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Earlier this month, Xavant Technology (Pty) Ltd., the Pretoria, South Africa manufacturer of nerve stimulators for anesthesia, announced the launch of their Stimpod NMS460 device in the U.K. The Stimpod NMS460, a noninvasive neuromodulation device, is focused on the symptomatic relief and management of neuropathic pain as well as an adjunctive treatment in the management of post-surgical pain, post-traumatic acute pain problems, and an adjunct for pain control due to rehabilitation.

The device’s therapeutic effect is based on cellular metabolic activity observed when a neuropathic nerve is subjected to electromagnetic effects caused by pulsed radio frequency. The resulting cellular metabolic activity has been shown to change the characteristics of the nerve, often causing the nerve to recover back to its normal function with instant and dramatic relief of pain. The Stimpod device uses technology featuring a nerve mapping probe that enables practitioners to locate nerves and evaluate the

As neurotechnology researchers continue to advance new neuromodulation approaches such as optogenetics that make use of optical stimulation, there will be a need for new tools and techniques that take advantage of the novel properties of light energy. Two such techniques have recently been reported, one involving computer-generated holography and the other involving miniaturization of optical stimulators.

A team of investigators at University of California, Berkeley has devised a holographic projection system that can activate or suppress dozens and ultimately thousands of brain cells at once, hundreds of times each second. The goal is to read neural activity constantly and decide, based on the activity, which sets of neurons to activate to simulate the pattern and rhythm of an actual brain response, for example, to replace lost sensations after peripheral nerve damage.

“This has great potential for neural prostheses, since it has the precision needed for the brain to interpret the pattern of activation. If you can read and write the language of the

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Surgical Precision

Among the most intriguing announcements at the recent AAN meeting in Los Angeles [see conference report, p7] was a discussion of a new precision medicine initiative by Francis Collins, director of the National Institutes of Health. Speaking by video from Washington, D.C., Collins described a bold new effort, called the All of Us research program, to get 1 million Americans to participate in a study of the relationship between genomic and environmental factors contributing to diseases. Patients will participate in a variety of ways, including sharing their electronic health records, donning wearable sensors, providing blood samples, and responding to questionnaires collected by phone or internet.

The NIH has already enrolled 30,000 people in a beta test of the initiative, and Collins said the NIH will announce a nationwide launch in coming weeks with funding from Congress. He plans to use two parallel pathways to reach the 1 million-participant goal: a direct pathway targeted at individual patients, and a provider pathway targeted at insurance companies. Although the ask is not insignificant, since participants will be yielding a considerable amount of personal health information, the reward is tantalizing. The NIH will supply patients with significant personalized medicine recommendations that are likely to dramatically improve their own healthcare outlook.

Collins told the AAN audience that this initiative will have particular benefits for the neurology and psychiatry communities. He pointed out that migraine affects 15 percent of the population, chronic pain 11 percent, Parkinson’s disease 2 percent, epilepsy 0.6 percent, and stroke 0.3 percent. This means that the initiative will collect meaningful and statistically significant data from hundreds of thousands of individuals with neurological disorders. With data gathered from wearable devices, smart phones, and numerous other sources, investigators will be able to piece together a treasure trove of information on what migraine therapies work best, for example, or which factors most affect recovery from stroke.

Though the NIH will face considerable hurdles in reaching the 1 million-participant goal—not least of which is concern for privacy—we are encouraged by the potential benefits and laud the director for his enthusiasm and efforts promoting the idea. Aside from the valuable clinical data that All of Us will offer to neurologists, psychiatrists, physiatrists, and other professions, the initiative meshes well with ideas we have proposed in this space to speed commercialization of neurotech therapies. In particular, the ability to evaluate neurotech therapies via a vis pharmaceutical interventions—as opposed to ridiculous “sham” controls—looms large if this initiative succeeds. And ultimately, it may obviate, or at least lessen, the need for multiple clinical trials for new neurotech therapies before a device can be approved.

James Cavuoto
Editor and Publisher
the infarct size was significantly (by 26 percent) smaller in PEMF-treated animals as compared to controls.

