

Bankers predict 25% growth for U.S. IPO market in 2010

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

According to a recent study by **BDO** (Chicago), an accounting and consulting organization, capital markets executives at leading investment banks are bullish on the U.S. initial public offering (IPO) market for 2010. Furthermore, those surveyed say that the technology, energy, biotech and healthcare industries will lead IPO activity this year – in that order.

The study found that 68% believe IPO activity will increase this year compared to 2009, with 24% describing the increase as substantial. Only 5% of the survey participants expect a decrease in IPOs this year, while 27% forecast activity as flat with 2009. Overall, bankers predict a 25% increase in the number of U.S IPOs in 2010. They expect those offerings to average just over \$400 million in size, BDO noted. The 2010 BDO IPO Outlook survey, which examined
See BDO, Page 6

Navistar ThermoCool Catheter more effective than drug therapy

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

Biosense Webster (Diamond Bar, California), a **Johnson & Johnson** (J&J; New Brunswick, New Jersey) company, had a strong showing for its Navistar ThermoCool Catheter this week, as the company reported results from a study that demonstrates the device works better than most drugs to control irregular heartbeats in patients.

In the study, David Wilber, MD, of **Loyola University Medical Center** (Maywood, Illinois), and colleagues evaluated 167 patients at 19 hospitals that were treated with either drugs or the Navistar ThermoCool Catheter.

According to the group's results, which were published in the Jan. 27 issue of *Journal of the American Medical Association*, nearly 66% of the Atrial fibrillation (AF) patients who underwent catheter ablation had less recurring irregular heart beats compared to the 16% that were
See ThermoCool, Page 7

International report

Imaging Diagnostic Systems appoints distributor for Brazil

A Medical Device Daily Staff Report

Imaging Diagnostic Systems (IDS; Ft. Lauderdale, Florida) a developer of laser optical breast imaging systems, reported that Ultra-X BH has been selected as the exclusive distributor for the CT Laser Mammography (CTLM) system throughout Brazil. The company will market the system to the private and public sector.

"We are pleased to have representation in Brazil, and to have the opportunity to introduce CTLM technology to the market," said Deborah O'Brien, IDS's Senior VP. "Through the efforts of our new distributor, CTLM could provide a solution to some of the clinical problems that physicians and women in the region are currently facing."

Ultra-X was founded in 1987 specializing in software and hardware diagnostic solutions with locations in Brazil, Europe and Asia. Ultra-X Brazil will introduce the CTLM system
See International, Page 8

Deals roundup

VisEn acquires key fluorescence agent IP portfolio from Bayer

A Medical Device Daily Staff Report

VisEn Medical (Bedford, Massachusetts) has acquired the fluorescence imaging agent intellectual property portfolios and related technology platforms from **Bayer Schering Pharma** (Berlin).

The patent acquisition includes more than 45 issued patents worldwide covering a wide range of fluorescence agent constructs and imaging methods, and consolidates VisEn's patent and technology leadership position in the emerging markets of fluorescence imaging from preclinical research through clinical molecular diagnostics.

Terms of the deal were not disclosed.

"We have closely tracked the very high quality of Bayer Schering Pharma's fluorescence agent technologies and extensive patent portfolios over the last decade, and we are pleased to now integrate these platforms into VisEn's
See Deals, Page 9

Don't miss today's MDD Extra: Diagnostics

INSIDE:

FTC PROPOSES MDS SELL-OFF FOR ACQUISITION BY DANAHER2
HEARTWARE PRICES OFFERING AT \$35.50 AND BUMPS UP SIZE.....3

AHC Media LLC

*Washington roundup***FTC proposes MDS sell-off for acquisition by Danaher****A Medical Device Daily Staff Report**

The Federal Trade Commission announced yesterday that it has proposed terms for the acquisition of **MDS Analytical Technologies** (Mississauga, Ontario) by **Danaher Technologies** (Washington).

According to FTC's Jan. 27 announcement, the agency has required that MDS will have to sell off its laser microdissection division, which offers the equipment under the Arcturus brand name, in order for the \$650 million transaction to proceed (*Medical Device Daily*, Sept. 3, 2009).

FTC indicated that its concern revolves around preservation of competition in North America for laser microdissection equipment, which is capable of separating small groups of cells from other tissues, a technology that has proven useful in the isolation of cells for extraction of DNA, RNA and various proteins. According to the FTC statement, Danaher and MDS are presently two of only four firms that supply the North American market for this type of equipment. Danaher has expressed an intent to sell the Arcturus unit to **Life Technologies** (Carlsbad, California) to satisfy FTC's divestiture requirement.

The FTC statement indicated that the commission's vote on the proposed consent order was 4-0. The agency is accepting comments on the proposed order until March 1, 2010.

NIH technology for licensing

The National Institutes of Health has offered a raft of technologies for licensing this week, listing at least 10 items in the *Federal Register*.

Today's MDD food for med-tech thought

"Healthcare seems to have new products and new devices every day and from that standpoint if those devices are successful and prove to be useful in treating [diseases and ailments]... it's a logical place for the market [to invest in]."

– Lee Graul, national director of accounting for BDO, an accounting and consulting organization, on the firm's new survey in which 62% of respondents predict a resurgence in healthcare IPOs in 2010, "Bankers predict 25% growth for U.S. IPO market in 2010," pp. 1, 6.

For those in the imaging business, NIH offers a technique for enhancing the signal-to-noise ratio that can be applied to numerous types of imaging equipment, from conventional X-ray imaging to SPECT procedures. The *FR* notice, dated Jan. 28, states that the technique reduces noise by drawing a sub-region from each of multiple images of the same area of the body that are then assembled either as pixels to produce two-dimensional images or voxels to generate three-dimensional images. These images are apparently filtered for changes in amplitude that meet a predetermined threshold so as to permit a clearer view of the area of interest. The concept is said to have survived proofing, but further data are needed to establish the clinical utility of this technique.

Another of the items for licensing is a 72-gene model of a fine-needle aspiration (FNA) diagnostic designed to pick up less common forms of thyroid gland cancer. Although the *FR* notice goes into little detail, the tool picks up differentially expressed genes from thyroid tissue and offers greater precision than other FNA approaches. This diagnostic is said to be in the pre-clinical stage of development, however.

