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The silver lining

K2M launches new spinal system following a string of advances

By LYNN YOFFEE

Medical Device Daily Staff Writer

While many larger med-tech firms might be tightening belts to cope with the challenging economic climate, a smaller spinal device company continues to produce new products and report on expansions at a steady clip.

"We are continuing to grow at a rapid pace since we started in 2004," Lane Major, VP of marketing at **K2M** (Leesburg, Virginia), told *Medical Device Daily*. "We've had well beyond double-digit growth. So far this year is looking to be no different."

K2M – which produces devices to treat complex spinal pathologies – has just launched the Caspian Spinal System, an all-inclusive system for rigid posterior fixation in complex cervico-thoracic spinal conditions.

This latest news follows a steady string of other
See K2M, Page 6

International report

Cancer research alliance links U.S. and five Latin countries

A Medical Device Daily Staff Report

A new alliance between the U.S. National Cancer Institute (NCI), part of the National Institutes of Health, and the Ministry of Health of the Republic of Chile, aims to accelerate progress against cancer in Hispanic populations in both the U.S. and Latin America.

The alliance endeavors to strengthen and expand cooperation in a broad range of mutual interests, emphasizing basic and clinical cancer research, bioinformatics, data systems and informatics, and transfer of technology. Also, the nations seek to develop competencies and training of researchers by sharing technology and expertise. Further, the partners will work to enhance already existing cancer registries and execution of early phase clinical studies with cultural sensitivity.

In 2006, cancer was estimated to be the second-leading cause of death in Chile. Each year, 36,500 new cases are diagnosed. Cancer mortality rates for Chilean males are
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AST gets FDA green light to continue Stabilimax NZ trial

By AMANDA PEDERSEN

A Medical Device Daily Staff Writer

Sometimes a small change to a product – say, using a different surface finishing technique – makes a huge difference to its overall effectiveness. That's the lesson **Applied Spine Technologies** (AST; New Haven, Connecticut) has learned with its Stabilimax NZ Dynamic Spine Stabilization System.

AST, a device company focused on motion preservation of the lumbar spine, said it has received permission from the FDA to proceed with enrollment in its IDE trial of the Stabilimax NZ Dynamic Spine Stabilization System. The trial resumes after AST voluntarily suspended enrollment in August 2008 following three reports of screw fracture. The company says it has collaborated with **Exponent**, an engineering and scientific consulting firm, and made changes to the surface finishing technique used on the
See AST, Page 7

Financings roundup

SpineGuard completes round; nets \$4M to reach \$15M goal

By OMAR FORD

A Medical Device Daily Staff Writer

Less than three months after securing \$11 million in financing, **SpineGuard** (Paris), a medical device start-up has made its \$15 million goal by securing \$4 million last week, the company said.

The recent \$4 million investment was by Delta Partners (Boston) and will help to establish the company's FDA-cleared and CE-Marked PediGuard device as the standard of care for safer pedicle screw placement in spine surgery.

"This additional funding and the support of Delta Partners and Maurice Bourlion will fortify our efforts to establish
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Holiday notice

Medical Device Daily's offices were closed on Friday, July 3, in observance of the Independence Day holiday in the U.S., and no issue was published that day.

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*Washington roundup***CMS proposes to set Part B imaging usage rate at 90%**

By MARK McCARTY

Medical Device Daily Washington Editor

The announcement of a proposed physician fee schedule for Medicare Part B routinely sets physician societies abuzz, but the proposed fee schedule for next calendar year is already generating more ink and electrons than is typically the case.

One of the more controversial provisions is an adjustment to the assumed usage rate of imaging equipment owned and operated by Part B providers, which previously had been set at 50% of a 50-hour work week. That set point was again subjected to criticism by the Medicare Payment Advisory Commission in its March 2009 report to Congress as well as in a meeting held in November 2008 (*Medical Device Daily*, Nov. 11, 2008), and CMS responded.

Comments heard during the MedPAC meeting included an acknowledgement that regional variations in utilization rates hinged on population density and that consequently, rural imaging rates could not be assumed to match those in suburban or urban areas. One utilization rate that was floated by a MedPAC analyst at the hearing was 75%, but the commission did not come to any hard and fast conclusions during the meeting.

CMS's July 1 fact sheet, which accompanied the CMS statement, notes that a survey conducted in 2006 by the **National Opinion Research Center** at the **University of Chicago** (NORC; Chicago) indicated that physician-owned magnetic resonance equipment typically ran 52 hours a week and computerized tomography machines 42 hours a week. The survey covered only six major markets in the U.S., a point that was not missed by specialty societies and some

Today's MDD food for med-tech thought

"Although the market is being hit, we have such great opportunities that we're not seeing some of the same challenges other companies do to date. We're hitting our forecasted plan; we're doing well."

– Lane Major, VP of marketing at K2M (Leesburg, Virginia) explaining how his company has been able to forge ahead in the difficult economic environment, "K2M launches new spinal system following a string of advances," pp. 1, 6.

members of MedPAC. The CMS fact sheet notes further that another source of data indicates CT usage at 50 hours a week, twice the 25-hour-a-week CMS assumption, and thus adding fuel to the reimbursement rate fire.

Pam Kassing, senior director of economics and health policy at the **American College of Radiology** (ACR; Washington), told *Medical Device Daily* that ACR members find the NORC numbers to be something of a stretch. "We were disappointed that CMS is pointing to the NORC data," she said, adding that a study conducted by the **Radiology Business Management Association** (RBMA; Fairfax, Virginia) indicated that the overall imaging rate for rural providers was more in the neighborhood of 48% and for providers across all population densities was about 58%.

Kassing also mentioned that a 75% utilization rate is being proposed, including in a draft of legislation that is currently under consideration in the House of Representatives. However, most in the imaging business also hasten to point out that imaging costs have more or less flattened after passage of the Deficit Reduction Act of 2005.

