MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

WEDNESDAY, APRIL 11, 2007 VOL. 11, NO. 69 PAGE 1 OF 10

Biosite says it will consider IMI's richer offer over rival Beckman

By HOLLAND JOHNSON
***Medical Device Daily* Managing Editor**

Two days after a deadline expired in a hostile bid to acquire it, **Biosite**'s (San Diego) board of directors said it will consider the possibility of an acquisition by new suitor **Inverness Medical Innovations** (IMI; Waltham, Massachusetts) and begin negotiations, after determining it is likely to lead to a superior proposal than its current offer from **Beckman Coulter** (BC; Fullerton, California).

After consultation with its financial and legal advisors the Biosite board said the IMI offer — which at $90 a share is about a 5.9% premium over the BC offering price of $85 a share (about $1.55 billion) — first disclosed last month (*Medical Device Daily*, March 27, 2007) was "likely to lead to a superior proposal." The board noted, however, that it "has not determined that the Inverness acquisition proposal constitutes a superior proposal."

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Deals roundup

Cardinal completes $3.3B PTS asset sale to Blackstone Group

A *Medical Device Daily* Staff Report

Cardinal Health (Dublin, Ohio), a provider of products and services supporting the healthcare industry, reported that it has completed the $3.3 billion sale of its Pharmaceutical Technologies and Services (PTS) unit to the **Blackstone Group**.

The deal, first disclosed in January (*Medical Device Daily*, Jan. 26, 2007), was designed to allow Cardinal to focus resources on its four remaining segments serving healthcare provider customers.

PTS is a provider of advanced technologies and outsourced services for the pharmaceutical, biotechnology and consumer health industry. It develops pharmaceutical and other products for customers in nearly 100 countries, employs about 10,000 at more than 30 facilities worldwide and generates more than $1.7 billion in annual revenue.

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World Health Care Congress

European ministries report patchwork eHealth progress

By JOHN BROSKY
***Medical Device Daily* Contributing Writer**

BARCELONA — The accelerating costs of chronic diseases, the progressive aging of Europe's population and a hoped-for miracle to solve the problem through information technology (IT) drove the agenda at the **World Health Care Congress Europe**, held here late last month.

1st of 3 articles

Behind the headlines was an unspoken but well-known theme: European state health insurance funds are sagging to the breaking point under current pressures and are poorly prepared to absorb the coming shock.

Six health ministers participated in the program, and key executives from health ministries in 10 other European countries addressed the gathering of more than 500 participants from 40 countries.

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3M Diagnostics reports first test launch in the EU market

By KAREN YOUNG
***Medical Device Daily* Staff Writer**

3M Diagnostics (St. Paul, Minnesota), a new business unit of **3M**, unveiled in early March (*Medical Device Daily*, March 13, 2007), introduced its first product last week, in Europe, at the 17th European Congress of Clinical Microbiology and Infectious Diseases in Munich, Germany.

This first product, launched last week and designed for hospitals fighting the battle to stop the spread of methicillin-resistant *Staphylococcus aureus*, is the 3M BacLite Rapid MRSA test. 3M said it is the first rapid culture-based test that can "effectively and reliably" detect the presence or absence of MRSA in high-risk patients within five hours.

"[MRSA] is not symptomatic, so this is a test for screening to determine if they are carriers of MRSA," Angela Dillow, global business manager for 3M Diagnostics, told *Medical Device Daily*. "It's preventative in nature."

Dillow said that typically patients are screened when they arrive at a hospital to determine if they are carriers. Or,

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Patent watch

Synergetics paying $6.5 million to settle IP disputes with Iridex

A *Medical Device Daily* Staff Report

Synergetics USA (O'Fallon, Missouri) reported reaching a settlement of all outstanding claims in two patent disputes with **Iridex** (Mountain View, California), resolving all claims between the parties.

The terms of the agreement require payments from Synergetics to IRIDEX totaling $6.5 million over a period of five years. The first payment of $2.5 million by Synergetics is to be paid on April 16, followed by annual payments of $800,000 on each date of April 16 until 2012.

Other terms include dismissal of all legal actions between the parties and cross-licensing of various patents. Synergetics obtained the right to manufacture and supply various laser disposables, which it said could result in about $3 million in revenue over the next five years.

