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Coherex FlatStent EF PFO closure device wins CE mark

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

After using a new PFO closure device on opposite sides of the globe, two cardiologists say they are not surprised that the Coherex FlatStent EF PFO Closure System has received a CE mark for use in closing patent foramen ovales (PFOs).

Coherex Medical (Salt Lake City) reported Wednesday that the device has been granted a CE mark for use in Europe and other countries to close PFOs, a common defect found in roughly 20% of the worldwide population. Although many adults with PFOs never have any problems because of the defect, the condition is linked to strokes and migraine headaches.

Coherex said it has begun initial efforts to ramp-up sales and marketing in Europe for the FlatStent EF device. According to the company, the device is similar in use and

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Ultrasound may accurately ID heart attack, stroke risk

By LYNN YOFFEE

Medical Device Daily Staff Writer

Imaging technologies are used to screen for colon and breast cancers. Why not heart attack and stroke? That's the early news from the High Risk Plaque (HRP) Initiative, one of the largest studies underway — 6,822 participants — designed to discover and validate tests that will find individuals with vulnerable plaque before they have a heart attack or stroke.

Currently, physicians diagnose patients in danger of heart attack or stroke via risk factors such as high cholesterol, hypertension, smoking, an inactive lifestyle, diabetes and obesity.

"The problem in first heart attacks and strokes is that the vast majority of people are missed — even the day before a heart attack," Pieter Muntendam, MD, president/CEO of **BG Medicine** (Waltham, Massachusetts)

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Report from Europe

CardioFocus gets CE mark for its Endoscopic Ablation System

A Medical Device Daily Staff Report

CardioFocus (Marlborough, Massachusetts) reported that it has received a CE mark allowing the company to commence European marketing of the Endoscopic Ablation System (EAS) to treat patients with atrial fibrillation (AF). The EAS is the latest generation, percutaneous catheter system that has been used clinically to treat patients with AF. This novel device incorporates both a micro-endoscope and light energy fibers to give physicians the capacity to actually see within the heart, and for the first time, visually direct the application of energy through a catheter.

"The EAS represents a new era for catheter ablation of this complex arrhythmia. The CardioFocus device provides the electrophysiologist with a direct view of the cardiac anatomy that simply has not been available using other catheters. I believe that seeing the true orientation of the anatomy in full color and in real time, combined

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RCA has short-term benefits; still unclear over long-term results

By OMAR FORD

Medical Device Daily Staff Writer

Real long-term benefits for radio frequency catheter ablation (RCA) have yet to be seen, but a report compiled by the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) on the procedure, which sends targeted energy into the heart to treat a common type of irregular heart beat, is showing that in the short-term RCA has tremendous effectiveness.

The report, which findings come from several studies

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A little something Extra

You asked for it . . . you got it. Tacked onto the end of your regular issue today are two pages of *MDD's Ortho Extra*, which we have tagged "Additional Developments in One of Med-Tech's Key Sectors." This is the latest added weekly feature of the publication as part of increasing *MDD's* value to you.

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*Washington roundup***Biden says deal struck with hospitals to cut payments**By **MARK McCARTY****Medical Device Daily Washington Editor**

Vice President Joseph Biden reported yesterday that the Obama administration has struck a deal with the hospital industry to shave as much as \$155 billion from federal payments over a decade.

Biden said that hospitals have committed to “\$155 billion in Medicare and Medicaid savings” via “a combination of delivery system reforms” and “reductions in annual inflationary updates.”

“Reform is on track and it is coming” Biden said, adding, “we have never . . . been as close as we are today” to an overhaul of healthcare in the U.S. Regarding the subject of the press conference, he said “hospitals have acknowledged that significant healthcare savings can be achieved by improving efficiencies [and] realigning incentives to reward quality of care instead of quantity of procedures.” He described the deal, said to have been worked out with Senate Finance Committee chairman Max Baucus (D-Montana), as a plan of savings to allow “healthcare reform that is deficit neutral.”

Wire services abounded with reports Tuesday that President Obama and Baucus had agreed in principal to a mechanism by which government could recoup payments made to hospitals for care provided to the uninsured. The rubric mentioned in many reports was that the Centers for Medicare & Medicaid Services would trim those payments by about 10% per year after 2014, which is projected to save Uncle Sam \$40 billion in the ensuing decade. This would serve as the budgetary offset for an expansion of Medicaid, with the Senate Finance Committee proposing to expand

Today's MDD food for med-tech thought

“The problem in first heart attacks and strokes is that the vast majority of people are missed — even the day before a heart attack.”

— Pieter Muntendam, MD, president/CEO of BG Medicine (Waltham, Massachusetts) discussing the need for an imaging test for the screening of potential heart attack and stroke victims “Ultrasound may accurately ID heart attack, stroke risk” pp. 1, 7.

eligibility to 133% of the federal poverty level (FPL) while the Senate Health, Education, Labor and Pensions Committee will likely propose a set point of 150% of the FPL.

The idea of using increased enrollment of low-income Americans in public plans to enable the Centers for Medicare & Medicaid Services to trim payments to hospitals for otherwise uncompensated care has been batted around in policy circles for some time, and was discussed briefly in a Senate Finance Committee earlier this year (*Medical Device Daily*, May 14, 2009).

Tax exclusion on shaky ground

Another detail in the overall architecture of reform may be primed to blow up in the faces of reformers as several members of the Senate’s Democratic majority have hinted that they have grown skittish over plans to reduce the tax-exempt status of healthcare premiums. Senate Budget Committee chairman Kent Conrad (D-North Dakota) is on record as acknowledging that recent polls indicate a distaste among a large majority of Americans for pulling back on the exemption. Conrad is quoted as saying that he sees opposition “in the 70% range” and that “when you go out and ask people across the country their initial reaction ... is they don’t like it.”

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ATLANTA NEWSROOM: Managing Editor: **Holland Johnson**.
Washington Editor: **Mark McCarty**.
Staff Writers: **Omar Ford, Amanda Pedersen** and **Lynn Yoffee**.
Senior Production Editor: **Rob Kimball**.