Contracting snags another device firm

Contract manufacturing has been a persistent issue in
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Court report

L.A. jury finds PA guilty in Medicare fraud scheme

A Medical Device Daily Staff Report

A federal jury in Los Angeles convicted a physician assistant for his role in a \$7.7 million Medicare fraud scheme.

After a seven-day trial in federal court in Los Angeles, a jury found Ronald Luis Bradshaw, 59, guilty on all charged counts, including conspiracy to commit healthcare fraud, multiple counts of health fraud and aggravated identity theft for prescribing medically unnecessary durable medical equipment to hundreds of Medicare beneficiaries under the stolen identity of a doctor.

According to the evidence presented at trial, Bradshaw worked as a licensed physician assistant at a Los Angeles clinic, **Glenmountain Medical Group**, allegedly under the supervision of a doctor. Evidence at trial established that from about April 2005 to April 2008, Bradshaw prescribed hundreds of motorized wheelchairs and custom-fitted orthotics to Medicare beneficiaries under the apparent authority and supervision of a doctor. Bradshaw also ordered diagnostic tests for these beneficiaries under the same doctor's apparent authority.

The doctor, whose unique physician identification number had been used by the defendant to forge medically unnecessary prescriptions, testified that he never worked at Glenmountain and that he never authorized the defendant to use his number. The total amount billed under this doctor's name for medical equipment and tests prescribed by the defendant was \$7,708,069.

At sentencing, scheduled for Nov. 12, 2009, Bradshaw faces a maximum penalty of 10 years in prison on each of the four healthcare fraud counts as well as the conspiracy to commit healthcare fraud count for which he was convicted. In addition, he faces a mandatory two-year prison sentence on the aggravated identity theft count, which must be served consecutive to the sentence on the fraud counts.

The case was prosecuted by Trial Attorney Steven Kim of the Criminal Division's Fraud Section and Assistant U.S. Attorney Christopher K. Lui, with the investigative assistance of the HHS Office of the Inspector General and the FBI. The case was brought as part of the Medicare Fraud Strike Force. Federal prosecutors have indicted 115 cases with 257 defendants in Miami, Los Angeles and Detroit since the inception of strike force operations in March 2007. Collectively, these defendants are alleged to have fraudulently billed the Medicare program for more than \$600 million. ■

Washington

Continued from Page 2

FDA warning letters for the past 18 months and the trend continued with the June 5, 2009, warning letter to **Frantz Design** (Austin, Texas), maker of mandible-adjusting devices designed to treat obstructive sleep apnea (OSA). The agency cited Frantz for a total of eight deviations from good manufacturing practices and two for medical device reporting (MDR) violations, casting a doubt on the company's overall compliance regime.

FDA led the warning letter with a citation for failure of management to ensure that an effective quality system was in place, noting that this class of violations accounted for 15 hits on the inspectional form 483. Among these problems was a failure to conduct quality audits of an unnamed contract manufacturer.

The issue of contract manufacturing popped up again in a citation dealing with validation of design changes to straps used to fix the device in place in the wearer's mouth. Frantz is said to have directed the contractor not to use a component – the identity of which was redacted – in the manufacture of the straps because of complaints that the straps were prone to breakage. This citation dealt with a lack of procedures for validation of design changes, but the same problem with straps was cited subsequently as a failure to validate the related design change as well.

FDA also cited Frantz for lack of procedures to set out the responsibilities of both parties in contract manufacturing arrangements, but also stated that the company had no contract with its then-current outsourcing company. At press

time, the company had not responded to calls for comment.

Off-label promo slammed in warning

The March 11 warning letter to **Best Vascular** (Springfield, Virginia) cited the company for an ad that appeared in the November 2008 edition of the *American Journal of Cardiology* for the firm's Beta-Cath system, which the agency states is approved for radiological brachytherapy to treat restenosis in arteries into which a bare-metal stent (BMS) has been placed. FDA states that the ad, which highlights an analysis of data compiled in the Rescue registry, constitutes marketing of the device for a new intended use, specifically treatment of restenosis in patients with drug-eluting stents (DES).

The agency noted specifically that Best does not have an application on file that addresses the effect radiation might have on stent polymer and drug, and FDA voiced a similar concern as to how radiation might affect intimal tissue treated with anti-proliferative drugs. According to FDA, the offending passage in the ad describes the Beta-Cath as "adjunct therapy to PCI for patients presenting with [in-stent restenosis] of a DES" that is "safe and associated with low rates of recurrence" and major adverse cardiac events. The ad is also said to include the statement that brachytherapy for this condition "appears to be superior in efficacy in comparison to repeat" stent placement "and should be considered the therapy of choice for this difficult subset of patients."

At press time, the company had not responded to calls for comment. ■

Agreements/contracts**AirStrip, CliniComp to pair product offerings to hospitals****A Medical Device Daily Staff Report**

With the goal of improving safety for patients and strengthening communication among healthcare providers, **AirStrip Technologies** (San Antonio) and **CliniComp** (San Diego) have reported an agreement that will begin pairing both companies' product offerings at hospitals nationwide.

AirStrip Technologies provides physicians with virtual real-time remote access to labor and delivery and intensive care unit data on a host of mobile devices, including the iPhone, BlackBerry and other Windows Mobile smart phones, offering the potential to increase patient safety regardless of the doctor's location.

CliniComp provides clinical documentation and electronic medical record (EMR) systems, giving physicians and nurses the most powerful and reliable tools of its type. The Essentris product suite delivers broad, deep clinical functionality for all acute care settings throughout the enterprise.

