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European Congress of Radiology

Philips expands MRI product line with new 3 Tesla machine

By JOHN BROSKY

Medical Device Daily European Editor

VIENNA, Austria – At the European Congress of Cardiology here last week, **Philips Healthcare** (Eindhoven, the Netherlands) rolled out a new 3 Tesla MRI machine to enter a market its says is rapidly expanding and currently dominated by **GE Healthcare** (Waukesha, Wisconsin) and **Siemens** (Erlangen, Germany).

Boosting the power of an MRI provides higher resolution but also poses a higher risk to patients and Philips engineered the new Achieva 3.0T X-Series to deliver distinguishing features on both counts.

Robert Körbler, managing director for healthcare in Austria with Philips, said the company's analysis shows installations of 3 Tesla machines have grown from less than 10% of the MRI market to almost a third of units sold
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Study cites favorable results with Abiomed Impella in PCI

By OMAR FORD

Medical Device Daily Staff Writer

A study published in the February issue of the *Journal of American College of Cardiology* cites favorable results in the use of **Abiomed's** (Danvers, Massachusetts) Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (PCI).

The study shows results from the Protect I trial, and concludes that the system is "safe, easy to use and provides excellent hemodynamic support during high-risk PCI."

The PROTECT I trial enrolled 20 patients undergoing high-risk PCI at seven centers between July 2006 and April 2007. Eligible patients had left ventricular ejection fraction (EF) of less than 35% and were required to undergo PCI on either an unprotected left main coronary artery or the last patent coronary conduit.

Patients with recent ST-segment elevation myocardial
See Abiomed, Page 7

International report

Province of Quebec awards Zoll \$12M defibrillator pact

A Medical Device Daily Staff Report

Zoll Medical (Chelmsford, Massachusetts), a maker of resuscitation devices and related software solutions, said that the Ministry of Health for the Province of Quebec has awarded the company a contract valued in excess of \$12 million to equip all ambulances in Canada's largest geographical province with the Zoll E Series defibrillator.

This order represents the first time that Quebec province will standardize its entire system to one model of defibrillator.

About 700 E Series defibrillators, along with CPR statpadz, will be purchased under the terms of the contract, which marks the largest agreement to date ever received by Zoll in Canada. The transition to Zoll will be made region by region, 16 regions in total, with the first order already having been placed by **Urgences-Santé**, the EMS provider for the city of Montreal.

The Ministry of Health shares responsibilities with 16
See International, Page 8

Washington roundup

White House confirms Hamburg and Sharfstein for FDA posts

By MARK McCARTY

Medical Device Daily Washington Editor

The Obama administration said over the weekend that it is nominating Margaret Hamburg, MD, for the job of FDA commissioner and Joshua Sharfstein, MD, as deputy commissioner, putting to rest months of speculation regarding who would take the jobs. The March 14 announcement indicates a greater focus on the part of the Obama administration on food safety than on regulation of drugs and devices, which would not have been the case had the White House tapped **Cleveland Clinic** (Cleveland) cardiologist Steven Nissen, MD, for the commissioner's job, which had been rumored for weeks.

The March 14 announcement, which was posted at the web site for the White House, quotes President Obama as saying that "in recent years, we've seen a number of problems with the food making its way to our kitchen tables," and that "many of the laws and regulations governing food
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 **AHC Media LLC**

NIH to decide questions on stem cell research spending

By **DONNA YOUNG**

Medical Device Daily Washington Writer

WASHINGTON – While the ban now has been lifted on federal funding for human embryonic stem cell (hESC) research, several questions remain, including what constitutes responsible and scientifically worthy stem cell research, which has been left to the National Institutes of Health (NIH) to decide.

The executive order, signed by President Barack Obama early last week, revokes an order signed by George W. Bush on June 20, 2007, and his presidential statement of Aug. 9, 2001, that limited federal funding of research involving hESCs.

The Bush administration allowed the NIH to fund hESC research on cell lines created before Aug. 9, 2001, but prohibited research on those created after that date. Obama's new order instructed the NIH to develop guidelines for "responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law."

The NIH was given 120 days to develop the guidelines and was told that in so doing, it must review the agency's existing guidance and "other widely recognized guidelines" on hESC research, including "provisions establishing appropriate safeguards," the executive order commanded.

NIH officials said the 120 days includes the posting of draft guidelines for public comment and finalizing the rules.

"NIH will do its part to implement the policy and to develop guidelines as expeditiously as possible to ensure both that the best science is funded and that the research is conducted in a responsible manner," said Lawrence Tabak, NIH's acting deputy director.

During a conference call with reporters last week, Tabak said the agency anticipated that funds from the \$10

Coming Wednesday in MDD Perspectives

Of sticky notes and staplers: At last, a common-sense stem cell policy

As supporters rave and opponents rant about President Barack Obama's executive order expanding federal funding of human embryonic stem cell research, scientists are getting back to work. And somewhere, a pile of sticky notes is being burned. Read about it in tomorrow's edition of *MDD Perspectives*, an op-ed e-zine that provides fresh commentary and opinions on issues that you can't find anywhere else. And best of all, it's free.

If you don't already subscribe to this complimentary e-zine, go to medicaldevicedaily.com to sign up.

billion the NIH is getting as part of the \$787 billion stimulus package "will be able to be used under the context of the new guidelines."

However, officials were unable to say how quickly any grant money would be available.

Officials also were unable to comment whether any of the funds could be used for hESC product clinical trials, such as the one being conducted by **Geron** (Menlo Park, California) – the only company so far that has received FDA clearance for human testing of an hESC product.

"NIH is working very hard to establish a process and set of policies that would enable us to make sure that grants can be funded as quickly as possible," said Story Landis, director of the National Institute of Neurological Disorders and Stroke at the NIH. "But to be perfectly honest, given the fact that the executive order just came out and we have 120 days, it's really much too early to speculate," she told reporters.

