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SPRINT Percutaneous Peripheral Nerve Stimulation (PNS) System for Pain Management providing an effective Alternative to Opioid Medications or Neurosurgery



Maria Bennett
President, CEO and Founder

SPR Therapeutics
www.sprtherapeutics.com

Contact:
Mark Stultz
MStultz@sprtherapeutics.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

"The opioid epidemic in the United States demands that we find a beyond-the-pill approach to pain relief. With 78 Americans dying every day from an opioid overdose and 1,000 people being treated in emergency rooms daily for misusing prescriptions opioids, we have no choice but to find drug-free alternatives for pain relief. Not to mention, the long-term costs of opioid abuse and addiction to our healthcare system are astronomical."- Maria Bennett

CEOCFO: Ms. Bennett, what is the current focus at SPR?

Ms. Bennett: SPR Therapeutics is preparing to commercialize its first product, SPRINT, which is the only intentionally-reversible and the least-invasive percutaneous peripheral nerve stimulation (PNS) system cleared by the FDA for the management of acute and chronic pain. The device is a safe, effective and drug-free alternative to opioids.

CEOCFO: How does your technology work?

Ms. Bennett: The SPRINT system delivers electrical stimulation to target nerves that impact pain sensation. Our system has been used to treat chronic pain in the back, joints and extremities as well as acute pain such as that following knee replacement.

The SPRINT PNS System includes a threadlike lead and a wearable stimulator about the size of an Apple watch. The lead is placed percutaneously, or through the skin, using a fine needle and connects externally to the wearable stimulator. The stimulator delivers electrical stimulation through the lead, which activates peripheral nerves to achieve pain relief.

SPRINT is unique in its ability to enable lead placement as far as two to three centimeters from the targeted nerve, which gives physicians the distinct ability to preferentially stimulate specific fibers within the nerve to maximize pain relief. The device is removed without surgery at the end of the 30-day treatment period. We have seen significant and sustained pain relief throughout multiple clinical trials studying the safety and effectiveness of SPRINT.

CEOCFO: You say, "intentionally-reversible". Where is the device inserted?

Ms. Bennett: The lead is a threadlike wire pre-loaded into an introducer needle and inserted percutaneously, or through the skin, often using ultrasound guidance to place the lead in proximity to the target nerve that is causing the pain. The needle is removed, and the wire remains in place for up to 30 days. For example, if a patient were suffering from chronic shoulder pain, the lead would be placed near a nerve in the shoulder where a portion of the wire stays in the body, another portion of the wire exits the body where it is connected to a small wearable stimulator. The stimulator provides the electrical stimulation to the lead that then stimulates the nerve to provide pain relief.

CEOCFO: How does the doctor decide how long the device should be used each day?

Ms. Bennett: The doctor first considers the type of pain. For example, in cases where patients have what we call musculoskeletal pain, as is common in the back and joints, physicians typically prescribe the therapy for up to six hours a day. In these cases, a patient may choose to use SPRINT for three hours in the morning and three hours in the afternoon,

it just depends upon what fits into their daily routine. For neuropathic pain that is typical of nerve injuries, the SPRINT system is used all day long for the 30-day therapy period. Regardless of the type of pain, our clinical studies have shown that the majority of patients experience significant pain relief during the 30-day therapy and often experience sustained pain relief after the 30-day therapy period is completed.

CEOCFO: *Is there consensus in the medical community that this is the method that will work? Are there still mixed feelings about whether the concept itself is valid?*

Ms. Bennett: Great question. It's well accepted that neurostimulation can treat pain effectively. Traditionally, it has been done with larger devices that are intended to be required long term. They are surgically implanted in an operating room with a patient under general anesthesia. SPR has taken a very effective therapy and made it user friendly. We have reduced the invasiveness of this therapy given that SPRINT does not require surgery or a permanent implant; rather it can be placed by a physician in an outpatient setting in roughly 10 minutes then completely reversed at the end of the treatment period.

Physicians are seeking less invasive and lower cost alternatives to opioids and other pain management methods that can be employed in the periphery. Most neurostimulation systems are designed to be permanently implanted next to the spinal cord making it difficult to provide an early intervention and cost-effective solution for peripheral pain, acute pain and the like.

CEOCFO: *Is this something to use before you go to opioids or would it start with people who have had a bad rate of success or having problems treating the pain already?*

Ms. Bennett: Several of the top interventional pain specialists plan to use SPRINT as a first-line of defense, long before they write a prescription for opioids. So, yes, this therapy would be used earlier in the pain treatment continuum. Many patients suffering from chronic pain fail earlier interventions such as physical therapy, over-the-counter medications or opioids. When those treatments fail, those patients are referred to the pain specialists who will consider SPRINT as a replacement for or in advance of opiates in the hopes that they can avoid the many side effects including the potential for addiction and abuse.

