
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

WEDNESDAY, JANUARY 24, 2007

VOL. 11, No. 16

PAGE 1 OF 10

Stark hammers plan

White House crafts healthcare coverage plan via tax breaks

By MARK McCARTY

Medical Device Daily Washington Editor

WASHINGTON — The Bush administration is not known for having a heavy hand in the nation's healthcare game, but the President spelled out a new coverage proposal in last night's State of the Union message with a plan called the Affordable Choices Initiative.

Reaction to previews of the plan has been mixed among congressional Democrats, and at least one major player in the House says the idea is dead on arrival.

Under the Affordable Choices Initiative, families with health insurance would pay no income tax on the first \$15,000 of income (\$7,500 for individuals), but healthcare premiums would no longer come out of paychecks before Uncle Sam gets his cut.

Coupled with this rewrite of the tax code would be a
See Healthcare plan, Page 6

Minnesota, Michigan, Ohio lead the list

Devices top Midwest financing of startups for a record year

By DON LONG

Medical Device Daily Executive Editor

Medical device firms, by a slim margin, were the leaders in healthcare startup funding in the Midwest during 2006, according to the latest report from **BioEnterprise** (Cleveland, Ohio). And the funding for these healthcare startups in 2006 set the record over previous years.

Device firm startups raised \$356 million in 2006, or 45% of a total of \$792 million, recorded by the BioEnterprise report.

Biopharmaceutical companies were only slightly behind, with \$349 million raised, 44% of the total.

And healthcare software and services startup firms raised \$349 million, 11% of the total.

The \$792 million raised in 2006 was a 25% increase over 2005, according to BioEnterprise's "Midwest Health Care Venture Investment Report," which called that "a sig-
See Midwest, Page 7

International report

Cook nears reimbursement OK for Zenith approval in Japan

A Medical Device Daily Staff Report

Cook Medical (Bloomington, Indiana) reported that it has received preliminary hospital reimbursement for endovascular repair (EVAR) of abdominal aortic aneurysms (AAA) in Japan. The company's Zenith AAA stent graft is the only device approved for sale in Japan for this type of procedure, it said.

Cook said it expects full reimbursement in Japan in March, receipt of which will launch a complete rollout of the Zenith stent graft system across the Asian country.

"Cook was first to the market with this life-saving medical device technology in August 2006 and in just four months we have hit another major milestone with this news of preliminary reimbursement," said Barry Thomas, global leader of Cook's Endovascular Therapies division. He said the company's rapid progress in Japan is the result of a collaborative effort between Cook and its Japanese distributor, **Medico's Hirata**.

See International, Page 8

Zeiss gets fast FDA clearance for its Visumax laser system

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Carl Zeiss Meditec (Dublin, California) reported it has received FDA clearance to market the laser keratome applications of its Visumax femtosecond laser system and that it received the clearance sooner than expected. The company had projected the clearance would be granted in the second half of this year.

The Visumax system is designed to provide smooth and precise flap cutting capabilities for refractive laser surgery. A femtosecond is an interim of a quadrillionth of a second (*Medical Device Daily*, Jan. 9, 2007).

Carl Zeiss said the technology, combined with its MEL 80 excimer laser, delivers "excellent clinical outcomes" coupled with the potential for a "unique optimized workflow for refractive surgeons and improved comfort for their patients."

Using a pivoting patient bed and an integrated data management system, the refractive surgeon will be able to
See Zeiss, Page 9

INSIDE: A WEEK AFTER AED SHIPMENT HALT, PHYSIO-CONTROL MULLS LAYOFFS2
BRIDGEPOINT MEDICAL ADDS \$10M; OCULUS LOWERS PRICING OF IPO3

 **AHC Media LLC**

A week after AED shipment halt, Physio-Control mulls layoffs

A Medical Device Daily Staff Report

Less than a week after **Physio-Control** (Redmond, Washington) reported that it suspended shipment of products to U.S. customers (*Medical Device Daily*, Jan. 18, 2007), the automated external defibrillator (AED) company has told its employees that it is considering layoffs, according to an article in the *Seattle Post-Intelligencer*.

In December, the firm's parent company **Medtronic** (Minneapolis) reported that it would spin off Physio-Control into an independent company (*MDD*, Dec. 5, 2006). However, those plans were put on hold last week when the company reported problems with Physio-Control's manufacturing processes. No products are being recalled, the company said.

Physio-Control, which provides AEDs and other emergency response products to hospitals, emergency response organizations and various public and private enterprises, said the decision to suspend U.S. product shipments was made to "address quality system issues" in the company's Redmond facility. The FDA was involved in the decision to cease shipments, but it is still unclear just how great of a role it played in the company's "voluntary" decision.

"We've told our employees that we may, in fact, have to reduce the size of the force," Medtronic spokesman Rob Clark told the *Post-Intelligencer*. "Clearly with the suspension of operations, the work is scaled back. That will have an effect on the resources that we need during this period."

Although the company has voluntarily stopped shipping its products to U.S. locations, it still ships to its overseas customers. Medtronic will be reaching out to the regulatory bodies in other countries, Clark said.

U.S. sales account for two-thirds of Physio-Control's business, according to a Prudential Equity Group research report issued Sunday. The report predicts a 70% decline in sales at the plant and gives revised earnings estimates for

Medtronic assuming that the company can cut 30% of its fixed costs at Physio-Control and that U.S. sales resume within one year.

