MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

FRIDAY, OCTOBER 20, 2006 VOL. 10, NO. 202 PAGE 1 OF 10

Pacemaker-like device made by CVRx for hypertension wins IDE

By HOLLAND JOHNSON
***Medical Device Daily* Associate Managing Editor**

If ongoing trials are successful, the device sector may one day have another innovative implantable technology, this one used to treat difficult-to-manage high blood pressure, particularly in patients who have a resistance to hypertension drugs.

CVRx (Minneapolis) reported that it has received FDA approval for a conditional investigational device exemption (IDE) to begin a pivotal clinical to evaluate the safety and effectiveness of its Rheos baroreflex hypertension therapy system, an implantable device to treat high blood pressure.

The blinded study, sponsored by the company, is a prospective, randomized, multi-center trial that will be conducted at up to 40 sites in the U.S. The study seeks to determine the safety and effectiveness of the Rheos System

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Trancervical Pelvic Venogram diagnostic in launch by Cook

By KAREN YOUNG
***Medical Device Daily* Staff Writer**

Cook Women's Health (Spencer, Indiana), a division of **Cook** (Bloomington, Indiana), is introducing its Transcervical Pelvic Venogram, designed to diagnose Pelvic Congestion Syndrome, one of the many causes of chronic pelvic pain at the **International Pelvic Pain Society** (Birmingham, Alabama) annual meeting, held today and Saturday in San Antonio.

The company said chronic pelvic pain affects about 15% of women ages 18-50 and has a "drastic negative impact" on the quality of a woman's life.

A number of causes can be the source of pelvic pain, including endometriosis, interstitial cystitis or pelvic injury. The challenge for physicians has always been to diagnose the correct source of the pain.

"In the market today, there is no product like that

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Report from Europe

Longport International to lead $2 million ultrasound project

A *Medical Device Daily* Staff Report

Longport International, the UK subsidiary of **Longport** (Glen Mills, Pennsylvania), is the lead participant in a $2 million project to develop a high resolution, phase-array ultrasound imaging system, partly supported by a grant from the UK's **Department of Trade & Industry**.

The system under development will be capable of imaging at center frequencies greater than 25 MHz as well as at lower frequencies, according to the company, and is expected to exceed the imaging resolution of all current commercial multi-element ultrasound systems.

The project involves the **University of Manchester**, **Phoenix Inspection** and **Newbury Electronics**. The system under development will combine very high performance with affordability through the use of novel transducer and system designs and the development of specialist integrated circuits.

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Financings roundup

Ivivi IPO targets raising $12.5M; Xthetix gathers 'A' round $2M

A *Medical Device Daily* Staff Report

Ivivi Technologies (Northvale, New Jersey) reported the pricing of its initial public offering of 2.5 million shares of its common stock at $6 a share. Net proceeds are expected to be about $12.5 million.

The underwriters of the offering have been granted an option for a period of 45 days to purchase up to 375,000 more shares of common stock from the company to cover any over-allotments.

The shares will be listed on the American Stock Exchange and will trade under the symbol II.

Maxim Group is acting as representative of the underwriters of the offering, and Brean Murray, Carret & Co. acted as co-manager.

Ivivi is an early-stage company developing electrotherapeutic technologies. These technologies use electric or electromagnetic signals to help relieve pain, swelling and

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INSIDE: HEALTHGRADES: BEST AND WORSE HOSPITALS HAVE WIDENING GAP 2
PAINCARE TO SPIN ASCS; FREUDENBERG-NOK ADDS HELIX 3

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HealthGrades: Best and worst hospitals have widening gap

A *Medical Device Daily* Staff Report

HealthGrades' (Golden, Colorado) most recent study of hospital quality in America found that a typical patient has, on average, a 69% lower chance of dying in a 5-star hotel compared to a 1-star hospital.

The gap widened by about 7% from last year's study, even though overall mortality rates improved nearly 8%.

The Ninth Annual HealthGrades Hospital Quality in America Study analyzes 40.6 million Medicare hospitalization records from 2003 through 2005 to rate the quality of care at each of the nation's more than 5,000 non-federal hospitals. Hospitals were assigned a 1-star (poor), 3-star (as expected) or 5-star (best) rating.

The full study is available on the organization's web site, HealthGrades.com.

"This year's study finds that mortality rates among Medicare patients continues to decline; however the differences in patient outcomes between 5-star and 1-star hospitals remains large and is getting larger, a concerning finding," said Samantha Collier, MD, the author of the study and the vice president of medical affairs at HealthGrades.

"But these are more than numbers," she added. "According to the study, more than 300,000 Medicare lives could have been saved during the three years studied if all hospitals performed at the level of hospitals rated with 5 stars."

For example, the study shows a typical person having coronary bypass surgery has a 72.9% lower risk of mortality, on average, if he or she has the procedure at a 5-star rated hospital compared with a 1-star rated hospital. If all Medicare coronary bypass surgery patients from 2003 to 2005 went to 5-star hospitals, 5,308 lives could have been saved, HealthGrades reported.

