



Washington roundup

FDA approves Boston Sci for expanded indication for CRT-D

By MARK McCARTY

Medical Device Daily Washington Editor

FDA reported last week that it has approved the application for expanded indications for cardiac resynchronization therapy/defibrillation (CRT-D) by **Boston Scientific** (BSX; Natick Massachusetts), an approval the company invested millions to win. If one uses the outcome of an advisory committee hearing as the starting point, BSX had to wait six months to gain FDA's approval, which applies to three of its CRT-D units, but the euphoria is likely to be short lived as the company must now wrestle with reimbursement issues.

The process of development of evidence started in 2003 when **Guidant** – a firm BSX won in a bidding war with **Johnson & Johnson** (New Brunswick, New Jersey) *See Washington, Page 5*

SBI sees uptick in patients implanted with STAR system

By OMAR FORD

Medical Device Daily Staff Writer

Not many patients undergo elective procedures in the summer months. Oftentimes, potential patients for these procedures are on vacation, or because of recent financial woes stemming from a strained U.S. economy, they've resigned to live with the pain for a little bit longer.

But these trends don't seem to be affecting orthopedics firm **Small Bone Innovation** (SBI; New York). In fact, SBI said that in August it saw a large number of surgeons using the Scandinavian Total Ankle Replacement (STAR) system to treat patients. Roughly, the company saw a 40% increase in the amount of surgeries that were done with STAR in August than July.

"August was our best month ever in North America for STAR surgeries," Anthony Viscogliosi chairman/CEO *See STAR, Page 6*

International report

Masimo reports the Japanese clearance of SpHb component

A **Medical Device Daily Staff Report**

Masimo (Irvine, California) reported the Japanese Ministry of Health, Labor and Welfare (MHLW) regulatory clearance of its noninvasive and continuous hemoglobin (SpHb) measurement, available as part of the Masimo rainbow SET platform. Representing a breakthrough solution for noninvasively and continuously measuring a patient's hemoglobin level in real-time, SpHb tracks and trends hemoglobin levels without needles, time-consuming laboratory analysis, and risk of contamination associated with traditional blood tests, the company said.

The availability of noninvasive, continuous, and immediate hemoglobin measurements is expected to have wide-ranging clinical impact in Japan – from surgery and *See International, Page 7*

Researchers aim to link robotic limbs to the brain

A **Medical Device Daily Staff Report**

It sounds a bit like something out of a science fiction novel but researchers from **Southern Methodist University** (SMU; Dallas) are working on developing a fiber optic interface to provide lightning-fast connections between robotic limbs and the human brain - a tremendous advancement for amputees.

The research is funded by a Department of Defense initiative and also involves scientists from **Vanderbilt University** (Nashville, Tennessee), **Case Western Reserve University** (Cleveland), the **University of Texas at Dallas**, and the **University of North Texas** (Denton, Texas). SMU says this connection will be key to operating realistic robotic arms, legs and hands that not only move like the real thing, but also "feel" sensations like pressure and heat.

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Don't miss today's MDD Extra: Neurology



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*Deals roundup***Medco Health Solutions completes UBC acquisition****A Medical Device Daily Staff Report**

Medco Health Solutions (Franklin Lakes, New Jersey) reported that it completed its acquisition of **United BioSource** (UBC; Bethesda, Maryland) in an all-cash transaction valued at nearly \$730 million, creating a complementary and comprehensive research organization that extends Medco's core capabilities in data analytics and research to accelerate pharmaceutical knowledge – advancing patient safety and contributing to the body of evidence-based medicine.

"With its global presence and emphasis on post-approval drug research that is designed to guide the safest and most efficient use of the most effective medicines, this acquisition is perfectly aligned with our broader strategy to 'make medicine smarter,'" said David Snow Jr., Medco chairman/CEO. "There is a large pipeline of new, complex biotechnology products – including oncology drugs – that will require an on-going collection of evidence in the commercial market to ensure safety, manage risk, address effectiveness and evaluate economic outcomes. These medicines are the same class of products that benefit most from specialty distribution. The combination of UBC, Accredo and our world class mail-order pharmacy positions Medco to offer unique and innovative services that offer the benefit all players in the healthcare system seek: getting the right medicine to the right person as efficiently as possible."

UBC is now a wholly-owned subsidiary of Medco, that will run independently from Medco's core business to ensure compliance with contractual requirements and client expectations.

The transaction was funded with the proceeds of Medco's recently completed senior notes offering. The new business is expected to be slightly accretive to Medco shareholders in 2011, excluding one-time items and amortization. ■

Medical Device Daily Fun Facts

Editor's note: In an effort to lighten your day, we now offer a weekly chuckle or two . . .

Where's the parade, street sign or honorary degree for life sciences?

Many feats that beget membership in select clubs inspire, gratify, bring self-fulfillment, benefit society, etc., but which is the most prolific and vital? That's life sciences!

To put world-renown achievements into perspective, more than 3,000 people have successfully climbed Mt. Everest during the past 60 years. Fewer than 250 people have sailed alone around the world since 1898. Approximately 500 people have been to outer space, while less than 5,000 own a Super Bowl ring, and only 44 men can put "U.S. President" on their resumes.

Now, if you're forming a club comprised of, say, people who have overcome chronic disease or acute physical affliction, well, that membership roll call would tally hundreds of millions of people . . . thanks to its founder, the life sciences – makers of devices, drugs and medical technologies that, on a daily basis, rescue patients from the danger of joining the dreaded, ever-growing, billions-of-members-strong ranks of those who unfortunately succumbed to ill health.