Medtronic officials do not yet have a timeline for any potential layoffs, Clark said. Physio-Control employs 1,200 people, about 800 of them in Redmond.

The FDA sent warning letters to Medtronic about its Lifepak defibrillators in 2000 and 2005, notifying the company about several violations the agency had found during its inspections. Among the complaints outlined in a letter dated June 9, 2005, were that Medtronic did not follow proper procedures on a complaint involving a patient death.

Those issues have since been resolved and are not related to the current problem, Clark said. The current problem is a "quality systems related issue," not affecting any particular product on the market. But it could take awhile to fix, he said.

"We're working very quickly to try to resolve it," Clark said. "We understand that we have employees that are anxious to know."

Clark told *MDD* last week that Medtronic still plans to spin off Physio-Control once business is back to normal, though the spin-off likely won't meet its October deadline.

Physio-Control brings in about \$400 million per year, Clark said, which represents about 3.5% of Medtronic's \$11.3 billion annual revenue.

Founded in 1955, Physio-Control is one of Redmond's 20 largest employers, according to the city. In 1992, the company shut down its manufacturing, sales and marketing because of alleged violations of good manufacturing practices found by the FDA. ■

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AHC Media LLC

*Financings roundup***BridgePoint Medical adds \$10M;
Oculus lowers pricing of IPO****A Medical Device Daily Staff Report**

BridgePoint Medical (Minneapolis), a private company developing technology in the field of interventional cardiology for crossing coronary and peripheral chronic total occlusions (CTO), reported completing a second round of private equity financing of about \$10 million.

Participants in the round include new investor Foundation Medical Partners and existing investors Michael Berman, New Enterprise Associates and Polaris Venture Partners.

Bridgepoint says that interventional cardiologists are currently unable to broadly treat patients with CTOs which comprise about one-third of all patients diagnosed with coronary artery disease. For these patients, the common alternative is open heart bypass surgery or palliative care.

The company says that 1.3 million patients worldwide could benefit from its CTO technology each year.

Chad Kugler, BridgePoint's president and general manager, said that the company's technology "will enable interventional cardiologists to offer a fast, safe and effective therapy to an under-served patient population, while reducing the need for invasive surgery or life-long medical management."

Andrew Firlik, general partner at Foundation Medical Partners, has joined the BridgePoint board.

Founded in 2005 by Michael Berman, Robert Atkinson, and Kugler, BridgePoint is the first spin-out from the medical device incubator **Prospex Medical** (Arden Hills, Minnesota).

To date, with the inclusion of funds raised for the incubator Prospex, BridgePoint reports having raised about \$12.5 million through two rounds of financing.

Oculus Innovative Sciences (Petaluma, California) reported that it has increased the number of shares of its proposed initial public offering, but lowered the share pricing of the shares to be offered.

The offering was originally set for 3.1 million shares at \$12 to \$14 a share, and it is now set for 3.5 million shares at \$8 to \$10 a share.

The company hopes to generate about \$26.2 million net from the offering. It said it will use the proceeds to expand sales and marketing capabilities and fund debt and clinical trials.

Underwriters, which include Roth Capital, Maxim Group and Brookstreet Securities, are entitled to purchase another 525,000 shares to cover over-allotments.

Oculus manufactures products intended to help prevent and treat infections in chronic and acute wounds.

It describes its platform technology, called Microcyn, as "a non-toxic, electrically charged, or super-oxidized, water-based solution that is designed to treat a wide range of organisms that cause disease, or pathogens, including viruses, fungi, spores and antibiotic resistant strains of bacteria, such as methicillin-resistant *Staphylococcus aureus*, or MRSA, and

vancomycin-resistant *Enterococcus*, or VRE, in wounds."

The company says that it does not have regulatory approvals to market Microcyn in the U.S. as a drug but that in clinical testing and studies, its products "were effective against a wide range of pathogens and were found to be non-toxic, easy to use and complementary to most existing treatment methods in wound care."

In other financing activity:

- **Matritech** (Newton, Massachusetts), a developer of protein-based diagnostic products for the detection of cancer, reported closing a \$4.36 million private placement of Series B 15% secured convertible promissory notes maturing Dec. 13, 2007, and warrants to purchase 4,157,143 shares of common stock of the company.

Matritech said the net proceeds from the financing are about \$3.8 million.

Current investors SDS Capital Group, H&Q Life Science Investors and various ProMed funds were participants in the financing. Matritech said it will use the proceeds for R&D, selling and marketing expenses, working capital and for general corporate purposes.

Stephen Chubb, CEO and chairman of Matritech, said, "The new financing affords Matritech the opportunity to continue the momentum we have developed in the sales of our NMP22 BladderChek Test."

The notes are convertible into 6,928,572 shares of common stock and allow for payment of interest and principal in cash or by issuing common stock. The warrants have an exercise price of 63 cents a share and are exercisable for five years.

Until stockholder approval of certain provisions in the notes and warrants, stock issuances under the notes and warrants may not be made at an effective conversion price below 63 cents. Matritech also has issued to the placement agent in the financing a warrant to purchase 55,556 shares of common stock at 76 cents a share exercisable for five years.

Chubb said the company would give a 2007 outlook report, along with its report of its full-year 2006 results, on Feb. 6.

The company also reported that its board has been expanded to 11 members and that David Musket and Robert Rosenthal, PhD, were elected to its board on Jan. 22.