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Deals roundup**Roche sets Innovatis purchase; Tepnel shareholders okay sale****A Medical Device Daily Staff Report**

Roche (Basel, Switzerland) reported that it has signed a definite agreement to acquire privately held **Innovatis** (Bielefeld, Germany), a provider of automated cell analysis solutions, especially focusing on cell counting, viability testing, and cell function analysis in research, as well as bioproduction.

The purchase price is €15 million (\$19.5 million).

"This acquisition is a further step in our strategy to strengthen our position as a complete solution provider in the cell analysis research market," said Dr. Jürgen Schwiezer, CEO of Roche Diagnostics "Innovatis' technology will complement the existing Roche cell analysis portfolio and is synergistic to the xCELLigence technology launched in 2008."

"Roche has been one of our key customers for many years, in particular since the successful development of our cell analysis technology over 10 years ago," said Michael Grohmann, CEO of Innovatis. "The innovatis technology is very well-placed for future growth as part of Roche Applied Science."

Innovatis will become a fully-integrated part of Roche Applied Science, a global business area of the Diagnostic division of Roche. The company will continue to develop and market products for cell analysis through Roche Applied Science's extensive worldwide network.

The transaction is expected to be completed within the next few weeks, subject to shareholder approval and regulatory clearance.

Shareholders of **Tepnel Life Sciences** (Manchester, UK/Stamford, Connecticut) have approved the \$132.2 million acquisition of the company by **Gen-Probe** (San Diego) by the requisite majorities.

More than 99% of Tepnel shareholders voted in favor of the acquisition, which was first reported on Jan. 30 and is structured as a "scheme of arrangement" under British law. The transaction is expected to close on or around April 8, pending additional court proceedings.

Tepnel is an international life sciences products and services group with two divisions, molecular diagnostics and research products and services. The company has laboratories, manufacturing and operations in the U.S., UK, France and Belgium, with more than 200 employees worldwide.

Gen-Probe develops nucleic acid tests used to diagnose human diseases and screen donated human blood.

In other dealmaking news:

- Home health nursing company **Amedisys** (Baton Rouge, Louisiana) reported that it has signed an agreement to purchase a home health and hospice agency from **Upper Chesapeake Health System** and **St. Joseph Medical**

Center (Baltimore).

This acquisition represents Amedisys' initial entry into the hospice market in Maryland and increases its home health presence throughout Northeast Maryland. Maryland is a Certificate of Need state for both home health and hospice.

The agencies had revenue for their year ended Dec. 31 of about \$11 million, but are not expected to add materially to Amedisys' earnings in 2009.

Amedisys also reported that it has closed on a previously reported acquisition from the **White River Health System** (Batesville, Arkansas), consisting of three home health agencies and one hospice agency (*Medical Device Daily*, Jan. 28, 2009).

- **Acacia Research Corp.** (ARC; Newport Beach, California) said its **Hospital Systems Corp.** subsidiary has entered into a license agreement with **McKesson Information Solutions** (San Francisco) covering a portfolio of patents that apply to medical picture archiving and communication system (PACS) technology.

This agreement resolves the parties' dispute that was pending in the District Court for the Eastern District of Texas, the companies noted. ■

Financings roundup**Insulet gets \$60M credit facility; Stereotaxis extends its facility****A Medical Device Daily Staff Report**

Insulet (Bedford, Massachusetts) reported that it has entered into an agreement with **Deerfield Management Co.** to provide Insulet with up to \$60 million in financing through a flexible credit facility.

"We are pleased that Deerfield, an acknowledged leader in healthcare investing, sees the potential of our business strategy and that we now have a flexible credit facility enabling us to continue to expand the market for the OmniPod System," said Duane DeSisto, president/CEO of Insulet. "This \$60 million facility is an attractive form of financing that limits dilution for our shareholders and gives Insulet access to capital to fuel our growth."

Deerfield will provide Insulet with \$27.5 million within 15 business days of signing and has committed up to \$32.5 million in additional funding to be drawn by Insulet at its discretion over the next 20 months based on the achievement of certain financial performance milestones. Any amounts drawn will accrue interest until maturity at a rate of 9.75% per annum which is payable on a quarterly basis. Insulet will pay a 2.75% per annum interest rate on undrawn amounts. The funds drawn are repayable in September 2012.

"The OmniPod System is an innovative product with significant growth potential in the diabetes market and other applications," said Howard Furst, MD, Deerfield part-

See Financings, Page 7

*Court report***OrbusNeich in lawsuit against Boston Sci for infringement****A Medical Device Daily Staff Report**

OrbusNeich Medical (Hong Kong) a developer of devices for the treatment of vascular diseases, reported that it has filed a lawsuit against **Boston Scientific** (Natick, Massachusetts). The lawsuit, filed in the U.S. District Court for the Eastern District of Virginia, asserts claims against Boston Sci for patent infringement, breach of contract and for misappropriation of trade secrets.

The suit seeks unspecified monetary damages and injunctive relief in connection with its claims.

Orbus is the owner by assignment of all right, title, and interest in U.S. patent No. 7,329,277, titled "Stent Having Helical Elements," and U.S. patent No. 6,821,292, titled "Crimpable Intraluminal Endoprosthesis Having Helical Elements."