Gregg Scheller, president/CEO of Synergetics, said, "The resolution of this dispute allows us to focus our energies on our business and move forward with an industry partner. This agreement allows Synergetics to continue marketing its proprietary and patent-pending, new two-connector system under a fully-paid, irrevocable Iridex license. The elimination of a significant portion of our legal fees associated with going to trial in the current adapter case and our pending directional laser probe case, in addition to gross profit we will derive from manufacturing probes for Iridex should more than offset our cross licensing fees in this settlement.

Barry Caldwell, president/CEO of Iridex, said, "The two companies had to work hard to get this settlement completed and together came up with some creative solutions. We now have the opportunity in the future to find ways in which we might work together to better serve the ophthalmic retinal community. Finally, the conclusion of this litigation will enable us to save a substantial amount of legal fees during the second quarter and positions us to improve our operating performance."

Synergetics resulted from the 2005 combination of **Valley Forge Scientific** and Synergetics, linking their capabilities in bipolar electrosurgical generators and design, and manufacture of microsurgical hand instruments.

Iridex is a provider of therapeutic based laser systems, disposable laser probes and delivery devices to treat eye diseases in ophthalmology and skin diseases in dermatology markets.

In other patent action: **Medela Holding** (Zug, Switzerland) reported that Judge Royal Ferguson of the U.S. Federal District Court for the West District of Texas upheld the Aug. 3, 2006, jury verdict that the combination of Medela's Vario 18 (resold as Versatile 1) constant-intermittent aspirator and Chariker-Jeter type dressing materials did not infringe on patents held by Kinetic Concepts (KCI; San Diego) for a similar device.

Urs Tanner, a member of Medela's board, said that the judgment by the court "clearly supports Medela's position that we did not infringe upon KCI. This decision allows Medela to quickly enter the negative pressure wound therapy [NPT] marketplace, where we are committed to improving the health and well-being of patients and providing competitive, high quality, research-based products for healthcare providers."

Medela's Vario 18 is an electrical and battery-powered suction pump used for wound healing by applying negative pressure to the wound site and continually draining away wound effluent and infectious materials. Medela said it is in the process of launching its own NWPT system in the second quarter for 2007. ■

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

"Healthcare is a topic that loses elections, a great way to burn your fingers as a politician."

*— German Chancellor Angela Merkel commenting on Germany's plans for a central insurance fund at the **World Health Care Congress** in Barcelona. World Health Care Congress, p. 1*

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Financings roundup

HearUSA eliminates $6.2 million of its long-term debt via restructuring

A *Medical Device Daily* Staff Report

HearUSA (West Palm Beach, Florida) has completed a transaction with the holders of the company's 2003 subordinated convertible notes. The participating holders converted $5.4 million of the outstanding principal of the notes into shares of the company's common stock at $1.75 per share in accordance with the original agreement as contemplated by the notes.

The company made cash payments to the participating holders of notes for the remaining principal balance of $409,000, canceling such notes. One of the 2003 investors did not participate in the transaction. The company paid that investor $375,000 of principal, leaving about $42,000 in principal unpaid. As part of the transaction, the company adjusted the exercise price of the outstanding warrants held by the investors and the participating investors exercised all of those warrants for cash. The company issued 2.5 million warrant shares to those warrant holders and received about $1.7 million in cash.

The company will no longer be required to make quarterly principal payments in the amount of $625,000 plus interest to the 2003 note holders. It will have one final principal payment to the non-participating investor of about $42,000 in June 2007.

After making the various aforementioned payments, the company will receive net cash of about $1 million.

The conversion of 14 of the 15 units and the exercise of the warrants combined with the cash pay down will eliminate most of the non-cash debt discount amortization charges and the cash interest expense related to the financing in future periods, the company said. These expenses for 2006 totaled about $2.6 million, or 8 cents per common share. As a result of the transaction, the company will take a one-time final non-cash charge of about $2.4 million in 2Q07 resulting from the acceleration in the amortization of the debt discount related to the convertible notes for this transaction and the reduction in the price of the warrants to the investors, which accounted for about $1.4 million of the one-time charge.