Musket is president of Musket Research Associates, an investment banking firm focused on emerging health-care companies which served as placement agent for the company in financing transactions completed in 2005 and 2006.

Rosenthal has been president/CEO and a member of the board of Magellan Biosciences, a private biotech company engaged in the development and marketing of rapid point-of-care analyzers and automated systems for hospital-based labs and near-patient testing, since 2005.

- **Revolutions Medical** (Mount Pleasant, South Carolina) reported completing a 20-to-1 reverse stock split intended, it said, to improve its capital structure and to

See Financings, Page 4

*Deals roundup***Reflect completes ATE purchase;
Dade licenses test from RUNMC****A Medical Device Daily Staff Report**

Reflect Scientific (RSI; Orem, Utah), a distributor of scientific equipment and related supplies to the life sciences industry, reported the closing of the merger agreement with **All Temp Engineering** (ATE; San Jose, California).

All Temp Engineering will be integrated into CSI's **Cryometrix** unit, and both businesses will operate from a new facility located in San Jose, California.

According to RSI, technology, marketing and other resource sharing will enable ATE and the Cryometrix Products group to take advantage of synergistic and growing market opportunities while improving the overall efficiency of their operations.

"The outlook for both businesses is excellent, and this merger has strengthened our foundation to facilitate and support their future growth," said John Hammerman, general manager of Cryometrix.

Reflect first disclosed its intent to acquire ATE last August (*Medical Device Daily*, Aug. 8, 2006).

ATE says that it serves more than 1,450 companies in business sectors such as medical device, biotech, pharmaceutical, research, universities, semiconductor, aerospace, military and industrial food processing.

Dade Behring (Deerfield, Illinois) reported that it has signed a license agreement with **Radboud University Nijmegen Medical Centre** (RUNMC; Nijmegen, the Netherlands) granting Dade Behring the exclusive rights for a new coagulation test called the Nijmegen Hemostasis Assay (NHA), anticipated by researchers at RUNMC to become accepted for testing a broad range of coagulation disorders.

A research agreement was also signed granting Dade Behring with the rights to results from future NHA research and development performed by RUNMC.

Hemostasis is a complex process in which multiple components regulate blood flow and clot formation. Coagulation, fibrinolysis and platelet aggregation are a part of this process. The NHA is viewed by researchers to be important because it could provide insight into the whole blood-clotting process—simultaneously in one test. This type of test is commonly called a "global" test, referring to its potential for screening a broad range of coagulation disorders including thrombophilia and fibrinolytic abnormalities.

In other dealmaking news:

- **Affiliated Computer Services** (ACS; Dallas), a provider of business process outsourcing and information technology solutions, reported that its wholly owned subsidiary, **ACS State and Local Solutions**, has signed a definitive agreement with **Cambridge Solutions** (Greenwich, Connecticut) to acquire certain assets of **Albion** (Atlanta), a company specializing in integrated eligibility software solutions for the health and human services (HHS)

market. The assets of Albion will be purchased for about \$30 million, subject to adjustments, through a combination of cash and borrowings under ACS' existing credit facility. The acquisition is subject to customary closing conditions, including the consent of current Albion customers.

- The **University of Pennsylvania Health System** (UPHS; Philadelphia) has agreed to purchase **Graduate Hospital** (Philadelphia) from **Tenet Healthcare** (Dallas).

UPHS said it will convert the hospital into a comprehensive rehabilitation center and operate it in partnership with **Good Shepherd Rehabilitation Network** (Allentown, Pennsylvania). Once Graduate Hospital is refurbished, it will also house a long-term acute care hospital and provide enhanced educational and research opportunities related to the science of rehabilitation medicine.

UPHS said that Graduate Hospital employees will have the opportunity to pursue a transfer to other Tenet hospitals or to UPHS for positions for which they are qualified, or apply for positions at the new facility when it reopens.

Good Shepherd Penn Partners will convert the hospital. Construction is expected to begin after the sale is complete and take about 15 months, and the new facility is expected to open to patients in the summer of 2008.

- **Document Storage Systems** (DSS; Jupiter, Florida), a provider of software integration for healthcare information systems, reported purchasing **Sage Health Management Solutions** (Minneapolis), a private evidence-based healthcare technology company and developers of RadWise. Sage will become a wholly owned subsidiary of DSS

RadWise provides clinicians with evidence-based ordering recommendations based on the patient's diagnosis, symptoms and procedure requested. By ensuring that the appropriate procedures are ordered, RadWise can improve quality and outcomes, as well as reduce the estimated 30% to 40% of healthcare costs that are attributed to inappropriate test orders, DSS said.

RadWise is a secure, encrypted Internet-based tool that can be implemented inside or outside of an institution's firewall and can be integrated with existing practice management or radiology information systems. ■

Financings

Continued from Page 3

raise the capital needed for product sales and marketing, and product development.

Revolutions Medical says it operates in the safety-engineered medical devices arena, its products including the ReVac Safety Syringe, safety blood-drawing device and the ReVac Safety IV Catheter.

"This was an enormous move forward for Revolutions Medical Corporation as we make the transition from a strictly R&D company to a company that is going into sales and marketing of its first products, while developing new products internally and through acquisition," said Ron Wheet, president/CEO of the company. ■

Agreements roundup

Biolmagene in collaboration with HP for digital platforms

A Medical Device Daily Staff Report

Biolmagene (Cupertino, California), a provider of image informatics solutions for life science research, drug discovery and development and digital pathology, reported a collaboration with **HP** (Palo Alto, California) to bundle its high-content analysis and digital pathology platforms with HP servers.