See Washington, Page 5

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*Financings roundup***HeartWare prices offering at \$35.50 and bumps up size****A Medical Device Daily Staff Report**

Cardiac-device maker **HeartWare International** (Framingham, Massachusetts) reported the pricing of its public offering of 1,537,305 million shares of its common stock at a price to the public of \$35.50 a share. The size of the offering has been increased from the previously disclosed 1.5 million shares, HeartWare noted.

The company said it has granted the underwriters an option to purchase up to an additional 230,595 shares of common stock to cover over-allotments. HeartWare expects to use the net proceeds of the offering for general corporate and working capital purposes.

J.P. Morgan Securities is acting as the sole book-running manager of the offering, and Canaccord Adams, Lazard Capital Markets and Wedbush PacGrow Life Sciences are acting as the co-managers of the offering. The offering was first disclosed earlier this week (*Medical Device Daily*, Jan. 28, 2010).

In other financing activity:

- **Neovasc** (Vancouver, British Columbia) said it has completed the first tranche of its previously disclosed non-brokered private placement of about 7.4 million units at a price of 27 cents a unit for aggregate gross proceeds of up to \$2 million.

The proceeds will be used primarily to fund the COSIRA trial, Neovasc said, a multi-center trial intended to demonstrate the safety and efficacy of its Reducer product for treating refractory angina.

The completion of the private placement is subject to TSX Venture Exchange approval and the execution of definitive documentation with investors. The securities issued pursuant to the offering will be subject to a four-month hold period from the date of issuance.

Each unit consists of one common share of Neovasc and one-half of one common share purchase warrant of Neovasc. Each whole warrant entitles the holder thereof to purchase one common share of Neovasc at the exercise price of 40 cents a share for a period of one year after the closing date of the offering. The majority of the offering was placed with existing investors, including members of Gagnon Securities, the Frost Group, company management and medical and scientific advisors.

- **iMedicor** (Nanuet, New York) said it has received \$750,000 in bridge funding from a private investment group and has received expressions of interest from other investors to expand the bridge to a total of \$1.5 million within the next 30 days. The initial funding of the bridge began in October and is just now being completed, the company noted.

The bridge funding is the forerunner of \$4 million in

long-term financing that is anticipated to close by the end of the first quarter of 2010. The long-term financing is subject to the negotiation of a definitive agreement and approval by the company's board.

The company said that proceeds from the financings would be used to repay the bridge funding, strengthen the company's balance sheet, improve working capital, and allow iMedicor to accelerate its business activities with pharmaceutical clients and health information exchanges. ■

*Patent watch***Kinetic Muscles gets okay from USPTO for neuromuscular patent****A Medical Device Daily Staff Report**

Kinetic Muscles (KMI; Tempe, Arizona) a provider of home-based rehabilitation therapy for stroke victims, reported that the U.S. Patent and Trademark Office has issued a notice of allowance for KMI's U.S. patent application, titled "System and Method for Neuromuscular Reeducation."

"This foundational patent is noteworthy," said Grant Farrell, president/CEO of KMI, "because it covers the unique combination of device features in our Mentor technology platform for providing rehabilitation therapy to victims of stroke or other neurological injury. Clinical studies carried out by KMI and by independent investigators show that our devices offer the potential for effective and economical home therapy for these patients. Recovery of limb function and independence has eluded millions of stroke victims, but now patients are beginning to see benefits in hand therapy and treatment of drop foot using KMI devices in the convenience of their homes." ■

Med-Tech Notes**SYBE opens 3 new offices**

SYBE Medical Management (Los Angeles), a firm specializing in processing physician billing, reported the opening of three new offices. The new locations include San Francisco, San Diego and Las Vegas.

"More than ever, physicians are looking for ways to improve their bottom lines because of increased paperwork and reduced compensation from insurance companies and government programs," said Steven Garrett, manager of SYBE.

SYBE says the key to its success is the high staff-to-client ratio for superior attention to detail. Typically, the SYBE team works directly with an office manager, keeping the physician's office informed with detailed reports and monthly analysis.

*Agreements/contracts***Novella, OSI Pharmaceuticals expand services agreement****A Medical Device Daily Staff Report**

Novella Clinical (Research Triangle Park, North Carolina) and **OSI Pharmaceuticals** (Melville, New York) will expand their existing clinical service agreement. Under terms of the new agreement, effective Feb. 1, 2010, Novella will provide clinical research and related services to OSI for a period of two years as OSI transitions its clinical operations to its new Ardsley, New York campus.

Novella will assume use of some of OSI's facilities in Boulder and employ members of OSI's Boulder staff.

"We are excited to be expanding our footprint and adding to our Novella family," said Richard Staub, president/CEO of Novella Clinical. "This agreement offers many advantages to Novella and will help us realize a number of our corporate objectives. As a CRO focused on biotech and medical device companies, many of our clients are located on the west coast and having an office in the western part of the country will allow us to better service their needs. Additionally, as OSI's pipeline is primarily focused on oncology products, the OSI staff joining Novella will bring a depth of experience that will strengthen what is already our largest therapeutic category."

OSI had previously reported in July 2009 plans to consolidate its U.S. operations onto a single campus located in Ardsley, New York. OSI has begun consolidation of approximately 350 current U.S. employees from its facilities in Melville and Farmingdale, New York, Boulder, Colorado, and Cedar Knolls, New Jersey.

"This is a win-win agreement between OSI and Novella and for the OSI Boulder employees who have chosen not to relocate with the Company," said Colin Goddard, PhD, CEO of OSI Pharmaceuticals. "As we execute our plan to capture the full strategic value of our oncology franchise and to simplify our business by bringing all our U.S. employees onto one campus, the expanded agreement will provide continuity of clinical operations, biostatistics, medical writing and regulatory affairs for certain ongoing clinical studies as the company transitions functions to its new campus in Ardsley, New York."

In other agreements/contracts news:

- **Medrad** (Warrendale, Pennsylvania) has entered into a co-marketing and trademark license agreement with **B. Braun Melsungen** (Melsungen, Germany) to promote the Paccocath technology, a technology used to treat blocked vessels without stenting. The Paccocath technology has been shown in multiple clinical trials to keep the artery open wider (reduce late lumen loss) over time in patients with peripheral arterial disease and coronary artery disease.

The Paccocath technology will be used in both

Medrad's and B. Braun's drug-eluting balloons. Under the agreement, B. Braun is permitted to use the Paccocath trademark in connection with promotion and marketing of its drug eluting balloon products.

