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Trial halt: Boston Sci filter fails to reduce cardiac complications

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

A study assessing **Boston Scientific**'s (Natick, Massachusetts) EZ FilterWire to catch bits of plaque and blood clot that break loose during percutaneous coronary intervention (PCI) in patients with acute coronary syndrome has been discontinued after it failed to show that it can reduce rates of major cardiovascular complications.

ACC notebook, p. 4

The A-F study was presented in a late-breaking clinical trials session at the annual meeting of the **Society for Cardiovascular Angiography and Interventions** (SCAI; Washington), in partnership with **American College of Cardiology** (ACC; Washington) at the ACC annual meeting in Chicago this week.

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CardioMind begins study of small-diameter Sparrow DES

By JIM STOMMEN
***Medical Device Daily* National Editor**

CardioMind (Sunnyvale, California), a decidedly under-the-radar developer of coronary stents, has its eye on a specific, underserved sector of the drug-eluting stent (DES) market that it believes can result in growing the worldwide market for the vessel "scaffold" devices.

The company's first-in-human CARE II trial, which has had its start "Down Under" at **St. Vincent's Hospital** (Melbourne, Australia), is analyzing the use of its Sparrow DES in small, difficult-to-treat blood vessels.

The start of the trial triggered a second-tranche closing of a $33 million venture round raised in June 2007. That round, CardioMind's third since its founding in 2003, included an initial tranche of $11 million for continued R&D and the just-released $22 million for completion of the CARE II study and further development.

See CardioMind, Page 7

Report from Europe

CE-mark approval is awarded to Abiomed's Portable Driver

A *Medical Device Daily* Staff Report

Abiomed (Danvers, Massachusetts) reported receiving the CE mark for its Portable Circulatory Support Driver, allowing sale of the device in the European Union countries as well as many other countries worldwide that accept that approval. The Portable Driver supports Abiomed's AB5000 Ventricular Assist Device (VAD) for both in-hospital and out-of-hospital patients.

The AB5000 Portable Driver is lightweight and quiet, "demonstrates reliable performance," Abiomed says, "and has the potential to improve patient care while lowering costs to hospitals." The company said the device "provides patients requiring VAD support a greater degree of mobility and improved quality of life during treatment aimed at myocardial recovery."

The driver weighs 18 pounds and is "the lightest and most powerful bi-ventricular system in the industry," according to the company, delivering pressures and vacu-

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Deals roundup

Boston Sci sells EVAR unit for $30 million plus minority stake

A *Medical Device Daily* Staff Report

Boston Scientific (Natick, Massachusetts) reported the sale of **Boston Scientific Santa Rosa** (Santa Rosa, California), formerly known as **TriVascular**, to privately held **TV2 Holding** (Santa Rosa).

The Boston Sci unit holds equipment and intellectual property related to the TriVascular endovascular aortic repair (EVAR) program, acquired in 2005 (*Medical Device Daily*, April 19, 2005). Boston Scientific discontinued its EVAR program in 2006.

Sale terms include $30 million in cash, paid at closing, and a warrant allowing Boston Scientific to purchase a minority interest in TV2.

The company said it sold the division as part of its effort to sell off non-strategic assets. The company reported late last year that it would lay off more than 2,000 employees globally in a restructuring (*MDD*, Oct. 19, 2007).

"The sale of this business is the latest example of

See EVAR, Page 9

AHC Media LLC

By 'reducing operating layers,' other cuts, Steris to save $30M

A *Medical Device Daily* Staff Report

Steris (Mentor, Ohio) reported that it has initiated a program to boost profits and improve efficiency by generating annual operating savings of about $30 million.

The company expects to reduce its salary and benefits expenditures by "reducing management layers" – though not reporting the number of staff cutbacks – "eliminating redundancies and consolidating functions where appropriate." Other savings are anticipated to come from reduction in indirect overhead expenses through reduced consumption of goods and services and consolidation of service providers.

The company said that the program and estimated savings reflects a focus on North American operations but that other cost reductions will be identified in international operations.

The company said it will incur a pre-tax charge of about $15 million during the quarter ended March 31, 2008, related to severance benefits and asset write-downs. Excluding the charge, the company reiterated its previously reported earnings range of $1.30 to $1.35 per diluted share for FY08.

The company anticipates 50% to 70% of operating expense savings during its fiscal year ending March 31, 2009, and will provide more detail on expected FY09 performance in its May 7 earnings announcement.

"[I]t is important that we re-shape the operating model of the company to drive profitable growth," said Walt Rosebrough, president/CEO of Steris. "We very much appreciate the contributions of those employees who have been affected. However, it is important that we become more disciplined with our overhead expenditure levels, which . . . have increased at a faster pace than revenues . . . ."

Steris develops infection prevention, decontamination and health science technologies, products and services.

In other restructuring news: Synergetics USA (O'Fallon, Missouri), a maker of microsurgery devices, said it will close its Philadelphia plant and merge the operations and production of generator products into its plant in O'Fallon Missouri.

The company said the move is part of its strategy to improve product and component integration and increase operational efficiencies at all levels.

The Philadelphia plant currently has 25 employees and the company expects to record non-recurring, pre-tax severance and related costs associated with this action of about $400,000, with the majority of these being cash costs. Ongoing annual cost savings from the closing are expected to be about $1.5 million, or 5 cents a share.