Using a cell phone connection on a mobile device, AirStrip OB and AirStrip Critical Care will work together with Essentris Perinatal and Essentris Critical Care to provide doctors with remote access to fetal heart tracings, maternal contraction patterns, patient monitoring data from the ICU, as well as physician and nursing documentation from those clinical areas.

The data is sent directly from the hospital labor and delivery or ICU unit. The AirStrip OB and Critical Care services are purchased by the hospital and provided to physicians.

"Time-sensitive waveform and patient monitoring data is inherently visual information, and physicians are at a distinct disadvantage when they cannot actually see the data – and can lead to delays in delivering proper care," said Alan Portela, chief operating officer at CliniComp. "Together, AirStrip and CliniComp can improve communication while reducing risk by giving doctors the ability to view this critical information at will on a mobile device."

Built on the latest mobility platforms, AirStrip OB is FDA-cleared and HIPAA-compliant. AirStrip OB, which is now in use in nearly 100 hospitals across the U.S., incorporates robust security measures to ensure confidential patient data is fully protected.

"We hear regularly from doctors who credit AirStrip OB with helping them catch abnormalities on the maternal and fetal strips – information that can literally help save lives," AirStrip co-founder and chief medical officer Cameron Powell, MD, said.

In other agreements/contracts news:

- **Connectyx Technologies Holding Group**

(Palm City, Florida) reported that it has entered into an agreement in which **Healthy Directions** will promote and sell Connectyx's MedFlash products through its various distribution channels. Healthy Directions is a provider of science-based vitamin and nutritional supplement formulas and other wellness related products. By the end of August, Healthy Directions expects to offer the MedFlash EPHR through its established distribution channels.

- **Roche NimbleGen** (Madison, Wisconsin) has entered into a partnership with the **Korea Centers for Disease Control and Prevention** (KCDC; Seoul) and **MacroGen** (Rockville, Maryland) to conduct an eight-month intensive Copy Number Variation (CNV) study of Korean individuals. This two-phase study will include large-scale characterization of CNVs in Korean populations and analysis of common CNVs in genome-wide association studies for complex disease including diabetes.

- **Allscripts** (Chicago) reported that **Omega Medical Solutions** (Myrtle Beach, South Carolina), a medical billing and consulting agency, has selected Allscripts Practice Management and Allscripts Payerpath claims management solution for its physician practice clients across South Carolina and the surrounding states. ■

M E D - T E C H N E W S A N D N O T E S

Neovasc to postpone U.S. stock listing

Neovasc (Vancouver, British Columbia) said that it has voluntarily filed a Form 15 with the SEC in order to deregister its common stock. As a result, Neovasc's obligation to file annual reports and furnish other information under the Exchange Act is suspended.

The company's decision to deregister its Exchange Act registration is part of its larger plan to reduce discretionary expenses and allocate the cost savings to the further development and commercialization of its highest potential products. Neovasc will continue to undertake all activities required to maintain its Canadian public listing on the TSX Venture Exchange.

The company's decision to postpone its plans for a U.S. listing is based upon the additional financial and administrative costs and burdens associated with being a publicly traded company in the U.S. and therefore subject to the additional reporting regulations promulgated under the Exchange Act.

Neovasc estimates the cost savings from suspending its planned listing to be about \$200,000 annually. The company said it intends to redirect these funds to its program to commercialize the Neovasc Reducer for the treatment of refractory angina and to further expansion of the company's custom tissue business.

*Deals roundup***J&J acquires \$1B stake in Elan; Interleukin sells unit to Pep****A Medical Device Daily Staff Report**

Johnson & Johnson (J&J; New Brunswick, New Jersey) reported that it will acquire the assets and rights of **Elan** (Dublin, Ireland) related to its Alzheimer's Immunotherapy Program (AIP Program), through a newly formed company. In addition, J&J, through its affiliate, will invest \$1 billion in Elan in exchange for newly issued American Depositary Receipts (ADRs) of Elan which will represent 18.4% of Elan's outstanding ordinary shares.

The AIP Program represents Elan's interest in a collaboration with **Wyeth** (Madison, New Jersey) to research, develop and commercialize selective products for the treatment and/or prevention of neurodegenerative conditions, including Alzheimer's disease.

J&J will assume and continue Elan's activities with Wyeth under the AIP Program and will initially commit up to \$500 million to continue the development and launch activities of bapineuzumab, a potential first-in-class treatment that is being evaluated for slowing the progression of Alzheimer's disease, as well as other compounds. The agreement provides for additional funding obligations of the parties if needed.

In consideration for the transfer of these rights and assets, Elan will receive a 49.9% equity interest in the newly formed J&J company that will acquire the AIP Program. Elan will be entitled to a 49.9% share of the profits and certain royalty payments upon the commercialization of products under the collaboration with Wyeth.

"Alzheimer's disease is a significant unmet need in aging populations globally," said Sheri McCoy, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "Johnson & Johnson's development capabilities, commercial experience and global reach will provide the foundation to accelerate the AIP Program development, and increase its potential availability for patients globally."

The boards of both companies have approved the transaction, which represents the culmination of an in-depth strategic review by Elan. The transaction is conditioned on clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions.

Interleukin Genetics (Waltham, Massachusetts) reported that it executed an agreement to sell the Alan James Group assets of its subsidiary AJG Brands to **Pep Products**, a subsidiary of **Nutraceutical** (Park City, Utah), for about \$4.6 million in cash. The transaction was completed following the close of business on June 30.

"The sale of AJG provides non-dilutive cash to continue development and promotion of our genetic testing services and products including our new brand of Inherent Health tests," said Lewis Bender, CEO, Interleukin Genetics.

Interleukin develops genetic tests, including its new

brand of Inherent Health genetic test products that are designed to empower consumers to maintain health and wellness, and assists pharmaceutical companies in the development and marketing of targeted therapeutics.

