

Neurotech

business report

from medical technology to commercial products

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BioControl Looks to Break Into Computer Input Market

by James Cavuoto, editor

BioControl Systems, Inc., the South San Francisco neurotechnology firm that developed the BioMuse neural interface system, has set its sights on the mass market for computer input products. Although the company has sold more than 100 of its \$20,000 BioMuse systems to corporate, government, and private research institutions, company founders Benjamin Knapp and Hugh Lusted have decided to abandon this high-end market in favor of lower-cost, higher-volume consumer products.

Hands-Free Controller

With the help of Moto Development Group, a San Francisco technology design and product development firm, BioControl has recently produced a prototype of a consumer neural interface product that the company says



more on page 4 **BioControl Corp.'s HFC interface uses an EMG sensor and an accelerometer.**

Success of Neurotech Devices Hinges on Reimbursement

by David E. Griffith, senior editor

Bringing a new product to market in the United States is never easy. You have to secure production capacity, open distribution channels, and execute a marketing strategy. But multiply all those difficulties by 10 and add a healthy dollop of state, federal, and commercial health insurance issues, and you have an idea of the challenges that face any company attempting to launch an implantable neurotechnology device.

The most successful implantable neurotechnology device in the U.S. market is the cochlear implant, a neural prosthesis that replicates sound in a profoundly deaf individual by electronically stimulating the auditory nerve. First to market with the cochlear implant was Cochlear Corp., an Australian company, that held its first U.S. cochlear implant trials in 1983. Two years later the FDA approved Cochlear's

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A Mutual Investment

Thank you for reading the premier issue of Neurotech Business Report. Our primary goal in launching this publication is to help commercialize the neurotechnology industry: to help drive funding from public and private sources and to promote technology transfer from research to clinical, industrial, and commercial markets.

One of the first places we'd like to start is the venture capital community. While many leading-edge VC firms make an effort to stay on top of technology developments, too many others just follow the pack when it comes to financing start-ups, a strategy that gave rise to the dot-com craze of the last few years. During the time that many VC firms tripped all over themselves to fund the umteenth e-commerce web portal, neural engineering firms working to restore function to people with disabilities were operating on a shoestring budget. If we do our job right, we'll let the VC community know that unlike online pet food buyers, quadraplegics will not change their mind about wanting products that help them regain use of their limbs; people with Parkinson's disease or chronic pain will not lose interest in getting effective treatment for their conditions.

Today, VC firms are more likely to fund biotech or genomic start-ups than dot-coms, but it's not clear that they've learned the danger of following the herd. While biotech/pharma/genomics technology offers great promise, they are not the only approach to treating diseases and disorders. For example, no pharmaceutical company has yet marketed a drug that restores hearing to deaf people, no biotech firm has restored hand function to a quadriplegic, no genomic advancement has enabled a paraplegic to stand up. And while there are currently numerous pharmaceutical treatments for neurological disorders such as epilepsy and chronic pain, not all of them work all the time, and neurotechnology approaches are making headway as an alternative.

And so they should, since we're talking about disorders of the nervous system. An endocrinologist or molecular biologist could argue that all nervous system function is the result of chemical or molecular activity, but that's a little like saying we should debug computer software by analyzing the chemical processes occurring within each semiconductor element.

A "magic bullet" mentality seems to prevail in many funding organizations. "It's just a matter of time before they discover the [drug/genome/stem cell, etc.] that will cure all that ails us." For neural engineers working with spinal cord injury, that magic bullet is regeneration of spinal cord tissue. That development, if it comes, would be welcomed enthusiastically by all who work in this field (and in fact, there is ample evidence that electrical stimulation can play a significant role in the regeneration process). But it would not necessarily restore coordinated functional neuromuscular activity to the paralyzed individual, nor would it obviate the progress in therapeutic stimulation and rehabilitation that has been made to date with stroke patients and people with other neurological disorders.

In short, we have not launched this publication to enter into competition with biotechnology, genomics, or any other leading-edge field of bioscience. Rather, we advocate for a cooperative coexistence where we share knowledge and resources and adopt the most appropriate treatment strategies to the conditions confronting us. But we will also argue that the allocation of private and public funds to neurotechnology should be at least in some sense proportional to the level of success it has already achieved.

James Cavuoto
Editor and Publisher

Meet the Editors of Neurotech Business Report

Neurotech Business Report has been launched to provide strategic information on the new and growing field of neurotechnology. Neurotechnology is defined as the application of electronics and engineering to human nervous system function. It is a distinct field from biotechnology, which concerns itself largely with molecular and genetic engineering approaches to human biology.

Neurotech Reports was founded by James Cavuoto, the president and publisher of Micro Publishing Press, Inc., a publishing company that helped launch the market for electronic publishing and digital imaging. Cavuoto has a degree in biomedical engineering from Case Western Reserve University in Cleveland, OH, where he studied under the pioneers of the emerging field of functional electrical stimulation. He was previously a member of the technical staff at Hughes Aircraft Company, where he worked on simulation, training, and publication products. Cavuoto is an adjunct professor at Rochester Institute of Technology and a member of the IEEE Engineering in Medicine and Biology Society.

Editorial director for Neurotech Business Report is David Pope, an experienced science and technology editor who has served on the board of editors of *Scientific American* magazine and was senior editor of *Psychology Today* magazine. He also served as a senior science writer for Battelle Memorial Institute.

Clifford Numark serves as research director for the new venture. Numark is the former CEO of the San Diego Regional Technology Alliance and was previously COO of the Los Angeles Regional Technology Alliance. He has authored numerous market research studies on topics such as venture capital funding and federal technology funding. Rounding out the editorial team is David Griffith, an experienced business and technology journalist who has covered healthcare, industrial, and information processing firms in the U.S. and Japan.

Linda Kazares is the marketing and events director of Neurotech Reports. She was publisher of two computer industry newsletters and has organized conferences in the Internet market.

Market Research Report Estimates Size and Growth of Neurotechnology Market

A new market research report from Neurotech Reports examines the rapidly developing market for neurotechnology products and devices. Neurotechnology is the application of electronic and engineering methods to the human nervous system. Current neurotechnology products include neural prostheses, such as cochlear implants and hand-grasp stimulators, and neuromodulation devices, which have proved successful in treating chronic pain, tremors, urinary incontinence, and other neurological disorders.

The new market research report, titled "The Market for Neurotechnology, 2001-2005," estimates the current worldwide market for neurotechnology products in healthcare is over \$1 billion per year and will grow to more than \$4 billion by 2005. Product categories making up this market include neural prostheses, neuromodulation, therapeutic electrical stimulation, and neurodiagnostics.

The report is authored by the editors of Neurotech Business Report, including James Cavuoto, Clifford Numark, David Pope, and David Griffith.

It includes financial projections on the size and growth rates for specific segments of the neurotechnology industry, as well as detailed descriptions of the current manufacturers, research institutions, and funding organizations. The report also examines the potential market for neurotechnology in a number of new application areas, including brain-computer interfaces, neural-silicon hybrid chips, and virtual reality-based training.

