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St. Jude in the dealmaking mood with Radi, MediGuide

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

'Tis the season to make big deals, at least that seems to be the case for **St. Jude Medical** (St. Paul, Minnesota). The company reported two acquisitions back to back this week – **Radi Medical Systems** for \$250 million cash and **MediGuide** (Haifa, Israel) for \$283 million in cash plus \$17 million net liabilities. The deals were reported Sunday and Monday, respectively.

Deals roundup, p. 3

For 2008,

Radi is expected to generate roughly \$80 million in sales, a 19% increase over last year, according to St. Jude. The company's pressure measurement guidewire, PressureWire Certus, comprises about a 70% share of the global market for physiological assessment of coronary lesions. Radi's FemoStop and RadiStop product lines comprise about a

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Mauna Kea/Cellvizio push R&D microscopy/endoscopy link

By DON LONG

Medical Device Daily National Editor

As a diagnostic procedure to identify a malignancy, biopsy is fairly definitive. Take a piece of tissue, put it under a microscope and you know what you've got.

"Taking" that material, of course, is a problem. It means invasiveness – perhaps even triggering disease in some cases, it is thought. And the whole procedure takes time, is expensive and delays treatment.

So how do you avoid biopsy?

Well, let's say we add a microscope to the business end of an endoscope. That is one of the leading-edge strategies in the device world currently called probe-based confocal laser endomicroscopy (pCLE).

The technique was first introduced in 2004 by Optiscan Imaging (Melbourne, Australia) in an R&D collaboration/marketing partnership with Pentax (Tokyo). Pentax

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Report from Europe

German vote seen helping get newest products to patients

A *Medical Device Daily Staff Report*

In a move that proponents say paves the way for improved introduction of new medical technologies, the German parliament last week passed the Hospital Financing Reform Act (Krankenhausfinanzierungsreformgesetz, or KHRG).

In a statement, the German medical technology association, **BVMed** (Berlin), said the amendment of the innovation clause – Section 6 of the hospital reimbursement act – will offer hospitals the opportunity to request the reimbursement of innovative technologies for a patient of the German health insurance funds in a flexible way, instead of linking it to a set deadline.

"This is an important step," said BVMed Director General Joachim Schmitt.

While the innovation clause existed previously, BVMed said that in practice, little usage had been made of the reimbursement provided by the clause, "due to problems

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ReGen meniscus repair implant wins 510(k) path market okay

A *Medical Device Daily Staff Report*

After two previous failed attempts to win FDA PMA approval for its Menaflex collagen meniscus implant, **ReGen Biologics** (Hackensack, New Jersey) has finally received 510(k) clearance to market the product, a scaffold designed to reinforce and repair soft tissue knee injuries of the medial meniscus.

The company switched from a PMA (premarket application) – considered the FDA's most stringent type of marketing review, usually for devices that are used more invasively and with significant risk – to the less arduous 510(k) regulatory pathway.

An FDA advisory committee met in November to review ReGen's 510(k) application, usually reserved for products for which PMA approvals are sought. And in doing so the agency appeared to be signaling its intent to more closely regulate all medical devices, not just those that come under PMA review (*Medical Device Daily*, Nov. 18, 2008)

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 **AHC Media LLC**

Financings roundup**ATS reports close on \$20M,
\$7.5 settlement of lawsuit****A Medical Device Daily Staff Report**

ATS Medical (Minneapolis), a manufacturer of cardiac surgery products, reported closing of a \$20 million equity financing with Essex Woodlands Health Ventures.

In connection with the financing, ATS issued and sold to Essex Woodlands 8,510,639 shares of its common stock for \$2.35 a share, and warrants to purchase 2,533,192 shares of common stock for \$2.475 a share during the first year after the closing, \$2.85 per share during the second year, and \$3.10 thereafter.

The company also reported the settlement of its lawsuit with **CarboMedics** (Austin, Texas), initiated in 2007 and related to its supply agreement with Carbomedics for certain mechanical heart valve components (*Medical Device Daily*, Jan. 30, 2007).

ATS will pay CarboMedics \$3 million on Dec. 29, and another \$4.5 million on April 30, 2009. Under the terms of the settlement, ATS maintains all rights to manufacture, market and sell its ATS Open Pivot mechanical heart valve.

"With this financing, we have significantly strengthened our balance sheet and added one of the most respected health-care investors in the United States to our shareholder base," said Michael Dale, president/CEO of ATS. "In addition, this financing will allow the company to settle a longstanding dispute and related litigation on terms we believe serve the best interest of shareholders. We are pleased to be eliminating the uncertainty and distraction of ongoing litigation."

In other financing news, **Helicos BioSciences** (Cambridge, Massachusetts) said it has agreed with certain investors to raise about \$18.6 million in gross proceeds through the sale of shares of its common stock and warrants.

Helicos, a life science company focused on genetic analysis technologies for the research, drug discovery, and diagnostic markets, estimates net proceeds from the offering of about \$17.9 million, after deduction of placement agent fees and esti-

Today's MDD food for med-tech thought

"This acquisition [of Radi] immediately makes St. Jude Medical the leader in two new cardiology product categories that have good growth potential."