– Michael J. Harris, Fun Facts Editor

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*Agreements/contracts***Revolutions, MIG to deliver five million safety syringes***A Medical Device Daily Staff Report*

Revolutions Medical (Charleston, South Carolina) has finalized a manufacturing agreement with **Medical Investment Group** (MIG; Jiangsu, China). Pursuant to the manufacturing agreement, MIG has guaranteed the production and delivery of a minimum of 5 million 3cc safety syringes per month for a period of five years.

"By securing this first manufacturing relationship and having the ability to produce and ship a minimum of five million safety syringes per month beginning in the first quarter of 2011, we now are in a position to sign initial distributors and begin to gauge preliminary sale volumes," said Ron Wheet, CEO of Revolutions Medical. The facility has the ability to increase production up to 50 million 3cc syringes per month. When we initiate the manufacturing process on our 1cc, 5cc, and 10cc RevVac safety syringes, we will plan to produce those in South Carolina."

MIG's manufacturing facility is a 250,000 square foot factory located on 35 acres in Jiangsu, China. The factory is fully compliant with all FDA and CE/EC requirements and has extensive experience producing and shipping similar medical products for worldwide delivery. This factory has 20 sets of injection molding machines, and with several units of ethylene oxide sterilizer and testing equipment for optimal quality compliance, it is capable of handling Revolutions's needs. In 2007, the factory implemented the ISO13485 standard and has passed each annual review since, in addition to passing a recent onsite FDA audit.

Tom O'Brien, president of Revolutions, said, "Initially we planned to begin manufacturing in Brazil and although we are moving forward with MIG, we still view Brazil as a great potential distribution opportunity and potential future manufacturing location. I have also had the opportunity to see other FDA approved medical products that MIG's contracted facility has mass produced, and feel very comfortable we have selected a first class manufacturing facility that will guarantee the quality of our safety syringes, as well as providing us with the flexibility to rapidly expand production."

Revolutions is a safety medical device and software application company. Its products include the RevVac safety syringe, safety blood drawing device and safety IV catheter. The company also provides RevColor, RevDisplay and Rev3D – software solutions and proprietary tools that are compatible with standard MRIs and standard PACS.

In other agreements/contracts news, **RevitalVision** (Lawrence, Kansas) reported a non-exclusive distribution agreement with Advantage Hoya, an exclusive membership program to augment the growth of Eyecare practices. The RevitalVision program will be promoted through Advantage

Hoya's Regional Business Consultants.

RevitalVision says it represents a new category in vision improvement – a non-invasive technology that enhances eyesight neurologically. This computer-based, neural therapy is clinically and scientifically proven to improve patient's visual outcomes.

"We are extremely pleased to have established this joint effort with Advantage Hoya," said Dennis Depenbusch, CEO of RevitalVision. "The Advantage Hoya mission of improving ophthalmic practice operations and enhancing patient outcomes through value added services aligns well with RevitalVision. This national network of qualified and trained representatives will ensure a close relationship is maintained with our participating eye care professionals as we both grow our networks." ■

*Patent watch***Shrink Nanotech files patent applications for CellAlign***A Medical Device Daily Staff Report*

Shrink Nanotechnologies (Carlsbad, California), a nanotechnology company developing products and licensing opportunities in the alternative energy industry, medical diagnostics and sensors and biotechnology research and development tools businesses, reported that certain patent applications related to its advanced tissue engineering technology platform, CellAlign, have been filed.

CellAlign's key feature is a micro-fabricated substrate with non-periodic (or random) linear patterned grooves that allow for the alignment of cells along a single axis. The company said the design is ideal for growing biological tissues from stem cells, especially those that naturally grow in a linear fashion such as in cardiac and nerve tissues.

"CellAlign has the potential to grow sheets of living tissues that may one day act as 'band-aids' to patch and repair, and possibly regenerate, damaged or diseased organs," said Mark Baum, CEO of Shrink Nanotechnologies. "Clinical practices and medical specialties are increasingly turning to cellular-based therapies to solve some of the world's most perplexing health maladies. As our intellectual property position improved with CellAlign, future licensing potential represents a significant market opportunity for Shrink." ■

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*HIT roundup***Medseek's eHealth Council to cover meaningful use****A Medical Device Daily Staff Report**

Converge, Medseek's (Birmingham, Alabama) eHealth strategy group, will host its second annual eHealth Council in Savannah, Georgia on Sept. 30 and Oct. 1. eHealth Council is open to healthcare executives and thought leaders from across the country who are interested in interacting with peers and gathering information and best practices around eHealth.

Guest speakers include Don Seymour, independent advisor to hospitals boards, CEOs and medical staff leaders, and Fabienne Moore, MD, senior director with the advisory board company. Seymour will summarize national trends, make the case for becoming specialized, integrated and connected, and provide a list of questions to ask regarding key strategic issues. Moore will address key trends affecting healthcare including Stage 1 Meaningful Use criteria and emerging delivery systems such as accountable care organizations (ACOs). "There has been a significant shift away from clinical transformation toward information technology as a means of increasing service line revenue, achieving physician recruiting goals and attracting patients," said Rich Grehalva, senior VP of Converge and senior VP of marketing for Medseek. "However, while eHealth is one of the most cost-effective strategies to deploy in healthcare, its value remains largely unrecognized."

Medseek launched the eHealth Council last year to address this issue.

"We feel it's important for today's healthcare executives to have a forum where they can learn about eHealth best practices, what works and what doesn't," Grehalva said. "We have created an opportunity for thought leaders to share experiences and practical methods to implement and sustain eHealth initiatives."