- **Ingen Technologies** (Yucaipa, California) has signed a contract with **KGMA Business Solutions** (Frisco, Texas) to pursue U.S. government contracts. KGMA maintains relationships with thousands of contracting and small business specialists within the federal government. KGMA prepared and submitted the GSA application for Ingen on Sept. 22, 2009. The application has been under review with the VA National Acquisition Center, and was delayed back in November 2009 due to facility reorganization with the VA National Acquisition Center. KGMA reported that the application is near completion and will likely be approved. ■

*Court report***Cooper owner pleads guilty to \$1M in false Medicare claims****A Medical Device Daily Staff Report**

The owner and operator of a Los Angeles durable medical equipment (DME) company pleaded guilty to submitting nearly \$1 million in false claims to Medicare, according to Assistant Attorney General Lanny Breuer of the Criminal Division and Acting U.S. Attorney George Cardona for the Central District of California.

Ajibola Sadiqr, 51, pleaded guilty before U.S. District Court Judge John Walter in the Central District of California. Sadiqr, the owner of **Cooper Medical Supply** (Canoga Park, California), admitted that between January 2006 and September 2009, he conspired with Leonard Nwafor, the owner of another DME supply company who was convicted of Medicare fraud in September 2008, and others to purchase fraudulent prescriptions and medical documents. Sadiqr then used those documents to submit false claims to Medicare for expensive power wheelchairs and DME.

Sadiqr admitted that he knew the beneficiaries did not need the DME. Sadiqr also admitted that he knew the doctor and beneficiary information contained in the fraudulent prescriptions and medical documents came from fraudulent medical clinics and marketers. As a result of this scheme, Sadiqr admitted that he submitted or caused the submission of about \$950,000 in false and fraudulent claims to Medicare through Cooper Medical Supply.

At sentencing, scheduled for April 12, 2010, Sadiqr faces a maximum penalty of 10 years in prison and a \$250,000 fine for defrauding Medicare.

The case is being prosecuted by trial attorney Jonathan Baum of the Criminal Division's Fraud Section and Assistant U.S. Attorney Kerry O'Neill of the Central District of California. The case is being investigated by the California Department of Justice. The case was brought as part of the

See Court, Page 8

Washington

Continued from Page 2

Among the other offerings are a method for treating HIV infections with acyclovir, a molecular entity based on diazeniumdiolate for treatment of lung cancer, and a method by which extracellular proteases can be imaged with the use of a mutated antigen that is protective against anthrax.

AHRQ, ACC to study ICD outcomes

The **American College of Cardiology** (Washington) and the Agency for Healthcare Research and Quality have announced that they will collaborate on a study to assess the long-term risks and benefits of the use of implantable cardioverter defibrillators in patients at risk of death from ventricular defibrillation, also known as sudden cardiac death.

The topic is highly relevant to AHRQ's parent department, the Department of Health and Human Services, inasmuch as Medicare pays for a huge percentage of the ICDs that are implanted each year in the U.S., many of which never fire when used prophylactically to ward off sudden cardiac death. The study is also co-sponsored by the National Heart, Lung and Blood Institute at the National Institutes of Health.

AHRQ director Carolyn Clancy, MD, said in the AHRQ statement that the study "will provide critically important data from the real world of everyday medicine to inform discussions about the long-term benefits of ICD use." She characterized the study as "an excellent example of how government and the private sector can work together to advance research and improve the quality and safety of health care services."

The study will be financed with \$3.5 million to track 3,500 patients who have received ICDs for three and a half years in an effort to determine "how often the devices deliver shocks, whether the shocks are appropriate, and to identify those patients who are most likely to require ICD shocks," AHRQ states. The agency notes that it will provide \$2.1 million of the funding, which will go toward construction of the study sample and collection of ICD shock data in the first two years of the study. ACC will fund the balance of the money, which will finance the collection and analysis of the data for the remaining one and a half years.

NIH to confer on CRC screening

The National Institutes of Health has announced that it will hold a three-day conference on the use and quality of screening for colorectal cancer (CRC). The conference will take place Feb. 2, 3 and 4 at the Natcher Conference Center at NIH's campus in Bethesda, Maryland.

Screening for CRC looms large for healthcare costs, given the high rates of fatalities and the associated treatments. The Centers for Medicare & Medicaid Services announced last year that it would not cover computer-

ized tomography as a screening tool for CRC (*MDD*, May 15, 2009) because the supporting data dealt with populations younger than those who are typically eligible for Medicare.

The NIH announcement notes that CRC "is the second-leading cause of cancer-related deaths" in the U.S., and probably claimed 50,000 Americans in 2009. However, NIH states that screening is generally underutilized despite multiple testing procedures. The statement notes also that screening is sometimes overused and misused.

Among the issues the conference will examine are determining which strategies "are effective in increasing the appropriate use of colorectal cancer screening and follow-up" and what sort of capacity is required to offer screening and surveillance at the population level. According to the NIH announcement, the conference will also be webcast at <http://videocast.nih.gov>.

MedPAC urges tweaks to ESRD bundles

The Medicare Payment Advisory Commission gave a thorough vetting to the proposed prospective payment system for end-stage renal disease (ESRD) issued by the Centers for Medicare & Medicaid Services, and while MedPAC expressed appreciation for the agency's efforts, the Dec. 16 letter from MedPAC to acting CMS administrator Charlene Frizzera indicated a few adjustments might be in order.

According to MedPAC's Dec. 16, 2009, letter to Frizzera, the commission is of the view that the payment rubric should include ESRD drugs covered by Medicare Part D. Such an inclusion, the letters states, "would prevent providers from shifting costs by substituting Part D drugs for services covered" under the bundling rubric. This fix would require that CMS include all drugs related to end-stage dialysis in both oral and injectable forms in the payment bundle. According to MedPAC, the bundle proposed by CMS omits injectable vitamin D analogues as well as oral dosage forms of levocarnitine.

CMS names imaging accreditation bodies

The Centers for Medicare & Medicaid Services has announced that it has named three organizations to handle the task of accrediting imaging facilities for Medicare medical imaging.