In the life sciences, drug discovery and healthcare industries, extracting information and knowledge from image data is still manual, inefficient and expensive, the company said. As two-thirds of the data is in the form of images, efficient management of image data is a mission-critical component for successful decision making.

The integration of Biolmagene and HP technologies is expected to allow for better management of the "huge" amounts of image/data generated in discovery, life sciences, and clinical laboratories, Biolmagene said.

"HP is a trusted name in enterprise servers, and [Biolmagene] is the leader in image management, processing and analysis for both high content analysis and digital pathology," Mat Rashidi, PhD, interim VP of marketing and business development for Biolmagene, told *Medical Device Daily*. "These are two huge markets, and basically this announcement is just the beginning of a broad . . . collaboration."

Biolmagene products include CellMine, TissueMine and 3i. Bundling of Biolmagene technologies with HP servers will be designed to offer users a cost-effective solution for rapid image analysis, image processing, and image management on a proven platform for life sciences, drug discovery, and digital pathology work.

Biolmagene has developed a product line from the flagship management platform 3i, built on a web-enabled platform. Biolmagene's products are designed to deliver a searchable image database while maintaining processing and analysis algorithms. Biolmagene products currently are for research use only; however, Rashidi said the company is seeking FDA clearance for certain of its software.

In other agreements news:

- **Allscripts** (Chicago), a provider of clinical software, connectivity and information solutions designed to help physicians improve healthcare, and **Wolters Kluwer Health** (Conshohocken, Pennsylvania), a provider of medical and drug information services and content to physicians, reported a multi-year agreement to deliver Wolters Kluwer Health's clinical content to users of Allscripts Electronic Health Record solutions. The agreement expands an existing alliance between the two companies.

Wolters Kluwer Health will work with Allscripts and its clients to develop customized clinical content including customizable documentation templates, order sets, care plans and best practices for use in the TouchWorks and HealthMatics EHR solutions and other Allscripts applications.

That is expected to enable physicians using Allscripts solutions to document patient care using information appropriate to their area of specialty, including the latest scientific and clinical information about drug therapies, and established best practices to support safe and effective clinical decisions, the companies said.

Additionally, the agreement enables Allscripts to offer clients integration between Allscripts applications and Wolters Kluwer Health's products, such as ClinicalResource@Ovid, a source of scientific and clinical information about drug therapies and evidence-based treatment guidelines designed to support clinical decisions.

The agreement will initially integrate Wolters Kluwer Health content into TouchWorks Version 11, the latest and most advanced version of the leading ambulatory Electronic Health Record, and will be rapidly extended to other Allscripts product lines.

- **Affymetrix** (Santa Clara, California) reported that it has granted **Tessarae** non-exclusive access to its microarray technology to develop and market epidemiological research tests for public health and biodefense surveillance.

As part of the Powered by Affymetrix program, the TessArray kits simultaneously detect and identify hundreds of strains of natural and emergent viral and bacterial pathogens, as well as biothreat agents, the company said. The resulting information is expected to enable researchers to better understand and respond to pandemic infectious disease threats.

The TessArray kits are based on multiplexed genotypic signatures present on the Affymetrix CustomSeq Resequencing Arrays.

Those arrays have been designed and fabricated to detect a set of upper respiratory pathogen-specific target sequences provided by the U.S. Naval Research Laboratory. Public health officials can use the resulting information to quickly identify the most likely agent strain(s) associated with disease outbreaks, the company said.

"The new Affymetrix microarray-based TessArray kits represent common viral and bacterial pathogens associated with acute respiratory disease and pneumonia, as well as biothreat agents that can elicit similar respiratory symptoms," said Clark Tibbetts, PhD, co-founder and chief technology officer at Tessarae. "For example, the TessArray RPM-Flu Kit detects and distinguishes avian H5N1 from other influenza strains and respiratory pathogens, and simultaneously identifies any known or previously unknown mutations that may elevate strain virulence and pandemic risk."

The Powered by Affymetrix program enables commercial entities to license GeneChip technology to develop microarray products for applications in diagnostics, forensics, animal testing, industrial testing and food testing.

Tessarae offers a solution for simultaneous detection and identification of known and unknown strains and variants of pathogenic agents. ■

Healthcare plan

Continued from Page 1

pool of federal funding that would go into state coffers to help the uninsured buy private insurance should they not find it affordable, even with the tax break.

The White House says this mechanism will spread healthcare coverage “without creating a new federal entitlement or new federal spending.”

According to White House explanation and analysis of the plan, the effect on four out of five households will be to lower overall taxes. Families that currently pay for insurance would get an average tax break of \$3,650 in 2009, and those that currently do not would see their tax bills fall by \$3,350 that year.

The plan essentially bypasses federal bureaucracies by putting the money into state coffers and places the onus on each state to provide coverage, continuing a trend that governors from across the nation seem to be embracing. However, Congress would have to authorize the use of funds to provide coverage for those who cannot afford it by means of a “disproportionate share hospital” (DSH) grants mechanism.

