and increase in Common Stock Shares of 25,200,000. The net change in par value in the amount of $25,197 between the decrease in Preferred Shares in the amount of $3.00 and the increase in par value of Common Stock Shares of $25,200 was not separately reported in Note 6, but evident on the Statement of Changes in Stockholder's Equity.			
3	**Conversion of preferred series I**	Preferred Stock Shares	(16,590)	**Note 6**
		Common Stock Shares	6,639,045	
		Additional Paid-in Capital	(6,638)	
	Reported under Series H and Series I Convertible Preferred Stock reported the sale of all the shares of Series I Preferred Shares, the issuance of 3,276,000 Commons Shares to Mr. Moscato and 3,354,645 Common Shares to Mr. Salvo for a total of 6,639,045 common shares as reported. The net change in par value in the amount of $6,638 between the decrease in Preferred Shares in the amount of $1.00 and the increase in par value of Common Stock Shares of $6,639 was not separately reported in Note 6, but evident on the Statement of Changes in Stockholder's Equity.			
4	**Exercise of call option to acquire noncontrolling interest**	Additional Paid-in Capital	(6,951,015)	**Note 6 / Note 13**
		Non-controlling Interest	5,565,285	
	In Note 13, 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. In Note 6, Non-controlling Interest - the net change of $5,565,285 was			

stated in the note, but the separate components the activity is, reconciling to the balance on the Consolidated Statement of Changes in Stockholder Equity . . .

5	**Issuance of common stock payable**	Common Stock Shares	6,068,517	**Note 6 / Note 13**
		Common Stock Payable	(1,967,657)	
		Additional Paid-in Capital	1,961,589	

In Note 6, Common Stock - the Company reported the issuance of 1,238,517 shares of common stock payable, and it was reported that on January 18, 2017 pursuant to the NGDx acquisition, the Company was obligated to issue 4,830,000 shares in a prior period issued during the year ended July 31, 2019 as noted and reported in Note 13, related to the acquisition of NGDx, the Company reported 4,830,000 of common stock. The combined total to the two components equals 6,068,517 and the Common Stock at Par Value of $6,068, but not separately reported on the Statement of Changes in Stockholder's Equity. The amount of embedded value Common Stock Payable of ($1,967,657) and Additional Paid-in Capital of $1,961,589 were not separately presented in the aggregate in Note 6.

6	**Issuance of stock options**	Additional Paid-in Capital	3,006,203	**Note 16**

The amount of $3,006,023 was not specifically mentioned, except in Note 16, Stock Option Plans - Noted a total of compensation expense of $3,000,974 for the year ended July 31, 2019. The remaining difference of $5,229 related to options issued by Regentys as part of stock compensation.

7	**Issuance of common stock for conversion of debt**	Common Stock Payable	1,953,257	**Note 9 / Note 13**
		Additional Paid-in Capital	18,404,731	

These amounts were not specifically referenced in the Notes to the Financial Statements, but the result of accumulated conversions of debt issued for acquisitions and various converted notes payable.

8	**Conversion of debt to equity**	Additional Paid-in Capital	15,176,629	Note 9 / Note 13

These amounts were not specifically referenced in the Notes to the Financial Statements, but the result of accumulated conversions of debt issued for acquisitions and various converted notes payable was reported:

1,060,000	*Note 9 – The note issued on May 25, 2018 was converted in May 2019*
187,500	*Note 9 – Pursuant to the Regentys acquisition, $187,500 was converted Reported in the Unaudited Condensed Interim Consolidated Statement of*
13,929,129	*Changes in Stockholder's Equity for the period ending April 30, 2019 as April 30, 2019 – Conversion of Debt to Equity – Veneto*
15,176,629	Total

9	**Antigen dividend**	Additional Paid-in Capital	(1,070,456)	**Note 6**
		Non-controlling Interest	1,070,456	

The amount of $1,070,456 was referenced as fair value of the shares issued for the stock dividend of NGIO shares on February 25, 2019.

10	**Issuance of warrants**	Additional Paid-in Capital	5,592,244	**Note 13**
	This amount was not specifically referenced in the Notes to the Financial Statements, but the amount represents the accumulated value of warrants issued in the Acquisition of NGIO and subsequent changes in FV related to these warrants			
11	**Acquisition of NCI of Regentys**	Non-controlling Interest	9,873,553	**Note 13**
	Fair Value of the Regentys Acquisition -- This amount was not specifically referenced in the Notes to the Financial Statements, but the fair value table, the initial fair value of the Non-Controlling Interest with respect to the Regentys Acquisition of $9,870,762 was disclosed less an additional allocation adjustment of $2,791 which was not properly footed on the table that reflected the adjusted total of 9,873,553, but this amount as reported on the Statement of Changes in Stockholder's Equity is correct.			
12	**Acquisition of NCI of Olaregen**	Non-controlling Interest	11,999,559	**Note 13**
	Fair Value of the Olaregen Acquisition -- this amount was specifically mentioned as the value of the Non-Controlling interest in the fair value table.			
13	**Acquisition of Olaregen Series A Preferred Stock**	Additional Paid-in Capital	2,520,000	**Note 6**
		Non-controlling Interest	(4,520,000)	
	Non-Controlling Interest -- Although the acquisition of the additional Series A Preferred Stock in Olaregen was disclosed, the value of the shares held in trust and issued was not mentioned or the change in the non-controlling interest.			
14	**Reclassification of equity to liability**	Common Stock Payable	(201,294)	**None**
	This amount is not referenced in the Notes to the Financial Statements.			
15	**Extinguishment of derivative liability associated with convertible notes**	Additional Paid-in Capital	1,570,174	**None**
	This amount is not referenced in the Notes to the Financial Statements.			
16	**Currency translation adjustment**	Other Comprehensive Income	(1,206)	**None**
	This amount is not referenced in the Notes to the Financial Statements, except as part of the Statement of Operations and Comprehensive (Loss) Income.			

Revenue Recognition, page 86

5. You disclose several different types of revenue streams such as product sales, pharmacy prescriptions, laboratory services, and management services. Please revise to provide the following or tell us why additional disclosure is not required:

- **disaggregated revenue recognized pursuant to ASC 606-10-50-5 and ASC 606-10-55- 89 through 55-91, including disclosure relating to geographical regions if applicable.**

Response: Revenue in fiscal 2019 resulting from the acquisition of Veneto Holdings, LLC on October 3, 2018 was approximately $6.1 million or 98% of the approximately $6.2 million in revenue recognized by the Company. The Company's other subsidiaries are clinical stage development companies with insignificant revenues in fiscal 2019. In accordance with the guidance in 606-10-50-1, the Company considered the nature, amount, timing and uncertainty of revenue and cash flows to determine the necessity of disclosure guidance contained in Topic 606. As explained in the Basis for Conclusion of ASU 2014-09, the FASB does not intend the disclosures described in the guidance to be a checklist of minimum requirements. The Company believes that further disaggregation of its revenue would not provide investors with meaningful information regarding the nature, timing, amount and uncertainty of revenue and cash flows. The Veneto pharmacy services business accounted for $6.1 million or 98% of the Company's revenue. The Company's

other subsidiaries are clinical stage development companies with insignificant revenues in fiscal 2019. (Olaregen - $68,000 and NGDx- $37,000). As disclosed in Note 1 to the consolidated financial statements, in March 2019 the Company changed its business model to no longer utilize existing pharmacies. Since that strategic shift the Veneto subsidiary has generated minimal revenue.