Dan Starks, chairman, president/CEO of St. Jude Medical speaking during a conference call yesterday, about his company's proposed \$250 million acquisition of Radi Medical Systems, part of double deal announcement that also saw the company offering to buy MediGuide for \$283 million in cash plus \$17 million net liabilities, "St. Jude in the dealmaking mood with Radi, MediGuide," pp. 1, 6.

mated offering expenses.

The company said it plans to use the proceeds for working capital and general corporate purposes.

Helicos has agreed to sell a total of 42,753,869 units, each unit consisting of one share of common stock and one warrant to purchase 0.6 shares of common stock at 45 cents a share, for a price of about 44 cents a unit, representing the closing bid price, plus an additional amount for the warrants.

Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately. The warrants will have a five-year term and will be exercisable immediately following close of the transaction.

The company said it expects the deal to close this week. Leerink Swann was placement agent for the offering. Institutional investors and certain current investors, which include Flagship Ventures, Atlas Venture, Highland Capital and Versant Ventures, provided the financing.

Helicos describes its True Single Molecule Sequencing technology as allowing direct measurement of billions of strands of DNA, "enabling scientists to perform experiments and ask questions never before possible." ■

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*Deals roundup***ATA set to merge with Bioness; Emageon demands closing date****A Medical Device Daily Staff Report**

Advanced Technology Acquisition (ATA; Ramat Gan, Israel) reported its intent to merge with **Bioness** (Valencia, California). The company said that the execution of its letter of intent affords it a six-month extension for completion of a business combination, until June 22.

ATAC is a blank check company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase or other similar business combination with a technology or technology-related business that has operations or facilities located in Israel, such as R&D, manufacturing or executive offices.

Bioness is a neuromodulation company marketing non-invasive medical devices and developing minimally-invasive implantable products intended to treat disabling conditions caused by various neurological events and conditions (such as stroke and multiple sclerosis), chronic pain and urological syndromes. Bioness' non-invasive technologies are used for central nervous system disorders and may provide such patients with increased levels of physical independence, productivity and symptom management, the company noted. Its investigational lines of minimally-invasive implantable devices target the peripheral nervous system; they are in various stages of research and design, including clinical trials, and are intended to be smaller, less invasive, less expensive, more site-specific and safer than current implantable devices.

Bioness will commence a tender offer for the purchase of ATAC's outstanding warrants for four cents per warrant. As a condition to the tender offer, 100% of the outstanding warrants will be tendered and not withdrawn.

Emageon (Birmingham, Alabama) said it has formally demanded a closing of its pending merger with **Health Systems Solutions** (New York) by today.

"We believe we have an obligation to consummate our merger in an expeditious manner in accordance with the requirements of both parties under the merger agreement," said CEO Chuck Jett. "We also believe our stockholders, who have resoundingly supported this transaction, desire us to move forward without delay. Health Systems has not agreed to set a closing date, instead making additional due diligence requests. This news was especially surprising given Health Systems' recent public and private support of the transaction."

Jett added that there is no due diligence condition in the merger agreement and the time for due diligence ended when the parties signed the agreement.

"Health Systems has also asserted purported breaches of our representations, warranties and covenants under the merger agreement, which we categorically deny and reject as immaterial," Jett said. "Health Systems is clearly

stalling for reasons that are not apparent to us and unrelated to any purported breaches of the merger agreement. We believe we have satisfied our conditions to closing and that it is time for Health Systems to comply with its obligations and close the merger."

Jett said that if closing does not occur by today, the company intends to pursue its "rights and remedies under the merger agreement."

Emageon provides information technology systems for hospitals, healthcare networks and imaging facilities.

In other dealmaking news:

- **U-Systems** (San Jose, California) reported a technology licensing agreement with the Ultrasound Business Unit of **Siemens Medical Solutions USA** (Mountain View, California). The U-Systems' somoVIEWer advanced workstation for Automated Breast Ultrasound has been licensed for use with Siemens' ACUSON S2000 Automated Breast Volume Scanner (ABVS) recently introduced at RSNA 2008. According to the company, this will allow physicians to obtain the comprehensive 3D view of the breast volume which features U-Systems' "intuitive" anatomical coronal plane not available with conventional ultrasound systems.

- **Johnson & Johnson** (J&J; New Brunswick, New Jersey) said it has extended its previously reported cash tender offer for all outstanding shares of common stock of **Omrix Biopharmaceuticals** (New York) until midnight, EDT, on Friday, unless further extended. The offer was originally scheduled to expire at midnight, EDT, on Tuesday.

The depository for the tender offer has advised J&J that so far about 4,101,234 shares of Omrix common stock were validly tendered and not withdrawn (including roughly 2,000 shares subject to guaranteed delivery procedures), representing about 23.4% of Omrix's common stock on a fully diluted basis.

Upon closing of the tender offer, stockholders of Omrix will receive \$25 in cash for each share of Omrix common stock tendered in the offer, less any required withholding taxes. It is expected that Omrix will operate as a stand-alone entity reporting through **Ethicon** (Somerville, New Jersey), a J&J company.

- **IPC The Hospitalist Company** (North Hollywood, California) said it has acquired **National Medical Affiliates** (Punta Gorda, Florida).

IPC is a national hospitalist physician group practice company focused on the delivery of hospitalist medicine services. ■

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Agreements/contracts**Massachusetts hospitals enter consolidation services contract****A Medical Device Daily Staff Report**

Hubbard Regional Hospital (HRH; Southbridge, Massachusetts) has entered into a contract with **Harrington Hospital** (Webster, Massachusetts) for the supervision of its day-to-day operations, effective Jan. 1, 2009. Hubbard Hospital will continue offering healthcare services under the agreement.