Dr. Jerry Malis will remain as CSO and will lead five engineers and technicians in the further development of Malis generators and provide technical continuity.

Synergetics focuses on making instruments for vitreoretinal, neurosurgery and ear, nose and throat surgeries. ■

Today's *MDD* food for med-tech thought

FDA is seeking $2.2 in civil money penalties from AB due to quality control problems and a failure to notify the agency of a change of outside vendors.

— From today's story, "Advanced Bionics says moisture problems are a thing of the past," p. 5, 9.

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Financings roundup

Triage closes on strategic $20.3M; CryoLife enters $15 million facility

A *Medical Device Daily* Staff Report

Triage Wireless (San Diego) reported that it closed on a $20.3 million strategic investment round led by Qualcomm Ventures. Other participants in this round included existing investors Sanderling Ventures and 3i Group and new investor, Intel Capital.

The new proceeds will be used to fund the commercialization of the company's wireless vital signs monitoring system, OmniScan, which features a proprietary method for measuring blood pressure.

To date, the company said it has raised $25.8 million.

"The expanded implementation of monitoring technology in hospitals can not only improve care, but also enhance efficiency," said Nagraj Kashyap, Senior Director and head of Qualcomm Ventures. "We believe the wireless capabilities of the Triage technology will make such monitoring practical in both the hospital and the home settings."

Triage is developing a new generation of vital signs monitoring technology that merges the benefits of wireless body-area network communication with improved biosensors. The first generation of new sensors allow blood pressure measurements to be made continuously for long periods of time without relying on frequent inflations of an arm-worn cuff. With its wireless capabilities, patients do not have to be tethered to the monitor and results can be sent to any wireless network.

CryoLife (Kennesaw, Georgia) said it has entered into a credit facility with GE Healthcare Financial Services, which provides for up to $15 million in revolving credit for working capital, acquisitions and other corporate purposes. The credit agreement expires in March 2011.

Amounts borrowed bear interest at LIBOR or the lender's base rate, as defined, plus an applicable margin, and are secured by substantially all of the assets of the company and its subsidiaries.

"This credit facility further enhances the financial flexibility of the company and allows us to continue to evaluate opportunities that create value for our shareholders," said Steven Anderson, president/CEO of CryoLife.

CryoLife processes and distributes implantable living human tissues for use in cardiac and vascular surgeries throughout the U.S. and Canada. ■

Court report

Cook wins in preliminary injunction against Endologix

A *Medical Device Daily* Staff Report

Cook Medical (Bloomington, Indiana) reported winning a preliminary injunction against **Endologix** (Irvine, California) and four former sales representatives, barring them from violating Cook's non-compete agreement.

The ruling, handed down March 25 in the U.S. District Court Southern District of Indiana, also enjoins Endologix, which manufactures a device to treat abdominal aortic aneurysm (AAA) that is a direct competitor to Cook's Zenith line of AAA endografts — from hiring Cook sales representatives and placing them in their former territories and accounts.

"This ruling further supports Cook's position that it is improper for competitors to ignore non-compete agreements that are fair and reasonable," said Pete Yonkman, executive VP for sales and marketing of Cook. "In addition, we believe the practice of hiring a direct competitor's sales representatives contributes to unnecessary escalations in healthcare costs. We spend a great amount of time and resources training our sales representatives to be valued partners in the delivery of quality healthcare to patients."

Cook develops devices used to perform minimally invasive medical procedures.

In other legalities: The U.S. International Trade Commission (ITC) reported that it will consider a request by **CryoCor** (San Diego) to bar imports of catheters and other medical equipment made by **CryoCath** (Montreal).

CryoCor, asked the ITC last month to investigate CryoCath Technologies and decide whether the company is infringing patents that CryoCor licensed from **AMS Research** (Minnetonka, Minnesota). AMS joined CryoCor in the request.

The patents at issue are for catheters, consoles and other equipment used to treat cardiac arrhythmias, or irregular heartbeats, the ITC said last Thursday.

The ITC, an independent federal agency, investigates unfair trade practices and has the authority to bar imports that infringe U.S. patents and trademarks.

The case will be referred to an administrative law judge, the ITC said, who will investigate the complaint. The agency said it will set a target date for completing the investigation within 45 days.

CryoCor and CryoCath have also filed lawsuits accusing each other of patent infringement in U.S. and Canadian courts.

In a lawsuit filed in January, CryoCor said patents for its Cryoablation system, which is used to treat irregular heartbeats, were infringed by CryoCath's products. Cryotherapy generally involves the use of freezing temperature to treat diseased tissue (*Medical Device Daily*, Jan. 18, 2007).

CryoCor said in that suit that it is the exclusive licensee for the patents and is seeking monetary damages and sales injunctions against CryoCath.

CryoCath filed its own patent infringement suit against CryoCor in October (*MDD*, Oct. 18 2007). The company said last month that CryoCor and AMS Research illegally extended "at least one patent beyond its scope." ■

GE Healthcare launches smaller, more accessible Vivid S5

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

GE Healthcare (Waukesha, Wisconsin) says it is scaling down both the size and cost of big cardiovascular ultrasound equipment with a product that's more accessible to physician offices and imaging centers, launching, at this year's meeting of the **American College of Cardiology** (ACC; Washington), the mobile Vivid S5 cardiovascular ultrasound system.