"Better than expected outcomes are achievable and hundreds of thousands of lives could have been saved if all hospitals could improve to a performance level comparable to 5-star rated hospitals," the study said. "Even moving just the bottom group of hospitals up to the national averages would result in substantial improvement." ■

BRIEFLY NOTED

World Blood Market Exceeds $20 billion

Kalorama Information (New York) reported that the worldwide market for human-derived blood products, testing, and typing products, and plasma and blood collection equipment exceeded $20 billion at the end of 2005.

Kalorama said the total global value of blood products alone is just shy of $14 billion in 2005, with the lion's share attributable to red blood cells (RBCs) at more than $7 billion.

Demand for immunoglobulins or antibodies stood at nearly $3 billion in 2005 and is rising by 6%-8% per year, making it the driving force behind plasma collection. Other human plasma-derived products, such as platelets, clotting factors, and alph-1 proteinase inhibitors, also played a significant role in strong revenues, valued at $2.5 billion, Kalorama said.

At the same time the blood products market escalates, so too are the markets for blood testing and typing products, blood collection equipment, and synthetic blood products. Nucleic acid tests, for example, currently at $953 million, are expected to increase by 11.5% to over $2 billion by 2012. Similarly, the market for recombinant factors, which currently stands at over $4 billion, is expected to rise to more than $7 billion by 2012.

"Global demand for blood products, particularly in developed countries where the technology is readily available and rapidly advancing will continue to rise at a healthy rate as the world population ages and requires increasingly intricate operations and testing," said Alison Sahoo, the report's author. "As they reach the market by 2007, we also anticipate the emergence of hemoglobin-based oxygen carriers and PFC-based products to play a significant role in market growth."

Kalorama Information, a division of MarketResearch.com, supplies independent market research for the life sciences.

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Deals roundup

PainCare to spin ASC holdings; Freudenberg-NOK adds Helix

A *Medical Device Daily* Staff Report

PainCare Holdings (Orlando, Florida), a provider of pain-focused medical and surgical services, said that it plans to sell its interests in its ambulatory surgery centers (ASCs) as part of its financial restructuring.

PainCare said the proceeds of the proposed sales are expected to help reduce or retire its debt obligations, thus strengthening its balance sheet.

"Following extensive review of PainCare's available financing alternatives, including debt renegotiation and private and public equity raises, we determined that it was in the best interest of our company and our shareholders to pursue a more creative and non-dilutive means to eliminate liquidity issues and access necessary growth capital," said Randy Lubinsky, CEO of PainCare.

Lubinsky said PainCare's ASC holdings have been complementary to its overall business but not central to its mission.

"Recognizing that our surgery centers were valuable properties of interest to those companies who are actively engaged in consolidating assets within the ambulatory surgery center market, the sale of our ASCs became a logical and prudent solution to address the restructuring of our balance sheet, while also enhancing our cash position," Lubinsky said.

PainCare has engaged The Bloom Organization (New Jersey), an investment banking firm with expertise in the sale and acquisition of ambulatory surgery centers.

Freudenberg-NOK General Partnership (Plymouth, Michigan) reported it has acquired the assets of **Helix Medical** (Carpinteria, California) to expand its elastomeric seals and custom molded offerings for the healthcare and medical markets. Terms of the agreement were not disclosed.

Founded in 1984 by Edmund Seder and Edward Jesle, Helix makes silicone components and products for the medical device, pharmaceutical and biotech markets. Freudenberg-NOK, founded in 1989, makes precision-molded products for a variety of markets including healthcare and medical.

Helix Medical will continue to make custom molded products, extruded silicone and voice restoration devices at its California facility and serve the biomedical and pharmaceutical industries through its sales and marketing departments.

InHealth Technologies, a division of Helix that makes Blom-Singer voice restoration products, will continue to operate as a business unit under Helix Medical. Freudenberg-NOK said the acquisition will allow InHealth to focus on expanding the scope and quality of its product lines, while leveraging the financial resources, manufacturing and R&D expertise of Freudenberg-NOK.

In other dealmaking activity:

• **Medegen** (Scottsdale, Arizona) reported the sale of its Medical Products division to **Medical Action Industries**, a publicly-held supplier of medical and surgical disposable products. Financial terms were not disclosed.

Medegen will retain its Medical Manufacturing Services (MMS) division and its factories in Ontario, California, and Tijuana, Mexico. The MMS division supplies specialty I.V. therapy products and devices.

Medegen provides products and services to the medical community, providing branded and OEM specialty infusion therapy disposables as well as cost-effective outsourcing strategies to medical device and pharmaceutical OEMs.

• **Constella Group** (Durham, North Carolina), a professional health services provider, reported signing an agreement to acquire **Lineberry Research Associates** (LRA; Research Triangle Park, North Carolina), a contract research organization and consulting firm.

Founded in 1995, LRA is a provider of regulatory affairs, medical writing, product development strategy, clinical trial management and data management services for pharmaceutical and biotech companies. LRA employs more than 75 people who will join Constella's pharmaceutical product development business unit. Deal closure is expected within the next 30 days.

