

# Neurotech

## business report

*from medical technology to commercial products*

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## PNS Market Attracts Host of New Competitors

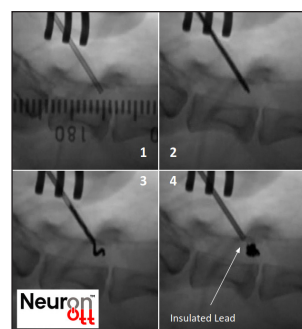
*by James Cavuoto, editor*

The market for peripheral nerve stimulation systems has become increasingly crowded in recent months, as new competitors have emerged to treat neurological disorders such as chronic pain and overactive bladder.

At the recent mid-year meeting of the North American Neuromodulation Society in Orlando, FL [see conference report, p6], executives from six PNS vendors described their product offerings. These included Nalu Medical, SPR Therapeutics, Stimwave, BlueWind Medical, Mainstay Medical, and Neuspera Medical. Several speakers at that session related that growth in the PNS market will be driven by moving neuromodulation up in the continuum of care. In treating bowel and bladder disorders such as OAB, for example, neuromodulation needs to move from a third-line therapy to a first or second option.

Other new players in the PNS market are touting novel implantation strategies. Neuronoff recently disclosed that they have developed a fully removable ver-

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Neuronoff recently showed that its Injectrode is removable with a 16-gauge needle.

## Investors and MedTechs Rush to Fund BCI Startups

*by Jo Jo Platt, contributing editor*

Investor interest in funding startup and early-stage vendors of implanted brain devices continued to flourish in recent weeks. Coming on the heels of Peter Thiel's and re.Mind Capital's \$10 million investment in Blackrock Neurotech [NBR May21 p2], Elon Musk's Neuralink earlier this month announced a \$205 million series C round led by Vy Capital, with participation from Google Ventures, DFJ Growth, Valor Equity Partners, Craft Ventures, Founders Fund, and Gigafund.

Coupled with previous investments of \$70 million across Synchron, Paradromics, and Blackrock, this funding activity indicates that the interest in implantable devices to achieve optimal signal acquisition remains strong. Wearables, while certainly appealing and valuable, seem to represent a device equivalent of over the counter options, while implantables offer the more intense, prescription-like solutions. Sometimes, an aspirin just doesn't cut it.

With implantables, investigators will be able to learn and do more in a shorter time span while wearables can attract casual and consumer users while addressing conditions that can be manipulated closer to the surface.

A number of prominent entrepreneurs joined the Neuralink funding round. These include Robert Nelson, co-founder of ARCH Venture Partners; Blake Byers, founder

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## Facing the Crowd

One of the signs that a new industry or industry segment is poised for growth is the emergence of new competitors to challenge the incumbent players in that space. We are clearly seeing that come to pass in the neurotechnology industry.

The first neuromodulation industry segment to experience this was spinal cord stimulation when Advanced Neuromodulation Systems (now Abbott) and then Advanced Bionics (now Boston Scientific) challenged Medtronic's dominance in that space. Nevro later joined the club with their paresthesia-free technology and now Saluda, Biotronik, and perhaps one or two others are ready to jump in.

As we report in our article on page 1 of this issue, a similar phenomenon is taking place in the much younger, but highly promising peripheral nerve stimulation market segment. The early market leaders Bioness (now Bioventus), SPR Therapeutics, and Stimwave are being challenged by newcomers Nalu, BlueWind, Neuspera, and Neuronoff. Our recently published market report, *The Market for Implanted Pain Neuromodulation Systems: 2021-2026*, projects the impact that some of these new players will have on both SCS and PNS market share in the years ahead.

Another neurotech market segment facing new competition is hypoglossal nerve stimulation, where Nyxoah is challenging incumbent Inspire Medical, with LivaNova and a bevy of startups like X-Nerve and Sonosa Medical waiting in the wings. With the help of some well heeled investors, the market for implanted BCI devices is getting crowded [see article p1]. Though Blackrock (and its predecessor Cyberkinetics) was the first real player in this small but emerging market segment, Neuralink, Synchron, and Paradromics are well positioned and several smaller players like Modular Bionics and Neurosoft are likely to join later on.

The issue of how many players can a market segment can support came up during the recent i3 session at the NANS Mid-Year meeting in Orlando, FL [see conference report p6]. While some medtech sectors like cardiac devices can flourish with a half-dozen or more competitors, the SCS market is not yet that big. On the other hand, the penetration of neuromodulation devices in the potential population of people with chronic pain is still very low, so there should be more room for other vendors.