Michael Leavitt, secretary of the Department of Health and Human Services, on Monday said that the administration’s intent is to employ its regulatory authority in addition to congressional action to get the DSH grants into play. The funding grants could total as much as \$30 billion, and Leavitt said that while competing ideas constitute having “the federal government insure everybody,” the White House suggestion “is to let the states lead” in providing health insurance for all Americans.

The White House estimates that paring back the standard deduction for health insurance would generate enough savings to spur 5 million uninsured Americans to buy into a health plan. The overall effect of the initiative is said to be budget neutral.

Opinions vary widely on the initiative inside and outside Capitol Hill.

Joseph Antos, a policy analyst with the **American Enterprise Institute** (Washington), in a statement described the plan as a “Nixon-goes-to-China moment” — an acknowledgement that “high income Americans get too much of a particular tax break.”

Paul Ginsberg, the president of the **Center for Studying Health System Change** (Washington), said that the move puts the administration “back into the health policy debate” and that the idea of reducing the tax-free status of healthcare premiums has the support of “a fairly large majority of policy wonks, although not from across the entire political spectrum.”

Ginsberg said that as currently written, the proposal will go nowhere, but the appeal of putting a cap on tax-deductible healthcare premiums has a lot of appeal if the increase in tax revenue is used to expand coverage.

The chairman of the health subcommittee of the House

Ways and Means committee, Pete Stark (D-California), made the case that the “so-called healthcare proposal won’t help the uninsured, most of whom have limited incomes and are already in low tax brackets.”

Stark played the middle class card, insisting that the loss of the tax exemption for healthcare insurance premiums “will hurt middle-income Americans, whose employers will shift even more cost and risk to their employees.”

Stark also lambasted the plan as a “policy designed to destroy the employer-based healthcare system through which 160 million people receive coverage” and will end up excluding those with less than ideal family histories as well as those with existing illnesses or genetic makeup. Despite advocating a Medicare-type system, Stark also decried the possibility that the White House plan will disallow enrollees to “take advantage of the cost savings that currently result from sharing risk company-wide.”

Stark also said, “I do not intend to consider this particular healthcare proposal in the Ways and Means Health Subcommittee.”

Not all Democrats are dead-set against the plan.

The chair of the Senate Finance Committee, Max Baucus (D-Montana), indicated that he is open to “[a]ny serious healthcare proposal [that] will target healthcare savings toward new coverage to Americans who are currently uninsured, and [offer] better coverage to those who don’t have enough.” While Baucus said he “applaud[s] the President for putting healthcare at the fore of his State of the Union address,” he nonetheless will “look closely to see whether his proposal will help to cover the uninsured and help to meet the needs of those with real medical expenses.”

Baucus said he wants to emphasize “extending insurance coverage to children through a renewal and expansion of CHIP,” the children’s health insurance plan that is financed via Medicaid, but is open to “exploring the idea of new and innovative pooling arrangements to expand affordable healthcare coverage.”

Karen Davenport, the director of health policy at the **Center for American Progress**, a Washington think tank, told *Medical Device Daily*, “our view is that this will not do much for the uninsured” because many are below the poverty line and do not pay sufficient income taxes, if any, to be able to take advantage of the income tax break.

In reference to comments by Rep. Pete Stark (D-California) and others, Davenport said, “I think that there have been enough grumblings that [the President’s plan] will have a tough row to hoe,” but she cited the flurry of proposals and concomitant interest in Congress that “there is certainly momentum to do something with healthcare.”

As for Stark’s proposal to use Medicare as a model, Davenport said a couple of years ago, “we had proposed a mandatory enrollment with generous subsidies and a national insurance pool and a generous expansion of Medicare” because “we feel that this is the fastest and most efficient way to provide universal coverage.” ■

Midwest

Continued from Page 1

nificant jump that outpaces national industry growth.”

Baiju Shah, president of BioEnterprise, called 2006 “the breakout year for the Midwest as a whole: a record amount of financing across 135 separate companies, a number of successful public offerings, and several significant exits through acquisitions.”

He added: “Venture capitalists are increasingly finding rewarding investment opportunities in the Midwest, and we expect the momentum built in 2006 will continue into 2007 and beyond.”

According to the BioEnterprise report, Minnesota, the Midwest’s traditional leader in healthcare ventures, led all states with 22 startups, attracting \$233.9 million in investments in 2006.

A number of Minnesota medical device companies raised more than \$20 million each last year, including **Anulex** (Minneapolis), **Atritech** (Plymouth) **Cardiovascular Systems** (St. Paul), **CVRx** (Maple Grove), **Disc Dynamics**, (Eden Prairie) and **Enteromedics** (St. Paul).

Following Minnesota was Michigan with \$135.5 million raised by 11 companies. Several Michigan biotechnology startups attracted significant investment, including **NanoBio** (Ann Arbor) and **Cerenis Therapeutics** (Ann Arbor).

Ohio finished third in the Midwest with \$113.9 million raised by 39 companies, including many seed and early-stage financings.

The report aggregates venture investment in 10 Midwest states and Western Pennsylvania.

Following these leaders were Illinois (\$101.6 million), Western Pennsylvania (\$54.4 million), Kentucky (\$51.4 million), Missouri (\$39.2 million), Indiana (\$37.2 million), and Wisconsin (\$25.2 million).

States with no reported financings included Iowa, Kansas, and West Virginia.