- **significant judgments and changes in judgments pursuant to ASC 606-10-50-17, including how variable consideration was determined for each significant revenue stream,**

Response: The majority of the Company's revenues in fiscal 2019 derived from pharmacy sales. This revenue is recognized when the prescription is dispensed. Judgement is not required to determine when this performance obligation is met by the Company. Also, there is no variable consideration associated with Pharmacy services. Finally, the nature of Pharmacy Service revenue does not result in significant contract assets or liabilities as payment is received and the time the prescription in delivered to the patient. Further, we believe that discussion of price and volume would not be a meaningful disclosure in MD&A as almost the entire change in revenue resulted from the Veneto acquisition.

- **contract balances pursuant to ASC 606-10-50-6 through 606-10-50-11, and**

Response: Finally, the nature of Pharmacy Service revenue does not result in significant contract assets or liabilities as payment is received and the time the prescription in delivered to the patient.

- **additional disclosure in Management's Discussion and Analysis quantifying each significant factor that resulted in significant changes in revenue and the extent to which the change relates to price vs. volume. Refer to item 303(a)(3) of Regulation S-K**.

Response: In the MD&A, page 70, we disclosed "The increase in revenue was generated from Veneto which was acquired during fiscal year 2019." We believe the disclosure in Management's discussion and analysis is compliant with the requirements of S-K 303(a)(iii) because the increase in revenue is due solely to the "introduction of new products or services" related to the Veneto acquisition. None of these increases and/or decreases in revenue were a result of volume of sales and not price. Therefore, a discussion of the extent to which such increases are attributable to increases in prices or increases in volume would not be material.

Notes to the Consolidated Financial Statements
Note 2 - Summary of Significant Accounting Policies Research and Development Costs, page 88

6. You state on page 11 that you have entered into agreements with Merck and NSABP to conduct a Phase II trial to evaluate the safety and efficacy of AE37 in combination with KEYTRUDA. You also state that you are advancing AE37 for the treatment of prostate cancer through a licensing and research agreement with Shenzhen.

For these agreements and any other agreements entered into subsequent to July 31, 2019, tell us the date of the agreements, the nature and significant terms of those agreements, including the rights and obligations of each party and any commitments and contingencies with respect to the agreements.

Response:

(i) Clinical Trial Collaboration and Supply Agreement. Merck Sharp & Dohme B.V., Antigen Express, Inc. June 28, 2017

The following disclosure was provided in the Company's 8-K filed August 1, 2017:

In June, 2017, the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen") entered into a Clinical Trial Collaboration and Supply Agreement (the "Collaboration Agreement") with Merck Sharpe & Dohme B.V. ("Merck"). The Collaboration Agreement provides for Phase I clinical trial to evaluate the pharmacokinetics, pharmacodynamics and preliminary efficacy of administering Merck's Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine in patients with triple negative breast cancer.

> The Collaboration Agreement provides for Antigen to sponsor the study and to make the regulatory filings for approval of the trial. Merck will supply Antigen with Keytruda® for the trial. Antigen will provide its AE37 cancer vaccine and will generally be responsible for the costs of the trial.

A copy of this Agreement was filed as an Exhibit to the 8-K.

We did not believe the details of the agreement were required to be reiterated in the 10-K pursuant to S-K item 101. However, going forward we will include the detail stating that Antigen (now NuGenerex Immuno-Oncology) is responsible for the conduct and costs of the trials.

In Management's Discussion and Analysis, page 40, subheading *NuGenerex Immuno-Oncology (formerly Antigen Express) Research& Development Expenditures* in the 10-K, the Company disclosed that the trial will require additional funding estimated at roughly $1.5 million over the next three years. The Company believes this is sufficient information for the MD&A.

This Agreement was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit.

(ii) Clinical Trial Agreement, Phase II Study, NSABP and Antigen Express, November 20, 2018.

NSABP is the clinical research organization contracted to conduct the trials under the Merck Agreement. Antigen express is to pays for the trials, with a cap of $2,118,461.

The following disclosure was provided in the Company's 8-K filed 11.26.18:

> On November 20, 2018, the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen") entered into a Clinical Trial Agreement with NSABP Foundation, Inc. ("NSABP"). Pursuant to the Clinical Trial Agreement, NSABP will conduct a Phase II Study to evaluate efficacy of administering Merck Sharpe & Dhome's ('Merck") Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine for the treatment of metastatic triple negative breast cancer. While Merck is not a party to the Clinical Trail Agreement, Merck is expected to provide Keytruda® for the study pursuant to the Clinical Trial Collaboration and Supply Agreement between Antigen and Merck.
>
> An initial payment from Generex in the amount of $340,000 is due by December 20, 2018. If the study runs the full anticipated term, Generex will be responsible for an aggregate $2,118,461.

The initial payment of $340,000 was paid by Generex. The future payments required under the NSABP agreement will be funded through the proceeds received from the Shenzhen licensing agreement discussed below. We did not believe the details of the agreement were required to be reiterated in the 10-K pursuant to S-K item 101. However, going forward we will include the detail stating that Antigen (now NuGenerex Immuno-Oncology) is responsible for the conduct and costs of the trials. As noted above, the aggregate cost of the trial in the next three years is disclosed in the MD&A pursuant to Item 303 of S-K.

This agreement should be filed as an Exhibit to the 10-K as it was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit.

(iii) License and Research Agreement between Antigen Express, Inc. and Shenzhen Bioscien Pharmaceuticals Co., Ltd. November 29, 2017.

The following was disclosed in our 8-K filed 12.11.17:

> The Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen"), entered into a License and Research Agreement (the "License Agreement") with Shenzhen BioScien Pharmaceuticals Co., Ltd., ("Shenzhen") dated November 29, 2017. Under the License Agreement, Antigen granted Shenzhen an exclusive license (the "License") to use Antigen's patents, know-how, data and other intellectual property relating to Antigen's AE37 peptide to develop and sell products for the prevention and treatment of prostate cancer in China (including Taiwan, Hong Kong and Macau).

In exchange for the License, Shenzhen has agreed, *inter alia*, to the following financial consideration:

- a $700,000 non-refundable initial payment;
- milestone payments of $1,000,000 each upon completion of Phase II and Phase III studies;
- a milestone payment of $2,000,000 upon regulatory approval of a product covered by the License; and
- a 10% royalty on net sales, provided the patents are in force and there are no approved generic equivalents.

Shenzhen, generally, will be responsible for conducting clinical trials, securing Chinese regulatory approvals, and marketing in China for all products developed under the Agreement.

Because Generex has limited obligations going forward under this Agreement, we believe the following to excerpts from the 10-K are sufficient disclosure for purposes of item 101 and 303.

Risk Factors Page 43:

> 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.

Page 11:

> 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.

This agreement was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit.