The Vivid S5 features stress echo capabilities and raw data digital imaging with console benefits of a full-sized 17 inch LCD monitor, four active transducer connectors and room for on-board peripherals retained in a miniaturized console weighing less than 160 pounds. Standard machines of similar purpose weigh up to 400 pounds and have a larger footprint, according to GE.

ACC notebook

"We're now moving our console technology, with the same level of performance into a mid-price range for smaller clinics and doctor's offices," Al Lojewski, global marketing manager for cardiovascular ultrasound technology at GE told *Medical Device Daily* from the ACC exhibit floor of the meeting.

Vivid S5 costs $60,000 to $90,000, compared to standard models that range in price form $100,000 to $200,000, he said. While the larger units provide 4D imaging, the Vivid model has 2D imaging.

The new system features the "ergonomically friendly" features of its sibling, Vivid S6, according to the company, and Flex-Fit mechanism enables continuous pivoting height adjustment of the control panel, keeping optimal distance from the user and leaving legroom for standing or sitting.

A Flex key, next to the trackball, can be assigned to assume the function of other, more distant keys for minimal effort, increased speed and ease of use. The high contrast wide-angle display monitor includes an auto sensor, automatically adjusting brightness, contrast and gamma levels for environment light, ensuring minimal eyestrain.

In other news from the ACC:

• Data showing strong clinical efficacy for **Medtronic** (Minneapolis) Endeavor drug-eluting stent were presented. Entitled "One-Year Clinical and Angiographic Results in Diabetics from ENDEAVOR IV: A Randomized Comparison of the Endeavor Drug Eluting Stent System Versus Taxus in *de novo* Native Coronary Lesions," the study featured an analysis of 477 diabetic patients from the ENDEAVOR IV clinical study a head-to-head comparison of the Endeavor and Taxus stents, from **Boston Scientific** (Natick, Massachusetts) in 1,548 patients.

"Performance of drug-eluting stents in diabetic patients is scrutinized by doctors because diabetes complicates so many aspects of the angioplasty procedure. Achieving good efficacy is more difficult, and safety concerns are significantly increased." said Jeffrey Popma, MD, director of Invasive Cardiovascular Services, **Caritas Cardiovascular Center** for the **Caritas Saint Elizabeth's Medical Center** (Boston), and director of the core lab that performed the angiographic analysis for the ENDEAVOR clinical program, including ENDEAVOR IV.

Launched in the U.S. in February and available in more than 120 countries, the Endeavor indicated for improving coronary luminal diameter in patients with ischemic heart disease due to *de novo* lesions of length = 27 mm in native coronary arteries with reference vessel diameters of = 2.5 mm to = 3.5 mm.

Also presented at the meeting were the findings from two sub-studies from the ENDEAVOR IV clinical trial. One analysis, "The Impact of Mandatory Angiographic Follow-up on the One-Year Clinical and Angiographic Results From Endeavor IV: A Randomized Comparison of the Endeavor Drug Eluting Stent System vs. Taxus in De Novo Native Coronary Lesions," illustrated the artificial impact of routine angiography on revascularization rates.

A second sub-analysis, "The Fate of Side-Branches Among Patients Treated With Zotarolimus-Eluting and Paclitaxel-Eluting Stents: An ENDEAVOR-IV Substudy," looked at side-branch occlusion post-stenting. The analysis was conducted as doctors seek to explain the significantly increased rate of periprocedural MI with Taxus when compared to Endeavor observed in the ENDEAVOR IV clinical trial.

ENDEAVOR IV is evaluating 1,548 patients at 80 clinical centers in the U.S., with a primary endpoint of Target Vessel Failure (TVF) at nine months; a secondary endpoint of Major Adverse Cardiac Events at 30-days.

• **Boston Scientific** (Natick, Massachusetts) reported positive two-year results from **Abbott**'s (Abbott Park, Illinois) prospective, randomized, single blind, non-inferiority SPIRIT II Trial comparing the safety/efficacy of the Promus Everolimus-Eluting Coronary Stent – the Boston Sci brand name for the Xience stent – and Taxus Express2 Paclitaxel-Eluting Coronary Stent System in 300 patients in Europe.

Boston Scientific notes that it offers two distinct drugs on two deliverable platforms: the Taxus and Promus Stents.

At two years, results from the SPIRIT II trial demonstrated no numerical difference between the Xience V/Promus and the Taxus in their angiographic outcomes, nor were there statistically significant differences in the clinical outcomes.

Xience is currently pending approval by the FDA, expected in the first half of 2008.

Early results of the SPIRIT II study showed that the Xience V stent was superior to the Taxus stent in six-month findings on angiography and trended better on one-year clinical outcomes. ■

Advanced Bionics says moisture problems a thing of the past

By MARK McCARTY
***Medical Device Daily* Washington Editor**

The bad recent news about **Advanced Bionics** (AB; Sylmar, California) would seem less conspicuous but for the cash paid to the firm and its executives for the termination of its merger agreement with **Boston Scientific** (Natick, Massachusetts) last year (*Medical Device Daily*, Aug. 13, 2007), a sum that came to $1 billion. Given the headaches Boston Scientific inherited with its purchase of Guidant, however, the recent news about AB, a maker of cochlear implants, might make the billion-dollar payout seem like a fair price to avoid more FDA scrutiny.