The acquisition will provide Constella with expansion of its U.S. regulatory, product development, quality assurance, data management, medical writing and clinical trials capabilities.

The combined organization will give Constella greater capacity and additional resources to expand its global platform to deliver full service drug development programs, the company said.

The news follows Constella's acquisition of Origin, a European CRO headquartered in the UK, in March.

• **HCA** (Nashville, Tennessee) said that it has established a record date and special meeting date for its shareholders to vote to adopt the previously disclosed agreement for the acquisition of HCA by an investor group led by Bain Capital, Kohlberg Kravis Roberts & Co., Merrill Lynch Global Private Equity and HCA founder Thomas Frist, Jr, MD.

The $33 billion acquisition was first disclosed in July (*Medical Device Daily*, July 25, 2006).

The special meeting will be Nov. 16 at HCA's executive offices in Nashville.

HCA's affiliates are owner/operators of 176 hospitals, 92 freestanding surgery centers and facilities and partners in joint ventures that own and operate seven hospitals and seven freestanding surgery centers. The company's facilities are located in 21 states in the U.S., England and Switzerland. ■

Around the Beltway

'Opportunities' focus on tech for environmental exposures

A *Medical Device Daily* Staff Report

As part of the new Exposure Biology Program, the **National Institute of Environmental Health Sciences**, a component of the **National Institutes of Health**, has issued $74 million in grant opportunities for the development of new technologies to improve the measurement of environmental exposures that contribute to human disease.

The three grant opportunities will support research to develop portable, easy-to-use sensing devices that will accurately measure personal exposure to a variety of chemical and biological agents. The grants will also support the development of biomarkers, based on changes in DNA structure, proteins, metabolites and other molecules enabling scientists to study how the body responds to environmental stress.

The Exposure Biology Program is one of two complementary research programs outlined in the Genes and Environment Initiative, a five-year, NIH effort to identify the genetic and environmental underpinnings of asthma, diabetes, cancer and other common illnesses. The program will focus on technologies to assess chemical and biological agent exposures, dietary intake, physical activity, psychosocial stress and addictive substances, plus methods for quantifying the biological responses to these stressors.

David Schwartz, MD, director of NIEHS, said, "The discoveries made with these new tools will ultimately lead to new strategies for the prevention and treatment of many illnesses."

"The technologies used for the detection and measurement of environmental exposures should be as precise as the measurement tools currently used for genetic research," said Brenda Weis, PhD, senior science advisor at NIEHS and program coordinator for the Exposure Biology Program.

The following are the grant opportunity descriptions:

• "Environmental Sensors for Personal Exposure Assessment" will support the development of field-deployable or wearable devices that provide direct measurements of exposure to ozone, fine particles, diesel exhaust, heavy metals, volatile organic compounds, pesticides, microbial toxins, and other environmental agents that have been linked with respiratory disease, cancer and other illnesses.

• "Biological Response Indicators of Environmental Stress" will focus on development of sensitive biomarkers that reflect subtle changes in inflammation, oxidative damage and other pathways that can lead to disease.

• "Biological Response Indicators of Environmental Stress Centers" will focus on the development of sensitive biomarkers that reflect subtle changes in inflammation, oxidative damage and other pathways that can lead to disease, and the incorporation of these markers into field- and laboratory-based sensing devices.

The Exposure Biology Program also includes two other grant opportunities:

"Improved Measures of Diet and Physical Activity for the Genes and Environment Initiative" and "Field-Deployable Tools for Quantifying Exposures to Psychosocial Stress and to Addictive Substances for Studies of Health and Disease."

"Any individuals with the skills, knowledge and abilities required to carry out the proposed research, including scientists who work in NIH laboratories, are encouraged to submit an application for participation in the program," said Weis.

NIEHS will host an information meeting and videoconference, Oct. 20, 2006 in Research Triangle Park, North Carolina, to allow potential applicants to obtain information and clarify any questions about the funding opportunities.

Ohio Reps. seek power mobility cut delays

Six Ohio congressmen have written to Michael Leavitt, secretary of Health and Human Services (HHS), asking that he postpone Medicare cuts that the industry says would prevent seniors and people living with disabilities from having access to power wheelchairs.

The **Centers for Medicare & Medicaid Services** has issued a new fee schedule calling for 35% to 41% cuts in reimbursement rates for power wheelchairs, a move that the industry claims will "severely impact" patient access for those most in need, as well as dramatically impact small businesses in Ohio, and across the country.

"We implore you to take immediate action and postpone the Nov. 15, 2006 fee schedule for power mobility devices," the Representatives wrote. "It is imperative to establish a new fee schedule using rational methodology…so that beneficiaries with ALS and other debilitating diseases that progress over time will not be without the necessary mobility when they need it most."

The letter says that "trying to save dollars at the expense of someone's quality of life is not good public policy." The letter was signed by Democratic representatives Tim Ryan (Youngstown), Ted Strickland (Marietta), Dennis Kucinich (Lakewood), Sherrod Brown (Lorain), Marcy Kaptur (Toledo) and Stephanie Tubbs Jones (Cleveland).

