

Generex Biotechnology Provides 2019 Year-End Summary & 2020 Plans

MIRAMAR, FL, January 16, 2020 - Generex Biotechnology Corporation (www.generex.com) (OTCQB:GNBT) (<http://www.otcmarkets.com/stock/GNBT/quote>) is happy to provide the investment community with a review of the many challenges overcome and accomplishments achieved in 2019, with a vision for revenue and growth in 2020 by Generex President & CEO Joseph Moscato.

Dear Generex Shareholders,

Since the new management team was put in place 3 years ago in January 2017, we have transformed Generex Biotechnology into an integrated healthcare holding company with end-to-end solutions for patient centric care from rapid diagnosis through delivery of personalized therapies. The NuGenerex family of subsidiary companies offers a broad range of products and services to meet the needs of physicians and patients.

Generex is building a new kind of healthcare company that extends beyond traditional models providing support to physicians in a management services organization (MSO) network, and ongoing relationships with patients to improve the patient experience and access to optimal care.

We started out the year focused on accelerating the geographic growth of our highly valuable MSO and planned the launch of a new software and service offering, DME-IQ that orthopedic practices can use to manage DME inventory and payments from both insurers and patients. After significant due diligence we determined that there were distressed assets which we could acquire at a significant discount and reconfigure into a novel, public company MSO model aligning our shareholders and MSO ownership. We are behind on the plan, however, because months after we closed the deal, federal authorities alerted us to “undisclosed and unknown” compliance issues involving the sellers in years way prior to our purchase, which affected our ability to move forward rapidly. We complied with the government’s requests, terminating personnel they identified as bad actors and immediately reconstructed our MSO in a public company structure ready and desired in the marketplace. All legal remedies against the sellers are under way. Meanwhile, as soon as funding is in place, we will launch our public platform MSO. We have received positive feedback from potential partner practices that indicated that they will sign up faster under our novel, public company structure than for any private company offering, so we are confident of a significant success with

our plan. Our goal is to generate significant revenues and profits as we fund the enterprise to restart operations and expand the model nationally.

To advance our end-to-end strategy for our MSO, Generex identified several acquisition targets that provide products and services to the MSO physicians. The first acquisition completed in 2019 was Olaregen Therapeutix, manufacturer of Excellagen® wound conforming gel matrix, a Cellular Tissue Product (C/TP) that is cleared by FDA for the management of 17 types of wounds, including diabetic foot ulcers and venous leg ulcers. In mid-year, the Olaregen team, headed by CEO Anthony J. Dolisi launched Excellagen in the VA system where we are seeing excellent early clinical results, and we are beginning to achieve uptake by VA hospitals across the country.

Excellagen sales are expected to accelerate in 2020 as the VA adopts the use of the product throughout the system. Additionally, Olaregen is preparing to launch a product line extension with Excellagen Aesthetic, which is positioned in the aesthetic dermatology market for the management of skin lesions following chemical peel, laser treatment, or micro-needling procedures that are used widely in the skin rejuvenation field. Further, Olaregen is launching new products in the wound care space including our patent pending Olarex umbilical cord tissue.

At the start of the year, we also began evaluating select companies in orthopedic implant and the surgical supply space that could provide an array of implants, surgical kits and supplies, and particularly biologics to our MSO physician practice partners. We evaluated several organizations that wished to become part of the NuGenerex family of integrated companies and our end-to-end model for healthcare. After a rigorous due diligence process, through which several companies were eliminated from consideration, we acquired 100% interest in Pantheon Medical, a manufacturer of orthopedic implants and foot & ankle surgical kits, and MediSource Partners, a national distributor of orthopedic implants and surgical kits & tools, with a catalogue of biologics and tissue products that fit perfectly with our new business model. These acquisitions were finalized in August of 2019, and today are performing above expectations, with significant growth in revenue from the current customer base and substantial upside potential as we expand distribution nationally in 2020.