Many of these topics will be on tap in a session entitled "Neuromodulation Battlegrounds: Insurgents Seek to Capture Share from Incumbents," at the 20th Anniversary Neurotech Leaders Forum on November 8 in San Francisco. We look forward to continuing the discussion in more detail then.

James Cavuoto  
Editor and Publisher

## New PNS Players

from page 1

sion of its Injectrode, an electrode that can be injected using an 18-gauge needle to reach any location currently targeted by lidocaine or steroid injections, such as transforaminal epidural injections which commonly take about 10 minutes in an office setting. The Injectrode conforms with an anchor at the target location, designed to prevent unwanted dislocation or movement in the future.

A TENS-like device is able to stimulate the nerve target tissue deep inside the body by passing current through the Injectrode. Most recently, the team disclosed that the Injectrode can be fully recovered using a 16-gauge needle, which is a first for minimally invasive neuromodulation technologies. The team is reportedly working on integrating its device with other vendors' implantable pulse generators.

Perhaps spurred on by the financial success of Axonics Modulation, PNS startups targeting OAB have attracted considerable investor interest. Earlier this month, Neuspera closed a \$65 million C round [see article, p3]. Last year, European device manufacturer Coloplast acquired Nine Continents Medical, Inc., an early stage company developing an implantable tibial nerve stimulation system, for \$145 million plus milestone payments. Also this month, BlueWind announced that the 100th patient has been enrolled in its OASIS of its RENOVA iStim tibial nerve stimulation system for OAB.

Another new PNS player that emerged on the NANS show floor is a spinoff, of sorts, of Stimwave's injectable neurostimulation system. Stimwave's former CEO Laura Tyler Perryman showed an injectable device called Moventis PNS, which is targeting knee pain. The company marketing the device, Pain Specialists Group Ltd., is likely to face legal scrutiny from Stimwave [see vendor profile, p7]. Perryman said that firm is owned by a group of clinicians who invested in the startup.

Sharing the booth with Moventis was Uro Medical Corp., another Perryman-affiliated firm that recently acquired the assets of Micron Medical Corp. (formerly StimGuard), including the Protect PNS device for treating OAB. Perryman said that firm was owned by her husband and her son.

## Nevro Announces FDA Approval of Senza for Diabetic Neuropathy

Nevro Corp., the Redwood City, CA manufacturer of neuromodulation systems, announced receipt of FDA approval of its Senza system for the treatment of chronic pain associated with painful diabetic neuropathy. This approval is specific to Nevro's 10 kHz stimulation, and Nevro now has the only SCS system approved by the FDA with a specific indication to treat PDN. The company will immediately initiate commercial launch activities in the U.S. under its recently launched HFX branding.

"This FDA approval marks a capstone achievement that demonstrates the strength of our clinical data and provides a proven, new breakthrough SCS treatment option for PDN patients who are struggling with debilitating pain and who are unable to find relief with currently available pharmacologic options," said D. Keith Grossman, chairman, CEO, and president of Nevro. "We are thrilled that we can now begin commercial launch activities in the U.S. and believe this new indication will be an important driver of the long-term growth of our business for years to come."

Study participants demonstrated significantly improved and sustained outcomes with 10 kHz SCS, including substantial, sustained pain relief and improved health-related quality of life. The six-month results for the SENZA-PDN randomized controlled trial were published in *JAMA Neurology* in April 2021, and the 12-month follow-up results and 6-month cross-over patient data were presented at the American Diabetes Association meeting last month.

"The substantial pain relief and improved quality of life demonstrates that 10 kHz therapy can safely and effectively treat this patient population," stated Erika Petersen, professor of neurosurgery at the University of Arkansas for Medical Sciences, and lead investigator of the study.

## Neuspera Medical Announces \$65 Million Series C Funding Round

Neuspera Medical Inc., the San Jose, CA manufacturer of neuromodulation systems, announced the closing of the company's \$65 million series C equity financing. The round was co-led by Vertex Ventures HC and Treo Ventures. Lori Hu, a managing director at Vertex Ventures HC and Mudit Jain, managing partner, Treo Ventures, joined the board of directors. Returning investors include Action Potential Venture Capital and Windham Venture Partners. The proceeds will fund the company's SANS-UII pivotal clinical study of its miniaturized implantable neuromodulation technology platform for use in subjects with urinary urgency incontinence, a symptom of overactive bladder. "We are excited to see the first cohort of patients experiencing the known benefits of sacral nerve stimulation through the use of our ultra-miniaturized neuromodulation platform—driven by the support of the physician investigators in the SANS-UII clinical trial," said Milton Morris, president and CEO of Neuspera Medical. "We are excited to continue our focused efforts on enabling access to the known benefits of neuromodulation to patients who are struggling with chronic and debilitating medical conditions."

