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PAGE 1 OF 11

MEDICA 2008

Philips, Draeger both enter drugs-of-abuse test market

By JOHN BROSKY

Medical Device Daily European Editor

DÜSSELDORF, Germany – The current market is small and the laws are not clear, but two major medical device manufacturers moved into roadside testing for drugs-of-abuse with product introductions at MEDICA, the world's largest trade fair for medical devices.

Draeger Medical (Lübeck, Germany) showed a medicalized version of a test it launched in the law enforcement market earlier this year, while **Philips Personalized Healthcare** (Eindhoven, the Netherlands) introduced a hand-held drug test technology for law enforcement that it said will later prove to be a breakthrough in medical diagnostic applications.

Neither product will be released commercially until next year.

See MEDICA, Page 6

VEITHsymposium 2008

Study indicates Ekos device helps dissolve clots faster

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

A study presented Sunday at the 35th annual VEITH-symposium in New York suggests that the use of thrombolytic drug therapy along with **Ekos'** (Bothell, Washington) device designed to accelerate the dissolution of vascular blood clots is more effective at treating vascular thrombosis than standard non-ultrasound catheter directed thrombolysis (CDT). According to the data, Ekos-treated patients received half the thrombolytic drug dose or were treated in half the time, or both, when compared to standard non-ultrasound CDT.

By Friday, Ekos President/CEO Bob Hubert's voice was nearly hoarse from talking for three days at the VEITH-symposium about the company's technology for the treatment of vascular thrombosis. The Ekos booth was busy, Hubert

See Ekos, Page 8

Deals roundup

J&J plans to acquire Omrix in \$438M cash tender offer

A Medical Device Daily Staff Report

Johnson & Johnson (J&J; New Brunswick, New Jersey) has agreed to acquire **Omrix Biopharmaceuticals** (New York), a biopharmaceutical company that develops biosurgical and immunotherapy products, for roughly \$438 million in a cash tender offer.

J&J said it agreed to purchase all outstanding shares of Omrix at \$25 a share in an offer expected to close by the end of the year. The company said it expects Omrix to operate as a stand-alone entity reporting through **Ethicon** (Somerville, New Jersey), a J&J business that makes suture, mesh, hemostats and other products for surgical procedures.

According to the company, the acquisition of Omrix would provide Ethicon with an opportunity to strengthen its presence in active, biologic-based hemostats and convergent products for various surgical applications.

Ethicon currently has exclusive distribution rights in

See Deals, Page 9

Baucus' plan gives universal coverage push a running start

By OMAR FORD

Medical Device Daily Staff Writer

When it comes down to implementing a plan for health-care reform, President-elect Barack Obama has a few things going for him that the Clinton administration didn't have when it tried to push through its plan for universal coverage nearly 15 years ago.

Those extra little somethings include a climate that has lobbyist and interest groups (the same entities that maligned Clinton's attempts) on the same page for some type of reform, and Sen. Max Baucus (D-Montana), who has just floated an 89-page plan much similar to Obama's.

"Fifteen years ago when the Clinton [administration] introduced [a plan for healthcare reform] from the time they announced that they were moving in a health reform initiative to the time something substantive was sitting in front of the congress it took several months," Ken Thorpe, executive director of the **Partnership to Fight Chronic Disease** (Washington), said during a press conference last

See Baucus, Page 10

INSIDE:

LETTER TO DINGELL CRITICAL OF CDRH CHIEF DANIEL SCHULTZ2

KILLER' CELLS, MICROSCOPY 'MOVIES,' SENSORS IN A TWIST3



*Washington roundup***Letter to Dingell critical of CDRH chief Daniel Schultz**By **MARK McCARTY****Medical Device Daily Washington Editor**

An Oct. 14 letter to Congress from officials at the Center for Devices and Radiological Health at FDA to Rep. John Dingell (D-Michigan), has stirred up a hornet's nest of controversy that hints at a shake-up at CDRH, but also suggests that the current approach to clearance of 510(k) devices is on shaky ground.

The Government Accountability Office is scheduled to release a report on the process at any time, and any bad news in that report may end up making device clearance a much more cumbersome process in the years to come.

The Oct. 14 letter, the names of whose authors were redacted, alleges "serious misconduct" on the part of senior management at CDRH, including charges that "managers at CDRH have corrupted and interfered with the scientific review process of medical devices."

Prior to the letter to Dingell, who last week was displaced as chairman of the House Energy and Commerce Committee, the matter was taken up by William McConaha, the agency's director for integrity and accountability, but the authors of the letter argue that the investigation has yielded little action and that "the director of CDRH [Daniel Schultz] has further aggravated the situation by knowingly allowing a continuation of management reprisals." However, the letter fails to make specific accusations on these charges.

The authors call for "new legislation that modernizes the regulatory structure of the 510(k) program so that complex medical devices are not allowed on the market without a comprehensive . . . clinical evaluation of their safety and effectiveness." The authors of the letter state that "there has been enormous internal resistance from the entrenched managers at CDRH, including the center direc-

Today's MDD food for med-tech thought

"Rather than waiting months and months for the administration to produce a healthcare plan, the Congress will already have produced one very quickly."

— Ken Thorpe, executive director of the Partnership to Fight Chronic Disease, discussing the outlook for national healthcare reform, "Baucus' plan gives universal coverage push a running start," pp. 1, 10.

tor and the director of ODE," a reference to Donna Bea Tillman, PhD, director of the Office of Device Evaluation.

Former FDA commissioner Bill Hubbard, now with the **Alliance for a Stronger FDA** (Washington), told *Medical Device Daily* that "its not unusual for employees to complain, but it is unusual" for employees to send a letter to Congress. "Part of the problem with reviewers is that some tend to overreact to management decisions," Hubbard observed, but noted that in some instance, "they were quite right" in reference to unspecified drug approval decisions.