Suppliers in the state say they may be forced to close their businesses, lay off workers or stop providing power wheelchairs.

"The problem that CMS doesn't understand is that we don't have anything to cut," said Carol Gilligan, president of **Health Aide** (Cleveland). "At these reduced rates, the cost of acquiring a wheelchair, fitting the patient, servicing the chair and doing the documentation paper work will exceed the amount that Medicare will pay for the chair." ■

Grants/contracts

InHealth awards grants for MRI and CT imaging research

A *Medical Device Daily* Staff Report

The **Institute for Health Technology Studies** (InHealth; Washington) has awarded one-year research grants to two teams at **Stanford University** (Palo Alto, California). The grants, totaling $538,207, are part of InHealth's goal of bringing objective data and perspective to understanding the impact of medical technology on patients and the healthcare industry.

One project will examine the socio-economic value of MRI and computed tomography (CT) imaging. The other will document the current regulatory and commercialization processes required of new medical technologies.

The first study, "The Diffusion of Imaging Technologies, Health Care Costs and Quality," will investigate the relationships among the availability of advanced diagnostic imaging services, usage, patient outcomes and healthcare spending.

The second study, "Medical Device Development Models," will document how medical devices are approved and enhanced, pre- and post-market, including the role of the FDA. In addition, the study will clarify the different paths followed by medical devices, pharmaceuticals and biotech products. Results from both studies are anticipated by fall 2007.

In other grant news:

• **Inovio Biomedical** (San Diego) said it is slated to receive $1.1 million from the **U.S. Department of Defense** to develop applications of its electroporation-based gene delivery technology for vaccination against infectious disease, including potential bioterrorism agents.

Congress appropriated the funding in the Defense Appropriations Bill for 2007 as a continuation of prior funding from the Army to the company, focused on the development of a more effective delivery system for gene-based vaccines.

Inovio said it is working on this project with Connie Schmaljohn, MD, a world-renowned virologist and chief of the Department of Molecular Virology at the **U.S. Army Medical Research Institute of Infectious Diseases** (Ft. Detrick, Maryland).

The premise of gene-based immunization is that for a particular targeted pathogen, selected DNA sequences can be introduced into muscle where they will produce one or more antigens and thereby elicit both cellular and humoral immune responses against that pathogen.

Inovio's system is designed to use intramuscular electroporation to enhance the cellular delivery and expression of the DNA agents to produce the desired antigens. Compared to conventional vaccines, DNA vaccines delivered using electroporation may accelerate the onset and enhancing the level of immunity generated, critical in attempting to address threats posed by pandemics or bioterrorism, the company says. Pertinent genes can be quickly identified and isolated from potential infectious organisms, sequenced, and synthesized for vaccination of the general population or military in order to induce a protective immune response.

The company said in a statement: "DNA vaccines delivered with electroporation are of interest to the medical community, Inovio said, because they provide the advantage of rapid and robust immune responses. They are effective at triggering both enhanced cellular and humoral immune responses — mediated by certain white blood cells and antibodies, respectively — that are difficult to achieve by conventional vaccine technology and provide superior immunity to the toxic challenge posed by infectious agents.

The company said that DNA vaccines delivered by electroporation "have been shown to reprogram the immune system to recognize antigens on cancer cells that had not otherwise been recognized." ■

Agreements roundup

U.S. Genomics, Lahey Clinic in pact to study microRNAs

A *Medical Device Daily* Staff Report

U.S. Genomics (Woburn, Massachusetts) and **Lahey Clinic** (Burlington, Massachusetts) reported the signing of a discovery agreement to study the role microRNAs play in the development of urologic cancers.

The objective of the collaboration is to develop more accurate prognoses for bladder and prostate cancer patients. The collaboration combines U.S. Genomics' patented Trilogy 2020 platform and Direct miRNA assay with Lahey Clinic's expertise in the analysis of tumor progression and experience in disease management.

In other agreement news:

The **Massachusetts eHealth Collaborative** (MAeHC; Cambridge, Massachusetts) has selected **Wellogic** (also Cambridge) as its technology vendor to build a health information exchange connecting three hospitals and more than 100 physician practices, as well as reference labs, imaging centers, pharmacies, and other healthcare service providers and trading partners. Financial terms were not disclosed.

Development of this exchange utility marks the second phase of MAeHC's charter to bring together the state's major healthcare stakeholders for the purpose of establishing an interoperable electronic health record system.

The MAeHC was formed in 2004 with a $50 million commitment from Blue Cross Blue Shield of Massachusetts. ■

CVRx

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when used in drug-resistant hypertension patients. To be enrolled in the trial, patients need to be resistant to treatment with at least three anti-hypertension agents, including a diuretic. Their systolic blood pressure must be greater than or equal to 160 mmHg.

Data from this clinical trial is intended to support the pre-market approval application for the Rheos system to the FDA.

CVRx's flagship product, the Rheos system is intended for use in patients who cannot control their blood pressure with medications, or medication combined with lifestyle modifications. The device provides what physicians might describe as a "physiologically rational" method to reduce blood pressure. It is designed to do this with the use of mild electrical signals to influence the body's blood pressure regulation system, called the baroreflex.