The 2010 eHealth Council will be hosted at the Mansion on Forsyth in Savannah, and will set aside specific time for healthcare executives to meet and interact with their peers, as well as the guest speakers.

In other HIT news:

- **Electronic Health Systems** (EHS; Birmingham, Alabama) said it is changing its name, and the name of its flagship product CareRevolution, to **SuccessEHS**.

"Over the past 15 years we have distinguished ourselves as a customer-focused, privately-held company that is in it for the long haul," said Sanders Pitman, CEO of EHS. "With the many changes taking place in healthcare we felt it was important to position our company for the future. As part of this positioning we felt it was very important for our name to reflect the core values and mission of our company. Ultimately it is our goal to make our customers successful, so we decided to match our name to our mission: SuccessEHS."

- **Clinical Care Options** (CCO; Reston, Virginia) reported the release of handheld versions of its point-of-care digital textbook, CCO inPractice. The release includes two iPad apps, two iPhone apps, and a mobile web site that now provide HIV treaters, hematologists, and oncologists immediate access to the answers they need to provide optimal care for their patients.

Through an online handheld device, CCO inPractice delivers all of the primary resources of the web site including original textbooks written by expert authors as well as integrated drug lookups, PubMed abstracts, and links to management guidelines. Even when offline, users of the iPad/iPhone apps have access to the expert information provided by the continually updated textbooks as well as the drug database information and PubMed abstracts. ■

*Med-Tech Notes***Illinois proton center coming next month**

Proton therapy, an alternative to radiation for the treatment of cancer, will be available in Illinois sooner than expected. Originally slated to open in early 2011, the **CDH Proton Center** (Warrenville, Illinois) will open its doors Oct. 19, making it the first proton therapy center in Illinois and only the ninth in the country.

"We are very excited to be able to bring the power of protons to patients," said William Hartsell, MD, medical director of the CDH Proton Center, A ProCure Center. "We are looking forward to treating our first patient and are already receiving inquiries and evaluating patients to determine if they would benefit from proton therapy."

Proton therapy is an alternative to X-ray radiation for patients with cancer. The precision of proton therapy spares healthy tissue and results in far fewer short- and long-term treatment side effects. Proton therapy has been shown to be beneficial in the treatment of a broad range of tumor types including head and neck, brain, central nervous system, prostate, lung, sarcomas, gastrointestinal and many pediatric cancers. The precision of proton therapy makes it especially effective for treating children and adults with anatomically complex tumors such as base of skull and tumors along the spinal cord.

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Washington

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Jersey) in 2006 – ramped up the study as a build-on to the MADIT I and II trials. MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) randomized more than 1,800 patients to a CRT-D unit and an implantable cardioverter defibrillator, and BSX reported the results of the study late last year (*Medical Device Daily*, Sept. 4, 2009).

Writ large, the results of the study are that CRT-D cut the risk of death and heart failure in patients with blocked left bundle branches (LBBB) by 57% compared to patients on implantable cardioverter defibrillators. Roughly seven in every 10 patients in MADIT-CRT exhibited symptoms of LBBB.

BSX took the application to an FDA advisory panel earlier this year (*MDD*, March 22, 2010) and won a resounding near-unanimous vote for approvability for the expanded indication to a large number of patients with class II heart failure and a small group of patients in class I, namely those with left bundle branch block who have normal sinus rhythm and QRS intervals of at least 130 milliseconds. The clinical trial data scored superbly on safety scores, with 85% of patients on CRT-D avoiding system-related complications compared to the target of 70%. More than 90% of controls avoided those complications, but much of the difference was due to complications incurred with the use of the extra lead needed for pacing of the left ventricle.

The news is decidedly helpful for BSX as it tries to recoup its investment in Guidant, an investment that has come with plenty of baggage. The impact of the announcement on the firm's shares at the New York Stock Exchange was negligible, however, inasmuch as the market had already factored the expected approval into share prices. BSX shares ticked up briefly from \$5.35 to \$5.50 last Thursday, closing at \$5.45, but had lost almost all that gain by mid-morning Friday. A Sept. 17 statement by **Piper Jaffray** (Minneapolis) described the news as "an incremental positive" for BSX and for "the market as a whole," but the gains from sales of CRT-D units, which are generally pricier than ICD devices, may be at least partly offset by anticipated price pressures. Piper gave the company's shares a neutral rating and a target price of \$7.

As is commonly the case, the approval comes with post-market study requirements. According to a Sept. 16 statement at the FDA web site, the agency has decreed that BSX must conduct two post-approval studies (PASs), one of which will "evaluate complications and long-term mortality benefits of CRT-D in patients with left bundle branch block," although the company will be able to use the National Cardiovascular Data Registry to handle that study. The second study entails further follow-up of MADIT-CRT enrollees twice a year for five more years "to assess long-term mortality benefits" of the two device types.

Gordon Tomaselli, MD, an electrophysiologist and the chief of cardiology at **Johns Hopkins University School**

of Medicine (Baltimore) told *Medical Device Daily* that while there are a number of patients who can benefit from CRT-D, he does not anticipate a flood of CRT-D units finding their way into patients' chests in his practice.

"I don't think there's all that much" need for this class of device compared to some classes of electrophysiology equipment, Tomaselli said, adding, "the downsides are that you have to put in another lead, and there are potential complications," as the trial demonstrated.

Tomaselli declined to play weather forecaster with regard to a national coverage analysis at the Centers for Medicare & Medicaid Services. "I don't know what CMS is going to approve. One thing that's interesting about MADIT-CRT is that those folks are younger" than the typical Medicare enrollee, he noted. The trial's average age for controls was 64 years plus/minus 11 months, and for patients on the study article, the average age was 65 years plus/minus 11 months.