Alan Collier, Endonovo CEO, said, "It has always been our plan to complete a single center, prospective, controlled, clinical trial of PEMF to evaluate the effects of PEMF in patients with brain injury and external ventricular drain in an intensive care unit setting. This clinical study is an extension of a safety trial and will be open to all patients who have or are fitted with an external ventricular drain to remove excess cerebrospinal fluid."

Edwin Nemoto, principal investigator for the study said, "Inflammation is the primary process of injury propagation after TBI and suppression of inflammation is the proven mechanism of action of the Endonovo PEMF device. We are studying the effectiveness of this device in suppressing the release of brain injury, blood brain barrier, and inflammatory biomarkers in the CSF and blood for up to one week after severe TBI with neurologic outcome follow up at one and three months."

The company's tPEMF technology works by restoring key electrochemical processes that initiate the anti-inflammatory and growth factor cascades necessary for healing to occur. tPEMF technology has been shown to accelerate the production of the endogenous constitutive nitric oxide synthase systems: the anti-inflammatory system, resulting in increased blood and lymph flow, and decreased pain and edema.

### Financial News

**Abbott Reports Financial Results for First Quarter**

Abbott, the Abbott Park, IL manufacturer of neuromodulation systems, reported financial results for the first quarter ended March 31, 2018. The company reported sales of $7.4 billion during the first quarter, representing growth of 16.7 percent on a reported basis or 6.9 percent on an organic basis, compared to the prior year period. Neuromodulation sales in the first quarter were $212 million, a 21 percent increase compared to the first quarter of 2017. The company reported earnings of $418 million (23 cents per diluted share), compared to earnings of $419 million (24 cents per diluted share) a year ago. “We’re off to a strong start to the year as we forecasted,” said Miles White, chairman and CEO, Abbott. “We’re particularly pleased with the continued strong growth in medical devices and improving performance in our nutrition business.”

**Inspire Medical Files for IPO in Effort to Raise $75 Million**

Inspire Medical Systems, Inc., the Minneapolis, MN manufacturer of neuromodulation systems for treating obstructive sleep apnea, announced that it has commenced an initial public offering of 5,000,000 shares of its common stock. Inspire also expects to grant the underwriters a 30-day option to purchase an additional 750,000 shares of its common stock. The initial public offering price is expected to be between $14.00 and $16.00 per share. All shares of common stock to be sold in the proposed offering will be sold by Inspire. Inspire has been approved to list its common stock on the New York Stock Exchange under the ticker symbol “INSP.” BofA Merrill Lynch and Goldman Sachs & Co. LLC are serving as joint lead book-running managers for the proposed offering. Guggenheim Securities, Stifel, and Wells Fargo Securities are acting as co-managers for the proposed offering.

**Helius Medical Raises $14 Million in Public Offering**

Helius Medical Technologies, Inc., the Newtown, PA manufacturer of noninvasive neuromodulation systems, announced the pricing of an underwritten public offering of 2,141,900 shares of its Class A common stock and warrants to purchase 2,141,900 shares of its Class A common stock at a public offering price of $7.47 per share and accompanying warrant, before underwriting discounts and commissions. The net proceeds to the company from this offering, after deducting the underwriting discounts, commissions and estimated offering expenses payable by the company, are expected to be approximately $14.1 million. Helius intends to use the net proceeds from this offering primarily to fund its manufacturing activities for the PoNS device, activities related to its submissions for marketing authorization of the PoNS device to the FDA and other regulatory authorities, commercial launch preparations, working capital and general corporate purposes. The company’s Class A common stock has been approved for listing on the Nasdaq Capital Market and began trading under the symbol HSDT. The company’s Class A common stock will continue to trade on the Toronto Stock Exchange under the symbol HSM.

**Boston Scientific Announces Financial Results for First Quarter**

Boston Scientific Corp, the Marlborough, MA manufacturer of neuromodulation systems, reported financial results for the first quarter ended March 31, 2018. The company generated sales of $2.38 billion during the first quarter, representing growth of 10.1 percent on a reported basis, 6.2 percent on an operational basis and 5.2 percent on an organic basis, all compared to the prior year period. Neuromodulation sales in the first quarter were $169 million, a 19 percent increase compared to $141 million in the first quarter of 2017. The company reported earnings of $298 million (21 cents per share), compared to earnings of $290 million or (21 cents per share) a year ago.