In September 2019, we signed letters of intent with Arizona Endocrinology Center and Paradise Valley Family Medicine to establish NuGenerex Health, LLC to establish a new MSO focused on the delivery and management of healthcare services for patients with

chronic, complex medical conditions, particularly diabetes. Together, the two medical practices currently work in concert to provide primary care and specialty endocrinology healthcare services for a patient population of roughly 65,000 patients, 25,000 of whom are insulin-dependent diabetes patients. Under the terms of the agreements, Generex Biotechnology will establish NuGenerex Health, LLC as a multispecialty health services provider that provides ancillary specialty healthcare services and disease management solutions for patients living with diabetes. NuGenerex Health is designed as an MSO partnership with the medical groups to offer ophthalmology, podiatry, neurology and ancillary health services that will provide patients with integrated, concierge care to improve outcomes and reduce costs. By bringing specialty ancillary care directly to the patients who regularly visit the practices, NuGenerex Health provides an integrated, collaborative care model not only to enhance patient wellbeing, but also to comply with CMS guidelines for diabetes and chronic care management that can lead to 5-star ratings and increased reimbursements. In addition, we are establishing the Diabetes Research Center of Excellence to advance the clinical development of not only our own diabetes products, but also new cutting-edge therapies, particularly in the cell therapy and regenerative medicine space. We plan to initiate operations for NuGenerex Health in the first quarter of this year, with the ultimate goal of building an HMO to service Medicare Advantage plans.

One of the most exciting things that happened this year was my introduction to Gary Harlem and his company ALTuCELL last summer. I learned that Gary, the Founder & CEO of ALTuCELL has a son with Type I diabetes, and that after divesting his highly successful vitamin and supplement company, went on a global search for a cure. When he found Dr. Ricard Califiore and his research team at the University of Perugia in Italy ten years ago, Gary found his life's focus, providing financial support for the development of advanced cell encapsulation technology aimed at the cure of diabetes through cellular therapy. He formed ALTuCELL and patented the chemistry, engineering, purification, and utility of the capsules on a global basis, and he continues protecting the technology through an ongoing, global patent strategy. Following payment of the upcoming dividend, we plan to close the acquisition and work with the ALTuCELL team to initiate clinical trials for Types I & Type II diabetes through our Diabetes Research Center. Additionally, we will be identifying partnership opportunities with cellular and gene therapy companies to which we plan to license the patented AltuCaps technology for the treatment of autoimmune and inflammatory diseases.

In 2019, we also made significant progress in revitalizing our oncology franchise. Generex has a long, 15-year history of developing immunotherapeutic products including our lead immunotherapeutic product AE37, a HER2/neu peptide linked to li-Key that has shown activity in breast cancer. The value of our technology, however, has been locked in NuGenerex Immuno-Oncology (formerly Antigen Express) under the Generex subsidiary structure. In 2018, we announced plans to spin out NuGenerex Immuno-Oncology (NGIO) as a separate public company, and in 2019 we explored a number of options, including the evaluation of several acquisition targets and potential merger partners. At the end of the year, we made the decision to bring NGIO directly to the public markets in order to unleash the inherent value of our immune system activating li-Key technology that activates T-cells against cancer antigens. Our technology platform has been rejuvenated by the huge market success of the PD-1, PDL-1, and CTLA 4/6 immune checkpoint inhibitors, six of which have been approved by FDA in the last couple of years. This was demonstrated by our success this past year in resurrecting the clinical development of AE37 in breast cancer, and we are currently conducting a phase II clinical trial of AE37 in combination with pembrolizumab (Merck's Keytruda®) for the treatment of triple-negative breast cancer. The first cohort of patients has completed the initial safety evaluation for AE37/Keytruda combination therapy, and we are looking forward to completing the patient enrollment this year.

In addition to the Merck research agreement, we have a licensing and development agreement with Shenzhen Bioscienc, a Chinese biopharmaceutical company for the use of AE37 in the treatment of prostate cancer in China. Our partners at Shenzhen are working with the Chinese regulatory authorities to obtain approval for conducting trials in China, which includes fulfilling manufacturing and pre-clinical requirements. As per our licensing agreement, Shenzhen is planning a global trial in China and in Europe using one of our clinical research sites that have previous experience conducting clinical trials with AE37. We look forward to seeing further progress with the prostate cancer clinical program in 2020.

We expect to achieve the public spin-out of NGIO in the first quarter of calendar 2020. Following funding of the newly-public NGIO, we have plans to conduct a Phase II clinical trial of AE37 in combination with checkpoint inhibitor therapy for the treatment of bladder/urothelial cancer and another Phase II trial using the li-Key peptides GP-100 and TYR in combination with checkpoint inhibitors for the treatment of melanoma. Both of

these trials are being planned with two leading oncology research institutions, and additional announcements will be forthcoming regarding these clinical collaborations.