The electrophysiologist said clinicians as a whole are not utterly skeptical about CRT-D, but not entirely sold, either. "The reigning thought is that if you have left ventricular (LV) dysfunction and a wide QRS interval, and [the patient's CHF] is mild and you don't pace, you may actually be fine," Tomaselli said, pointing out that the severity of congestive heart failure often abates upon the commencement of medical therapy. On the other hand, he remarked, "if the patient has a problem down the line, you can always put in an LV lead."

Tomaselli also observed that the driving dynamic for a physician's recommendation to the patient about CRT-D is not at all dissimilar to the dilemma as to whether to recommend an ICD to stave off any risk of sudden cardiac death. "The calculus has always been 'do I want to put in a few extra devices and not miss' a patient" who would have died, Tomaselli said. According to statements made by a representative of BSX at the March advisory panel hearing, 27 class I patients have to receive CRT-D in order to stave off one fatality at three years. For class II patients, the number-needed-to-treat falls to 10.

Tomaselli said he would not be averse to requesting that a local carrier cover CRT-D for the indication if CMS seemed to be lagging on a national coverage decision, "particularly if there was hard evidence" to support efficacy. "In some people it really does work," he said, even if it's for patients "who require pacing for only a short period of time." ■

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STAR

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of SBi told *Medical Device Daily*. “This performance is very encouraging for a number of reasons. First, August and December are historically the slowest months of the year for surgeries. But STAR offers patients a product where they can get full restoration. We are affecting their quality of life. The device was developed to solve the unmet need of the patient and eliminate pain in a simple manner, and we’ve been successful.”

Viscoglisi said that strong clinical research that backs up the STAR’S effectiveness and the ability for surgeons to reduce the amount of time it takes to implant the device (about 1 hour) also contribute to the recent increase in procedures.

So far, SBi has seen strong revenue growth in its small bone & joint portfolio of about 35% in the first half of 2010.

The prosthesis is a mobile-bearing device, which relies on bearings that move across a surface of polyethylene, a flexible plastic. It is an alternative to fusion surgery and may allow for greater rotation and movement in the joint. Fusion surgery involves cementing the shin bone (tibia) – the thicker of the two bones in the lower leg – to the talus bone in the ankle. The procedure stabilizes the ankle, but significantly decreases the ability to move the foot up and down. Once arthritis or injury destroys the cartilage that cushions the ankle bone, the joints can become painful enough to warrant total ankle replacement.

The STAR total ankle replacement system received a PMA from the FDA on May 27, 2009 and is indicated for replacement of painful arthritic ankle joints affected by osteoarthritis, post-traumatic arthritis or rheumatoid arthritis (*Medical Device Daily*, May 29, 2009).

The implant is a three-piece, cementless, mobile-bearing, total ankle replacement system and has a titanium plasma spray coating that allows for better bone in-growth, stabilization and bone preservation.

That’s one of the advantages of the implant, according to Viscoglisi, who said that the device was taking away market share from other players in the space such as **Depuy Orthopedics** (Warsaw, Indiana) with its Agility product; **Wright Medical’s** (Arlington, Tennessee) Inbone solution; and **Tornier’s** (Edina, Minnesota) Salto Talaris implant.

He said that while all have viable solutions, most use cement, and rely on fusion surgery.

“Patients want motion instead of fusion,” he said. “Also cement is only as good as it is ever going to get the first day it’s implanted. With our device patients have actually reported better outcomes over time.”

SBi has been attracting considerable attention in recent months in both the financial and the orthopedics sector. Out of nearly 5,200 companies considered, SBi was the only orthopedic company on the list of the top 50 U.S. VC-backed companies in the *Wall Street Journal* article “Sizing Up Promising Young Firms” on March 9, 2010.

Additionally, SBi was the 7th highest-ranked healthcare company and was 24th among the 50 companies highlighted.

The company also closed on \$12 million in Series E funding from Olympus (Center Valley, Pennsylvania) in March 2010. It secured a \$30 million debt facility from Fortress Investment Group to fund accelerated business expansion and refinance existing indebtedness late last year (*MDD*, Dec. 15, 2009). And in mid-2009, SBi closed on \$144 million in Series D and Series C funding from a host of investors.

As for the future of the company, Viscoglisi said that it is in a position to gain even more market share.

“We’re experiencing growth because there are many surgeons who were doing ankle fusion, that are now converting from fusion to our implant,” he said.

But growth opportunities don’t just stop there.

Of the nearly 390,000 patients in the U.S. diagnosed annually with ankle arthritis, Viscoglisi said he believes that as many as 70,000 of them could benefit from the STAR implant. The company also believes it is well positioned to take full advantage of a vastly under served market and, more importantly, enable surgeons to advance the standard of patient care.

“The company plans to continue with the launch phase of the technology in 2010 and the rollout phase of the technology in 2011,” he said. ■

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Financings roundup

Alere bumps the size of its debt offering up to \$400M

A Medical Device Daily Staff Report

Alere (Waltham, Massachusetts), previously known as **Inverness Medical Innovations**, said that, in connection with its previously reported private placement of senior subordinated notes due 2018, it entered into a purchase agreement with the initial purchasers of the notes on Sept. 15. The size of the offering was increased from \$350 million to \$400 million.

The notes have a coupon of 8.625% and are being offered at 100% of the aggregate principal amount of the notes. Alere expects to complete the offering on or about Tuesday and intends to use the net proceeds from the offering for working capital and other general corporate purposes.

