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RHM market to see big growth, as well as adoption roadblocks

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Remote health management (RHM) is the fastest growing segment of a burgeoning home health management market, according to a market review released this week by **Scientia Advisors** (Cambridge, Massachusetts), a global strategy consulting firm. But the RHM segment's full potential will not materialize unless health insurers adopt reimbursement practices that encourage greater physician adoption, the firm concluded.

Harry Glorikian, a managing partner at Scientia, spoke candidly with *Medical Device Daily* Thursday about some of the more surprising findings in the review, and ways this segment might overcome the adoption roadblocks in its path.

Reimbursement is to healthcare – and in this case, RHM

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VBAS touted as a major change for neurosurgical retraction tech

By OMAR FORD
***Medical Device Daily* Staff Writer**

Eighty years seems like a lifetime, and that's about how long it's been since there have been any changes to neurosurgical retraction technology, according to **Vycor Medical** (Bohemia, New York). The company recently broke this long standing record and reported that it launched its ViewSite Brain Access System (VBAS), a less-invasive way to access surgical locations and preform critical procedures with minimal damage to surrounding tissue.

The devices used in brain surgery now have been in existence for nearly 87 years. These metal retractors, which, according to Vycor resemble "metal nail files," are used by neurosurgeons to move brain tissue to enable access to the target lesions and tumors.

The tools have their drawbacks, such as brain tissue

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International report

Accuray reports establishment of direct sale force in India

A *Medical Device Daily* Staff Report

Accuray (Sunnyvale, California), a developer of radio surgery products, reported that the company has established a direct sales presence in India. The recently established sales, marketing and service organization demonstrates the company's focus on this burgeoning market and expanding patient access to CyberKnife radio surgery.

India, the second most populous nation in the world, has a rapidly aging population with life expectancy rates that have increased to almost 70 years as of 2009. More than 850,000 new cancer cases are diagnosed every year and it is estimated that healthcare expenditures will increase from the current 7% to 13% in the next 10 years.

Presently there are two CyberKnife systems installed

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AGA Medical gets IDE for cardiac plug designedto prevent stroke

By LYNN YOFFEE
***Medical Device Daily* Staff Writer**

The abnormal heart rhythm known as atrial fibrillation (AF) carries a high risk of stroke, which is why many AF patients are put on a lifelong regimen of warfarin (Coumadin). But the side effects of this blood-thinning drug, mainly bleeding, can be dangerous. **AGA Medical Holdings** (Minneapolis) has introduced a new technology, the Amplatzer Cardiac Plug (ACP), that would fix the problem and eliminate the need for warfarin.

The percutaneous transcatheter device is intended to prevent thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation. The ACP has just received a conditional investigational device exemption (IDE) approval from the FDA to evaluate the safety and efficacy of the device when

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Don't miss today's MDD Extra: Diagnostics

INSIDE:

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Washington roundup

Brazil to expand enforcement of device GMPs in May

A *Medical Device Daily* Staff Report

As the markets for diagnostics and therapeutic devices expand, so do the regulatory regimes, and Brazil has just announced that it will soon expand the number of devices and diagnostics that are subject to good manufacturing practices requirements. According to an alert published by the **Emergo Group** (Austin), a regulatory consultancy, Brazil's health surveillance agency, ANVISA, will start enforcing good manufacturing practice (GMP) requirements for a subset of class I and II devices in addition to all class all III and IV devices on May 22. ANVISA is said to be prepared to apply those standards to class II, III and IIIa diagnostics as well on that date.

The requirements are nothing new for firms that are already registered with ANVISA, but companies that are new to the market may find that Brazil's approach has little in common with ISO standards, although they bear some resemblance to FDA's GMP approach. Applicant firms are advised that the required inspection of their facilities by Brazilian authorities may require 60 days or more to schedule.

Getting past the GMP requirements may prove easier than getting past Brazil's heavy tariff structure. According to a 2008 document published by the U.S. Trade Administration, imports were at the time subject to a variety of tariffs and taxes, including a common tariff of as much as 20% imposed by members of **Mercosur** (Common Market of the South) on non-member nations. Brazil's national products tax was as high as 15% in 2008, while a value-added tax imposed by any of Brazil's 25 states can add 7%-25% to the tax load. A web search suggests all three are still in play.

Mercosur does not appear to be an impenetrable clamshell, however. According to an article at *Mercopress.com*, Israel recently became the first non-Mercosur nation to achieve a free-trade agreement with the Mercosur block, which went into effect with Paraguay yesterday. The agreement will be in force with the remaining Mercosur nations as of April 1.

The Emergo Group notice states that the Brazilian code dealing with GMPs, RDC 59/2000, covers a fairly typical list of requirements, including purchasing controls, corrective action, and packaging and labeling controls. The Google search engine provides a translation of RDC 59/2000 into English.

Today's MDD food for med-tech thought

"We believe that large-scale clinical trials, sponsored by government or manufacturers, could demonstrate the value of wider spread remote health monitoring to payers, who in turn would change their reimbursement practices."

— Harry Glorikian, a managing partner at Scientia Advisers, discussing a logical way to insure more rapid adoption of remote healthcare monitoring by practitioners, "RHM market to see big growth, as well as adoption roadblocks" pp. 1, 4,8

AdvaMed says publish 510(k) summaries

The **Advanced Medical Technology Association** (AdvaMed; Washington) has published its recommendations to FDA regarding the 510(k) program, including that the agency should make public the decision summaries filed by reviewers for 510(k) applications.