In its complaint Orbus alleges, among other things, that Boston Sci has infringed these two patents relating to its proprietary luminal stent technology. Specifically the complaint alleges:

- In July 2000, the company entered into a Confidential Disclosure Agreement (CDA) with Boston Sci in advance of discussions related to a potential business relationship;

- In connection with these discussions, Orbus provided Boston Sci with a variety of proprietary stent samples and design details, including improved designs present in Orbus' patent application filed in December 2000, which Boston Sci tested, disassembled and destroyed;

- Orbus filed provisional patents on certain elements of its design on Dec. 11, 2000, and Feb. 9, 2001. The final associated patents were lawfully issued on Feb. 12, 2008, and Nov. 23, 2004, respectively;

- Boston Sci filed a patent application with new stent design drawings that were not included in any of the provisional applications over which this new application claimed priority;

- Boston Sci has been manufacturing and selling its line of Liberté stent products without consideration to Orbus, the original designer of major aspects of the Liberté product architecture, itself.

In other legalities:

- **MedQuist** (Mount Laurel, New Jersey) a provider of medical transcription services, reported that it has resolved an investigation by the Securities and Exchange Commission regarding the company's historic billing practices.

Under the settlement, the company agreed to the entry of final judgment in prospective litigation by the SEC, including an injunction prohibiting MedQuist from violating federal securities laws. Under the settlement, the company will not pay any fines or penalties to the SEC, and it does not admit to or deny any liability or wrongdoing.

As originally reported by MedQuist in 2004, the SEC opened an investigation regarding the company's historic billing practices after the company announced it had undertaken an internal review of its billing practices and was delaying the filing of its annual report on Form 10-K for the year ended Dec. 31, 2003. MedQuist cooperated fully with the SEC investigation and is pleased to conclude this matter.

Resolution of the SEC investigation follows the company's resolution of the previously disclosed Department of Justice investigation, the previously disclosed settlements reached in the South Broward customer class action, the consolidated medical transcriptionist class action, and the Steiner shareholder class-action lawsuits, and dismissal with prejudice of the Kanter shareholder derivative class action.

Upon court approval and entry of final judgment in the SEC matter and medical transcriptionist litigation, MedQuist will have completely resolved all class-action litigation and governmental investigation matters arising from the internal review of its historic billing practices.

- A former **Department of Veterans Affairs** (VA) social work associate was convicted by a jury on four counts of honest services mail fraud, violating the criminal conflict of interest statute and making a false statement to agency officials, according to Acting Assistant Atty. Gen. Rita Glavin and U.S. Attorney David Nahmias of the Northern District of Georgia.

On Nov. 14, 2006, Bridgette Davidson and Darrick Frazier, both of Atlanta, were charged in a six-count indictment alleging that the two created and engaged in a scheme to defraud the VA of Davidson's honest services.

Davidson also was charged with one count of violating the conflict-of-interest statute and one count of making a false statement to VA officials investigating the fraudulent scheme.

On Sept. 2, 2008, Frazier pleaded guilty to one count of honest services mail fraud and entered into a plea agreement with the government. In December 2008, he was sentenced to 12 months and one day in prison and ordered to pay \$20,200 in restitution.

At sentencing, Davidson faces a maximum sentence of 26 years in prison and a \$250,000 fine on each count, as well as \$23,400 in restitution. A sentencing date has not yet been scheduled by U.S. District Judge Richard Story. ■

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*Agreements/contracts***Lumedx, Mennen in accord for integrated cath lab solution****A Medical Device Daily Staff Report**

Lumedx (Oakland, California) and **Mennen Medical** (Horsham, Pennsylvania) reported signing a partnership agreement to provide a total, integrated cath lab data solution and seamless stream of hemodynamic cardiovascular patient data.

The agreement is part of both companies' desire to complement their individual product lines so that their mutual customers will enjoy a consolidated cath lab solution. Combining the CVIS and PACS software modalities of Lumedx with Mennen Medical's suite of hardware products for the cath lab, including its new hemodynamic system, the Horizon XVu, its patient monitoring and its EP recording systems into one integrated system will provide a unique market solution.

This partnership is intended to help heart centers to perform cath lab procedures, using an efficient and flexible workflow and continuous clinical patient data from the holding area, throughout the procedure room and into the recovery room.

Mennen Medical's new XVu System is embedded with an interface and analysis system. Combined with windows and an intuitive graphic interface, the system enables various layouts to suit both cardiac and peripheral angiography procedures, including the most advanced pediatric package that is available in the market.

Mennen's front-end vital signs acquisition unit, the CFE, with its small size, allows it to be rail-mounted on the procedure table for maximum space utilization and comfort. It is designed to operate under the demanding workload conditions that exist in both the cardiac and peripheral angiography environments while offering very high reliability.

"This strategic partnership between Lumedx and Mennen Medical will provide cath labs with the widest and strongest integrated data solution that is currently offered in the U.S. market and it takes advantage of the different technologies that exists in each of the companies," said Angelia Adzic, president of Mennen Medical in the U.S. "We hope that the next stage of this partnership will be to take this powerful solution global."

In other agreements/contracts news:

- **Mediwatch** (Warwickshire, UK) has signed a five-year agreement for the worldwide distribution of PSAwatch, its point-of-care total PSA measuring system for prostate cancer, with **Inverness Medical Innovations** (Waltham, Massachusetts). Inverness has an extensive global sales force which will complement Mediwatch's own worldwide distribution network and provide the company with more market reach.

- **DR Systems** (San Diego) reported four new contracts, including two data migrations from legacy PACS,

totaling almost \$1.57 million. The four facilities are **Hillsdale Community Health Center** (Hillsdale, Michigan), **Salem Clinic** (Salem, Oregon), **Contemporary Imaging Associates** (Livonia, Michigan) and **Advanced Radiology Imaging Associates** (Fort Myers, Florida).

"Had these new customers selected a PACS from a different company, they would probably have to maintain five or more different systems and interfaces and deal with five different vendors," said Rick Porritt, President and CEO of DR Systems. "In addition to the complexities of managing all that, they would also have a PACS that cost more and did less than the one they got from DR Systems," Porritt said. "We provided them one unified system that will be a lasting solution – while raising their profitability and simplifying their tech support."