Alere offers products that, according to the company, merge rapid diagnostics and health management. In July, the company changed its name to Alere from Inverness (*Medical Device Daily*, July 19, 2010). ■

International

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intensive care units to less acute care settings, including the emergency department and physician offices. SpHb may help clinicians determine whether a patient has a low hemoglobin level (known as anemia) and facilitate prompt detection of internal bleeding and more appropriate administration of blood transfusions – by referring to the SpHb measurement that is continuously displayed on Masimo rainbow SET Pulse CO-Oximeters.

“Receiving full MHLW regulatory approvals for SpHb makes the noninvasive, continuous measurement of hemoglobin universally available to Japanese clinicians,” said Joe Kiani, Masimo founder/CEO. “This arms clinicians throughout Japan with the real-time assessment of hemoglobin, enabling more appropriate management of patients both inside and outside of the operating room.”

BSD reports additional systems in China

BSD Medical (Salt Lake City) reported that **Dalian Orientech**, the company’s exclusive China distributor, has ordered two BSD-2000 Hyperthermia Systems (BSD-2000). The BSD-2000 System utilizes BSD’s synchronous phased array technology to non-invasively target therapeutic heating (hyperthermia) to certain cancerous tumors, including those located deep within the body. Clinical studies have shown that hyperthermia treatment can kill cancer cells directly as well as increase the effectiveness of other cancer therapies, including radiation therapy, for the treatment of certain tumors.

Hyperthermia cancer therapy has a strong following in China, and Orientech controls about 65% of the market. The Orientech sales force covers 23 provinces. After shipping the two systems, the company will have sold 19 BSD-2000 Hyperthermia Systems to Orientech.

Hyperthermia has been used in China for the treatment of cancer for many years. The hyperthermia market in China has historically been supported by Chinese manufactured systems. The market objective for BSD in China is to continue to expand and upgrade the existing market for clinical hyperthermia equipment to the advanced features of the BSD-2000.

BSD develops systems to treat cancer and benign diseases using heat therapy delivered using focused radio frequency (RF) and microwave energy. Its product lines include both hyperthermia and ablation treatment systems.

Z-Medica in Finnish distribution for QuikClot

Z-Medica (Wallingford, Connecticut), a company developing hemostatic agents, reported that it has signed an exclusive distribution agreement with **Fenno Medical** (Helsinki, Finland), a medical device distributor. The agreement allows Fenno the exclusive right to distribute Z-Medica’s QuikClot line of hemostatic agents to the hospital and emergency medical services (EMS) markets

throughout Finland for the first time.

QuikClot products received the CE mark in November 2009 and the company has been negotiating distribution agreements with a series of best-of-breed medical device distributors since then. “Fenno’s extensive contacts across a wide array of medical specialties and professional and skilled sales staff make it the perfect partner to introduce Finnish doctors and first responders to QuikClot and educate them on the product’s benefits,” said Brian Herrman, CEO, Z-Medica.

QuikClot is a surgical gauze impregnated with kaolin, an inert mineral with no known contraindications, and can achieve hemostasis in severe bleeding situations in as little as three minutes. QuikClot is widely used throughout several clinical specialties, including cardiology, interventional radiology, critical care, dermatology, emergency medicine, orthopedics and OB/GYN, and after months of testing against 12 other hemostatic products in the marketplace, the military version of the kaolin gauze (Combat Gauze) was chosen as the exclusive product for use by all U.S. military forces in 2008.

St. Jude Medical opens plant in Costa Rica

St. Jude Medical (St. Paul, Minnesota) has made good on its plans to open a plant in the El Coyol Free Zone in Alajuela, Costa Rica, to make heart valves.

The company plans to invest an estimated \$670 million in Costa Rica and employ up to 2,000 of its people over the next five years, according to the *Tico Times*.

“The arrival of St. Jude is not only a great opportunity for Costa Rica, but also represents an enormous challenge that will test our institutional muscle,” Costa Rican President Laura Chinchilla said during a ribbon-cutting ceremony on Friday, the *Tico Times* reported. “It obliges us to strengthen our innovation technology, commit greater effort to developing our young professionals, and keep fighting to improve the competitiveness of our economy.”

The St. Jude Medical plant in Alajuela, which is northwest of San Jose, already employs 250 people and plans to hire another 50 workers by the end of the year. The plant will specialize in making aortic valve replacements.

However, the Minnesota device maker said in January 2009 it would enter Costa Rica by investing more than \$40 million to build a 20,000-square-meter facility that could employ as many as 500 people by the end of this year. Then, the plan was to begin exporting heart valves by the end of 2010.

“St. Jude Medical has chosen Costa Rica as an expansion site because of its robust business environment, talented workforce and its strategic location in an area where we see strong growth potential,” Michael Rousseau, group president of St. Jude Medical, said in the 2009 release. “We appreciate the opportunity to do business in Costa Rica and look forward to a mutually beneficial relationship.”

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Robotic

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The Department of Defense initiative will fund a \$5.6 million research center led by SMU engineers, the university noted. The Neurophotonics Research Center will develop two-way fiber optic communication between prosthetic limbs and peripheral nerves.

Successful completion of the fiber optic link will allow for sending signals seamlessly back and forth between the brain and artificial limbs, allowing amputees revolutionary freedom of movement and agility.

Partners in the Neurophotonics Research Center also envision man-to-machine applications that extend far beyond prosthetics, leading to medical breakthroughs like brain implants for the control of tremors, neuro-modulators for chronic pain management and implants for patients with spinal cord injuries.

The researchers believe their new technologies can ultimately provide the solution to the kind of injury that left actor Christopher Reeve paralyzed after a horse riding accident.