(iv) Collaborative Agreement among Generex Biotechnology Corporation and Beijing Zhonghua Investment Fund Management Co LTD and Sinotek-Advocates International Industry Development (Shenzhen) Co., LTD for li-Key Peptide For The 2019 Coronavirus Disease Application

The following is disclosed in the Company's 8-K filed March 2, 2020:

> On February 28, 2020, Generex Biotechnology Corporation ("Generex") entered into a Collaboration Agreement (the "Agreement") with Beijing Zhonghua Investment Fund Management Co., LTD and Sinotek-Advocates International Industry Development (Shenzhen) Co., Ltd. (an affiliate of China Technology Exchange) (the "Chinese Parties"), to develop a COVID-19 vaccine using the Ii-Key Peptide vaccine technology of Generex's majority owned subsidiary, NuGenerex Immuno-Oncology, Inc. ("NGIO").
>
> Under the Agreement, Generex will make the Ii-Key Peptide vaccine technology available to the Chinese Parties. The Chinese parties will provide facilities and personnel for the development of the COVID-19 vaccine under Generex/NGIO technical guidance. The development will include synthesis, analysis and human trials through

Phase III, if warranted, in China. The Chinese parties will have exclusive rights to use and commercialize the COVID-19 technology and products in China.

The Chinese Parties have agreed to set-aside $1,000,000 for Generex/NGIO expenses during development and human clinical trials.

If development and testing are successful, the parties will enter into further collaboration and technology transfer agreements. In this event, the Chinese Parties will pay, for the benefit of NGIO, the following:

- A technology transfer fee of $5 million.
- A 20% royalty.
- Its accumulated cost for development of the technology.

The Agreement provides Generex will receive a $2,000,000 breakup fee if China develops a cure for COVID-19. If Generex ceases its participation, Generex would be required to repay all amounts paid by the Chinese Parties on behalf of Generex.

The parties' activities under the Agreement, including the clinical trials, are subject to approval under China Technology Import Contract Management Regulations as well as the Chinese version of the FDA.

This Agreement is included as an Exhibit 10.90 (by reference to the 8-K exhibit) to Generex's 10-Q for the quarter ended January 31, 2020. We will include a description in our next 10-K if the agreement is still material at that time.

Tell us your consideration of providing additional disclosure in the filing in accordance with ASC 450, 730, and 808;

Response: On June 28, 2017, the Company's wholly owned subsidiary NuGenerex Immuno- Oncology (Formerly known as Antigen Express, Inc.) entered into a Clinical Trial Collaboration and Supply Agreement (the "Agreement") with Merck Sharp & Dohme B.V. ("Merck"). The Collaboration Agreement provides for Phase I clinical trial to evaluate the pharmacokinetics, pharmacodynamics and preliminary efficacy of administering Merck's Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine in patients with triple negative breast cancer. When preparing its July 31, 2019 financial statements, The Company analyzed the Agreement against Accounting Standards Codification ("ASC") Topics 450 Contingencies ("ASC 450"), 730 Research and Development ("ASC 730") and ASC 808 Collaborative Arrangements ("ASC 808").

The Company determined that the Agreement is a collaborative arrangement as defined in ASC 808 because (a) both the Company and Merck are active participants in the activity and both are subject to the risks and rewards related to the outcome of the clinical trial contemplated by the Agreement. The Company began enrolling patients in the trial in September 2019. As of November 12, 2019, the date the Company's financial statements were issued, the company had not enrolled a significant number of patients or incurred material costs related to this collaborative agreement. Further there have not been any transactions between Merck and the Company related to the Agreement.

There is only one possible contingency subject to the Guidance in ASC 450. The contingent loss could occur if Merck terminated the Agreement pursuant to certain sections of the Agreement, then the company could be liable to Merck for the cost of manufacture of the Merck compound produced for the trial. As of the date the financial statements were issued, Merck had not terminated the agreement therefore accrual of any liability under this agreement is not warranted. The Company believes that disclosure of this potential claim is unnecessary because until Merck terminates the Agreement there is not an indication that a loss is reasonably possible.

The Company will account for any costs it incurs pursuant to the Agreement as Research and Development and will record a charge against income or loss from operations in the period incurred, in accordance with the guidance contained in ASC 730.

The Company will continue monitor the need for additional disclosures under ASC 450, and ASC 808 in its financial statements.

Tell us your consideration of providing additional disclosure in the filing in accordance with items 101, 303, and 601 of Regulation S-K; and any other applicable guidance.

Response: The Company believes the disclosure of the Agreements on page 11 meets the requirements of Regulation S-K item 101. Since expenditures pursuant to this agreement are not material, discussion of these Agreements Under S-K item 303 Management's Discussion and Analysis is not necessary. Each Agreement is analyzed below for S-K 101, 303 and 601 considerations:

(i) Clinical Trial Collaboration and Supply Agreement. Merck Sharp & Dohme B.V., Antigen Express, Inc. June 28, 2017

The following disclosure was provided in the Company's 8-K filed August 1, 2017:

> In June, 2017, the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen") entered into a Clinical Trial Collaboration and Supply Agreement (the "Collaboration Agreement") with Merck Sharpe & Dohme B.V. ("Merck"). The Collaboration Agreement provides for Phase I clinical trial to evaluate the pharmacokinetics, pharmacodynamics and preliminary efficacy of administering Merck's Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine in patients with triple negative breast cancer.
>
> The Collaboration Agreement provides for Antigen to sponsor the study and to make the regulatory filings for approval of the trial. Merck will supply Antigen with Keytruda® for the trial. Antigen will provide its AE37 cancer vaccine and will generally be responsible for the costs of the trial.

A copy of this Agreement was filed as an Exhibit to the 8-K.

We did not believe the details of the agreement were required to be reiterated in the 10-K pursuant to S-K item 101. However, going forward we will include the detail stating that Antigen (now NuGenerex Immuno-Oncology) is responsible for the conduct and costs of the trials.

In Management's Discussion and Analysis, page 40, subheading *NuGenerex Immuno-Oncology (formerly Antigen Express) Research& Development Expenditures* in the 10-K, the Company disclosed that the trial will require additional funding estimated at roughly $1.5 million over the next three years. The Company believes this is sufficient information for the MD&A.

This Agreement was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit..

(ii) Clinical Trial Agreement, Phase II Study, NSABP and Antigen Express, November 20, 2018.

NSABP is the clinical research organization contracted to conduct the trials under the Merck Agreement. NGIO (formerly Antigen) express agreed to pay for the trials an amount not to exceed $2,118,461. Including: Start-up Activities in the amount of $340,000 *(an upfront non-refundable payment expensed at the time paid)*, Accrual and Treatment Period in the amount of $1,458,461 *(in the future additional liabilities to be recorded when incurred pursuant to the agreement to be amortized over the estimated life of the study)* , Follow-Up Period in the amount of $240,000 and the Primary Endpoint in the amount of $80,000. The initial $340,000 was paid by Generex. The remaining payments are expected to be funded through the collaboration and licensing agreement with Shenzhen Bioscien Pharmaceuticals Co., Ltd. noted below.

The following disclosure was provided in the Company's 8-K filed 11.26.18:

> On November 20, 2018, the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen") entered into a Clinical Trial Agreement with NSABP Foundation, Inc. ("NSABP"). Pursuant to the Clinical Trial Agreement, NSABP will conduct a Phase II Study to evaluate efficacy of administering Merck Sharpe & Dhome's ('Merck") Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine for the treatment of metastatic triple negative breast cancer. While Merck is not a party to the Clinical Trail Agreement, Merck is expected to provide Keytruda® for the study pursuant to the Clinical Trial Collaboration and Supply Agreement between Antigen and Merck.