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**Neurotech Reports Announces Dates for 2018 Leaders Forum**

Neurotech Reports, the publisher of this newsletter, announced dates for the 18th annual Neurotech Leaders Forum. The event will take place October 15-16 in San Francisco, CA.

Cirtec Medical is the Platinum sponsor of the event. Micro Systems Technologies is the Gold sponsor.

The conference will feature presentations from several early stage and startup neurotechnology firms. For information on sponsoring or presenting at the conference, contact Neurotech Reports at 415 546 1259.
Calista Health, the Burlingame, CA manufacturer of noninvasive neuromodulation systems, announced that the FDA has granted a de novo request for Cala ONE, an individualized prescription neuromodulation therapy for transient relief of hand tremors in adults with essential tremor. Cala ONE is the first noninvasive, targeted nerve stimulator for the treatment of ET to receive FDA marketing authorization. The device is worn on the wrist like a smart watch to deliver patterned electrical stimulation to nerves through the skin. “Cala Health has brought together a team with expertise in neuroscience, medical devices, and digital therapeutics to develop a new class of therapies that give essential tremor patients relief from their hand tremors without invasive brain surgery or drugs,” said Kate Rosenbluth, founding CEO of Cala Health. “Receiving FDA authorization is an exciting milestone for our team and the patients we serve. It’s just the beginning for a new class of accessible electrical medicines.”

eNeura Announces Publication of Migraine Data from ESPouse Study
eNeura, Inc., the Baltimore, MD manufacturer of noninvasive neuromodulation systems, announced the publication of a study in the peer-reviewed journal, Cephalalgia, demonstrating the company’s portable, transcranial magnetic stimulation (sTMS) technology, significantly reduces the frequency of migraine headache following daily administration. sTMS is indicated both for the acute and prophylactic treatment of all types of migraine headache. The paper, “A Multicenter, Prospective, Single Arm, Open Label, Observational Study of sTMS for Migraine Prevention,” by Amaal Starling, et al., reported findings from eNeura’s clinical migraine prevention study, the ESPouse study, which was conducted at eight U.S. headache centers. Data from the study indicated that 46 percent of patients following a protocol of daily use reported at least a 50 percent reduction in headache attacks. The treatment was shown to be as effective as currently prescribed medications but better tolerated without the debilitating side effects often associated with migraine medications. There were no serious adverse events reported during the study. David Rosen, president and CEO of eNeura, commented, “The ESPouse study was instrumental in the FDA’s recent decision to approve sTMS for both acute treatment and prevention of migraine. The publication of these findings in Cephalalgia provides further validation of the tremendous value that sTMS offers to patients as an effective, well-tolerated migraine treatment.” The sTMS mini is a convenient, cost-effective treatment option and is usually reimbursed under commercial insurance plans.

LivaNova Launches Feasibility Trial of Burst Stimulation VNS Therapy
LivaNova plc, the London, U.K. manufacturer of neuromodulation systems, announced the launch and enrollment of the first patient in a clinical study to examine the use of LivaNova’s new microburst VNS therapy system. This feasibility study will determine the initial safety and effectiveness of delivering VNS therapy using high frequency bursts of stimulation in patients who have drug-resistant epilepsy. “LivaNova is launching this study to enrich our understanding of epilepsy patient populations and the significant role VNS therapy can play in the overall management of this disease,” said Edward Andrle, LivaNova’s general manager of its neuromodulation business franchise. “Through the microburst feasibility study, we have the opportunity to evaluate a prospective new feature for VNS therapy where stimulation is delivered in higher frequency bursts rather than gradual intervals.” The microburst feasibility study’s first patient was enrolled by Rebecca O’Dwyer, assistant professor of neurology at Rush University Medical Center in Chicago, IL. Each patient will participate in the study for a minimum of 15 months. Primary endpoints will measure the percent change in seizure frequency and occurrence of stimulation-related adverse events in comparison to baseline.