- **Biolmagene** (Cupertino, California) and **Visuvi** (Redwood City, California) reported a partnership for PathSearch, a visual search product for digital pathology. PathSearch enables visual search for PathXchange community pathology portal and Virtuoso end-to-end digital pathology solutions. This partnership will allow pathologists to search with images without the need for detours via meta-data, potentially incorrect mark-ups and tags.

- **AMDL** (Tustin, California) reported that it has entered into a collaborative agreement with **Mayo Clinic** (Rochester, New York) to conduct a clinical study for the validation of AMDL's FDA-approved DR-70 (FDP) cancer test.

Through this validation study, AMDL and Mayo Clinic will perform clinical diagnostic testing to compare AMDL's DR-70 (FDP) cancer test with a new test. The primary goal of the study is to determine whether DR-70 (FDP) serves as a higher-performing test to its existing predicate test and can lead to improved accuracy in the detection of early-stage cancers. For FDA approval on the new test, AMDL intends to perform an additional study to demonstrate the safety and effectiveness in monitoring colorectal cancer.

- **MedAssets** (Atlanta) said it has expanded its revenue cycle management services agreement with the Hospital Division of **Kindred Healthcare** (Louisville, Kentucky). Software and service solutions have been added to the expanded agreement in order to help Kindred's Hospital Division track, appeal and recover underpayments or lost revenue from payers. The expanded agreement includes the implementation of MedAssets' revenue cycle management software and service solutions to improve the monitoring, identification and recovery of reimbursement underpayments from payers.

- **Centene** (St. Louis) said its wholly-owned subsidiary, **Celtic Group**, through a joint venture with **Caritas Christi Health Care** (Boston), was awarded a contract to manage healthcare services for Commonwealth Care members in Massachusetts. Effective July 1, 2009, the two entities will serve the Central, Northern, Boston and Southern regions operating as Commonwealth Family Health Plan. ■

ECR

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today.

In Europe, Siemens leads the market, he said, with GE strong in the UK and France, but that GE “disappears in Germany, Austria and Switzerland.”

Philips’ installed base in Europe is stronger than North America and it would be ranked third on the Old Continent, he said.

Sales of 3 Tesla machines started off strong but then stalled in 2004-2006 due to reports of risk of injury to patients caused by overheating.

“The requirement with 3 Tesla was to let a patient cool down between exposures, and in some early cases, this was improperly done,” said Körbler, adding that it would be fair to say the risk is to cook a patient with the microwave-like strength.

Competitors offer insulating pads for patients to absorb the extra energy, he said, or require long periods between scans for the patients to cool down.

Philips is taking a different approach with the Achieva 3.0T, offering a novel dual-source transmission of the radio frequency (RF) that is safer for patients while also rendering the higher resolution images.

With the 3.0T X-Series Philips engineered the transmission from dual coils with different phasings at the same frequency.

In the initial phase a pulse is fired to determine patient-specific parameters for density.

In the following phase opposing coils send tailored signals adapted to the patient’s anatomy that optimizes the specific absorption rate (SAR) and reduces the risk of overheating.

Dual-transmission also reduces procedure time, he said.

In a study conducted by **Bonn University** (Bonn, Germany), an average 3 Tesla scan with a single transmitter required 4-1/2 minutes, while the Philips dual-source technology completed the same scan in two minutes and 23 seconds.

In musculoskeletal procedures, the time reduction was less significant, though reduced by one minute and 20 seconds from an 8-1/2 minute procedure with conventional single-source transmission.

“Multi-source transmission is 40% faster on average,” Körbler said.

Dual source transmission also greatly enhances image quality, he said, by eliminating a phenomenon with 3 Tesla machine called dielectric shading, which was the primary objective for Philips engineers in developing the novel technology.

“Think of a light bulb,” Körbler said, “it casts shadow behind the object it is illuminating. But if two lights are used from opposite directions, the shadow is removed,” he said, showing a series of before-and-after images with shadows on single source RF images vs. even resolution across the Philips dual source images.

“The difference is going from underdiagnosed conditions to a correct, confident diagnosis,” he said.

Körbler said the Achieva 3.0 T X-Series is priced under €3 million (\$3.84 million) “and if an institution is buying two units, it may come at less than 2 million per unit,” he said.

He said the installation of 3.0 T-X machines are scheduled for Austria before the end of 2009, “and I know there is at least one installation already scheduled in Germany.”

Körbler said another market advantage for Philips is that the dual-transmission technology can be installed by customers as an upgrade to existing 3 Tesla machines and the Achieva XR system can be ramped from 1.5 Tesla to 3 Tesla.