According to the CMS declaration, which appeared in the Jan. 26 edition of the Federal Register, the three named bodies are the **American College of Radiology** (Reston, Virginia), the **Joint Commission** (formerly known as the Joint Commission for the Accreditation of Healthcare Organizations, Oakbrook Terrace, Illinois), and the **Intersocietal Accreditation Commission** (Ellicott City, Maryland). The designation of these three gives them the authority to set the standards for accreditation, a task the three seem sure to be able to fulfill. Imaging centers have to be accredited by Jan. 1, 2012 per the Medicare Improvements for Patients and Providers Act of 2008. ■

BDO

Continued from Page 1

ines the opinions of 100 capital markets executives at leading investment banks, was conducted in December.

Among the investment bankers surveyed, 83% expect the technology industry to experience an increase in IPOs, 78% predict the energy industry will see an increase in IPO activity, 72% believe the biotech industry will achieve an increase in IPOs, and 62% expect the healthcare industry to see a rise in IPO activity this year. No other industry is expected to achieve an increase in IPOs by a majority of the survey participants, BDO said.

When asked if the results of the survey, particularly as it relates to the biotech and healthcare industries, were surprising at all, Lee Graul, national director of accounting for BDO, told *Medical Device Daily* that the findings were not all that surprising.

"Healthcare seems to have new products and new devices every day and from that standpoint if those devices are successful and prove to be useful in treating [diseases and ailments] ... it's a logical place for the market [to invest in]," Graul said.

According to BDO, 25% of survey participants believe the biotech industry IPO activity will remain flat with last year while 21% expect the same to happen in healthcare. Only 2% of bankers surveyed said that IPO activity would drop in the biotech industry, but 15% said the healthcare industry could see a decrease in IPOs.

"The real issue is that as the population ages, healthcare becomes more important; with us baby boomers who are moving into our later years, I think people are looking at it and saying 'okay these people are going to start needing more and using more and more healthcare,'" Graul said. "There's more of an interest in extending the life and extending the quality of life."

He added that biotech feeds the healthcare industry through research and bringing out new products for things like the further reduction of cancer – such as treating it sooner and treating in a less invasive way than chemotherapy.

According to the BDO survey, 39% of capital market executives cite private equity portfolios as the greatest source of IPOs in 2010. Another 22% cited spinoffs and divestitures, 21% said venture capital portfolios, and 17% predicted that owner-managed, privately held businesses would be the biggest source of IPOs this year.

"Though still well below 'pre-crisis' levels of 2007, in predicting an increase of 25% for U.S. IPOs in 2010, this inaugural survey reveals broad-based optimism among the capital markets community that offering activity in the new year will build on the momentum established this past fall," said Christopher Tower, a partner in the BDO Capital Markets Practice.

BDO also noted that capital markets executives at the very largest banks or "bulge bracket" firms mirror the

responses of the total capital markets community on most topics in the survey. However, they are even more bullish about IPO activity, predicting a 38% year-over-year increase, and are even more likely (62%) to view private equity portfolios as the greatest source of IPOs in 2010.

"Overall, the bankers' outlook for IPOs is very positive, but some industry sectors are clearly seen as stronger than others," said Jay Duke, a partner in the BDO Capital Markets Practice. "When you consider the buzz surrounding rumored offerings of online networking businesses like Facebook, Twitter and LinkedIn, and the emphasis the current administration has placed on developing alternative energy it makes sense that bankers expect the technology and energy sectors to lead the way in IPOs in the coming year."

On average, according to the BDO survey, bankers feel IPOs will need to achieve a 12% one-day and 20% six-month, after-market return to be considered successful in 2010. When asked what type of offering attributes the investment community will value the most in the coming year, more than a third of bankers (38%) cite long-term growth potential. Other attributes that will be valued this year are profitability (28%) and stable cash flow (25%), the survey noted. Some bankers, 9%, see the strength of a company's industry vertical as the most valuable attribute of an IPO in 2010.

The BDO survey also found that, on average, bankers think businesses will need to offer 38% ownership to achieve a successful IPO this year.

Of the 68% forecasting an increase in IPO activity this year, almost half (46%) expect activity to peak in the third quarter, according to the survey, while a third (33%) feel the second quarter of the year would set the high water mark for activity. 1Q and 4Q are less likely to see a peak in activity, according to survey respondents.

The performance of the stock market, of course, is viewed as the most important factor in determining the health of the IPO market, the BDO survey noted. The rebound of the stock market (44%) and improved investor confidence (25%) are viewed as the main reasons for the increase in IPO activity during the second half of 2009. By the same token, almost half (48%) of the investment bankers surveyed identified poor stock market performance as the greatest threat to IPOs going forward. Constrained bank lending is viewed as the greatest threat by almost a third (30%) of the participants, BDO noted.

"The studies, I think, reflect an optimism based upon the trend of the markets towards the end of the year and towards the last few weeks," Graul said. "The markets are scared these days about what's going on in Washington," he added, noting that political influence has a lot of impact on the market and the psychology of the market. If BDO were to conduct the same survey today, two days after

See BDO, Page 7

ThermoCool

Continued from Page 1

treated with drugs.

Enrollment occurred between October 2004 and October 2007, with the last follow-up on January 19, 2009. Patients were randomized to catheter ablation (n=106) or antiarrhythmic drug therapy (ADT) (n=61), with assessment for effectiveness in a 9-month follow-up period.

The study goes on to say that similarly, 70% of patients treated by catheter ablation remained free of symptomatic recurrent atrial arrhythmia vs. 19% of patients treated with ADT. In addition, 63% of patients treated by catheter ablation were free of any recurrent atrial arrhythmia vs. 17% of patients treated with ADT. Patients in the catheter ablation group also reported significantly better average symptom frequency and severity scores at three months on measures of quality of life.

"Our multicenter randomized trial demonstrates the superiority of catheter ablation over ADT in the treatment of patients with paroxysmal AF who did not respond to 1 or more drugs. Catheter ablation provided significantly better rhythm control and improved quality of life with a favorable safety profile. These findings argue for early use of catheter ablation therapy in patients with paroxysmal AF unresponsive to initial attempts with pharmacologic control," according to the authors of the study.

The catheter ablation procedure involves inserting a thin tube into a blood vessel, usually through a site in the upper leg or neck, then threading it through the body until it reaches into the heart.

Once the tube reaches the area causing the abnormal rhythms, the device emits radio frequency energy to destroy the tissue.

