

Generex Biotechnology Signs Letter of Intent to Acquire 51% in ALTuCELL, Inc. and their Cellular Therapy Product Altsulin® with Patented Microencapsulation Technology for the Treatment of Type I Diabetes Mellitis

- Patented Cell Encapsulation Technology Enables Cell Implantation for Therapeutic and Regenerative Medicine Application Without Immune System rejection
- Microcapsules formulated with ultra-purified alginates and poly-L-ornithine previously have received authorization from the EMEA and Italian Medicines Agency for use in patients with type 1 diabetes (T1D)
- 4 transplanted human patients with long-standing T1D have shown evidence of grafted encapsulated islet cell function throughout 5 years of post-transplant follow-up
- Altsulin® (Microencapsulated Sertoli Cells) currently in human proof-of-concept clinical study in patients with Laron syndrome
- Clinical development of Altsulin for the treatment of T1D

MIRAMAR, FL, September 9, 2019/PRNewswire/ -- Generex Biotechnology Corporation (OTCQB: GNBT) is pleased to announce that the Company has signed a binding letter of intent (LOI) to partner with ALTuCELL, a privately held biotechnology company in a stock and cash transaction. ALTuCELL, Inc. is a cellular engineering and biotech company backed by sound research and science focused on fulfilling a large "unmet need" in cell, molecular and regenerative therapy for treatment of diabetes and other autoimmune and neurodegenerative diseases. The company's proprietary and unique technology overcomes the major barriers to transplantation by a novel strategy utilizing patented microencapsulation technology, enabling a transplantable, cell-based therapy that avoids detection and rejection by the immune system.

ALTuCELL is presently engaged in a human proof of concept study designed to evaluate the ability of Altsulin to increase serum levels of Insulin-Like Growth Factor-1 (IGF1) in patients with Laron Syndrome (aka Laron-type dwarfism), an autosomal recessive disorder characterized by an insensitivity to growth hormone (GH), usually caused by a mutant growth hormone receptor. Patients with Laron Syndrome, a pediatric orphan disease, have the lowest level IGF1 values seen in any disease. Altsulin has demonstrated significant effectiveness in increasing serum levels IGF1 in all pre-clinical animal models tested to date, providing the pharmacologic basis for the implanted

Sertoli Cell therapy. For additional information please visit the Altucell web site (<https://altucell.com/home>).

In animal models, ALTuCELL's microencapsulated cell technology have been proven safe and effective not only in the treatment of T1D, but also of other chronic diseases, including neurodegenerative diseases such as Huntington's disease and lethal neuromuscular disorders like Muscular Dystrophy. As for the latter, pre-clinical data look very strong toward clinical application.

The ALTuCELL microencapsulation technology has also demonstrated effective implantation of numerous cell types including Mesenchymal Stem Cells extracted from the post-partum human umbilical cord (Wharton's Jelly) for the treatment of early onset type 1 diabetes and other regenerative medicine applications.

Joe Moscato, President & Chief Executive Officer of Generex stated, "We can't be more excited about this partnership with ALTuCELL and their CEO Gary Harlem to join forces in our common goal to conquer diabetes. With this acquisition, we are reigniting our diabetes-focused development efforts, gaining a clinical-stage cellular therapeutic product, Altsulin for the potential cure of Type I diabetes, as well as the best-in-class, globally patented cellular microencapsulation technology that enables rapid, patent-protected pipeline expansion of cellular and regenerative therapy products. We are building NuGenerex Health MSO with a team of endocrinologists and primary care physicians to provide integrated specialty healthcare services for patients with diabetes. Plus, we are now positioned to bring back the Oral-Lyn program with the clinical development of our reformulated Oral-Lyn II that is designed to require only two sprays for glycemic control. Generex will once again be a force in diabetes, and we are happy to have ALTuCELL as an integral part of our plans."

Gary Harlem, ALTuCELL's President & Chief Executive Officer commented, "I have made it my life's mission to find a cure for Type I Diabetes, and have been working for nearly a decade with Dr. Riccardo Calafiore, Dr. Giovanni Luca and Dr. Giuseppe Basta from the University of Perugia Department of Medicine to perfect the technology for cellular implantation. Our patented process ensures that our microcapsules are pure and virtually endotoxin free and maintain their immunoisolatory properties in vivo, with no toxicities nor immune rejection. We are excited to begin U.S. trials over the next few months, working closely with our expert scientific team and founders.

Mr. Harlem continued, "We are extremely happy to join Generex and to work with their highly experienced management team to bring Altsulin through clinical development to the market. It is great to have a diabetes expert like Dr. James "Andy" Anderson on the Generex team for guidance on our development program. Additionally, the NuGenerex MSO model provides a number of benefits to us,

including access to physician researchers and a large population of patients with diabetes who will be eligible for clinical trials. With the Generex end-to-end model, these doctors and patients are not only research partners but also future customers. We are excited for the future.”

Generex will provide additional details on the deal as the transaction is finalized.

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.

In addition to advancing a legacy portfolio of immune-oncology assets, medical devices, and diagnostics, the Company is focused on an acquisition strategy of strategic businesses that complement existing assets and provide immediate sources of revenue and working capital. Recent acquisitions include a management services organization, a network of pharmacies, clinical laboratory, and medical device companies with new and approved products.

Our newly formed, wholly-owned subsidiary, NuGenerex Distribution Solutions (NDS), integrates our MSO network with a pharmacy network, clinical diagnostic lab, durable medical equipment company (DME-IQ) and dedicated call center.

About Olaregen Therapeutix

Olaregen Therapeutix, Inc. is a regenerative medicine company focused on development, manufacturing and commercialization of products that fill unmet needs in the current wound care market. Generex aims to provide advanced healing solutions that substantially improve medical outcomes while lowering the overall cost of care. Olaregen's first product introduction, *Excellagen* (flowable dermal matrix) is a topically applied product for dermal wounds and other indications. *Excellagen* is a FDA 510K cleared device for a broad array of dermal wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/ grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds, enabling Olaregen to market *Excellagen* in multiple vertical markets. Additionally, *Excellagen* can

serve as an Enabling Delivery Platform for pluripotent stem cells, antimicrobial agents, small molecule drugs, DNA-Based Biologics, conditioned cell media and peptides. Olaregen's initial focus will be in advanced wound care including diabetic foot ulcers (DFU), venous leg ulcers and pressure ulcers. Future products focusing on innovative therapies in bone and joint regeneration comprise the current pipeline. Generex's mission is to become a significant force in regenerative medicine and advance the science of healing.

About our Service-Disabled Veteran-Owned Small Business (SDVOSB)

This a Service-Disabled Veteran-Owned Small Business (SDVOSB) that specializes in the sale, marketing, and distribution of innovative medical products through a nationwide network of veteran owned distribution services.



About Pantheon Medical

Pantheon Medical is a manufacturer of a physician friendly, “all-in-one”, integrated kit that includes plates, screws, and tools required for orthopedic surgeons and podiatrists conducting foot and ankle surgeries. Generex is developing and submitting several new product lines to the FDA which will include cannulated surgical screws, plates, and implants.

About MediSource Partners

MediSource Partners is a 10-year-old private company, currently contracted with over 25 vendors (including Pantheon Medical) for nationwide distribution of implants and devices for spine, hips, knees, foot, ankle, hand, and wrist surgeries. Additional product lines include biologics (blood, bone, tissue, stem cells), durable medical equipment, and soft goods. Generex also supplies kits to process bone marrow aspirates and platelet rich plasma biologics at the time of surgery.

Cautionary Note Regarding Forward-Looking Statements

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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