AdvaMed's March 22 statement notes that the decision summaries, which are currently published for *in vitro* diagnostics only, "would provide interested parties with meaningful information about the subject of the submission and the predicate device." The issue of lost details regarding

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EDITORIAL
Holland Johnson, **(404) 262-5540**
Amanda Pedersen, **(229) 471-4212**
Omar Ford, **(404) 262-5546**
Lynn Yoffee, **(770) 361-4789**
Mark McCarty, **(703) 268-5690**

SVP/GROUP PUBLISHER
Donald R. Johnston,
(404) 262-5439

INTERNET
www.medicaldevicedaily.com

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Deals roundup

Steward buys Caritas Christi; CryoLife nixes Medafor deal

A *Medical Device Daily* Staff Report

Caritas Christi Health Care (Boston) said it has agreed to be acquired by **Steward Healthcare System** (Euless, Texas), a newly formed affiliate of private investment firm **Cerberus Capital Management** (New York).

The deal is subject to customary closing conditions, including approvals from the Massachusetts Attorney General and the Massachusetts Department of Public Health, as well as the approval of the Archbishop of Boston, the companies noted.

Caritas stands to get roughly $830 million of capital support, including the assumption of all pension obligations, the repayment of all outstanding debt, and a significant capital investment to fund operations. The deal also brings a commitment to about $400 million of capital projects, the companies said.

President/CEO Ralph de la Torre will continue to lead Caritas Christi, along with its current management team, and the company's headquarters will remain in Boston.

Six Caritas Christi hospitals will retain their Catholic identities, and their existing policies on charitable and pastoral care, community benefits, and approach to labor relations from a social justice perspective, the organization noted.

The system also said that the acquisition and the conversion of Caritas Christi to a taxable entity, upon approval, are expected to generate significant state and local tax revenues. The process for obtaining the necessary approvals will begin immediately, the company said.

In other dealmaking activity, **CryoLife** (Kennesaw, Georgia) said it has withdrawn its $2 a share proposal to acquire **Medafor** (Minneapolis).

CryoLife said it previously notified Medafor of its intention to withdraw its offer. Medafor recently reported sending a letter to CryoLife threatening litigation over a distribution agreement breach (*Medical Device Daily*, March 22, 2010).

Prior to that letter, CryoLife reported sending a letter to Medafor's board urging the company to negotiate an acquisition deal (*MDD*, Feb. 9, 2010).

That was after CryoLife bought about 740,000 additional shares of Medafor's common stock for $2 a share, giving the company roughly 11% ownership of Medafor and making it the company's largest shareholder. CryoLife then proposed acquiring the rest of Medafor's outstanding common stock for $2 a share in a combination of cash and CryoLife stock (*MDD*, Feb. 4, 2010). ■

Financings roundup

iTech Medical enters into funding agreement with investor for $2.2M

A *Medical Device Daily* Staff report

iTech Medical (Huntington Beach, California) a medical information technology company, reported that it has entered into a financing agreement with a European investor for $2.2 million of equity financing throughout the next 12 months. The investor has the option to provide another $1 million of equity financing during the following six months. The company intends to use the proceeds for working capital and to complete the clinical and regulatory work on its proprietary Muscle Pattern Recognition (MPR) System and introduce the MPR System in North America and Europe, anticipated to be in the fall of 2010.

Under the financing agreement, the investor has agreed to purchase, on a monthly basis through March 2011, a total of 4 million shares of common stock for 30 cents per share and a total of two million shares of common stock for 50 cents per share. In connection with those purchases, the investor will receive warrants to purchase a total of 6 million shares of common stock at prices ranging from 40 cents per share to 80 cents per share, expiring between Aug. 31, 2013, and Feb. 28, 2014. Pursuant to the financing agreement, the investor may elect to pay the purchase price for the shares of common stock in either U.S. dollars or euros. These purchase prices were based on the U.S. dollar/euro exchange rate on Dec. 5, 2009. This release reflects the purchase obligation in U.S. dollars.

In addition, for a 60-day period, commencing upon the date the company files with the FDA its 510(k) application covering its MPR technology, the investor will have right to elect to provide an additional $1 million of equity financing through the purchase of common stock at 50 cents per share throughout a six-month period. In connection with those purchases, the investor will receive warrants to purchase a total of 4 million shares of common stock at prices ranging from 40 cents per share to 80 cents per share, expiring Oct. 31, 2014.

In other financings news; **Venn Life Sciences** (Dublin, Ohio) has just completed a significant funding round of more than $3 million, to enable it to further accelerate the growth of its business.

Venn Life Sciences provides clinical trial services to companies in the pharmaceutical, biotechnology and medical device sectors.

Reflecting solid growth achieved by the company throughout the last two years this financing round was sourced from a select group of private investors with significant expertise and experience in facilitating rapidly growing companies in the Life Sciences arena.

Venn Life Sciences expansion strategy centers on growth through acquisitions, organic growth and preferred partner selection. ■

Scientia

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adoption – what location is to real estate sales. Instead of "location, location, location," the mantra in healthcare seems to be "reimbursement, reimbursement, reimbursement," Glorikian said.

He explained that when doctors treat patients they are doing both their job and their passion. "Doctors don't often admit it," Glorikian said, but they're often doing their "job first and passion second." In other words, "if they don't get paid to perform a particular service, they aren't particularly motivated to do so."