The study results come almost a year after Biosense Webster received FDA approval for the device to give physicians the safety and convenience of steering the catheter remotely, away from fluoroscopy exposure, during procedures to eliminate abnormal heart rhythms (*Medical Device Daily*, March 2, 2009).

The results also come on the heels of a report compiled by the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) giving radio frequency catheter ablation procedures a favorable boost in terms of effectiveness (*MDD*, July 9, 2009). The report found that the procedure has been shown to help patients in maintaining normal heart rhythm for short periods of time. AHRQ's report shows that that short period of time could be up until one year.

AHRQ's study results also helped open up the door for J&J and other companies vying for dominance in this particular market.

Already **Medtronic** (Minneapolis), **Boston Scientific** (Natick, Massachusetts), and **St. Jude Medical** (St. Paul, Minnesota) have been developing these catheters and looking for a means of entry into the U.S. market.

Medtronic has said that it hopes to bring its catheter to the U.S. market later on this year, pending FDA approval.

St. Jude reported that it has permission from FDA to start enrollment in a medical trial of the safety and effectiveness of the company's catheter ablation system for AF, and Boston Scientific said that it didn't have catheters indicated for treatment of AF in the U.S.

AF represents an important public health problem, with patients having an increased long-term risk of stroke, heart failure and all-cause death. Although antiarrhythmic drugs are generally used as first-line therapy to treat patients with AF, they are associated with cumulative adverse effects over time and their effectiveness remains inconsistent.

It's a reason why plans are now being called for a larger study in the future to determine if AF patients who receive ablation live longer than those taking medicine. Researchers of this study say that results probably won't be available for five or six years. ■

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BDO

Continued from Page 6

President Obama's State of the Union address, "I don't know if those bankers would be" as optimistic as they were a few weeks ago.

"Markets are here today and gone tomorrow and back the next day based upon the psychology," Graul said. "Markets are a sensitive area right now and from that standpoint a little bit of bad news [can do a lot of damage]. Right now I think we're positive, it seems like the people that actually do the transactions in the invest banks remain positive in the long run hoping it won't be as dire a situation as it was the last two years."

When asked about follow-up offerings, 81% of the bankers said they view a secondary offering as an important factor in a business's IPO decision. According to the survey, 32% believe a secondary offering is "very important" vs. 49% who say it is only "somewhat important," and 19% think a secondary offering has no importance in an IPO decision. Of those who view follow-up, secondary offerings as an important component in an IPO decision, 58% believe the second offering should take place at least a year after the initial offering, but another 41% said it can take place in as little as six months after the IPO, BDO noted.

BDO said its IPO outlook survey is a national telephone survey conducted by Market Measurement, an independent research consulting firm, whose executive interviewers spoke directly to capital markets executives. ■

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International

Continued from Page 1

tem to the private and public sector, government officials, exhibit at local trade shows, and support additional clinical studies for future applications of the CTLM technology.

IDS has developed a new imaging device to aid in the detection and management of breast cancer. The CTLM system is a breast imaging system that utilizes patented continuous wave laser technology and computer algorithms to create 3-D images of the breast. The procedure is non-invasive, painless, and does not expose the patient to ionizing radiation or painful breast compression. CTLM is designed to be used in conjunction with mammography. It reveals information about blood distribution in the breast and may visualize the process of angiogenesis, which usually accompanies tumor growth.

SBI reports 1st Malaysian SR PIP surgery

Small Bone Innovations (SBI; New York), a privately held orthopedics company focused exclusively on technologies and treatments for the small bones & joints, reported the first surgeries in Malaysia using SBI's SR PIP (Surface Replacement Proximal Inter Phalangeal) replacement finger joints to reduce pain, restore form, function and motion. This followed the recently formation of SBI Asia Pacific Sdn. Bhd. (SBI APAC), a joint venture with Khazanah Nasional Berhad and Malaysian Technology Development Corp. Sdn. Bhd. that is based in Kuala Lumpur, Malaysia.

Ranjit Singh Gill, MBBS, FRCS, AM, a hand and micro-surgery consultant at both the **Pantai Medical Centre** and **Kuala Lumpur Sports Medicine Center**, completed the finger joint replacements at each facility using SBI's SR PIP joint replacement devices on patients presenting with finger arthritis.

The SR PIP Implants are designed to replace the anatomic joint surfaces while, preserving the maximum amount of bone and minimizing soft tissue disruption. The SR PIP Implants consists of two pieces: one piece has two components, a cobalt chrome stem and an attached ultra-high molecular weight polyethylene (UHMWPE) component, and the other piece is a titanium alloy stem. Both stems have a textured surface that facilitates osseointegration.

"SBI's formation of a joint venture in Malaysia is something of a breakthrough opportunity for us, because it not only brings SBI's technologies to the Asia Pacific region, including the SR^T PIP implants, but also demonstrates SBI's commitment to develop implants specifically designed for Asian anatomies. Obviously, this is good news for thousands of patients and future arthritis sufferers," said Gill.

"These first surgeries mark an important milestone for SBI, and the doctors and their patients as we embark on our objective to establish the company as the global first mover in the Asia Pacific region to provide a portfolio of arthroplasty and trauma reconstruction solutions for the

small bone & joint anatomies," said Anthony Viscogliosi, chairman /CEO of SBI.

LP&P to acquire Brazilian healthcare system

London Pacific & Partners (LP&P; El Segundo, California), an international advisory and investment firm, reported that **LP Healthcare Group**, (LPHC), a joint venture between London Pacific and Incite Financial, has signed an agreement to acquire **Santos Administracao e Participações** – a regional healthcare system including a 125,000-member health maintenance organization (HMO), three hospitals with a total of 290-beds, three full-service primary care centers and other related interests in the state of Sao Paulo, Brazil. The three hospitals include a 250-bed comprehensive regional hospital and two local hospitals.

LPHC has agreed to acquire a 100% controlling interest in Santos which owns 100% of the HMO and a 57.4% controlling interest in the hospitals and primary care centers and other related interests for \$50 million in cash.

LP&P presently owns 30% of LPHC with an option to acquire an additional 20% ownership and will manage the healthcare system via a long-term contract.

Santos, a 53 year old healthcare system headquartered in a rapidly growing coastal region of the state of Sao Paulo in southeastern Brazil, generated about \$173 million in revenues and \$23 million in earnings before interest, taxes, depreciation and rentals for the year ended Dec. 31, 2009. The system is currently undergoing an aggressive expansion and modernization program.