BRIEFLY NOTED

Medwave reports auditor's going concern

Medwave (St. Paul, Minnesota) reported that its financial statements for the fiscal year ended Sept. 30, 2006, included in the company’s Form 10-K filed Jan. 16, contain a going concern modification to the audit opinion from its independent accounting firm, Carlin, Charron & Rosen. The going concern modification is based on the company’s continuing recurring net losses from operations, and its accumulated deficit of about \$34 million. NASDAQ Marketplace Rule 4350(b)(1)(B) requires separate disclosure of receipt of an audit opinion that contains a going concern qualification.

Medwave makes sensor-based non-invasive blood pressure solutions. Medwave trades on the NASDAQ capital market under the symbol MDWV. ■

The report also reports financings in terms of Midwest cities.

Minneapolis-St. Paul and Chicago were the leaders, followed by Detroit-Ann Arbor, Cleveland, and Pittsburgh. (*See table, this page, for complete listing.*)

“The region is reaping the benefits of a number of programs that have been put in place to stimulate healthcare venture activity,” said Shah. “The region has always been rich in research and industry assets. That rich base is now translating into a growing stream of high quality health care start-ups due to progressive policies and programs such as state investments in research institutions, creation of new capital sources, and professional technology development groups.”

BioEnterprise is a business formation, recruitment and acceleration effort designed to support the growth of bio-science companies, providing management counsel and support services to healthcare companies.

BioEnterprise’s partners are **Case Western Reserve University, The Cleveland Clinic Foundation, University Hospitals Health System**, and **Summa Health System**.

Additional technology partners include the **NASA Glenn Research Center, Cleveland State University, NorTech**, and **Omeris**.

BioEnterprise says that with these partnerships it has created, recruited and accelerated more than 50 countries in four years. ■

Table: Midwest Healthcare Venture Investments (2006)

Region	\$millions	# of Cos.
Chicago	101.6	12
Indianapolis	18.4	6
West Lafayette (IN)	18.8	2
Lexington, KY	40.0	1
Louisville, KY	11.4	3
Detroit-Ann Arbor	98.3	8
SW Michigan	6.7	2
UP Michigan	30.5	1
Minneapolis, St. Paul	233.9	22
St. Louis	20.2	9
Kansas City	19.0	1
Cincinnati	13.6	4
Cleveland	87.9	23
Columbus	12.4	12
Pittsburgh	54.4	22
West Virginia	—	0
Wisconsin	25.2	7
Total	792.3	135

Sources: Compiled by BioEnterprise team from Venture Wire, Private Equity Week, Wall Street Journal, Venture Source, SEC Filings, company press releases, and www.biospace.com.

International

Continued from Page 1

A requirement of approval includes providing detailed clinical training to Japanese physicians to ensure their safe and effective use of the device. The device, which Cook said is the most widely used AAA endograft in the world, has a nine-year history of successful use in Europe and a seven-year history in the U.S., according to the company.

Prior to the development of endovascular treatment, patients diagnosed with a large, swelling abdominal aortic aneurysm that could rupture faced extensive open surgery requiring days of recovery time in the hospital and weeks of post-procedural recovery time before they could resume normal activities.

During endovascular repair, a physician makes two small incisions in the groin to insert catheters that are guided under fluoroscopy to the site of the aneurysm. Once in place, the catheters deploy a self-expanding endograft constructed of polyester surgical graft material supported by stainless steel Z-stent bodies.

Cook said the major benefits of the Zenith design for endovascular AAA repair include suprarenal fixation with anchoring barbs to ensure maximal stability and graft-to-vessel sealing, woven polyester graft material that is lightweight, strong and shrink-resistant, and the H&L-B One-Shot Introducer System that allows simple, accurate deployment and positioning of the graft.

Digital pathology solutions launched in India

Biologene (Cupertino, California), an image informatics company, reported the launching of its Digital Pathology solutions for the Indian market at the 12th International Continuing Medical Education in Surgical Pathology and Cytology conference in Pune, India.

The company said it is viewing the Indian market to expand its global outreach in the digital pathology market. Its product offering is a complete end-to-end solution that "will enable scientists and pathologists to implement a comprehensive scientific data/image management, processing and analysis solution where image data and meta-data will be accessed, viewed and analyzed securely through a web browser."

According to the company, the system's flexibility would support remote consultations for projects focused on the cancer market.

Biologene CEO Mohan Uttarwar said, "Biologene would like to take digital pathology to a whole new level by making it easy and affordable for pathologists to manage, analyze, share, and report on their images with simple mouse clicks."

The company said its digital pathology solutions will benefit pathologists by digitization of glass slides and their better visualization on a computer screen; simultaneous image access for more than one pathologist, easing peer review/second opinion processes with online sharing and collaboration of images; and image manipulation to assist

in subspecialties such as immunohistochemistry and cytology, especially Pap smears."

Biologene develops image informatics solutions for digital pathology, life sciences research, and drug discovery and development, with a line of products from the firm's flagship management platform known as 3i.

Canada okays Abbott assays, instrument

Abbott Molecular (Des Plaines, Illinois) and **Celera** (Rockville, Maryland) reported that Health Canada has approved the Abbott m2000 automated molecular diagnostic instrument and the Abbott RealTime HIV-1 and hepatitis C virus (HCV) viral load tests for marketing in Canada.

Abbott Molecular markets the m2000 system and a menu of tests throughout the world as part of a strategic alliance with Celera.