"We are very pleased with this agreement as we believe it is a win-win situation for stockholders and the note holders alike," said Stephen Hansbrough, president/CEO of HearUSA. "Specifically, this deal is immediately accretive to the company as it eliminates the quarterly interest expense and non-cash charges related to the notes and brings in additional capital."

HearUSA provides hearing care to patients primarily through its company owned hearing care centers, which offer a complete range of hearing aids, with an emphasis on the latest digital technology. HearUSA Centers are located in California, Florida, New York, New Jersey, Massachusetts, Ohio, Michigan, and Missouri and the province of Ontario. ■

eHealth

Continued from Page 1

Immediately following the 50th anniversary celebration of the European Union (EU), the picture of European healthcare emerging from the congress was strikingly similar to the bewildering patchwork of the expanded union that now counts 27 member states. Under the treaty that underpins the EU, each state manages its own program and problems.

The moderator for the keynote session, Stanislaus Cozon, managing director for global public sector at **Capgemini** (Paris), acknowledged the widely different approaches and pilot projects for meeting the challenges of healthcare, but said, "considerable progress has been made since we met last year."

Marina Géli i Fabrega, minister for health for Spain's Catalonia region, responded in discussions with the audience that "IT is good, but only with expectations set for quality metrics and measuring outcomes. This is what the systems are supposed to achieve."

Catalonia spends €1,100 per person per year, she said, "which is low but is also fragile," as 60% of the expense is for staff not paid very well and not motivated to meet ministry goals for care. "The burn-out factor is significant," she said.

"We are clearly betting on communities" to off-load a growing pressure on hospital centers," said Géli, who described her strategy for mainstreaming health services through the creation of an agency promoting personal care and supporting neighborhood health plans with local governments.

Austrian Minister of Health and Women's Affairs Andrea Kdolsky reported a surplus of beds in acute-care centers and she said that the challenge is to convert capacity to elderly care facilities.

Across the Danube, the Czech Republic is struggling with financing. Minister of Health Tomas Julinek told the Congress flatly that problems cannot be solved with the existing financing formula. "A critical moment for the Czech Republic is coming in 2015 with our aging population," he said. "An increase in financing is impossible," given the current tax burden and level of insurance premiums.

"The only solution is to link responsibility of individuals to the healthcare costs that they impose on the system," he said.

Flavio Tosi, minister of health for the Venato region of Italy, reminded attendees that the EU includes 27 nations but is actually comprised of 250 regions. Spain, Italy and Germany are three of the largest EU member states and between them hold 53 separate regions with autonomous authority for delivering and managing healthcare, a decision-making that can be influenced, but not controlled, by national ministries.

The healthcare reform won by German Chancellor

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Court report

Former executives of Endocare indicted for sham transactions

A *Medical Device Daily* Staff Report

Two former executives at a California medical device maker have been indicted in a scheme that bilked investors out of $200 million by inflating revenue and concocting sham transactions.

A federal grand jury in Santa Ana charged Paul Mikus, the former chief executive at **Endocare** (Irvine, California), and John Cracchiolo, the company's former CFO, with 27 counts of securities fraud, false statements to federal regulators and wire fraud, among others, between 2001 and 2003.

Mikus and Cracchiolo have agreed to surrender to federal authorities later this month, authorities said.

Last July Endocare agreed to settle charges of accounting fraud and making false and misleading public statements about the results of an internal investigation, the Securities and Exchange Commission said. Endocare agreed to pay a $750,000 civil penalty and be permanently enjoined from future violations, without admitting or denying the charges (*Medical Device Daily*, July 21, 2006).

The SEC said that the company's senior vice president of sales, Kevin Quilty, and Jerry Anderson, the former president of an Endocare subsidiary, agreed to settle charges of recordkeeping and internal controls violations and in the case of Quilty, for aiding and abetting Endocare's violations.

Quilty agreed to pay $23,749 in disgorgement and interest and a $25,000 penalty. Anderson agreed to pay a $35,000 penalty.

Endocare manufactures a medical device, known as the Cryocare Box, used to freeze cancerous tissue for treatment of prostate cancer, and, according to prosecutors, Mikus and Cracchiolo overstated the number of past and projected procedures involving the device.