In other dealmaking news:

- **RehabCare Group** (St. Louis) has entered a joint venture that will acquire certain assets of **Gulf States LTAC** formerly owned by **Gulf States Health Services** (both, Dallas) and a group of Dallas area physicians. RehabCare will own 80% of the interests and the physicians will own the remaining 20%.

RehabCare will manage the daily operations of the hospital and the approximately 190 staff members will become employees of the new joint venture.

- **Kindred Healthcare** (Louisville, Kentucky) reported that it has completed the previously reported acquisition of the real estate related to six under-performing nursing centers previously leased from **Ventas** (also Louisville) for \$55.7 million. In addition, the company will pay a lease termination fee of \$2.3 million. The annual rents for the Nursing Centers were nearly \$6 million.

The Nursing Centers, which contain 777 licensed beds, generated pretax losses of nearly \$3 million for the year ended Dec. 31, 2008 and nearly \$2 million for the three months ended March 31, 2009.

The company expects to account for the operations of the Nursing Centers and the loss on these transactions as discontinued operations when it reports its operating results for the second quarter ended June 30, 2009.

The company intends to dispose of the Nursing Centers as soon as practicable. The company expects to generate about \$15 million to \$20 million in proceeds from the sale of the Nursing Centers and the related operations. The company expects to record a net loss of nearly \$27 million to \$31 million in the 2Q09 relating to these divestitures. ■

MED - TECH NEWS AND NOTES

St. Joseph Hospital gains SCPC accreditation

St. Joseph Hospital (Orange, California) has been designated with accredited status by the Chest Pain Center Accreditation from the **Society of Chest Pain Centers** (SCPC; Columbus, Ohio).

"The Chest Pain Team at St. Joseph Hospital demonstrated its expertise and commitment to quality patient care by meeting or exceeding a wide set of stringent criteria and completing on-site evaluations by a review team from the Society," said Kevin Lundon, VP, Operations at St. Joseph Hospital.

St. Joseph Hospital underwent a rigorous re-evaluation and refinement of heart care processes in order to integrate the industry's best practices and newest paradigms into its cardiac care services.

K2M

Continued from Page 1

progressions for the company, highlights of which include:

- In April, K2M launched an injectable polymer, with testing indicating that the polymer may have various applications for treating a variety of spinal disorders. The polymer will serve as a platform for the development of new implantable technologies, such as spinal nucleus replacement, or micro-access surgical approaches for annular decompression and repair (*MDD*, April 30, 2009).

- Last fall, K2M formed a new biomaterials division for bone grafting to substitute for the metals commonly used in spinal fusions. Biological materials allow for increased cellular activity, growth and differentiation which may increase bone formation and stimulate a spinal fusion (*MDD*, Oct. 15, 2008).

- Around the same time, the company expanded its facility to include an additional 13,000 square feet of space, 2,500 of which will make up a conference and training amphitheater. K2M's facilities will now total 49,000 square feet (*MDD*, Oct. 8, 2008).

- These moves followed receipt in September 2008 of ISO 13485 certification and CE-mark clearance for its spinal devices marking the company's entrée into the international markets. It started with the introduction of its products in Spain and the UK. The product portfolio cleared for sale encompasses an array of devices developed to treat complex spinal conditions, including stabilization systems, minimally invasive systems and motion preservation systems (*MDD*, Sept. 3, 2008).

How is K2M able to forge ahead while other companies might be missing a few steps or worse?

"It's challenging in that we're a growth company," Lane said. "Although the market is being hit, we have such great opportunities that we're not seeing some of the same challenges other companies do to date. We're hitting our forecasted plan; we're doing well."

The Caspian Spinal System targets the trauma and deformities portion of the orthopedic spine market.

"It's intended for the upper thoracic spine for traumatic events like whiplash and for different forms of degenerative pathologies," he said.

The new system builds on the technology behind existing spinal devices. In fact, it combines the best of two completely different polyaxial screw options, Mini Denali and Mini Mesa, as well as Mini Hooks, Mini Connectors and 3.5 mm rods.

The Mini Denali screw is an improved version of a traditional set screw designed implant featuring off-axis screw height adjustment, whereby the screwdriver does not need to be co-linear with the screw shaft to adjust the screw during surgery.

The Mini Mesa screw includes the company's flagship

Zero-Torque Technology, which applies zero twisting forces, to the spine when locking the system.

When asked "what's new?" compared with existing similar devices already on the market, Lane explained that by consolidating the two systems, surgeons get the best of both worlds in one package.

"We had such interest in both of those that we took those product lines and downsized them, made it simple for our customer base so surgeons can have a choice," he said, adding that the product development is a result of surgeon feedback on devices needed to treat the upper thoracic spine.

According to Juan Uribe, MD, co-director of spinal neurosurgery at the **University of South Florida**, "The low profile feature [of the Caspian System] is unlike any other posterior cervical system and offers a significant clinical advantage."

So, while K2M may not be launching the next killer app technology, it's delivering what's requested and needed by surgeons. And that business plan is exactly in line with what industry analysts are suggesting: skip the fancy technologies that may have more "wow" factor than "value-add" to the healthcare system, according to Michael Thompson, principal at **PricewaterhouseCoopers'** (New York) global human resource solutions group, whose **Health Research Institute** just released projections that healthcare costs for U.S. businesses are expected to grow by 9% next year.

"Long term, the focus is going to be on value," Thompson told *MDD*. "New medical technologies will have to be focused on adding value to the system and weeding out technologies that are costly and don't add as much value" (*MDD*, June 22, 2009).