## Abbott Announces Financial Results for Second Quarter

Abbott, the Abbott Park, IL manufacturer of neuromodulation systems, announced financial results for the second quarter ended June 30, 2021. Second-quarter sales of \$10.2 billion increased 39.5 percent compared to \$7.3 billion a year ago. Neuromodulation sales for the second quarter increase 98 percent to \$210 million. Net earnings for the second quarter were \$1.19 billion (66 cents per diluted share), an increase of 121 percent compared to \$537 million (30 cents per diluted share) in 2020. "We're achieving very strong growth across our portfolio," said Robert B. Ford, president and chief executive officer, Abbott. "Perhaps most impressively, excluding COVID testing-related sales, our sales grew more than 11 percent on an organic basis compared to pre-pandemic levels in the second quarter of 2019, which demonstrates the fundamental strength of our performance."

## Boston Scientific Announces Financial Results for Second Quarter

Boston Scientific Corp., the Marlborough, MA manufacturer of neuromodulation systems, announced financial results for the second quarter ended June 30, 2021. Net sales for the quarter were \$3.08 billion, an increase of 53.6 percent compared to the prior year period. Neuromodulation sales for the quarter were \$247 million, an increase of 102 percent compared to \$122 million a year ago. The company reported net income of \$172 million (12 cents per share) in the second quarter, compared to a net loss of \$153 million (11 cents per share) a year ago. "We delivered excellent results this quarter, with strong momentum throughout our portfolio and faster-than-market growth in most segments, fueled by our team's dedication to customers and patients all over the world," said Mike Mahoney, chairman and CEO, Boston Scientific. "We are confident that our focus on meeting customers' needs today, and our innovative pipeline to solve tomorrow's challenges, will continue to deliver value for patients, customers and shareholders."

## electroCore Announces \$18 Million Public Offering of Common Stock

electroCore, Inc., the Rockaway, NJ manufacturer of neuromodulation systems, announced the pricing of an underwritten public offering of 18,000,000 shares of its common stock at a public offering price of \$1.00 per share. In addition, the company granted the underwriters a 45-day option to purchase up to an additional 2,700,000 shares of common stock at the public offering price, less underwriting discounts and commissions. The company intends to use the net proceeds of the offering for sales and marketing, working capital, and general corporate purposes.



### NeuroMetrix Announces Breakthrough Designation for Fibromyalgia

NeuroMetrix, Inc., the Woburn, MA manufacturer of neuromodulation systems, announced that its Quell device has received breakthrough designation from the FDA for treating the symptoms of fibromyalgia in adults. Fibromyalgia is a common form of chronic pain that is also accompanied by fatigue, sleep, cognitive and mood disturbances. It affects an estimated 2 to 6 percent of the U.S. population. Quell is a wearable noninvasive nerve stimulation device that is enabled by a custom designed microchip that provides flexible, precise, high-power nerve stimulation in a form factor the size of a credit card. The data submitted by NeuroMetrix in support of the breakthrough designation included results from a double-blind, randomized, sham-controlled trial. A total of 119 subjects with fibromyalgia were enrolled and randomized to a standard (active) or modified (sham) Quell device for three-months of at-home use. In an intention-to-treat analysis of all subjects, 56 percent of those on active treatment exhibited a clinically meaningful improvement in health-related quality-of-life compared to 35 percent that received sham treatment. “The breakthrough device designation is an important milestone in the company’s effort to make Quell technology available to people living with fibromyalgia,” said Shai Gozani, president and CEO of NeuroMetrix. “We are moving forward with a regulatory filing that could position us to launch Quell for this indication in the second half of next year.”