"Hubbard Regional Hospital and Harrington Hospital are envisioning the possibility of a consolidated healthcare system in South Central Massachusetts in the long term," said Chris Robert, HRH board chair. "The first step toward a two-campus healthcare system is a management contract relationship. The agreement will place Harrington as a managing agent to the Hubbard Hospital Board of Directors."

The contract affords the opportunity to improve the performance of Hubbard Hospital, recognizing its strengths and exploring areas which have the potential to be further developed. The relationship between the Hubbard and Harrington health systems has the potential to collaborate in ventures designed in the best interest of their patients.

The contract, signed Dec. 18, 2008, will include two Harrington managers on site, responsible for all aspects of Hubbard's operations. The managers will investigate whether synergies exist and cost savings can be realized in support services that both institutions provide, such as purchasing, information technology, food service or engineering.

"Being only 12 miles apart gives us the opportunity for our staffs and our physicians to support each other and explore the opportunities for a stronger health care system in south Worcester County," said Edward Moore, president/CEO of Harrington Hospital. "All services will be evaluated with an eye toward maintaining those that are both needed for the community and are financially viable."

In other agreements/contracts news, **The Female Health Company** (Chicago) said it has received an order for the delivery of 8.1 million female condoms from **John Snow** (Boston), which implements the USAID I DELIVER PROJECT, a U.S. Agency for International Development (USAID)-funded project, working to increase the availability of essential health supplies to clients and customers around the world.

For many years, USAID has been among the largest international donors of contraceptives and condoms.

The agency developed an operational plan for its HIV/AIDS "expanded response" strategy which includes the establishment of the Commodity Fund to centrally-finance male and female condoms for HIV/AIDS programs and to ensure their expedited delivery to countries.

O. B. Parrish, chairman/CEO of FHC, said, "In continuing

female condom procurement, USAID is demonstrating its commitment to supporting HIV/AIDS prevention efforts around the World. This commitment is particularly critical as the Global Community recognizes the increasing numbers of females affected by AIDS." ■

Patent watch**Aperio's claims approved for its method to view 3-D 'virtual' slides****A Medical Device Daily Staff Report**

Aperio Technologies (Vista, California) reported that the U.S. Patent and Trademark Office has issued the company patent No. 7,463,761, entitled "Systems and Method for Creating and Viewing Three Dimensional Virtual Slides."

This patent includes claims for the general technique of acquiring 2-D digital slide images, and using these images as a map to then acquire 3-D images known as z-stacks.

"The ability to create and view z-stacks while a glass slide is still in the scanner is critical for specimens that have multiple focal planes, such as frozen sections for example," said Ole Eichhorn, Aperio's chief technical officer.

The patent also includes claims for high-performance, remote viewing of 3-D digital slides across a network, including the Internet.

"The ability to create and efficiently view three-dimensional whole slide images makes it possible for Aperio to extend the benefits of digital pathology to the field of cytology, including Pap smears," said Dirk Soenksen, CEO of Aperio. "The recent expansion of our patent portfolio to encompass TDI-, fluorescence- and 3-D-scanning, viewing and analysis continues to reassure customers that Aperio has the broadest freedom to operate in all niches of digital pathology." ■

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MED - TECH NEWS AND NOTES

Encision now on OTCBB

Encision (Boulder, Colorado) reported that it is now quoted on the OTC Bulletin Board with a trading symbol of

ECIA.OB. The company will continue to be a Securities and Exchange Commission reporting company and believes that it is current in all of its required SEC and regulatory filings.

ArthroCare receives Nasdaq listing extension

ArthroCare (Austin, Texas) said the Nasdaq Listing Qualifications Panel has conditionally granted the company's request for continued listing on the Nasdaq Global Select Market, and that the company has received

the consent of the lenders under its credit agreement to the extension of the delivery deadline for the company's June 30 and Sept. 30 financial statements.

ArthroCare makes minimally invasive surgical products.

Covidien's Hi-Lo named part of QUEST program

Covidien (Boulder, Colorado) said that its Hi-Lo Evac endotracheal tube was named part of Premier Healthcare Alliance's QUEST Comparative Innovation Program (CIP). The Hi-Lo Evac tube, which facilitates continuous aspiration of subglottic secretions to reduce ventilator-associated pneumonia, was selected based on clinical evidence and potential impact on the five QUEST measurement areas - mortality, cost of care, evidence-based care, patient experi-

ence and harm avoidance.

"The QUEST initiative stresses optimal performance in the areas of quality and cost of care, as well as patient satisfaction," said Mike Alkire, president of **Premier Purchasing Partners** (San Diego). "The Hi-Lo Evac tube aligns well with these goals, having been shown repeatedly to reduce the incidence of VAP and also ICU length of stay and duration of mechanical ventilation. These are issues of importance to our hospital members and their patients."

ACS releases new policy statement

As President-elect Barack Obama and the incoming 111th Congress prepare for the many policy issues potentially complicating the process of achieving healthcare reform, the American College of Surgeons (ACS; Chicago) has released a comprehensive policy statement to help frame the debate.