Lane said K2M expects to keep up the pace with more new product lines launched before the end of this year. Next up for K2M: spinal products that address the need for a more minimally invasive approach. ■

MED - TECH NEWS AND NOTES

ikaSystems relocates corporate headquarters

Following a year of intensive sales activity, **ikaSystems** (Southborough, Massachusetts), a provider of enterprise-level web-based technologies for the healthcare payer market, has relocated its corporate headquarters and hired additional sales executives to accommodate its explosive growth.

ikaSystems' headquarters remains in Southborough, Massachusetts, but has moved from 257 to 134 Turnpike Road to a state-of-the-art facility specifically designed to facilitate the company's rapid development and deployment methodologies.

AST*Continued from Page 1*

screws. The result was a significant increase in the longevity under fatigue loading of the screw according to testing data.

CFO Terry Brennan told *Medical Device Daily* the system itself is doing great and has been all along. But in late July of last year the company saw on some of the X-rays that some pedicle screws had fractured. Brennan said the patients were unaware of the fractures and were asymptomatic at the time, but the fractures did show up on X-ray.

"We feared it might be the result of fatigue on a surface finish . . . it was probably not the best surface finish to use," Brennan said.

The Stabilimax NZ system uses pedicle screws and Brennan says the difference between it and other devices on the market is that AST uses a ball and socket system and then a spring system on top of its pedicle screws. The device is designed that way, he said, to allow for near-normal physiological motion – and that is what the company hopes the IDE trial will prove.

"Voluntary suspension of enrollment late last year was the correct decision to make and management showed terrific fortitude in making that decision," said recently appointed President/CEO Craig Corrance. "AST is now eager to resume patient enrollment and we look forward to building upon the impressive results we have obtained so far."

Brennan said the company's goal is to complete enrollment within 18 months to 24 months.

"I am most pleased to commence with re-enrollment," said clinical investigator Neel Anand, MD. "The Stabilimax NZ system has the potential to address an important sector within the degenerative lumbar spine segment. Preserving motion while reducing pain, and offsetting the risk of future adjacent level symptoms, is an attractive proposition for both patient and physician."

The IDE trial is a multi-center, randomized, controlled clinical trial to compare posterior dynamic stabilization using the Stabilimax NZ system to traditional spinal fusion stabilization to treat degenerative lumbar spinal stenosis. AST has enrolled over 100 patients to date.

According to AST, the Stabilimax NZ is expected to offer numerous advantages over current spinal fixation products and even new artificial disc products – including a much less invasive and less traumatic implant procedure, maintenance of spine motion and disc function, and the potential to prevent or slow adjacent-segment disc disease.

Brennan said AST follows a "science first" philosophy and that the company does not think there are a lot of other devices on the market that are based on the physiological science.

"Our device provides more stability and more motion than any other device out there so we think it is incredibly important to get this to market because it is a new technol-

ogy that will benefit thousands of thousands of patients," Brennan said. "It's definitely important to the company, but there is a true value to future patients out there." ■

M E D - T E C H N E W S A N D N O T E S

KCM Holding plans registrations in 2010

KCM Holdings (Frisco, Texas) reported that it aims to complete three public registrations in 2009 and early 2010, after profitably weathering the worst economy in decades. KCM registrations are part of its incubation of companies in the healthcare, technology and alternative investment sectors.

KCM focuses its operations on the incubation of companies with little to no debt and have the ability to go to scale quickly across multiple sectors. KCM's first two registrations will be:

- CT Dental America (www.ctdentalgroup.com), a dental products, prosthetics, dental education and lifestyle member organization, projecting revenues of \$120 million by its 4th year of operations.
- Geenius (www.geenius.com), a Web 3.0 company that has developed a social networking platform combined with a powerful user created content revenue model, and backed by a patented knowledge transfer technology. Geenius projects annual revenues of \$300 million within five years.

The third registration will be in the Alternative Investment sector, with more details to be released soon.

HITRUST forms leadership roundtable

The **Health Information Trust Alliance** (HITRUST; Frisco, Texas) said it has formed the Leadership Roundtable to support the growing role of the healthcare chief information security officer (CISO), as corporate responsibility for the protection of electronic health information. The company says the new forum is the first to bring together information security executives representing the diverse segments of the healthcare industry - from providers, health plans and pharmacies to distributors, health data exchanges and pharmaceutical manufacturers – and help advance their careers through networking, learning and driving industry direction.

"Health organizations are required to address security and privacy risks to ever increasing levels. The protection of information can be significantly accelerated when embraced as part of an organization's cultural DNA. The HITRUST Leadership Roundtable is helping define what information security leadership means to a healthcare organization as well as the industry at large and is an invaluable resource for information security leaders," said Michael Wilson, VP/chief information security officer, McKesson.

International

Continued from Page 1

highest in stomach, lung and prostate cancers, while for Chilean females the highest mortality rates are in gallbladder, breast, and stomach cancers.

In mid-June, Chilean Undersecretary of Public Health Jeanette Vega, MD, representing the Ministry of Health of Chile, and John Niederhuber, MD, National Cancer Institute director, representing the U.S. Department of Health and Human Services, signed a letter of intent where the institutions will work under a collaborative agreement to advance cancer research that meets the needs of Chile and the U.S.

"We're eager to work with the U.S. on this very important effort," said Vega. "Chile and the U.S. have much to share in the area of cancer. We can share our longstanding experience in the area of gallbladder cancer and the U.S. can share their knowledge in the area of breast cancer. The key to be able to advance globally in these areas is to collaborate, collaborate and collaborate."

Niederhuber said, "Cancer knows no borders and we must conquer this disease globally. This new partnership holds great promise to facilitate science that elucidates why cancer so often affects patients of different ethnicities and nationalities in unique ways, such as the high prevalence of stomach and gallbladder cancer in Chile."

Chile joined four other Latin American countries — Argentina, Brazil, Mexico, Uruguay — and the U.S. in the collaboration, known as the United States-Latin America Cancer Research Network. The network is responsible for developing a comprehensive understanding of the burden of cancer and the current status of the research and care infrastructures in Latin America.