The report covers over 100 manufacturers and research institutions that are involved with neurotechnology products and services. It includes over a dozen charts, tables, and graphs summarizing market projections and data.

"The Market for Neurotechnology, 2001-2005" will be available this month from Neurotech Reports. The publishers are offering a free summary of the report to qualified professionals in the healthcare, medical devices, manufacturing, or financial services industries

To request your free summary, visit:
<http://www.neurotechreports.com/pages/marketdata.html> .

Financial News

Cochlear Ltd. Announces Increase in Sales and Implant Shipments

Cochlear Ltd., the Australian manufacturer of cochlear prostheses, announced that revenues for fiscal year ending June 30, 2001 reached 220 million Australian dollars, a 53 percent increase over fiscal 2000 revenue of A\$144 million. The Australian dollar is currently trading for about US\$0.52. Operating profit increased 47 percent from A\$31.7 million in 2000 to A\$46.5 million in 2001. After-tax profit increased 54 percent from A\$20.2 million in 2000 to A\$31.2 million in 2001. Cochlear CEO Jack O'Mahony attributed the results to the launch of the ESPrit 22 processor and to growth in system sales, which were up over 20 percent in each region. The relatively weak Australian dollar also played a role, though the company hedges its positions using foreign exchange cover.

Cyberonics Reports Quarterly Results and Record Epilepsy Income

Cyberonics, Inc., the Houston-based manufacturer of vagus nerve stimulation systems, announced that net sales for the first quarter 2002, ended July 27, increased 8 percent to \$14.6 million compared to \$13.5 million a year ago. All but \$1.4 million of first quarter sales were from the U.S. market. Net loss for the first quarter was \$6.6 million, or 31 cents per share, compared to a net loss of \$1.1 million, or 6 cents per share a year ago. Net income from the company's epilepsy business unit reached a record \$2.8 million, compared to \$79,000 a year ago. The company also has business units for treating depression and obesity/other indications that are currently undergoing trials.

EU Technology Group Sponsors Initiative for Life-Like Perception Systems

The Future and Emerging Technologies arm of the European Union's Information Society Technologies Programme recently launched an initiative to fund research into life-like perception systems. Awards will range from 100,000 to 3 million euros. Examples of the types of projects to be funded include hybrid networks of biological and silicon neurons, new architectures for more natural forms of machine perception, and sensory-based navigation. Proposal deadline is October 17, 2001. Contact www.cordis.lu/ist/fethome.htm for more information.

Pentagon's 2002 Budget Request Includes Potential Funds for Neurotech

The U.S. Department of Defense is taking a keen interest in research areas where neurotechnology may have application. The Pentagon's 2002 budget request for the Defense Advanced Research Projects Agency (DARPA) includes \$65 million in basic research in Bio/Info/Micro Sciences to "explore and develop potential technological breakthroughs that exist at the intersection of biology, information technology, and micro/physical sciences." Of this amount, about \$20 million is targeted at "biological software, physical interfaces between electronics and biology, computations based on biological materials, and interactive biology." In addition some of DARPA's budget request for basic research in Information Science is set aside for "novel human computer interfaces."

Image-Guided Neurologics Signs Distribution Deal with Medtronic SNT

Image-Guided Neurologics (IGN), a Melbourne, FL-based manufacturer of neurosurgical navigation and delivery products, signed a distribution and licensing agreement with Medtronic Surgical Navigation Technologies (SNT), based in Louisville, CO. Under the distribution agreement, Medtronic SNT will distribute IGN's line of Navigus Frameless Trajectory Guides, primarily in the U.S. and Europe. The licensing agreement covers IGN's use of Medtronic SNT's patents related to basic frameless image-guided surgery. IGN's Navigus Trajectory Guide is used to lock the trajectory guide in place and deliver devices such as surgical instruments, or deep-brain stimulation (DBS) electrodes.

News Briefs

Paralyzed Veterans Group Objects to VA Funding

The Paralyzed Veterans of America lashed out at the Congress and the U.S. Veterans Administration for its "wholly inadequate" budget request for veterans' health care. Joseph L. Fox, Sr., national president of the PVA, expressed grave concerns at the Bush administration's budget request, calling it "simply not enough to meet the needs of sick and disabled veterans." The group has called for at least a \$2.7 billion increase in VA healthcare spending. PVA is one of the largest funding organizations for research in spinal cord injury.

Cleveland FES Center Gets Renewed Funding

The U.S. Department of Veterans Affairs awarded the Cleveland FES Center \$750,000 annual funding through 2006. The five-year program is a renewal of the VA's Rehabilitation Research & Development Service, which funds nine "centers of excellence" across the U.S. The Cleveland FES Center is jointly administered by Case Western Reserve University, the Cleveland VA Medical Center, MetroHealth Medical Center, and the Edison BioTechnology Center.

Neurotech Research Comes Up Short in New Jersey Spinal Grants

The New Jersey Commission on Spinal Cord Research awarded \$2.3 million in grants to researchers in the state who are studying spinal cord injury and disease. Nearly all of the money, however, went to pharmacological, neurobiological, or genetic engineering approaches. The grants, 14 in all, ranged from \$50,000 to \$200,000. One \$100,000 grant was awarded for acupuncture as a treatment for pain in spinal cord injury, while \$192,000 was awarded for studying impaired spermatogenesis after spinal cord injury. The fund was created in 1999, when the state legislature founded the New Jersey Commission on Spinal Cord Research. Speeders contribute \$1 to the fund for every traffic violation. Traffic accidents are responsible for much of the 300 new injuries that occur each year in New Jersey.

Dynatronics Corp. Ready to Market Pain Stimulators in Europe

Dynatronics Corp., the Salt Lake City, UT manufacturer of the STS line of pain stimulators, has achieved two milestones that will ready the firm for marketing in Europe. In July, the company's Salt Lake City facilities received ISO 9001/EN 46001 registration. The company also recently completed CE Mark testing for the STS chronic pain therapy devices and expects to receive certification shortly.

BodyMedia Introduces Armband Computer Interface

BodyMedia, Inc., a Pittsburgh-based manufacturer of physiological monitoring equipment, introduced its first body-monitoring product, the SenseWear Pro Armband, along with a development kit that manages the data collection process. Data collected from the Armband, which incorporates six sensors, is uploaded to the SenseWear Pro Development Kit, which runs on Windows 98, 2000, or NT. The armband technology uses a two-axis accelerometer and sensors for heat flow, galvanic skin response, skin temperature, and ambient temperature. The SenseWear Pro Armband costs \$995 per device.