### NeuroPace Announces BRAIN Initiative Award for Lennox-Gastaut Syndrome

NeuroPace, Inc., the Mountain View, CA manufacturer of neuromodulation systems, announced that it has received an NIH grant through the BRAIN Initiative that will provide up to \$9.3 million over five years to evaluate the use of NeuroPace’s RNS system to treat Lennox-Gastaut syndrome. LGS is a form of childhood-onset epilepsy that causes cognitive dysfunction and frequent generalized onset seizures that often lead to injury. The IDE study, which will be the first to evaluate a neuromodulation device in patients with Lennox-Gastaut syndrome, is projected to start enrolling patients in the second half of next year. In addition to the potential therapeutic benefits, the ability of the RNS system to provide continuous monitoring and recording of brain activity could help to optimize therapy for each individual, and may offer new insights into this condition. “We are pleased that the NIH recognizes the promise of responsive neuromodulation to potentially address the current gap in therapeutic options for patients with debilitating seizure disorders such as LGS,” said Martha Morrell, CMO of NeuroPace and principal investigator of the study.

### Neuroliief Teams with NeuroFront for Relivion Device in China and Korea

Neuroliief, the Israel-based manufacturer of wearable neuromodulation systems, and NeuroFront, a clinical stage biotech company focusing on innovative neuroscience therapies, jointly announced an exclusive licensing agreement for NeuroFront to develop and commercialize Relivion, non-invasive medical devices for the treatment of migraine and depression, in greater China (mainland China, Hong Kong, Macau, and Taiwan) and South Korea. “With 90 million people suffering from migraine and nearly 50 million suffering from depression in greater China and South Korea, we believe this collaboration with NeuroFront is critical to our mission of helping patients globally,” stated Neuroliief chairman Chris Richardson. “We are confident that the NeuroFront team’s compelling expertise will accelerate the development and commercialization of Relivion in key Asian markets.” “Because of our commitment to developing the most innovative and effective neuroscience therapies to improve the lives of patients in Asia, NeuroFront is very excited to partner with Neuroliief to bring Relivion to the many patients in greater China and South Korea suffering from migraine and depression,” commented June Yan, co-founder and CEO of NeuroFront.

### BCI Investment

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of Byers Capital; Sam Altman, chairman of YC Group and CEO of OpenAI; Fred Ehrsam, co-founder of Paradigm and Coinbase; and Ken Howery, co-founder of PayPal and Founders Fund.

For its part, Paradromics announced a \$20 million seed funding round led by Prime Movers Lab, including investment from Westcott Investment Group, Dolby Family Ventures, Synergy Ventures, Pureland Global Venture, IT-Farm, and Alpha Edison. The company’s first commercial product, the Connexus Communication Device, will restore communication for patients who have lost the ability to speak due to severe paralysis. Last year, Paradromics successfully completed testing of its platform, demonstrating the largest ever electrical recording of cortical activity that exceeded more than 30,000 electrode channels in sheep cortex.

“We are combining the best of neural science and medical device engineering to create a robust and reliable platform for new clinical therapies,” said Paradromics CEO Matt Angle. “This funding round is a validation of both our technology and strategic vision in leading this important developing market.”

Meanwhile, Blackrock Neurotech continued its ambitious efforts to capitalize on its early lead in implanted BCI technology. The company announced a joint agreement with ClearPoint Neuro, Inc., a vendor of neurosurgical navigation tools, to develop an automated surgical solution for implanting BCIs into patients. This partnership will seek to leverage ClearPoint’s platform and software to deliver, for the first time, a clinical solution for surgeons that is more streamlined and effective than other BCI implantation surgeries performed to date.

“The challenge of making people walk, talk, move and feel again is an enormous one,” said Marcus Gerhardt, co-founder and CEO of Blackrock Neurotech. “To make this vision a reality, we believe in partnering and collaborating with the best in the field. We are excited that ClearPoint is joining us in this endeavor to provide their expertise in navigation and surgical processes to create an integrated solution.”

“The partnership with Blackrock will

allow us to leverage our expertise in neuro-navigation and robotic delivery to create a system capable of assisting surgeons to implant these BCI arrays in a predictable and replicable manner,” said Joe Burnett, president and CEO of ClearPoint.

Under the agreement, Blackrock will help fund the development of this new surgical solution, which will leverage the ClearPoint platform and growing global installed base. Blackrock’s recent infusion of capital from re.Mind Capital and others was designed to accelerate enrollment in clinical trials, advance surgical procedures such as this, and prepare for a commercial launch across multiple clinical indications.

Last month, Synchron Inc. announced a \$40 million investment round led by Khosla Ventures [NBR Jun21 p3]. The FDA recently approved its IDE for a feasibility study of its Stentrode motor neuroprosthesis.