The first collaborative pilot project of the United States-Latin America Cancer Research Network will focus on breast cancer because it is among the deadliest cancers in each of the five participating Latin American countries. The alliance will conduct research on those cancers that have the greatest impact on Latin America.

Canada moves to ban BPA baby bottles

The government of Canada is moving forward with proposed regulations to prohibit the advertisement, sale and importation of polycarbonate plastic baby bottles that contain bisphenol A, otherwise known as BPA, to reduce newborn and infant exposure to this substance, said Minister of Health Leona Aglukkaq.

BPA is used in the production of polycarbonate, a clear hard plastic used to make many products, including baby bottles. When in contact with hot or boiling liquid, bisphenol A can migrate from the plastic into the liquid and be ingested.

"Our government is acting to protect its most vulnerable citizens — newborns and infants," said Aglukkaq. "Canada is the first country to move ahead with regulations to prohibit polycarbonate baby bottles that contain bisphenol

A. We want parents to feel confident that they can safely bottle-feed their newborns and infants."

The government has concluded that exposure levels for newborns and infants up to 18 months of age are below those that could cause health effects. However, due to the uncertainty raised in some studies relating to the potential effects of low levels of BPA, it wants to further limit exposure.

Health Canada has now published these proposed regulations in *Canada Gazette Part 1* for a 75-day public comment period to consult with interested parties.

Aussie firm eyeing rapid virus test

A scientist in Melbourne, Australia, has unveiled a test able to detect swine flu or any other virus within hours. The test, known as the Reticif test, is carried out on a patient sample such as a nasal swab. Any viruses present in the sample are grown rapidly in a culture before being examined under a fluorescent microscope.

The company behind the test is **Pallane Medical Pty Ltd** (Caulfield North, Australia). The company says the Reticif test is "almost 100% accurate" and is currently the most effective way of testing for live viruses, including the swine flu virus.

The test, developed by virologist Dr. Robert Alexander, has been used extensively at **Royal Children's Hospital** (Melbourne, Australia). It has been used to diagnose viruses in patients but, to date, has never been widely available to the general community or on a commercial basis.

Pallane CEO Peter King said the Reticif test had the potential to revolutionize viral testing around the world, and not just in relation to swine flu. "Within one to three hours, we can . . . tell if someone has a virus — and to tell you what type of virus or multiple viruses a patient has takes approximately 24 hours."

The Reticif test is expected to be commercially available internationally within 24 months.

Larger stake taken in subsidiary

Novartis (Basel, Switzerland) reported completing an open offer to acquire an additional stake in its majority-owned Indian subsidiary, **Novartis India Ltd.**, increasing its holding to about 76.4% from the previous level of 50.9%.

The transaction represents a total value of some Rs 3.7 billion (about \$76 million). Almost all large institutional investors and quasi-institutional shareholders participated in the offer, Novartis said. ■

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Financings

Continued from Page 1

lish PediGuard as a standard of care for safer spine surgery," said Pierre Jérôme, CEO of SpineGuard told *Medical Device Daily*. "Now we are completely secure that we have the right level of funding."

SpineGuard says the PediGuard is the only wireless, handheld instrument capable of accurately detecting changes in tissue type, thus alerting surgeons to potential pedicular or vertebral breaches during pedicle screw site preparation. The device provides real-time feedback via audio and visual signals, giving surgeons additional information. The company notes that the device does not require any change in surgical technique.

On April 9, SpineGuard reported an \$11 million round of financing from Crédit Agricole Private Equity (lead), Innoven Partenaires (co-lead), and A Plus Finance.

The company acquired PediGuard from **SpineVision** (also Paris) with the initial funding it received (*Medical Device Daily*, April 10, 2009).

Jérôme says that the market for the device is perfect and that the company should settle in nicely.

According to the company, nearly one million spine procedures using pedicle screws were performed last year. Published studies say that pedicle screws show high rates of *misplacements* — as high as 40% — which can lead to a number of serious complications for patients, including quadriplegia. Consequently, liability risks for spine surgeons are high.

Several peer-reviewed publications now validate the value proposition of PediGuard for spine professionals and their patients: pedicle breach anticipation plus reduction of radiation exposure and surgery time. It has a stake in the ground on all continents: impressive ramping-up of sales in the U.S., a strong base in Europe, a great start in Latin America, and significant interest from the Pacific Rim. SpineGuard is partnering with the best distributors to allow more spine surgeons throughout the world to use PediGuard and more patients to benefit from safer spine stabilization.

In other financing activity:

- **PhysioSonics** (Bellevue; Washington), an innovator of noninvasive neurologic monitors, reported the closure of the second tranche of Series A financing for \$2 million from a strategic investor.

The first tranche of Series A closed for \$4 million in 2008. This follow-on investment of \$2 million by another strategic partner will bring the total Series A funds raised to \$6 million.

The company will use these funds for commercialization of their first product "We are very excited with the continued validation of our product development as more neurosurgeons, anesthesiologists and cardiologists view our technology," says Brad Harlow, president/CEO of PhysioSonics.

- **NanoCor Therapeutics**, (Chapel Hill, North Car-

olina) reported it has secured a \$2.5 million infusion from medical technology company **Medtronic** (Minneapolis, Minnesota).

In 2007, Medtronic committed to invest \$7.5 million in NanoCor. NanoCor said that the additional investment will be used to develop and commercialize its gene therapy. Medtronic has agreed to invest additional amounts upon NanoCor's achievement of certain milestones. NanoCor will also seek additional funding from institutional investors.

NanoCor's technology was developed at the **University of North Carolina at Chapel Hill** and was licensed to the company. The treatment delivers a proprietary gene that strengthens the heart, improving its ability to pump blood.