NESS Obtains FDA Clearance for Handmaster Prosthesis

Neuromuscular Electrical Stimulation Systems Ltd. (NESS), the Israel medical device manufacturer, announced it had obtained FDA clearance for its Handmaster neural prosthesis. The Handmaster restores hand function to patients with C5 spinal cord injuries. It consists of a forearm splint housing transcutaneous stimulating electrodes. The product is currently on the market in Holland and Israel and NESS expects to hit the US market early next year. The company is currently looking for a U.S. marketing partner and also exploring the possibility of using the product for stroke patients.

BioControl

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could sell for under \$200. The slick-looking HFC (hands-free controller) consists of a strap-mounted sensor that contains a single electromyographic surface electrode and an accelerometer. Up to four such wristwatch-like sensors can be connected to a belt-worn controller that communicates via radio-frequency signals to a computer within proximity of the controller. Knapp said he expects that future versions of the product will eliminate the belt-worn controller, embedding a miniature RF transmitter in each sensor.

Each sensor samples acceleration and EMG signals 4,000 times per second, with an 8-bit depth for EMG and 12-bit signal from the accelerometer. Knapp, the company's technology director, says that the HFC's use of both external (accelerometer) and internal (EMG) signals offers computer users and software developers an unprecedented level of man-machine interaction. According to Knapp, if positioned properly on the arm, a single EMG sensor can discriminate among the five fingers with 80 percent accuracy. This information, combined with the accelerometer's feedback on arm motion, could enable a game developer, for example, to produce a much-more realistic interface than current computer mice, joysticks, and other input devices offer.

BioControl has developed patented signal-processing technology, built into the controller, that transforms the analog input signals into meaningful and linearized digital data. A brief training session would enable each user to calibrate the system with his/her physical attributes and the location of the sensor. Besides the arm/wrist sensors, BioControl has developed a head-mounted sensor that converts head movements and forehead muscle contractions into computer data.

Knapp said that the firm has had discussions with computer peripheral manufacturers such as Kensington as well as software giant Microsoft. The company is looking for an OEM partnership or venture capital deal that would enable it to produce the HFC in quantity, which he estimates would be at least 1,000 units per month initially.

Another promising application involves repetitive strain injuries. The firm has identified specific EMG patterns that can

predict hand and wrist positions and motions that could lead to RSI after extended periods of keyboard use.

BioControl Background

Knapp and Lusted founded BioControl in 1989, after working together on a number of neurotechnology projects, including the cochlear prosthesis. Lusted earned a Ph.D in neurophysiology from the Stanford medical school; Knapp received his Ph.D in electrical engineering from Stanford. They developed BioMuse in 1992 as an eight-channel biocontroller capable of reading EEG, EMG, EOG, and EKG data. Among the users of this system were NASA, British Telecom, the U.S. Air Force, and Honeywell.

The pair elected to remove the EEG, EOG, and EKG options from the consumer-oriented HFC prototype because of the inherent noise, complexity, and difficulty of working with those signals. At the same time, the accelerometer sensor offered a key component for gaming and virtual reality applications. Lusted is working with a company called SGS Interactive that has developed an online virtual arm-wrestling game in which two remote players equipped with an arm sensor attempt to “pin” their opponent’s on-screen arm.

Future Outlook

Looking down the road, Knapp sees magnetoencephalographic recording as a viable interface technology for “thought-controlled” computers. Although current MEG technology requires relatively large sensors and massive power, future developments in technologies such as SQUID (superconducting quantum interference device) will make this more practical.

Unlike EEG signals, magnetic sensing is more able to penetrate skin, bone, and other tissue, enabling the sensors to be removed from the human body. Magnetic signals emitted by neurons in the brain would also be less susceptible to attenuation caused by the varying orientations of neural cells in the cerebral cortex, a problem faced by EEG technologists.

While other vendors are working on brain- or neural-computer interface products, BioControl seems to have an advantage because of its engineering expertise and its flair for industrial design and consumer marketing garnered from its relationship with Moto.

Research Highlights

Illinois Surgeons Implant Three New Patients with Artificial Retina

Optobionics Corp., the developer of an experimental visual prosthesis based on microminiature solar cells, announced that two teams of doctors in Illinois implanted three new patients with the firm’s artificial silicon retina (ASR). This brings to six the total number of patients who have undergone the experimental surgery to treat retinitis pigmentosa. Two patients were implanted during a two-hour operation in Central DuPage Hospital in Winfield, IL, and a third at Chicago’s Rush Presbyterian-St. Luke’s Medical Center in late July. The 2-mm diameter chips each contain 3,500 miniature solar cells connected to stimulating electrodes that attempt to stimulate foveal retina cells from the under surface of the retina. The cells are self powered, so no connections or telemetry is required. Citing FDA regulations, Optobionics was mum about the functional results of the most recent surgeries. Skeptics say if the patients had seen anything, we’d know about it.

Behavioral and Mood Disorders Subject of New Stimulation Studies

Several psychiatrists in the U.S. and Europe are studying vagus nerve stimulation for treatment of behavioral and mood disorders. At the World Congress of Biological Psychiatry in Berlin in July, investigators from Baylor College of Medicine, the University Hospital for Epileptology in Bonn, and the Columbia College of Surgeons presented positive results in pilot studies of VNS therapy for treatment-resistant depression. A University of Texas Southwestern researcher presented positive results on sleep abnormalities in depressed patients at the American Psychiatric Association annual meeting. And a team at the Medical University of South Carolina recently implanted Cyberonics’ NCP stimulator in a patient with obsessive-compulsive disorder.

CWRU Researchers Investigate New Design of Magnetic Stimulators

Researchers at Case Western Reserve University in Cleveland are working on a design for a magnetic stimulator that could potentially be worn by a patient. Reporting in the IEEE Transactions on Biomedical Engineering, Rafael Carbutaru and Dominique Durand describe a toroidal coil design for a magnetic stimulator that reduces the required driving current by three orders of magnitude over the current generation of magnetic stimulators. Unlike an electrical stimulator, a transcutaneous magnetic stimulator would not require surgical implantation for activation of deep nerves and it would eliminate problems with discomfort and electrochemical reactions at the electrode site.

German Team Devises Chip to Align Brain Cells with Recording Sites

A team of researchers at the Max Planck Institute for Polymer Research and the Institute of Physiological Chemistry and Pathobiochemistry in Germany has devised a method of semiconductor lithography using biological proteins to control the position and growth of neural cells. The researchers “printed” extracellular matrix proteins on silicon chips and gold microelectrodes using a glass ring mounted on the circuit as a miniature petri dish for cell culture. The team was able to align neuronal growth projections to the microelectronic contacts with an accuracy of under 2 microns. The device promises to improve brain recording systems by mating the activity of neurons and microelectronic devices.

Washington U Engineers Develop Sensory Shoe For Diabetics

A team of engineers at Washington University in St. Louis has developed a shoe-based sensory system for patients with diabetes and peripheral neuropathy. These patients lack critical pain, pressure, and other sensory input, which leaves them at risk for developing skin ulcers and subsequent amputation. The shoe contains four pressure and temperature sensors positioned under the heel and toes, plus a humidity sensor, signal processing hardware, microprocessor, and flash RAM.