Specifically, the ACS calls on policymakers to support a reform approach that improves access to safe, high-quality and affordable surgical care. A key objec-

tive of the ACS effort is to address the crisis of access to quality surgical care by emphasizing policies that will remedy the surgical workforce shortage affecting the country.

The ACS's focus on and concern about patient access to safe and effective surgical care and the looming surgeon shortage is supported by a recent public opinion poll it conducted. Results of the survey indicate that 86% of Americans feel a potential surgeon shortage is an important issue to be addressed as part of any healthcare reform process.

HealthGrades releases patient satisfaction list

HealthGrades (Golden, Colorado), a healthcare ratings organization, has identified those hospitals that rank in the top 15% nationally in patient experience and posted the hospitals on www.HealthGrades.com. The ratings are based on patient satisfaction survey results that hospital patients provided as part of a new federal initiative to increase public reporting of hospital performance.

The Hospital Consumer Assessment of Healthcare Providers and Systems survey, or HCAHPS, includes 27 questions related to physician and nurse communication, responsiveness, hospital cleanliness and noise levels, medication information, and post-discharge care instructions. It is the first national, standardized, publicly reported survey of patients' perspectives of hospital care. HCAHPS is an initiative of the Centers for Medicare & Medicaid Services.

Report warns of global cancer burden

Cancer is projected to become the leading cause of death worldwide in the year 2010, according to a new report the **International Agency for Research on Cancer** (IARC; Washington).

According to the report, the burden of cancer doubled globally between 1975 and 2000, and cancer is expected to become the leading cause of death worldwide in 2010.

Now, IARC is asking the government would help fund cancer prevention and research initiatives and

international tobacco control policies.

The report states that reasons for the growing cancer burden include the adoption in less developed countries of "Western" habits such as tobacco use and high calorie, high-saturated and trans-fat diets.

"These factors are also significant contributors to the global burden of cardiovascular disease. The IARC's aggressive support of tobacco control is particularly important, as cigarette smoking is the main preventable cause of premature death in the U.S., as well as worldwide," said Timothy Gardner, MD, president of the AHA.

St. Jude

Continued from Page 1

60% share of the global market for manual compression-assist products for vascular closure. This market totaled nearly \$45 million in 2008 and is projected to continue to grow at least at a mid single-digit rate, according to St. Jude. The FemoStop and RadiStop product lines, together with St. Jude's Angio-Seal line of active vascular closure products, will be part of an expanded program by St. Jude Medical to fully develop the potential of a global vascular closure device market that is only about 27% penetrated, the company said.

"This acquisition [of Radi] immediately makes St. Jude Medical the leader in two new cardiology product categories that have good growth potential," Dan Starks, chairman, pres/CEO of St. Jude said during a conference call yesterday, during which he discussed both deals. "Both product lines can benefit from more field support and more investment in market development than Radi has been able to provide as a standalone company. The cardiology programs of Radi and of St. Jude Medical both are stronger together than either program is separately."

For example, Starks noted that Radi's products are already approved for market release and for reimbursement in Japan. Although Japan is the second largest medical device market in the world, he said, Radi is small enough that its organization in Japan totals only nine employees. In comparison, St. Jude has more than 400 direct employees in Japan, including a "strong cardiology group that is hungry for more products," he said.

For MediGuide, St. Jude paid \$138 million this month, will pay \$111 million in November 2009, and up to \$34 million in April 2010. St. Jude said it has acquired all of the outstanding shares of MediGuide, including the 41.3% interest (on a fully-diluted basis) owned by **Elbit Systems** (Tel Aviv, Israel). MediGuide has developed a navigation system, the Medical Positioning System (gMPS) that uses technology for real-time tracking of sub-millimeter sized sensors. These sensors can be mounted on needles, guidewires, catheters, and other devices used for minimally-invasive intra-body navigation, St. Jude said. The 3-D position and orientation of the sensors can be calculated in real time and projected graphically on a fluoroscope, CT, MRI, ultrasound, or 3-D reconstructed image of the anatomy.

Starks said MediGuide brings St. Jude a new platform technology that it believes may benefit almost all of its major growth programs.

"MediGuides' navigation technology is the result of 30 years of intense development in Israel for jet fighter pilot applications," Starks said. "MediGuide has devoted the last eight years full time, under exclusive license, to apply this technology to intrabody navigation in the context of catheter and other minimally invasive medical procedures. All of this technology for medical applications now belongs

to St. Jude Medical."

Starks said St. Jude expects to use the new navigation technology in the electrophysiology catheter lab, the cardiology catheter lab, in deep brain stimulation, and in the operating room. He said the technology can be attached to a conventional X-ray C-arm and be used in a way that can improve visualization of intrabody anatomy, improve accuracy of information regarding device location and orientation in relation to that anatomy, and potentially reduce exposure to radiation.

St. Jude expects to integrate the MediGuide technology with CT images, MRI images, ultrasound images and its own Insight images, as well as with fluoroscopic images, Starks noted.

"It will take time and ongoing investment in R&D, but we can envision a future where a cath lab staff does not have to wear lead, where medical careers are not shortened by back injuries or radiation exposure, and where catheterization and other minimally invasive procedures can be completed more quickly, more safely and more cost effectively, due in part to our MediGuide navigation technology."

Both acquisitions were funded with cash on hand outside the U.S. and the proceeds of a new three-year term loan; and both transactions have closed.