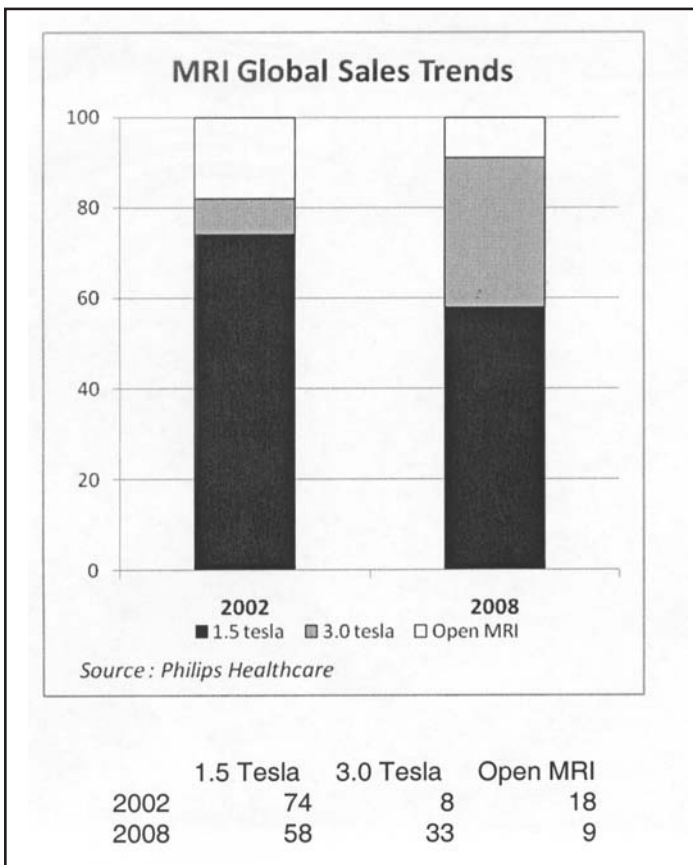
A short-bore version of the Achieva 3.0 T X-Series is available in a mobile configuration, the only 3 Tesla machine that can be transported to remote locations.

The semi-tractor trailer is field-ready for “park, plug and scan” upon arrival.

Philips opens Panorama MRI sales in Europe

At ECR 2009 Philips also launched in Europe the Panorama vertical high-field MRI open platform, offering a 360-degree open platform with 160 cm wide (63-inch)

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Abiomed

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infarction or cardiogenic shock were excluded. The primary safety end point was the incidence of major adverse cardiac events at 30 days. The primary efficacy end point was freedom from hemodynamic compromise during PCI (defined as a decrease in mean arterial pressure below 60 mm Hg for more than 10 minutes).

The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 ± 0.6 h (range: 0.4 h to 2.5 h). Mean pump flow during PCI was 2.2 ± 0.3 l/min. At 30 days, the incidence of major adverse cardiac events was 20% (two patients had a periprocedural myocardial infarction; two patients died at days 12 and 14).

There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia. Two patients (10%) developed mild, transient hemolysis without clinical sequelae. None of the patients developed hemodynamic compromise during PCI.

"The advantage to having a small heart pump is that it is minimally invasive," said a company spokesperson via e-mail to *Medical Device Daily*. "Other LVADs require a sternotomy, or cracking of the chest, for implantation. Impella 2.5 is implanted percutaneously via the femoral artery and up through the aorta, hooking into the left ventricle. Impella increases the blood flow and oxygen supply to the heart, while decreasing demand, essentially reducing the workload on the heart by doing 30% of the work for pumping blood, with a pump that is 100th the size of the heart."

The study shows that the Impella provides hemodynamic support by directly unloading the left ventricle and reducing oxygen demand and the work on the heart, while increasing oxygen supply.

The device was initially developed in Aachen, Germany, by **Impella CardioSystems** (Aachen Germany). Abiomed acquired Impella CardioSystems in the spring of 2005 for \$1.8 million in cash (*Medical Device Daily*, April 28, 2005).

The Impella device then received 510(k) clearance from the FDA in June 2008 for partial circulatory support for periods up to six hours.

Now approved in more than 40 countries, including in Europe under the CE mark, Impella 2.5 has been used to treat more than 1,700 patients worldwide and has been the subject of more than 50 peer-reviewed publications.

The company said that it also is conducting two U.S. pivotal studies comparing the Impella 2.5 to the IABP (Protect II for high-risk percutaneous coronary intervention, or PCI; and Recover II for acute myocardial infarction, AMI or heart attack).

There are an estimated 60,000 annual high-risk PCI patients and 100,000 AMI anterior infarct patients annually in the U.S.

Other companies developing similar devices include **Ventricor** (Chatswood, Australia) **HeartWare** (Framingham, Massachusetts/Sydney Australia) and **Thoratec**

(Pleasanton, California).

Ventricor offers the VentraAssist, a VAD that operates on a hemodynamically-suspended titanium impeller. The VentraAssist has a CE mark, and is currently enrolling patients in a U.S. pivotal trial (*MDD*, Sept. 19, 2007).

HeartWare developed its HeartWare Left Ventricular Assist System (LVAS) at **Washington Hospital Center** (WHC; Washington), which marks the start of the company's U.S. bridge-to-transplant clinical trial. Steven Boyce, MD, surgical director of the heart failure program at WHC, performed the surgery. The pump is small enough to fit in the pericardial space adjacent to the heart.

Thoratec won an approvable recommendation with conditions from the circulatory systems advisory panel of the FDA late last year for the HeartMate II, the newest generation of the company's HeartMate LVAD (*MDD*, Dec. 4, 2007). ■

Financings

Continued from Page 3

ner. "We are confident in the strength of Insulet's business strategy and are pleased to be facilitating the continued expansion of these opportunities for OmniPod. We believe this performance driven financing aligns the incentives and goals of both investors and management."

In conjunction with the initial \$27.5 million draw, Insulet has agreed to issue warrants for 3.75 million shares of common stock with an exercise price of \$3.13 per share. As financial milestones are achieved, Insulet may draw from the remaining \$32.5 million available in \$6.5 million increments.

Stereotaxis (St. Louis) said that it has extended its credit facility with **Silicon Valley Bank**, a member company of SVB Financial Group. Under the new agreement, which matures on March 31, 2010, the company can borrow up to \$25 million.

"This extension of our line of credit, combined with our existing cash position and other financing sources, provides us with the financial resources we believe we need to execute our business plan," said Mike Kaminski, Stereotaxis president/CEO. "In light of our recent \$20 million capital raise, our outlook on our financing needs and the opportunity to reduce the cost of borrowing, we voluntarily reduced the size of the line from \$30 million to \$25 million. Silicon Valley Bank has been a valued partner in our growth and this extension demonstrates their continued confidence in our strategy and ability to achieve our objectives." ■

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International

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regional authorities that are responsible for the organization of services within their region.