Cala Health Launches FDA Clearance for Wearable Neuromodulation Device
Cala Health, the Burlingame, CA manufacturer of noninvasive neuromodulation systems, announced that the FDA has granted a de novo request for Cala ONE, an individualized prescription neuromodulation therapy for transient relief of hand tremors in adults with essential tremor. Cala ONE is the first noninvasive, targeted nerve stimulator for the treatment of ET to receive FDA marketing authorization. The device is worn on the wrist like a smart watch to deliver patterned electrical stimulation to nerves through the skin. “Cala Health has brought together a team with expertise in neuroscience, medical devices, and digital therapeutics to develop a new class of therapies that give essential tremor patients relief from their hand tremors without invasive brain surgery or drugs,” said Kate Rosenbluth, founding CEO of Cala Health. “Receiving FDA authorization is an exciting milestone for our team and the patients we serve. It’s just the beginning for a new class of accessible electrical medicines.”

News Briefs

Optical Techniques
from page 1

The Berkeley team constructed the holographic brain modulator by making better optogenetic switches to insert into cells to read from and write to more neurons in a chunk of brain, they used computer generated holography, a method of bending and focusing light to form a three-dimensional spatial pattern. The holographic image was projected into a thin layer of brain tissue at the surface of the cortex, about a tenth of a millimeter thick, though a clear window into the brain.

The researchers have already tested the prototype in the touch, vision, and motor areas of the brains of mice as they walk on a treadmill with their heads immobilized. While they have not noted any behavior changes in the mice when their brain is stimulated, Mardinly said that their brain activity—which is measured in real-time with two-photon imaging of calcium levels in the neurons—shows patterns similar to a response to a sensory stimulus. They’re now training mice so they can detect behavior changes after stimulation.

The area of the brain covered, now a slice one-half millimeter square and one-tenth of a millimeter thick, can be scaled up to read from and write to more neurons in the cortex. And the laser holography setup could eventually be miniaturized to fit in a backpack a person could haul around. The Berkeley team constructed the holographic brain modulator by making better optogenetic switches to insert into cells to turn them on and off. The switches—light brain, you can speak to it in its own language and it can interpret the message much better,” said Alan Mardinly, a post-doctoral fellow in the UC Berkeley lab of Hillel Adesnik, an assistant professor of molecular and cell biology. Mardinly is one of three first authors of a paper appearing in journal Nature Neuroscience that describes the holographic brain modulator, which can activate up to 50 neurons at once in a three-dimensional chunk of brain containing several thousand neurons, and repeat that up to 300 times a second with different sets of 50 neurons.

Each of the 2,000 to 3,000 neurons in the chunk of brain was outfitted with a protein that, when hit by light, turns the cell on to create a brief spike of activity. One of the key breakthroughs was finding a way to target each cell individually without hitting all at once. To focus the light onto just the cell body of nearly all cells in a chunk of brain, they used computer generated holography, a method of bending and focusing light to form a three-dimensional spatial pattern. The holographic image was projected into a thin layer of brain tissue at the surface of the cortex, about a tenth of a millimeter thick, though a clear window into the brain.

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activated ion channels on the cell surface that open briefly when triggered—turn on strongly and then quickly shut off, all in about 3 milliseconds, so they’re ready to be re-stimulated up to 50 or more times per second, consistent with normal firing rates in the cortex.

Meanwhile, Japanese researchers reported in *AIP Advances* on a new microminiature implantable optical stimulator that converts infrared light into blue light to control neural activity. Takashi Tokuda, an associate professor at the Nara Institute of Science and Technology, has been investigating ways to miniaturize implantable optical devices.

The new device uses a CMOS chip that controls photovoltaic power. “We integrated two sets of photovoltaic cells onto semiconductor chips. Ten cells were integrated for powering, and seven cells for biasing,” he said. The device includes an InGan LED chip, which causes the it to emit blue light. It can also be activated with infrared light, which can penetrate deeper in the body than blue wavelengths. At just 1 mm$^3$ and 2.3 mg, the volume and weight of the device are almost one order of magnitude than any other reported device, leading Tokuda to call it “the world’s smallest wireless optical neural stimulator.”

### FDA Approves Medtronic DBS System for Treating Refractory Epilepsy

The FDA Centers for Devices and Radiological Health earlier this month approved Medtronic’s PMA supplement for DBS for treatment-resistant epilepsy. The approval was based on Medtronic’s SANTE study dating back to 2008, although the company may have submitted more recent data to the FDA.