According to Robert Kieval, founder and current vice president and chief technology officer of CVRx, the Rheos is a pacemaker-like device designed to stimulate tissues within the body.

"We stimulate areas of the vascular system that have sensors in them that report blood pressure to the brain," he told *Medical Device Daily.* "The brain compares what it believes is the blood pressure to the needs of the body and then makes the appropriate adjustments."

Kieval said the signals that the device generates are interpreted by the body as a rise in blood pressure that needs to be corrected. The brain then works through the body's own blood pressure control mechanisms to attempt to restore blood pressure to normal. Thus, in essence, it fools the body and leads to a net reduction in blood pressure.

Kieval likened this mechanism of action to the ability to cool a room by holding a match under a thermostat: "The heat of a match fools the thermostat into thinking that the entire room has become too warm and causes the air conditioning system to be activated."

The device has thus far enjoyed early clinical success in European and U.S. feasibility clinical trials for its evaluation. European patients started enrolling in the trial in 2004. Early results for the first 12 patients were reported at the **European Society of Hypertension** meeting in June 2006.

In this study, after three months of active Rheos therapy, systolic blood pressure was reduced by an average of 24 mmHg (189 mmHg vs. 165 mmHg). There were no unanticipated serious adverse events related to the system or procedures.

"The Rheos System represents a fundamentally new approach to therapeutic intervention for resistant hypertension," said principal investigator, Thomas Pickering, MD, professor of medicine, **Columbia University Medical Center – Presbyterian Hospital** (New York). "This pivotal study will help us further understand the potential role of this device in treating patients with difficult-to-manage high blood pressure. Reducing high blood pressure can help prevent serious heart and kidney disease, stroke and death."

The company said initial U.S. results will be presented at the **American Heart Association** (AHA; Dallas) annual meeting being held in Chicago in November.

Kieval, now chief technology officer, was previously president/CEO of the company but stepped down earlier this month in order to let somebody else lead the company though the clinical trials and ultimately to commercialization. Nadim Yared assumed those titles on Oct. 4.

Yared was most recently the vice president and general manager of **Medtronic Navigation**, a unit of **Medtronic** (Minneapolis) that makes integrated image-guided surgery products.

Before joining Medtronic Navigation in 2002, Yared worked with **GE Medical** (Little Chalfont, UK) for 10 years as an engineer and manager and was eventually promoted to vice president and general manager or GE's European X-ray business.

Kieval explained that the company grew out of a medical technology incubator called ProtoStar, formed by Piper Jaffray Ventures, NEA and several former executives of **Boston Scientific SciMED.**

To date, the company has undergone three rounds of financing, he noted: an $8 million round in 2001, a $22 million round in 2003 and a $30 million round this past May, making it one of the biggest venture capital deals of the year for a device company. In all, the company has raised more than $60 million in private funding.

Kieval feels the company's financing success underscores the importance of the treatment and its market potential.

That potential is enormous since 25% of the 65 million people in the U.S. who have hypertension cannot control their high blood pressure, despite the use of multiple medications.

And hypertension then leads to huge stressors on the individual and the healthcare system as a whole since it is a leading cause of stroke, heart attack, heart failure and kidney disease. It is estimated to cause one in every eight deaths worldwide. ■

Cook

Continued from Page 1

available," Christina Anné, global leader of Cook's Women's Health, told *Medical Device Daily*. "Right now, it's always been a guess of where does that pelvic pain come from. The [device] will actually give one target, so they don't have to look at all targets any longer. [Physicians] will know straightaway if the pain is Pelvic Congestion Syndrome."

Cook said that pelvic veins are vulnerable to chronic dilation, which can lead to vascular congestion. Because pelvic veins are thin-walled, unsupported and are attached "relatively weakly" to supporting tissue, they may bulge, stretch or dilate.

That bulging or dilating causes pelvic congestion, essentially similar to varicose veins found in the legs. That condition leads to chronic pelvic pain.

"Pelvic congestion can be severe and hinder a woman's ability to walk, exercise, sleep, conduct chores and, in some patients, may inhibit any type of activity," the company said.

Cook's solution to the problem of diagnosis begins with a catheter through which is threaded a tiny needle, Anné said. That catheter is inserted intravaginally, forwarded through the cervix and on toward the very top of the uterus.

At the top of the uterus, the needle is inserted and injects a dye, which reveals the veins of the abdomen. That, in turn, enables physicians to determine if the veins of the pelvis are congested when used in conjunction with a fluoroscope, which would show the veins fluorescently on a small screen in real-time using X-ray.

This, in some cases, will work to determine that a hysterectomy is not needed, if a patient knows the precise source of her pain. Or it might avoid medication treatment for endometriosis, when PCS is actually the cause of the pain.

Cook will be marketing not only to gynecologists — and training them in the procedure — but also to radiology departments, with an educational component to its marketing.