Insurance Coverage

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groundbreaking Nucleus 22 for sale in the U.S. FDA approval is a critical step in launching a neurotechnology device, but it's just one of many barriers to reaching the market.

Securing Coverage

In general, neurotechnology devices are expensive. Cochlear implants, for example, list in the range of \$23,000 and that's just for the device. Tack on the evaluation of the patient, surgery, in-patient treatment at a hospital, and postoperative rehabilitation, and the price tag easily soars to \$50,000. Very few Americans can afford a \$50,000 medical expense even if it substantially improves the quality of their lives. So they rely on either public or private health insurance to shoulder at least most of the bill.

Consequently, convincing insurers to cover a neurotechnology device is one of the most critical aspects of marketing that device. "You could market a device without insurance coverage," says Shawn Lunney, vice president of Houston-based Cyberonics Inc., manufacturers of the NCP vagus nerve stimulus system "But any product that lacks broad and deep support from the third-party payer community is not going to be as successful as it otherwise could be."

Securing coverage from health insurers

for neurotech devices is so critical to the manufacturers that many have insurance reimbursement departments integrated into their marketing offices. There are three manufacturers of cochlear implants operating in the U.S., Cochlear Corp. in Denver, Advanced Bionics in Santa Clarita, CA, and Med-El Corp. in Durham, NC. All three have insurance reimbursement departments.

John McClanahan, manager of reimbursement services for Cochlear Corp., says insurance coverage of cochlear implants is so integral to the growth of the market for the auditory prosthesis that competitive companies have been known to share notes on the issue and combine their resources to exert influence on insurers. "Often times [insurance reimbursement] is the only place that we collaborate," he says.

Getting Medicare Support

When most neurotech concerns want insurance companies to stand up and take notice of their devices, they go to the feds, not for regulations that require the insurers to cover the product, but for Medicare support. Cyberonics' Lunney explains, "Medicare approval is the big domino at the start of the chain. Once the first one falls, the others rarely stand against it. If the federal government insurance program is paying for it, what possible reason could you as a private insurer have for not doing the same?"

Cochlear's McClanahan agrees, "When you launch a new product, it's very difficult to let the commercial health insurance providers know that you have this new service ready and they need to cover it. But if you can benchmark it and say that Medicare covers it, then you can send a letter to all the major carriers saying, 'my device is approved by the FDA, and you're going to start seeing it on your claims forms.'"

From the insurance side, Dr. Andrew Krueger of the Louisville, KY-based health insurance giant Humana Inc., says Medicare coverage definitely carries some weight with commercial carriers. "Medicare coverage certainly is a piece that gets weighed in the decision. It can be a significant piece."

Insurance reimbursement through Medicare is administered by a federal agency now called the Centers for Medicare and Medicaid Services (CMS), but almost everyone in the business still refers to it by the old name "Hicfa" spelled HCFA, an acronym for the Health Care Financing Administration. CMS has a set policy for determining coverage of devices, procedures, and medications.

A physician, a patient, or even a manufacturer can request Medicare coverage for a new device, pharmaceutical, or procedure. But that just gets the ball rolling. The follow up requires all the support materials on the efficacy of the device the petitioner can muster. Once CMS receives the request and supporting materials, it can render a decision within 90 days, but in many cases, more information is required and the process is delayed.

Enlisting Patient Support

Veterans of insurance coverage battles say that whether petitioning CMS or a private insurer, the manufacturer should let physicians and patients take the lead. "When asked, we provide all the support and materials we can," says Lunney. "But from an overall success standpoint, a manufacturer asking for a payer to pay is an inherently losing proposition. Our interests seem to be too transparent."

Cyberonics' example is a good one for other neurotechnology companies to follow. In 1997, the company's NCP vagus nerve stimulation system received FDA approval for use in reducing the frequency and severity of epileptic seizures. Some 18 months later, the NCP system

VA Establishes Two New Neurotechnology Centers

The US Department of Veterans Affairs has established two new research facilities to investigate neural prosthesis and electrical stimulation technologies. The first new facility, the Center for Innovative Visual Rehabilitation, is located at the Jamaica Plains VA Medical Center in Boston. That center will employ researchers from nearby Massachusetts Institute of Technology, Harvard Medical School, and the Massachusetts Eye and Ear Infirmary working on developing a visual prosthesis and new surgical techniques.

The second center, the Center of Excellence in Functional Recovery in Chronic Spinal Cord Injury at the Miami VA Medical Center, will study pain management, recovery of motor and sensory function, and other areas of critical importance to spinal cord injury patients. A third new center at the Bronx VA Medical Center will explore pharmacological approaches to spinal cord injury.

The new facilities, with a combined budget of more than \$11.1 million over five years, join nine other VA "Centers of Excellence." "With these centers, VA is building upon its long history of accomplishments in medical research and using the latest medical knowledge to improve the lives of our veterans," said Secretary of Veterans Affairs Anthony J. Principi.

The VA funds about \$32 million each year in research related to rehabilitation, part of an annual VA medical research budget of \$351 million.

was covered by Medicare and a long list of private insurers. “Within the first 18 months of approval, the product went from non-existent to being covered by virtually every major payer,” says Lunney.

The secret of Cyberonics’ success in winning approval from insurance companies for its NCP vagus nerve stimulation system was imagining the battle and all its variables before it was fought. “We had a long-term plan as to who we wanted to approach and when and with what message,” Lunney explains. In addition to a plan, Cyberonics had plenty of ammunition to argue the efficacy of the NCP system. “We had very solid clinical science. We had peer-reviewed, double-blind, active-control trials with large numbers of patients,” Lunney says.

Unfortunately, sometimes a company can have a well-designed battle plan, all the valid scientific evidence in the world, and a patient base that desperately needs its product, and it still loses, or at the very least, pays dearly for victory. Such has been the case with the manufacturers of cochlear implants. They have fought long and hard for adequate insurance coverage of their products and in many cases coverage is still not adequate.

From the get-go cochlear implant companies have been faced with a major educational obstacle, convincing the public, the government, and private insurers that their products are not “hearing aids.” For the record, hearing aids amplify sound; cochlear implants replicate sound by stimulating the users’ auditory nerves with electric impulses.

The hearing aid issue was important because many insurers routinely reject hearing aid coverage. “In the beginning it was very hard because a lot of the insurance companies didn’t know what a cochlear implant was,” says Cheryl Anderson, an insurance reimbursement specialist for Cochlear. “It was a matter of educating the insurance companies.”

Cochlear implant manufacturers say the “hearing aid” battle has largely been fought and won. But insurance companies still occasionally attempt to reject a claim for a cochlear implant based on a misguided belief that the technology is a failure. The manufacturers long ago devised an ingenious strategy for shooting holes in this argument. They put cochlear implant recipients on the phone to argue insurance claims.