So, if a doctor is paid for office visits, but they are not paid to call patients on the phone, they are going to continue seeing patients in the office rather than adopt remote healthcare monitoring services.

The trick, according to Glorikian, is to promote a shift towards outcomes-based reimbursement. In such a scenario, doctors would be given responsibility of their patient's health, not just the service they provide, he said.

In its review of this industry, Scientia found that the global home health management (HHM) market is expanding at a compound annual growth rate (CAGR) of 10% through 2012.

"This growth is driven in part by strains in the healthcare system, high healthcare costs, insufficient personnel and an aging population with chronic conditions that, in many cases, can be most cost effectively monitored or treated at home," Glorikian said.

According to the report, home health agencies – organizations that provide skilled nursing and other therapeutic services in patients' homes – account for 80% of the HHM market. However, RHM – with a 14% market share – is the smallest, but fastest growing segment. Scientia projects that RHM will double from $1.8 billion in 2007 to $3.6 billion in 2012, representing a CAGR of 15%.

Since 2007, other home health segments, including point-of-care diagnostics, infusion and respiratory therapy services, drug delivery, durable medical equipment, and supplies, have exhibited CAGRs ranging from 7% to 10%, Scientia noted.

One finding that did surprise the firm, Glorikian told *MDD*, is the low level of RHM adoption among home health agencies. "We thought that home health agencies [would have] a much higher level of adoption of remote health management because we see it as a good fit," he said, explaining that reimbursement for such agencies is already beginning to be linked to patient outcomes.

It makes sense for home health agencies to keep people out of the hospital because their reimbursement rate goes down when the patient is readmitted to the hospital within 60 days of discharge, Glorikian said. If such agencies had "a different way of keeping on top of everything it would be a much better way for them to make money," he said.

RHM includes telehealth services and remote patient monitoring (RPM) products. Telehealth involves the use of telecommunications technologies to support long-distance clinical health management, education, coaching, and assessment. RPM products refer to the tools patients themselves use to collect medical data (such as blood pressure or glucose level) that is electronically transmitted to nurses and doctors, who determine if further action is required.

"Daily patient self-monitoring and centralized data analysis increase the effectiveness of preventive care, lessen strain created by personnel shortages, allow healthcare professionals to attend to more patients than they otherwise might, and control rising healthcare costs by helping reduce hospital readmissions," Glorikian said.

When thinking about remote health management, the Big Brother theory tends to come to mind – but unlike in George Orwell's *Nighteen Eighty-Four* novel, this isn't necessarily a bad thing.

"Remote health helps patients be vigilant in managing their disease," Glorikian said, explaining that when people know somebody is watching, their behavior tends to be different. "This act of monitoring also seems to encourage better behavior as patients see positive or negative results," he said. "Like an automated feedback loop; patients who really watch their diabetes number are much more vigilant about [managing their blood sugar level]."

The problem, of course, comes down to cost. If a small firm needed to buy 50 remote monitors at $1,000 a pop, that would add up to a lot of money, Glorikian said. Perhaps a solution would be to rent the equipment to home health agencies, he suggested. Or bundle the rent costs with ongoing service fees. "Tie the RHM payments to income stream of the home health agency and kind of spur adoption," he said.

Not surprisingly, major electronics and computer companies such as **Intel** (Santa Clara, California), **IBM** (Armonk, New York), **Motorola** (Schaumburg, Illinois) and **Philips** (Amsterdam, the Netherlands) are partnering with or acquiring companies to produce products for remote health management (see Sidebar, p. 8).

"Besides reimbursement, lesser hurdles are broadband connectivity," Glorikian said. "Some of these systems are going to require more data, or more information, to go back and forth, and – I hate to say it – but a phone line might do it."

He also noted there are some technology standardization concerns that could stand in the way of full RHM adoption.

"We're also seeing a flurry of product, which makes selecting the platform for the buyer a big decision," Glorikian said.

Those who attended this year's **Healthcare Information and Management Systems Society** (HIMSS; Chicago) meeting in Atlanta earlier this month can attest to the vast choices available in this sector. HIMSS attendees were dazzled with healthcare IT products – remote patient monitoring and electronic health record products in particular – available, literally, in the palm of

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Vycor

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potentially causing injury or target shift, which can limit a neurosurgeon's visualization.

As a result of this, neurosurgeons have opted to forego using blade retractors during craniotiomies whenever possible. And in other cases, just the opposite happens, and surgeons are forced to use two or three retractors during the removal of deep subcortical tumors.

"Sometimes the surgeon has to use several of the metal retractors to perform the surgery," Heather Vinas, Vycor's president told *Medical Device Daily*. "And [the surgeon] still needs to have a clear channel working."

She added that a clear view can be difficult to obtain with so many tools being used at once.

But Vycor's VBAS is said to produce less tissue trauma and allow surgeons to see the surrounding tissue during the procedure and require less retractor repositioning. The device, which resembles a glass cone has been said to lead to a speedier recovery and increase the precision of treatment, while at the same time significantly lowering the cost.

One of the reasons VBAS can cut costs is because of the material used to make the device.

"These devices are disposable and made from a polycarbon resin," Vinas said.

The company also said that it has an advantage in the market that other device makers don't have: the cost of its offering can be bundled as part of a procedure and will not require a separate reimbursement decision.

VBAS, which has been touted as a simple common sense solution to a complex surgery, was conceptualized back in 2005, according to Vinas.

"It was a concept that was sketched out to me on a napkin and has since transformed into a viable commercial product," she said.