An initial payment from Generex in the amount of $340,000 is due by December 20, 2018. If the study runs the full anticipated term, Generex will be responsible for an aggregate $2,118,461.

We did not believe the details of the agreement were required to be reiterated in the 10-K pursuant to S-K item 101. However, going forward we will include the detail stating that Antigen (now NuGenerex Immuno-Oncology) is responsible for the conduct and costs of the trials. As noted above, the aggregate cost of the trial in the next three years is disclosed in the MD&A pursuant to Item 303 of S-K.

This agreement was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit.

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The following was disclosed in our 8-K filed 12.11.17:

The Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen"), entered into a License and Research Agreement (the "License Agreement") with Shenzhen BioScien Pharmaceuticals Co., Ltd., ("Shenzhen") dated November 29, 2017. Under the License Agreement, Antigen granted Shenzhen an exclusive license (the "License") to use Antigen's patents, know-how, data and other intellectual property relating to Antigen's AE37 peptide to develop and sell products for the prevention and treatment of prostate cancer in China (including Taiwan, Hong Kong and Macau).

In exchange for the License, Shenzhen has agreed, *inter alia*, to the following financial consideration:

- a $700,000 non-refundable initial payment;
- milestone payments of $1,000,000 each upon completion of Phase II and Phase III studies;
- a milestone payment of $2,000,000 upon regulatory approval of a product covered by the License; and
- a 10% royalty on net sales, provided the patents are in force and there are no approved generic equivalents.

Shenzhen, generally, will be responsible for conducting clinical trials, securing Chinese regulatory approvals, and marketing in China for all products developed under the Agreement.

Because Generex has limited obligations going forward under this Agreement, we believe the following to excerpts from the 10-K are sufficient disclosure for purposes of item 101 and 303.

Risk Factors Page 43:

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.

Page 11:

> 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 addition, the Company appropriately recorded the upfront licensing fee as Licensing Revenue in its year ended July 31, 2018 financial statements. Since the most significant income statement item included in the Company's July 31, 2018 and 2019 financial statements relate to the changes in fair value of contingent consideration ($39 million and $19 million for the years ended July 31, 2018 and 2019, respectively), the Company believes that discussion of this item in its Management Discussion and Analysis required by Regulation S-K Item 303 will not impact a reasonable investors decisions regarding the Company.

This agreement should be filed as an Exhibit to the 10-K as it was filed as a material agreement to an 8-K. Since the Company has previously filed an 8-K on this, we do not believe that it is necessary to amend the 10-K to file this exhibit.

Collaborative Agreement among Generex Biotechnology Corporation and Beijing Zhonghua Investment Fund Management Co LTD and Sinotek-Advocates International Industry Development (Shenzhen) Co., LTD for li-Key Peptide For The 2019 Coronavirus Disease Application

The following is disclosed in the Company's 8-K filed March 2, 2020:

> On February 28, 2020, Generex Biotechnology Corporation ("Generex") entered into a Collaboration Agreement (the "Agreement") with Beijing Zhonghua Investment Fund Management Co., LTD and Sinotek-Advocates International Industry Development (Shenzhen) Co., Ltd. (an affiliate of China Technology Exchange) (the "Chinese Parties"), to develop a COVID-19 vaccine using the Ii-Key Peptide vaccine technology of Generex's majority owned subsidiary, NuGenerex Immuno-Oncology, Inc. ("NGIO").
>
> Under the Agreement, Generex will make the Ii-Key Peptide vaccine technology available to the Chinese Parties. The Chinese parties will provide facilities and personnel for the development of the COVID-19 vaccine under Generex/NGIO technical guidance. The development will include synthesis, analysis and human trials through Phase III, if warranted, in China. The Chinese parties will have exclusive rights to use and commercialize the COVID-19 technology and products in China.
>
> The Chinese Parties have agreed to set-aside $1,000,000 for Generex/NGIO expenses during development and human clinical trials.
>
> If development and testing are successful, the parties will enter into further collaboration and technology transfer agreements. In this event, the Chinese Parties will pay, for the benefit of NGIO, the following:
>
> - A technology transfer fee of $5 million.
> - A 20% royalty.
> - Its accumulated cost for development of the technology.

The Agreement provides Generex will receive a $2,000,000 breakup fee if China develops a cure for COVID-19. If Generex ceases its participation, Generex would be required to repay all amounts paid by the Chinese Parties on behalf of Generex.

The parties' activities under the Agreement, including the clinical trials, are subject to approval under China Technology Import Contract Management Regulations as well as the Chinese version of the FDA.

This Agreement is included as an Exhibit 10.90 (by reference to the 8-K exhibit) to Generex's 10-Q for the quarter ended January 31, 2020. We will include a description in our next 10-K if the agreement is still material at that time.

Tell us your consideration of providing additional disclosure in the filing in accordance with ASC 450, 730, and 808;

Response: On June 28, 2017, the Company's wholly owned subsidiary NuGenerex Immuno- Oncology (Formerly known as Antigen Express, Inc.) entered into a Clinical Trial Collaboration and Supply Agreement (the "Agreement") with Merck Sharp &Dohme B.V. ("Merck"). The Collaboration Agreement provides for Phase I clinical trial to evaluate the pharmacokinetics, pharmacodynamics and preliminary efficacy of administering Merck's Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine in patients with triple negative breast cancer. When preparing its July 31, 2019 financial statements, The Company analyzed the Agreement against Accounting Standards Codification ("ASC") Topics 450 Contingencies ("ASC 450"), 730 Research and Development ("ASC 730") and ASC 808 Collaborative Arrangements ("ASC 808").

The Company determined that the Agreement is a collaborative arrangement as defined in ASC 808 because (a) both the Company and Merck are active participants in the activity and both are subject to the risks and rewards related to the outcome of the clinical trial contemplated by the Agreement. The Company was scheduled to begin enrolling patients in the trial in September 2019. As of November 12, 2019, the date the Company's financial statements were issued, the company had not enrolled a significant number of patients or incurred material costs related to this collaborative agreement. Further there have not been any transactions between Merck and the Company related to the Agreement.

There is only one possible contingency subject to the Guidance in ASC 450. The contingent loss could occur if Merck terminated the Agreement pursuant to certain sections of the Agreement, then the company could be liable to Merck for the cost of manufacture of the Merck compound produced for the trial. As of the date the financial statements were issued, Merck had not terminated the agreement therefore accrual of any liability under this agreement is not warranted. The Company believes that disclosure of this potential claim is unnecessary because until Merck terminates the Agreement there is not an indication that a loss is reasonably possible.

The Company will account for any costs it incurs pursuant to the Agreement as Research and Development and will record a charge against income or loss from operations in the period incurred, in accordance with the guidance contained in ASC 730.

The company will continue monitor the need for additional disclosures under ASC 450, and ASC 808in its financial statements.

7. With respect to your historical business discussed on page 42 and elsewhere in your filing, clarify the dates in which you completed significant research and development milestones.

Response: NuGenerex Immuno-Oncology R&D milestones:

- June 28, 2017 - Signed Agreement with Merck
- November 28, 2018 - Signed NSABP agreement for FB-14 protocol - AE37 + Keytruda in TNBC
- June 24, 2019 - 1st patient enrolled in FB-14 Protocol"

Tell us your consideration of providing additional disclosure in the filing. For example, tell us when you completed the Phase IIb clinical trial of AE37 immunotherapeutic peptide vaccine with the Ii-Key technology in over 300 women with breast cancer.