"When a woman is in pain, her first gatekeeper is a gynecologist," Anné said. "When we have pelvic pain, we don't tend to go to a radiologist or surgeon. We may be referred to those people, but . . . a gynecologist can do this procedure."

Anné noted that Cook has seven divisions, one of which is devoted to radiology and diagnostics, and the device would be offered by that division, as well.

Cook's Women's Health unit was launched in May at the **American College of Obstetrics and Gynecology** (ACOG; Washington) annual meeting in Washington (*Medical Device Daily*, May 9, 2006).

The division's mission is to develop solutions for health problems specific to women, such as infertility, pelvic organ prolapse and incontinence.

Anné said that the company is targeting the development of products to treat health problems throughout a woman's life-cycle, from age 20 to 60 and older.

In July, for example, the Cook Women's Health division introduced the Bakri Postpartum Balloon, which is intended to treat women suffering from hemorrhage following childbirth (*MDD*, July 18, 2006). ■

BRIEFLY NOTED

StatSure to restate earnings

StatSure Diagnostic Systems (Framingham, Massachusetts) reported that on Oct. 12, the audit committee of its board concluded, based upon the recommendation of the company's management and independent auditors, that the company will restate its previously issued financial statements for the quarters ended March 31, 2005, June 30, 2005, and Sept. 30, 2005, and for the year ended Dec. 31, 2005, included in the company's annual report on Form 10-KSB, and for the quarters ended March 31 and June 30.

The company's previously issued financial statements for these periods should therefore no longer be relied upon, it said.

In the course of a routine SEC review of the prior Company periodic filings, the SEC issued a comment letter dated Oct. 4, 2006, alerting the company to a possible incorrect application of certain accounting principles.

The need to restate the company's financial statements arises from incorrect application of generally accepted accounting principles related to the beneficial conversion feature on the issuance of the convertible debt by the company, and revised calculations of the Employee Stock Options pursuant to FIN 28:

StatSure Diagnostic Systems is engaged in the development, manufacture and marketing of rapid immunoassay tests for the detection of sexually transmitted and other infectious diseases. In addition, the company has developed and is marketing a product line of patented, oral-fluid collection devices.

Del Global relocates HQ

Del Global Technologies (Valhalla, New York) reported that it has relocated its corporate offices from Valhalla, New York, to Franklin Park, Illinois, in suburban Chicago. The new address is 11550 West King Street, Franklin Park, IL 60131. The company said that the relocation will consolidate Del Global's corporate office into the headquarters of the company's Del Medical Systems Group, which markets and sells medical imaging and diagnostic systems worldwide.

Del Global manufactures diagnostic imaging systems for medical, dental and veterinary applications through the Del Medical Systems Group.

Longport

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Initial applications for this system are expected to be cancer imaging, including the mapping of skin cancers, wound assessment and prevention and superficial musculoskeletal imaging as well as specialist engineering inspections.

Lord Sainsbury, UK Science and Innovation Minister, said, "This initiative provides a real opportunity to harness the world class expertise that we possess in the UK and direct it towards the task of wealth creation. By providing a focus for collaboration and delivery, this partnership should establish British industry as the world leader in this area and be an attractive proposition for investors."

Paul Wilson, managing director of Longport International, termed the project "a logical evolution of Longport's established medical imaging technology. The development is expected to bring the benefits of faster imaging as well as a broader range of image enhancement and processing techniques, including Doppler imaging, to Longport's current customer groupings."

Viatronix reports 14 hospital installs

Viatronix (Stony Brook, New York) reported the installation of its V3D Colon module for virtual colonoscopy at 14 hospitals throughout France and that it expects to install at other sites in the coming months.

All the hospitals are taking part in the STIC trial under the direction of Denis Heresbach, a gastroenterologist, and Yves Gandon, a radiologist, from Rennes, France. The clinical trial, to begin shortly, is expected to take 24 months to complete.

"All the sites have been equipped with the latest version of the robust and well-known Viatronix V3D-Colon platform that provides unique workflow optimized tools," said Zaffar Hayat, president of Viatronix. "Some of the hospitals in France that have already used the Viatronix V3D-Colon software find it to be user friendly and its unique diagnostic tools to be of great help in patient diagnosis.

"The latest version provides optimized automatic post processing, enhanced electronic cleansing, interactive 2D and 3D windows, and proven diagnostic tools such as missed regions, supine and prone registration, automatic center line and translucent rendering that are available on the fly; allowing a radiologist to seamlessly read a case in under 10 minutes."

Zaffar Hayat, president of Viatronix, said, "Radiologist Training for the virtual colonoscopy exam is an important function as highlighted in some of the earlier publications and by many leaders in the industry. To this end Viatronix has worked with leading radiologists in France and elsewhere to develop a strong training program for radiologists."

Viatronix is a developer of 2D/3D medical imaging and diagnostic software, enabling physicians to interactively view vital organs and anatomical structures within the body from data acquired by standard medical imaging equipment in minimally or non-invasive methods.