## Neurotech Reports Announces Agenda for 2021 Leaders Forum

Neurotech Reports, the publisher of this newsletter, announced the agenda for the 20th anniversary Neurotech Leaders Forum, which will take place in San Francisco on November 8-9, 2021. The event will also include speakers and attendees who prefer to participate via videoconference.

The agenda includes sessions devoted to obtaining reimbursement for neurotech devices, key competitive battlegrounds in the neuromodulation industry, wearable devices, and psychiatric disorders. Executives from several early-stage and startup neurotech firms will make presentations during two entrepreneur panels, including Kunal Ghosh, CEO of Inscopix, Inc., and Scott Hiatt, CTO of IRIS Biomedical.

Cirtec Medical returns as the Platinum sponsor of the 2021 Neurotech Leaders Forum, while MST is the Gold sponsor. For more information on speaking and sponsorship opportunities, contact Neurotech Reports at 415 546 1259.

## Cognito Therapeutics Presents Data on Gamma-Frequency Stimulation for AD

Cognito Therapeutics, the Cambridge, MA manufacturer of bioelectronic medicine therapies for neurodegenerative disorders, presented key findings from clinical research involving its lead digital therapeutic candidate at the Alzheimer’s Association International Conference 2021 in Denver, CO, earlier this month. These results, disclosed in six poster presentations at AAIC, included data on gamma frequency neuromodulation on cognitive function in Alzheimer’s disease, which showed improvements in sleep, improvements in memory and cognition, as well as a reduction in brain atrophy and volumetric loss. The Phase 2 OVERTURE study is a prospective six-month treatment study in mild-to-moderate AD. In the study, anatomical and structural magnetic resonance imaging data were acquired at screening/baseline, 3-months and 6-months using 1.5 Tesla MRI. These imaging data were used for safety monitoring and longitudinal biomarker outcomes including quantification of neurodegeneration via MRI. The study demonstrated that gamma frequency neuromodulation led to a significant reduction in brain atrophy in AD patients. Accelerated brain atrophy is associated with cognitive decline and loss of function in AD patients and is a driver of mortality and morbidity in the disease progression. Over a six-month treatment period, significant treatment benefits were observed in the active group versus the sham group. The treatment group demonstrated a significant, 65 percent reduction in whole brain volume loss as compared to the sham group over the same interventional period. Gamma frequency neuromodulation over a six-month period reduced night-time active durations and maintained day-time activities. Nighttime active durations in the treatment group were significantly reduced in the second three months compared to the first three months but the opposite change was observed in the sham group. “Our results demonstrate that our unique neurophysiological medicine approach can affect disease modification by improving memory, cognition, and functional symptoms while also reducing brain atrophy, the brain volume loss seen with Alzheimer’s progression,” said Brent Vaughan, CEO, Cognito Therapeutics. “The improvements we have now reported in nighttime sleep for patients with Alzheimer’s provide further support for our mechanism of disease modification in this patient population.”

## SpineX Announces Publication on Neuromodulation for Cerebral Palsy

SpineX, Inc., the Los Angeles, CA manufacturer of neurorehabilitation systems, announced the publication of new data in journal *Neurotherapeutics* which supports the implementation of the company’s SCONE device providing non-surgical treatment for children with cerebral palsy. The article, titled, “Transcutaneous Spinal Neuromodulation Reorganizes Neural Networks in Patients with Cerebral Palsy,” discusses how spinal neuromodulation and activity-based rehabilitation triggers neural network reorganization and enhances sensory-motor performances involving the lower limbs, the trunk, and the upper limbs. This study describes how acute spinal neuromodulation improved the postural and locomotor abilities in 11 out of 12 patients including the ability to generate bilateral weight bearing stepping in a two-year-old (GMFCS level IV) who was unable to step. Cerebral palsy affects more than 17 million individuals worldwide and is the most common motor disability in childhood. Co-author Susan Hastings said, “SCONE therapy is potentially the most effective treatment for children with Cerebral palsy that exists today; it enables voluntary muscle activity at the level needed for a functional activity such as walking with successful therapy being contingent upon proper alignment, posture, and orientation.” According to SpineX CEO, Parag Gad, the company plans to continue testing and developing SCONE therapy for children with CP and will evaluate the long-term effects of combining it with activity-based neuro-rehabilitation.