“One of my staff members had a Nucleus 22 (Cochlear Corp.’s implant), and she had conversations regularly with insurance companies in which they claimed that cochlear implants didn’t work. Then she mentioned that she had one. She did that numerous times,” says McClanahan. The ultimate test of any assisted hearing device is the ability for a profoundly deaf person to have a telephone conversation, so it’s easy to imagine the reaction of the insurance company when they heard that their arguments about the capabilities of cochlear implants were falling on (no longer) deaf ears.

Coverage Levels

Today, most public and private insurance providers offer policies that cover cochlear implants. However, that doesn’t mean the work of the insurance reimbursement departments at the manufacturers is done. Many policies specifically exclude “implanted prosthetics.” And the big fight now is over adequate coverage.

As recently as a few years ago, many clinics and hospitals that performed cochlear implant services were taking it in the shorts, selling their services and the devices at a huge loss.

Under the contracts that the health-care providers negotiated with the insurers, they received \$2,000 per day for implantable prosthetics, which amounts to \$4,000 for a cochlear implant. “If you’re talking about a \$23,000 cochlear implant system, then the hospital starts to scream,” says Cochlear’s McClanahan. Faced with such a discrepancy in payment and costs, many cochlear implant clinics shut down until they could renegotiate their insurance contracts.

Today, most of those briefly closed clinics are open and operating again. And others have joined them. McClanahan says there were 200 clinics when he joined Cochlear Corp. four years ago. Now there are about 250.

The astonishing thing is that many of these cochlear implant clinics are still operating at a loss, not a staggering loss like they were before, but a loss nonetheless. For example, current Medicare guidelines pay for the device at cost, but barely dent the expense of assessment, surgery, and after care.

Still, clinics continue to perform cochlear implant operations at a record rate. “The demand is there,” says McCla-

nahan. “And many hospitals that have established cochlear implant programs want to keep them.”

Demand is indeed high. The Cochlear Implant Association—a non-profit advocacy group of physicians, cochlear implant recipients, and the parents of cochlear implant recipients—estimates that there are as many as 25,000 implanted patients in the United States. Slightly more than one-third of the recipients are children.

The statistics on deaf children are the likely answer why many cochlear implant clinics are willing to operate at a loss. Most cochlear implant clinics are part of a larger institution, a hospital, a university, etc. Such institutions love to promote the medical miracles performed by their staffs, and few human interest stories look as good in the local papers or on the local news as a human interest piece on how the XYZ Clinic made a deaf child hear. Good publicity often means additional funding and grants for cochlear implant clinics and the institutions that operate them.

“Cochlear implant programs will never be money makers like cardiac bypass programs, which make millions of dollars,” says McClanahan. “But it’s a feel-good program, and it’s a program that works and one that the community associates with the hospital being a benevolent healthcare provider. It’s a really high-profile device, and hospitals try very hard to maintain their programs even though they are money losers.”

Clinics operating in the red on cochlear implant services may, on the surface, seem to invalidate the argument that insurance reimbursement is critical to the advancement of neurotechnology devices in the U.S. market. But it’s important to remember that clinics are only willing to operate so far in the red, and that they were shutting their doors until Medicare and the private health insurers amended their contracts.

Also most patients who have insurance policies that cover cochlear implants are unaware of a shortfall between the insurer and the clinic. This is especially true for those patients who have HMO policies with minimal co-payments. If these devices were not covered by Medicare, Medicaid, and private insurers, all cochlear implant patients would face frightening medical bills, and demand for the technology would surely dissipate.

Functional Electrical Stimulation Field Converges in Cleveland

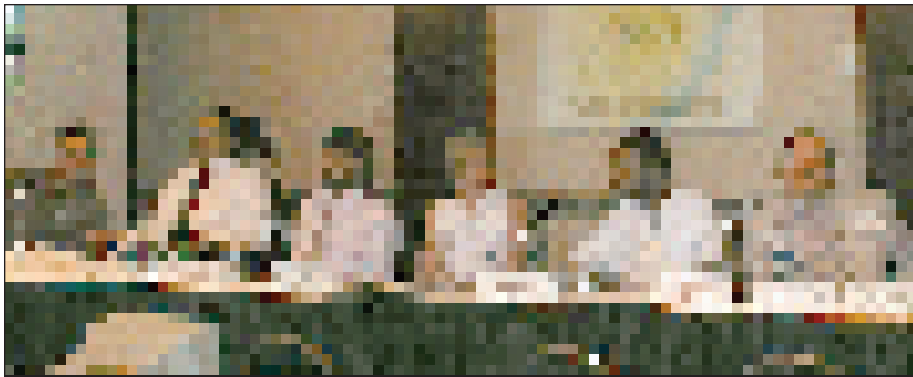
by James Cavuoto, editor

The spirit of a new industry and the promise of groundbreaking medical technology was in the air in Cleveland at the sixth annual conference of the International Functional Electrical Stimulation Society meeting in June. The five-day event, themed “Envisioning a New Century of Breakthroughs,” highlighted six “millennium” papers on key areas

Looking beyond medical therapeutics, Lozano sees a coming merging of mind and machine as computational power increases and device miniaturization continues to create systems that rival the brain’s connective population of 10^{15} synapses and 1 millisecond time scale. He mentioned the possibility of someone acquiring preformed neural circuits

neural tissue. Researchers have found that an electric field oriented in the direction of a damaged neural fiber can enhance axonal regrowth. Panelists also discussed efforts underway to build hybrid neural/silicon devices that can be implanted in the nervous system to improve communication between artificial devices and neural centers. Entirely new or rebuilt pathways can be constructed in the nervous system by using stimulation to direct neurons and neurites to migrate and connect in the desired locations.

In another example of interdisciplinary cooperation, IFESS, composed largely of biomedical engineers, aligned with the International Neuromodulation Society, an association of surgeons and clinicians, to coproduce a new journal called *Neuromodulation*.



A panel of spinal cord injury patients offered critical feedback on devices and future directions.

of neurotechnology, a truly international assembly of presenters, a small but solid core of neurotech manufacturers and sponsors, and several unique attributes not often found at a scientific or engineering meeting.

A ubiquitous spirit of interdisciplinary cooperation linked this assemblage of biomedical engineers, neuroscientists, clinicians, therapists, and funding agencies. Several vividly interactive sessions featured frank, if at times cutting, discussion of research and product directions. A team of spinal cord injury patients was on hand—not just as poster children—but as active participants offering feedback and product suggestions to the engineers in attendance.

In a gripping keynote address, neurosurgeon and deep-brain stimulation pioneer Andres Lozano from the University of Toronto presented an overview of the use of DBS systems for treating neurological disorders such as Parkinson’s, stroke, and tremors. Lozano related some impressive results treating serious cases with implanted electrodes in subcortical nuclei in the brain. He expects that neurodegenerative disorders will overtake cancer as the number two killer by 2040, when approximately one-third of the population will be affected.

that would endow the recipient with vital knowledge bases or motor skills. He also believes brain stimulation may have applications treating obesity, depression, and other conditions.