The company first received FDA approval for VBAS in 2006, but didn't launch the device until 2009.

Vinas said that the company waited three years for the launch so it could ultimately have greater control in the commercialization and the development of the device.

"We wanted to have all of our ducks in a row," Vinas told *MDD*. "We didn't want to dump this onto big manufacturers and lose control of the commercial aspect of the device."

Vycor also obtained approval by Health Canada in 2008 and a CE mark last year.

According to the company, the tool comes in 12 different sizes (allowing for differing shapes and sizes of the human head) and each system consists of an introducer and a working channel port that allows the surgeon an easy entry to the targeted site while distributing brain tissue evenly.

Most recently the company said that it has started the process of registering its ViewSite brain access system with China's State Food and Drug Administration (*Medical Device Daily*, March 18, 2010).

And Vinas said that there are even more plans underway for VBAS as the company plans to gain 70% market share with the device.

"The scope of VBAS has changed since that initial napkin sketch back in 2005, " Vinas said. "It's now a 12-device brain access system with more products, based off the platform, to come." ■

Omar Ford, 404-262-5546;
omar.ford@ahcmedia.com

Washington

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510(k) device submissions emerged during the agency's meeting on the topic last month (*Medical Device Daily*, Feb. 19, 2010), with Heather Rosecrans, director of the 510(k) program, stating that records of existing and legacy 510(k)s are often unavailable for a variety of reasons.

AdvaMed also recommends that FDA publish a guidance on the contents of a 510(k) summary as well as a template for such summaries, adding that a similar process for *de novo* applications would help.

AdvaMed closed the statement by remarking that while the association supports the reviews of the 510(k) program by FDA and the Institute of Medicine, the industry would like to see FDA offer evidence "that any proposed [fundamental] changes are warranted" in the interest of avoiding "a premature response to popular public or media misperceptions."

Senate passes healthcare reconciliation

The U.S. Senate yesterday passed by a vote of 56-43 the healthcare reconciliation package drafted by the House of Representatives amid threats purported to have been made against the Senate parliamentarian, Alan Frumin. The Capitol Police had released no details regarding the threats at press time yesterday, but had advised members of the Senate to "remain vigilant."

The reconciliation bill, H.R. 4872, managed to win passage in the House on Sunday despite token bipartisan opposition (*MDD*, March 23, 2010), and will impose a tax on device makers of 2.9%. Also included in the bill is an instruction to the Centers for Medicare & Medicaid Services to calculate reimbursement rates for imaging and radiotherapy providers based on the assumption that these clinics are busy 75% of the workweek. The previous standard, 50%, has come under scrutiny by a number of parties, including the Government Accountability Office and the Medicare Payment Advisory Commission, but the 75% set point has sparked opposition by provider groups. The Senate vote of 56-43 again indicates some bipartisan opposition to the bill.

Because the Senate imposed two changes to the bill dealing with provisions for federal student loan programs, the amended bill must get through the House again, an action that was scheduled for last night.

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International

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in India; the first at **Apollo Specialty Hospital** (Chenai), which went live in March 2009, and the second at H**ealth Care Global** (HCG; Bangalore), which went live in June 2009. While these systems were sold through an external distribution channel, the recently established internal organization will enable local Accuray personnel to sell directly within the country.

"We recognize the needs of this important market and have chosen to make a special investment in dedicated local resources to increase the availability of innovative cancer care for its people," said Euan Thomson PhD, Accuray's president/CEO.

"The CyberKnife offers patients a non-surgical treatment alternative, which is imperative for our large elderly population, of whom many are not candidates for other forms of therapy," said B. S. Ajai Kumar, MD, director CyberKnife Center and chairman HCG, Bangalore.

Oridion, Masimo sign distribution agreement

Oridion (Jerusalem), creator of Smart Capnography, and **Masimo** (Irvine, California), the inventor of Pulse CO-Oximetry and Measure-Through Motion and Low Perfusion pulse oximetry, reported a distribution agreement naming Masimo as a non-exclusive distributor for the Oridion Capnostream 20 portable bedside capnography monitors throughout the U.S., Canada, and Europe.

This distribution agreement further enhances last year's agreement between Masimo and Oridion which established connectivity between the Capnostream 20 bedside monitors and the Masimo Patient SafetyNet remote monitoring and clinician notification system. By making the Capnostream 20 available as part of Masimo's general floor monitoring solutions, Masimo Patient SafetyNet is the first remote monitoring and clinician notification system to feature Oridion's newest Smart Capnography innovation – the Integrated Pulmonary Index (IPI) – enabling real-time tracking and trending of Oridion etCO2 and respiration rate in combination with Masimo SET SpO2 and pulse rate, for a comprehensive assessment of the patient's oxygenation and ventilatory status.

NexMed inks Japanese marketing accord

NexMed (San Diego) reported that its wholly-owned subsidiary, **Bio-Quant** has signed a distribution agreement with **Cosmo Bio**(Tokyo) under which Cosmo Bio will market Bio-Quant's discovery and pre-clinical contract research services throughout Japan.

Cosmo Bio is a distributor of life sciences products and services to academic researchers, biotechnology and pharmaceutical companies, specializing in oncology, inflammation, immunology and metabolic diseases.