## Neuromodulation Executives Share Data and Talk Data at NANS Mid-Year Meeting

by James Cavuoto, editor

Several hundred pain clinicians, neurosurgeons, and neuromodulation industry professionals assembled in Orlando, FL earlier this month for the 2021 Mid-Year meeting of the North American Neuromodulation Society. The event, which augmented the society's January 2021 web conference, was the first in-person neuromodulation meeting for many attendees since the onset of the coronavirus pandemic.

The meeting featured a pre-conference commercial session called i3 (invention, investment, and invigoration), which was devoted to "Innovation in a Hyper-Connected World." Course director Ash Sharan from Thomas Jefferson University kicked off the session with a discussion of technology tools used in the delivery of healthcare including chatbots, telehealth, and networking tools.

Erika Ross from Abbott gave an overview of the company's efforts to integrate neuromodulation therapies with digital health tools. Abbott's digitally enabled patient-centricity incorporates artificial intelligence, virtual reality, telehealth, and wearable components. In one study, patients wore Apple watches to help map parameters like heart rate and steps climbed with pain scores. Her team created a "random forest" model that mapped those metrics to the perception of pain. "We could actually predict with a high degree of accuracy what patient's pain scores would be," she said.

Abhi Kulkarni from Medtronic described his company's efforts at data-enabled neuromodulation. Historically, neuromodulation devices were "data-poor," he said. But advances in biosignals have promised to change that situation. In particular, he mentioned evoked potentials, local field potentials, and EMG signals as examples. "The combination of biosensing and data acquisition is going to bend the curve of neuromodulation in the future," he said.

Kulkarni predicted that the amount of data collected per session would increase and the amount energy consumed would decrease in the years to come. "Data that comes through the therapy will have as

much value as the therapy itself," he said.

Other presenters in the morning session included Yelana Yesha, the director of the NSF Center for Accelerated Real Time Analytics and professor of computer science at the University of Miami. She spoke about the role of blockchain and AI/machine learning concepts in the healthcare ecosystem. Danica Marinac-Dabic, the associate director of the Office of Clinical Evidence and Analysis at FDA/CDRH, addressed regulatory issues confronting device firms.

Mark Domyahn from JD Lymon spoke of the challenges confronting neuromodulation vendors when it comes to reimbursement pathways. "Getting value out of the reimbursement system is a journey that each technology has to figure out," he said. "And figuring it out early is really important."

Domyahn said that the gap between what the FDA wants and what CMS wants was very narrow 15 years ago. Now it's getting to be a chasm the size of the Grand Canyon, he said. "Payers write checks—the FDA does not. Payers are built to say no—never forget that," he exhorted. "Come at them with something meaningful."

Domyahn advised attendees to make sure they understand that CMS' concept of "medically reasonable and necessary" is not the same as the FDA's "safe and effective" metric. He stressed the three most important factors in reimbursement: coverage, coding, and payment. Of the three the most important is coverage.

Neuromodulation device vendors seeking reimbursement coverage need to answer several questions early on in the commercialization process. These include: What's the unmet need? How does your product address it? What are the value propositions, both clinical and economic, and for whom do they apply? Domyahn advised attendees to avoid the thinking that their product will save society money. "Society doesn't write a check," he quipped. Instead, it's important to know your specific target population and how your product will benefit that population. It's also important to

consider whether your product is novel or a "me-too" product. Either route could work, but being first to market changes the reimbursement landscape dramatically, he said.

The i3 morning session concluded with a panel discussion with executives from the big four firms in SCS: Abbott, Medtronic, Boston Scientific, and Nevro. Dave Anderson from Medtronic mentioned the company's new Vanta primary cell SCS system. Brad Maruca from Abbott shared his perspective on innovation. "Our approach to every problem starts with the patient," he said.

Nevro CEO Keith Grossman said that innovation is part of the company's DNA. "We consider innovation in the form of evidence," he said. He also mentioned service and support as key elements of innovation. He also highlighted his firm's impending foray into painful diabetic neuropathy. "This is an enormous group of patients who are not being treated effectively," he said.

Boston Scientific Neuromodulation president Maulik Nanavaty mentioned that compared to five years ago, patients are more informed and have more knowledge when they walk into a physician's office. "At the end of the day, the physician, the patient, and the device all have to work together," he said.

The executives seemed to agree that there could be room in the SCS market for one or two new players if they had unique technology, in response to a question about the impending entry of Saluda and Biotronik. But they cautioned that entering this market was not for the faint of heart and that it could take several years for a new player to achieve a foothold.