"The acquisition of Santos will represent a watershed in the development of London Pacific," said Stuart Bruck, executive chairman of the company. "Our experience in healthcare services, development and management should help Santos achieve greater long term growth and profitability. In addition, we intend to leverage our presence in Brazil to acquire additional healthcare properties in the region, as well as look for strategic opportunities for hospitality and natural resources investments and projects which fit our company profile." ■

Court

Continued from Page 4

Medicare Fraud Strike Force, supervised by the Criminal Division's Fraud Section and the U.S. Attorney's Office for the Central District of California, according to the Assistant Attorney General

Since its inception in March 2007, Strike Force operations in seven districts have obtained indictments of more than 500 individuals who collectively have falsely billed the Medicare program for more than \$1 billion. In addition, the U.S. Department of Health and Human Services' (HHS) Centers for Medicare and Medicaid Services, working in conjunction with the HHS Office of the Inspector General are taking steps to increase accountability and decrease the presence of fraudulent providers. ■

Deals

Continued from Page 1

programs," said Kirtland Poss, president/CEO of VisEn Medical. "The acquisition of these assets significantly expands VisEn's patent coverage of in vivo fluorescent imaging agents, and adds to our R&D capability and pipeline of pre-clinical agent products and clinical imaging agents going forward."

With this acquisition, VisEn's intellectual property portfolio covering fluorescence imaging agents now includes more than 150 patents and patent applications worldwide. The collective patent estate provides comprehensive coverage of a broad range of core agent components and chemistries, as well as key preclinical and clinical applications and methods. Included in the acquired portfolio are key patents covering physiologic agents, bioconjugates and targeted fluorescence agents, and certain activatable imaging agents for measurement of diverse biomarker activity in living systems. With the addition of these new platforms, VisEn plans to further expand the aggressive development of its preclinical agent product offerings, as well as its clinical imaging agent pipeline and related programs.

VisEn recently reported the launch of its new Cat B 680 FAST imaging agent for measuring and monitoring cathepsin B activity associated with disease progression and therapeutic response in vivo. Cathepsin B expression is known as a key biomarker and therapeutic target in a range of diseases, including atherosclerosis, oncology, and arthritis (*Medical Device Daily*, Jan. 25, 2010).

Prior to that, VisEn launched a new Fluorescence Molecular Tomography (FMT) imaging system the FMT 1500, and an advanced version of its FMT 2500, the FMT 2500 LX. The FMT 2500 LX offers more imaging channels, greater functionality, increased imaging speeds and a broader range of application areas than previously available. Both the FMT 1500 and FMT 2500 LX are based on VisEn's FMT Quantitative Tomographic Imaging platform and both enable unparalleled true quantification of in vivo biomarkers for measuring disease progression and therapeutic efficacy in research and drug development (*MDD*, Sept. 24, 2009).

VisEn's *in vivo* fluorescence imaging technologies, including its fluorescence agent portfolio and its fluorescence molecular tomographic imaging systems, provide robust fluorescence molecular imaging performance in identifying, characterizing and quantifying ranges of disease biomarkers and therapeutic efficacy *in vivo*.

Last year, VisEn reported that its imaging technology was used to generate data that enabled scientists to discover a new biologic pathway using an integrated array of in vitro readouts and advanced in vivo imaging technologies. According to the company, the newly reported biologic pathway relates to monocyte deployment from the spleen to inflammatory sites, including myocardial infarction. The findings are expected to open up new areas of

research and potentially advance therapeutic approaches to key disease areas including inflammation and myocardial injury, VisEn said at the time (*MDD*, Aug. 3, 2009). ■

Grants roundup

NCI offers new SBIR funding to reach up to \$10 million

A Medical Device Daily Staff Report

The **National Cancer Institute** (NCI; Bethesda, Maryland) Small Business Innovation Research Program (SBIR) said a new NCI SBIR Bridge Award funding opportunity which will make available up to \$10 million in fiscal year 2010. The Bridge Award is designed to support the next stage of development for previously funded NIH-wide SBIR Phase II projects in the areas of cancer therapies, diagnostics, and cancer imaging technologies. The application due date for the Bridge Award is March 2, 2010.

Bridge funding helps small businesses overcome the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization, which is especially critical during these economic times. The Bridge Award represents a cutting-edge new model for both the NCI and investors to share in the investment risk in order to accelerate the most promising small business innovations to commercialization.

The new Bridge funding opportunity that is now available will fund up to 10 small business projects. Each small business can apply for up to \$3 million over three years (\$1 million per year). ■

Off-label promotion vs. scientific exchange: Ensure effective and compliant medical affairs communication

Medical Science Liaisons (MSLs) are legally empowered to engage in scientific exchange with prescribers. They are *not* allowed to promote off-label uses for prescription drugs or medical devices.

A simple concept, but ensuring, in practice, this line is not crossed is far from easy. And, when that line is blurry, do you insist on compliance at all costs, or do you lean toward getting product information out?

In this 90 minute audio conference, former FDA Regulatory Counsel **Richard Lev**, and MSL expert **Robin Winter-Sperry, MD** will provide strategies on how to ensure effective scientific exchange and education, while maintaining off-label compliance.

Scheduled for **Thursday, February 25, 2010**; 1 pm-2:30 pm EST registration for the event is \$325. Call **1-800-688-2421** to register! Mention conference code **TI0604**.

Product Briefs

- **IVF Florida Reproductive Associates** (IVF; Mergate, Florida) reported new tests against birth defects: a coupling of technologies that will allow couples to avoid passing along more than 100 genetic diseases to their newborn. IVF is optimistic that the combination of a brand-new saliva test – administered before pregnancy – to identify couples at risk of bearing children with genetic diseases, along with an ultra high-tech biopsy process, conducted after conception, will help prevent the inheritance of many genetic disorders. The tests screen disorders ranging from Tay-Sachs to cystic fibrosis to sickle cell disease, said Steven Ory of IVF Florida and former president of the American Society of Reproductive Medicine. The process lets parents screen for genetic diseases before pregnancy—rather than face unwelcome news later in pregnancy when tests such as amniocentesis and chorionic villus sampling are done.