Complaint, CAPA hits dot warnings

The number of warning letters addressing corrective and preventive action (CAPA) and complaint procedures seems to never fade very much, and a Nov. 3 warning letter to **Spacelabs Healthcare** (Issaquah, Washington) is a recent instance.

Spacelabs, which makes a variety of patient monitoring and telemetry devices, was under the FDA magnifying glass in April and May, but despite four letters from the company between June and September, the firm landed a warning letter with five citations for complaint handling and CAPA, as well as another two dealing with medical device reports (MDRs).

FDA states in the letter that the company's complaint files includes a number of files that were not closed out within the 90 days required by Spacelabs' standard operating procedures (SOPs). According to FDA, more than one

See Washington, Page 5

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*New in basic science***‘Killer’ cells, microscopy ‘movies,’ sensors in a twist**By **DON LONG****Medical Device Daily National Editor**

Here’s a look some interesting basic science research reports issued recently:

- Researchers at the **Stanford University School of Medicine** (Stanford, California) say they have developed a technique for locating and tracking those cells of the body that naturally hunt down and fight defective and diseased cells.

Use of these disease-fighting “killer” cells has been attempted, but researchers have been unable to monitor them after introduction to the body or get a complete picture of their location and operation.

Senior author of this research report, Sanjiv Gambhir, MD, PhD, director of the Stanford Molecular Imaging Program, described the two-step strategy for understanding how and where these cells might work: first, the therapeutic cells were modified to express a unique reporter gene shared by no other cells in the body; second, an imaging agent that is trapped only in cells expressing the reporter gene is injected into the patient.

Each time the imaging agent was used, the researchers obtained an up-to-date map showing the cells’ locations.

Gambhir’s team used the technique in a middle-aged man with an aggressive brain tumor (a glioblastoma) in a clinical trial of cell-based therapy at **City of Hope** (Los Angeles), saying that similar strategies will work to monitor cell-based therapies for other disorders.

“The cells were actually good at finding the tumor,” said Gambhir, who pointed out that the same technique could be used to follow other immune cells or eventually stem cells throughout the body.

The researchers said that these repeated “snapshots” of the location and survival of such cells could help clinicians assess the disease-fighting performance of such cells over time, as well as for researchers trying to design more effective cell-based therapies.

“This has never before been done in a human,” said Gambhir. “Until now, we’ve been shooting blind – never knowing why failed therapies didn’t work. Did the cells die? Did they not get where we wanted them to go? Now we can repeatedly monitor them throughout their lifetime.”

Gambhir, a professor of radiology and a member of Stanford’s Cancer Center, collaborated in the research with researchers at City of Hope and at **University of California Los Angeles**.

The study was reported online Nov. 18 in *Nature Clinical Practice Oncology*.

- Microscopy goes to the “movies” . . . and adds a dimension to 3-D.

The Physical Biology Center for Ultrafast Science and

Technology of the **California Institute of Technology** (Caltech; Pasadena) reported development of a technique, billed as “4-D” electron microscopy, providing for the first time real-time, real-space visualization of fleeting changes in the structure and shape of matter barely a billionth of a meter in size. The researchers compared their breakthrough to the initial development of moving pictures.

A patent on the framework of this approach was granted to Caltech in 2006, and the recent work was directed by Ahmed Zewail, the Linus Pauling Professor of Chemistry, professor of physics at Caltech, and winner of the 1999 Nobel Prize in Chemistry.

The “movies” obtained with the technique – of atomic changes in materials of gold and graphite – are featured in a paper appearing in the Nov. 21 issue of the journal *Science*.

The method is an advance over electron microscopy which can image the static structure of objects with a resolution better than a billionth of a meter in length. An electron microscope generate a stream of individual electrons that scatter off objects to produce an image.

Zewail and colleagues say they have added the fourth dimension of time into electron microscopy via ultrafast “single-electron” imaging. The resulting image produced by each electron represents a femtosecond “still.” Like the frames in a film, these sequential images can be assembled into a digital movie at the atomic scale.

“With this 4-D imaging technique, atomic-scale motions, which lead to structural, morphological, and nanomechanical phenomena, can now be visualized directly and hopefully understood,” Zewail said.

His team is expanding the research to biological imaging within cells in collaboration with Grant Jensen, an associate professor of biology at Caltech. The 4-D microscope is being used to image the components of cells, such as proteins and ribosomes, producing images of a stained rat cell and, more recently, of a protein crystal and cell in vitreous water.

“The goal is to enhance the structural resolution in the images of these biomaterials by taking single-pulse snapshots before they move or deteriorate, and to follow their dynamics in real time,” Zewail said.

- Two researchers have developed a method for fabricating electronics that increases the range in which they can be stretched (as much as 140%), allowing circuits to be subjected to extreme twisting.

This compares to standard electronic components that are flat and unbendable because silicon is brittle and inflexible. Bend or stretch them in any significant way and they break and become unusable.

The new bendable electronics may find important uses in medical sensors and other electronics used for human monitoring, according to the research partnership of Yonggang Huang, a professor of civil and environmental and

See Science, Page 7

Financings roundup**EnteroMedics gets \$20M loan; IRIS to buy back more shares****A Medical Device Daily Staff Report**

EnteroMedics (St. Paul, Minnesota), a developer of devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, reported that it has closed a new \$20 million working capital loan, replacing its existing debt agreement.

Silicon Valley Bank, Western Technology Investment and Horizon Technology Management are providing the financing.