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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

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Deals roundup

Synovis to acquire assets of Pegasus for \$12.1M in cash

A Medical Device Daily Staff Report

Synovis Life Technologies (St. Paul, Minnesota) said it has agreed to acquire substantially all the assets of **Pegasus Biologics** (Irvine, California), a private medical device company focused on the development of advanced biological solutions for soft tissue repair.

The purchase price is \$12.1 million in cash and resulted from a sealed bid auction process, Synovis said. The company expects to close the deal by July 15, using current cash reserves.

According to the company, roughly 10,000 patients had been treated with Pegasus' equine pericardial products in various orthopedic and complex wound applications from March 2006 to May 2009, when Pegasus effectively ceased operations after attempts to raise additional operating capital were unsuccessful due to the overall economic climate. Previously, Pegasus had obtained more than \$38 million in venture equity and debt. In 2008, Pegasus generated \$9.1 million in revenue and had about 75 employees at year-end. Synovis said it plans to maintain Pegasus' manufacturing operations in Irvine and will operate the acquired assets as a separate division.

"Growth through acquisition, in addition to organic growth, is a strategic priority for Synovis," said Richard Kramp, Synovis president/CEO. "We are very pleased to have the opportunity to combine the talent, technology and products of Pegasus with our own and to enter two additional high potential markets. Pegasus is an especially strong fit for Synovis; the company has complementary technologies and soft tissue repair products – already FDA cleared and CE marked – giving Synovis access to the large and growing orthopedic and wound care markets. Pegasus products are consistent with our mission of providing surgical solutions that minimize risks, improve patient outcomes and reduce healthcare costs."

Synovis said it plans to market the acquired products with a combination of direct sales people recruited from the recently disbanded Pegasus sales force, and independent sales distribution, and to focus this sales team solely on the acquired products. Synovis expects to regain Pegasus' 2008 revenue levels in fiscal 2010 and to make immediate and meaningful reductions in operating expenses from those historically incurred by Pegasus. However, Synovis also anticipates the new division will incur operating losses between \$1 million and \$2 million in the fourth quarter of fiscal 2009 and potentially \$5 million in fiscal 2010, while reaching breakeven during fiscal 2011 and being accretive after that, the company noted. Kramp said, "As we move forward, we see opportunities to leverage our infrastructure and certain operating expenses to reduce

costs, as well as the potential to achieve gross margins similar to our current gross margins. Given the compressed timeline of the auction process, these future estimates are preliminary and could change materially as we integrate the new business."

Kramp continued, "We have the knowledge and resources to drive the Pegasus technologies and products to a significant place in their respective markets, and this transaction is an important investment in our long-term growth. Our immediate priorities for this acquisition are to appoint leadership and rebuild the sales staff for our newest division while reconnecting with physician customers."

In other dealmaking activity:

- **iMedX** (Shelton, Connecticut), a healthcare software and services company, reported that it has acquired **Medware** (Orlando, Florida). With this acquisition, iMedX says it expands its reach into the hospital market and emerges as one of the largest medical transcription companies in the U.S.

- **VeriChip** (Delray Beach, Florida), a provider of radio frequency identification (RFID) systems for healthcare and patient-related needs, said it has sold the VeriTrace system, including 1,000 RFID microchips, for disaster preparedness and emergency management needs to **Calvert Memorial Hospital** (Prince Frederick, Maryland).

The VeriTrace system was created in the aftermath of Hurricane Katrina where it was used by the Federal Disaster Mortuary Operational Response Team to help identify, track and account for the remains of hurricane victims.

- **NexMed** (East Windsor, New Jersey), a developer of products based on the NexACT drug delivery technology, reported a mutual decision with **Novartis** (Basel, Switzerland) to terminate the licensing agreement for NMI00060, a topically-applied treatment for nail fungus. The companies entered an agreement in September 2005, under which Novartis assumed all clinical development, regulatory, manufacturing and commercialization responsibilities for the product.

NexMed said that the results from the comparator study of NMI00060 vs. Loceryl, a topical nail lacquer currently marketed in Europe, showed comparable safety and efficacy profiles for the two products in patients with mild to moderate toenail fungus. In the post hoc analysis of patients with mild fungus, NMI00060 showed higher efficacy, which was consistent with the results from the two Phase III pivotal studies completed by Novartis in 2008. However, the study results were insufficient to support filing for marketing approval, the company noted.

"There were lessons learned from the studies which warrant further development of this product," said Vivian Liu, NexMed's CEO. "We decided that NexMed will proceed with potential new licensing discussions. We have already received inquiries from companies with a focus in dermatology who are interested in commencing discussions." ■

Agreements/contracts**SunTech's BP tech part of ExpressMD's telemedicine****A Medical Device Daily Staff Report**

SunTech Medical (Morrisville, North Carolina), a manufacturer of blood pressure monitors and non-invasive blood pressure modules, reported the inclusion of its clinical-grade blood pressure technology in ExpressMD's Electronic House Call remote patient monitoring device for telemedicine.

The Electronic House Call received its FDA clearance in April and will be used by healthcare professionals who manage patients with chronic conditions, such as heart disease, chronic obstructive pulmonary disease and diabetes. SunTech Medical's OEM NIBP module will provide professional grade BP monitoring in combination with the Eclipse D-ring blood pressure cuff to allow easy self-application for in-home use.

"ExpressMD has included best-in-class technology like the SunTech OEM NIBP module to ensure a high-quality, accurate and reliable telemedicine product," said Ronald Mills, managing director at ExpressMD Solutions.

Patients use the monitoring device in their home to measure their vital signs and to motivate them through education and reminders, allowing professionals to better manage patients with chronic illness. The Electronic House Call monitor securely transmits information to its data center making it conveniently available to each licensed care provider via a secure website.

Dayn McBee, CEO of SunTech Medical added "We're excited that the value of our OEM NIBP technology contin-

ues to be recognized by the home telemedicine market. Blood pressure has been our focus for over 25 years and we're still finding new ways to improve the performance and reliability of BP technology. It's great to work with a company who shares our vision of improving healthcare for the benefit of patients and their care providers."