"The distribution agreement provides us with a formal presence in Japan, where we have already established an initial foothold with a number of leading Japanese pharmaceutical companies," said Bassam Damaj, PhD, CEO of NexMed. ■

Washington

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FDA announces surveillance workshop

FDA has announced that it will hold a workshop regarding its device surveillance collaboration with academe, the Medical Device Epidemiology Network, or MDEpinet. According to the March 25 FDA statement, the intent of the workshop is "to facilitate discussion among FDA and academic researchers with expertise in epidemiology and health services research on issues related to the methodology for studying medical device performance."

The workshop will take place April 30 at the agency's new White Oak campus in Silver Spring, Maryland, and is expected to run from 8:00 a.m. to 5:00 p.m. The agency says that it intends to "reach out to academic centers that have epidemiologic, statistical, and clinically relevant expertise to establish a network" for the purpose of "determin[ing] the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of medical devices," which the agency indicates will include comparative effectiveness studies. Participating entities are expected to participate in other workshops dealing with "methods for medical device comparative analyses, best practices and best design and analysis methods."

The agency's White Oak campus presents two security checkpoints, one in the parking lot and another inside the main entrance, and the statement urges participants "to arrive early to ensure time for parking and security screening," which will commence an hour before the meeting starts. On-site registration and check-in will begin at 7:30. Those who wish to register ahead of time can e-mail Kristen.VanDole@fda.hhs.gov. ■

AGA

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used to close the left atrial appendage.

"The reason you potentially want the left atrial appendage closed is, if you're a patient with atrial fibrillation, the left atrial appendage remodels and gets thicker. There are lots of nooks and crannies – hiding places where clots have been shown to form. Those clots are associated with 90% of strokes. If you close it off and seal it, then you no longer have a place for clots to form and hide," Rachel Ellingson, senior director of AGA's business development, told *Medical Device Daily*.

The company is sponsoring a trial designed to demonstrate efficacy in preventing stroke in AF patients who are eligible to receive warfarin, as well as safety of the device and the procedure. The multicenter trial will include a two-to-one randomization between the ACP and medical management with warfarin, which is the current standard of care.

"Warfarin is a tough drug to tolerate," Ellingson said. "Many patients just can't tolerate it and it has a very narrow therapeutic window. If you take too much, you risk bleeding. If you take too little, there's not enough benefit."

President/CEO John Barr said, "Stroke can be a debilitating condition, and is a significant concern to the approximately 4.5 million people in the U.S. and Europe suffering from atrial fibrillation. Approval of this study will now allow us to further evaluate our approach to reducing strokes in patients with atrial fibrillation by using our ACP to permanently seal the appendage, hopefully sparing patients from spending the rest of their lives on anticoagulants."

Ellingson said the company has not yet disclosed study locations or the principal investigators. But she expects to have the first 400 patients enrolled sometime during the second half of 2010. An interim analysis will be performed after the first 400 patients are enrolled and at pre-determined periodic intervals thereafter, until a possible maximum of 2,000 patients are enrolled. These interval analyses will determine when the trial has achieved its endpoints and if AGA is able to conclude the trial prior to enrolling 2,000 patients.

The trial design will include a feasibility phase to be followed by a pivotal phase. The results of the feasibility phase, which consists of the first 30 patients to receive the ACP, will serve to further validate safety conclusions demonstrated through preclinical testing. These patients will be followed for 45 days after the procedure and evaluated for adverse events. The 45-day feasibility data will be reviewed by an independent data safety monitoring board prior to FDA review. Additional subjects will be enrolled in the pivotal phase of the trial after the FDA has completed its review.

The only other cardiac plug being developed in the U.S. is **Atritech's** (Plymouth, Minnesota) experimental Watchman. An FDA panel narrowly backed the device last spring, but the agency has since asked for a confirmatory trial to substantiate the effectiveness.

AGA is used to being a pioneer. In fact, last year, the company competed an initial public offering, raising $199.4 million, one of the few to succeed in the dismal market (*MDD*, Oct. 22 2009).

"We were the only medical device company to do an IPO last year," Ellingson said. "I think we truly view it as a significant testament to our company to go public when no other company could."

The ACP received European CE mark approval in December 2008, and is currently sold in Europe, South America and parts of the Pacific Rim. ■

Lynn Yoffee; 770-361-4789;
lynn.yoffee@ahcpub.com

Med-Tech Notes

SpectraScience facility remains in compliance

SpectraScience (San Diego) said that the FDA has conducted an unannounced inspection of its facility. No Form 483 was issued and the company remains in compliance with all regulations.

Jim Hitchin, the company's CEO said, "The inspection is part of an ongoing review of our Class III facility where we manufacture our patented and proprietary WavSTAT Optical Biopsy System and LUMA Cervical Imaging System. Both systems are used by physicians as an adjunctive tool to assist in determining if tissue is normal, pre-cancerous, or cancerous within seconds.

"This is our second unannounced inspection in two years. No adverse observations were made in either visit. I believe this is an excellent indicator of the quality system we have developed and the standards we hold ourselves to in manufacturing our products."

Ingenix teams up with QualityMetric

Ingenix (Eden Prairie, Minnesota), a health information, technology, consulting and services company, said that it has expanded its health outcomes measurement capabilities with the acquisition of QualityMetric. QualityMetric assists health care companies assess health outcomes as reported by patients themselves, known as patient-reported outcomes.

Patient-reported outcomes (PROs) are an important measure of the ultimate effectiveness of healthcare. QualityMetric provides general and disease-specific health surveys for measuring patients' own assessments of their health. QualityMetric's health surveys have been used in thousands of clinical trials since 1997 and cited in more than 14,000 peer-reviewed articles. therapies.