Proceeds from the loan will supplement the company's \$28.6 million in cash, cash equivalents and short-term investments as of Sept. 30, and will be used to repay the existing balance of the company's working capital loan, to fund clinical studies and for general corporate needs.

The loan requires interest-only payments until June 2009, followed by principal and interest payments amortized over the next 30 months.

The loan agreement is part of EnteroMedics' long-range capital plan, including additional cash financing in 2009, which allows the company to reach its projected FDA approval date for use of the Maestro System in obesity, following positive data from the EMPOWER pivotal trial.

"These steps to add capital allow us to fund operations well into 2010, a period of significant consequence which includes pivotal data from the EMPOWER study in obesity as well as additional data in diabetes and hypertension, and reduce our dependence on the volatile capital markets over the next 12 to 18 months," said President/CEO Mark Knudson, PhD.

IRIS International (Chatsworth, California), a manufacturer of urinalysis systems and consumables for use in hospitals and commercial laboratories worldwide, reported that, effective immediately, its board has approved a new repurchase program for up to \$10 million in shares of the company's common stock over a 12-month period.

"The board believes that reactivating a share repurchase program at this time is a prudent use of the company's cash and reiterates our commitment to enhancing shareholder value," said César García, president/CEO and chairman.

The company said the repurchase program will be funded through its existing strong cash position. As of Sept. 30, IRIS had about \$30 million in cash with no debt and is expecting strong cash flows from operations through the remainder of 2008 and 2009.

Share repurchases under this program may be made through a variety of methods, which may include open market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions or other-

wise, or by any combination of such methods.

Under the company's previous share repurchase program disclosed in March, it repurchased about 490,000 shares at a cost of about \$5.7 million.

In other financing news, **Healthnostics** (New York) said it has approved a reverse split of its Class A common stock at a ratio of 100-for-1, with a planned effectiveness by the end of the year. Each 100 shares of issued and outstanding common stock will be converted into one share of Class A common stock.

The company said the action is being taken "so that Healthnostics' stock price can return to a level more in line with the value of the company and to encourage greater interest in the stock by the investing community."

It also allows Healthnostics to increase shareholder value by capitalizing on and highlighting the continued growth and expansion of **Global Medical Direct**, in which Healthnostics has a major ownership interest.

Healthnostics is a medical and biotechnology analytics company. It provides comprehensive patient clinical monitoring and risk management systems to acute-care hospitals and utilizes its Internet portals to deliver medical and biotechnology resource information both to industry professionals and the public. ■

Agreements/contracts**Visage to market Viatronix's virtual colonoscopy product****A Medical Device Daily Staff Report**

Visage Imaging (Carlsbad, California) a subsidiary of **Mercury Computer Systems**, reported it has signed a comprehensive marketing agreement with **Viatronix** (Stoney Brook, New York), a developer of 2-D/3-D medical imaging and diagnostic software.

Under the agreement, Visage Imaging will act as a representative for Viatronix's V3D-Colon Virtual Colonoscopy product in the U.S. The agreement expands Viatronix's domestic marketing arm, while extending Visage Imaging's applications portfolio for advanced visualization products.

"We are extremely excited to be working with Viatronix," said Jim Schumacher, VP/COO of Visage Imaging. "Virtual colonoscopy is becoming a requirement within our customer base, and the planned, seamless integration of V3D-Colon with our Visage CS platform is the solution. We are proud to team up with a true market leader in providing this critical technology."

In other agreements/contracts news, **IVAX Diagnostics** (Miami) reported that it has signed an agreement with **Lin-Zhi International** (Sunnyvale, California) that allows it to market and sell Lin-Zhi's full product line of oral fluid and urinary homogeneous enzyme immunoassay test products in Europe and the U.S.

See Agreements, Page 8

*Restructuring roundup***Philips to cut 5% of Healthcare workforce; X Dx trims 25 jobs****A Medical Device Daily Staff Report**

Royal Philips Electronics (Amsterdam, the Netherlands) reported that it will lay off 5% of its workforce at its Philips Healthcare division (Best, the Netherlands/Andover, Massachusetts) as part of an accelerated cost savings push sparked by the global economic slowdown.

Company spokesman Arent Jan Hesselink said in a statement that some 32,000 workers are employed at Philips' healthcare division, which is one of the world's top three hospital equipment makers, giving a total number of 1,600 job cuts.

When it reported its third-quarter results last month, Philips said it would take measures to maintain profitabil-

ity across all three business lines and the restructuring at the healthcare unit represents the first specific steps to have been revealed.

Philips aims to improve its healthcare margins and streamline operations, particularly in its imaging systems business.

"The 5% reduction in the workforce is one of the borders of the programs we are working on," Hesselink said.

Philips said last month it would take about a €50 million (\$63 million) charge for the healthcare restructuring in the fourth quarter, but Hesselink declined to indicate how much of that charge will be linked to the layoffs.

Philips in October posted sharply lower core profit for the third quarter that missed estimates, partly hurt by its healthcare unit, which saw an order slowdown due to the credit crisis.

See Restructuring, Page 9

Washington

Continued from Page 2

complaint was open for more than 500 days.

The company's response to this finding was deemed inadequate because the revised procedures were apparently not yet in place despite training exercises in the new SOPs.

Another citation states that technical support manager had not reviewed 12 complaints that product support specialists had disqualified, listing this finding under a CAPA heading. According to FDA, the company had implemented the SOP requiring the review by technical support managers in December 2007.

Again, the firm's responses were deemed inadequate, but FDA offers no specific explanation, asking only that Spacelabs forward a summary of the firm's review of these records as well as an explanation "of the corrective and preventive actions . . . that you will implement to address this deviation."