"This technology has the potential to patch the spinal cord above and below a spinal injury," said Marc Christensen, center director and electrical engineering chair in SMU's Lyle School of Engineering. "Someday, we will get there."

The Defense Advanced Research Projects Agency is funding the \$5.6 million center with industry partners as part of its Centers in Integrated Photonics Engineering Research (CIPHER) project, which aims to dramatically improve the lives of the large numbers of military amputees returning from war in Iraq and Afghanistan.

Currently available prosthetic devices commonly rely on cables to connect them to other parts of the body for operation – for example, requiring an amputee to clench a healthy muscle in the chest to manipulate a prosthetic hand. The movement is typically deliberate, cumbersome, and far from lifelike, SMU said.

The goal of the Neurophotonics Research Center is to develop a link compatible with living tissue that will connect powerful computer technologies to the human nervous system through hundreds or even thousands of sensors embedded in a single fiber.

Unlike experimental electronic nerve interfaces made of metal, fiber optic technology would not be rejected or destroyed by the body's immune system.

"Enhancing human performance with modern digital technologies is one of the great frontiers in engineering," Christensen said. "Providing this kind of port to the nervous system will enable not only realistic prosthetic limbs, but also can be applied to treat spinal cord injuries and an array of neurological disorders."

The Neurophotonics Research Center's industrial partners include **Lockheed Martin** (Bethesda, Maryland), **Plexon** (Dallas), **Texas Instruments** (Dallas) and **National Instruments** (Austin, Texas).

Every movement or sensation a human being is capable of has a nerve signal at its root.

"The reason we feel heat is because a nerve is stimulated, telling the brain there's heat there," Christensen said.

The center formed around a challenge from the industrial partners to build a fiber optic sensor scaled for individual nerve signals: "Team members have been developing the individual pieces of the solution over the past few years, but with this new federal funding we are able to push the technology forward into an integrated system that works at the cellular level," Christensen said.

The research builds on partner universities' recent advances in light stimulation of individual nerve cells and new, extraordinarily sensitive optical sensors being developed at SMU. Volkan Otugen, SMU site director for the center and Lyle School mechanical engineering chair, has pioneered research on tiny spherical devices that sense the smallest of signals utilizing a concept known as "whispering gallery modes." A whispering gallery is an enclosed circular or elliptical area, like that found beneath an architectural dome, in which whispers can be heard clearly on the other side of the space.

The ultimate combination of advanced optical nerve stimulation and nerve-sensing technologies will create a complete, two-way interface that does not currently exist, according to the researchers.

At press time, SMU researchers involved with the project had not responded to *Medical Device Daily* for additional comment.

"Science fiction writers have long imagined the day when the understanding and intuition of the human brain could be enhanced by the lightning speed of computing technologies," said Geoffrey Orsak, dean of the SMU Lyle School of Engineering. "With this remarkable research initiative, we are truly beginning a journey into the future that will provide immeasurable benefits to humanity." ■

International

Continued from Page 1

WMT unit signs Panamanian distribution deal

Wound Management Technologies (Fort Worth, Texas) said that its subsidiary, Wound Care Innovations (WCI), signed a distribution agreement with **Bivium** to distribute its advanced wound care collagen product, Cellerate RX in Panama. The addition of Panama now puts WCI's distribution channels in 6 countries in Central America, to include Belize, El Salvador, Honduras, Nicaragua and Guatemala.

Cathy Bradshaw, President of WCI said, "We are extremely excited to see the growth of Cellerate RX in the Central American region. Cellerate RX is FDA cleared for use on all acute and chronic wounds except 3rd degree burns and so many will benefit from having it available. It has been found to be very effective in managing diabetic wounds, a problem in this region as well as throughout the world."

Wound Management Technologies' primary focus is the distribution of its collagen product, Cellerate RX. ■

Product Briefs

• **Accuray** (Sunnyvale, California) has introduced the CyberKnife VSI System, at ESTRO 29 in Barcelona, Spain. Clinical research presented during the symposium demonstrated the benefits of CyberKnife radiosurgery in the treatment of primary early stage and metastatic lung cancer, including excellent disease control and preservation of quality of life. Enabling these outcomes are the CyberKnife System's motion management capabilities including the Synchrony Respiratory Tracking System, which enables real-time tracking and correction for tumors that move with respiration, the company said. Accuray says the CyberKnife Robotic Radiosurgery System is the world's only robotic radiosurgery system designed to treat tumors anywhere in the body non-invasively. Using continual image guidance technology and computer controlled robotic mobility, the CyberKnife System automatically tracks, detects and corrects for tumor and patient movement in real-time throughout the treatment. This enables the CyberKnife System to deliver high-dose radiation with pinpoint precision, which minimizes damage to surrounding healthy tissue and eliminates the need for invasive head or body stabilization frames.

• **Elixir Medical** (Sunnyvale, California) reported initiation of patient enrollment in the EXCELLA BD randomized clinical trial designed to evaluate Elixir's next generation Novolimus eluting coronary stent system (CSS) with bioabsorbable coating, the Elixir DESyne BD Novolimus Eluting CSS. The Elixir DESyne BD Stent combines a low drug dose (5µg/mm stent length) of the novel, internally developed macrocyclic lactone Novolimus, a metabolite of sirolimus, and a low polymer load of a polylactide-based bioabsorbable polymer resulting in one of the thinnest coatings (<3 µm) available on a polymer-coated drug eluting stent (DES) system, Elixir said. The polymer is applied onto the stent without the need for an underlying primer polymer coating and is designed to bioabsorb over several months leaving behind a bare metal stent. EXCELLA BD is a randomized, single-blind, multi-center clinical trial designed to enroll 145 patients at 10 sites in Europe and Brazil. The trial will compare the DESyne BD CSS to the Medtronic Endeavor Zotarolimus Eluting CSS. The primary endpoint of the trial is the in-stent late lumen loss at 6 months measured using quantitative coronary angiography (QCA) with an additional evaluation in a sub-set of patients by intravascular ultrasound (IVUS) at 6 months.