In 2010, an FDA neurological devices panel recommended approval of the therapy by a vote of 7 to 5. Although the SANTE study failed to meet its primary endpoint, it’s possible that new guidelines, including one allowing approval based on trial sub-populations, may have contributed to the agency’s decision.

### Canadian Team Reports Results from Theta-Burst TMS for Depression

In the largest study of its kind, a three-minute version of a transcranial magnetic stimulation treatment was shown to be just as effective as the standard 37-minute version for hard-to-treat depression. These results were published in a new Canadian study in *The Lancet* co-led by the Centre for Addiction and Mental Health and the University Health Network’s Krembil Research Institute, in collaboration with the University of British Columbia. Traditional rTMS uses magnetic field pulses to noninvasively stimulate the dorsolateral prefrontal cortex, which is associated with mood regulation. The study compared standard rTMS treatment, which uses high frequency (10 Hz) brain stimulation for 37.5 minutes per session, with a newer form of rTMS called intermittent theta burst stimulation (iTBS), that mimics the brain’s natural rhythms and takes just over three minutes per treatment. “The main impact of this study is that the number of people who are able to be treated using theta burst stimulation compared to the standard form of rTMS can be increased by three to four fold,” said lead author Daniel Blumberger, co-director of the Temerty Centre for Therapeutic Brain Intervention at CAMH. The study, conducted with Fidel Vila-Rodriguez, assistant professor, University of British Columbia, focused on people with treatment-resistant depression, defined as a condition whereby people do not experience a sufficient improvement in their symptoms after trying antidepressant medications. Up to 40 percent of people with depression may experience treatment resistance. In the study, 414 participants were randomly allocated to receive either the standard form of rTMS treatment or the shorter iTBS treatment for five days a week for up to six weeks. For 49 percent of study participants who had the iTBS treatment, depression symptoms reduced significantly, with 32 percent reporting a remission of depression symptoms. Those who received standard rTMS had a remission rate of 27 per cent. Those results are consistent with previous large-scale studies and meta-analyses over the past 20 years that have confirmed the efficacy and safety of the standard form of rTMS.

### Purdue Researchers Report Cross-Like Shape Increases Electrodes’ Capacity

A cross-like shape helps the electrodes of implantable neurostimulation devices to deliver more charge to specific areas of the nervous system, possibly prolonging device life span, says research published in *Scientific Reports*. The shape, called “fractal,” would be particularly useful for stimulating smaller areas, such as deep brain structures or the retina, since it maximizes perimeter within a smaller surface area—providing the higher resolution needed for restoring bodily functions and potentially enabling neurostimulation devices to last longer in the body without a recharge. “There are challenges with shrinking the size of these electrodes,” said Hyowon Lee, assistant professor of biomedical engineering at Purdue University. “If you shrink them too small, then you can’t inject enough energy to be able to activate the underlying substrate.” Industry currently produces circular or rectangular electrodes for neurostimulation devices. “There’s really no reason to maintain these shapes other than the fact that it makes it easier for the conventional manufacturing techniques to facilitate,” Lee said. “But microfabrication allows batch processing or even more scalable roll-to-roll fabrication, in which we have the design freedom to create any type of electrode design with high resolution to improve their functionality.” Lee’s lab experimented with other shapes that could better inject charge with electrode size limitations. The fractal shape outperformed conventional shapes and the “serpentine,” or snake-like shape, even though it has a similar perimeter to surface area ratio as fractal. This could be because the repeating patterns of the fractal design better facilitate the continuous diffusion of charge transfer species, or reactants, to the platinum electrode surface. “When you have a lot more diffusion of species to the surface, it allows for faster Faradaic charge transfer from the electrode surface,” Lee said. The charge then reaches a threshold on neurons to trigger an action potential, or electrochemical signal, to stimulate a target.
Highland Instruments Combines Two Treatment Modalities in New Neuromod Device

by Jennifer French, senior editor

Highland Instruments, Inc., based in Cambridge, MA, is a pre-clinical neurostimulation company developing solutions for chronic disease management and movement disorders. Emerging from researchers at Harvard Medical School and MIT, Highland is developing a non-invasive brain stimulation platform.