In other agreements and contracts news:

- The **Premier** (San Diego) healthcare alliance reported eight new hospital supply categories were added to help members achieve savings. With an estimated member spend of \$19.5 million, the categories include materials management, nursing, women's and children's services, food services and information technology services.

"The addition of these new categories is in direct response to the needs of Premier members," said Premier Purchasing Partners President Mike Alkire. "These new categories offer Premier's more than 2,100 member hospitals access to a variety of categories at the lowest possible prices."

- **HealthTrio** (Laurel, Maryland) said that **Johns Hopkins HealthCare** (JHHC; Baltimore, Maryland) selected HealthTrio connect and HealthTrio personal health record (PHR) /electronic health record (EHR) solutions to give members and providers greater access to patient and administrative health data. The integrated solutions can improve medical and business communications between the various healthcare stakeholders.

The HealthTrio-powered HealthLink@Hopkins portal will be available across all of the Johns Hopkins HealthCare sites including JHHC, Employer Health Programs, Priority Partners and US Family Health Plan at Johns Hopkins. ■

Washington

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On the other hand, Sen. Max Baucus (D-Montana), chairman of the Senate Finance Committee, is said to be sticking with the plan to at least trim back on the exclusion, which is widely seen in the committee as essential in keeping healthcare reform in a budget-neutral state. Behind all the negotiations is a push to get a bill onto and off the Senate floor before the August recess so that the Senate bill and its counterpart in the House can be reconciled by October.

House leaders bugged over coverage

Meanwhile on the other side of Capitol Hill, members of the three committees working on the House draft slammed a report appearing recently in *Congress Daily* said to have alleged that CBO has scored the work of the House tri-committee healthcare bill. The press officers of the House Ways and Means, Energy and Commerce, and Education and Labor Committees released a statement Tuesday blasting the *CD* report as "premature and entirely fabricated." The statement also claims "none of the reporters working on this piece contacted our press offices to fact-check their story," pointing out that the draft is still a work in progress.

Long-term care bill in the works

Long-term care is also part of the reform agenda, and a new version of a bill that first surfaced in 2007 has been revived by Sen. Ted Kennedy (D-Massachusetts). The bill, dubbed the Community Living Assistance Services and Supports (CLASS) Act would provide a cash per-diem of \$50 or more, which could be used to pay for in-home services or nursing home expenses.

As currently written, the bill would set up a long-term care insurance program into which enrollees would pay \$65 a month for five years before they could file any claims. The CLASS Act, which would become section 191 in the Affordable Health Choices Act currently under consideration in the Senate HELP Committee, is projected by CBO to save the federal government almost \$58 billion in the first decade, but the CBO memo also remarks that those savings hinge largely on the surplus run up during the five-year vesting period of the first wave of enrollees. In the program's second decade, CBO notes, "the effects of the program could be quite different." CBO suggests that one fix for the long-term health of the long-term care program might be to reduce benefits and increase premiums. ■

*Financings roundup***Rapid Micro Biosystems raises nearly \$19 million in funding****A Medical Device Daily Staff Report**

Rapid Micro Biosystems (Bedford, Massachusetts) a company developing products for faster detection of microbial contamination, reported that it has successfully raised \$18.6 million in venture financing.

Investors in the Series A round include Kleiner Perkins Caufield & Byers (Menlo Park, California) TVM Capital (Munich, Germany) Quaker BioVentures (Philadelphia), and VIMAC Milestone Medica Fund (VMM; Boston). Rapid Micro Biosystems will use the financing to expand its market presence and current product portfolio.

The Growth Direct System, the lead product of Rapid Micro Biosystems, greatly reduces microbial contamination testing time by using proprietary digital imaging technology to replace detection by the human eye. The system delivers high throughput analysis with its proprietary consumable Growth Cassettes and automates otherwise error-prone manual steps.

In other financing news:

- **Bellus Health** (Quebec, Canada) reported that it is filing a preliminary short form prospectus in each of the provinces of Canada for a C\$12,080,018 million rights offering to holders of its common shares.

Under the terms of the rights offering, one right will be issued for each common share outstanding as of a record date which is yet to be determined. Holders of common shares of Bellus Health resident in Canada will be entitled to exercise rights to subscribe for common shares of Bellus Health. Each 0.80 of a right will entitle eligible shareholders to purchase one common share of Bellus Health at \$0.185.

- **CCS Medical**, (Clearwater, Florida) a direct-to-consumer provider of medical supplies, said that it has reached an agreement with certain holders of its first lien loan to significantly reduce the company's debt and improve its capital structure.

To facilitate this financial restructuring, CCS Medical elected to file petitions for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware.

The filing was made with the support of holders of the majority of the company's obligations under the first lien loan for the proposed terms of a prearranged plan of reorganization. As a result, the company expects that it will be able to complete its restructuring process on an accelerated basis.

- **Lifeline Biotechnologies** (Reno, Nevada) said that its **First Warning Systems** subsidiary completed a Series A private placement of \$125,000.

Jim Holmes, Lifeline's CEO, said that "Lifeline's subsidiary, First Warning Systems has completed a private placement of promissory notes in the amount of \$125,000. The promissory notes, due in mid-2010, are convertible into common stock of First Warning Systems. This initial fund-

ing has provided us with important resources needed to move forward on our expected FDA filings. While this funding was essential, we are preparing for the next round, a Series B private placement of common stock for up to \$1.5 million. This amount should see us through the FDA process and clearance. With clearance by the FDA, we would expect to be ready for the process of market introduction of the First Warning System." ■

*Grants roundup***NYU Langone gets \$100M gift to start neuroscience institute****A Medical Device Daily Staff Report**

NYU Langone Medical Center (New York) reported a \$100 million gift from the **Druckenmiller Foundation** (New York) to establish a neuroscience institute at the Medical Center.

This gift will provide for the recruitment and support of the highest caliber neuroscientists, reinforcing NYU Langone Medical Center's existing strengths and enabling it to become a leader in translational neuroscience, bringing expertise from the research bench to the clinical bedside. It will also help promote the education and training of future generations of neuroscientists — a hallmark of the institution — as well as support a dedicated neuroscience facility.

This gift is the latest milestone in a multi-year transformation of the Medical Center.