The Abbott RealTime HIV-1 and HCV assays are intended for *in vitro* diagnostic use as an indicator of disease prognosis and an aid in the management of patients undergoing antiviral therapy. They are not intended to be used as screening tests for HIV-1 or HCV, or as diagnostic tests to confirm the presence of HIV-1 or HCV infection.

Both tests have been developed for use on the Abbott m2000 system, an automated instrument intended to improve DNA and RNA testing in molecular laboratories. The m2000 system is based on real-time polymerase chain reaction (PCR) technology and is designed to accurately detect and measure life-threatening viruses and bacteria in patient serum or plasma samples in less than five hours, the company said, compared to other testing methods that may take up to two days.

"By automating all of the complex and heavily manual steps often associated with molecular testing, the m2000 system gives molecular laboratories the ability to prepare patient samples and deliver test results fast and efficiently," said Edward Michael, president of Abbott Molecular. "It is expected to help physicians improve medical care through earlier intervention and the ongoing monitoring of a patient's response to therapy."

Celera is an **Applera** (Norwalk, Connecticut) business.

Grey adds majority interest in Spanish agency

Grey Healthcare Group (GHG; New York), a WPP company that is one of the world's largest healthcare communications firms, said it has acquired a majority stake in **Comunicacion y Servicio Consultores de Marketing Publicidad** (CyS; Madrid, Spain), an independent healthcare communications services agency.

GHG said the acquisition of CyS deepens its European presence and adds an additional level of expertise to the company's network of 43 offices in 22 countries.

Founded in 1997, CyS's clients include Bristol-Myers Squibb, Pfizer, Abbott Laboratories, GlaxoSmithKline, Schering-Plough and Boehringer Ingelheim.

CyS will continue to be managed by General Manager Jose Antonio Alguacil. ■

Zeiss

Continued from Page 1

complete a full refractive procedure without the need to move the patient or to perform redundant data entries, Zeiss said. Alternatively, either platform may be used separately and/or in conjunction with other laser systems, but without the full system integration benefits.

Jim Taylor, president/CEO of Carl Zeiss Meditec, told Medical Device Daily that commercial launch of the femtosecond technology is planned for later this year.

"We're going to continue to do clinical work to further develop and demonstrate the capabilities [of the Visumax system], both as a laser keratome and as a patient management application, and we're now putting together the global market and business platform for the combined solution," Taylor told MDD.

Both MEL 80 and Visumax technologies were recently displayed and demonstrated at the annual meeting of the **American Academy of Ophthalmology** (AAO; San Francisco) in Las Vegas.

The MEL 80 is an advanced refractive laser system that has been marketed outside the U.S. since 2002 and recently gained FDA clearance for sale in the U.S. The company reported that the related clinical trials showed that 93% of patients were corrected to 20/20 or better visual acuity, with 41% achieving 20/12.5 or better at six months (*MDD*, Aug. 28, Nov. 16, 2006).

With the subsequent FDA clearance of the Visumax femtosecond platform, the company said it is now positioned to more fully exploit the technology advantages and clinical benefits of its full refractive laser portfolio.

"We believe that the field of refractive laser surgery offers significant opportunity for the type of technology innovation that Zeiss has pursued throughout our 160-year history," Taylor said. "Since our initial disclosure of the clinical progress of our femtosecond system, we have been gratified by the enthusiastic encouragement and support that we have received from experienced refractive surgeons around the world. They recognize the inherent potentials in these advances along with the significant benefits that will emerge for patients and for clinicians who expect and require the most advanced refractive correction technologies and techniques."

"The apparent advantages of the Visumax system are not limited to those normally recognized for a femtosecond laser flap cut," said Walter Sekundo, MD, of the **University of Mainz** (Mainz, Germany). "Due to the special design of the contact glass and the low IOP increase, the perfusion of the central retinal artery has not been impaired, and our patients were able to see the fixation light throughout the procedure.

"Moreover, the Visumax provides a new level of cutting accuracy for corneal incisions, as evidenced by the results of our successful demonstration of the so-called Femtosecond Lenticule Extraction procedures."

"In my opinion," Sekundo said, "these features con-

tributed significantly to our excellent visual acuity results of up to 20/10 one day post-op, and we saw no incidence of transient light sensitivity syndrome [TLSS] or DLK in any of the study group patients."

The company said it will demonstrate the MEL 80 and the Visumax systems at the meeting of the **American Academy of Refractive and Cataract Surgery** (ASCRS; Fairfax, Virginia) in San Diego, April 27-May 1, and at the meeting of the **European Society of Refractive and Cataract Surgery** (ESCRS; Dublin, Ireland) in Stockholm, Sweden, Sept 8-12.

Carl Zeiss Meditec develops eye care solutions to diagnose and treat the four main diseases of the eye: vision defects (refraction), cataracts, glaucoma and retinal disorder.

Other companies in this sector include **IntraLase** (Irvine, California) which reported filing a lawsuit against Carl Zeiss Meditec last November, alleging that Zeiss breached an intellectual property agreement by improperly using proprietary information on IntraLase which Zeiss wrongfully induced IntraLase to disclose (*MDD*, Nov. 10, 2006). The suit seeks damages for breach of contract and payment of all revenues and profits derived by Zeiss for the sale and use of its laser.

IntraLase makes what it calls an ultra-fast laser-based technology used to create a corneal flap prior to laser refractive surgery. At the time the lawsuit was filed, IntraLase was heavily promoting its new corneal procedure called the IntraLase-Enabled Keratoplasty (IEK) that it launched in September 2006.