CEOCFO: *Is there much training that a physician needs to use your system?*

Ms. Bennett: SPRINT can be placed by a physician in an outpatient setting in roughly 10 minutes. The interventional physicians we work with have been trained to identify and target the nerve that's causing the pain. We've adopted lead placement procedures that leverage interventional techniques physicians are already quite familiar with. We believe this will allow SPRINT to be easily incorporated into the physician's practice. We have a video that demonstrates how to use the system and we provide on-site training and support to help the physician become self-sufficient without requiring procedure scheduling around a company representative's schedule.

CEOCFO: *We are a society that always looks for a pill to make it better. How do you overcome that so patients are willing to try this before the pill?*

Ms. Bennett: The opioid epidemic in the United States demands that we find a beyond-the-pill approach to pain relief. With 78 Americans dying every day from an opioid overdose and 1,000 people being treated in emergency rooms daily for misusing prescriptions opioids, we have no choice but to find drug-free alternatives for pain relief. Not to mention, the long-term costs of opioid abuse and addiction to our healthcare system are astronomical. In our own market research data, we are finding that patients are fully aware of the addiction risk of opioids and other types of pills and they are proactively seeking alternatives. When faced with a treatment that could lead to drug addiction and even death, versus a safe, non-surgical and effective therapy, I absolutely believe chronic and acute pain sufferers will choose the latter.

CEOCFO: *What was the biggest challenge in creating the technology?*

Ms. Bennett: We've had so much opportunity with our PNS system to serve as a platform technology across so many different types of pain, that we've been challenged to identify the target areas and the target markets, where we believe patients and physicians will benefit most while making sense for the company. We are working hard to navigate the massive opportunity we have so we can focus our resources on those markets where we can have the greatest impact.

CEOCFO: *One of the things I see from press releases is that SPRINT™ is the only completely reversible system. What are the other choices?*

Ms. Bennett: There are two other technologies including the implantable technologies, like spinal cord stimulation devices that I referenced earlier. Those devices are surgically implanted by a neurosurgeon or an anesthesiologist with surgical capabilities, and to remove it or to reverse it, would require more invasive surgery. Another technology used today is radio

frequency ablation, or RF ablation. RF ablation uses radio frequency to target the nerves that are the sources of pain and applies the radio frequency to them, killing the nerves to stop the pain signal. Collateral damage is a very real possibility with significant risks and while nerve regeneration is possible, it's not reversible in the same manner as our therapy. For the SPRINT system, the technology is placed, often under ultrasound guidance, during a non-surgical, percutaneous procedure and at the end of the therapy the wire is removed. There's no surgery or tissue destruction, making it completely reversible.

CEOCFO: *What care does the patient have to take with the wire? What does the patient need to do on their side?*

Ms. Bennett: The wire that exits the skin is covered by a bandage. It has a cable that connects to the stimulator when the patient is using the stimulator. When showering, a patient would disconnect the cable and the stimulator to take it off the body. A small part of the wire remains under the bandage. The patient would change the bandage daily to keep it clean. The stimulator lets the patient know if anything is not connected completely, by giving them an error signal. They would consult their physician if that happened. The physician will program the stimulator to have three different modes, so that during the day or during a patient's therapy, if they want to feel it a little bit more or feel it a little bit less, they have these pre-programmed sessions and options all within their therapeutic range. This allows patients to operate their system at home for that 30-day period without repeat visits to their physician for re-programming.

CEOCFO: *Would you tell us about your commercialization strategy?*

Ms. Bennett: We're focused on key geographies and centers of excellence with key opinion leaders that we have worked with during our extensive clinical studies. We're targeting centers in which physicians understand the technology and the challenges of changing the standard of care. We're being methodic and responsible in our roll-out strategy to ensure that we have significant data to support the use of the product in a way that will also garner value-based reimbursement from insurance companies.

CEOCFO: *Are you funded for your next steps?*

Ms. Bennett: We are currently completing a convertible debt offering that will close later this month. We have engaged a banking organization to represent us in a Series C fundraise that will be initiated in the fourth quarter of this year targeting institutional investors who support companies seeking growth capital in the early stages of commercialization.

CEOCFO: *What surprised you through the whole process?*

Ms. Bennett: The amount of patience and education required across multiple areas to get to FDA clearance surprised me. Being close to the product, understanding the therapy, seeing the benefit to patients and working with our physicians, the SPR team believed this should have been a slam dunk to get to market. But there are so many elements in the medical device industry that are out of our control, including FDA's review and approval, the process to obtain reimbursement and the clarification of our offering amidst the noise. We've had to make sure that we can operate as a lean business while being flexible and patient along the way. Every day we're not in the market costs another invested dollar for us. We have to make sure we hire the right people and have the right resources that are capable, flexible and amenable to tackle the challenges we face. Thankfully, our team has been imminently capable and up to the task. One of our board members has called our team "the chameleon" because we deftly adapt to outside forces, decisions and changes, yet still stay on track with our core mission of providing an innovative technology that will be a game changer in the field of pain management and greatly improve patients' lives.