- **Laboratory Corporation of America Holdings** (LabCorp; Burlington, North Carolina) reported that it has completed the redemption of all of its outstanding zero coupon subordinated liquid yield option notes due 2021 (LYONs) and \$369.1 million principal amount at maturity.

The total cash used for these redemptions was nearly \$289 million. As a result of certain holders of the zero coupon notes electing to convert their zero coupon notes, the company also issued 432,787 additional shares of common stock.

As of March 31, 2009, LabCorp had an aggregate of \$576.3 million of accreted principal amount outstanding of the LYONs and of the Zero Coupon Notes. As a result of the redemptions, LabCorp reduced the outstanding accreted principal amount of this convertible debt by nearly \$289.6 million, leaving nearly \$286.7 million in accreted principal amount, or \$369.1 million of principal amount at maturity, of the Zero Coupon Notes outstanding. ■

MED - TECH NEWS AND NOTES

Goodroe approved for 14th gainsharing project

Goodroe Healthcare Solutions (Atlanta) reported that the Office of the Inspector General's (OIG) has approved Goodroe's fourteenth gainsharing project in seven years. This project includes cardiologists, radiologists and vascular surgeons. This approval is also Goodroe's thirteenth cardiac-related gainsharing approval.

This announcement came after three of the nation's major health care associations, The American Hospital Association, Federation of American Hospitals and Association of American Medical Colleges, expressed their support for Goodroe's gainsharing model earlier this year.

Gainsharing allows hospitals to share cost savings with the physicians who help them improve operational efficiencies. Currently, Goodroe's gainsharing model is used in clinical areas where physicians control the majority of costs, such as cardiac catheterization procedures, open heart surgery and orthopedic and spine procedures.

PRODUCT BRIEFS

• **Alcon** (Huenenberg, Switzerland) said that it has discontinued development of anecortave acetate for the reduction of intraocular pressure (IOP) associated with glaucoma. The company recently reviewed interim efficacy and safety data from more than 200 patients in a large, controlled Phase 2 trial. These data confirmed previous pilot clinical results that anecortave acetate applied through a single anterior juxtasclear injection measurably reduced IOP for an extended period of time. However, based on a detailed analysis of the data, and after gaining input from a panel of expert clinical advisers, the company determined that the amount of IOP reduction and the responder rate provided by even the highest dose were not sufficient to support this novel approach as a viable way to address the problem of patient compliance with eye drop therapy.

• **Nephros** (River Edge, New Jersey) reported that it has FDA approval to market its Dual Stage Ultrafilters (DSU) for in-line purification of dialysate water and bicarbonate solution. The DSU is the basis for Nephros's line of water filtration products. The dual stage cold sterilization ultrafilter has the capability to filter out bacteria and, due to its filtration levels, filter out many viruses, parasites and biotoxins. The company claims the Nephros DSU filters particles down to the 0.005-micron level and addresses dialysate contaminants at crucial points: after the reverse osmosis module and at the dialysis machine entrance from the water distribution loop. The DSU filter can be used as the last step in the water purification process to ensure ultra pure water for dialysis procedures.

PEOPLE IN PLACES

• Molly Coye, MD, was named president/CEO of **CalRHIO** (San Francisco). Coye was a principal founder of CalRHIO and has served as the chair of the board since 2007. CalRHIO is the California statewide information exchange founded in 2005.

• Mark Wagner was named president/CEO of **Celleration** (Eden Prairie, Minnesota). Wagner will also serve on Celleration's board of directors. Most recently, Wagner co-founded and is board chairman of Orasi Medical. Celleration makes the MIST therapy system, an ultrasound device to heal wounds.

• **HealthSpring** (Nashville, Tennessee) said that Andy Flatt, the company's senior VP and chief information officer, has begun a two-year term as the chairman of the **Nashville Technology Council** (NTC), an affiliate of the Nashville Area Chamber of Commerce. Since 1999, the NTC has been devoted to helping the Middle Tennessee technology community succeed. HealthSpring is a coordinated care plan with a focus on the Medical Advantage market.

• **IMS Health** (Norwalk, Connecticut) has named Kimberly Gray as chief privacy officer, Americas. Previously, Gray was chief privacy officer at Highmark insurance company. IMS Health provides market intelligence to the pharmaceutical and healthcare industries.

• Karl Broussard was named VP of contracting and provider relations for **XLHealth** (Baltimore). Most recently, Broussard was VP of network development at Coventry Health Care. XL Health specializes in improving the quality of care for seniors with chronic illness.

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MDD'S CARDIO EXTRA

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MONDAY, JULY 6, 2009

PAGE 1 OF 2

Keeping you up to date on recent headlines in cardiovascular healthcare:

Study shows Lap-Band lowers co-morbidity risk in teens . . . According to a new study of obese teens, laparoscopic gastric banding surgery – the “Lap-Band” procedure – not only helps them achieve significant weight loss but can also improve and even reverse metabolic syndrome, reducing their risk for cardiovascular disease and diabetes. The study was led by Ilene Fennoy, MD, Jeffrey Zitsman, MD, and colleagues at **NewYork-Presbyterian Morgan Stanley Children's Hospital** and **Columbia University Medical Center** (New York) and presented at the annual Endocrine Society (Chevy Chase, Maryland) meeting in Washington. Fennoy and her colleagues followed 24 morbidly obese adolescents between the ages of 14 and 17 who underwent the Lap-Band procedure. The study participants either had a BMI of greater than 40 or greater than 35 if already suffering from diabetes or obesity-related illnesses. Six months after surgery, they noted a significant drop in participants' BMI, waist circumference, and blood levels of C-reactive protein. These indicators continued to improve among the 12 patients being followed up at the one-year point, the authors noted.