In connection with a 2001 stock offering, the two told investors that the company's largest distributor was immediately reselling Cryocare Boxes for use in medical procedures. In fact, the devices were unused and unopened in the distributor's warehouse, prosecutors said.

In other cases, the men claimed to investors, accountants and regulators that some of its Florida customers were obligated to pay for the devices when, in fact, they were not.

Prosecutors said that, as a result, the company inflated revenue by $4.2 million in November 2001. Three months later, the two executives concealed that the transactions were fake when they claimed the company had beaten revenue forecasts by $500,000.

When allegations of fraud surfaced in 2002, the company's stock price collapsed on the NASDAQ, producing more than $200 million in investor losses. The company was delisted in January 2003.

Mikus and Cracchiolo also face securities fraud charges filed in a civil case brought by the U.S. Securities and Fraud Commission.

In other court news: A jury in Dallas County in Texas has ordered a physician group serving **Presbyterian Hospital** to pay a local doctor $6.3 million in a defamation and breach of contract case.

Neal Fisher, MD, was a shareholder in **Pinnacle Anesthesia Consultants** (Dallas), a provider of obstetric anesthesiology services to Presbyterian Hospital. Although Pinnacle advertised as being "in-network" for all major healthcare plans, it had in fact adopted a business plan of intentionally being "out-of-network" for its services, according to Fishser's lawyers. Pinnacle thus collected higher revenues than it would have by matching patients with in-network doctors.

When Fisher voiced concerns about the practice, Pinnacle accused him of abusing alcohol and drugs and made accusations about his administrative and medical abilities. It then fired Fisher even though it had no proof of the charges and in fact believed most of them to be false.

Fisher submitted to drug and alcohol testing of samples of his blood and hair, through Presbyterian's Impaired Physician Program. Though he passed every test, Pinnacle neither apologized nor offered him his job back. His lost job and damage to his reputation cost him millions in lost income, according to his attorney, Mike Richardson of Rose Walker.

"The jury has spoken and has totally vindicated Dr. Fisher," Richardson said. ■

BRIEFLY NOTED

Omeris renamed BioOhio

Omeris, Ohio's bioscience membership and development organization, reported it would change its name to **BioOhio** (Columbus). A new logo with their stylized shape of the state has been launched, and the changes become effective immediately.

Tony Dennis, president/CEO of BioOhio, said the new name builds better branding outside of Ohio. The organization is responsible for attracting out-of-state company relocations and capital investment for emerging entrepreneurial companies. BioOhio recently received a three-year, $1.5 million grant from Ohio's Third Frontier Commission to recruit bioscience companies from around the world.

BioOhio is the Ohio affiliate of the **BioIndustry Organization** (Washington), and it is affiliated with **AdvaMed** (Washington).

The organization's web address will change to www.BioOhio.com, but address and phone numbers will remain the same.

Grants/contracts

Reliant provides $1M to advance laser-based R&D skin therapy

A *Medical Device Daily* Staff Report

Reliant Technologies (Mountain View, California) reported that it is providing more than $1 million in research funding to expand the science of fractional skin treatment in search of new laser-based therapies for dermatological conditions.

It is making the grant over three years to the **Massachusetts General Hospital** (MGH; Boston), where its **Wellman Center for Photomedicine** will undertake the effort, including studies that test technology developed at MGH and Reliant.

"This important funding will help us find new ways to optimize the benefits of fractional skin treatment technology for a broad array of skin conditions," said Dr. Dieter Manstein of MGH's Wellman Center, principal investigator for the fractional technology research grant. "We want to ensure that this therapy is widely available to help patients around the world."

Reliant said that fractional skin treatment is growing as it has proven to offer safe and effective treatments for a number of conditions.

Reliant's flagship product is the Fraxel SR laser, developed through an earlier collaboration between MGH and Reliant. Reliant says that in 2004 it was the first company to introduce a commercial product based on the science of fractional skin treatment, licensed exclusively from MGH. It says that since then, the laser, marketed as Fraxel-brand laser systems, has become the "category leader" in the laser skin rejuvenation market.