During the question and answer session of the call, one listener asked Starks if St. Jude would have done both of these deals if they were U.S. entities.

"Philosophically, these deals both stood on their own strategically, regardless of their location," Starks responded. "I think the ability to put our [outside U.S.] cash to work was really just a bonus."

MediGuide's gMPS technology and its gMPS Enabled Guided Measurement Catheter (GMC) are European CE Mark certified and are currently limited to investigational use only in the U.S., St. Jude noted. Also, Starks said that MediGuide currently does not bring in revenue.

Gera Strommer, president/CEO, and Uzi Eichler, VP of technology for MediGuide, are expected to join St. Jude.

"We look forward to working with the St. Jude Medical team," Strommer said. "With their support, we will have the resources to more fully capitalize on MediGuide's innovations and successfully move through the next stage of our development plans."

Joanne Wuensch of **BMO Capital Markets** (New York) said in a research note the acquisitions appear to follow St. Jude's pattern of building its franchise through small, technology-based companies that could broaden the long-term growth potential of the company.

MediGuide will become part of the St. Jude Medical Atrial Fibrillation Division. In connection with the transaction, St. Jude said it would record a special charge of about \$300 million for in-process R&D in the fourth quarter of 2008. This acquisition does not change the company's outlook for 2008 or 2009 consolidated earnings per share,

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Endomicroscopy

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then was first to market in 2006 with its OptiScan device, a system integrated into Pentax instruments and used primarily for assessment in the gastrointestinal tract.

Pursuing broader pathways with this optical imaging approach is **Mauna Kea Technologies** (Paris), which last year launched its U.S. subsidiary **Cellvizio** (Fort Washington, Pennsylvania).

Mauna Kea/Cellvizio has developed the Cellvizio, a pCLE system that can be used as an accessory to endoscopes made by many manufacturers, so that it can be used by a larger number of clinicians, in a broader number of applications.

The device is essentially an endoscopic accessory which, when placed against mucosal tissue, provides microscopic visualization of the tissue. The images obtained have a resolution 500 to 1000 times greater than a regular endoscope, and the system has been described as a disruptive technology in its clinical applications, after finding initial use in lab research in animals.

Cellvizio delivers up to 12 images per second and is designed to be used with almost any endoscope. It has 510(k) clearance and the CE mark for use in the gastrointestinal and pulmonary tracts.

While, like Pentax, Mauna Kea/Cellvizio also is focused on gastrointestinal applications, it is exploring various other uses for detection of cancer.

For instance, it recently reported the first patients enrolled in an international, multi-center study designed to assess the use of the Cellvizio to determine the condition of Barrett's Esophagus, in particular whether or not it has progressed to a cancerous condition.

Importantly, the quick determination of cancer enables treatment more quickly, with fewer biopsies, and Mauna Kea/Cellvizio say that positive data in the Barrett's trial will add confirmation to its overall clinical usefulness.

Chris Tihansky, president of Cellvizio, told *Medical Device Daily*, "We're doing a fair amount of physician education – to help them understand what they're looking at" with the device. A key strategy being used by the company is to place the device with "opinion leaders" in the field, with many of them doing their own trials.

Tihansky reported 80 installations of the system "worldwide." While he declined to state the number of users in the U.S., he said that there is a "tremendous amount of interest in the U.S. We're on track to meet our objectives with the company, and over the next several years, to make [the Cellvizio] a standard of care."

More than 100 patients will be enrolled in the Detection Of Neoplastic Tissue in Barrett's Esophagus with In vivo Probe-based Confocal Endomicroscopy (DON'T BIOPCE) study the at four sites: **Columbia-Presbyterian Medical Center** (New York), the **Veteran Affairs Hospital** (Kansas City, Missouri), **Mayo Clinic** (Jacksonville, Florida)

and **Klinikum rechts der Isar** (Munich, Germany).

Collection of data for the primary outcome measure is expected in June, with study completion set for September of 2009.

Principal investigator Prateek Sharma, MD, professor of medicine in the Division of Gastroenterology and Hepatology at the **University of Kansas School of Medicine** and the **Veteran Affairs Medical Center** (both Kansas City, Missouri), said, "Until now, we haven't been able to differentiate dysplastic and cancerous tissue within the Barrett's segment, so we take random biopsies from the area in hopes that this will represent an accurate sample."

Barrett's occurs when gastroesophageal reflux disease (commonly called GERD) causes stomach acid to leak back into the esophagus, damaging the lining and increasing the risk of cancer of the esophagus (adenocarcinoma).

Besides exploring the esophageal application, the company is doing R&D for use of its systems in gastroenterology and hepatology, and the assessment of pancreatic cancer, lung cancer and bile duct cancer.

Tehansky acknowledges that the Optiscan system from Pentax is "a compelling technology," but also that the pCLE sector will continue to grow and be available to the Cellvizio device "because of its compatibility with any endoscope on there on the market."

Characterizing the Cellvizio as a platform opportunity he said is "a fair comment – it potentially has broad applications in detection of early-stage cancers across a number of specialties and some of those specialties are very encouraging to us."

"We hope to reproduce the positive results of our earlier Barrett's Esophagus studies in a wider group of physicians and patients," said Sacha Loiseau, founder and president/CEO of Mauna Kea.