Liverpool to get new cancer emphasis

Three major Liverpool cancer service providers will collaborate in a multi-million-pound project in new cancer therapies. The **University of Liverpool**, the **Royal Liverpool University Hospital** (RLUH) and the **Clatterbridge Centre for Oncology** (CCO) will combine their resources to provide improved treatment for various cancers, including head and neck, lung and lymphoma.

The merger also will serve to establish the **Liverpool Experimental Cancer Medicine Centre** (LECMC) to facilitate clinical trials of new cancer therapies. The center, funded by £750,000 from **Cancer Research UK**, will include the addition of beds for cancer patients at RLUH to participate in cancer trials as well as a new Chair of Medical Oncology, to oversee the trials and related projects. The LECMC's resources will be accessible to external users in science and industry. The LECMC also will be supported by a £1.1 million transfer of six cancer specialists from the **Clatterbridge Cancer Research Trust** on Wirral to the **University of Liverpool Cancer Research Centre** (ULCRC).

Professor John Caldwell, dean of the Faculty of Medicine, said: "Liverpool plays a vital role in the development of new treatments for cancer — 15.2% of cancer patients in the area are recruited to trials — one of the highest rates in the UK. The merge with our cancer research partners will allow us to double the number of patients to early phase clinical trials as well as increase the capacity for treating cancer patients."

The developments are part of an overall £20 million investment in cancer research and follow the recent launch of the University's School of Cancer Studies, newly created to focus entirely on research for new cancer treatments and therapies, incorporating the former Divisions of Surgery and Oncology, Haematology; and Pathology.

Trial backs carotid surgery vs. stents

A trial conducted in France, comparing surgery to stents for preventing strokes in patients with carotid artery blockage, was cut short because it quickly became evident that surgery was twice as effective as stents, according to researchers at the Hospital Sainte-Anne (Paris).

In the study, "Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis," reported in the *New England Journal of Medicine*, researchers found that twice as many patients had a stroke 30 days and six months after being given a stent, when compared to patients who underwent the surgical procedure known as endarterectomy.

Dr. Jean-Louis Mas, lead author, said that patients who

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Financings

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inflammation and promote healing processes and tissue regeneration.

• **Xthetix** (Mesa, Arizona), a company developing therapeutic ultrasound targeting the consumer aesthetics market, said it has raised $2 million in Series A funding from venture capital and private equity firm 3i.

Xthetix was formed to develop ultrasound products for the over-the-counter aesthetics market. Its first product is for acne treatment and prevention, a condition affecting 85% of all adolescents and 25% of adult women in the U.S.

With the funding, Allan Ferguson, senior partner with 3i, joins Xthetix co-founders, Chairman Michael Slayton and CEO Brian O'Connor on the board.

O'Connor describes the Xthetix technology as a platform for addressing unmet needs in the consumer aesthetic market. He notes, "Additional devices in the product pipeline target skin rejuvenation, hair removal and inflammation-related skin diseases such as rosacea. The value of these combined markets will exceed $12 billion in 2006."

Xthetix is the second company spun off by the founders. 3i made a previous investment in **Ulthera** (Phoenix), a company addressing non-invasive facelifts for the professional dermatology and plastic surgery market.

In other financing activities:

• **NMT Medical** (Boston) has filed a shelf registration statement with the SEC to offer and sell up to $65 million of equity or debt securities.

The company said that this offering of securities will provide it with the flexibility to take advantage of financing opportunities, subject to market conditions and its capital requirements.

NMT describes its implant technologies as enabling interventional cardiologists to treat structural heart disease through minimally invasive, catheter-based procedures. It is investigating the potential connection between a patent foramen ovale heart attacks and brain attacks such as migraine headaches, stroke and transient ischemic attacks

• Commercial genetic testing provider **Tm Bioscience** (Toronto) reported that it has amended its license agreement with **Sirius Genomics** (Vancouver, British Columbia) to defer a $2 million license fee payment originally due on Sept. 5.

This payment will now become due in October 2007 or 90 days after completion of certain milestones by Sirius. Amendments related to the delay of the license fee payment have been made to the interest rate calculation used when determining the aggregate amount which Tm is eligible to set off against its licensee fee obligations. All other terms of the original license agreement remain in effect.

• **HealthSouth** (Birmingham, Alabama) reported that its stockholders have approved a 1-for-5 reverse stock split. The reverse split will become effective Oct. 26, to coincide with HealthSouth's relisting on the New York Stock Exchange under the ticker symbol HLS.

It said that more than 95% of its shareholders participated in the vote, and more than 90% of the participating shareholders voted approval.

The company noted that the reverse split will affect all of its stockholders uniformly and will not change the proportionate equity interests.

With the reverse split and relisting, the company said it has made substantial progress toward recovery from "the fraud perpetrated by the previous management team."

HealthSouth is one of the nation's largest providers of outpatient surgery, diagnostic imaging and rehabilitative healthcare services. ■

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have symptomatic stenosis benefit from endarterectomy, not stenting. He stressed that the study did not include patients at high risk of complications from surgery, such as those with severe heart disease.