Regeneration

One of the most productive sessions at the conference was a workshop devoted to neural repair and functional restoration. It highlighted several strategies for combining stimulation with neurobiological means of regenerating and repairing

Control and Engineering

Several sessions at the conference looked at progress in improving first-generation neural prostheses for hand grasp, bladder control, and standing/walking systems. Attendees argued for more natural human interfaces in the devices. For example, instead of the shoulder-actuated control currently used in many hand-grasp prostheses, a system controlled using electromyographic signals from the arm muscles, or a sensor that is based on the user’s wrist angle, is felt to be more natural. In the bladder control stimulator market, current products such as NeuroControl’s



This surgically implanted wrist-angle sensor developed at the Cleveland FES Center offers a more natural user interface to a hand-grasp prosthesis.

VoCare system work only by performing a surgical procedure known as rhizotomy, which deprives male patients of sexual function. New products that no longer require the rhizotomy are under development at a number of research institutions.

Development of lower-extremity neural prostheses for standing and walking was the subject of pointed discussion during many sessions. Control engineers trying to perfect closed-loop feedback electronics that enable paralyzed patients to walk clamored for better sensors that offer precise information on biomechanical properties such as limb position and muscle force. Some neural engineers dismissed the overdependence on control theory as “mental masturbation.”

One participant, Gerald Loeb from the University of Southern California, claimed that efforts to build a walking prosthesis over the last 20 years have been misguided and the resources could have been directed to more achievable problems. Nonetheless, progress to date on standing and walking prostheses has many paraplegic patients and clinicians understandably excited, and the problems that remain appear to be engineering issues and not limitations of basic science.

Consensus

Participants agreed that progress in smaller and smarter microelectrodes, including electrodes with multiple contact points and electrodes coated with neurophilic substances that promote electrode/neuron interaction, will be a key factor in the development of future products. There was also general agreement that the timing and sequence of patterned muscular activity after a spinal cord injury, stroke, or other neurological incident is critical to the patient's prospects for regaining function. Passive muscle stimulation and exercise patterns of simulated walking in paralyzed patients not only help counteract muscle atrophy and pressure sores, they also increase the probability that the patient will regain either natural or artificial use of the lost muscle function. Rahman Davoodi from USC showed a rowing machine for paraplegics that uses electrical stimulation to direct the sequenced activity of leg motions. This type of product appears to have considerable commercial potential for rehabilitation centers and even in-home use.

Government representatives on hand included Michael Weinrich, director of the NIH's National Center for Medical Rehabilitation Research, William Heetderks, of the National Institute of Neurological Disorders and Stroke, and Laura Bowman of the Department of Veterans Affairs. The two NIH organizations are the largest U.S. government funders of neural engineering programs, about \$50 million per year—an amount that seems paltry given the promise of this technology. Weinrich said that the newly estab-

lished National Institute of Biomedical Imaging and Bioengineering would have a budget of about \$40 million in new funds, not counting funds diverted from existing institutes. Researchers in this field are nervously watching developments at the new institute. Some are optimistic that neural engineering can get a foothold in the new funding source; others are worried that key researchers and existing funds will be diverted from NINDS and NCMRR or that medical imaging will dominate at NIBIB.

Neurotech Firms at IFESS

Exhibitors and sponsors at the event included several of the early manufacturers of neurotechnology products and systems. NeuroControl Corp. showed its FreeHand hand grasp prosthesis, the VoCare bladder stimulation system, and a new miniaturized multi-channel programmable stimulator call StIM. The device is targeted at stroke patients suffering from shoulder pain caused by the separation of the shoulder joint and weak muscles after stroke.

Medtronic, probably the largest corporation in the business—even though its neurotechnology product line is dwarfed by its cardiac products—promoted its InterStim urinary control system and DBS product line.

Cleveland Medical Devices showed its BioRadio 110, a compact and wireless brain monitoring device. Besides EEG signals, the product can transmit sensed ECG, EMG, EOG, and PSG signals to a nearby PC-based monitor. EIC Laboratories in Massachusetts exhibited its range of electrode coating products and services, which work with gold, platinum, silicon, iridium, and other materials. Empi showed its line of stimulators for pain treatment and neuromuscular rehabilitation. NeuroStream Technologies, a Canadian manufacturer, showed its line of implantable NeuroCuff interfaces, which accommodate electrodes as well as catheters for fluid infusion. Neopraxis Pty Ltd., an Australian firm, promoted its 22-channel Praxis stimulator, targeted at paraplegic patients. Advanced Bionics, one of the leaders of the cochlear implant business, promoted its line of BION leadless stimulators. The compact devices, measuring 16 mm long by 2 mm in diameter, can be inserted in a patient with a 12-gauge needle and controlled by a wearable RF transmitter.

In an intriguing prelude to the conference, nearby Case Western Reserve University, home of many of the pioneers of functional electrical stimulation, sponsored an Applied Neural Control Research Day, which updated attendees on developments in neuromuscular stimulation, electrode design, and other emerging technologies. The Cleveland FES Center, which organized the conference, had a large contingent of researchers, presenters, and technicians on hand. The non-profit organization is funded by the VA, CWRU, and MetroHealth Medical Center, and helps design neural prostheses which are later spun off to private industry.

Southern California was also well represented at the event. Besides the team from Advanced Bionics, the newly established Alfred E. Mann Foundation, as well as related teams from USC, the Alfred Mann Institute, and visual prosthesis company Second Sight llc were on hand.

4-D Neuroimaging Looks for Magnetic Sense in Neurodiagnostics Market

by James Cavuoto, editor

4-D Neuroimaging is a manufacturer of magnetoencephalographic (MEG) equipment for neurodiagnostic testing and research studies on human neurophysiology. The company's MEG systems feature 150 to 300 electrical coils placed over the head, which are able to read extremely small magnetic fields produced by the electrical activity of neurons in the brain.

The company was formed in 1999 with the merger of San Diego-based Biomagnetic Technologies Inc. (BTi) with Neuromag Oy of Helsinki, Finland. BTi's Magnus systems were directly competitive with Neuromag's Vectorview systems. Both product lines are still offered.

BTi was established in 1970 as a manufacturer of custom laboratory and research equipment for magnetic field testing and low-temperature physics. The company began pursuing clinical products in 1984. Neuromag was formed in 1989 as a spinoff of the low-temperature laboratory of the Helsinki University of Technology.

D. Scott Buchanan has served as the president and chief executive officer of the company since 1997. He joined the company in 1986 as a staff physicist.

4-D Neuroimaging is publicly owned and traded over the counter as FDNX. For fiscal year 2000, the company had a loss of \$8.1 million on revenues of \$8.4 million, compared with a loss of \$7.5 million on revenues of \$3.3 million in 1999. For the first quarter of 2001, the company had a loss of \$1.3 million on revenues of \$3.1 million. In May, 2001, the company announced that it had exchanged about 41 percent of its voting equity for a combination of cash and debt cancellation valued at \$12.5 million.