In an interview with NBR, Boston Scientific ice president of medical affairs Nilesh Patel described some of the competitive advantage of the firms' new fast-acting sub-perception (FAST) and Contour therapies. Patel said that FAST provides profound paresthesia-free pain relief in minutes, while Contour delivers stimulation in a more efficient manner than traditional SCS.



# Stimwave Moves Beyond Legal Battles to Claim its Share of Neuromodulation Market

by James Cavuoto, editor

Stimwave Technologies Inc., the Pompano Beach, FL manufacturer of injectable neuromodulation systems, has seen its share of turmoil and legal action in recent years. But the company is intent on moving beyond its past disputes with competitors and prior management to become a serious player in both the SCS and PNS markets.

Last month, the company offered a business update that promised continued growth acceleration in both PNS and SCS and an expansion of its network of providers. The company also touted recent legal victories that awarded them patents previously licensed from Micron Devices LLC, a company controlled by former CEO Laura Tyler Perryman. Stimwave reached a settlement with Micron which was confirmed in court, resulting in final and clear confirmation of the company's ownership of its core intellectual property assets, including substantial ownership of its subsidiary StimQ Medical LLC. Stimwave had previously settled patent litigation with Nevro over high-frequency stimulation.

Micron Devices has filed chapter 11 bankruptcy and Stimwave is seeking to recover funds advanced to Perryman for legal fees associated with a Department of Justice investigation. In that action, a judge opined that Perryman did not testify truthfully with respect to an indemnification agreement the judge believed was backdated.

In 2019, Stimwave's board removed Perryman as CEO and the two parties are currently engaged in litigation over alleged misconduct and a DoJ investigation into Stimwave's activities. Paul LaViolette was named interim CEO, replacing Tyler-Perryman. In 2020, Aure Bruneau was named CEO. LaViolette remained as chairman of the board. Bruneau brings more 20 years of medical device experience to the role, with specific experience in international management, business development, commercial leadership and new technology development. Most recently, he led the Robotic, CMF/Thoracic, and Spine businesses of Zimmer Biomet.

In an interview with NBR, Perryman blamed the Stimwave board for its woes with the feds, claiming she tried unsuccessfully to get them to correct improper coding claims for PNS applications that differed from SCS codes. She said that as a result, Stimwave is looking at \$100 million in penalties, a figure that a Stimwave representative disputed.

In its update, Stimwave noted that it had completed commercial launch of its upgraded SCS and PNS platforms, bringing extended battery life, enhanced software connectivity, and value-added quality improvements to the market. The company has also trained more than 1,000 healthcare providers virtually and in lab settings through the first half of 2021.

"I am incredibly proud of the accelerated growth and transformation our organization has been able to achieve over the last 14 months during what was an extremely challenging macro-economic environment that included an ongoing global pandemic. We have been able to successfully drive the rapid adoption of our PNS technology and continue to grow our SCS business while at the same time attract market leading talent throughout Stimwave and working through a number of headwinds," said Bruneau. "Looking ahead, we will continue to drive the adoption of our SCS and PNS platforms through the growth of our global commercial organization, medical education, R&D innovation, and acceleration of our ongoing clinical data development."

In June, the company completed the full commercial launch of its updated PNS and SCS products. The upgraded versions of both the PNS and SCS platforms incorporate an upgraded power supply which further extends the length of time needed between charges, as well as enhanced software connectivity. "This upgraded technology is manufactured within the company's recently expanded manufacturing operation center. All of which brings valued-added quality to our customers and patients," the company said.

To support the continued adoption of its SCS and PNS products, Stimwave is

planning to launch several successive SCS and PNS clinical trials starting in this year that are designed to deliver Level 1 clinical evidence across multiple areas of the body.

The company has completed a restructuring of its management and operational team to build out its operational capabilities. Within the last year, it has added significantly to key areas of the business including, compliance, quality, regulatory, accounting, legal, manufacturing operations, R&D, and medical education.

Stimwave was founded in 2010 in Scottsdale, AZ. In 2012, the company closed a \$3 million B round from investors including RCT BioVentures and Thomas Fogarty. In 2018, the company received more than \$50 million in additional financing.