On the other hand, FDA and AB see the current controversy differently, and the CEO of AB is of the position that not only has the moisture problem dried out, but also that FDA is pursuing an issue that has been dead since 2003.

As was reported late last week, FDA is seeking $2.2 million in civil money penalties from AB due to quality control problems and a failure to notify the agency of a change of outside vendors. According to the March 28 FDA announcement, the agency's concerns were that the hearing aids "pose a public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss," but also because Advanced changed vendors for an unspecified component of the devices.

FDA dealt AB an 11-page warning letter dated Feb. 1, 2005, which cited the firm for lack of management reviews in connection with a "significant manufacturing deficiency" that led to "moisture being hermetically sealed in the Hi Res 90K cochlear implant." FDA stated further in that letter that moisture was detected in product reviews "dating back to 2002."

The rest of the 2005 warning letter ran to 17 additional citations and included a citation that AB failed to validate "two of the three vacuum bake ovens," which are responsible for removing the moisture from ceramic articles (the company's previous warning letter, from September 2001, cited AB for marketing its Clarion II bionic ear prior to issuance of a 510(k)). The company obtained a PMA for the Hi Res 90k, an implantable cochlear stimulator, in July 2003.

Jeff Greiner, the firm's CEO, told *Medical Device Daily* "the issues pertain to things that happened in 2003, so it's old news."

Greiner said the 2005 warning was from an audit in early 2004 and that "we fixed those problems and cleared that warning letter." The most recent inspection was this past February, he said, adding that "they did issue a 483, but there were no major deficiencies" with any significance "in terms of patient health." The 483 from this year cited the company for a laser welding validation that "could have been done better," Greiner said, and another citation involved "a decision we made more than two years ago not to report a meningitis incident that the doctor said was unrelated" to the device. FDA's view was that AB should have reported it.

"The thing that's most surprising about the announcement is that they talk about it in the present tense, and that's misleading," Greiner said.

However, these events should not affect funding for the privately financed company. According to Greiner, "we don't have any problems with financing and won't have any problems with financing" in the future. As for the agency's pursuit of civil money penalties, Greiner said "we're working with the agency to resolve it."

FDA spokesperson Peper Long confirmed that "the moisture problems occurred . . . in March 2006 and the company stopped using that vendor at that time." However, she could not say whether the agency typically pursued such cases after resolution of the underlying problems.

CMS launches consumer hospital guide

It's all about quality when it comes to hospitals, and many are of the opinion that when consumers can see how hospitals score on quality points, they'll flock to the best and ditch the rest.

Hence the Centers for Medicare & Medicaid Services reported last week the posting of a substantial base of survey information at its web site that gives consumers a look at the quality scores of hospitals across the U.S.

Thanks to the information at the site, located at www.hospitalcompare.hhs, Medicare beneficiaries will have access to data on "a number of certain elective hospital procedures provided to those patients and what Medicare pays for those services." CMS said that the site provides "quality information, patient satisfaction survey information, and pricing information for specific procedures" that are essential to making "effective decisions about the quality and value of the healthcare available to them through local hospitals."

Mike Leavitt, the Secretary of the Department of Health and Human Services, said the site will give beneficiaries "more choice about the quality of their healthcare and how they may be able to lower their healthcare costs."

Leavitt also said: "To achieve goals around providing consumers with the information necessary, and the incentive, to choose hospitals based on quality and value, HHS is continuing to work with partners such as the Hospital Quality Alliance to drive quality up and the cost down."

The Hospital Compare site "currently provides information on 26 quality measures, which include process of care and outcome measures," according to the March 28 announcement, with the latest 10 measures giving consumers "a better picture of the quality of care delivered at their local hospitals."

See Bionics, Page 9

Trial

Continued from Page 1

The EZ system was first approved by the FDA in August 2004 for use in coronary saphenous vein graft, and then for the application of carotid artery stenting in 2006 (*Medical Device Daily*, Aug. 25, 2004/Dec. 15, 2006).

The device is a coronary guidewire, with a plastic sack attached to it shaped like a windsock. The "windsock"-like sack features small holes allowing blood to flow through but catching larger debris. During PCI the FilterWire is positioned in the coronary artery downstream of the lesion; both the device and, with it, any debris are removed after the procedure.

The study was originally designed to include 450 patients but was stopped after an analysis of the first 150 patients. The researchers found that rates of major cardiovascular complications during hospitalization — consisting of death, heart attack, emergency bypass surgery, or repeat procedure in the treated artery — were no different in the two groups (12% in the FilterWire group vs. 10% in the control group).

Investigators were focused on patients with arterial blockages that appeared particularly likely to be a source of downstream debris during PCI. In addition, myonecrosis, or debris-caused damage to the heart muscle resulting from blockage of tiny blood vessels, is fairly common. PCI is associated with myonecrosis in about 25% of patients with non-ST-elevation myocardial infarction (STEMI) acute coronary syndromes. The condition also encompasses unstable angina.