NYU Langone Medical Center reported four historic 9-figure gifts in a 15-month period and said it believes it is the only nonprofit organization in the U.S. to have done so. In 2008, the Medical Center raised \$506 million — believed to be the largest amount raised by any academic medical center in a 12-month-period — and has raised nearly \$700 million in less than two years.

In other grant news, Marion Sandler, chairman of the **American Asthma Foundation** (AAF; San Francisco), named twelve distinguished scientists, chosen from a pool of 327 applicants, to receive a total of \$8 million in research grants. These awards are given to outstanding scientists to investigate cutting-edge approaches to improving treatments, prevention and, eventually, curing asthma. In announcing these awards, Sandler stated, "These grants reflect the AAF's emphasis on innovation as the major weapon in the fight against asthma, a disease that affects one in every 13 Americans."

The \$8 million will be allocated among awardees who will each receive up to \$750,000 over a three-year period. This year's winners join the past 110 grant recipients researching potentially groundbreaking approaches to address the asthma epidemic. As in previous years, awardees come from outstanding academic institutions in the U.S. and foreign countries and include a range of scientific disciplines, such as biology, aerospace engineering, immunology, and imaging. ■

Coherex

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function to self-expanding vascular stents that are widely used by interventional cardiologists. However, the FlatStent EF device combines a planar Nitinol structure with a polyurethane substrate in a unique fusion of PFO closure mechanisms designed with the intent to naturally seal PFO tunnels, Coherex said.

The company believes it is the first device cleared by any regulatory body that operates almost entirely in the PFO tunnel, allowing doctors to treat the condition from within the PFO tunnel itself.

“Current devices on the market are not bad devices, but they are an older technology,” Randall Jones, MD, chief medical officer at Coherex, told *Medical Device Daily*. He said all of the current devices for PFO closure are at least 15 years old and were developed originally to close atrial septal defects, not necessarily PFOs. With the FlatStent EF device, Jones said, “we’re just treating the tunnel, not the whole septum.”

Compared to the older devices, the FlatStent EF contains a lot less foreign material and therefore there are fewer chances for problems, Jones said.

Horst Sievert, MD, principal investigator of the COHEREX-EU clinical study using the FlatStent EF system, said the device is unique among PFO closure technologies in the way it is used to repair PFO.

“The most common approach taken today for repairing a PFO is to use a device that clamps two metal mesh-like disks on either side of the PFO opening, with these disks exposed inside the left and right atria (or upper chambers) of the heart,” Sievert said. “And to be clear, this approach works. However, anytime you insert any foreign object into the heart, there are several risks, including: blood clot formation, damage or erosion of the septal wall that separates the left and right atria, and even the potential for interfering with the electrical signals within the heart muscle itself.”

Sievert said these risks appear to be reduced with the Coherex FlatStent EF device. “In fact, the Coherex FlatStent EF is the first in-tunnel device to receive regulatory clearance for PFO closure,” he said. “Its rapid exchange system allows a physician to deliver the Nitinol and polyurethane structure of the FlatStent EF quickly and easily to the PFO where it can easily be maneuvered within the PFO tunnel before its anchors secure it into place — and that’s the key. As a result, there is very little exposed surface area within the left atrium, little or no damage to the septal wall, and significantly less metal mass than current devices. The rapid exchange design also reduces the risk of introducing an air embolism into the left atrium by eliminating the need for a large bore delivery catheter common to other devices.”

The COHEREX-EU study – a clinical trial conducted by Coherex to pursue CE mark clearance for the device – was conducted at sites in Germany, Switzerland, New Zealand and Australia. Sievert is the director of the **CardioVascu-**

lar Center Frankfurt, Sankt Katharinen, and the Department of Internal Medicine, Cardiology and Vascular Medicine of the **Sankt Katharinen Hospital** (Frankfurt, Germany). He is also an associate professor of internal medicine/cardiology at the **University of Frankfurt**.

Another physician who participated in the study was Peter Ruygrok, MD, clinical director of the Green Lane Cardiovascular Service at **Auckland City Hospital** (Auckland, New Zealand). Ruygrok is also on staff at the **Auckland Heart Group**, a private cardiology practice in New Zealand.

“I was delighted with the high rate of closure immediately after implantation, something I was not expecting, but I suspect we saw such results because the Coherex FlatStent EF functions almost entirely within the PFO tunnel,” Ruygrok said. “Six months after implantation, it was clear the Coherex device functioned exactly as we had anticipated – the PFO tunnels were closed, there was no more shunting of blood from the right to left atrium, and no damage to the septal wall. The final results were very encouraging and that’s what I was hoping for from an in-tunnel device like the Coherex FlatStent EF.”

A foramen ovale is a tunnel-like opening between the upper chambers of the heart that allows blood to bypass the lungs and is present in all fetuses, Ruygrok said. Normally, the foramen ovale closes soon after an infant is born. However, if this opening fails to close naturally after birth the opening is said to remain patent and the defect is called a PFO.

Trent Loveless, CFO at Coherex, told *MDD* that the company has been in discussions with FDA and is also working with world leaders in neurology and cardiology in an effort to design a migraine trial which could show a connection between migraine and PFO and being able to improve the symptoms of migraine using this device. “We anticipate being able to begin a trial with FDA in the near future, although we don’t have any fixed dates that I can give you at this time,” he said.

Coherex has already begun its initial efforts to ramp-up sales and marketing in Europe for its Coherex FlatStent EF, and the company expects to make future announcements about its progress as it moves forward in these areas.

“Although there are a handful of older, legacy devices cleared for closing PFOs, these devices are significantly larger than the Coherex FlatStent EF and they close PFOs by completely overlapping PFO openings on both sides of the septal wall,” Richard Linder, Coherex president/CEO said in a company statement. “Conversely, by its very design, the Coherex FlatStent EF represents the next generation approach to PFO closure.” Linder added that the FlatStent has “dramatically less mass and less exposed surface area” than other PFO closure systems and is deployed almost entirely within the PFO tunnel – the exception being two tiny anchors.