In parallel with the reorganization of our corporate assets and operations, we made a concerted effort to fix our balance sheet in 2019. I am happy to report that we were successful in building shareholder value by converting a shareholder liability of negative \$43 million to a positive shareholder's equity of \$7.7 million, as stated in our 10-K. We plan to continue our progress in building shareholder value in 2020 when we spin out NuGenerex Immuno-Oncology (NGIO) as a separate public company in the hot field of immunotherapy for cancer. Once NGIO is a separate, public company, Generex will continue to own the majority share of a highly valuable oncology company, and this value will be reflected in our balance sheet.

We are determined to correct and turn into a positive overall outcome for Generex shareholders recent problems that have caused a decline in our share price since September resulting from illegal trading by two groups: Creek Mountain Fund from whom we acquired 20% of Olaregen in exchange for 4 million shares of Generex stock, and Veneto Holdings who owned 8.4 million restricted shares of Generex stock despite never transferring the associated Veneto assets to Generex. Last September, these groups started selling all of their shares to create major downside pressure on the stock price. In the case of Creek Mountain, the Fund signed an agreement to waive the upcoming dividend and to hold their 4 million shares in book entry until after the dividend was paid. Unbeknownst to Generex, and in violation of our written agreement, Creek Mountain took their shares out of book entry and sold them without filing the requisite regulatory documentation with the regulatory authorities, delaying our planned dividend to shareholders.

In the case of Veneto Holdings, they received restricted shares of Generex with a restrictive legend. Since the assets underlying the deal were never transferred by Veneto Holdings to Generex, they were not entitled to have the legend removed from the restricted shares which are in dispute. Unfortunately, the transfer agent, without Generex' consent, transferred 8.4 million shares to Veneto Holdings and removed the restricted legend. The transfer agent acted despite numerous warnings from Generex management and legal counsel, as well as the filing of an 8K attesting to the fact that the Veneto assets were never delivered. Following this egregious action by the transfer agent, the Veneto partners proceeded to dump their now unrestricted shares into the market without filing a Form 144, which must be filed with the SEC by an affiliate of the issuer as a notice of the proposed sale of securities.

Since Creek Mountain Fund and Veneto Holdings started illegally selling shares and putting downside pressure on the stock, our price per share has plunged 75%. We hold these groups as well as the transfer agent liable and responsible for this illegal activity, Their actions were taken without regard to Generex, our shareholders, or financial regulations, and we are pursuing all civil and criminal remedies to rectify this matter, including legal actions to recoup financial losses and filing complaints with regulatory agencies that oversee publicly traded companies. Our attorneys have contacted the SEC in regard to these matters, and we expect a favorable outcome. We will keep our shareholders apprised of our activities and actions in regard to this ongoing matter, as we believe that eventually justice will be done to the benefit of Generex and our shareholders.

In conclusion, this week marks the three-year anniversary from the start of a transformation and revitalization of Generex for our loyal shareholders. We are positioned to realize our vision of building a new kind of healthcare company that is dedicated to rebuilding the patient/physician relationship by providing end-to-end solutions that restructure healthcare economics and optimize health outcomes for the benefit of doctors and their patients. We have filed the Generex S-1 registration statement with the SEC, we expect to pay our shareholder dividends shortly, the NGIO public spin-out is in progress, and we are restarting our orthopedic MSO and planning to start our Arizona operations. And perhaps most exciting, we will be closing our ALTuCELL deal shortly, and we will be revealing exciting news about the potential to cure Type I diabetes with cell therapy. Our plans for revenue revitalization and growth are in place, and we look forward to making 2020 the year that Generex is back on top.

I will discuss our year in review and provide [Additional](#) details about our 2020 plans on our shareholders call next Tuesday January 21 at 9:30 AM; details for the call will follow.

About Generex Biotechnology Corp.

Generex Biotechnology is an integrated healthcare holding company with end-to-end solutions for patient centric care from rapid diagnosis through delivery of personalized therapies. Generex is building a new kind of healthcare company that extends beyond traditional models providing support to physicians in an MSO network, and ongoing relationships with patients to improve the patient experience and access to optimal care.

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This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

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