- **McKesson** (Atlanta) reported the general availability of Horizon Practice Plus 12.0, a comprehensive practice management system for hospital-employed and large to mid-sized physician practices. This latest release features advanced scheduling and billing capabilities designed to streamline workflow and remove complexity from financial and administrative processes. Horizon Practice Plus 12.0 is installed at the Mankato Clinic, a multi-specialty group practice in Mankato, Minnesota. Mankato credits the practice management system for helping ensure that financial and patient information is integrated across multiple locations. In addition to processing more than 47,000 claim transactions per month – a number that far exceeds industry benchmarks – Mankato said it has seen dramatic reductions in both claims denial rates and days in accounts receivable.

- **Medtronic** (Minneapolis) said that pivotal data for the Medtronic Arctic Front CryoAblation Catheter System will be presented as a late breaking clinical trial at the Scientific Session of the American College of Cardiology. The STOP-AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) clinical trial is evaluating the safety and efficacy of the Arctic Front CryoAblation Catheter System for paroxysmal atrial fibrillation patients. Additionally, data from the Medtronic-sponsored CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) clinical trial also will be presented as a late breaker. The trial is assessing how the use of the Medtronic CareLink Network to remotely monitor patients with Medtronic cardiac resynchronization therapy-defibrillators and implantable cardioverter-defibrillators equipped with Conexis Wireless Telemetry might effectively enable better patient care and reduce unnecessary healthcare costs.

- **Merge Healthcare** (Milwaukee) has launched its

etrials eDiary 5.0 platform to conduct a Phase II urology clinical trial involving 750 patients. Merge said it was awarded the project because of its eDiary technology, experience in global ePRO (electronic patient reported outcomes) trials and ability to manage the complex logic required by this study. The trial also uses Merge's new eDiary Inventory Module to track shipping and supply of study devices in real-time. Patient reported information is increasingly critical to the success of a clinical trial, but the data is prone to subjectivity, and is difficult to economically collect in a timely and scientifically valid manner. Handheld devices that upload patient-entered responses in real time into centralized electronic repositories provide fast and accurate data to clinical trials managers and can reduce overall trial costs. Merge says it has conducted hundreds of global ePRO trials and can provide solutions optimized to meet the needs of each individual trial and sponsor.

- **Oculus Innovative Sciences** (Petaluma, California) reported the introduction of the Microcyn Solution with preservatives. The Microcyn Solution for professional use is intended for the irrigation and management via debridement of post-surgical wounds. Microcyn Solution is available in 500 mL and 990 mL units with attached phar-masling hangers, and the company claims it has no known drug/treatment interactions or contraindications; is non-foaming and safe to use around nose, mouth and eyes; does not contain antibiotics and will not facilitate bacterial resistance. With a laboratory-proven inactivation of bacteria, fungus and spores in-solution, Microcyn delivers a six-log reduction of MRSA, VRE, *Pseudomonas*, *Acinetobacter* and many other pathogens in just 30 seconds as labeled and cleared by the FDA.

People in the News

- **A-Life Medical** (San Diego) said that it has promoted Spencer Wood to VP of client services. Wood joined A-Life in 2007 as director of client services. A-Life Medical makes computer-assisted coding products for the healthcare industry.

- **Broadlane** (Dallas) reported that Patrick Ryan, Broadlane's chairman, will assume the additional responsibilities of CEO. Thomas Sherry, Broadlane's COO, will take on the additional responsibilities of president. David Ricker, Broadlane's president/CEO, has elected to step down from his full-time role, but he will continue as a member of the board. Broadlane supplies technology, sourcing, supply chain and workforce management services for healthcare providers.

- **GCI Health** (New York) has named Wendy Lund as CEO, effective Feb. 8. Lund previously was executive VP of global business and client development for MS&L Worldwide. GCI Health is a healthcare communications firm.

MDD'S DIAGNOSTIC EXTRA

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

FRIDAY, JANUARY 29, 2010

PAGE 1 OF 2

Keeping you up to date on recent headlines in diagnostics.

New tech gives cardiologists greater view of heart arteries. . . New technology that allows doctors to see three-dimensional images of heart arteries in the catheterization lab passed its first major testing hurdle - moving doctors closer to understanding its impact on clinical practice, researchers report in *Circulation: Cardiovascular Interventions*, an **American Heart Association** (AHA; Dallas) journal. Still in the early stages of testing, the 3-D images may allow cardiologists to more accurately and quickly assess the length, branching pattern, and angles of heart arteries and any blockages. "Coronary interventions may be improved by having a realistic, 3-D image of the coronary artery tree," said John Carroll, MD, an investigator for the study and professor of medicine and director of interventional cardiology in the Division of Cardiology at the **University of Colorado** (Aurora). Currently, doctors take multiple two-dimensional X-ray images from different views to visualize what the arteries look like inside the body. The new software, which uses existing X-ray systems, could reduce the need for multiple X-rays, thus decreasing patients' exposure to radiation and contrast dye and cutting the time doctors spend analyzing the images. During a cardiac catheterization procedure, doctors insert a thin tube called a catheter into a patient's leg artery, and then thread it up to the heart. The catheter is then used to inject contrast dye that temporarily fills the coronary arteries allowing x-ray visualization of the inner diameter of the artery. This allows doctors to detect plaque build up, then plan and execute, if needed, the insertion of a coronary stent to open a blocked artery and allow normal blood flow. X-rays are generated below the patient and 2-D shadow-like images of coronary arteries are created by a detector above the patient. These shadow images have been the standard method of presenting coronary angiographic images for over 50 years. In the study, researchers compared these standard 2-D images to automatically generated, computer-reconstructed 3-D images of 23 patients' coronary artery systems. To generate realistic 3-D images, the detector was rapidly rotated around the patient during the injection of contrast dye, a technique called rotational angiography. "This is the first in-human use," Carroll said about the feasibility study. "The next step is to test it in multiple centers around the world. In addition, we'll formally test it to see the impact on clinical care. The bottom line is that this is very exciting technology that holds great promise."