“The device works just like it was designed to and really offers patients a benefit and advantage that they haven’t had until now,” Jones said. ■

Ultrasound

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told *Medical Device Daily*. "There's been tremendous work on risk factors and the Framingham Heart study came up with various markers that were predictive of increased risk of heart attack and stroke. They really work well in the long term, but they fail in the short term."

BG is one of six companies sponsoring the HRP Initiative, along with **Humana** (Waltham, Massachusetts) to advance the understanding and management of high-risk plaque, which is believed to be the primary underlying cause of heart attacks and strokes. The other companies include **Merck** (Whitehouse Station, New Jersey), **Astra Zeneca** (London), **Philips** (Amsterdam, the Netherlands), **Abbott** (Abbott Park, Illinois) and **Takeda Pharmaceutical Company** (Osaka, Japan) (*MDD*, Feb. 13, 2008).

There are actually four separate studies underway as part of the HRP Initiative. The information about using imaging technologies to diagnose a person at risk for heart attack or stroke comes out of the observational Bioimage study. Enrollment was completed at the end of June and participants underwent an advanced ultrasound examination of arteries in the neck (carotid arteries) and a CT-scan measurement of calcium deposits in the coronary artery. Additionally, participants provided blood samples for future research.

Muntendam said the participants will be followed for three years, or until 600 of them have developed a heart attack or stroke. The study's goal is to determine whether any of the methods and tests used at the time of enrollment are a valid way to identify those people with a higher risk to develop a future heart attack or stroke.

"We have already made some important observations as it pertains to use of 3-D ultrasound," he said. "We have made ultrasound a standard to view the carotid arteries. We decided to pursue a scanning of carotid arteries because you have a beautiful major artery right under the skin that you can characterize and we have found a high proportion of plaque in these arteries. We're finding people who have this build-up of plaque and a degrading-plaque phenomenon. We're looking for disease as opposed to looking at risk factors. We're so excited about the ultrasound finding."

Muntendam's comments about these early findings come from anecdotal cases since the data has not yet been released. He said a series of articles analyzing these early results will be published later this year.

In addition to the imaging aspect of the study, the primary objective HRP Initiative is to develop a simple blood test that would alert physicians to the fact that a person is at risk for heart attack or stroke.

BG Medicine is conducting a study with the Copenhagen Heart Study and Copenhagen General Population Study in conjunction with the HRP Initiative to discover biomarkers that would predict the risk of a first heart attack. This study enrolled 250 people who suffered a first heart

attack within four years of entering in the Copenhagen General Population Study. At the time of their entry into the Copenhagen General Population Study, those subjects were free of cardiovascular disease. A total of 500 subjects are matched controls with no cardiovascular disease.

"The primary objective is to develop a simple blood test," Muntendam said. "But it may well be that the blood test alone isn't sufficient and you need an imaging back-up. Ultrasound meets all the criteria for ideal imaging modality.

"Out of the gate we said we wanted to develop a new clinical paradigm," he said. "You can find people in the general population who are ticking time bombs. We always thought it would be a combination of blood test to screen everyone because it's lowest cost and imaging when you have a positive hit."

What's in it for BG Medicine?

"There's no doubt that if we can bring to market a blood test to find people before their first heart attack, it could be the largest proprietary diagnostic on the market," he said.

The HRP Initiative is unique in that the healthy volunteers (age 55-80 for men and 60-80 for women) came from a health benefits company. Participants are from diverse ethnic backgrounds and live in both Chicago and South Florida areas.

"It's the first time there's a collaboration between a health benefits provider and a life sciences company to discover new treatments," he said.

Muntendam said that data which emerge from the HRP Initiative will also likely be valuable in the ever-growing call for comparative effectiveness research. ■

Court report

Millipore files patent suit vs. Gore for STA-PURE samplers

A Medical Device Daily Staff Report

Millipore (Billerica, Massachusetts) said it has filed a lawsuit in the U.S. District Court for the District of Massachusetts against **W.L. Gore & Associates** (Newark, Delaware) for infringement of Millipore's patent rights under U.S. Patent No. 7,293,477, "Disposable, Pre-Sterilized Fluid Receptacle Sampling Device," by selling one or more of its STA-PURE samplers.

Gore's product competes with components of Millipore's NovaSeptum sampling system for the pharmaceutical and biopharmaceutical industries, according to the company. The NovaSeptum sampling system is a sterile, disposable, completely enclosed sampling system for aseptic and sterile processes, Millipore says. The company notes that sampling is critical for biopharmaceuticals; an imprecise or false positive result can lead to batch loss and may also require repeat sampling and analysis at additional costs.

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Europe

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with the ability to safely and reliably deliver energy to the right target, increases the likelihood of delivering effective therapy," said Vivek Reddy, MD, Director of Electrophysiology Laboratories at The **Mount Sinai Medical Center** (New York).

"CE marking for our product highlights the great progress our company has made; our entire group has been dedicated to achieving this milestone. This facilitates more ambitious international research and European commercialization of our device. Cardiac electrophysiology is a focused area of medicine where a small company can make a big impact with the right product," said Stephen Sagon, CardioFocus president/CEO.

Researchers developing artificial nerve cell

Scientists at the Swedish medical university **Karolinska Institutet** (Solna, Sweden) and **Linköping University** are well on the way to creating the first artificial nerve cell that can communicate specifically with nerve cells in the body using neurotransmitters. The technology has been published in an article in *Nature Materials*.

The methods that are currently used to stimulate nerve signals in the nervous system are based on electrical stimulation. Examples of this are cochlear implants, which are surgically inserted into the cochlea in the inner ear, and electrodes that are used directly in the brain. One problem with this method is that all cell types in the vicinity of the electrode are activated, which gives undesired effects.

Scientists have now used an electrically conducting plastic to create a new type of "delivery electrode" that instead releases the neurotransmitters that brain cells use to communicate naturally. The advantage of this is that only neighboring cells that have receptors for the specific neurotransmitter, and that are thus sensitive to this substance, will be activated.

The scientists demonstrate in the *Nature Materials* article that the delivery electrode can be used to control the hearing function in the brains of guinea pigs.