RHM market opens door for big IT names

Not that long ago it might have seemed strange to see company names like **IBM** (Armonk, New York), **Intel** (Santa Clara, California), **Motorola** (Schaumburg, Illinois), and **Microsoft** (Redmond, Washington) making headlines in *Medical Device Daily*. After all – these companies might be giants in their own industry, but what do they have to do with healthcare?

But in recent years these and other IT companies have become regulars on the pages of *MDD*.

The recent market review on the remote health monitoring (RHM) segment from **Scientia Advisors** (Cambridge, Massachusetts) highlights the healthcare opportunity these technology companies are trying to seize. According to Scientia, RHM is the fastest growing segment of the home health management market, and is projected to double from $1.8 billion in 2007 to $3.6 billion in 2012 – representing a compound annual growth rate of 15%.

So it is no wonder that companies like IBM, Intel, Motorola, Microsoft, and others, are "waking up and saying, 'hold on, we know electronics . . . sensors, we know that too. This is our right to play," Harry Glorikian, a managing partner at Scientia, told *MDD.*

And the expertise from these IT companies certainly seem to play a valuable role in transforming healthcare delivery.

In the Cleveland Clinic-Microsoft pilot project, which was reported on earlier this month (*MDD*, March 9, 2010), participants used at-home heart rate monitors, glucometers, scales, pedometers or blood pressure monitors, depending on their disease. These devices uploaded the patient's data to Microsoft's HealthVault – a security-enhanced, Web-based data storage platform for patients – which then connected to the patient's personal health record at the Cleveland Clinic, MyChart, by **Epic Systems** (Verona, Wisconsin) and the EMR system used by the patient's healthcare providers at the hospital, MyPractice, also by Epic.

In October, IBM CEO Sam Palmisano wowed attendees at the Cleveland Clinic Medical Innovation Summit when he told them why the U.S. healthcare system isn't a "system" at all and explained why the time has come for a smarter healthcare system (*MDD*, Oct. 7, 2009).

"At IBM this is something we know quite a bit about; we know about systems," Palmisano said. He outlined four essential qualities any system must have to be well-functioning: first, there must be clarity on the system's purpose or goal; second, its elements must be connected – interfaces matter; third, we must be able to know, continually and with confidence, the status of the system and its critical components; and last, the system must be able to adapt as conditions change.

According to Palmisano, the world is becoming smarter, more instrumented, and more interconnected. He pointed out that the UPC was originally developed to help supermarkets improve checkout speed. We now know, he said, that the invention of the UPC "did much more than improve checkout speed." He said it also "streamlined global supply chains." Many of the Cleveland Clinic attendees who listened to Palmisano's speech walked away asking themselves if the electronic medical record could be for the healthcare industry what barcodes were for the retail industry.

- Amanda Pedersen

Scientia

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their customers' hand via an **Apple** (Cupertino, California) iPhone or similar mobile device (*Medical Device Daily*, March 3 - March 10, 2010).

Another roadblock standing in the way of full RHM adoption, Glorikian noted, is clinical data.

"The most convincing data is on small scale populations or on specific [disease areas]," Glorikian said. "The data can't be applied on a broader scale."

For example, he said, if someone ran a study demonstrating that patients in the south benefit from remote healthcare management it won't convince providers and payers in other geographies that RHM services will benefit their patients. A small study is much less convincing than a large, properly controlled trial, Glorikian said. But of course cost, capability, and risk are the key reasons a larger trial has not yet been conducted.

Such data may not be that far off, though. Earlier this month the **Cleveland Clinic** (Cleveland)and **Microsoft** (Redmond, Washington) reported that the use of at-home medical devices to connect doctors and patients via the Internet can help patients and their physicians work more efficiently together to manage chronic conditions. The two organizations collaborated on a pilot project in December 2008 that pairs the hospital's electronic medical records system with the software company's online HealthVault service to monitor patients' health conditions. More than 250 participants enrolled – 26% with diabetes, 6% with heart failure and 68% with hypertension – making it the first physician-driven pilot project in the country to follow multiple chronic diseases in a clinical setting, according to the hospital (*MDD*, March 9, 2010).

"While remote monitoring presents great opportunities for improving healthcare and cutting costs, RHM will not realize its full potential unless it is adopted by practitioners," Glorikian said. "We believe that large-scale clinical trials, sponsored by government or manufacturers, could demonstrate the value of wider spread remote health monitoring to payers, who in turn would change their reimbursement practices." ■

Amanda Pedersen, 229-471-4212;
amanda.pedersen@ahcmedia.com

Product Briefs

• **BioImagene** (Washington) has introduced the iScan Coreo Au digital slide scanner and the newest version of Virtuoso software. The iScan Coreo Au is a high-speed scanner that enables digital pathology applications such as image analysis, telepathology, remote microscopy, and education. The iScan Coreo Au allows walk-away scanning of up to 160 slides, and includes several other features including an automated turret with multiple objectives, volume scan (z-stacked) images with multiple planes, and iScan Coreo Au Live, an application supporting remote microscopy and collaboration. The Virtuoso uses web technology and offers users Companion Algorithms for a complete breast, prostate, and colon panel. Some of the unique features in Virtuoso include work-list management, real-time collaboration between users, and the fastest viewing experience.