Their signature device, the ESStim, uses a combination of transcranial direct current stimulation along with transcranial ultrasound. The combined fields focus and boost neurostimulation currents via tuned electromechanical coupling in neural tissue. Two versions of the device are being developed; one for clinical use and a second for home use which adheres to the FDA requirements for home-use medical devices. The home device also features a compliance-monitoring and clinical control communication component.

The device is positioned to complement compensatory treatments such as physical therapy for osteoarthritic knee pain, pharmaceutical management for Parkinson’s disease, or injections for chronic lower back pain.

Highland Instruments holds 28 patents with significant intellectual property covering the combined energy treatment as well as imaging and wearable technologies. The company is currently pursuing regulatory approval in the U.S. and has their eye to expand to Europe in the future. The company’s ElectroSonic stimulation device is a non-invasive brain stimulation system combining transcranial ultrasound with transcranial direct current stimulation. The system allows for focused regional treatment and also to deep regions of the brain. Results can persist several weeks following treatment and the system allows for adjustment of energy levels.

Highland has completed five clinical trials, two for osteoarthritis and two for PD plus the early stage healthy patient safety and efficacy study. The ALGEEA 1 a & b trials for OA involved a treatment regimen of 20 minutes per day for five continuous days with 47 subjects (23 active, 24 sham). VAS scores were taken at baseline, post treatment, and follow-up of two, four, and six weeks. The results showed a 66 percent decrease in pain score at day 5 and a persistent 45 percent decrease in pain score at six weeks post treatment. Significant effects were also seen in secondary endpoints in QOL, mood, WOMAC, and quantitative sensory tests. Trial results have been presented and are now in preparation for publication.

The JANUS 2 trial for Parkinson’s disease involved treatment of 20 minutes per day for 10 days (five days per week). In the trial, 48 subjects with PD were divided into four cohorts: 12 active ESStim, 12 active tDCS plus sham TUS, 12 sham tDCS plus active TUS, and 12 sham. Assessments were made in the “ON” phase of medications and completed at baseline, immediately following the last treatment, and on follow-up one, two, four, and six weeks post treatment. The primary endpoint was 25 percent improvement in UPDRS scale, where ESStim separated clinically and statistically from all other treatment groups as assessed throughout the trial. Secondary results showed significant improvements in balance/postural sway testing, bradykinesia testing, and walking times. Results have been presented and are currently in preparation for publication.

Highland is currently evaluating pricing models for a lease or purchase strategy along with pricing of the disposable components. There are current CPT codes for both the clinical and home-use devices.

Bill Edelman, CEO of Highland, has 38 years of medical device experience including Pfizer, St. Jude Medical, Baxter International, FibraSonics, MicroSense, and TYRX. He is also chairman of the board for Paragonix Technologies, MindChild, Amsel, and Corsen.

Timothy Wagner is the founder and CSO of Highland Instruments. He serves as a lecturer in the division of health sciences technology at Harvard Medical School and MIT. He holds a Ph.D. in both medical and electrical engineering. Highland also has a team of scientific advisors from Case Western Reserve University, Boston Medical Center, Harvard Medical School, and MIT.

In 2015, Highland announced it was awarded a Fast Track SBIR grant from the National Center for Complementary and Integrative Health for the clinical evaluation of ESStim technology for noninvasive brain stimulation for pain suppression in patients with osteoarthritis of the knee. The main academic partner collaborator in this grant and location of the clinical trial was Spaulding Rehabilitation Hospital’s Laboratory of Neuromodulation in Boston, MA. Felipe Fregni, director of the Laboratory of Neuromodulation at Spaulding and associate professor of physical medicine and rehabilitation and neurology at Harvard Medical School, served as lead clinical investigator.

Fregni commented, “Receiving this highly competitive grant is encouraging for the development of this novel method of stimulation as we continue to investigate the clinical utility of ESStim as a possible therapy for OA. Our preliminary analysis in a series of 18 patients with OA of the knee undergoing ESStim treatment demonstrated statistically significant improvement in key clinical measurements employed to manage OA patients. The additional award of this NIH grant will be important to advance our knowledge of noninvasive brain stimulation and we are glad that our Neuromodulation Center at Spaulding Rehabilitation Hospital is a critical component of this investigation. We look forward to further clinical evaluation of ESStim in this collaborative grant.”

