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Generex Biotechnology partners with Olaregen Therapeutix

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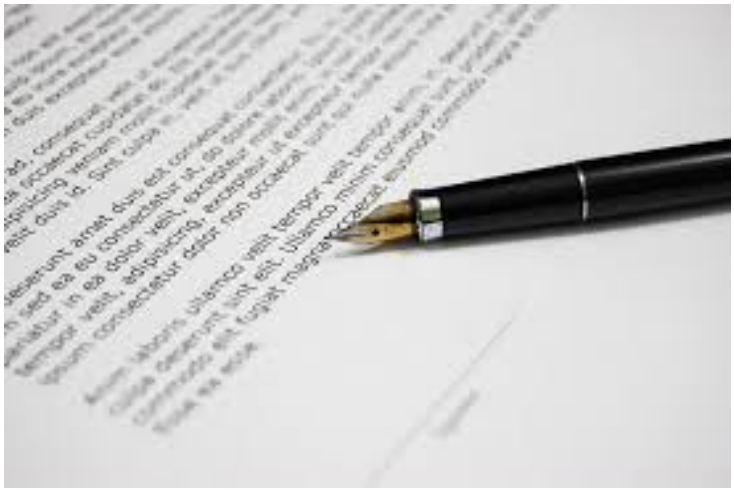

Generex Biotechnology Corporation has announced that its partially, soon to be fully-owned subsidiary, Olaregen Therapeutix, Inc. has signed critical manufacturing agreements for Excellagen with Collagen Solutions, a highly-regarded supplier of medical grade collagen biomaterials for use in research, medical devices, and regenerative medicine applications, and with Berkshire Sterile Manufacturing (BSM), a state-of-the art, GMP fill/finish manufacturer providing formulation and sterile filling as well as analytical development and stability services to the biotech and pharmaceutical industries. The two contract manufacturers will produce and package Excellagen in two dose formulations for the initial product launch in the first quarter of 2019, with a third dosage option for large wounds to follow shortly thereafter.

The wound care market is expected to reach $22.8 billion by 2023 from roughly $19 billion in 2018 at a compounded annual growth rate of 3.7%, according to a report from Markets & Markets. Advanced wound care products are designed to cure and treat a variety of complex wounds, such as diabetic foot ulcers, venous ulcers, and pressure ulcers, burn, trauma and other types all of which Excellagen are cleared for use. The rising incidence of difficult to treat wounds are driving the growth of advanced wound healing products resulting from Increasing prevalence of diabetes, a rapidly aging population as well as developments and innovations in enhanced wound care products such as Excellagen.

In the United States, it is estimated that as many as 4.5 million people have chronic wounds, resulting in substantial economic and psychosocial costs. Various pathologic states result in chronic wound development, including arterial or venous insufficiency, diabetes, undue skin pressure, presence of a foreign body, and infection.

Anthony J. Dolisi, CEO of Olaregen Therapeutix commented: “We are extremely pleased to announce the initiation of production of Excellagen and our partnership with Collagen Solutions and BSM. These premier manufacturing companies have the scale and flexibility to ensure that Olaregen is prepared for commercial introduction with multiple dosing options for Excellagen. We now have access to vast resources and customer/support networks with a common goal of reducing waste and allowing vertical markets to select the optimal, cost-effective Excellagen dose based on the patients’ needs. Wound

healing is clearly a market that needs to address these issues. With a comprehensive understanding of the needs of physicians and patients, combined with a strategy that embraces improved product offerings along with a competitive economic advantage we are confident is our roadmap to success.”

Joe Moscato, CEO of Generex said, "We are excited that Olaregen has begun its commercialization efforts for Excellagen in 17 FDA-cleared treatment indications, especially in surgical applications and in areas of high unmet medical need like Mohs surgery (for skin cancer) and diabetic foot ulcers. As we advance the aims of Generex in building a best-in-class regenerative medicine company, I am pleased to announce that Generex has signed a term sheet for a $15 million equity line to make our obligatory payments to fund the manufacturing and commercial launch of Excellagen, and to ultimately close the full acquisition of Olaregen. The equity line, once complete, will also be available to fund the clinical development of Regentys Extra-Cellular Matrix Hydrogel (ECMH) that will culminate in FDA submission and approval. The equity line enables Generex to manage its financials by making payments to our subsidiaries based on value-driven milestones rather than through immediate shareholder dilution. We plan to provide details of this equity financing agreement in the coming days as we finalize the closing documents and receive Generex board approval on the full transaction".

Mr. Moscato continued, “The closing documents for Regentys are complete and in attorney review, and that closing should take place in the coming days, followed shortly thereafter by Olaregen. In addition, we will be announcing plans to add two new acquisitions to the NuGenerex family of companies that will add significant revenues to NuGenerex Distribution Solutions.”

Generex Biotechnology is a strategic, diversified healthcare holdings company with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development. The mission of the company is to provide physicians, hospitals, and all healthcare providers with an end-to-end solution for patient centric care from rapid diagnosis through delivery of personalized therapies, streamlining care processes, minimizing expenses, and delivering transparency for payers.

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. 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.