"This was a study in a new population," Mark Webster, MD, director of the cardiac catheterization laboratory at **Auckland City Hospital** (Auckland, New Zealand), told *Medical Device Daily*. And he called this group "the bread and butter of our work: unstable angina patients. We tried to pick a high-risk group within that population. They were required to have pain at rest and other features, like being at risk for distal embolism."

He added: "I believe that there are a bunch of patients with acute coronary syndrome who would benefit from these devices, but we didn't identify them with this study."

Although the FilterWire captured debris in the bloodstream in nearly half of patients, it did not reduce damage to the heart muscle. This was the first trial to evaluate a vascular protection device in patients with NSTEMI acute coronary syndromes.

"Although there are other mechanisms, distal embolism of atherosclerotic plaque and/or thrombus is recognized to be a frequent cause," Webster said.

Webster said that he did not know of any other studies that are being planned for this particular indication.

In another study from the ACAI-ACCi2 Summit related to aspiration with PCI:

An analysis of the Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction (TAPAS) study showed that the link between deep myocardial perfusion and better clinical outcomes, apparent at 30 days, is still strong after one year.

The one-year results of TAPAS − analyzing the effectiveness of the Export Aspiration Catheter from **Medtronic** (Minneapolis) and focusing on patients suffering from STEMI — were reported in a late-breaking clinical trials session.

Felix Zijlstra, MD, PhD, of the **University Medical Center Groningen** (Groningen, the Netherlands) and his colleagues recruited 1,071 patients with STEMI, assigning 535 to PCI, supported by the Export aspiration catheter, and 536 to PCI using conventional techniques.

To assess the quality of myocardial perfusion, the researchers documented myocardial blush grade, a myocardial blush grade of 0 or 1 indicating that little or no X-ray dye has reached from the surface artery into the heart muscle, a sign that the microcirculation is blocked; a myocardial blush grade of 3 indicating that X-ray dye has reached deep into the heart muscle, a sign of good blood flow through the microcirculation. A myocardial blush grade of 2 falls in between.

Analysis of the elevated ST-segment on the electrocardiogram — its return to normal baseline — was also used to gauge the quality of blood flow to the heart muscle.

During angiography, researchers observed a blush grade of 0 or 1 in 17% of patients treated with the aid of the aspiration catheter and in 26% of patients treated with conventional PCI (p less than 0.001). At 30 days, clinical outcomes were strongly related to the degree of myocardial reperfusion.

The rate of death in patients with a myocardial blush grade of 0/1, 2 and 3 was 5.2%, 2.9% and 1.0% respectively (p equals 0.003). The combined rates of repeat heart attack, repeat procedure in the target artery and death in patients with a myocardial blush grade of 0/1, 2 and 3 were 14.1%, 8.8% and 4.2%, respectively (p less than 0.001).

At one-year follow-up, mortality was significantly lower in patients treated with the aspiration catheter (p equals 0.04), as was a combination of death and heart attack. A similar, highly significant relationship was observed between myocardial blush grade and death, or a combination of death and repeat heart attack (p equals 0.001).

The researchers concluded that the degree of blood perfusion into the heart muscle helps to predict the patient's clinical condition and that aspiration of debris from the treated artery during PCI can reduce the risk of death and repeat heart attack, even one year later.

SCAI is a 4,000-member organization promoting quality in invasive and interventional cardiovascular medicine through physician education and representation. ■

CardioMind

Continued from Page 1

Leading the round were SV Life Sciences and De Novo Ventures, with added funding coming from four existing investors.

The cleverly-named Sparrow stent has a .014" crossing profile, some 70% smaller than in diameter than any approved stent currently on the market. Rather than riding to the site of the lesion over the guidewire, as is the case with every other stent, the CardioMind device travels within the guidewire lumen.

It has, as President/CEO Charles Maroney told *Medical Device Daily*, "a much smaller profile" than other stents on the market.

The mere fact that CardioMind has reported on its new trial activity is news unto itself. It truly is a "stealth" company, an adjective used by media outlets carrying infrequent news about the firm. Only four mentions of the company are found in *MDD*'s archives.

The CARE II trial, which in addition to Australia will enroll patients in Asia, Europe and South America, eventually will enroll 220 patients. The randomized study will compare three different stents – bare-metal and DES versions of the Sparrow, plus a competitive stent, the Micro-Driver from **Medtronic** (Minneapolis), characterized by Maroney as that company's "bare-metal, small-vessel stent [which many interventionalists] feel is the best small-diameter stent" on the market today.

He said that the SynBiosys polymer that CardioMind has licensed from **SurModics** (Eden Prairie, Minnesota) "allows the Sparrow stent to gradually return to a bare-metal state, where we as an industry have 15 years of data showing no increase in late stent thrombosis."

The start of the trial, which thus far has seen 12 patients implanted, has shown "very encouraging results," said Robert Whitbourn, MD, associate professor and director of the **Cardiovascular Research Center** at the Melbourne hospital. "I am impressed with the overall deliverability and performance of this new delivery system."

He said the Sparrow system "opens up the possibilities of stenting in small vessels, branch vessels and other difficult-to-access vessels."

Whitbourn said such use "could . . . expand the types of lesions in coronary artery disease that can be treated in more difficult patient populations."