Although the clinical use of the device touches a wide variety of specialties, Highland is focusing on OA as the main thrust to introduce the device to the market.

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Market: Neuromodulation
Founded: 2007
Privately held
CEO: Bill Edelman
CSO: Timothy Wagner
Neurology, Neurosurgery, and related professionals from across the globe attended the 2018 annual meeting of the American Academy of Neurology, held in Los Angeles, CA earlier this month. Neuromodulation therapies and neurosensing devices featured prominently in the meeting sessions, posters, and on the exhibit floor.

In an opening plenary session, Walter Koroshetz, director of the NIH’s National Institute of Neurological Disorders and Stroke, spoke of a “golden age in neuroscience,” rivaling what the field of physics saw in the 1920s. He pointed out that in recent years, stroke dropped from number three to number five as a leading cause of death in the U.S. He also pointed to progress in treating migraine and ALS.

Koroshetz highlighted the NIH’s $6.7 billion budget for neuroscience, the largest the agency has seen after 12 flat years. This figure includes another $400 million for the Brain Initiative and $500 million in new federal funding to address the opioid crisis. Noting that large pharma companies have shied away from funding new CNS therapies, Koroshetz highlighted DBS as a promising alternative, though he said the technology is still “incredibly primitive.” He also noted progress in spinal cord stimulation for pain, vagus nerve stimulation for headache, visual cortex stimulation for neuroprosthetics, and new probes that offer recording and stimulation capabilities for closed-loop neuromodulation.

DBS technology was also on display on the exhibit floor, as Medtronic, Abbott, and Boston Scientific showed their systems for treating movement disorders and other conditions.

At the meeting, Boston Scientific announced one-year data from the INTREPID study, a prospective, double-blind, randomized, sham-controlled, multi-center study of DBS for advanced, levodopa-responsive Parkinson’s disease. The study evaluated 292 patients at 23 sites in the U.S. and successfully met its primary and secondary endpoints. The data, which supported the recent FDA approval of the company’s Vercise DBS system for the control of symptoms of PD, demonstrated the safety and effectiveness of the system.

Highlights of the one-year results include a 49.2 percent improvement in motor symptoms as measured by UPDRS III scores compared to pre-surgery screening; a six-hour improvement in on time without dyskinesias; and an overall sustained improvement in quality of life as measured by the Parkinson’s Disease Questionnaire 39.

“This study meets a new level of rigor in evaluating the effectiveness of a DBS system,” said Jerrold Vitek from the University of Minnesota Medical School and coordinating principal investigator for the INTREPID study. “The double-blind design gives us confidence that the improvements in patients on time with good symptom control, as evaluated by the diary data, are an objective measure of the outcomes and suggests patients will benefit from the Vercise system.”

Neuronix displayed its NeuroAD Therapy system combining rTMS with cognitive training as a treatment for Alzheimer’s disease. The Israeli firm has regulatory approval in Europe and Australia and hopes to obtain FDA approval this year. The treatment protocol consists of 30 sessions lasting one hour each over the course of six months. The company is considering different economic models for marketing the system, which could carry a price tag around $100k in the U.S.

ElectroCore displayed a sleeker version of its gammaCore VNS device, which received FDA clearance for migraine earlier this year and cluster headache last year. The new surface stimulation device features replaceable electrode caps, unlike the previous system, which was meant to be discarded after the depletion of its doses. The new device ships with a refillable RFID card that enables the user to administer up to 30 doses of therapy per day for 31 days. The monthly therapy cost will be in the neighborhood of $400 to $600. The company has obtained reimbursement from one private provider so far, though many patients will elect to pay out of pocket.

The Belgian firm Cefaly displayed its supraorbital transcutaneous neurostimulation device for treatment of migraine, which received FDA approval in 2015. The trigeminal nerve stimulation system is available with settings for acute treatment sessions of one hour with high frequency or preventative sessions of 20 minutes daily with low frequency.

Neurosensing firms present at the meeting included Natus, Nihon-Kohden, Cadwell, and Compumedics/Neuroscan. A Pittsburgh, PA firm called NeuroKinetics displayed their I-PAS system, a portable device for assessing brain injuries. It incorporates oculomotor, vestibular, and reaction time measures.