Market

The company's market includes clinical and basic research facilities in neuroscience and biological psychiatry. The systems' price, ranging from \$2.0 to \$2.4 million, makes them suitable only to the most highly funded institutions.

In a clinical setting, installations are able to recoup the cost of the machine with neurodiagnostic sessions that range from 45 minutes to 2 1/2 hours in length and generate billings of between \$1,500 and \$3,500 per session. The company estimates that customers can achieve

break-even with their products by performing five to six sessions per week.

Currently, reimbursement for MEG diagnostic session from private and public health insurers occurs on a case-by-case basis. However, in 2001, the company obtained approval of Current Procedural Terminology (CPT) codes for magnetoencephalographic testing for epilepsy treatments from the American Medical Association that will facilitate more generalized approval for reimbursement beginning in 2002. 4-D has obtained FDA approval for its MEG systems, allowing their use in the U.S. for clinical applications involving the brain. The company also has CE marking approval in Europe and clinical clearance from the Japanese Ministry of Health and Welfare.

Competition

There are only a small number of manufacturers of magnetoencephalographic equipment for neurodiagnostic and research applications. 4-D Neuroimaging is believed to have a 60 to 75 percent market share. Yokogawa Electric in Japan is one of the largest competitors.

To a lesser degree, the company competes with manufacturers of non-magnetic neurodiagnostic products such as Nicolet, Cadwell, and Neuroscan, whose products sell for \$50,000 to \$150,000. In the research market, the company competes with manufacturers of functional magnetic resonance imaging (fMRI) systems such as a Siemens and General Electric. fMRI systems are modified versions of magnetic resonance imaging (MRI) systems that have been customized for brain research. These systems cost approximately \$600,000.

Compared to neurodiagnostic equipment based on electroencephalography (EEG), MEG systems can produce a much more meaningful map of brain activity in large part because magnetic fields waves are able to penetrate the human skull and other biological elements that seriously degrade electrical signals. MEG systems are capable of distinguishing brain activity from areas of the cerebral cortex within 2 to 3 millimeters.

Compared to brain research tools such as Positron Emission Tomography (PET) and fMRI, MEG systems can produce

maps with much higher time resolution, to within 1 or 2 milliseconds, compared to 1 or 2 seconds with other systems. As a result, MEG represent the most accurate and complete noninvasive technology for mapping human brain function.

Outlook

Currently, 4-D Neuroimaging's MEG systems are used in clinical practice for epilepsy evaluation and presurgical mapping that enables neurosurgeons to precisely locate the source of epileptic activity. However, studies are currently underway to develop MEG-based tests that detect schizophrenia, dyslexia, and depression.

If a clinically accepted and reliable test of disorders using MEG were to be developed, these tests would add significantly to 4-D's market potential. Also, the development of tests that require less-sophisticated imaging or fewer sensing coils might enable the company to offer lower-priced and segmented neurodiagnostic systems. For example, a lower-cost system that reliably performed clinical testing of dyslexia in children could prove popular in schools.

4-D Neuroimaging's products will also prove useful as the market for deep-brain stimulation systems develops since MEG can help the neurosurgeon locate the precise brain region for implantation of electrodes, and evaluate the location and performance of the electrodes after surgery.

While the current financial condition of the company is not worth bragging about, MEG systems are well positioned in the market for neurodiagnostics, which is projected to exceed \$1 billion by 2005, according to Neurotech Reports. If it can weather the current storm, 4-D Neuroimaging stands to capitalize on this market potential.

4-D Neuroimaging

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858 453 6300
858 453 4913 fax
www.4dneuroimaging.com

Founded: 1970 (merged with Neuromag in 1999).

Symbol: FDNX

Market: Neurodiagnostic equipment based on magnetic sensing technology
FY 2000 Revenues: \$8.4 million
CEO: D. Scott Buchanan

Neurotech Entrepreneurs Confront Venture Capital Firms' Geographic Bias

by David E. Griffith, senior editor

Financing a start-up company in any field is never easy, but securing the funds to launch a neurotechnology or medical device firm is a truly herculean task. So that leaves most biomedical entrepreneurs desperately seeking funding from venture capitalists at some point during the development of their companies.

The good news for biomedical businesses is that venture funding is increasing. The bad news is that much of that funding is geographically localized and that venture capitalists have a tendency to favor certain types of biomedical companies over others.

Leading Regions for Biomed Funding

Executive director of the Southern California Biomedical Council (SCBC) Ahmed Enany says it's no secret that certain regions of the United States are blessed with biomedical venture funds and others go begging. According to Enany's figures the L.A./Orange County area finishes a distant fifth in biomedical venture money behind Silicon Valley, New England, San Diego, and the Southeast.

The problem, according to Stephen O'Connor, president of microfluidic componentry company Nanostream, is one of proximity. He argues that if you need venture funding for your business, it's a good idea to start your company in an area where there are a lot of venture funds focusing on your field.

"VCs don't like to drive to board meetings," O'Connor told a recent gathering of the SCBC. "It's really as simple as that. They want to be able to drive 15 minutes to a board meeting, and that's important because a start-up company has a board meeting once or twice a month."

Alan Kleinman, an analyst with the Encino, CA office of Pacific Venture Group, says that O'Connor's argument is a bit simplistic and that VCs are looking for the right "opportunity," no matter the geographic distance from their home offices, but then he reluctantly adds that "all things being equal" between two opportunities, a VC is likely to invest in the opportunity closest to its offices.

The issue of geographic distribution of biomedical venture funds is about much more than just the distance between a start-up company and the offices of the

venture fund. "There's a herd-like mentality among VCs," said Sidney Edwards, a principal with TL Ventures, a Wayne, PA-based venture fund. "They tend to focus on specific regions like Boston and San Francisco and hot fields like pharmaceuticals and genomics where they have made money before."

One of the things that venture capitalists look for before they fund a biomedical start-up is the presence of seasoned biomedical executives not just in the company they are considering but in the community as a whole. And what they really want is a CEO with a track record of making money for their fund. "Venture companies love to fund someone they funded successfully before," says Carolyn Siegal, senior vice president of Cell Matrix, an L.A.-based pharmaceutical company.

Attracting VC Attention

Even if a biomedical entrepreneur is located in an area of the country that's not thought of as a biomedical hotbed, he or she can still attract VC attention. It's just the odds are against them. VCs say the best way to even the odds is by knowing how to play the game. Frustrated biomedical executives reply that they are very willing to learn how to play the game, but the rules are constantly changing.

Matthew Hanson, vice president of business development at Integrated Medical Systems Inc., likens the experience of trying to please venture capitalists to Dorothy's trials in the Land of Oz. "She spends the whole movie getting apples thrown at her by evil trees and running away from flying blue monkeys, and then when she finally defeats the Wicked Witch and takes her broomstick back to the Wizard, he says, 'Nice job. Come back tomorrow.'"