"This research is critical to expand the use of fractional skin treatment throughout the dermatological community," said Len DeBenedictis, Reliant's chief technology officer. "Only through rigorous studies can we confidently continue to develop the kinds of breakthrough products that physicians have come to expect from Reliant. Collaborating with the Wellman Center, the leader in photomedicine in the treatment of skin conditions, ensures that the science and the technology we develop will be well-grounded and effective.

Dr. Rox Anderson, director of the Massachusetts General Hospital's Wellman Center for Photomedicine and on the faculty of the Harvard Medical School dermatology department, described the technology as "nothing short of a revolution for safe and effective treatments in dermatology. These tools are something the dermatology community has wanted for some time."

Reliant's laser devices are used to treat periorbital wrinkles, pigmented lesions of the face and body, acne scars and surgical scars. ■

Boston Scientific notifies docs of defibrillator battery risk

A *Medical Device Daily* Staff Report

Boston Scientific (Natick, Massachusetts) reported that it has notified doctors that some of its implantable heart defibrillators contain batteries that could deplete early, shortening the life span of the devices.

The company said in its letter, dated last Thursday and posted on the web site of its Guidant unit, that there have been no patient deaths or serious injuries associated with the battery voltage problem.

Accelerated battery depletion was found to have occurred in 19 of about 73,000 devices in the Vitality family of implantable cardioverter defibrillators, which restore heart rhythms, and the Contak Renewal line of cardiac resynchronization therapy devices.

Boston Scientific bought Guidant last year for $27 billion primarily to acquire its portfolio of heart rhythm management devices. But high-profile recalls of some of the devices have depressed sales. More than 100,000 Guidant heart rhythm devices were recalled between 2005 and 2006.

Bear Stearns analyst Rick Wise, wrote in a research note that he considers the development an "incremental negative" for Boston Scientific. "While we are not sure if this capacitor issue is related to past capacitor issues, or if the incidence of 19/73,000 ICDs with the known issue will increase, the additional vigilance required for doctors and patients to monitor this issue puts Boston Scientific products in a negative light."

In its letter to doctors, Boston Scientific estimated that fewer than 2% of the devices identified were at risk for early battery depletion. The average implantable defibrillator lasts five to seven years.

The firm provided guidelines for identifying which patients have devices with faulty batteries and recommended monitoring them every month instead of the usual three months. ■

BRIEFLY NOTED

CardioTech introduces web site

CardioTech International (Wilmington, Massachusetts), focused on materials science technology, medical device engineering services and contract manufacturing, said it has launched a new web site: www.cardiotech-inc.com.

The new web site provides access to CardioTech's array of polymer technology, products and medical device contract development and manufacturing services.

Some of CardioTech products and services include: orthopedics/artificial joints; spine/spinal implants; drug delivery/oncology ports and catheters; and cardiovascular/stents and stent coatings.

Biosite

Continued from Page 1

The Biosite board went on to say that it has not "approved, endorsed or recommended the Inverness acquisition proposal," and added that it has not "withdrawn, qualified, modified, changed or amended its recommendation with respect to the Beckman Coulter tender offer, and the merger agreement between Biosite and Beckman Coulter remains in effect."

Expressing confidence that its deal is still superior, even at a reduced price, Scott Garrett, Beckman Coulter's president/CEO, said the company remains committed to its acquisition of Biosite and will waive the merger agreement provision that Biosite provide the company with 48 hours notice before negotiating with Inverness.

"The conditional and uncertain terms of the Inverness offer should give the Biosite board and its stockholders enormous pause," said Garrett. "In our view, the fact that Inverness has not proposed a tender offer, which could be concluded relatively quickly, speaks volumes about the firmness of its financing. Inverness' financing 'commitments' contain remarkably broad conditions and contingencies. It is not surprising, therefore, that Inverness instead is suggesting a one-step transaction — one that would take months to complete."

Garrett further suggested that the Biosite board should communicate the risks and uncertainties of the Inverness offer to Biosite's stockholders who, based on trading levels in the marketplace, may be unaware of these risks.

"We remain committed to our transaction with Biosite and continue to be very enthusiastic about the prospects for developing Biosite and Beckman Coulter as a combined business," Garrett added. "We believe Biosite stockholders will conclude that Inverness is unable to make an offer for Biosite that is as compelling as the definitive transaction between Beckman Coulter and Biosite which is scheduled to be completed within the next 25 days. By waiving this 48-hour notice period, we are seeking to resolve the uncertainty in the marketplace resulting from Inverness' offer as quickly as possible."