"The ability to deliver exact doses of neurotransmitters opens completely new possibilities for correcting the signaling systems that are faulty in a number of neurological disease conditions", said Professor Agneta Richter-Dahlfors who has led the work, together with Professor Barbara Canon.

The scientists said they intend to continue with the development of a small unit that can be implanted into the body. It will be possible to program the unit such that the release of neurotransmitters takes place as often or as seldom as required in order to treat the individual patient. Research projects that are already under way are targeted towards hearing, epilepsy and Parkinson's disease.

Spectrascience in French distribution partnership

SpectraScience (San Diego) reported that it has established a distribution partnership in France through Medipartner (Paris), a firm specializing in the marketing and distribution of gastrointestinal devices.

The company said it believes that building an effective distribution network in France will also enhance sales in the emerging North African and Middle Eastern markets due to their relationship with France.

"We decided to add the WavSTAT to products that we distribute because it is both innovative and it will translate into progress for cancer detection. Our focus is in the gastrointestinal market, and based on our experience and understanding of that market, I think that the WavSTAT is a great fit for us, and our customers," said Medipartner's CEO, Christian Arnould.

The company's WavSTAT optical biopsy system uses light to optically scan tissue and provides the physician with an immediate analysis. In addition, the company's Luma cervical imaging technology has received FDA approval as an optical non-invasive system that is proven to more effectively detect cervical cancer precursors than conventional methods available today.

Berlin Heart reports restructuring

Berlin Heart (Berlin) reported that Dr. Johannes Mueller, the company's general manager, CEO and CSO is leaving the general management of the company at the end of September.

Mueller belongs to the company's founders and is one of the intellectual fathers of the successful ventricular assist device Incor, the company noted. The company said Mueller will continue to contribute his wealth of experience in this area as coordinator for projects with external cooperation partners. He will further support the company in developing new markets.

Mueller was a member of the general management from the very beginning when the company was founded as a start-up enterprise with venture capital in 1996.

In October, Dr. Stefan Thamasett will join the general management of Berlin Heart to succeed Mueller. Thamasett has more than seven years of experience in clinical cardiology and possesses long-standing experience as head of marketing and sales in well-known medical device companies, the company said. He will manage the company together with Dr. Dirk Lauscher, the company's present General Manager.

Berlin Heart develops implantable and external ventricular assist devices for patients of every age and body size. The products Excor and Incor provide mechanical support of the heart for patients suffering from severe end-stage heart failure. ■

RCA

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on the procedure, specifically targets the use of RCA on atrial fibrillation (AF).

The new comparative effectiveness report found that the procedure has been shown to help patients in maintaining normal heart rhythm for short periods of time. AHRQ's report shows that that short period of time could be up until 1 year.

"Overall the evidence seems to show that the procedure has a temporary affect on symptoms for atrial fibrillation," Elise Berliner, Director of Technology for AHRQ, told *Medical Device Daily*. "What we still don't know is if there are any long term benefits."

Radio frequency catheter ablation – a procedure in which a long, thin, flexible tube is put through a blood vessel into the heart – often is used when medications do not work. In this procedure, energy pulses are delivered through the catheter to the heart, destroying small areas of heart tissue where abnormal electrical signals may cause an arrhythmia to start.

The report, which compared radio frequency catheter ablation to medication-based therapy, also found that the effect of the procedure on stroke, a major risk for patients with atrial fibrillation, is unknown.

AHRQ officers did say that the report calls for more research on the effect of radio frequency catheter ablation on quality of life. In particular, more research is needed for groups of patients for whom the research is especially lacking, such as women, the elderly, and patients who have other conditions such as heart failure or high blood pressure.

Earlier this year, **Johnson & Johnson** (New Brunswick, New Jersey) got the nod from the FDA to market the NaviStar ThermoCool saline irrigated radio frequency ablation catheter and the EZ Steer ThermoCool Nav, which can be used to create small, strategically placed scars in heart tissue to block irregular electrical waves that cause atrial fibrillation (*MDD*, Feb. 6, 2009).

In the past the FDA approved other ablation catheters to treat arrhythmias such as atrial flutter and ventricular tachyarrhythmia, but not for AF.

However, physicians often use other catheters that have not been approved by the FDA for AF. The FDA also found that there is no conclusive evidence that people whose symptoms are reduced with ablation are less likely to have a stroke. Therefore, the FDA explicitly endorsed existing clinical guidelines that recommend that patients at risk for stroke continue to take preventive blood-thinning medications after radio frequency catheter ablation.

As a condition of catheter approvals, the FDA mandated that the catheter's manufacturer must conduct two post approval studies (PAS) to collect long term safety data.

The mandated studies apply only to FDA-approved catheters, and not to devices used off-label in clinical practice.

The first PAS is a post approval registry, which will collect safety (adverse event) data and operator experience information through seven days post-treatment with the approved ablation catheters. The study will also collect data on long term safety (adverse events) data, such as death, stroke, myocardial infarction, clinically manifested pulmonary vein stenosis, etc., at five years post-treatment.

The second PAS is a subgroup analysis from an ongoing larger study that will look at the incidence of stroke, and compare the three-year incidence of stroke between patients treated with the approved ablation catheters versus patients treated with medication. This study will analyze total mortality, serious bleeding and cardiac arrest.

AF, the most common type of irregular heartbeat in adults, affects more than 2.2 million Americans, putting them at risk for heart failure, blood clots, or stroke. Patients with AF are typically treated with medication first, but medicines only work for about half of patients for preventing recurrence of AF. ■

Court report

Continued from Page 7

"This filing reflects our intention to vigorously defend our intellectual property, which is a fundamental component of the innovation we provide to our customers," said Jean-Paul Mangeolle, president of Millipore's Bioprocess Division.

According to Roland Heinrich, VP of Millipore's Process Monitoring Tools, "Millipore's NovaSeptum sampling system has broad industry acceptance. With our strong patent position, I am confident we will remain an industry pioneer in sampling systems."

In other legalities, **Endocare** (Irvine, California) and **Galil Medical** (Yokneam, Israel) reported a settlement agreement to terminate its merger agreement and the settlement of all related litigation in Delaware Chancery Court.