Policies may impede EMS efforts to resuscitate . . . Local laws, insurance reimbursement and public misperceptions impede emergency medical services (EMS) workers from using best resuscitation practices, according to a study reported in *Circulation: Cardiovascular Quality and Outcomes*. The researchers said less than half of local EMS systems follow national guidelines on transporting cardiac arrest patients and terminating unsuccessful out-of-hospital resuscitation efforts. Researchers identified three key areas where policies or perceptions may impede local efforts to follow the guidelines for terminating unsuccessful resuscitation efforts: private insurers and Medicare who provide higher reimbursement to EMS for patient transport, regardless of whether the cardiac arrest victim is successfully resuscitated in the field or not; state legislation that requires transport to hospitals and restricts the ability of responders to follow do-not-resuscitate (DNR) orders; and community members who overestimate the chance for survival and believe a hospital can provide better care than responders on site.

Endovascular treatments more common than bypass . . . According to a new study published in the July issue of the *Journal of Vascular Surgery*, endovascular interventions are now performed much more commonly than bypass surgery in the treatment of lower extremity peripheral arterial disease (PAD). Researchers from **Dartmouth-Hitchcock Medical Center** (Lebanon, New Hampshire) published the study about the trends in lower extremity endovascular interventions (angioplasty and atherectomy), lower extremity bypass surgery and major above and below the knee amputations in Medicare beneficiaries (Part B claims). The study was done between 1996 and 2006. According to the authors, it is unclear from past research if these newer endovascular treatments are as effective as conventional surgical bypass in preventing amputation. The authors said that larger and broader clinical trials should occur to compare bypass and endovascular interventions in patients with claudication and critical limb ischemia. These trials would further evaluate what medical steps can be taken and resources should be used to obtain the best functional outcomes in patients with PAD, and to prevent death and disability from lower extremity amputation, they noted.

Stem cell treatment seeks to reverse heart attack damage . . . Doctors at the **Cedars-Sinai Heart Institute** (Los Angeles, California) recently completed the first procedure in which a patient's own heart tissue was used to grow specialized heart stem cells that were then injected back into the patient's heart in an effort to repair and re-grow healthy muscle in a heart that had been injured by a heart attack. The minimally-invasive procedure was completed on the first patient on June 26. The procedure is part of a Phase I investigative study approved by FDA and supported by the Specialized Centers for Cell-based Therapies at the National Heart, Lung, and Blood Institute and the Donald W. Reynolds Foundation. The 24 patients participating in the study have hearts that were damaged and

scarred by heart attacks. The patients will be monitored for six months. Complete results are scheduled to be available in late-2010.

UCSF study explores bone marrow extract for heart attack . . . A **University of California, San Francisco** (UCSF) study for the treatment of heart failure after heart attack found that the extract derived from bone marrow cells is as effective as therapy using bone marrow stem cells for improving cardiac function, decreasing the formation of scar tissue and improving cardiac pumping capacity after heart attack. The findings were published online and in the July issue of the *Journal of Molecular Therapy*. The studies were done in mice using a novel stem cell delivery method developed by UCSF researchers to show that the extract from bone marrow cells is as beneficial to cardiac function as are intact, whole cells. Both the cell and cell extract therapies resulted in the presence of more blood vessels and less cardiac cell death, or apoptosis, than no therapy. The study also showed that heart function benefitted despite the finding that few of the injected cells remained in the heart at one month after therapy.

Pig heart valves fail sooner than expected, study finds . . . A report from cardiac surgeons at **Washington University School of Medicine** (St. Louis) says pig heart valves used to replace defective aortic valves in human patients failed much earlier and more often than expected. According to the researchers, this is the first report to demonstrate this potential problem. Between 2001 and 2005, four out of 106 patients with the pig valves implanted in the aortic position developed severe impairment after less than four years, and the patients required surgery to replace the valves. The findings are published in the June issue of the *Journal of Thoracic and Cardiovascular Surgery*. Lead author Jennifer Lawton, MD, a Washington University cardiothoracic surgeon at **Barnes-Jewish Hospital**, notes that the valves are expected to last 10 to 15 years in patients over 70 years of age. All four patients who needed a "redo" operation were over 70 years of age.

CRP not linked to heart disease after all . . . A British study published last week finds that a protein known as a key indicator of inflammation in the body and thought to cause heart disease is not linked to development of the fatal ailment. C-reactive protein (CRP), a target for studies of treatment for coronary heart disease, is not in fact directly involved in causing it, as once thought, said the research published in the *Journal of the American Medical Association*. However, the study did discover new genetic variations associated with coronary heart disease. If confirmed in other studies, these might offer clues to identify new targets to treat the disease, one of the researchers noted. Research teams examined a total of 28,112 people with the disease and 100,823 people without the disease. They reached their conclusion by comparing the genetic variations that play a role in the level of CRP with the prevalence of coronary heart disease in those that they studied.

Women who sleep less more likely to have heart problems . . . Lack of sleep apparently hits women harder than men. A study revealed that women who do not sleep well are at higher risk of suffering heart disease and heart related problems than men. Eight hours is the recommended length of time people should spend asleep, and women who get less than that have a higher chance of coronary problems than men with the same sleeping patterns, according to research by the **University of Warwick** and **University College London** (UCL). The study found levels of inflammatory markers – indicators of coronary heart disease – vary significantly with sleep duration in women, but not men. Published in the *American journal Sleep*, researchers found levels of Interleukin-6 (IL-6) were much lower in women who reported sleeping eight hours compared to those who slept for seven hours. Another marker, high-sensitivity C-reactive protein, which predicts future cardiovascular morbidity, were significantly higher in women who reported sleeping for five hours or less, the authors noted. The report was based on findings from the first large-scale study to investigate the associations between measures of inflammation and sleep duration in both men and women, which involved more than 4,600 white participants, of which 73% were men.

— **Compiled by Amanda Pedersen, MDD Staff Writer**

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