Response: The final study closeout for the Phase IIb trial was 11/15/19 - see attached. We obtained the database from Henry Jackson Foundation at that time. The study results were previously published by the principal investigator Elizabeth Mittendorf, MD *(Attachment)*

Note 12- Goodwill and Intangible Assets, page 100

8. With respect to your acquisition of Veneto on October 3, 2018 we note the following:

- **You state on page 66 that you are currently in litigation with Veneto regarding the assets and business transferred, many of the contractual arrangements you assumed have been**

terminated, and you have had to rebuild the business relationships and the structure of the contractual relationships you took over from Veneto. You also state on page 45 that the MSO was built through relationships between physicians and the previous Veneto administration.

- **You state on page 69 that the arbitration action alleges that Veneto never transferred the ownership rights in at least one pharmacy to NDS and that pharmacy was a necessary element in the operation of other assets transferred by Veneto.**

- **You state on page 94 that certain assets were never transferred due to regulatory impositions and that NuGenerex is not responsible for repayment of a loan on assets not transferred.**

- **You state on page 85 that in March 2019 you changed your business model to no longer utilize their existing pharmacies which resulted in you breaking your existing lease agreements with your pharmacies. In this respect we note your disclosure on page 95 which states that $292,681 of disposals pertain to Veneto and was mostly the result of your shift in business operations during March 2019.**

- **You disclose on page 105 that you revalued the assets during the measurement period in accordance with ASC 805-10-25-14 and reduced goodwill accordingly. However, your disclosure, as noted above, appears to imply that the assets recorded may need further consideration, including potentially an impairment for events occurring after the acquisition date such as the change in your business model.**

Please provide us your analysis regarding the valuation of the assets recorded in connection with the Veneto acquisition, including goodwill. Your analysis should at a minimum include the following:

- **the nature of each significant asset acquired in the acquisition**

Response:

A. Assets of (a) seven dispensing pharmacies, (b) a wholesale pharmacy purchasing company, and (c) an in-network laboratory. These assets included:

- Tangible property, furniture, fixtures and equipment,
- Cash on hand
- Accounts and notes receivable
- Inventory (including office supplies)
- Tenant improvements
- Goodwill, software
- Intellectual property
- Prepaid items
- Contracts
- Personal property leases
- Books and records *(including all customer lists and all patient lists to the extent transferable under applicable Law, but excluding any patient medical records and files to the extent required to be retained by the Seller and any communications which are subject to attorney-client privilege)*
- Seller policies and procedures relating to its business
- Telephone and email addresses
- All permits and certificates of need to the extent transferable to the Buyer

B. Equity and management interest in management services organization (MSO) business.

C. Two additional ancillary service companies – 1) the HDDL Laboratory in Prescott Arizona, and the DMEiq business which a scalable SAAS for Physician Practices.

- **the status of ownership and rights for each significant asset at the time of the acquisition and at your balance sheet date,**

	Significant Assets at the time of Acquisition	Significant Assets per Amended Agreement	Estimated Value as of July 31, 2019
Cash and cash equivalents	$ 2,410,150	$ 2,410,150	$ — *
Accounts receivable, net	1,935,078	1,490,638	33,556*
Inventory, net	1,068,856	1,068,856	1,095*
Prepaid expenses	95,804	95,803	— *
Property and equipment, net	652,590	652,590	147,903*
Other receivables	1,014,316	1,014,316	— *
Notes receivable - LT	1,387,763	1,387,763	— *
Other assets, net	25,745	25,745	— *
Intangible assets, net	7,145,603	846,603	621,350*
Goodwill	25,177,930	15,051,769	15,051,769*

** These working capital assets increase and decreased due to normal operations from the date of acquisition through July 31, 2019. The amounts are likely new amounts as reflected by operations and the original receivables, trade payables collected and/or paid.*

Response: At the time of acquisition and at the balance sheet date, the Company owned all of the assets referenced above other than the licenses to operate the pharmacies and any pharmaceutical inventory required to be owned by a pharmaceutical licensee. The Company had an agreement with the sellers to transfer the pharmacy licenses, and prior to such transfer, for the sellers to operate the pharmacies under contractual terms with the Company. However, once the Company realized it would be impossible to have the pharmacy licenses transferred due to the seller's legal and regulatory problems, the Company renegotiated the purchase price and payment terms as reflected in the amended purchase price allocation and the pharmacy assets mainly working capital assets had already been consumed in operations. The Company still owns and controls the MSO model and operations which is expected to continue.

The table above reflects the significant assets at the time of original acquisitions, followed by the value of the significant assets at the time the purchase agreement was amended, and lastly the remaining value of the assets held as of July 31, 2019. During the normal course of the operations, the current assets acquired from the pharmacies (cash, accounts receivable, prepaids, inventory and other elements of working capital) were either consumed in operations when collected, paid or written off. As pharmacy operations ceased, any associated fixed assets and other assets (furniture & fixtures, equipment and leasehold improvements) were written off. A single note receivable still currently owned and possessed by Generex was impaired due to non-collectability and expensed currently.

- **how each asset was affected by your change in business model,**

Response: The current assets as discussed above were either consumed in operations when collected, paid or written off as each pharmacy was closed and any associated fixed asset. The primary assets that were affected by the change in the business model were non-compete agreements and goodwill. These assets were revalued during the measurement period to reflect the new business model that retains the MSO operations without the pharmacy assets and operations reflected in the reduced purchase price and the allocation to goodwill. As of the July 31, 2019, the reduced value of the goodwill was tested again for any impairment and no further reduction in the fair value during the measurement period and/or impairment was required.

- **how each asset was affected by any terminated contractual arrangements,**

Response: The primary significant assets which were affected by terminated contractual arrangement were various leasehold improvements associated with leases held by the pharmacy operations. These assets were written off upon closing of these pharmacies during the normal course of operations. The other significant asset that were affected by the terminated contractual arrangements was the value allocated to the non-compete agreement associated with the sellers.

- **the extent to which you have had to rebuild business relationships, including the network of physician partners in the MSO acquired from Veneto, and**

Response: The operations of the MSO was limited as a result, but the MSO is still in place and the future utilization of the MSO still provide future income and considered the cornerstone of the acquisition. Although the assets and operations from Veneto Group pharmacies have ceased, the operations planned in the future will utilize third-party pharmacies to fulfill prescription orders without the need to have company owned pharmacies and achieve the same business model without the full capital requirements of creating or acquiring additional pharmacies.

- **the effect of the ongoing litigation with Veneto**

Response: After the acquisition, nearly all the tangible assets acquired from Veneto were consumed through operations and little or no tangible assets remain related to the Veneto Acquisition. The intangible assets acquired as discussed above were revalued during the measurement period pursuant to an amended purchase agreement that reduced the total consideration paid resulting in a change in the purchase price allocation computation and the fair value of the assets acquired. Except for the cost of litigation, the Company believes that is unlikely that any further losses due to the outcome of the litigation and could only recover costs, or shares to be returned to treasury. The Company does not believe that the litigation will affect its ability to utilize and operate the MSO, but any change in the MSO could cause additional losses due to a further impairment of the remaining Goodwill which would be reported in a future filing if such action is taken, but the Company has no plans to abandon the MSO business plan.