Among the MDR reports the firm is said to have failed to file was one in which a patient suffered a "hypoxic episode resulting in subsequent heart failure and brain damage." According to FDA, Spacelabs was conducting a review of incidents dating back to 2005 to establish whether any other reports should be filed, but the company had not updated the agency as of the date of the warning.

Roy Hayes, Spacelabs' VP-quality control and regulatory affairs, told *MDD* that the company's response "should go to them today or tomorrow" and that the company "came up with a pretty extensive plan to make improvements.

"At this point, we feel confident that the things we've done answer their questions," Hayes said. He also noted that "we went to the outside [for help on updating compliance efforts] and that's been very helpful," adding "I think everyone agrees we're a better company for it."

Hayes said the firm has been inspected "every two years or so, but none of the previous inspections" found

problems. He said that his impression is that where GMP and quality systems compliance standards are concerned, "the benchmark has changed over time," stating further, "this past inspection was different from previous ones."

A Nov. 4 warning letter to **Innovative Neurotronics** (Austin, Texas), maker of devices designed to augment the nerve system in limbs, commenced with a citation addressing the company's use of a contract manufacturer.

FDA cited Innovative for failure to evaluate the third party "for its ability to meet your quality requirements despite the fact that your firm experienced quality issues which resulted in many complaints and two product removals."

The company's response to this finding fell short because it indicated that Innovative "has been evaluating the contract manufacturer the past two years," but that process "has not been formalized."

FDA cited the firm's CAPA procedures for failure to include documentation of a rework of an unspecified device in which "inverted stimulation output" caused "interference with the components on a printed circuit board." The agency stated that Innovative "has not verified and documented that the rework actually corrected the interference," and had not effected a design change to eliminate the problem.

The agency states that the rework, which took place in February 2007, did not head off a similar problem that arose this past June, noting that Innovative had not established the exact nature of the "defects found in your contract manufacturer's production lines." This was also the source of a citation for failure to validate a change to the design of the unnamed product.

In an unattributed statement, the firm indicates that it is "working closely with the FDA to address the issues raised in the warning letter" and that Innovative has "implemented a vendor quality improvement plan to enhance our overall quality system." ■

Draeger: 'Pick your poison, and we have a test for it'

Draeger Medical (Lübeck, Germany) presented to medical personnel the one-two punch it has developed for law enforcement in the field of roadside testing – the Draeger DrugTest 5000-med and Draeger AlcoTest 6810-med roadside tests.

The accent is on the “med” application, as Draeger has slightly modified its products and recertified them both for the emergency department where arriving patients can be on drugs or alcohol or both.

Of every 100 people admitted to ER, 15 are on some drug of abuse, according to a product manager with Draeger, who added that a definitive study currently being conducted at **Charité Hospital** in Berlin will be reported in February 2009.

For the alcohol test, patients are asked to breathe into a small tube as in the roadside test.

The tube is then mounted on Draeger's hand-held AlcoTest 6810-med device, which rapidly delivers a quantitative reading of the blood alcohol level.

Pointing the device at the Draeger-supplied printer, the ER staff can pull documentation to include with the patient record, or download the results with a USB port and input the data directly into a treatment record.

For those patients too far gone upon arrival at ER,

passed out or otherwise incapable of blowing into the tube, the ER personnel need only wave the Draeger hand-held device within a few inches of the person's face to obtain a positive-negative indication of alcohol from skin pores or exhaled breath.

In contrast to the alcohol test, the Draeger DrugTest 5000-med analyzer is a table-top device, or in the case of law enforcement, a patrol car-mounted device, about the size of a kitchen counter espresso machine.

A saliva swab is inserted into a cartridge that contains six slim test strips which over a period of 10 minutes are pulled mechanically by the device past the saliva sample.

The analyzer returns only a positive-negative result with a cut-of threshold at 20 monogram per milliliter, which is stricter than the British Home Office cut-off threshold of 50 µg/ml.

The drug test was released through Draeger's Safety Division May, and the product manager said he knew that 30 units were sold for patrol cars for the Thüringen police and 100 units were ordered by police in NordRhein Westphalia.

Testing of the drug device is under way in German hospitals currently ahead of commercial release next year and according to the product manager 16 hospitals have expressed an interest.

– John Brosky, European Editor

MEDICA

Continued from Page 1

Both companies have an eye on the upward curve of roadside alcohol tests that reached 50 million units this year worldwide.

As public awareness for the dangers of driving while under the influence of drugs increases, the companies are betting that public tolerance for such behavior will fall and remove any remaining legal barriers to widespread roadside screenings.

In Victoria, Australia, random roadside screenings revealed that one driver in every 200 was legally drunk but that one in every 46 was high on something else.

Both products are saliva-based tests that can be performed through the driver's window and return a positive-negative result for opiates, cocaine, amphetamines, methamphetamine and THC, the active ingredient in the market-leading drug-of-abuse, marijuana.

This contrasts with alcohol testing that returns a quantitative result used for legal thresholds of a driver's impairment.

The Draeger test also includes a test for benzodiazepines, which are found in driver-impairing prescription drugs such as valium.

While sharing this common ground, the two testing platforms diverge significantly.

The Draeger test is a sophisticated adaption of the familiar test-strip technology, while the Philips test is based on the familiar technology of a DVD reader but adapted for an advanced application.

Recalling that the consumer products division of **Royal Philips Electronics** played a role in the development of digital versatile disc (DVD) technology, and that it is working on the next generation, Jos Rijntjes, general manager for point-of-care cardiac testing with Philips' Health Care Incubator in Eindhoven, said a DVD player “actually is a source for beautiful, and cheap, optics.”

The MAGNOtech platform Philips has designed quietly over several years for diagnostic assays uses the disposable injection-molded plastic cards common to point-of-care diagnostics.