• **InfraReDx** (Burlington, Massachusetts) said that its new LipiScan IVUS coronary imaging system will be highlighted during the annual Transcatheter Cardiovascular Therapeutics meeting in Washington. The device, which was recently cleared by FDA, will be featured in scientific and clinical symposia, live case broadcasts, product demonstrations and poster abstract sessions. The LipiScan IVUS system uses a multimodality imaging catheter; the first

ever to combine the complementary technologies of near-infrared (NIR) spectroscopy and intravascular ultrasound (IVUS). This combination enables interventional cardiologists to rapidly determine both the structure of plaque (via IVUS) along with its chemical composition (via NIR spectroscopy). NIR spectroscopy is the only technology cleared by the FDA for the specific task of detection of lipid-core coronary plaques (LCP). Such plaques can adversely impact the safety of stenting and are associated with heart attacks that occur in those who have received stents and in the general population. The system was designed by cardiologists for cardiologists and provides an unparalleled "one-stop" visual determination of critical coronary health features to assist in the care of coronary patients, including the identification of lipid-core plaques, degree of stenosis, reference vessel diameter, and plaque burden.

• **RyMed Technologies** (National Harbor, Maryland) said the InVision-Plus needleless IV connector helped three different organizations sharply reduce – and in some cases completely eliminate – central line-associated bloodstream infections (CLABSI), according to three poster presentations that will be presented at AVA 2010, the annual scientific meeting of the Association for Vascular Access. The three connector types tested were a split septum connector (SS); negative pressure mechanical valve (NPMV); and InVision-Plus. The company said the InVision-Plus outperformed the other connector types in one study. Use of the SS device produced a CLABSI rate of 6.0/1,000 catheter days. The rate for the NPMV device was 3.3/1,000 catheter days. InVision-Plus was the only connector that produced an acceptable rate by today's standards: 0.49/1,000, including a zero rate for the final 17 months of the test period – even though Methodist studied a patient population that is more infection-prone than most, the company added.

People in the News

• **Antares Pharma** (Ewing, New Jersey) said that Dario Carrara, PhD, has resigned from his position as senior VP and managing director – pharmaceutical group, effective Dec. 31. Carrara will transition to Ferring International Center, who purchased from Antares certain assets and assumed a leased facility in Switzerland along with a majority of the site's employees at the time of the purchase in November 2009. Antares Pharma focuses on self-injection delivery technologies and topical gel-based pharmaceutical products.

• **U.S. Preventive Medicine** (Dallas) has named Craig Niemiec as executive VP/CFO. Niemiec previously was CFO of McKesson Technology Solutions, U.S. Preventive Medicine provides an integrated continuum of prevention programs – primary, secondary and tertiary – that are based on the clinical science of preventive medicine.

MDD'S NEUROLOGY EXTRA

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

MONDAY, SEPTEMBER 20, 2010

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Keeping you up to date on recent developments in neurology

Brain stimulation could help stroke patients regain muscle control

■ ■ ■ Stroke patients who were left partially paralyzed found that their condition improved after they received a simple and non-invasive method of brain stimulation, according to research in the September issue of the *European Journal of Neurology*. Researchers from the **Ain Shams University** (Cairo, Egypt), studied 60 patients with ischemic stroke – where the blood supply is reduced to the brain who had been left with mild-to-moderate muscle weakness down one side of their body. Twenty of the randomly assigned treatment group received repetitive transcranial magnetic stimulation (rTMS) applied at 5-Hz over the brain hemisphere affected by the stroke and the other 20 received 1-Hz stimulation of the unaffected hemisphere. The remaining 20 formed the control group, receiving inactive placebo doses of the treatment. All patients received the same physical therapy. “When we compared the results between the three groups, we found that both of the treatment groups showed significant motor function recovery” said co-author Anwar El Etribi, professor of neurology and psychiatry at the Ain Shams University. “No improvements were seen in the control group who had received the placebo treatment and the same physical therapy protocol.” The majority of the patients (95%) had suffered their stroke in the last three years, having been enrolled in the study at least one month after their stroke. However, there was no difference between the level of clinical improvement and the interval since the patients’ strokes. “We believe that people develop partial paralysis down one side after they have a stroke because the hemispheres of the brain become unbalanced” said Etribi. “The hemisphere that has not been affected can become over-active, while the damaged hemisphere can become inhibited. Our treatment worked on the theory that increasing the activity of the hemisphere affected by the stroke and reducing the activity of the unaffected hemisphere can reduce muscle weakness and improve overall motor function,” Etribi said. The 60 patients who took part in the study had similar baseline characteristics, apart from a lower incident of ischemic heart disease in the 5-Hz rTMS group, which was unlikely to have had an effect on recovery.

Researchers identify genetic marker of aggressive Alzheimer's disease . . .