An earlier study demonstrating that use of the Cellvizio for assessing the progress of Barrett's Esophagus was published in the December issue of GUT, the international journal of gastroenterology and hepatology.

In the study, two independent examiners evaluated 199 and 200 biopsy sites in respective multi-centric studies.

The blinded diagnostic assessments matched in 176 cases, the physicians coming to an accurate diagnosis in 93.3% of those 176 cases. They accurately determined which patients had pre-cancerous tissue 80% of the time and correctly differentiated the non-cancerous tissue 94.1% of the time. Of the lesions which tested negative, the physicians were 98.8% accurate (negative predictive value).

Lead author of the study, Heiko Pohl, MD, of the Dartmouth-Hitchcock Medical Center, said, "Traditional endoscopic cameras don't differentiate cancerous or precancerous Barrett's tissue, so we take random samples from sections of the region in hopes that it represents an accurate sampling. A more precise, real-time, microscopic imaging device will help us more accurately target dangerous Barrett's tissue and remove or treat it immediately before it

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Europe

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with its implementation.”

Saying that last week’s vote marked “a significant improvement,” the association said the further step “was needed . . . to make the application and assessment procedure [Neue Untersuchungs-und Behandlungsmethoden, or NUB] for new examination and treatment methods more transparent and less bureaucratic.”

BVMed said the change will allow “full benefit of the innovation clause . . . [to] be developed.”

At the end of January, the German Institute for Hospital Reimbursement (Institut für das Entgeltsystem im Krankenhaus, or InEK) will publish its assessment of the reimbursement of NUB applications made in 2008.

The applications had to be made individually by those hospitals that wanted to offer innovative therapies to their patients. Under existing regulations, patients often have had to wait for up to a year before they might benefit from a positive InEK decision on new types of therapy.

That was due to the fact that hospitals can submit an application for reimbursement of the NUB with the health-care funds only once a year at the end of their budget negotiations.

Industry officials have regarded the regulation as a “significant obstacle” for innovation and the cause of “a healthcare gap,” in BVMed’s words.

It added: “This procedure has led to a slowing down of the speed of innovation in Germany.” In addition, it said, “systematic injustice in patient care results. This is due to the fact that innovations are available only for those patients who were lucky to be treated not at the beginning of the year but in autumn after the budgets had been authorized.”

It said lawmakers also noticed “this deplorable state of affairs,” and that last week’s vote means “the application procedure for the financing of innovations in the hospital sector will . . . be made more flexible.”

With the passage of the Hospital Financing Reform Act, the association said, “Remunerations can be agreed on earlier and independently of the agreement of the revenue budget.”

BVMed added: “Hospitals will now be able to settle new methods and innovative medical technologies independently of their yearly budget negotiations and in this way can use these methods and offer them to the patient immediately.”

Plans to enhance UK pathology services

Transforming **National Health Service** (NHS) pathology services in the UK will improve quality, safety and efficiency in diagnostic tests, according to a two-year review of those services published last week.

The independent review of NHS Pathology Services

looked at making services more responsive to patients’ needs and highlights the potential for substantial annual savings.

The UK Department of Health said pathology services “play a key role in around 70% of decisions on diagnosis and treatment.” This includes blood tests for diabetes, biopsies to diagnose cancer, and tests for infections. It said the growing use of genetics for preventive medicine and more personalized care “is likely to increase the need for pathology services.”

Recommendations include:

- Developing pathology networks with a single integrated management structure.
- Improving test turnaround times.
- Rapid adoption of new technology and approaches to delivering services.
- Enhancing IT connectivity.
- Centralizing non-urgent and specialist work in accredited core laboratories.

Professor Peter Furness, president of the Royal College of Pathologists, said, “We particularly appreciate the recommendations in relation to quality, the development of consolidated networks, and the need for an accreditation process that covers the diagnostic process from the decision to test to the delivery and interpretation of the results.”

An impact assessment on the review’s recommendations will report next summer, with three Strategic Health Authorities looking at the practical implications of the recommendations.

Italian, Russian centers order Neuromag

Elekta (Stockholm, Sweden) reported two orders for Neuromag, which it terms “the world-leading equipment for non-invasive measurement of brain activity using magnetoencephalography (MEG) technology.”

The company said Neuromag has been ordered by the **Moscow Municipal University of Psychology and Education** in Russia and the **University of Trento** (Trento, Italy).

MEG is a tool for studying normal brain function and brain disorders, providing real-time mapping of brain activity by non-invasively measuring the magnetic fields produced by the brain.

The company said neuroscientists and those in related fields at the Moscow facility plan to use Elekta Neuromag, the first whole-head MEG in Russia, for clinically oriented research applications, such as autism in children. The university also plans to employ MEG technology for cognitive neuroscience and neuropsychology research such as the study of human emotion and brain abnormalities.

Professor Tatiana Stroganova, head of the developmental psychophysiology department at the Moscow facility, said, “We plan to use the MEG extensively to

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ReGen

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Summarizing the views of the members at the advisory meeting, its chair, Jay Mabrey, MD, of **Baylor North Texas Orthopaedic Specialists** (Dallas), said, "the panel generally believes that the device is safe, but its effectiveness remains to be seen." He said "the sense of the panel is that yes, it is as safe and effective." The panel also generally agreed that the device was appropriate for use in both chronic and acute injuries.