The first application is for saliva drug testing, he said, in cooperation with **Concateno** (Oxfordshire, UK), a leading provider of such tests and the only one currently offering a hand-held analyzer being used in Australia.

In parallel, Rijntjes said Philips' POC group is developing medical applications.

Two distinguishing features of the new DVD-based technology platform are manipulation of targeted solutions sandwiched in the assay card, and then the fast optic scan of the resulting reaction with agents in the solution.

A sponge swab gathers the saliva sample and placed

See MEDICA, Page 7

MEDICA

Continued from Page 6

into a cartridge is squeezed onto the assay card.

A magnetic field in the reader forces the liquid to interact with agents in the solution that bind themselves to the targeted drug compounds, if present in the sample.

"The trick is that we move these particles, which now have a magnetic property because of the nano agents bound to them, through the solution 100 times faster" than a natural diffusion model, Rijntjes said.

The second technique, he said, is the ability to scan the surface of the card and see only the particles that are bonded.

A second magnet gathers the particles bound with the agents identifying them as a positive reaction in a circular patterns centered on the sandwiched assay layers. A light-emitting diode laser (LED) scans the surface and its wavelengths are reflected to a detector.

"It is so sensitive, and fast," Rijntjes said, requiring just 90 seconds for the roadside drug test.

And, critically, he said the lightweight scanner is truly hand-held, bringing the device to the patient, or in this case, a suspected perpetrator of a traffic violation.

The medical applications for the new DVD-optics platform are unlimited, he said, adding that after trying saliva and urine assays, the Philips POC development team decided to focus on blood-draw applications.

"We only need a 15 microliter droplet and in five minutes we can give results," Rijntjes said, for example for patients with chest pains using a cardiac troponin marker. "It is 100 million times more sensitive than a common glucose blood test," he said.

The device will prove valuable for its ease of use and for its portability, he said. "It can be used where speed is critical, and it can go where it is needed," he said, citing as examples a physician's office for screenings, or with a visiting nurse into a patient's home.

Neither the MAGNOtech platform nor the assay tests developed by Concateno have either a CE mark or FDA approval.

The partners also will be seeking a CLIA waiver so personnel not trained with a specific medical skill set can do the test.

Karon Hawthorne, marketing manager for the Philips project with Concateno, said the test will be commercially available at the end of 2009.

Concateno works in two of the world's few markets with a mandate for drug testing, she said.

Britain's Home Office has since 2001 required drug testing of all prisoners to separate those who may benefit from drug counseling from those whose crimes were influenced by other factors.

"Curiously, in the United Kingdom we do not have legislation allowing roadside drug testing and therefore can not prosecute based on results of testing," Hawthorne said.

She said Concateno receives about £2.5 million (\$3.7 million) on the Home Office contract and another £500,000 (\$743,000) in the Victoria, Australia, program.

"There have been a lot of articles recently in the UK about roadside testing for drugs," she said, "Clearly the issue is moving up the agenda."

David Browning, CEO of Philips Personalized Healthcare in Eindhoven, said a joint development agreement for the project with Concateno was started in 2005, with a public announcement for a partnership in January 2006.

An agreement to jointly sell the drug test product was signed in June 2007.

He said Philips started early and is committed to Concateno because "they are the market leader." At Philips, we see that it is critical to set the standards in a market that we enter," he said. "This hand-held unit and the technology onboard is going to become that standard, versus the test strips used widely today."

As for the new diagnostics being developed for medical markets, Browning said, "I cannot speak to what we are working on, but we will be announcing something by the end of 1Q09." ■

Science

Continued from Page 3

mechanical engineering at **Northwestern University** (Evanston, Illinois) and John Rogers, professor of materials science and engineering at the **University of Illinois** (Urbana-Champaign).

The work builds on previous research by the pair – Huang focused on theory, Rogers focused on experimental design. In 2005, they developed a stretchable form of single-crystal silicon that can be stretched in one direction without altering its electrical properties; those results published by the journal *Science* in 2006. Earlier this year they made stretchable integrated circuits, work also published in *Science*.

Next, the researchers developed a technology that allowed circuits to be placed on a curved surface. This technology uses an array of circuit elements about 100 micrometers square that were connected by metal "pop-up bridges." The circuit elements were so small that when placed on a curved surface, they didn't bend, but these elements were connected by metal wires that popped up when bent or stretched.

Huang and Rogers took these pop-up bridges and made them into an "S" shape, which, in addition to bending and stretching, have enough "give" that they can be twisted as well. "For a lot of applications related to the human body – like placing a sensor on the body – an electronic device needs not only to bend and stretch but also to twist," said Huang. "So we improved our pop-up technology to accommodate this."

Their research is published online by the *Proceedings of the National Academy of Sciences*. ■

Ekos

Continued from Page 1

told *Medical Device Daily* during a phone interview from the conference. But, "Busy is good, especially in this [economic] environment," he said.

Ekos says its MicroSonic Accelerated Thrombolysis (MSAT) is designed to provide faster, safer and more complete dissolution of thrombus. Hubert said the **American College of Chest Physicians** (Northbrook, Illinois) recently updated guidelines to suggest the use of thrombolytic drug therapy along with devices that accelerate the dissolution of vascular blood clots.

Ekos' infusion system is embedded with miniature ultrasound devices that pulse to open up the clot, making it more porous so the drug is absorbed into the clot, Hubert said, and the clot dissolves more readily. He likened the system to melting ice with water. If you take an ice cube and make it into a snow cone and drip water over it, the ice will melt faster than if you dripped water over the same ice cube before breaking it up into a snow cone, he said.