Zoll said that by standardizing on the Zoll E Series, the province's medical directors "will now be able to use and compare similar patient data."

It said that during the clinical evaluation, the E Series "scored the highest in the areas of data review and transmission," and "Real CPR Help feedback technology and See-Thru CPR were also cited as positive features for the delivery of high-quality CPR and reducing interruptions, respectively."

The U.S. firm said the Quebec Ministry of Health and Social Services "wanted to standardize its resuscitation technologies by offering advanced, high-performance equipment." It said the level of care that will be offered will be compatible with the **American Heart Association** (Dallas) and the **Heart and Stroke Foundation of Canada's** guidelines, which place "significant emphasis" on CPR.

The Zoll E Series is designed to meet the conditions that professional rescuers face every day, the company said. The E Series offers multiple data transmission options to a variety of destinations, including transmission of 12-lead ECGs to hospitals, which international guidelines now recommend for out-of-hospital use to help reduce time to perfusion in S-T segment elevation myocardial infarction (STEMI) patients.

Zoll said Real CPR Help in all of its devices "instantly provides first responders and advanced paramedics with technology to see how well they are performing the rate and depth of CPR chest compressions [and] See-Thru CPR helps them minimize interruptions in CPR that affect resuscitation success."

Canada okays Cepheid test

In other Canadian med-tech news, **Cepheid** (Sunnyvale, California) said Health Canada has issued a medical device license for the company's Xpert MRSA/SA Blood Culture (BC) test for the rapid detection of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA) in blood culture bottles showing gram-positive cocci.

The company said that, with results reporting in less than one hour, the Xpert MRSA/SA BC test "was designed to empower physicians with a new tool to aid in selecting the most effective antibiotic therapy to improve patient management and outcomes."

Rob Koska, Cepheid's senior VP of worldwide commercial operations, said, "Xpert MRSA/SA BC results enable physicians to initiate targeted therapy in septic patients far sooner than current culture-based methods — an important advancement in the timely management of potentially life-threatening infections."

He added, "With the addition of [this] . . . test, Canadian institutions are now armed with another tool in the arma-

mentarium for the rapid detection of MRSA and SA and overall management of infections."

Xpert MRSA/SA BC processes positive blood culture specimens to determine if a patient's blood is infected with MRSA or SA, frequent causes of sepsis in hospitalized patients. "This can enable physicians to quickly de-escalate from broad-spectrum antibiotic treatment to a more effective targeted therapy, thus reducing risk of resistance and improving patient outcomes," Cepheid said.

Typically, physicians will order a set of blood culture bottles drawn from patients presenting with symptoms of systemic infections. Currently, those additional tests — most notably to determine if the organism is methicillin-resistant or methicillin-susceptible *Staphylococcus aureus* — are done via slower culture testing methods.

According to a recent six-year **Queens University** study, published in the December 2008 issue of the *American Journal of Infection Control*, more than 250,000 Canadian patients experience infected surgical wounds, blood infections, and antibiotic resistant organisms while in the hospital each year. The study also states that, since 1999, rates of MRSA have more than doubled — from 2 to 5.2 per 1,000 hospital admissions across Canada.

Increased Chilean presence for Sigma-Aldrich

Sigma-Aldrich (St. Louis) has expanded its presence in Chile to directly serve research and manufacturing customers throughout the country. The company said it has acquired **Sigal Ltda** (Santiago), its primary distributor in Chile, and established **Sigma-Aldrich Quimica Ltda** to provide a foundation for future growth in the country.

Terms of the deal were not disclosed.

"Building on our strong customer base in Chile and throughout Latin America is a long-term strategy for Sigma-Aldrich," said Eric Green, vice president of international sales and operations. "We experienced 20% sales growth in Latin America in 2008 alone, and we believe our expanded presence in Chile, which will integrate sales, marketing and distribution, provides a solid base for consistent growth in the years to come."

The expansion in Chile is part of the company's strategic plan to accelerate growth in Canada, Asia Pacific and Latin America to 25% of corporate sales by 2010. As part of that strategy, Sigma-Aldrich established a representative office in Vietnam last October to serve the country's expanding research and manufacturing sectors.

Sigal Ltda was established in 1997 to supply research products to customers in Chile. Its general manager, Patricia Bravo, will become Sigma-Aldrich's sales and marketing manager for Chile.

Sigma-Aldrich's chemical and biochemical products and kits are used in scientific research, including genomic and proteomic research, biotechnology, pharmaceutical development and as components in pharmaceutical, diagnostic and other manufacturing. ■

Washington

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safety in America have not been updated since they were written in the time of Teddy Roosevelt.”

The statement includes the observation that because “our system of [food] inspection and enforcement is spread out so widely among so many people that it’s difficult for different parts of our government to share information, work together, and solve problems,” but Obama also mentions that FDA “has been underfunded and understaffed in recent years.”

The statement notes that Hamburg “was one of the youngest people ever elected to the National Academy of Sciences’ **Institute of Medicine**” and that as the health commissioner for New York City, she “brought a new life to a demoralized agency, leading an internationally-recognized initiative that cut the tuberculosis rate by nearly half, and overseeing food safety in our nation’s largest city.”

Obama said that as the health commissioner for the city of Baltimore, Sharfstein “has been recognized as a national leader for his efforts to protect children from unsafe over-the-counter cough and cold medications” and “designed an award-winning program to ensure that Americans with disabilities had access to prescription drugs.”

The White House also took the opportunity to announce the formation of a new food safety work group that will “bring together cabinet secretaries and senior officials to advise on how we can upgrade our food safety laws” and “a billion-dollar investment” in food safety, “a portion of which will go toward significantly increasing the number of food inspectors.”