In 2014, Stimwave received FDA clearance to market its four-electrode wireless, micro-technology neuromodulation device for relief of chronic back and leg pain. A year later the eight-electrode version was approved. The Freedom-8A SCS system became the world's first wireless, fully-programmable SCS neuromodulation device. In 2016, Stimwave received FDA clearance for the StimQ peripheral nerve stimulator, which is based on the same technology as the Freedom device. That indication allowed the use of wirelessly powered, micro-technology neurostimulators to be used for the treatment of various pain syndromes including, but not limited to: shoulder, upper extremity neuropathies, mid and low back pain, chest wall pain, abdominal wall pain, hernia pain, pelvic pain, as well as lower extremity neuropathies at the knee, tibia, ankle, and foot.

#### Stimwave Technologies Inc.

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800 965 5134  
www.stimwave.com

Market: Pain neuromodulation

Founded: 2010

Privately held

CEO: Aure Bruneau

Chairman: Paul LaViolette

VP of Innovation: Chad Andresen

# Johns Hopkins University Investigators Show Progress in Haptic Neuroprosthetics

## Staff report

Johns Hopkins University, in Baltimore, MD, has been at the forefront of neurotechnology for several decades. In particular, the Applied Physics Laboratory, in Laurel, MD, has pioneered several technologies in neuroprosthetics.

As part of a larger study exploring neural multiplexing and new modes of perception enabled by BCI technology, JHU researchers have demonstrated the ability to “feel” virtual objects by integrating neural stimulation in a mixed-reality environment.

The participant in the study, Robert “Buz” Chmielewski—an incomplete quadriplegic who previously demonstrated simultaneous control of two of the world’s most advanced prosthetic limbs through a BCI, and used brain signals to feed himself with two prosthetic limbs—has now demonstrated virtual tactile perception.

“All organisms rely exclusively on their sensory organs to perceive information about the world around them,” said Mike Wolmetz, who manages the Human and Machine Intelligence program at APL. “BCI creates a new pathway to perceive

information directly, in ways that are not constrained by, filtered through, or aligned with our specific sensory organs.”

The research is part of the Neurally Enhanced Operations project, funded by DARPA to investigate neural multiplexing: to what extent the brain can accomplish typical perception and control through the senses and muscles at the same time as perception and control through a BCI. Can an operator use their own hands and senses to interact with their computer while simultaneously using their brain to perceive and control other channels or dimensions?

“Right now, we’re focusing on the extreme version of neural multiplexing, to see if it is possible to have different signals either going to or coming from the same regions of the brain and still be able to interpret and act on all that information in a useful way,” said APL’s Luke Osborn, a neuroengineering researcher on the project. “Here we’re looking at how sensorimotor regions of the brain can successfully work in mixed reality when neural stimulation is part of that mix.”

The team has assembled what it likes to call “Buz’s playground”—complete with HoloLens and tablets—where he comes up with new tasks and concepts for things to try.

“We’ve been able to quickly implement and test these ideas with him,” said Francesco Tenore, APL’s NEO principal investigator, “and as a result, the team is making incidental discoveries on a regular basis, uncovering the first hints of what new modes of perception may be possible through neural stimulation.”

The team has been focusing on augmenting tactile perception in its work with Buz, but Wolmetz noted the possibilities likely go well beyond touch. “Just in terms of the current paradigms, augmented vision and hearing are somewhat accessible—we can all see and hear in mixed reality.”

In addition to NEO, APL works across the principal components of neural interface research to find new ways to restore lost function, augment natural abilities, integrate biological and artificial intelligence, and make neurotechnologies increasingly accessible noninvasively.

## Calendar

Aug. 5	Neurotech Commercialization Workshop, On-line. Contact <a href="http://www.neurotechreports.com">www.neurotechreports.com</a>
Nov. 8-9	Neurotech Leaders Forum, San Francisco, CA. Contact Neurotech Reports, 415 546 1259.
Nov. 8-11	Neuroscience 2021, Chicago, IL. Contact Society for Neuroscience, <a href="http://sfn.org">sfn.org</a>
Nov. 19-21	INS 2021 Interim Meeting, Mumbai, India. Contact <a href="http://neuromodulation.com">neuromodulation.com</a>
Dec. 3-7	American Epilepsy Society Annual Meeting, Chicago, IL. Contact <a href="http://aesnet.org">aesnet.org</a>
Jan. 13-16	2022 NANS Annual Meeting, Orlando, FL. Contact <a href="http://neuromodulation.org">neuromodulation.org</a>
May 21-26	International Neuromodulation Society 15th World Congress, Barcelona Spain. Contact <a href="http://neuromodulation.com">neuromodulation.com</a>

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Synchron Inc.	408 406 4236	<a href="http://synchronmed.com">synchronmed.com</a>

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