Karthikeshwar Kasirajan, MD, assistant professor of surgery at **Emory University School of Medicine** (Atlanta), presented data Sunday on 37 patients treated with catheter-direct pharmacological thrombolysis using recombinant tissue plasminogen activator (tPA) via the Ekos infusion system. The study, conducted from December 2006 to August 2008, showed that Ekos-treated patients received half the thrombolytic drug dose or were treated in half the time, or both, when compared to standard non-ultrasound CDT, the company noted. The purpose of the study was to evaluate the safety and efficacy of ultrasound as an adjunct to facilitate pharmacological thrombolysis.

Hubert noted that Kasirajan's study was generated using the company's first generation product. Its newest product, the EkoSonic Mach 4, was released in July and was showcased at the VEITHsymposium. He said the company already has installed 100 units of the new system and has received positive feedback to it.

Although the company has pegged the latest version of its product to be twice as fast as the first-generation device – making it four times faster than standard catheters – Hubert told *MDD* it looks as though the Mach 4 may actually exceed that.

Deep vein thrombosis (DVT) is a significant clot in the leg that affects more than 600,000 Americans a year, Hubert said, and a lot of those patients who are treated with drug regimen only end up with post-thrombotic syndrome (PTS), he added.

PTS develops as a result of damage to the venous valves when exposed to the occluding blood clot for more than a few weeks. The condition can subsequently develop over months or years into a serious irreversible debilitating condition, Ekos said. Thus, many physicians are now

performing interventional treatments, such as the Ekos procedure, to remove as much of the clot as possible immediately after diagnosis of significant DVT.

"Using the Mach 4, we already have case reports of complete DVT resolution in less than six hours. The Mach 4, like our earlier-generation product, often dissolves clot out to the vessel wall including clot formed behind the valves. Unlike mechanical devices, the Ekos products have a high percentage of complete thrombus resolution, do not create hemolysis and present a low risk of distal embolization," Hubert said. "Clearly Ekos is setting a new standard of clot removal in the peripheral vasculature."

Competing systems are considered mechanical devices, he said, because they use a mechanical action designed to whip or beat the clot into tiny fragments, a violate action that can cause hemolysis, he noted. "A couple of the companies [that make mechanical devices] actually have timers on their system because . . . there is a limit and a time that you can use some of these products."

During a phone interview with *MDD* on Friday, two days before his presentation, Kasirajan said he expected a positive response to the data. "I think people will be very happy to see there is something they can use with these clot busters with probably a much lower complication rate," he said.

From his experience using the Ekos product, Kasirajan said the device seems to make a big difference in terms of the speed at which a clot is dissolved and also in reducing the dose of drugs being used.

He also pointed out that the Ekos device doesn't really change the procedure, as far as the patient is concerned, and is similar to the catheter used to deliver the drugs. It also doesn't require the physician to learn anything new, Kasirajan said. ■

Agreements

Continued from Page 4

The assays that IVAX Diagnostics will be distributing include drugs-of-abuse (DOA) tests to detect Ecstasy, Oxycodone, methadone, cocaine metabolite, amphetamines, opiate, methadone metabolite, Cotinine, and ethyl alcohol, among others.

According to **BCC Research** (Wellesley, Massachusetts), the total worldwide DOA testing market was \$1.9 billion in 2007. BCC Research estimates that some 74% of the DOA testing value is located in the U.S., with the European Union representing another 19%.

Laboratory-based testing represents nearly 79% of the total worldwide DOA testing market.

IVAX Diagnostics develops proprietary diagnostic reagents, instrumentation and software in the U.S. and Italy. ■

Deals

Continued from Page 1

the U.S. and the European Union for Evithrom Thrombin Topical (Human) and Evicel Fibrin Sealant (Human), two active, biologic-based hemostats manufactured by Omrix. The two companies also are partnering on a Fibrin Pad product candidate, currently in Phase II clinical trials, as an adjunct to control mild-to-moderate soft-tissue bleeding.

J&J said the tender offer is conditioned on the tender of a majority of the outstanding shares of Omrix's common stock on a fully diluted basis. The closing is conditioned on Israeli antitrust clearance and other customary closing conditions.

The \$358 million estimated net value of the transaction is based on Omrix's 17.5 million fully diluted shares outstanding, net of estimated cash on hand at time of closing, the company noted. The boards of directors of J&J and Omrix have approved the transaction.

In addition, Robert Taub, Omrix's founder and CEO, and entities controlled by Taub, have agreed to tender about 16% of Omrix's outstanding shares in the offer.

"Our partnership with Omrix has already expanded our capacity to provide innovative, next generation products that raise the standard of surgical care," said Alex Gorsky, company group chairman for J&J with responsibility for the Ethicon business worldwide. "We believe this transaction will further enhance our efforts to bring new, science-based products to patients and the healthcare professionals who treat them."

Assuming this transaction closes in 2008, J&J is expected to incur an estimated one-time, after-tax charge of about \$120 million reflecting the write-off of in-process R&D charges. The acquisition is expected to be breakeven to slightly dilutive to J&J's earnings per share in 2009.

"Omrix and Ethicon have enjoyed a solid partnership for the past five years," Taub said. "As a formally unified entity, our successful distribution and development agreements will evolve into an even more attractive long-term growth strategy. Omrix's Israeli-based manufacturing and research & development expertise will be strengthened by the long-term stability and integration that this merger will create."

In other dealmaking activity:

• **Invitrogen** (Carlsband, California) and **Applied Biosystems** (Foster City, California) have officially merged. The new company, **Life Technologies Corp.**, began trading on the Nasdaq Global Select Market under the ticker symbol LIFE.