The key to minimizing such frustration, according to both VCs and biomedical executives, is to find the right fund and the right principal from that fund. Of course, that's easier said than done.

"It's a numbers game," says Cell Matrix's Siegal. "There are a lot of firms out there, but they don't all fit with your company for one reason or another. It's a relationship. It's a little bit like dating. Why you don't fit isn't important. It's more impor-

tant to find a venture fund that will work with you as a partner."

Pacific Ventures' Kleinman agrees, but adds the VC's perspective. "We're looking for a variety of pieces," he says. "It's critical to find that right match, not just with a particular venture fund, but targeting a specific partner within that fund. Make sure you do your homework on the fund and the people involved."

TL Ventures' Edwards advises entrepreneurs to be aware of the investment focus of the venture firm they are courting. And even so, he says companies pursuing venture capital must be persistent. "It's a business where you'll end up with 'no' a lot of times before you hear 'yes.'"

Working with Angels

Executives of start-up companies that hear "no" from venture funds are likely to seek investment from individuals or groups of individuals, so-called "angel" investors. That can be tricky and it can result in difficulties in securing additional financing to take a company from development to testing, or from testing to market.

There are good and bad aspects of angel funding. O'Connor says the last company he was involved in was funded by angels and it ran smoothly and sold for \$300 million. But O'Connor is also the first to say that angel financing for biomedical firms is problematic because of the amount of money involved to bring a product to market and the effects angels can have on subsequent financing.

Also, angel funding can be a very dynamic proposition, as many entrepreneurs have discovered in the wake of the recent stock market meltdown. "A year ago a lot of angel investors said they were in it for the 'long haul.' Then when the market tanked, they wanted their money back," says O'Connor.

Regardless of whether a start-up company is seeking funding from angels or VCs, it's critical that its management understand the ways of the business community and adhere to them in their business practices. "Entrepreneurs need to be more discriminating," says Siegal. "They need to subject themselves to the same standards that the investment community is going to subject them to further down the road."

UC Irvine Biomedical Engineering Center Revs for Industry Collaboration

by David E. Griffith, senior editor

Spurred on by the promise of neurotechnology and related industries, the University of California, Irvine's Center for Biomedical Engineering has begun to look at ways of collaborating with nearby industry. The institution's director, Steven C. George, M.D., Ph.D, made a presentation in June to the Life Sciences Industry Council of Orange County to inform the industry of future research directions and expansion efforts.

Currently, the UCI biomedical engineering (BME) program only offers an undergraduate minor as well as graduate degrees. But that's about to change. Next year, the program, which is housed in the School of Engineering, will begin a decade of rapid growth when it offers its first undergraduate major. George says UCI hopes to have 11 full-time BME faculty in place by 2003, and 25 full-time faculty by the end of the decade.

The schedule for the accelerated expansion of the BME program at the Irvine campus is timed to accompany projected growth of the biomedical industry in Orange County. George says there are 150 biomedical and diagnostic device companies in Orange County, and by the end of the decade, growth in the industry is expected to result in thousands of new

jobs for biomedical engineers. The mission of the UCI BME program is to train those engineers.

The BME program is designed to complement the strengths of the UCI medical school, including ophthalmology, cardiology, oncology, and neuroscience. Accordingly, the three primary research areas of the BME program are biophotonics, nanoscale systems, and biomedical computation and imaging.

However, neurotechnology research and education will be an important aspect of the program. "Neuroscience is a major strength of the UCI Medical School," George says, explaining that the combination of the neuroscience research at the medical school and the Reed Irvine Center for Paralysis will make neurotechnology a natural field of concentration for BME students and faculty.

Though the biomedical engineering program at UCI is not as established as other universities such as Case Western Reserve or USC, it has attracted a considerable amount of attention from researchers and funding agencies. In 1999, the program won a \$3 million Whitaker Foundation Development Award. "We were the least developed program to ever win the Development Award," said George.

The first major neurotech research at UCI is likely to be in the field of devices for artificial vision. UCI's medical school is recognized for its ophthalmology training and biophotonics is one of the core areas of research at the BME center. "The first faculty that we made an offer to was in artificial vision," said George. The professor in question declined the offer, but George says artificial vision research is still a priority for the BME program.

Neurotech Reports and Mayfield Fund to Sponsor Neurotech Leaders Forum

Neurotech Reports, the publisher of this newsletter, and Mayfield Fund are sponsoring a Neurotech Leaders Forum on October 10 in San Francisco. The full-day event will feature presentations on the market for neurotechnology and promising commercial applications, and a roundtable discussion of issues affecting this new industry. The event is open to executives and entrepreneurs in the industry, as well as financial and investment professionals. Attendance is limited to 25 people. For more information, contact Neurotech Reports at 310 371-1099.

Calendar

- Sep. 24-29 World Congress on Neuroinformatics, Vienna, Austria. www.neuroinformatics.cc
- Oct. 4-7 Biomedical Engineering Society Annual Fall Meeting, Durham, NC. Contact Biomedical Engineering Society, <http://mecca.org/BME/BMES/society/index.htm>
- Oct. 10 Neurotech Leaders Forum, San Francisco, CA. Contact Neurotech Reports, 310 371 1099.
- Oct. 17-19 32nd Neural Prosthesis Workshop, Bethesda, MD. Contact NIH, <http://npp.ninds.nih.gov>
- Oct. 25-28 IEEE Engineering in Medicine and Biology Society Annual International Conference, Istanbul, Turkey. Contact IEEE EMBS, 732 981 3433.
- Nov. 10-15 Society for Neuroscience Annual Meeting, San Diego, CA. Contact Society for Neuroscience, 202 462 6688, www.sfn.org

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Body Media, Inc.	412 288 9901	www.bodymedia.com
Cleveland FES Center	216 231 3257	www.fesc.org
Cleveland Medical Devices Inc.	877 253 8363	www.clevemed.com
Cochlear Corp.	303 7909010	www.cochlear.com
Cyberonics, Inc.	888 867 7846	www.cyberonics.com
Dynatronics Corp.	801 568 7000	www.dynatronics.com
EIC Laboratories	781 769 9450	www.eiclabs.com
Electromedical Products Intl.	800 367 7246	www.alpha-stim.com
Image-Guided Neurologics	321 757 8990	www.igneurologics.com
Med-El Corp.	919 484 9229	www.medel.com
Medtronic Inc.	763 514 4000	www.medtronic.com
NeoPraxis Pty. Ltd.	61294286350	www.neopraxis.com
NESS Ltd. (Israel)	9 7485738	www.nessltd.com
NeuroControl Corp.	216 231 6812	www.neurocontrol.com
NeuroStream Technologies	604 468 9960	www.neurocuffs.com
Optobionics Corp.	630 665 6050	www.optobionics.com
Second Sight LLC	661 775 3990	www.2-sight.com
SGS Interactive	530 692 9238	www.sgspartners.com

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