DIRECT SPINAL THERAPEUTICS INC.

NON-CONFIDENTIAL EXECUTIVE SUMMARY

Direct Spinal Therapeutics Inc. (DSTI) is a start-up medical device company founded in 2013 by researchers from the University of Iowa, University of Virginia and an experienced founding CEO. DSTI is developing the Iowa-Patch (I-Patch) as a next generation spinal cord modulation product platform that will enable better treatments for chronic pain, movement disorders, spinal cord injury and other debilitating conditions of the spine.

The I-Patch innovation is a unique, patented electrode array and system design which allows for safe, chronic implantation of the electrode directly on the spinal cord enabling a far greater dynamic range of targeted stimulation and using far less power than conventional spinal cord stimulators (SCS).

The Company has received $1M in seed funding in addition to significant departmental funding that has advanced the program from initial concept in 2011 through extensive chronic in vivo animal and human cadaver testing. In order to ensure a highly-capital efficient approach to the successful development of the I-Patch, DSTI has entered into a technology and device supply agreement with Cochlear Ltd, the leading manufacturer of cochlear implants with revenues approaching $800M. The company is also working with Evergreen Medical Technologies of St. Paul, MN, an expert contract medical device design and development firm, for engineering and pilot manufacturing of the I-Patch.

The Company anticipates closing a $4M-6M Series A round in late 2014 to fund FDA-required GLP testing and a first-in-human (FIH) proof-of-concept clinical study in patients with chronic debilitating pain. The University of Iowa Hospitals & Clinics (UIHC) has committed to cover clinical and surgical costs for the first 12 patients in the Pilot/FIH study.

Background

Chronic pain remains one of the largest and hardest to treat medical indications. Electrical stimulation of the spinal cord was first proposed as a method for pain treatment more than fifty years ago. Today, spinal cord stimulation systems (SCS) constitute a major segment of medical device market with annual sales approaching $2B and annual growth of 8-9%. The enormous scope of the chronic pain public health problem is driving growth in this device market despite the marginal efficacy of current SCS systems. Results of well-designed clinical trials show that approximately only 50% of patients implanted with current SCS systems experience sustained therapeutic benefit beyond one year. All current SCS systems deliver stimuli from electrodes placed over the fibrous lining of the spinal canal (dura) and must traverse several millimeters of circulating, highly conductive cerebrospinal fluid (CSF) to modulate the spinal cord. Today’s extradural SCS devices can only modulate neural elements that are within 250μm of the surface of the cord, equating to less than 1% of the neural structures present. This severely limited capacity to activate targeted spinal cord neural pathways is believed to be a major contributing factor to poor clinical outcomes with current SCS systems.
I-Patch Solution
The I-Patch exploits modern advances in neural stimulation technologies and materials science in a unique device capable of safely delivering electrical stimuli directly to any targeted sub-region of the human spinal cord.

The I-Patch intra-dural spinal modulation system is comprised of an externally powered subcutaneous pulse generator (supplied by Cochlear), which is connected to a lead-extension (tether), which is further connected to the active portion of the device, the I-Patch electrode lead, which is implanted directly on the spinal cord and held in-place with a standard dural patch seal and a patented fixation system.

I-Patch Opportunity and Value Potential
- Chronic pain, particularly low back and leg pain, affects a huge number of people (>30M) in the US which will continue to increase as the population ages.
- Spinal cord stimulation systems (SCS) have been demonstrated to provide pain relief in up to 50% of patients.
- The current SCS market is large (~$2B) and growing with three primary entrenched and several emerging competitors. SCS products offer these commercial companies attractive selling prices and gross margins.
- Current SCS products have limited differentiation. The majority of clinical data available for approved and marketed products demonstrates modest efficacy.
- Limited efficacy or the perception thereof is held out as a barrier to increased market penetration of SCS as a reliable and useful therapy for chronic pain conditions.

The I-Patch promises superior efficacy and reliability and if proven and approved could readily compete for share and potentially expand the overall market for SCS to treat pain conditions and, eventually, spinal cord injury.

Competition
The SCS market is dominated by three competitors (Medtronic, Boston Scientific, St. Jude Medial). Two emerging companies Spinal Modulation and Nevro are likely to heighten the competition in these markets. All of these competitors acknowledge the ‘current problem’ with SCS therapy and have attempted to address it through product innovation. However, none of these competitors is pursuing an intra-dural direct spinal cord simulation approach, nor can any of their devices be readily adapted to direct surface of the cord stimulation.

Intellectual Property
DSTI has entered into an exclusive worldwide license with the University of Iowa Research Foundation (UIRF) for rights to all I-Patch related intellectual property. UIRF and DSTI are working with leading medical technology patent counsel at Kilpatrick Towsend & Stockton LLP.
to optimize I-Patch filings and development strategy. As a large and competitive space, the IP landscape for the SCS field is complex. Though at an early stage of prosecution, the initial reviews of I-Patch IP indicate that there is strong basis for freedom-to-operate and the prospects for blocking claims on devices and methods look encouraging.

**Leadership**

Successful development of the I-Patch requires a unique combination of expertise spanning a diverse set of technical fields including biomedical engineering, biophysics, electrical engineering, software development, neurosurgery, pain medicine, pre-clinical and clinical research, and FDA-compliant medical device development and commercialization. DSTI's founders and active partners, provide the start-up company with an exceptional level of management experience, extensive expertise in the requisite domains and highly efficient development resources and capabilities.

**Founders:**
Matthew Howard MD, Chair, Dept. of Neurosurgery University of Iowa
Timothy Brennan MD PhD, Vice-Chair for Research, Dept. of Anesthesiology University of Iowa
George Gillies PhD, Professor, Medical Physics and Biomedical Engineering University of Virginia
Marcel Utz, DScTech, Dept. of Chemistry, University of Southampton
Daniel O’Connell, co-founder/CEO, Functional Neuromodulation; Managing Partner, NeuroVentures

**Partners:**

*Cochlear Corp*    *Jim Patrick PhD, Chief Scientist, Director, R&D New programs*
*NSW, Australia*    *Frank Risi, biomedical engineer, technical contributor*

*Evergreen Medical Technologies Inc.*    *Randy Nelson, President & CEO*
*St. Paul, MN*    *Rob Shurig – Biomedical engineer and project leader*

*NAMSA Inc.*    *Roy Martin DVM – regulatory consultant*
*Minneapolis, MN*    *Woods Rogers LLP, Russell Schundler*

**Financing & Milestones:**

DSTI has closed on $1M of a total $2M convertible seed funding round. The seed round is open through June 2014. A Series A round of $4M-6M is targeted for late 2014 and will fund the company’s FIH Proof of Concept Study in 2016.

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