Former FDA commissioner Bill Hubbard told *Medical Device Daily* that he sees Hamburg and Sharfstein as good picks because their resumes suggest that they’re up to the task and because their resumes do not set up a conflict with drug and device makers. “The reporting has been that Nissen was critical of industry,” Hubbard noted, which he said may have led to some headwind for that nomination. “You have to think Nissen would have had some opponents,” he remarked.

Hubbard, an adviser for the **Alliance for a Stronger FDA** (Silver Spring, Maryland), said “there are those who will say that any Democratic choice” will be anti industry, “but I don’t see either of their backgrounds indicating that. Peggy Hamburg is highly qualified,” he said, and “she brings no baggage since she has not been a big player in the food and drug world.”

“What people look for is whether these people have worked for industry or whether they’ve been hostile” toward industry, Hubbard said, noting that neither description fits either candidate readily.

By at least one account, the White House vetted the nomination fairly effectively, at least in political terms. Sen. Ted Kennedy (D-Massachusetts), chairman of the Senate Health, Education, Labor and Pensions Committee, which

has jurisdiction over FDA nominations, said in a closely-timed March 14 statement that Hamburg “is a strong leader and respected health professional and she’s an excellent choice to put the nation’s food and drug safety agency on the right course.” Kennedy stated further that she and Sharfstein “will bring dynamic new leadership to an agency that sorely needs it and will return sound scientific judgment to the FDA.”

BPA bills resurface in Congress

The question of whether bisphenol A (BPA) constitutes a health hazard continues, but Congress is weighing in with the Ban Poisonous Additives Act of 2009, which apparently has not yet been assigned an index number for either House or Senate versions. The bill, which would ban BPA from food and beverage containers, is a repeat of a bill by the same name introduced last year, but its prospects for passage this year may be improved, given the change of party in the White House.

Several national governments are on record on the question, with Canadian authorities indicating that the substance, which has been in use since the 1930s, is toxic. However, the governments in Germany and Japan have concluded that the available evidence shows no definitive link to toxicity. FDA reviewed the matter last year, but in a statement posted at the agency’s web site dated Oct. 28, 2008, FDA indicated that “additional research would be valuable” and “is already moving forward with planned research to address the potential low dose effects of bisphenol A.” However, the agency’s view at that time was also that “the present consensus among regulatory agencies in the United States, Canada, Europe, and Japan is that current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and babies.”

The fate of the bill is difficult to predict, but any ban of BPA in food and beverage containers could be followed by a similar move in medical devices, mostly in intravenous equipment and containers.

Representatives of **Becton Dickinson** (Franklin Lakes, New Jersey) and **Baxter Healthcare** (Deerfield, Illinois) were not available for comment.

New HHS office to oversee ARRA funds

The Department of Health and Human Services (HHS) last week opened a new office to help ensure the timely, organized and transparent distribution of the \$137 billion the agency is receiving through the American Recovery and Reinvestment Act (ARRA).

The Office of Recovery Act Coordination (ORAC) will be led by Dennis Williams, a 20-year HHS veteran.

HHS spokeswoman Jenny Backus said ORAC will enhance and streamline efforts to “get critical resources and potential new job opportunities to the American peo-

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NIH

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The NIH's grant process, Tabak added, "can take varying lengths of time," depending on the nature of an application.

Tabak noted that the \$10 billion stimulus funds must be used by September 2010.

"NIH is anxious to take advantage of the opportunity to expand research in human stem cells including human embryonic stem cells, and we will do whatever we can to expedite the development of the guidelines and the provision of grant funding," Landis said.

Tabak noted that the president's order "takes no position on specific scientific matters." In setting its guidelines, he said, the NIH "will undertake a very careful and deliberative look, and we also will have the benefit of public comment."

Tabak would not comment about whether he was surprised that the president's order was so open ended, only replying that the NIH was "very appreciative of the president's decision."

Landis acknowledge that the NIH had spent money and awarded grants under Bush's policy, which allowed tax dollars to be used for studies on 21 stem cell lines already extracted from embryos, as long as federal employees were not involved in extracting the cells.

"It was a start," she said, adding, "I think we were very clear that from a scientific point of view, more lines were needed and President Obama has now allowed us to expand this research."

Tabak noted that Obama's order does not address the 1996 Dickey-Wicker amendment, which placed a ban on federal funding for the creation of human embryos or research in which embryos are destroyed.

Jim Greenwood, CEO of the **Biotechnology Industry Organization** (BIO; Washington), said he expected Congress to take up legislation to overturn the Dickey-Wicker amendment. "The Dickey-Wicker amendment is bad policy," he said.

He noted that BIO plans to host a forum on March 24 for members of Congress and their staff on the science of hESC research and the policies that need to be in place on patent reform, follow-on biologics and reimbursement.

The lifting of the ban will have little, if any, immediate effects on the biotechnology industry or investment strategies for venture capitalists or biotech companies, said David Collier, managing director of venture capital firm **CMEA Capital** (San Francisco).

Stem cell research in general, he said, is an area that has not attracted a lot of venture funding, primarily because it is very early-stage research and venture capital investment is looking for returns on investments on a three-to-seven year time horizon.

VCs, Collier said, are looking for products that can gain approval or be on the market and generating sales or the

generate sale of a company within that timeframe.

"Most stem cell approaches are realistically probably 10 to 15 years out before they are going to produce any real significant treatments," he said. "So that's why you haven't seen a lot of venture capital investment there."

If VCs wanted to invest over the past decade in companies engaged in hESC research "they certainly could have done it," Collier said.

"Bush was preventing federal money from going into that field, but companies could certainly have been funded with private money and could have gotten around any U.S. restrictions by operating abroad," he said. "So if people thought that there was realistically money to be made in the relatively short term, there certainly could have been a lot more investment in the area than there has been."