NPL uses "phantoms" to identify early signs of cancer . . . A new technique to catch cancer early has taken an important step forward thanks to the **National Physical Laboratory** (NPL; London). NPL's 'phantoms' will ensure an exciting new screening technique can be relied upon by hospitals to identify early signs of cancer. The technique, Optical Coherence Tomography (OCT), is an increasingly popular method for looking beneath the surface of certain materials, notably human tissue. It is higher resolution and much quicker than techniques such as MRI or ultrasound, with no ionizing radiation, making it ideal for detecting changes in tissue structure which can indicate the early stages of cancer. However creating such images requires high precision, and any inaccuracy can lead to incorrect assumptions about cell disruption. This can mean missing opportunities for early, potentially life-saving treatment. A new NPL product, called a 'point-spread phantom', will eliminate the risk of such errors. The phantoms are translucent cylinders of resin containing specially arranged particles designed to reflect light in a very specific way. By viewing the phantom with an OCT machine and analyzing the image with NPL software, users can be certain the machine is producing accurate images, which they can rely on for important medical decisions. These 'phantoms' will also allow manufacturers of OCT technology to meet the necessary standards to guarantee to hospitals that their machines are sufficiently accurate. This will help speed the route to market of products using this important new technology, and assure hospitals of their ongoing reliability.

Researchers obtain 3-D images of neurons . . . A team of researchers from the **Max Planck Institute of Biochemistry** (Munich, Germany) led by the Spanish physicist Rubén Fernández-Busnadiego, has managed to obtain 3-D images of the vesicles and filaments involved in communication between neurons. The method is based on a novel technique in electron microscopy, which cools cells so quickly that their biological structures can be frozen while fully active. "We used electron cryotomography, a new technique in microscopy based on ultra-fast freezing of cells, in order to study and obtain three-dimensional images of synapses, the cellular structure in which the communication between neurons takes place in the brains of mammals," Rubén Fernández-Busnadiego lead author of the study and a physicist at the Max Planck Institute of Biochemistry said. During synapses, a presynaptic cell (emitter) releases neurotransmitters to another post-synaptic one (recipient), generating an electric impulse in it, thereby allowing nervous infor-

mation to be transmitted. During this study, the researchers focused on the tiny vesicles (measuring around 40 nanometers in diameter), which transport and release the neurotransmitters from the presynaptic terminals. "Thanks to the use of certain pharmacological treatments and the advanced 3-D imaging analysis method we have developed, it is possible to observe the huge range of filamentous structures that are within the presynaptic terminal and interact directly with the synaptic vesicles, as well as to learn about their crucial role in responding to the electrical activity of the brain," explains Fernández-Busnadiego. The filaments connect the vesicles and also connect them with the active area, the part of the cellular membrane from which the neurotransmitters are released. According to the Spanish physicist, these filamentous structures act as barriers that block the free movement of the vesicles, keeping them in their place until the electric impulse arrives, as well as determining the ease with which they will fuse with the membrane. The technique upon which these discoveries are based, electron cryotomography, makes it possible to obtain three-dimensional images of the inside of cells and to minimize any changes to their structure. This is possible because the cells are not fixed with chemical reagents, but are vitrified - in other words they are frozen so fast that the water inside them does not have time to crystallize, and remains in solid state. These samples, which are always maintained at liquid nitrogen temperatures (below -140 °C), can be viewed using specially-equipped microscopes. In addition, this method does not require any kind of additional staining, meaning the density of the biological structures can be observed directly.

TruTouch develops fingertouch biometric intoxication device . . . TruTouch Technologies (Albuquerque, New Mexico) a developer of non-invasive biometric intoxication detection systems, reported that it has successfully carried out human clinical trials of its newest finger-touch detection system for alcohol intoxication, in collaboration with **Lovelace Scientific Resources** (Austin, Texas). The trial is intended to support continued product commercialization and new technology development for the device, called TruTouch 2000. TruTouch and Lovelace Scientific Resources carried out a comparison alcohol level detection study in 55 patients, comparing effectiveness and sensitivity of the newly developed TruTouch 2000 finger touch device with the TruTouch Guardian forearm device, breathalyzer and the current gold standard for intoxication detection, venous blood. Dr. Richard Gill, President/CEO of TruTouch, said, "We are delighted to announce the successful calibration of our newly developed TruTouch 2000, which will help advance commercialization of our current TruTouch intoxication detection systems. These systems are already enjoying success in the law enforcement support, oil drilling, military and transportation operation markets. Additionally, we are looking forward to a successful launch through OEM partners into Medical, Workplace & Point of Sale markets." He added, "TruTouch's mission is to help eliminate alcohol-related dangers on our roadways and in our workplaces, by providing a simple, accurate and cost-effective test to ensure driver and equipment operator safety." The TruTouch Guardian and TruTouch 2000 are advanced intoxication detection devices that use light, instead of bodily fluids or other means, to measure a subject's alcohol level. With the TruTouch 2000, a subject places a finger on an infrared scanning system, which then analyzes the level of intoxicant in the subject's system. The device can produce accurate results in less than 15 seconds, and has a built-in biometric identification system to ensure test result integrity. Unlike a Breathalyzer, the TruTouch Guardian and TruTouch 2000 devices require no user training, no disposables, no samples, and need no operator assistance.

Phoenix Controls to offer room pressure monitor for hospitals . . . Phoenix Controls (Acton, Massachusetts) reported the introduction of the Advanced Pressure Monitor II (APM2), a device that monitors very low differential pressure between rooms. The APM2 verifies directional airflow, and is used in critical ventilation applications such as vivarium research, chemotherapy preparations, hospital procedure rooms, and biocontainment facilities. The product is available today. Conceived with input from a wide range of users, the APM2 is designed to meet the broad needs of laboratory, life sciences and healthcare markets. For the architect, the device has a faceplate and touch-screen that is attractive for use in the public spaces of modern facilities. For the design engineer, the product performs functions that can meet the specifications of virtually any room application. For the contractor and installer, the unit is designed for easy rough-in, simple installation and rapid commissioning. And for the end-user, the APM2 should provide years of continuous and reliable operation. "Pressure monitoring is a core part of our business because it verifies that our valves are properly pressurizing the space," said Vincent Schultz, general manager of Phoenix Controls. "The APM2 is also an exciting visual product in the finished space, and this helps put Phoenix Controls in front of new customers and brings us into new markets." The APM2 blends two key functions together in a single unit; room pressure monitoring and a bright touch-screen local display. The product is a highly accurate pressure monitor, using true differential pressure transducer technology. This means the APM2 can meet the most stringent applications that require measurement of room pressure to 0.0001" WC resolution, and with an accuracy of $\pm 0.25\%$ of full scale.

**– Compiled by Omar Ford, MDD Staff Writer
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