Maroney told *MDD* that it is such "difficult" populations – diabetics, for example, who tend to have smaller-diameter, more tortuous blood vessels in need of stenting – for which CardioMind's stent is particularly of use. 'Our focus is in the smaller vessels. And smaller vessels demand more flexibility, the ability to access in tighter spaces."

The combination, he said, "means that if you want to treat those smaller vessels, you need the most flexible, deliverable system available."

Maroney noted that interventional cardiologists "have been notorious for switching technologies based on deliverability," so that's a potential advantage for us."

In addition, he said, "since we started looking at small vessels and some of the things came to light about durable polymers, that's when we said, 'Hey, if we're going to deliver a drug there, in the end what we want is to have bare struts left,' so that's where we added the biodegradable polymer to the system."

And, Maroney said, "I think the combination of those two aspects makes [the Sparrow] the ideal small-diameter stent."

He said the potential for the small-diameter product can be evidenced in the reality that many interventionalists may be reluctant to treat a patient's small-diameter vessel. "They're reluctant because smaller vessels have poorer results," Maroney said. "So they say, 'Why do I want to put a risk on this patient to treat the smaller vessel? Maybe this is a good candidate for surgery.'"

Asked about the company's timetable for commercialization, he said that the data that will be collected in the CARE II trial will be able to be used in getting the CE mark. "We're using a limus drug, sirolimus, that is generically available," he said, "[but], in the end, we're going to have to have a drug license to commercialize this product in the U..S. and overseas."

That might be, Maroney said, either sirolimus, everolimus, zotarolimus or biolimus, the four limuses that are, in his words, "the most-developed limus drugs at this point." The company won't be trying to offer a new way of treatment with whatever drug is chosen, he said. "Our advantage is that we have a platform specifically designed for those smaller vessels, so we will end up with some sort of an agreement with the holder of one of those drugs, and that's what we will end up commercializing."

The company's expectation, he said, "is that we would end up launching in Europe in 2010."

Maroney said that the data gathered for the European approval "allows you to start your trial in the U.S. [It] would allow us to kick off that trial in even smaller vessels in the U.S. – in the normal 2.5 mm to 4.0 mm range, but also in the 2.0 mm to 2.75 mm range, and collect data for those patients as well."

In a company statement, he cited its target of treating blood vessels of smaller than 2.75 mm, which he said "currently constitute nearly 40% of all stent implants."

Maroney added that beyond the range of current stent practice, the CardioMind product "may also find use in vessels smaller than 2.25 mm and thus expand by up to 20% the worldwide market for stents." ■

Europe

Continued from Page 1

ums equivalent to its AB5000 console and the recently approved iPulse combination console. It said internal that testing showed that the Portable Driver is capable of providing full support for a year's intended use.

The unit is expected to require low maintenance, roughly every 5,000 hours of operation, estimated as three times longer than existing portable consoles that Abiomed said "weigh twice as much or more."

The company said the Portable Driver was designed with the latest "smart battery" technology for extended power. "The quiet operation of the Portable Driver provides for minimal disruption of the patient's quality of life at home," said Abiomed, which recently reported FDA labeling approval of one-year bench reliability for its AB5000 VAD, expected to complement the Portable Driver reliability.

"There is a clinical and financial demand for a highly reliable mobile driver that allows for patient discharge," said Michael Minogue, president/CEO and chairman of Abiomed. "We are now offering a complete portfolio of circulatory care products that help the heart recover, from the cath lab to the surgery suite to the ICU to home discharge."

The AB5000 VAD is CE-marked, and Abiomed said it has supported patients for up to 312 days. The Portable Driver is expected to enhance the company's bridge-to-transplant opportunity.

Health Care Without Harm raps EU report

The conclusions of an EU report on the safety of DEHP, a common additive to medical devices, are "fundamentally out of step" with many hospitals' rationale for materials selection when purchasing medical devices, according to **Health Care Without Harm Europe** (HCWHE).

The report, published by the EU Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR), "is correct to identify vulnerable groups, especially male infants, as 'at risk' of suffering adverse health effects when treated with medical devices treated with DEHP," said HCWHE.

It said that the SCENIHR report was weakened by a too-narrow interpretation of its remit, and the committee failed to examine plasticizer-free plastics used in alternative medical devices. Only plasticizers used as alternatives to DEHP were investigated, it said.

"Responsibility for the remit of the SCENIHR report lies with DG Enterprise in the European Commission, an entity not well-known for its support of the alternatives industry," WCWHE said.

Lisette van Vliet, EU policy advisor for the organization, said, "The most disappointing aspect of the report is SCENIHR's failure to investigate the safety of alternative plastics for medical devices. These are widely available on the European market, have passed the required tests and are already in use by a number of hospitals wanting to altogether avoid the health issues and uncertainties around plasticizers."

"Since [more than] 60 European hospitals are engaged in PVC phase-out projects, there is a reasonable likelihood that EU reports on DEHP and alternative plasticizers will be made redundant by a market shift toward alternative materials, driven by hospitals concerned with patient care issues rather than industry protecting its sales of PVC medical devices."

Transoma expands HealthLink Europe accord

HealthLink Europe (Tilburg, the Netherlands) said it has expanded its customer service and logistical services relationship with **Transoma Medical** (St. Paul. Minnesota) on behalf of its **Data Sciences International** (DSI) division, whose customers are research labs found in academic and government institutes and "nearly every major pharmaceutical company."