When neurofibrillary tangles form, brain cells die and release tau. An international team of Alzheimer's disease experts, led by **Washington University School of Medicine** (St. Louis), has uncovered a gene variation that appears to predict the rate at which Alzheimer's disease will progress. The investigators report their findings online in the journal *Public Library of Science (PLoS) Genetics*. Whereas previous studies have focused on factors that influence the risk for Alzheimer's, the new research points to a way to determine how rapidly Alzheimer's patients may develop full-blown dementia after their diagnosis. The investigators studied 846 patients with elevated levels of a protein called tau in their cerebrospinal fluid (CSF). Recent studies have found that the presence of a particular form of the tau protein in the CSF is an indicator of Alzheimer's disease. The researchers also looked at single DNA variations in the patients and identified a genetic marker linked to elevated tau levels. That marker turned out to be associated with rapid progression of Alzheimer's disease. “People who carry this genetic marker tend to have higher tau levels at any given stage of the disease than individuals without it,” said senior investigator Alison Goate, a Professor of Genetics in Psychiatry at Washington. “Until now, most studies of genetic risks associated with Alzheimer's disease have looked at the risk of developing the disease, not the speed at which you will progress once you have it. The genetic marker we've identified deals with progression.” For many patients and their families, that information may be more useful than the knowledge that a person may be developing Alzheimer's damage in the brain even if that individual hasn't yet developed clinical symptoms, according to Goate. Damage from the disease can be present for years before symptoms appear. But this study suggests that elevated tau, combined with the genetic marker, could be a sign that clinical symptoms may quickly advance from mild impairment to severe dementia. The study advances recent research that found it was possible to diagnose Alzheimer's disease, even in patients with no clinical symptoms, by measuring levels of the amyloid beta protein in the CSF. A-beta makes up the senile

plaques that form in the brains of Alzheimer's patients, but it turns out that low levels of A-beta in the CSF predict the presence of Alzheimer's pathology in the brain.

Multi-center project will map the brain's wiring . . . A five-year, \$30 million effort to generate a first-of-its kind map of all the major circuits in the human brain is being led by **Washington University School of Medicine** (St. Louis) and the **University of Minnesota's Center for Magnetic Resonance Research** (CMRR; Minneapolis). Thirty-three researchers at nine institutions will contribute to the Human Connectome Project. Using powerful, custom-built brain scanners, a supercomputer, new brain analysis techniques and other state-of-the-art resources, they will trace the anatomical 'wires' that interconnect thousands of different regions of the human brain's gray matter. A second Human Connectome Project grant for \$8.5 million has been awarded to a consortium led by investigators at **Harvard** (Cambridge, Massachusetts) and **UCLA** to develop a new brain scanner with improved sensitivity and spatial resolution. "This effort will have a major impact on our understanding of the healthy adult human brain," said lead investigator David Van Essen, PhD, the Edison Professor and head of the Department of Anatomy and Neurobiology at Washington University. "It will also enable future projects that probe what changes in brain circuits underlie a broad variety of disorders, such as autism and schizophrenia." The project is funded by 16 components of the National Institutes of Health via its Blueprint for Neuroscience Research. Brain scans of volunteer subjects for the connectome project will be carried out at Washington University, the University of Minnesota and **Saint Louis University**. Scientists will use instrumentation and methods developed at the CMRR with the participation of researchers at Advanced MRI Technologies. Subjects for the research will first come to Washington University for a comprehensive battery of behavioral tests and brain scans. Some will also be scanned at the University of Minnesota or St. Louis University. Scanning techniques will include: diffusion imaging, a new form of magnetic resonance imaging (MRI) that produces detailed information on cell structure by tracking the random movements of water molecules; resting state functional MRI, which monitors brain activity while subjects relax, to reveal which brain regions work in sync with each other via brain networks; task-related functional MRI, which helps associate particular capabilities with specific brain regions by tracking brain activity as subjects perform visual, motor, cognitive, and other tasks; and magnetoencephalography, which can monitor very rapid patterns of activity involving millions of brain cells but provides less specific spatial data.

Increased brain protein levels linked to AD . . . Elevated levels of a growth protein in the brains of Alzheimer's disease (AD) patients is linked to impaired neurogenesis, the process by which new neurons are generated, say researchers at the **University of California, San Diego** in the Sept. 17 issue of *The Journal of Neuroscience*. Eliezer Masliah, MD, professor of neurosciences and pathology in the UC San Diego School of Medicine and colleagues report that increased levels of BMP6 – part of a family of bone morphogenetic proteins involved in cell signaling and growth – were found in the brains of Alzheimer's patients and in mouse models of the disease. BMP6 is primarily known to be involved in bone growth and the proliferation of non-neuronal glial cells in developing embryos. Its purpose in adult brains is less clear. "As a growth factor, it might initially be expressed for protective effect, a response to accumulating amyloid plaque proteins in Alzheimer's patients," said first author Leslie Crews, a post-doctoral researcher in Masliah's lab. But too much BMP6 appears to be increasingly detrimental. Researchers found that levels of BMP6 grew in step with the progression of Alzheimer's disease. "In early stages of AD, there was less protein than there was in later, more advanced stages," said Crews. Higher-than-normal levels of BMP6 were found in the dentate gyrus of Alzheimer's patients and around characteristic amyloid plaques in the hippocampus. Both regions of the brain are critical to memory formation and storage. In cell cultures, the scientists found that BMP6 reduced the proliferation of cells, a discovery that suggests the protein could be a potential therapeutic target. "The next step is to see what happens when we normalize expression of BMP6," said Masliah. "If we can do that, it may be possible to impact this part of AD's pathogenesis." The protein provides an easier target than some molecules, said Crews, because it is secreted and circulates around cells in the brain. "We don't have to figure out how to get it into the brain and into cells," she said.

– **Compiled by Rob Kimball, MDD Staff Writer**
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