The panel's conclusions were then taken by the Center for Devices and Radiological Health as support for okay of the clearance. Two years ago, the company decided to opt out of the PMA route (*Medical Device Daily*, Jan. 5, 2006).

At the time, CEO Gerald Bisbee, Jr., PhD, said the rationale for taking the 510(k) route is based on the fact that predicate devices, including surgical patches recently had been cleared, including two in 2005.

The Menaflex is designed to guide new tissue growth, following removal of damaged meniscus tissue, using the body's own healing process. It provides a resorbable scaffold for the growth of new tissue in the meniscus.

"We are extremely pleased that the FDA has considered the recommendations of the Orthopaedic and Rehabilitation Devices Advisory Panel in support of our collagen scaffold 510(k) and that the FDA agreed to enable U.S. marketing for this important product," said Gerald Bisbee, Jr, PhD, CEO and chairman of ReGen. The announcement of FDA clearance, he said, "represents the culmination of many years of effort on the part of the company and the invaluable contribution of many supportive investors, advisors and surgeons, as we sought to bring the Menaflex product to the U.S. market."

The potential market for ReGen's Menaflex includes a large portion of the estimated annual 1.3 million partial meniscectomies worldwide. Partial meniscectomies increase for those patients who have had previous procedures. And, about 65% of partial meniscectomies occur on the medial meniscus.

ReGen said that it will seek expansion of the indication for use in the lateral meniscus through a new 510(k) application to be submitted to the FDA, with support by data from its ongoing European post-market study.

Menaflex is marketed in Europe for both medial and lateral indications.

Data backing up ReGen's claims of efficacy include a recent study of 311 patients with an irreparable injury of the medial meniscus or a previous partial medial meniscectomy, treated by a total of 26 surgeon-investigators at 16 sites.

Patients in the study, titled "Comparison of the Collagen Meniscus Implant with Partial Meniscectomy" received either the collagen meniscus implant, or served as a control subject treated with a partial meniscectomy only.

Patients who had a collagen meniscus implant were

required to have second-look arthroscopy at one year to determine the amount of new tissue growth and to perform a biopsy to assess tissue quality.

The study authors concluded that new biomechanically competent meniscus-like tissue forms after placement of a collagen meniscus implant, and use of the implant appears safe.

The implant supports new tissue ingrowth that appears to be adequate to enhance meniscal function as evidenced by improved clinical outcomes in patients with a chronic meniscal injury.

However, "The implant was not found to have any benefit for patients with an acute injury," the study's authors wrote in a report published in *The Journal of Bone and Joint Surgery*. ■

Endomicroscopy

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develops into esophageal cancer."

The company cites estimates that since the 1980s, the rates of adenocarcinoma of esophagus (ACE) have been increasing in both genders in developed countries, is the fastest rising malignancy among white men in the U.S., and is increasing faster than breast cancer, malignant melanoma, or prostate cancer.

The company reports that more than 2,000 of these procedures to assess Barrett's have been done, with publication of more than 25 peer-reviewed papers on the technology.

The company describes the in vivo cellular imaging market as focused on enabling the visualization, diagnosis and treatment of pathologies that can't be seen with other imaging techniques, and the company this year won the Wall Street Journal Technology Innovation Award.

Founded in 2000, Mauna Kea/Cellvizio investors include the Psilos Group, Seventure and Credev. The company in January reported the close of a \$30 million financing, lead by the Psilos Group (*Medical Device Daily*, Jan. 24, 2008). ■

Europe

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study temporal dynamics of cortical networks underlying normal and aberrant brain organization of perception, attention and emotion."

Dedicated to brain and cognitive neuroscience research, a large group of researchers at the University of Trento's Center of Mind/Brain Sciences plans to use Neuromag to explore various fields of neuroscience such as sensory processing, attention and action control, language, formation of concepts and cognitive development. ■

PEOPLE IN PLACES

- **ALung Technologies** (Pittsburgh), developer of a lung replacement therapy, reported the appointment of Peter DeComo to the position of CEO effective Jan. 1. DeComo was formerly CEO of Renal Solutions. DeComo has served as the ALung chairman for the past six months. Additionally, former chairman of Respironics, Gerald McGinnis, has committed to provide up to \$1.8 million in the form of convertible debt for bridge funding, to allow the company to complete necessary research and development of its Hemolung device, as it readies for 2009 clinical trials. Nick Kuhn, who has served as CEO of ALung since 2001 will assume the role of COO for ALung.

- Robert Bowen has been named VP and CFO of **Abio-med** (Danvers, Massachusetts), a provider of heart recovery and circulatory support products. Bowen previously was VP and CFO for GSI Group (Bedford, Massachusetts).

- **ArthroCare** (Austin, Texas) reported several senior management promotions, all effective immediately. James Pacek has been promoted to the position of senior VP, Strategic Business Units. Pacek previously served as VP and general manager, Interventional Therapies and also has experience in directing ArthroCare's Sports Medicine business. Sten Dahlborg has been promoted to president, International. Dahlborg previously served as senior VP and GM, International Operations. Richard Rew II, has been promoted to senior VP, legal affairs. Rew previously served as VP, general counsel and secretary of Activant Solutions and as general counsel of Ezcorp. Michael Moehring has been promoted to VP and general, Spine Businesses. Moehring previously served as senior director, Sales and Marketing, Spine businesses. Brian Simmons has been promoted to the position of VP finance and chief accounting officer. Simmons joined ArthroCare in February 2007 and previously served as VP, Finance. ArthroCare develops minimally invasive surgical products.