Kristi Lloyd, logistics manager for Transoma, describing itself as "pioneering technologies that are transforming how physicians gather cardio, vascular and other vital patient data in real-time," said, "HealthLink now is providing us with a full complement of customer service/sales-and-marketing support functions. HealthLink manages our European orders, talks to our customers, facilitates returning product from our European customers, and invoices our customers. HealthLink "is our fiscal representative in Europe."

Transoma manufactures implantable, subcutaneous, wireless diagnostic and monitoring products. Its DSI unit is a supplier of wireless, physiologic monitoring equipment and related data acquisition and analysis products used in biomedical research, including pre-clinical drug discovery and development.

HealthLink is an ISO 13485 device support services and distribution company that has provided European customer service and logistics support to the North American device industry since 1994.

Swedish NPO to use InterSystems' software

InterSystems (Cambridge, Massachusetts) reported that the Swedish national electronic health record, the National Patient Overview (NPO), will be supplied by **TietoEnator** (Espoo, Finland) using InterSystems HealthShare software. The contract is valued at about $19 million for the first five years, with an option to extend for an additional two years.

The NPO is designed to enable the sharing of patient information between regional and local care providers in both the public and private sectors. In a competitive procurement, the Swedish Healthcare Advisory Organization chose TietoEnator as prime contractor to deliver the development, implementation and hosting of the NPO.

InterSystems is a platform that will play a role as the core software with which the NPO will be delivered. The solution is expected to be ready for production within 12 months. ■

EVAR

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Boston Scientific's commitment to divesting non-strategic assets," said Jim Tobin, president/CEO of Boston Sci. He said that the divestitures and head count reductions "are helping realign our cost structure and simplify our operating model [to achieve] our overall goals of restoring profitable growth, increasing shareholder value and strengthening Boston Scientific . . . ."

In other dealmaking news:

• **Global Med Technologies** (Denver), an e-health company, said it has agreed to acquire **Inlog** (Lyon, France) and its German and related subsidiaries, a private European medical software firm, for a maximum of $11.5 million in cash, stock and earnout.

Global Med said it will utilize a combination of existing cash and debt to pay for the transaction, expected to close in 2Q08. Inlog's management plans to stay with the company, Global Med said.

Inlog's shareholders must use $500,000 of the cash proceeds to purchase Global Med common stock in the open market within three months of the closing. Inlog's unaudited revenues for their fiscal year ended June 30, 2007 were about €7.3 million ($11.4 million).

Inlog is a provider of donor center and transfusion information management systems, laboratory information systems and other ancillary medical softwares.

• **DRI Capital** (Toronto) and **Nanogen** (San Diego) have entered an agreement for DRI to acquire, for $10 million, all future royalties generated by **Applied Biosystems** (AB; Foster City, California) under a license AB has taken from Nanogen for minor groove binder (MGB) technology.

"Monetizing this royalty stream provides us with a nondilutive means of raising capital to fund our operations as we work towards achieving cash flow breakeven in late 2008," said Howard Birndorf, Nanogen CEO andchairman.

The royalties included in the agreement are related to Nanogen's MGB technology that has been licensed to AB for use in its TaqMan products.

Nanogen has a product and proprietary technology base of diagnostic solutions for two *in vitro* diagnostic (IVD) markets: molecular diagnostics and rapid point-of-care testing.

• **Manhattan Scientifics** (MS; New York) reported an agreement with Dr. Terry C. Lowe, president of **Metallicum** (Santa Fe, New Mexico), to acquire Metallicum and its patent rights to produce and market NanoTitanium and other ultra-fine grain nano-structured metals. Financial terms of the merger were not disclosed.

MS said it plans to form a new Advanced Technologies division focused on advanced science for medicine.

NanoTitanium, MS said, is highly compatible with bone and thought to provide stronger, faster bonding with greater strength and improved wear and tear. ■

Bionics

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Acting CMS administrator Kerry Weems said in the statement that beneficiaries "tell us . . . they want to know what their neighbors are saying about the care they received while in the hospital; they want to know how much it costs; and they want to know about the quality of that care." Weems said that the Hospital Compare site is among the tools the agency is deploying that will help consumers "to do just that."

Upcoming additions to the site include mortality measure for pneumonia and two pediatric asthma measures collected by the Joint Commission on the Accreditation of Healthcare Organizations. ■

Agreements

Cardinal Health, UltraSPECT in pact for imaging software

A *Medical Device Daily* Staff Report

Cardinal Health (Dublin, Ohio) reported an exclusive agreement with **UltraSPECT** (Haifa, Israel) to provide cost-effective imaging processing software to cut scanning time in half or double the image resolution of existing nuclear medical imaging equipment.

Terms of the multiyear agreement, give Cardinal exclusive U.S. distribution rights for UltraSPECT's Wide Beam Reconstruction image processing packages for cardiac and bone nuclear imaging applications. WBR products address the clinical needs for significant reduction in acquisition time, boosting patient throughput and comfort without sacrificing image quality, and for substantial improvement in image resolution in bone imaging, offering better lesion localization and higher diagnostic confidence. The image processing packages are compatible with most major brands of nuclear medical imaging equipment.