The trial, which included 527 patients, found:

• 30-day incidence of stroke was 3.9% for patients who had surgery;

• 30-day incidence of stroke was 9% for patients who had stents;

• 6-month incidence of stroke/death was 6.1% for patients who had surgery;

• 6-month incidence of stroke/death was 11.7% for patients who had stents

A U.S. study — SAPPHIRE — found the opposite among diabetic patients. ■

PRODUCT BRIEFS

• **Haemonetics** (Braintree, Massachusetts) reported launch of its SmartSuction Solo surgical suction system in the U.S. The product is designed to enhance a surgeon's ability to clear fluids from the surgical field by providing high air flow and self-regulating suction. The company said that the SmartSuction Solo system is the first product that it will sell into the general surgery market, expanding it "from a surgical blood salvage company into a broader blood management company." The product self-regulates, freeing operator time; it stands alone, ensuring consistent vacuum and air flow levels not subject to fluctuations created by demand from other operating rooms; and, it has a small, portable footprint for minimal intrusion in the surgical suite. The system received FDA 510(k) clearance in early October 2006 and is now in "customer acceptance trials" in the U.S. SmartSuction, acquired from Harvest Technologies in August of 2004, is the third system developed by Haemonetics under the SmartSuction family of products. Earlier this year, Haemonetics launched a related suction product, the SmartSuction HARMONY surgical suction system, used in surgeries assisted by surgical cell salvage.

• **Ultrasonix Medical Corporation** (Burnaby, British Columbia) reported launching its Sonix CEP, an ultrasound system designed for critical care and traumas. The Sonix CEP is intended to deliver high performance imaging in a compact portable system that rolls up to the patient's bedside or gurney. The device is built to power on in seconds with up to 30 minutes of rechargeable battery life to allow emergency medicine physicians to move from room to room and treat multiple patients without losing power. It features the QSonix Quick Exam Wizard that provides one touch access to major applications, probe selections, specific application presets and auto populating patient data targeted at treating critical and emergency patients. Ultrasonix makes diagnostic ultrasound imaging systems.

• **Vasomedical** (Westbury, New York) has introduced its Electronic Communication Module (ECM) for the Lumenair EECP Therapy System. The ECM uses Bluetooth technology to wirelessly transfer encrypted patient and treatment data to a dedicated computer. Users are then able to access print and archive patient data with the included laptop or desktop computer and printer. The ECM is designed to be integrated with an electronic medical record software system. Vasomedical develops enhanced external counterpulsation therapy, a noninvasive, outpatient therapy used in the treatment of ischemic cardiovascular disease.

• **Verathon** (Bothell, Washington) has introduced the GlideScope Ranger, a portable, compact video laryngoscope that provides a clear, real-time view of a patient's airway for fast intubations in unpredictable airway conditions. Designed for "Ist Pass Success" in military and emergency settings, the GlideScope Ranger features a blade angulation, a non-glare monitor visible in bright light, an anti-fogging mechanism that resists lens contamination, and rugged, high-impact construction. The device is designed to meet the needs of military physicians and paramedics who work in extreme conditions and regularly treat patients with severe trauma, but Verathon said non-military practitioners also appreciate the advantages of the instrument. The GlideScope Ranger provides a clear picture of the larynx and vocal cords on a display monitor, enabling visual control of the endotracheal tube in its trajectory toward the airway, Verathon said. Recently experiencing double-digit growth, Verathon was ranked among the fastest growing technology companies in Washington State in Deloitte's "Technology Fast 50" program for both 2005 and 2006.

PEOPLE IN PLACES

• Jean Boyle has been named VP of Service at **iCAD** (Nashua, New Hampshire). Previously, Boyle was VP of Service at Merge-eMed, a Merge Healthcare company, iCAD is a developer of computer-aided detection (CAD) technologies and offering upgradeable CAD systems for the high-, mid- and low-volume mammography markets.

Vicki Moore has been promoted from directory of regulatory affairs and customer services manager to VP of regulatory affairs at **Information Data Management** (Rosemont, Illinois). She will continue her role as manager of customer services. IDM develops software used for blood donor operations, including management and recruitment, blood component management and laboratory testing.

• Peggy Binzer, former senior FDA health counsel to the Senate Budget Committee, has been named as partner in Health Preparedness practice of **McKenna Long & Aldrige** (Washington). Binzer will focus her work on the firm's FDA and healthcare practice areas. As counsel to the Senate Budget Committee, she was a primary advisor to Chairman Judd Gregg (R-NH) and acted as lead staff on high-profile legislation. Binzer also served as counsel to the Senate Health Education Labor and Pensions Committee where she advised then-Chairman Gregg on FDA issues. She also worked for seven years in multiple roles at the FDA, including as special assistant for legal affairs to the director of the Office of Nutritional Policy, Labeling and Dietary Supplements at the Center for Food Safety and Applied Nutrition. McKenna Long & Aldridge's Public Health Preparedness is focused on the biodefense, pandemic preparedness and detection/diagnostic industries. The firm employs about 400 lawyers and public policy advisors and has additional offices in Albany, Atlanta, Brussels, Denver, Los Angeles, New York, Philadelphia, San Diego and San Francisco.