The merger agreement between Galil and Endocare was first disclosed in November (*MDD*, Nov. 14, 2008). However, the deal got held up by an investigation by the Federal Trade Commission. Last month Endocare said it was terminating the agreement and would be acquired by urology services provider **HealthTronics** (Austin, Texas) in a cash and stock deal worth about \$16 million (*MDD*, June 9, 2009).

Both Galil and Endocare develop cryotherapy products for the prostate cancer market.

Galil filed suit against Endocare for an alleged breach of the merger agreement last month (*MDD*, June 15, 2009). ■

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PRODUCT BRIEFS

- **AMDL** (Tustin, California) reported the launch of a new brand name for its DR-70 (FDP) *in vitro* diagnostic cancer test. AMDL said it will market DR-70 under the brand name Onko-Sure. The Onko-Sure *in vitro* diagnostic test helps physicians and their patients to monitor and/or detect solid tumor cancers by measuring the accumulation of specific breakdown products in the blood called Fibrin and Fibrinogen Degradation Products (FDP). The test is approved for the monitoring of colorectal cancer and as a lung cancer detection and monitoring tool.

- **Applied Biosystems** (Carlsbad, California) reported the introduction of a new line of TaqMan real-time PCR assays that enable researchers to rapidly detect and quantify proteins in human cell samples. The TaqMan Protein Expression Assays enable researchers to correlate relative levels of specific proteins with cell functions and behaviors, such as different disease conditions, or states of pluripotency or differentiation in stem cells. The initial release of these molecular tools includes assays that enable relative quantification of protein markers for pluripotency from limited quantities of cultured human embryonic stem cells. The new assays detect and quantify proteins by a technology that combines an antibody-oligonucleotide-tagged immunoassay with a TaqMan Assay to generate real-time PCR data for specific proteins present in as little as 10-250 cells.

- **Insulet** (Bedford, Massachusetts) said that it is introducing an environmentally friendly disposal program for its OmniPod Insulin Management System. Insulet says the EcoPod program will reduce the impact of used Pods on the environment, preventing hazardous waste from unnecessarily entering landfills. It is the industry's first program for the environmentally safe disposal of insulin pump components. Following procedures for bio-hazardous waste, the Pods are disassembled and metals are removed and recycled. The remaining components are then pulverized. The process takes hazardous waste that might leach into the ground water out of the waste stream; it also greatly reduces the volume of materials that are consigned to a landfill.

- **InTouch Health** (Santa Barbara, California) reported the release of Multi-Presence, a new clinical workflow software solution that expands its turnkey Remote Presence telehealth offering. Multi-Presence is designed to assist multiple physicians and healthcare specialists at different locations to simultaneously access the same Remote Presence consultation thereby allowing them to collaborate on patient care at anytime, from anywhere. Over one network and through a single interface, physicians can access a family of Remote Presence devices to provide care and expert collaboration across the entire continuum of healthcare, all delivered through a single backbone of SureConnect con-

nectivity services and support. Through a single broadband network and computer interface, physicians can access a host of Remote Presence devices to provide and document care into emergency rooms, critical care units, patient wards, and operating rooms. Wherever access to medical expertise is limited, Remote Presence can effectively extend the physician's reach to manage patient care, thereby removing critical time and distance barriers.

- **Premier Research Group Limited** (Philadelphia) said that it has implemented Oracle Remote Data Capture Onsite 4.5.3, the enhanced version of Oracle's EDC application featuring new functionality to meet the needs of trial sponsors as well as investigative site personnel. The system's zero footprint deployment allows sites to rely solely on a web browser without loading or maintaining additional software streamlining system and site management. Electronic case report form (eCRF) pages, developed in HTML, open in two to three seconds. The system requires few key strokes to navigate pages, displays all information (captured data, discrepancy and audit information) on a single CRF screen, and allows multiple pages to be opened simultaneously.

- **SonoSite** (Bothell, Washington) reported the introduction of its new 6-pound NanoMaxx ultrasound tool. The company says the NanoMaxx system is its latest innovation in point-of-care user design and features one button system control. Based on SonoSite's turbo technology platform, the NanoMaxx system uses advanced imaging algorithm technologies, including ColorHD to deliver image quality. It has a touch screen that responds easily to the tap of a finger, and one button optimization, clinicians can readily acquire high resolution images to increase clinical productivity at the point-of-care.

PEOPLE IN PLACES

- **BioTime** (Alameda, California) said that it has expanded its board to include four new members, Neal Bradsher, Arnold Burns, Abraham Cohen, and Alfred Kingsley, who will serve as chairman. Bradsher is president of Broadwood Capital. Burns is chairman of QuanStar Advisor Group, LLC. Cohen is an independent international business consultant and is chairman and president of Kramex. Kingsley is the general partner of Greenway Partners, and president of Greenbelt Corp. BioTime is a biotechnology company focused on regenerative medicine and blood plasma volume expanders.

- Stephen Lerch was named CFO of **MedeAnalytics** (Emeryville, California). Over the past 12 years, Lerch was the CFO and COO for Workstream. MedeAnalytics assists healthcare organizations to improve clinical, financial and operational performance through on-demand analytics and client services.

MDD'S ORTHO EXTRA

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

THURSDAY, JULY 9, 2009

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Keeping you up-to-date on recent headlines in orthopedic healthcare:

DeCODE discovers a gene linked to risk of kidney stones and osteoporosis . . .

A discovery by scientists at **deCODE genetics** (Reykjavik, Iceland) and academic colleagues from Iceland, the Netherlands and Denmark has pointed to a common biological mechanism contributing to both kidney stones and decreased bone mineral density (BMD). About 60% of the population carry two copies of a single-letter variation in the human genome (SNP) on chromosome 21, putting them at roughly 65% greater likelihood of developing kidney stones than those who carry no copies. This single variant may thus account for more than a quarter of the incidence of kidney stones, and in women carriers it is also associated with decreased BMD at the hip and spine. The SNP is in the gene encoding claudin 14 (CLDN14), a protein expressed in the kidney and one of a family of membrane proteins that regulate the passage of ions and small solutes between cells. As calcium is a key component both of most kidney stones and of bone, the deCODE team examined the relationship between CLDN14 and the metabolism of calcium. The results suggest that the SNP may be contributing to increased calcium excretion in urine, a major risk factor for kidney stones and also a sign of bone loss. "This is an exciting finding because it uncovers a highly plausible common biological mechanism leading to two diseases. This offers a potentially attractive new pathway for drug discovery, and the next task is to build on our understanding of how this SNP increases risk of these diseases and how this pathway could be targeted therapeutically to address this risk. As ever, deCODEme subscribers will see this new variant in their profiles, and we look forward building on this discovery," said Kari Stefansson, CEO of deCODE.

