DESTINATION STARTUP

Localis Therapeutics, LLC

One-Sentence Summary of What You Do: Localis Therapeutics translates patented technologies that locally suppress the immune response to a tissue transplant that is safer and more cost effective compared to the current standard of systemic (whole body) immunosuppression.

Affiliated Institution: University of Wyoming

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Venture Capital

Please describe your company and the problem you are trying to solve: Live tissue transplantation is often the most restorative implant after tissue injury because the transplanted tissue matches the complex biological and mechanical characteristics of the injured tissue. However, the necessity of immunosuppression prevents the use of transplanted tissue in many cases due to the health risks (pathogens, cancers, organ toxicity) of current systemic (whole body) immunosuppression methods, which are also very expensive to administer and monitor. Localis Therapeutics is a start-up company that holds exclusive license to the technologies patented by Dr. Jared Bushman at the University of Wyoming that create a localized zone of immunosuppression only around the tissue transplant rather than the whole body. This circumvents the risks and much of the costs of immunosuppression. The first application of this technology will be for peripheral nerve transplantation to regenerate motor and sensory function after peripheral nerve injury. Animal experiments show that the Localis technology leads to regeneration that is 2.5 to 10-fold more effective than current therapeutic options in this application. Localis is also working with two Denver-area industrial partners, AlloSource and Terumo Blood and Cell Technologies, who are committing resources “in-kind”. AlloSource is working with Localis to create a supply chain for human peripheral nerve tissue and Terumo is developing GMP methods to expand the cell population used in Localis’ patented technology. AlloSource has interest to be a supplier of nerve tissue for the device, and potentially sub-license it as it matures while Terumo’s interest is to expand clinical use of their Quantum ® Cell Expansion System.

What is/was your go-to-market strategy? Each year, approximately 515,000 individuals in the United States require surgical intervention to repair a damaged peripheral nerve, generating a market of 1.5-2.8 $ billion. Recovery is sub-optimal with current options and there are many patients who will not recover at all because their nerve injuries are too large and therefore untreatable. This results in permanent disability. Animal experiments show that Localis technology of localized immunosuppression paired with a live nerve graft significantly increases regeneration after severe nerve injury. Our strategy for market entry is for our device to initially be used to treat larger nerve

injuries that are currently untreatable, and therefore lack competition. As surgeons become accustomed to our device for the larger injuries, we anticipate increasing market share for smaller nerve injuries that are the largest part of the market. Our partner AlloSource is experienced in product development and has agreed to work with us on GMP production and future clinical trials, leveraging their GMP facilities and network of surgeons.

How will/do you generate revenue? Localis Therapeutics is an early stage company. It plans to develop its technology through Phase I clinical trials, which will establish the safety and preliminary clinical proof of concept. Localis will most likely sub-license the technology during Phase I or early Phase II clinical trials, with the potential for a trade sale of the company or an IPO based on the strength of the Phase I data. Localis is open to licensing its technologies earlier in the development process if desired. The value of the technologies, and thereby the company itself, grows with each developmental milestone. In the long term, revenue will be gained as surgeons purchase the device to treat patients. Grant funding has been an effective method to develop proof of concept data and Localis continues to apply for grant funding, with a $700,000 Phase I NIH STTR application currently under review.

How will this showcase benefit your company or technology? This showcase will provide us with the opportunity to present our technology and commercialization plan, highlight the innovative aspects of our technology and gain visibility with the investment and business leadership that is active in this community. Localis Therapeutics will require $6.5M to complete pre-clinical development of the technology in preparation for Phase I clinical trials. This will include validation in a pre-clinical large animal model and work to generate protocols for device assembly and storage in preparation for an IND. We would anticipate that this 6.5 M would be obtained in a series of phased milestones, starting with $1.9M, then $2.5M and lastly $2.1M to complete the pre-clinical development. With the completion of the pre-clinical period, we will then work with our partner AlloSource, who have committed facilities for GMP production that will be sufficient to carry through clinical trials. Additional rounds of funding will be necessary to carry through clinical trials, which would come from a commercial partner, venture capital and/or US Department of Defense funding. Preliminary discussions with the FDA indicate designation as a Regenerative Medicine Advanced Therapy is a possibility. In addition to device development, the primary goals with this early stage funding are to recruit personnel to Localis that can speed its development. In the short term, this will include a CEO and Board of Directors.

Who are the members of your team and why is this the right team to get the job done? Jared Bushman – Founder and President. Dr. Bushman has more than 18 years of experience in R&D, both within the academic community and within the Armed Forces Institute for Regenerative Medicine. He has worked on the development of multiple technologies in clinical trials and is an advisor for several regenerative medicine companies.