The companies first reported plans to merge in a cash-and-stock deal valued at \$6.7 billion over the summer (*Medical Device Daily*, June 13, 2008).

"This is an exciting time in the history of Invitrogen and Applied Biosystems," said Greg Lucier, CEO and chairman of the new company. "By combining these two highly respected brands, we are not only creating a stronger company, but an industry thought leader, uniquely positioned

to help our customers accelerate and drive new discoveries and commercial applications."

• **Covidien** (St. Louis) and **Depomed** (Menlo Park, California) reported that Covidien has licensed worldwide rights from Depomed to use its AcuForm gastric retentive drug delivery technology for the exclusive development of four undisclosed products. The products will target a key strategic focus of Covidien's pharmaceutical business and address major medical needs, according to the company.

Covidien agreed to make a one-time up-front payment of \$4 million, and could end up paying up to \$64 million in additional development milestone payments over the next several years. Covidien also said it would pay Depomed a royalty on sales of products developed under the agreement.

Depomed will retain the exclusive option to promote the products developed under this license agreement within the obstetrics/gynecology specialty field. Once Depomed begins to promote these products, Covidien will pay Depomed a significantly higher royalty on the resulting net sales in this specialty, according to the agreement. ■

Restructuring

Continued from Page 5

Hesselink said Philips expects to provide further details about the restructuring measures in reporting its fourth-quarter results in January.

The *Boston Globe* reported that fewer than 100 jobs in Andover were affected by the cuts. Philips has about 4,300 workers in Massachusetts, with nearly 3,000 in the health-care unit, making it one of the state's larger employers.

XDx (Brisbane, California), a molecular diagnostic company, reported that it is restructuring its business. In response to current market conditions, XDx said it is reprioritizing its efforts and will increase its research, development and commercial activities in support of AlloMap in the heart transplant market, while continuing selected activities in autoimmunity.

The company will focus on maximizing the current market opportunity for the FDA-cleared AlloMap product, restructure its internal development program and pursue external research collaborations in lupus, as well as suspend development activities in lung transplant.

As a result of the strategic restructuring, the company will realign the organization in support of these priorities, resulting in a reduction of 25 positions. XDx also is undertaking other cost-saving measures in response to the tightening economic situation. All of these measures together are expected to accelerate achievement of profitability.

CEO Pierre Cassigneul said, "The decision to restructure XDx is a difficult but necessary step given the current economic environment in which we are operating. We believe the steps we are taking to reprioritize our efforts and realign the organization will strengthen the company

See Restructuring, Page 10

Baucus

Continued from Page 1

week. "I think the good news for those who'd like to see a reform package pass is that the legislative outlines of it are there. I think the opportunity legislative specs will happen in January and February. So for an Obama administration that, if they so choose to move on this early, they already have a legislative vehicle to do so."

The organization held the press conference to discuss what the climate of healthcare reform looks like after the election, and to discuss how the Baucus plan impact on such measures.

Baucus' plan would have most employers be required to offer insurance to their workers or pay into a fund, with the contribution based on the size of the firm and its annual revenue. Small employers would get a tax credit if they offer insurance, with the size of the credit based on the size of the company and its earnings.

The only difference is that Baucus' initiative is a mandate, something Obama touted against on the campaign trail.

"As I read the plan through, it really is a more detailed explication of what Obama had in his major plan, because it does focus on primary prevention and modernizing the delivery system to more effectively manage chronic disease," Thorpe said.

There has been shown to be a direct correlation chronic illness and the lack of healthcare. A study titled "Chronically Ill and Uninsured: A National Study of Disease Prevalence and Access to Care in U.S. Adults," published in the Aug. 5 edition of *Annals of Internal Medicine*, reported that more than 11 million Americans with chronic physical illnesses aren't getting the medical care they need because of a lack of health insurance (*Medical Device Daily*, Aug. 8, 2008).

While a universal plan seems like the clear path to take, the cost in doing so could give lawmakers pause between signing off on such sweeping reform. But trying to lock down an exact figure during this time could be difficult.

"Medicaid expansions, addressing those in poverty, the S-CHIP reauthorization, making healthcare affordable for families up to four times the poverty line . . . any of these plans are going to be in the low triple digits," Thorpe said. "In combination you're probably looking at something in the low \$100 billion range, depending on the health plans they end up with and how generous the subsidies are, and a bunch of really key design decisions that have yet to be made. So, at this point, I don't think you can really speculate on what the number is because most of the key decisions that would drive [the reform plan] have not yet been made."

Thorpe was questioned specifically on a part of Baucus' plan that would reduce payments for Medicare Advantage plans.

"Isn't the whole theory behind those plans is that they manage chronic disease and reduce healthcare costs?" Carrie Ghose of *Columbus Business First* asked. "So, if these

for-profit companies that are managing these plans start exiting the system because the rates have gone down, it's kind of like you're unraveling one arm of the sweater to knit the other arm."

Thorpe offered a short interpretation of how the plan could get around this.

"If you look at the back end of his proposal, one thing he does talk about as a middle ground on Medicare Advantage is to say, for those Medicare Advantage programs or plans that move toward being a full-fledged medical home using the NCQA criteria, that at least in the interim there would be payments above 100% of fee-for-service as a way to try to build that type of medical home capacity more generally," he replied. "That's particularly, I think, opportunistic in the Medicare Advantage plans that are fee-for-service."

Thorpe said healthcare reform seems "very likely" this year, and not just as lip service.

"Certainly, the process is different. I think an important thing to keep your eyes on is the process in the Senate. As this progresses, I think that the House will start working with the Senate on putting together a consolidated plan as well. So rather than waiting months and months for the administration to produce a healthcare plan, the Congress will already have produced one very quickly." ■

Restructuring

Continued from Page 9

in the short run and position us for long-term success."