- **bioMérieux** (Marcy L'Etoile, France) reported that Alexandre Mérieux has been appointed directeur général délégué. Stéphane Bancel continues to be responsible for all functions in his role as CEO and to chair the bioMérieux management committee. Mérieux has been a member of the bioMérieux board since 2004. He also will continue as corporate VP of Industrial Microbiology. bioMérieux is a diagnostics developer.

- **LifeCare Holdings** (Plano, Texas) reported that Greg Floyd will join the company in the role of senior VP of regional hospital operations for the 20-facility, long-term, acute care system. Floyd joins LifeCare from Select Medical, where he has held positions as a regional VP, as well as VP/CEO of Select Specialty Hospital. Floyd has also held CEO positions in several other Select Hospitals, and clinical positions at Doctors Health Care Center, a long-term care center, and Zale Lipshy University Hospital, an acute care

teaching hospital. LifeCare operates 20 long-term acute care hospitals in 10 states.

PRODUCT BRIEFS

- **Acculis** (Denmead, UK) reported the extension of the worldwide launch of its Microwave Tissue Ablation (MTA) system for the coagulation of soft tissue in open surgery. The system is being used to treat liver cancers. The company said that MTA is the only FDA 510(k)-cleared, single-needle, high power 2.45GHz microwave system. It achieves 5 cm x 6.5 cm coagulations with single eight-minute applications and 4.3 cm x 6 cm diameter coagulations in only four minutes. The company said the system surpasses contemporary low-power 915MHz microwave systems which require complex multiple needle placements and longer times to achieve equivalent coagulations. Acculis said that the system was first distributed "to a cohort of the world's leading cancer centers." The roll-out is now being extended through the recruitment of distributors in several European countries, as well as in South America and Asia. "The MTA System has proven itself as an important additional tool for the liver surgeon," said Acculis CEO Stuart McIntyre. Acculis is a device company developing microwave energy ablation systems for oncology applications. It is part of the **Microsulis** (Denmead) group of companies.

St. Jude

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exclusive of the special charge, St. Jude noted. MediGuide was originally spun off from Elbit Systems, a global defense electronics company.

Radi will become part of the St. Jude Medical Cardiovascular Division. The transaction is expected to be neutral to St. Jude Medical's consolidated earnings per share in 2009 and is expected to be positive to consolidated earnings per share beginning in 2010. ■

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FDA Inspections: Are You Ready? (T09527)

Wednesday, January 7, 2009 - 1pm to 2:30 pm (EST)

In a new *BioWorld Today* audio conference, compliance attorney and expert Cathy Burgess will guide you through what it takes to pass an FDA inspection, both in terms of meeting FDA regulations, and in management of the inspection process itself.

CAPA: 8 Steps to Achieve Compliance (T09528)

Thursday, January 8, 2009 - 1pm to 2:30pm (EST)

Sue Jacobs, principal consultant at QMS Consulting Inc., will assist in developing and implementing a compliant and effective CAPA system in this *Medical Device Daily* audio conference. She will delve into processes and work operations, and will get into an 8-step workflow for executing the CAPA process from start to finish.

New Drug Exclusivity Provisions: How They'll Impact Your Product Lifecycle Management (T09529)

Tuesday, January 13, 2009 - 1pm to 2:30pm (EST)

In a new *BioWorld Today* audio conference, attorney Kurt Karst taps into new exclusivity provisions and the changing landscape concerning patent and non-patent market exclusivities. He will also analyze product portfolios to optimize product lifecycle management opportunities.

Design Control: Ensuring Compliance During Device Development (T09530)

Thursday, January 15, 2009 - 1:00 to 2:30pm (EST)

This new *Medical Device Daily* audio conference introduces former FDA investigator, Dennis Moore. He offers a thorough view of the design control process and discusses risk management during development. He also better defines design plans and contract manufacturer roles and responsibilities, including key differences between ISO 13485:2003 and the QS Reg.

Drug and Device Licensing: Formulate the Right Agreement (T09531)

Wednesday, January 21, 2009 - 1pm to 2:30pm (EST)

Consultant Alan Schechter will guide you through the maze of licensing options, identify the common pitfalls in developing licensing agreements, and provide strategies for making sound licensing decisions in the regulated environment. This audio conference is brought to you by *BioWorld Today* and *Medical Device Daily*.

90 Days Until Destruction: How to Release an FDA Import Hold (T09532)

Wednesday, January 28, 2009 - 1pm to 2:30pm (EST)

In this *BioWorld Today* and *Medical Device Daily* audio conference, attorneys Deborah Shelton and Philip Gallas and customs broker Joy Peterson explain what companies must do to get a hold lifted, and provide strategies for managing the communication process with the FDA and Customs.

New HHS and FDA: How Will It Affect Pharma? (T09533)

Thursday, January 29, 2009 - 2pm to 2:45pm (EST) ****AUDIO BRIEFING****

This *BioWorld Today* audio briefing will provide insider insight into how your work could change in the coming months and what current FDA priorities are likely to change. Former FDA deputy associate commissioner for regulatory operations Steve Niedelman and attorney Cathy Burgess are the guest speakers.

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