IEK is the first blade-free laser approach used to incise corneal tissue, according to IntraLase. The technology is designed to enable surgeons to create precisely shaped incisions that join the cornea and the transplanted tissue together like puzzle pieces (*MDD*, Nov. 14, 2006).

Earlier this month another California company in the laser vision correction market, **Advanced Medical Optics** (AMO; Santa Ana, California) reported it is acquiring IntraLase for \$808 million (*MDD*, Jan. 9, 2007), a deal expected to close in the second quarter of this year.

AMO's wavefront-guided laser vision correction technology (LVC) has been said to dramatically improving the outcomes of LVC by eliminating laser-induced spherical aberrations in the patient's vision (*MDD*, Nov. 14, 2006). ■

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PRODUCT BRIEFS

- **CytoCore** (Chicago) reported that it is ready to start manufacturing its e2 Collector sample retrieval device. CytoCore said it will start production on the e2 for clinical testing, FDA review and subsequent distribution worldwide. The company says that the sample-collecting device's handle and balloon disposable component offer excellent performance comparison and distinct patient comfort improvement over the brush-and-spatula method currently used by doctors in taking routine Pap samples for the early screening of cervical cancer. The company's immediate focus will be on a clinical trial, which should be completed within 90 days, with FDA review to follow shortly afterward and sales and distribution agreements anticipated both within the United States and abroad. CytoCore is a late-stage bio-scientific research company producing tools and testing for the early detection and diagnosis of reproductive cancers.

- **FlowCardia** (Sunnyvale, California) reported receiving FDA 510(k) clearance of the Crosser 14 chronic total occlusion (CTO) recanalization system. The Crosser 14 is designed to facilitate the placement of guidewires beyond CTOs in coronary arteries. This endovascular catheter is delivered using standard guidewires to the site of a chronic total occlusion in the coronary arteries. The CROSSER utilizes high-frequency vibration to facilitate guidewire crossing of CTOs allowing for subsequent balloon angioplasty and stent placement. This cath-lab based, minimally invasive approach to CTO recanalization can eliminate the need for potentially traumatic coronary artery bypass graft surgery. FlowCardia is a company developing endovascular devices for coronary and peripheral CTO recanalization.

- **Orthovita** (Malvern, Pennsylvania), a spine and orthopedic biosurgery company, reported FDA approval of its pre-market approval supplement for the Cellpaker plasma collection system, used in conjunction with its Vitagel surgical hemostat product. Vitagel is a composite liquid hemostat used in surgical procedures as an adjunct to hemostasis when control of bleeding by ligation or conventional procedures is ineffective or impractical. Orthovita is a spine and orthopedic biosurgery company with proprietary biomaterials and biologic technologies for the development and commercialization of synthetic, biologically active, tissue engineering products.

- **OXIS International** (Foster City, California) said that it has identified a new predictive diagnostic lipoprotein biomarker that has the ability to detect early cardiovascular disease. Traditional biomarkers, such as serum LDL levels, have limited predictive power, with as little as 12% of future heart attack victims identified by LDL screening in some studies. Additionally, the first sign of cardiac disease may be Sudden Cardiac Death (SCD), which is seen in up to 30% of heart attack victims according to some estimates. OXIS is a biopharma-

ceutical company focused on commercializing predictive biomarkers, clinical assays and nutraceutical and therapeutic products. The Oxis portfolio of predictive biomarkers includes assays for four different human peroxidase enzymes, as well as multiple assays designed to detect both specific and nonspecific oxidative damage at the level of protein, lipids and DNA.

PEOPLE IN PLACES

- Brad Lawrence has been appointed corporate group VP for **Esterline Corpor** (Bellevue, Washington). Lawrence has served as president of Esterline's Idaho-based advanced input systems subsidiary since 2002. Esterline serves the aerospace/defense and medical markets.

- Warren Dodge has joined **Oncology Metrics** (Dallas-Fort Worth) as president/CEO. Dodge was a member of the founding management team at Oncology Therapeutics Network in 1991 and one of the principals at the National Oncology Alliance. Oncology Metrics describes itself as a service and data business for the oncology community.

- Peter Fitzgerald, MD, has entered a consulting agreement with **Theragenics Corporation** (Buford, Georgia) to serve as chief medical director. Fitzgerald will advise the company on R&D, concentrating on cardiovascular and other opportunities within its surgical products segment. Theragenics makes products serving the cancer treatment and surgical products markets.

Cook Medical reports promotions, names three to new positions

A Medical Device Daily Staff Report

Cook Medical (Bloomington, Indiana), a diagnostic and therapeutic product company, reported three new promotions within the company.

Rob Lyles has been named VP for the diagnostic and interventional (D&I) products division. Along with his new title of vice president, Lyles will retain his position as global business unit leader for D&I. Lyles has held several positions since joining Cook in 2003, serving first as director of sales and national sales manager for D&I.

April Lavender has been promoted from VP of regulatory affairs to senior VP, regulatory affairs.

Ted Heise, PhD, has been named VP of regulatory scientific affairs. Heise had previously been director of regulatory scientific affairs. Heise has been a member of the Regulatory Affairs Professionals Society since 1993 and the American Chemical Society since 1988.

Cook manufactures minimally invasive medical device technology for diagnostic and therapeutic procedures.