Note 13 - Acquisitions Veneto, page 104

9. You appear to consolidate the assets acquired of Veneto. You state on page 45 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 your wholly-owned subsidiary NuGenerex Distribution Solutions 2) owns 1% and serves as the managing director of the LLC.

Please provide us with your analysis as to why consolidation is consistent with ASC 810.

Response: Under the scope of ASC 810-10 Consolidation, Variable Interest Entities the Company reviewed the MSO's operating agreement (Rapport) and concluded that because its sole decision-making authority over MSO determined that it has a variable interest in Rapport and that Rapport is a VIE. The Company has both the power to direct the activities of Rapport that most significantly impacts Rapport's economic performance with the obligation to absorb benefits from or losses of the Rapport that could potentially be significant. The Company consolidates Rapport as a VIE as it is considered to be the primary beneficiary. While the individual MSOs have more diverse ownership, their ownership does not have the ability to direct the activities of the entity, nor does their ownership have the ability to determine the timing or amount of distributions. As a result, the non-controlling interest represents the physician ownership. The Company consolidates entities in which it or its wholly owned subsidiary is the general partner or managing member and the limited partners or members, respectively, do not have substantive participating rights to overcome the Company's control.

If Veneto is not considered a variable interest entity, please provide your assessment of consolidation under the entities controlled by contract in ASC 810-10-25-60.

Response: Except for Rapport, the MSO (VIE) discussed above, the remaining operations known as Veneto was acquired pursuant to an "asset purchase agreement" and such assets and operations were deemed to be a business which the Company obtained a controlling financial interest through one or more of its wholly owned subsidiaries.

Regentys and Olaregen, page 106

10. Please provide us the following with respect to the $2,459,000 of in-process research and development recorded in the Olaregen acquisition and $3,391,050 acquired in the Regentys acquisition:

- **the specific nature and fair value of each significant in-process research and development project acquired.**

Response:

For Regentys, the primary value was attributed to Extracellular Matrix Hydrogel ("ECMH"), a proprietary, patented UC treatment that protects damaged tissue from waste flow and promotes tissue regeneration and healing rather than suppressing the immune system as other treatments currently do. ECMH is a first-in-class, non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis. Regentys. Regentys was to initiate the clinical studies necessary to obtain that approval of the FDA 510K in the future including any associated intellectual property, licensed patents and in-process research& development costs.

For Olargen, the primary value was attributed to Excellagen®, a flowable dermal matrix that is a 510K FDA cleared medical device for utilization for a variety of wound types that has recently been awarded a U.S. patent with a 17 year right of exclusivity. Excellagen is a highly-purified Type 1 collagen-based, flowable gel formulation approved for 17 types of 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, and limited value attributed to Cord Products and Exassome, and associated intellectual property, licensed patents and in-process research& development costs. Limited value was attributed to two additional product lines:

- **the completeness, complexity and uniqueness of the projects at the acquisition date.**

Response:

For Regentys:

- Completeness- 85% of the product development, 80% of preclinical work, 10% of Clinical Prep.

- Complexity- While there are challenges in scaling up any product from the science lab to commercial production, the product is not complex with the base product having been commercialized for 20 yrs. All other facets of clinical, production and commercialization are not considered highly complex

- Uniqueness- The company in-licensed certain patented hydrogel technology and co-developed technology with the University of Pittsburgh. As previously discussed, the ECM component of ECMH has been around for quite some time. Formulating ECM into a hydrogel is a patented process. The application to treat Ulcerative Colitis is also novel and unique for which several patents have been filed and several jurisdictions have issued claims.

For Olaregen: At the time of acquisition, Excellagen was FDA 510K cleared, but was not yet deemed to be commercially viable. On March 20, 2020 Excellagen®, was Awarded by the Strategic Acquisition Centers (SAC) a Biologic Blanket Purchase Agreement (BPA) Contract and IDIQ (Indefinite Delivery & Indefinite Quantity) contract from the National VA Approval through the SAC committee. The BPA contract facilitates the sales and distribution of Excellagen across the VA system's 165 hospitals and over 1000 clinics. As a result, the acquisition, Excellagen became commercially viable and had a single initial sale made to the Veterans Administration Hospitals (VA), In some VA hospitals, additional research and testing is required to permit its use in "room temperature" applications in VA hospitals that do not have refrigeration for storage of medical products. The Cord Products which can be sold in the marketplace requires additional research and development to remain commercially viable and competitive in order to generate future sales. Exassome can also be sold in the marketplace, but further research and development costs are expected to combine Exassome and Excellagen for the development of Excellasome® which had not begun its initial trials and still requires funding.

- **the nature, timing and estimated costs of the efforts necessary to complete the projects, and the anticipated completion dates**.

Response: *For Regentys:* The Company expects to finalize product development in the next 4 months, produce a clinical batch of product, conduct a 20-person pilot study in early 2021 which will take through the end of 2021. During this time frame the Company expects to incur approximately $7M of expenses. An additional $8M will be required to complete a

pivotal human clinical study and prepare regulatory submissions for approval to commercialize the product. If successful, Regentys' product would be commercialized by 2023.

For Olaregen: Excellagen® requires no future research and development and is now currently active in product sales. The Cord Products requires additional funding to remain viable in the competitive market to be initiated in 2020 provided there is ongoing interest within the marketplace. Excellasome® requires a Phase I trial pending funding to be provided by Generex and/or through a collaboration agreement with an industry partner anticipated to begin during 2020, but the completion and commercialization of Excellasome® is not expected to be completed or become commercially viable for several years.

- **the risks and uncertainties associated with completing development on schedule, and consequences if it is not completed timely**.

Response: *For both Olaregen and Regentys* the biggest risk is receipt of funds to continue development. Continued delays will result in loss of our exclusive license which would significantly impair the value of the company.

- **what appraisal method was used to value the projects**.

Response: *For Regentys:* The Intellectual Property/Licensed Patents/In-Process R&D Assets were valued using Cost Accumulation Methods. The Non–Competes were valued as a group using a "with or without" method which compares the value of the Company "with" the agreement in place – thereby assuming no competition from the seller and "without" the agreement in place – thereby assuming the seller competes with the Company.

For Olaregen, we valued Intellectual Property/Patents/In–Process Research & Development intangible assets using the Relief from Royalty Method (assuming obsolescence and assuming a terminal value) . Utilizing the fair value defined in Statement of Financial Accounting Standard No. 820–10–35–37 Fair Value Measurements and Disclosures.

- **the significant appraisal assumptions, such as: the period in which material net cash inflows from significant projects are expected to commence;**

For Regentys: The significant assumptions included:

- The developer's profit was measured as the profit margin for Drugs (Biotechnology) Drugs (Pharmaceutical) – Healthcare Products development/manufacturing firms determined to be 16.68% based on earnings as a percent of revenue.
- The entrepreneurial incentive was measured as the return on capital for venture capital firms using the average of First stage/prototype at 50%. These measures were sourced from Pellegrino Associates and NYU with original data sources from Morningstar, Capital IQ, and Bloomberg as well as QED Research and Harvard Business School Publishing.
- No un–booked direct costs were provided to the historical costs.
- Inflation rates in the 1% to 3% range.
- A 5-year life for the product research and development with obsolescence rates of 10% to 20% annually.