Cardinal Health provides products and services that help hospitals, physician offices and pharmacies reduce costs, improve safety, productivity and profitability, and deliver better care to patients.

In other agreements: Belimed (Anaheim, California) a developer of infection control systems, and 3M Sterilization Assurance (St. Paul, Minnesota), a developer of sterilization monitoring products and a part of 3M HealthCare (St. Paul), have formed a collaboration to jointly promote best practices in sterile processing in the U.S. With infection prevention a key issue in the industry today, the two organizations said they will work together to provide objective educational resources to customers on sterilization monitoring practices. This partnership was reported at the Association of periOperative Registered Nurses (AORN; Denver Colorado) Annual Congress being held in Anaheim, California this week. ■

PRODUCT BRIEFS

• **Cook Medical** (Bloomington, Indiana) reported the U.S. launch of the self-adhesive Surgisis Biodesign staple line reinforcement. The self-adhesive graft is a natural solution for the reinforcement of gastric staple lines during gastric bypass procedures. The graft is designed to improve staple line strength while decreasing bleeding, leakage and the subsequent risk of infection. Sturgisis offers resistance to infection and complete remodeling – with the benefits of moderate price, ease of use and ample shelf life for on-site availability. Upon deployment, the graft provides a seal along the staple line. Then, over time, the graft communicates with the patient's body, signaling surrounding tissue to grow across the scaffold where the tissue is stapled. While supporting the tissue, the naturally derived staple line reinforcement begins to remodel into strong, fully vascularised tissue, providing a secure reinforcement. Cook makes interventional devices.

• **Delcath Systems** (New York) reported results from a study of the chemotherapy agent melphalan, delivered via its percutaneous hepatic perfusion (PHP) system, in patients with inoperable liver metastases from primary neuroendocrine tumors. The Delcath PHP system was designed to isolate blood flow from the liver, deliver very high doses of anti-cancer agent, then filter a majority of the agent out of the blood from the treated area. This process allows patients with large and diffuse liver tumors to receive a concentrated, site-specific treatment where resection, ablation, and embolization are not feasible or have failed to halt spread of the cancer. Delcath is a developmental stage company testing its percutaneous perfusion technology for the isolated delivery of high doses of therapeutic and chemotherapeutic agents.

• **Encision** (Boulder, Colorado) said that it is launching its new disposable hand-activated fixed-tip electrode line of laparoscopic instruments. The new electrode line features hand activation for surgeons who prefer to energize the electrode via a fingertip switch rather than pressing their foot on a foot pedal. The new product line consists of a disposable handle with integral cord and disposable electrodes available in six popular tip styles. The disposable electrodes are available in both 35cm lengths for routine procedures and 45cm lengths for bariatric procedures. Encision makes surgical devices that allow surgeons to optimize technique and patient safety during a broad range of surgical procedures.

• A two component silicone rubber system called MasterSil 151MED made by **Master Bond** (Hackensack, New Jersey), has been certified for medical applications per the USP Class VI specification. The base resin, upon addition of the curing agent, cures at ambient or more quickly at elevated temperatures to a tough, flexible, optically clear silicone rubber. The low viscosity of this silicone elastomer compound assures complete fill-in around complicated contours in even very complex configurations. This characteristic together with its 160% elongation, low linear shrinkage of less than 0.1%, low outgassing, electrical insulation, in addition to its resistance to vibration and shock makes MasterSil 151MED suitable both medically and physically for the most demanding casting, potting and encapsulation applications. Master Bond makes medical adhesives for disposable, reusable and implantable medical device assembly.

PEOPLE IN PLACES

• · **Cerus** (Concord, California) said that Carol Moore was named VP of regulatory affairs and quality. Prior to joining Cerus, Moore was VP of worldwide regulatory affairs for Bayer. Cerus makes the Intercept blood system to enhance blood safety.

• · **Minrad International** (Orchard Park, New York) reported that its board approved the appointment of David DiGiacinto as president/CEO. DiGiacinto's appointment is the first step in a transition in which he will become CEO beginning on January 1, 2009. William Burns will continue to serve as CEO through the end of the year and will serve as chairman until the company's 2009 annual meeting. DiGiacinto is joining Minrad from Spencer Trask & Co. Minrad is an interventional pain management company with real-time image guidance and anesthesia and analgesia product lines.

• · **Synthetic Blood International** (SBI; Costa Mesa, California) reported new management roles and responsibilities for company board members to succeed the late Robert Larsen (Medical Device Daily, March 26, 2008). Chris Stern, who is the chairman of the board, assumes responsibilities of CEO. At the same time, Richard Kiral, PhD, VP of R&D, becomes president/CEO. Stern is best known for his writings and lectures on management techniques and managing multilingual and multinational companies. Kiral has served the company as VP of R&D since 1999 and has been responsible for developing products from SBI's perfluorocarbon technology platforms. SBI makes pharmaceuticals and medical devices in the field of oxygen therapeutics and continuous substrate monitoring.

• · **StatCom** (Atlanta) said Michael Holland will lead StatCom's sales team as it launches a targeted sales and marketing program. For the past five years Holland has held executive roles leading sales, marketing and business development at several start-up companies. StatCom is a provider of patient flow logistics and tracking solutions.