AlloMap, XDX's first commercial product, was launched through the company's CLIA-certified laboratory in 2005 and received clearance from the FDA as the first real-time PCR-based IVDMA in August 2008. AlloMap Molecular Expression Testing is a non-invasive test that uses genomic technologies to help physicians in their overall management of heart transplant patients.

In other restructuring news, **Henry Schein** (Melville, New York), a provider of healthcare products and services to office-based practitioners in the combined North American and European markets, reported that as of Nov. 18, it has exited the wholesale ultrasound business and will dispose of such operations in 4Q08. This business represented sales for the company's Medical Group of about \$13 million during 2008, and Henry Schein will record a loss from discontinued operations of about \$6.5 million (or 7 cents per diluted share) primarily related to the write-down of intangible assets during 4Q08. The operating results of the discontinued operation will be reported separately for all prior periods.

"We take pride in providing our physician customers with a wide array of value-added products and services for operating more efficient practices and delivering quality healthcare to patients. We will continue to sell ultrasound products to physicians, yet we have made the strategic decision no longer to sell ultrasound equipment for the wholesale channel, as it falls outside of our core business," said Chairman/CEO Stanley Bergman. ■

PRODUCT BRIEFS

- **Cimtek** (Boston) has reported an upgrade to its Magellon quality lifecycle management (QLM) software – giving medical device makers a streamlined way to rapidly deliver quality products and maintain compliance with FDA's Title 21 Code of Federal Regulations (CFR) Part 11. The FDA's 21 CFR Part 11 requires that electronic records and signatures be created, maintained and archived throughout medical product development cycles. Until now, collecting and organizing this information has been a resource-intensive, fragmented process for most medical manufacturers. Magellon generates full audit trails proving that authorized users are involved in key development phases, test devices are operating correctly, manufacturing teams are adequately trained from design through market delivery, and the integrity of manufacturing operations remain constant.

- **Covidien** (Mansfield, Massachusetts) said it is launching a new Magellan safety hypodermic needle. "We are transitioning to the new and improved Magellan Safety Needle technology as part of our strong and ongoing commitment to meeting the safety needs of our customers," said Jeff Hunt, president of patient care and safety products for Covidien. "There is litigation under way related to the current Magellan Safety Needle technology used on our Magellan family of products. We are optimistic that the litigation will ultimately be resolved in our favor."

- **Invitrogen** (Carlsbad, California) reported the introduction of its Invivofectamine delivery reagent, which enables short interference ribonucleic acid (siRNA) experiments *in vivo*. The company said the study of RNA interference (RNAi) has "revolutionized" biology by allowing researchers to directly observe the effects of the loss of function of specific genes in mammalian systems. The Invivofectamine delivery reagent allows researchers to directly study the effects of siRNA inside a living organism

for a variety of applications, including the drug discovery process. The Invivofectamine delivery reagent can be injected in small volumes and without high pressure, minimizing the potential of inconsistent results. It also provides extra stability to siRNA so the siRNA will arrive intact and ready to perform the selected knockdown. The reagent is non-viral and has minimal toxicity. Overall, these characteristics will enable researchers to more effectively optimize their siRNA experiments *in vivo*.

- **Ortho Clinical Diagnostics** (Raritan, New Jersey) has received FDA clearance for its Vitros 5600 integrated system. The system is designed to integrate clinical chemistry and immunoassay testing to increase laboratory productivity and will be able to perform more than 100 different chemistry, immunoassay and infectious disease assays on a single, high-quality system. The platform is designed to meet the centralized testing needs of customers managing skilled labor shortages, budget restrictions and increasing test volumes. One of its features is the "sample-centered" processing approach, where each individual sample is accessed independently and in parallel for chemistry and immunoassay testing. This "one tube in, one tube out" approach can optimize turnaround time and productivity by intelligently accounting for variable sample and test mixes, eliminating the need to split the sample on the analyzer or move sample trays between modules.

- **Smith & Nephew's** (Andover, Massachusetts) Endoscopy Division reported the launch of the Crosstrac hip guide system, which helps surgeons to accurately establish pathways to diagnose and repair the hip joint using arthroscopy, or minimally invasive, repair procedures. The Crosstrac is guided by an X-ray, and the surgeon establishes the first portal and inserts an arthroscope. With that portal in place, the Crosstrac is attached to the arthroscope and enables the surgeon to establish secondary portals in the appropriate place. The arthroscope enables the surgeon to see where the additional portals would penetrate the hip capsule before the penetration occurs.

PEOPLE IN PLACES

- John Collar has been named executive director of the **Colorado BioScience Association** (CBSA; Denver), effective Dec. 8. Collar, who is COO of Matrilinex (Westminster, Colorado), a start up mitochondrial DNA testing lab company, succeeds Denise Brown, founding executive director of the CBSA, who retired from the association in September. CBSA is a not-for-profit organization providing services and support for Colorado's growing biosciences industry.

- Christopher Coloian was named senior VP of health

services at **Health Dialog Services** (Boston). Coloian most recently was VP of health advocacy at CIGNA Healthcare. Health Dialog provides care management services.

- Francine Kaufman, MD, has been named vice president of global medical affairs for **Medtronic's** (Minneapolis) Diabetes business. Kaufman will help develop the company's global diabetes strategy, as well be a voice for multidisciplinary medical strategy across Medtronic. Distinguished professor of pediatrics and communications at the Keck School of Medicine and the Annenberg School of Communications of the University of Southern California, and head of the Center for Diabetes, Endocrinology and Metabolism at Children's Hospital Los Angeles, Kaufman will retain her academic title and remain on the board of CHLA.

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