• **IMDx** (Cambridge, Massachusetts) said that its IMDx 2009 influenza A H1N1 real-time RT-PCR assay has been granted Emergency Use Authorization (EUA) from the FDA. The test, which is authorized for use on multiple instrument platforms (the Applied Biosystems 7500, the 7500 FAST real-time PCR systems, and the 7500 Fast Dx Real-Time PCR Instrument) by CLIA High Complexity Laboratories to detect and differentiate 2009 Influenza A H1N1, uses a single test format and produces results in ninety minutes.

• **Masimo** (Irvine, California) said that a new clinical study presented at the IARS Annual Meeting in Honolulu, Hawaii, demonstrates that noninvasive and continuous hemoglobin (SpHb) from Masimo Rainbow SET Pulse CO-Oximetry provides comparable accuracy as point-of-care invasive measurements of total hemoglobin versus standard laboratory invasive measurements of total hemoglobin. The study confirms that SpHb is accurate, reliable, and a clinically-acceptable alternative for monitoring hemoglobin, and is the first SpHb study presented in pediatric patients. SpHb is available as part of Masimo Rainbow SET Pulse CO-Oximetry – a technology platform to noninvasively measure blood constituents and fluid responsiveness that previously required invasive procedures, including: total hemoglobin (SpHb), oxygen content (SpOC), carboxyhemoglobin (SpCO), methemoglobin (SpMet), PVI, and acoustic respiration rate (RRa). Masimo claims that SpHb and PVI have been shown in multiple clinical studies to provide accurate, reliable, real-time measurements that help clinicians to proactively monitor and manage hemoglobin and fluid volume levels more appropriately and optimally.

• **PreXion** (San Mateo, California) said that it has launched the PreXion3D Volumetric Imaging Software for its 3-D cone beam computed tomography system for dentistry. This new product uses a range of advanced features including tools for implant planning and placement and an enhanced version of its PrexViewer software. The PreXion3D software incorporates and is totally integrated with new implant planning tools that allow clinicians to immediately and easily locate and mark the mandibular canal, nerves and place virtual implants immediately showing up in the 3-D, axial, coronal and sagital views, visualizing patient's anatomy with accuracy and precision. This is done chair-side with the patient within moments of completing the 3-D CBCT scan and enhances patient consultations and treatment acceptance. Once the treatment planning has been completed, this work can be saved and referred to at a later date.

• **TriVascular** (Santa Rosa, California) reported the first European clinical study implants of its Ovation Abdominal Stent Graft. The graft system is designed to expand the patient population suitable for endovascular aortic repair (EVAR) by addressing a wider range of diseased anatomy. "The Ovation Abdominal Stent Graft performed exceptionally well," said Thomas Nolte, MD, the principal investigator for the European study. "The clinical benefits of the reduced profile and unique sealing technology were evident immediately. I believe this offering will expand the pool of patients to whom I can offer an endovascular solution."

• **VisEn Medical** (Bedford, Massachusetts) reported the launch of its new GastroSense 750 fluorescence agent for imaging gastric motility and related drug effects *in vivo*. Gastric motility, or the rate of nutrient transport through the gastrointestinal tract, is an established measure of overall gastric health, specific gastric disorders, and general physiologic health related to toxicity profiles of systemic drugs. The GastroSense 750 fluorescence imaging agent is designed to enable real time quantitative measurements of gastric motility in animal models, thereby enabling rapid and effective assessment of a wide variety of related diseases and drug effects in preclinical research and drug development.

People in the News

• Former U.S. Congressman Kweisi Mfume was named president of the **National Medical Association** (Washington). Most recently, Mfume spent nine years as CEO of the National Association for the Advancement of Colored People (NAACP). Mfume is a frequent lecturer and serves on the boards of several organizations, including the Boy Scouts of America National Advisory Council, Johns Hopkins University Board of Trustees, Morgan State University Board of Regents and Big Brothers and Big Sisters. The National Medical Association is a national professional and scientific organization committed to improving the quality of health among minorities and disadvantaged people through its membership, professional development, community health education, advocacy, research and partnership with federal and private agencies.

MDD's Diagnostic Extra

Additional Developments in One of Med-Tech's Key Sectors

Friday, March 26, 2010

Keeping you up to date on recent developments in diagnostics

Scientists move toward glaucoma detection test . . . Scientists are reporting progress toward a test that could revolutionize the diagnosis of glaucoma – the second leading cause of vision loss and blindness worldwide - by detecting the disease years earlier than usually happens at present. They reported the findings at the 239th National Meeting of the **American Chemical Society** (ACS; Washington). "We are confident that we're moving toward a breakthrough that will allow us to detect glaucoma at its earliest stage," said Chenxu Yu, PhD, who headed the study. "We hope it will benefit millions of glaucoma patients and individuals at risk for this devastating eye disease worldwide." Doctors now use two main techniques to detect the disease. One test is tonometry, which measures eye pressure by gently touching a special instrument to the outer surface of the eye. The other is ophthalmoscopy, in which an eye specialist uses an instrument called an ophthalmoscope to look directly through the pupil of the eye at the optic nerve. The nerve's color and appearance can indicate the presence of damage from glaucoma. "All too often, these tests detect glaucoma after the disease has been silently causing damage to the optic nerve," Yu explained. "Years may pass between the first biological change associated with glaucoma inside the eye and diagnosis. We need ways of diagnosing glaucoma earlier, before permanent damage has occurred, so that patients can begin taking medication to control it." In their ACS report, Yu and colleagues described development and early testing of a potential new early diagnostic method. It gives a mainstay tool in chemistry labs – Raman spectroscopy – a potential new life in medicine. The technique as used in chemistry and other laboratories involves focusing a beam of infrared laser light – invisible to the human eye – into a test sample to get information about the sample's composition. Yu's method uses Raman spectroscopy to shine laser light through the pupil of the eye. Optic nerve cells (retinal ganglion cells) inside the eye scatter the light, producing a rainbow-like "spectrum" or pattern revealing the chemical composition of the cells. Scientists can then use that snapshot to identify biochemical changes in retinal cells that announce the presence of glaucoma.

