

## **Generex Biotechnology Expands Medical Device Portfolio with Acquisition of Olaregen Therapeutix Inc.**

- Announces Commercial Launch of FDA Approved *Excellagen®*, Proprietary, Patented Wound Care Product Focused on the Treatment of Complicated Wounds including Diabetic Ulcers and 16 Other FDA Approved Indications -

**MIRAMAR, FL**, November 28, 2018 -- Generex Biotechnology Corporation (OTCMKTS:GNBT) announced today the signing of a Letter of Intent to acquire 51 percent of Olaregen Therapeutix Inc., a New York based regenerative medicine company. Generex made an initial payment of \$400,000 on November 27, 2018 to secure the agreement, and the company is in the process of completing the legal documents with a plan to close the transaction in the coming weeks.

Olaregen will introduce its first product, 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 indications , 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.

Excellagen® activates platelets, triggering the release of essential growth factors and providing a structural scaffold for cellular infiltration and migration, this process significantly accelerates the growth of granulation tissue. Excellagen's® unique flowable fibrillar collagen formulation is topically applied through easy-to-control, pre-filled sterile syringes, and is designed for application at once weekly intervals.

Additionally, Excellagen® can serve as an Enabling Delivery Platform delivering peptides, small molecule drugs, DNA biologics, antimicrobials, stem cell and exosomes. Exosomes, commonly referred to as extracellular vesicles are the residual components of stem cells responsible for cell-to-cell signaling, the most significant aspect of a cell's function. Combined with certain tissue types, Excellasome® can provide a significant advance in regenerative medicine.

Olaregen's pipeline will focus on developing Excellasome® for the regeneration of bones, joints and cartilage. R&D efforts will address the use of Excellasome® in the treatment Osteo and Rheumatoid Arthritis, cartilage repair and plantar fasciitis.

Excellagen® also offers an innovative opportunity in the treatment of the rare disease Ehlers-Danlos Syndrome, consisting of 13 subtypes. The Ehlers-Danlos syndromes are a

group of connective tissue disorders that can be inherited and are varied both in how they affect the body and in their genetic causes. They are generally characterized by joint hypermobility (joints that stretch further than normal), skin hyperextensibility (skin that can be stretched further than normal), and tissue fragility. Research statistics of the Ehlers-Danlos syndromes show the total prevalence as 1 in 2,500 to 1 in 5,000 people. Olaregen will seek Orphan Drug approval for the use of Excellagen® in this rare disorder with limited therapeutic options at this time.

*Excellagen®* has a reimbursement code by the Healthcare Common Procedure Coding System that has a unique Q Code designation 4149 referred to as a skin substitute.

“We are enthusiastic to bring Olaregen into the Generex family of companies,” stated Joe Moscato, CEO of Generex. This acquisition perfectly illustrates our corporate strategy as we build a new pharmaceutical company model. *Excellagen®* is FDA cleared and ready to launch using our investment, which is directed at building sales and commercial value almost immediately. We are launching *Excellagen®* through our direct to physician market channels established with our recently announced acquisitions in pharmacy and management services. As we have stated all along, Generex is focused on building an “end-to-end” solution to improve healthcare for doctors and patients, and the acquisition of Olaregen is a clear demonstration of this model. All of their pieces fit together beautifully in our current structure and in our plans for the future.”

Terry Thompson, COO of Generex and President of NuGenerex Distribution Solutions, added, “We are actively pursuing new products to support our MSO network of physicians and surgeons. Excellagen will be a game changer for our physician networks and their patients in providing a cutting-edge regenerative medicine solution to promote healing and tissue repair of difficult to treat diabetic foot ulcers and tunneling wounds. This acquisition clearly advances our overall mission to solidify the doctor patient relationship by providing innovative medicines that improve health outcomes.”

Anthony J. Dolisi, CEO of Olaregen, continued, “We are proud to be joining the Generex family of companies with this new venture. This is an exciting time for the team at Olaregen, which was established with the primary purpose of commercializing *Excellagen®*, a proprietary, patented, advanced wound healing product that has been FDA cleared based on excellent clinical results and has a 17 year patent protection. The Generex family of companies provides a unique opportunity to execute our commercial launch strategy to deliver product through surgical centers, department of defense, operating rooms, VA system, wound care centers, as well as podiatrists’ offices on the front line in the diagnosis and treatment of patients with wounds and ulcers resulting from diabetes and cardiovascular complications. Collectively Olaregen and Generex have a dedication to clinical excellence and patients and their families stand at the center of all we do.”

### **About Excellagen**

*Excellagen* is an FDA-cleared aseptically-manufactured, syringe-based, ready to use, topical, flowable, 3-dimensional dermal matrix that supports a favorable wound healing environment. *Excellagen* activates platelets triggering release of Platelet-Derived Growth Factor (PDGF), key wound healing growth factors. It is designed to accelerate granulation tissue growth by providing a structural scaffold for cellular migration and proliferation, and activates platelets, triggering the localized release of endogenous growth factors including PDGF. Upon contact with small amounts of blood, *Excellagen* immediately activates the expression of PDGF and activates the healing process. *Excellagen* is an FDA-approved medical device, a highly-purified Type 1 collagen-based gel extra-cellular matrix and delivery system approved for 17 indications in wound care, 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. *Excellagen* can also serve as an Enabling Delivery Platform for pluripotent stem cells, antimicrobial agents, small molecule drugs, DNA-Based Biologics, conditioned cell media and peptides. *Excellagen* is intended for use by healthcare professionals in the United States.

### **About Olaregen Therapeutix**

Olaregen Therapeutix, Inc. is a regenerative medicine company focused on the development, manufacturing and commercialization of products that fill unmet needs in the current wound care market. The company 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. The company is focused in advancing 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. The company's mission is to become a significant force in regenerative medicine and advance the science of healing.

### **About Generex Biotechnology**

Generex is a strategic, diversified healthcare holdings company with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development. The Company's direct-to-patient services support its strategy of all-inclusive access to doctors, diagnostics, therapeutics, and additional health-related services to greatly improve the patient experience in receiving care. On the provider side, Generex's management services remove administrative burdens in multiple provider settings, including private practice and hospital, allowing doctors to devote more time to patient care. Revenue from the Company's subsidiaries will support clinical advancement of its wholly owned therapeutic products with a focus in immunotherapeutics based on stimulating critical members of the immune response, known as T helper cells, and its proprietary buccal administration of insulin.

## **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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