Rajesh Pahwa from the University of Kansas Medical Center in Kansas City, KS reported that individuals with essential tremor may find some relief from a new, noninvasive type of nerve stimulation. Pahwa described two randomized controlled studies: an in-clinic study that included 77 participants and an at-home study that included an additional 61 participants. All had essential tremor. The treatment, a wrist-worn neuromodulation device developed by Cala Health, stimulates the median and radial nerves in the wrist and delivers a stimulation pattern that is tuned to interrupt a person’s tremor.

For the in-clinic study, participants received one session of either the treatment stimulation or sham stimulation to the wrist of the hand with the more severe tremor. The tremor was evaluated before and after the session. Physicians assessed the severity of tremor in the entire arm and the assessments showed a 65 percent improvement in the treatment group compared to 32 percent in those who received sham stimulation.

Participants performed certain activities of daily living in the clinic and were asked to rate their performance before and after stimulation. Those who received treatment stimulation showed a 27 percent improvement compared to 16 percent for sham stimulation. Overall, 88 percent of those receiving the treatment reported improvement in their tremor after receiving treatment stimulation.
Cochlear Center for Hearing and Public Health Established at Johns Hopkins

Staff report

Johns Hopkins University, in Baltimore, MD, is home to many areas of research in neuroscience, neurosurgery, and neuroengineering. The university will soon add a new center that will play a role in improving auditory neuroprosthetics.

In honor of World Hearing Day, Cochlear Ltd., the Australian manufacturer of cochlear implants, recently announced a gift of $10 million to the Johns Hopkins Bloomberg School of Public Health to establish the Cochlear Center for Hearing and Public Health. The Center will be a first of its kind at any academic institution focused on addressing hearing loss as a global public health priority led by Frank Lin.

The center will address hearing loss’ global impact by conducting research studies to determine the gravity of hearing loss (particularly among older adults) to public health, developing and testing interventions to mitigate the effects of hearing loss, and helping craft policies and strategies to ensure successful implementation of hearing loss interventions at the local, national, and global levels. Most importantly, the center will recruit and train the next generation of researchers and public health experts to advance these goals well into the future.

“At Cochlear, we are driven by our mission to improve the lives of people with hearing loss, and our gift to the Johns Hopkins Bloomberg School of Public Health supports this commitment,” said Dig Howitt, CEO and president, Cochlear. “Cochlear is making an investment to build collaborative partnerships within the global medical research community and to be actively involved in delivering evidence-based research so we can better understand, address, and provide access to treatment options for individuals and communities impacted by hearing loss.”

“The Cochlear Center for Hearing and Public Health represents a unique collaboration between industry and academia that is possible because of the shared vision that hearing and our ability to engage effectively with others and the environment is fundamental to human health but not yet a priority in public health,” said Lin. “Implementation of public health initiatives around hearing—or nearly any other public health problem—requires insights from industry into how to create scalable commercial and economic models for the development and delivery of services and technology. Cochlear will be able to provide these insights to the center.”

Cochlear’s $10 million gift will be made over a period of 10 years. Cochlear will collaborate with the center to help amplify its impact on worldwide public health. Cochlear will also have representation on the center’s advisory board to provide feedback and help identify opportunities for continued industry-academic collaborations in furthering the center’s core mission focused on hearing and public health.

Cochlear’s global headquarters is based on the campus of Macquarie University in Sydney, Australia and is also adjacent to the Australian Hearing Hub. The company believes its gift will help facilitate closer multidisciplinary engagement across industry, academic, and clinical to help spur future training and research partnerships. Opportunities include but are not limited to shared postdoctoral fellowships, a shared masters of public health program, shared Ph.D. programs, and faculty exchanges.

Calendar

May 1-2  Neurotech Investing & Partnering Conference, Boston, MA. Contact neurotechpartnering.com
Jun. 25-27  Neural Interfaces Conference, Minneapolis, MN. Contact neuralinterfacesconference.org
Jul. 17-21  EMBC ’18, Honolulu, HI. Contact IEEE EMBS, embs.org
Aug. 24-26  NYC Neuroumodulation and NANS Summer Series, New York, NY. Contact neuromodec.com
Nov. 3-7  Neuroscience 2018, San Diego, CA. Contact Society for Neuroscience, sfn.org

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