While Obama's order overall is a very positive development for hESC research by freeing up federal money for doing basic research, which could lead to companies and programs being "fundable" by venture capitalists in the next decade, "it doesn't change the fact that the whole area is really so early and so far out there that most VCs are not going to jump in," Collier asserted. ■

ECR

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patient aperture.

Open-platform sales fell off from 2004-2007 due to their lower power ranging from 0.3 Tesla to 0.7 Tesla.

According to Philips, the Panorama renders resolutions comparable to conventional vertical bore 1.5 Tesla machines, pushing performance of a 1 Tesla vertical field, while offering freedom of movement for patient positioning during a scan.

"Promoting these machines for the claustrophobic patient is nonsense," said Körbler. "The real drivers for purchasing the open platform are neuro and orthopedic applications," he said.

With a conventional bore, the patient's arms are either pinned to their sides or else extended out of the bore above their head," he explained.

The open platform facilitates a study of movement of the knees and shoulders, he said, adding that for neurology, an open platform is more conducive to intraoperative procedures.

Körbler said Philips is installing four Panorama MRIs in Austria and the company expects the higher power for open-platform MRIs will push sales for this segment above 8% of MRI sales this year. ■

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PRODUCT BRIEFS

• **Aethlon Medical** (San Diego) reported results of the “first-in-man” study of the Aethlon Hemopurifier to treat human immunodeficiency virus (HIV), the disease that causes AIDS. In the study, viral load was reduced by 92% in an HIV-infected individual who received a total of 12 Hemopurifier treatments administered thrice weekly over the span of one month. The Hemopurifier is a therapeutic filtration device that serves as an artificial adjunct to the immune system. In HIV care, the Hemopurifier targets the clearance of all circulating strains of infectious HIV, including varieties that cause patients to fail antiviral drug regimens.

• **Applied Biosystems** (Carlsbad, California) reported the introduction of a new line of genotyping assays that enable researchers to more closely study the role that DNA copy number structural variation plays in human health and disease. The TaqMan Copy Number Assays are designed to detect and quantify copy number variations (CNVs), which are one of the most frequently occurring forms of structural change within a genome. These assays will enable pharmaceutical, clinical and academic researchers to accurately detect CNVs, which are changes in the number of copies of a gene, a part of a gene, or a large stretch of DNA that occur throughout a genome.

• **Atherotech** (Birmingham, Alabama) reported the addition of apolipoprotein A (apoAI) to its VAP Cholesterol Test. The VAP (Vertical Auto Profile) Test is the only single cholesterol test that routinely reports apoAI, apoB, and the apoB/apoAI ratio. With the addition of this new marker, the VAP Test now reports apoAI and the apoB/apoAI ratio, increasing its clinical utility in the assessment of risk for heart disease, diabetes and other cardiovascular diseases.

The new, clinically validated heart disease risk marker is included with the VAP cholesterol test. ApoAI is the main protein component of protective HDL cholesterol while apolipoprotein B100 (apoB) particles are the main component of atherogenic (bad) LDL cholesterol. In general, the lower the apoB/apoAI value, the lower your risk for heart disease. A ratio of 1 to 2 is considered low risk, while a ratio approaching 1 to 1 would be considered high risk, and anything over that – where the small LDL particles would dominate – would be very high risk.

• **CPC of America** (Las Vegas) said it is pursuing the development of proprietary polyethylene glycol (PEG) synthetic sealants as part of its global commercialization strategy for MedClose. MedClose is an investigational-stage vascular closure system that is intended to seal arterial puncture sites following diagnostic or interventional catheterization procedures. CPC said it will develop synthetic PEG sealants as platform technologies for the MedClose vascular closure system using ultra-pure functionalized, biocompatible and biodegradable polymers. The sealants will have adjustable physical properties, making it possible to ‘fine tune’ the gel time and strength for varied clinical applications. The proprietary compounds will be sourced from multiple suppliers, providing flexibility and accessibility for global commercialization and cost savings.

• **I-Flow** (Lake Forest, California), through its AcryMed subsidiary, has received FDA clearance for its stabilized antimicrobial wound gel. The product, as yet unnamed, has been FDA cleared for both over-the-counter and prescription-only marketing and distribution. The new stabilized antimicrobial wound gel contains antimicrobial silver in an amorphous gel. AcryMed says that it pioneered the introduction of silver antimicrobial gels for controlling bioburden in wounds.

PEOPLE IN PLACES

• Jeffrey Sherman was named executive VP/CFO of **LifePoint Hospitals** (Brentwood, Tennessee), effective April 13. Sherman is currently VP and treasurer at Tenant Healthcare. LifePoint Hospitals is a hospital company focused on providing healthcare services in non-urban communities in 17 states.

• Douglas VanOort was named executive chairman and interim CEO of **NeoGenomics** (Fort Myers, Florida). VanOort is operating partner at Summer Street Capital Partners, managing director of Conundrum Capital Partners, and is a member of the board of several private-equity held companies. NeoGenomics is a clinical laboratory that specializes in cancer genetics diagnostic testing.

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ple during tough times.”

HHS already has distributed more than \$3 billion of ARRA funds to states to support a variety of policies and programs, including community health centers and Medicaid, Backus said. “HHS is committed to moving quickly and carefully to distribute Recovery Act funds in an open and transparent manner,” she added.

The National Institutes of Health last week said \$1.5 billion in ARRA grants was now available: \$1 billion for construction and improvement of research facilities, \$200 million for scientific research, and \$300 million for the purchase of scientific equipment.

The Obama administration earlier this month released \$155 million of ARRA funds for community health centers and last month made \$15 billion available to states for Medicaid programs. ■