ESC supports imaging testing . . . Following recent publications highlighting potential dangers of ionising radiation resulting from imaging testing, the **European Stroke Organization** (ESC; Heidelberg, Germany) said that it is important to voice support of the technology. "We want to reassure the public that for individual patients the benefits of receiving an accurate diagnosis are likely to far outweigh the small potential risks involved in having a scan," said Professor Juhani Knuuti, of the ESC Working Group on Nuclear Cardiology and Cardiac CT, from **Turku University Hospital** (Turku, Finland). "The most fundamental question that clinicians need to ask themselves is whether a test is appropriate for the individual patient, and whether that patient will derive benefit from it." It needs to be remembered, he added, that tests like CCTA are used to select patients for invasive procedures that themselves carry risks. "Any procedure is a balance of risks and benefits. What has been overlooked in recent publications is the risk of cardiovascular disease going untreated, which can even result in immediate sudden death. The potential risks of imaging tests are small relative to the diagnostic information obtained," said Knuuti. "We have real concerns that following the publicity around the papers, the public may avoid these tests out of fear and that authorities might create unjustified recommendations for imaging use. They need to appreciate that radiation is a single aspect of the risks involved, and that these are really useful tests for cardiologists. Everything needs to be considered in the wider context," said Knuuti.

Researchers develop test to measure blood flow in the brain . . . Thanks to new technology developed by researchers at **Lund University** (Lund, Sweden) it has for the first time become possible to measure blood flow in the brain directly and continuously. The technol-

ogy makes it easier for doctors to quickly identify the correct medication for patients affected by serious head injuries and stroke. It also makes it easier to investigate the physiology of the brain. Doctors have already discovered that the blood flow in the brain varies significantly more over time than previously thought. "In order to make diagnoses and quickly be able to see if the medication given is right for the brain, this information is very important in a neurointensive care unit. Today magnetic resonance imaging scans and other examinations are carried out, but these are expensive, unreliable, time-consuming and only provide information about blood flow at the time of the examination. With this method we not only get information about blood flow in the brain directly and continuously; the information can also be stored, which means that we can review previous care more easily," said Peter Reinstrup, a doctor at Skåne University Hospitals in Lund. This technology will also facilitate research. Research and development on head traumas and brain hemorrhages based on cerebral blood flow, CBF, has stalled, precisely because it has been so difficult to determine blood flow in the brain, which is measured in milliliters per 100 g of brain per minute. In normal cases the value is around 50. "If an individual suffers a head injury, e.g. after falling or receiving a knock on the head, the cerebral blood flow follows a course in which the flow varies with time. It is important for us to constantly regulate the flow so that it does not become too high, as the brain could then swell, or too low, as the brain could then suffer from a lack of oxygen," Reinstrup said. The technology came into existence as something of a happy coincidence and has been developed in collaboration between doctors, the hospital's medical technology department and Lund University's Faculty of Engineering.

Roche claims testosterone assay offers efficient, accurate results . . .

The new **Roche** (Basil, Switzerland) Elecsys Testosterone II Assay delivers enhanced accuracy against the Gold Standard ID-GC/MS methods for female samples (refl) (in the range of 0.025-l5 ng/ml). With greatly reduced matrix effect and DHEAS (Dehydroepiandrosterone Sulphate) interference compared to conventional assays, this new automated testosterone assay ensures accurate and reliable results, allowing clinicians to make better clinical decisions about the care of female patients. The improved performance of the Elecsys Testosterone II Assay is due to the use of a new high affinity testosterone monoclonal antibody. This antibody allows the assay to deliver optimized recovery of testosterone, even with female samples, and ensures excellent precision, especially at low concentration levels. It also reduces cross reactivity to DHEAS and susceptibility to matrix effect with female samples, which is a common problem with alternative assays (ref2). The Elecsys Testosterone II Assay demonstrated good correlation with LC-MS/MS for samples from male and female patients (ref3) and has also shown markedly improved accuracy in heamodialysis patients compared to first generation assays (ref4). First generation assays frequently over-estimate testosterone in the female matrix. This effect is variable and cannot be predicted for any given sample (ref2). The Elecsys Testosterone II Assay has been developed as part of Roche's continued commitment to improvement and in response to customer feedback about high recovery with female samples, which did not fit the clinical picture. The Elecsys Testosterone II Assay is for use on the Modular Analytics, cobas 8000, cobas 6000, cobas 4000 and Elecsys 2010 platforms. Roche offers the largest endocrinology menu currently available for automated platforms, which includes fully automated DHEAS, SHBG (sex hormone-binding globulin), Anti-TSHR (thyroid stimulating hormone receptor antibody) and ACTH (adrenocorticotropin hormone) assays. The short turnaround time of the Elecsys Testosterone II assay (l8 minutes) and small sample volume required improves workflow and allows complete endocrinology panel testing from one patient sample.

– Compiled by Omar Ford, *MDD* Staff Writer
omar.ford@ahcmedia.com