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Treatment-Enhancing Medical Device Software Technology

Dr. Matthew P Ward
Founder & CSO

CEOCFO: ***Mr. Ward, would you tell us the concept behind Drug Free Therapeutix?***
Mr. Ward: Drug Free Therapeutix (DFTx) is a medical device software company that provides innovative, treatment-enhancing solutions to medical device companies that sell implantable and external (e.g., TENS units) neurostimulators for chronic pain and other indications. Our medical device software technology (EXACT™) can tune the stimulator to patient physiology and preference in days as opposed to months without the use of EXACT™ technology. EXACT™ is designed to optimally measure and control all nerve impulses; it provides a standardized, intuitive programming interface, ensures therapy in a shorter amount of time, and ensures that the therapy lasts over time. This will save hospitals and patients a significant amount of time and money by eliminating the need for recurring, arduous device tune-ups that have prevented the broader adoption and use of neurostimulators as a first-line course of treatment.

CEOCFO: ***How does this compare to what else is available?***
Mr. Ward: Our medical device software will make modern neurostimulators more personalized and effective without a significant regulatory or financial burden to our industry partners and their customers; we want to become the "Intel Inside" of medical devices by making the benefits of our technology available to industry partners that seek an edge on competitors or deeper market penetration. EXACT™ is more versatile than the most closely related technology, which is a spinal cord stimulator that can lock in a nerve response voltage, but lacks a reference and the side effect control features provided by our technology. EXACT™ uses a stable physiological reference, one that is easy to measure and unique to each user. Devices running EXACT™ will always make sure that the response is at a certain level with respect to the user-specific reference point. This allows the neurostimulator to detect and adapt to natural changes in the patient's physiology, such as changes in body posture, electrode position, or electrode impedance, whether they are exercising, or whether the sensitivity of their nerves to electrical stimulation has changed due to the effects of certain drugs and chemicals that may alter nerve function.

CEOCFO: ***Is the device in use today?***
Mr. Ward: Neurostimulators with EXACT™ are being tested in research labs around the US, but they are not yet approved for human use or sale. We have taken the approach of designing device agnostic medical device software because we know that in the medical device space it is very challenging to get an entirely new device to market. We will add value to existing medical device companies with products and services that allow them to rapidly innovate without spending a lot of time and money on R&D. Many companies have devices that have been designed with the capabilities to accept our medical device software, and in most cases, there is a much simpler and more streamlined regulatory pathway for them.

CEOCFO: ***Is it easy to get an audience with the appropriate people?***
Mr. Ward: Finding the right audience is always a challenge. The regulatory process for bringing new medical devices to market in the US is a necessary, but significant barrier to innovation. Established medical device companies want to keep the existing device cost high and R&D cost low, while still being able to compete in the market space. We have tailored our business model to meet the needs of this audience. The use of medical device software to unlock new device functionality is an emerging trend, representing a shift in thinking that could help to accelerate the rate of innovation, reduce the time-to-market, and create a new class of medicine that competes with the best-available drugs and biologics. Many of the large and mid-stage companies have or are developing medical devices that support software upgrades.

Under this model, the regulatory process can be simpler to navigate if the original approved device (without the software upgrade) can serve as the predicate.

CEOCFO: ***Is the medical community aware; how do you reach out?***
Mr. Ward: I think they are becoming more aware through peer-reviewed publications, conferences, competitions and exposure in the media. We are located in Indianapolis, Indiana, but find that many of the people that reach out to us are from the east coast, west coast or the Minneapolis/St. Paul area. We have a web presence, but know that the key to positive awareness will be a strong, positive outcome from a pilot study that tests the safety and performance of EXACT™-enhanced devices against the same device without EXACT™.

CEOCFO: ***Do you find people are skeptical or is there a general acknowledgment of the concept?***
Mr. Ward: It is a mixture of both initially, but the concept is well established and proven in pre-clinical studies. People are naturally wary of new concepts and the burden of proof is in our hands. We have preliminary data demonstrating how this technology can be used in humans without the need for a software upgrade, but more focused studies are in the works. For early investors and adopters of new medical technology, there is an unspoken need for the company to further de-risk their product by completing a pilot study; this is what we are raising money for now. Down the road, our goal is to make EXACT™ a true plug and play solution so that it minimizes any development or upfront expenses required by a corporate partner to integrate EXACT™ into their product line.