New laser research may lead to earlier bone disorder diagnosis . . .

A new laser technique that could lead to bone disorders being diagnosed earlier is to be tested in a hospital for the first time. The study, which it's hoped will pave the way for future clinical trials, will apply a new approach known as SORS (Spatially Offset Raman Spectroscopy), to examine specific substances in non see-through surfaces deeper than has previously been possible, without damaging the surface. The research team hope ultimately that the method can be used both to detect and screen for early signs of diseases such as osteoarthritis and osteoporosis. "This exciting new approach has been developed by combining expertise in multidisciplinary research collaboration over a number of years. This has now culminated in a system for minimally invasive assessment of skeletal tissues and could with further development - form the basis of a rapid safe economical screening system for musculoskeletal disease," said Professor Allen Goodship of **University College London** (UCL; London), the project Principal Investigator. The basic technique, devised and patented in the Central Laser Facility at the Science and Technology Facilities Council (STFC), was developed for this application through an ongoing collaboration with the Institute of Orthopaedics and Musculoskeletal Science at UCL. The concept has been evaluated on bone samples with differing chemical composition but never before in a hospital on patients - as will happen in the next few years. Professor Pavel Matousek who is an STFC physicist and an honorary Professor at UCL is the lead inventor of the technique, he says; "The new method effectively suppresses otherwise blinding interfering signals from skin, making it possible to see subtle chemical changes within all the components of bone through the skin, without the need for a biopsies. The new approach is also able to provide far more information than conventional X-ray based systems that are limited to the mineral components only." While the technique is promising, it has to be fully understood. If these trials are successful it may take several years for the method to become fully realized for diagnostic use in the mainstream health service.

TAU develops new method for coating orthopedic and dental implants . . . Tel Aviv University

(TAU; Tel Aviv, Israel) researcher Prof. Noam Eliaz of the TAU School of Mechanical Engineering has developed an electrochemical process for coating metal implants which he said vastly improves their functionality, longevity and integration into the body. The new process could improve the lives of people who have undergone complicated total joint replacement surgeries so they can better walk, run and ultimately avoid rejection of the implant by their bodies. "The surface chemistry, structure and morphology of our new coatings resemble biological material," said Eliaz. "We've been able to enhance the integration of the coating with the mineralized tissue of the body, allowing more people's bodies to accept implants." His new coating resulted in a 33% decrease in the level of materials failure, or delamination, in these implants. Eliaz presented his findings to the 215th meeting of the Electrochemical Society in San Francisco in May 2009. In addition, a new 12-week implantation study, recently published in the journal *Acta Biomaterialia*, favorably compared the performance of the Tel Aviv University coatings to those of current commercial coatings. Eliaz's advance is in the application technique of the coatings rather than the elements used in the coatings themselves. Instead of the traditional plasma-spraying technique, he and his team from the TAU Materials and Nanotechnologies Program have developed a way to electrochemically deposit synthetic hydroxyapatite. In place of plasma-spraying the coating onto the metal, the metal implant is placed into a bath of electrolyte solution and an electric current is applied. According to Eliaz, a good coating is crucial to the stable fixation of the implant in the surrounding bone. Since human bones naturally contain apatite, covering the implant with a synthetic version allows the body to register the implant as similar to a real bone. This ensures integration and fixation of the implant, and also prevents poisonous materials from leaking from the metal of the implant into the blood stream. Eliaz has discovered that his method of coating circumvents the disadvantages of plasma-spraying. The electrochemical process allows synthetic hydroxyapatite to more closely mimic the real material. Examined under a microscope, it is virtually indistinguishable from the body's own material - which helps the body accept a new implant. The next-generation coating will include nano-particles to reinforce the coating. It will also have the potential to incorporate biological material or drugs during the process itself.

Study shows bone coupling factor key to skeletal health . . .

Researchers at the **University of Alabama at Birmingham (UAB)** have discovered a molecular coupling factor that helps bones grow and remodel themselves to stay strong, a finding that could lead to better bone-building therapies and new osteoporosis drugs, the researchers said. The coupling factor is a human protein called transforming growth factor beta-1, or TGF beta-1. Previously, scientists had searched for but missed the biological link between bone growth and bone remodeling - a natural give-and-take system that is crucial to skeletal health. The discovery is reported online in the journal *Nature Medicine*. "For the first time, we've identified TGF beta-1 is a coupling mechanism for bone resorption and bone formation," said Xu Cao, Ph.D., a professor in the UAB Department of Pathology and the study's senior author. "Osteoporosis, Paget's bone disease, Camurati-Engelmann disease, and many more, all involve a bone coupling disorder to some degree." Previous research has hinted at but failed to explain the coupling role of TGF beta-1 in skeletal health. Bone remodeling occurs through resorption, the body's way of removing old and brittle bone to avoid breaks and skeletal disorders. Bone formation happens as skeletons grow and as the body works to counter bone resorption by laying down new bone. Cao and his fellow researchers studied mice with Camurati-Engelmann disease, a genetic disorder that causes haphazard bone formation and poor skeletal health. They found the presence of TGF beta-1 in the mice could balance bone resorption and bone formation and prevent fractures and worsening bone disease. "The current treatment for many bone diseases does two things: it stimulates osteoblasts, which help form bone, and it inhibits osteoclasts, which trigger bone resorption. That's a coupling problem, and it can lead to minimal benefit for patients," Cao said. "There is no drug designed to balance bone resorption with formation, and hopefully we can help change that."

— **Compiled by Holland Johnson, MDD Managing Editor**

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