For Olaregen, we used the Income approach to estimate a value of the Company's intangible assets based on management approved projections of future cash flows using 5–year financials projections and multiple methods (including Relief from Royalty Methods; Multi–Period Excess Earnings Methods; With/Without Methods; and Residual Cash Flow Methods) assuming a risk adjusted weighted discount rates; management projections; and industry based long term growth rates. The projections utilized in our valuation included adjustments including revenue/expense growth rates; capital expenditures; working capital; and taxes. The financial projections utilized in the valuation of the IP & Non–Compete intangible assets are based the following assumptions:

- Olaregen projected sales of $ 3,288,000 in 12 trailing months ("TTM") to $37,845,000 in the TTM through 2021 with managements growth rates after 2019.
-

Projecting those revenues with management growth rates of 283.67% for 2020 and increasing long term to 200.00% in 2021 to 28.57% in 2024 resulting in $ 113,535,000 in sales. Industry growth rates of 10.580% are used following 2024.

- Costs of goods sold are expected at the Company projected rate in 2019 of 80.170% to 5.784% by the end of 2023.
- Operating expenses are 104.4% to 23.4% from 2019 through 2023.
- After–tax net margins excluding the non–controlling interest distributions are
- approximately 40.8% by 2023 and 20.4% by 2028 on the incremental revenue generated by the acquired assets.
- Taxes are estimated at 24.000% of net income.
- The forecast primary included revenue and sales associated with Excellagen® and limited revenues associated with Cord Products and Exassome.
- No value was attributed to Excellasome® as no Phase I trial has been scheduled and/or initiated.

- **material anticipated changes from historical pricing, margins and expense levels; and**

For Regentys, The reference data is based on market analysis of the 2830 – Drugs (Biotechnology); 2834 – Drugs (Pharmaceutical); and 8060 – Healthcare Products industries.

- *For Olaregen,* the reference data is based on market analysis of the 2830 – Drugs (Biotechnology); 2834 – Drugs (Pharmaceutical); and 8060 – Healthcare Products industries. **the risk adjusted discount rate applied to the project's cash flows**.

Response:

For Regentys, the following stages and investor expected rate of return for each stage were considered:

- 1st Stage – companies performing market studies, testing, prototypes, and perhaps manufacturing limited amounts of product. (Rate of Return from 30% to 60%)
- 2nd Stage – companies expanding where a viable product exists, and a market has been established. (Rate of Return from 25% to 50%).
- 3rd Stage – rapid ramp up of sales and profit margins are acceptable, but internally generated cash is insufficient to meet expansion needs. (Rate of Returns 15% to 30%).

The assets and consulting services acquired generated moderate historical revenue growth, consequently, we viewed Regentys transitioning from 1st stage to 2nd stage and that a discount rate in a range of 25% to 50% was appropriate to use in the valuation of the Company. The Company growth is highly dependent on the investment in sales/marketing while leveraging shared resources of the acquired businesses to bring the Company to significant revenue generation and positive fair value using the income approach. The discount rate within this range was quantified using a "Build–up" approach.

For Olaregen, revenues were projected to increase with long-term growth based on industry levels. Gross margins were projected to remain mostly flat at historical levels. Net margins were projected to increase based on a portion of operating expenses being fixed with only inflation adjustments. We evaluated four scenarios ranging from meeting management expectations to product failure. The cash flows were discounted at a 23.7% WACC and the scenarios were weighted equally (25% each) to account for the risk of success. Regentys expected material cash inflows start in 2022-2023 as sales ramp up. Revenues were projected to increase as market penetration increases in the short term and at industry growth rates in the long-term. Gross margins and net margins were projected to remain mostly flat. Upfront R&D expenses through 2021 were projected above $14M. The cash flows were discounted at a 23.1% WACC and a decision tree methodology was applied with a cumulative success rate to complete all phases of approval to product launch at 3.9%.

- **In periods subsequent to the purchase of significant in-process research and development, tell us the status of efforts to complete all of your significant in-process research and development projects, including those other than the assets acquired in the Olaregen and Regentys acquisitions,**

and the impact of any delays on your expected investment return, results of operations and financial condition.

Response: *For Regentys:* Since acquisition, Regentys has advanced the regulatory and clinical components to commence the pilot studies with the completion of the product development. However, delays in funding have slowed the final product development steps. The impact in delays caused by Coronavirus have not been fully determined.

For Olaregen: Since acquisition, Excellagen became commercially viable with active sales. The impact related the COVID-19 pandemic, and the reduction of elective surgeries and medical procedures, the sales of Excellagen have slowed, but the long-term viability has not been impacted. The further funding is required to permit its use in a "room temperature" application required in many VA hospitals will impact the overall potential sales associated with the VA. The Cord Products requires additional funding so that research and development can be completed to allow it to remain a commercially viable and competitive. Without funding, the Cord Productions would lack the ability to generate future sales which could significantly reduce it Regentys to full exploit and generate revenues from Cord Products. No value was attributed to Excellasome® as part of the valuation of In-Process Research and Development. Therefore, the lack of funding would not cause of reduction in the anticipated values, but long-term funding provided to complete this project could increase positively the value and return on the investment in Regentys.

Regentys, page 107

11. You state that you acquired a 51% interest in Regentys for total consideration of $15,000,000, which consisted of a $400,000 cash payment and a promissory note of $14,600,000. Please provide us the following:

- **a calculation of how the non-controlling interest of $9,870,762 was determined,**

Response: The total consideration paid is based on a convergence method in an Option Pricing Model ("OPM") using the Regentys capital structure and assigned value of each class of stock and equity instrument outstanding at the time of acquisition. See table below. The overall value of Regentys was determined to be $28,689,865. The net purchase price for 51% of the Regentys equaled $14,745,205 which included $14,345,205 representing the discounted value of the note payable of $14,600,000) and the original $400,000 cash deposit. Therefore, the initial calculation of the fair value of the non-controlling interest was determined to be $13,944,660. As part of the Regentys equity structure, an allocation of $4,073,898 was made to *"Redeemable non-controlling interest."* The remaining value was reported at the non-controlling interest in the amount of $9,870,762 ($13,944,660 less $4,073,898).

- **an analysis of the methodology and assumptions used as described on page 108 to determine the redeemable non-controlling interest of $4,073,898 were determined,**

Response: The Option Pricing Model was utilized to determine the fair value of the Series A Preferred shares as of 1/7/19 based on the various equity linked instruments in the capital structure of Regentys, including the 12,048,161 newly issued common shares issued to Generex. The assumptions utilized in the OPM included a 3 term to liquidity, a corresponding risk–free rate based on the term of 2.53%, 0% dividends, and a volatility based on the term of 101% (based on comparable company volatility analysis).

Based on the structure of the Company's equity linked instruments, we developed breakpoints based on the conversion prices and exercise prices of the various convertible debt, preferred stock, and outstanding options and warrants. These breakpoints were used to allocate value as each instrument would be exercised/converted as it was in the money. The first tranche, which consists of stock prices below the lowest conversion price of the convertible debt and preferred stock, all value is assigned to the liquidation preference/convertible debt balance. The Black –Scholes option pricing model was utilized to estimate the value of each tranche by utilizing the breakpoint as the exercise price.