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- Dr. Matthew P Ward

CEOCFO: ***Would you explain the technology?***
Mr. Ward: Our first focus is to integrate the medical device software into existing neurostimulators for chronic pain (e.g., spinal cord stimulators and TENS units). The simplest way to do this is to load the software/firmware onto a device that has an onboard microcontroller and a dedicated input for sensors that can be used to measure the neural response to stimulation. With existing neurostimulators, there is no way for the doctor to know how to program the stimulator to tune into the "correct channels" (i.e., neural pathways that transmit pain messages to the brain). They are meant to stimulate activity in very specific neurons in the spinal cord, but the wealth of information in the neural response to stimulation is not yet measured or used to help tune the stimulator. When the correct neurons are stimulated, they produce a numbing effect in specific regions of the body where pain is experienced. The problem is, thousands of channels are within reach of the stimulator, and only a few can ease chronic pain when stimulated. Without measuring and decoding the neural response to stimulation, it can take months to years to find an optimal device setting that stimulates the correct channels for pain relief. Our technology transforms the existing programming interface from something that is tuned like the old analog radio into something that is tuned to the desired channel with the press of a button. It is designed to measure a combination of device settings, neural responses and self-reported efficacy to quickly learn which range of settings on the stimulator is optimal for that particular person.

CEOCFO: ***You mentioned raising money. What is the interest of the investment community?***
Mr. Ward: Some of the bigger potential investors want to see a formal comparison of our technology against the gold standard in a representative patient population and that is what we are working towards right now. We have had some offers for an early acquisition, but we want to take this technology to market to see our vision realized, using non-dilutive funding sources and revenue from licensing agreements to carry us through the startup phase. We believe that neurostimulators, along with our technology and some minor changes to the way they are implemented, stand to become a mainstream treatment option with the same ease of use and higher performance than many drug-based alternatives.

CEOCFO: ***What will be your business model?***
Mr. Ward: Leveraging the device-agnostic nature of EXACT™, DFTx will provide pain management solutions as simple as a pill to chronic pain sufferers around the world, but without the dangerous side effects, decline in efficacy, or addictive qualities often attributed to many prescription painkillers. In one path, DFTx will upgrade 3rd-party stimulators to include EXACT™ control; in a parallel path, DFTx will develop and distribute a line of intelligent external (i.e., noninvasive) stimulators through big chain pharmacies and pain clinics as an alternative to over-the-counter drugs for everyday aches and pains. DFTx will forego many of the regulatory hurdles faced by competitors. EXACT™ is a therapy-boosting

software-based upgrade for existing neurostimulators, requiring little modification to function properly. As a result, we expect that our corporate customers will benefit from an expedited review process for devices under EXACT™ control via a 510(k) pathway (or similar), obtaining regulatory approval in as little as 3 months.

CEOCFO: ***What is the competitive landscape?***
Mr. Ward: The market is filled with general purpose, ineffective technologies that fail to account for individual patient needs, both physical and psychological. We compete with emerging pain management device companies whose product senses a biological response to stimulation and uses it to alter the strength or quality of therapy. EXACT™ is interoperable with most modern neurostimulation platforms. Drug Free Therapeutix distinguishes EXACT™ from emerging entrants' technology by giving the physician and patient total control over the quality of therapy and the management of side effects. EXACT™ "learns" how to most efficiently and effectively provide therapy, based on measured physiological signals and symptom scores entered by the patient. The proprietary learning algorithms of EXACT™ stores and analyzes the neurostimulator settings, the physiological effect at those settings, and symptom scores to better adapt to the unique and evolving treatment needs of each user. In doing so, EXACT™ replaces a complicated stimulus parameter tuning system with a simple set of dials that standardize and significantly simplify treatment customization.

CEOCFO: ***Why pay attention to Drug Free Therapeutix today?***
Mr. Ward: We are a nimble company with a strong team and low overhead. Our prototype has been extensively evaluated in preclinical models and the results have been published in two peer-reviewed journal articles within the last year. Two of our founders invented the technology and are currently the only ones in the world who know how it works and how it is applied. We have licensed additional technology from Purdue University and are a part of their award-winning incubator, The Foundry. The Foundry is providing many of the tools and resources that we will need to move Drug Free Therapeutix from the startup phase to an established, highly profitable company.

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