To allocate the value to the equity linked instruments, we calculated allocation percentages for each equity–linked instrument. The value of each tranche is determined by subtracting the value of the previous tranche, which is

multiplied by the applicable allocation percentages, and summed to yield the total value of each equity–linked instrument.

We iterated the total Regentys enterprise value until the value of the shares received was equal to the consideration paid. This yielded a fully-diluted market cap of $28,689,865. This yielded a per share value for the Series A shares at $1.46 with a total value of $4,073,898.

	Shares/ Units	Common Share Equivalent	Value Per-Share/Unit	Value Per CSE	Total Value To Class
Convertible Debt	0	-	0.00	0.00	0
Series A Preferred	2,793,192	2,793,192	1.46	1.46	4,073,898
Series B Preferred	0	-	0.00	0.00	0
Common Stock	18,419,897	18,419,897	1.22	1.22	22,543,288
Options at $0.02	69,000	69,000	1.21	1.21	83,480
Options at $0.04	165,000	165,000	1.20	1.20	197,411
Options at $0.28	78,000	78,000	1.07	1.07	83,196
Options at $0.29	6,000	6,000	1.06	1.06	6,373
Options at $0.34	171,000	171,000	1.04	1.04	177,905
Options at $0.36	4,000	4,000	1.03	1.03	4,128
Options at $0.41	627,000	627,000	1.01	1.01	634,503
Options at $0.71	118,000	118,000	0.91	0.91	107,451
Options at FV	979,375	979,375	0.79	0.79	778,232
Warrants at $1.50	0	-	0.00	0.00	0
Total				0.00	28,689,865

- **and how the fair value of the assets acquired of $907,833 equates to the amount of the assets disclosed in the table on page 107.**

Response: The line "Total Fair Value of Assets Acquired" is the sum total of all the lines and amounts above in the table on Page 107 and the line is missing an underscore line above to indicate a subtotal of the above.

Olaregen, page 108

12. You state on pages 5 and 109 that in January 2019 you acquired a 51% interest in Olaregen for total consideration of $400,000 of cash and a note receivable of $11,472,664. You state on page 113 that your interest was increased to 62% in May 2019 upon acquisition of the Series A preferred stock in Olaregen in exchange for 4 million shares of your common stock plus the issuance of a $2 million promissory note. In August 2019, subsequent to your balance sheet date, your interest increased to 76%.

Please provide us the following:

- **a calculation of how the non-controlling interest was determined,**

Response: The initial acquisition agreements provided for 51% on fully diluted basis to insure Generex would always have the controlling interest in Olaregen if an option or warrant was exercised. The non-controlling interest calculation was based upon the outstanding shares of Olaregen. Due to subsequent acquisitions of stock from third parties, Generex increased its interests (percentage) in Olaregen to 62% when it acquired the 592,683 outstanding Series A shares and further to 76% when it acquired an additional 900,000 shares.

	Post Closing	Fully Diluted %	**Post-Acquisition of Series A**	Undiluted %	**Post-Acquisition of 900,000 Shares**	Undiluted %
Olaregen Therapeutics LLC	900,000	14%	900,000	14%	—	0
All Other Shareholders	1,466,187	23%	1,466,187	23%	1,466,187	23%

Series A	592,683	9%	—	0%	—	0%
Generex Biotechnology	3,282,632	51%	3,875,315	62%	4,775,315	77%
Total Shares Outstanding	**6,241,502**	**96%**	**6,241,502**	**100%**	**6,241,502**	**100%**
Outstanding Warrants	177,800	3%				
Employee Options	60,000	1%				
Fully Diluted	**6,479,302**	**100%**				

- **how the fair value of the assets acquired of $2,461,400 equates to the amount of the assets disclosed in the table on page 109, and**

Response: The line "Total Fair Value of Assets Acquired" is the sum total of all the lines and amounts above in the table on page 109 and the line is missing an underscore line above to indicate a subtotal of the above

- **how you are accounting for the additional interest purchased in May and August 2019.**

Response: The line "Total Fair Value of Assets Acquired" is the sum total of all the lines and amounts above in the same table and the line is missing an underscore line above to indicate a subtotal of the above. The additional interest purchased in May and August 2019 was accounted for as an equity transaction in accordance with ASC 810-10-45-23.

Item 9A. Controls and Procedures, page 114

13. You state in your Management's Report on Internal Control Over Financial Reporting on page 115 that you have evaluated the effectiveness of your disclosure controls and procedures and concluded that your disclosure controls and procedures were not effective. Please present your assessment of the effectiveness of the disclosure controls and procedures under the subheading for "Evaluation of Disclosure Controls and Procedures" and a separate assessment relating to your assessment of internal controls over financial reporting under the Management's Report on Internal Control over Financial Reporting subheading. Refer to Items 307 and 308 of Regulation S-K.

Please also revise your Risk Factor on page 42 to address your determination of effectiveness of the disclosure controls and procedures and internal control over financial reporting separately.

Response:

Based on the Staff's request, please see the following:

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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.

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated, as of the end of the period covered by this Form 10-K, the design adequacy and operating the effectiveness of our disclosure controls and procedures (as defined in as required by Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as of such date were not effective at ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms.

On March 26, 2019 the Company issued a restatement of its Quarterly Report on form 10-Q for the quarter ended January 31, 2019. 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.

To address these deficiencies, 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. In addition, the Company is implementing a new centralized accounting system to provide cohesion across the enterprise and standardize the close process across all subsidiaries

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 0 PTe events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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 and as required by 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.

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.

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.

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.

Related Risk Factor on page 42, broken into separate risk factors:

Our disclosure controls and procedures may not be effective in future periods as a result of existing or newly identified material weaknesses in disclosure controls and procedures.

Effective disclosure controls and procedures are necessary for us 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 provide reasonable assurance with respect to our financial report. If we cannot provide reasonable assurance with respect to our financial reports, our reputation and operating results could be harmed. Pursuant to the Sarbanes-Oxley Act of 2002, we are required to furnish management's evaluation of the effectiveness of such controls and procedures. If we fail to maintain the adequacy of our controls and procedures, including any failure to implement required new or improved controls and procedures, 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 our disclosure controls and procedures were not effective at ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms. 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 and procedures 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 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 internal controls and procedures (as defined in Rules 13a-15(f) and 15d-15

(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and concluded that, subject to the inherent limitations, our internal controls 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.

14. You refer to a restatement which was included in your Form 10-Q/A for the period ended January 31, 2019. In this respect, please tell us the basis for eliminating the intercompany revenue of $1,406,529 against the general and administrative expenses as noted on page 12 of the 10-Q/A.

Response: As part of the acquisition of Veneto, there were services between provided between various subsidiaries. As part of a group pharmacy operations, one of the entities was providing administrative services for another subsidiary designated as Revenue - VSA Fees - Intercompany while another subsidiary recorded an expense of VSA Fees – Intercompany. Similarly, intercompany fees were charged for Adjudication Services recorded as income by on subsidiary and expenses by another subsidiary, and the same for intercompany MSO Fees. Since income and expense was being recognized between subsidiaries consolidated by the Company, then these amounts are required to be eliminated. In the previous filing, these expenses were reflected as general administration services as were deemed management services.

Thank you for your attention.

Sincerely yours,

Gary M. Miller

Gary A. Miller

cc: Joseph Moscato, Chief Executive Officer
Mark Corrao, Chief Financial Officer
Anthony Crisci, Esq.