Biosite, a biomedical company commercializing proteomics discoveries for the advancement of medical diagnosis, said last week that Inverness is offering "substantially similar business terms" to Beckman's offer.

In a letter to Biosite's board last week that coincided with its richer offering, Ron Zwanziger, IMI's president/CEO and chairman, pointed out that executives from Inverness "have made repeated attempts over the past 10 months to engage the Biosite management team and board in a meaningful dialogue about a potential combination of our two companies." He said that as recently as Feb. 20, Inverness submitted a proposal to acquire Biosite and subsequently entered into a confidentiality agreement for the express purpose of working with Biosite to explore the possibility of enhancing that offer. "We were therefore extremely surprised and disappointed by your announcement on March 25 of an agreement with Beckman Coulter," he added.

In his letter, Zwanziger also indicated that his company was prepared to bring its proposal directly to Biosite's shareholders" if they didn't hear back from Biosite by April 8, a deadline the Biosite board let expire without an immediate reply.

BC's tender offer for Biosite shares is set to expire on April 27, unless extended. ■

BRIEFLY NOTED

WorldHeart reports 'going concern' comment

World Heart (Oakland, California), a developer of mechanical circulatory support systems, reported that the company's independent auditors have issued a going concern statement in its annual report.

WorldHeart ended 2006 with cash and cash equivalents of $12.2 million, compared with $10.7 million at year-end 2005. The company completed a $14.1 million private placement with existing and new investors during the fourth quarter of 2006. In conjunction with the financing, the company restructured its operations to reduce operating expenses and realigned resources toward development of the company's next-generation products.

The company said management continues to control spending and manage working capital to preserve cash.

"WorldHeart will continue to focus its energies on the final development, evaluation, regulatory approval and commercialization of our next-generation Levacor Rotary VAD," said Jal Jassawalla, president/CEO of WorldHeart. "We expect to initiate clinical use of the Levacor Rotary VAD in Canada in the near-term and start a U.S. feasibility trial in the latter half of 2007."

Optivus Technology now Optivus Proton Therapy

Optivus Proton Therapy (San Bernardino, California), which focuses on proton therapy technology, reported that as its new name, a switch from Optivus Technology.

The changes are aimed at communicating Optivus' role as a leader in proton-based radiation oncology to a wider audience. The company is also launching what it called an "aggressive" marketing and sales strategy.

Optivus Proton Therapy's technology at **Loma Linda University Medical Center** (Loma Linda, California) the world's first Proton Beam Treatment Center, has treated more than three quarters of all proton cancer patients in the U.S., the company said.

Optivus said it boosted its sales staff five-fold and plans to present its proton beam therapy systems to more than 200 academic and medical institutions this year, nearly a six-fold increase over last year.

Cardinal

Continued from Page 1

Among its core offerings, PTS develops oral and sterile pharmaceuticals in nearly all major dosage forms, and it offers technologies used in many well-known prescriptions and over-the-counter products. PTS is also the largest contract packager of pharmaceuticals.

Greatbatch (Clarence, New York) reported that it has completed the $11.4 million acquisition of substantially all of the assets of **Biomec** (Cleveland) that was first disclosed last month (*MDD*, March 21, 2007).

The transaction, which was comprised of cash and future additional considerations, closed on April 3, following approval by Biomec shareholders.

Biomec was established in 1998 with the goal of accelerating promising technology from major medical and academic institutions, national laboratories, and internal developments to successful commercial products.

It reports that it is developing a polymer coating (biomimetic) that mimics the surface of endothelial cells of blood vessels with potential use on several medical devices, including in-dwelling central venous catheters, cardiac pacing leads, and extra-corporeal blood pump circuits in bypass surgery.

Greatbatch said it will maintain Biomec's operations in Cleveland, which includes a 25,000 square foot facility providing engineering, prototype manufacturing, and machining capabilities. The facility is FDA-registered and maintains a quality system certified to ISO 13485 standards.

"With the acquisition of Biomec, we can now offer our customers more robust device engineering expertise along with full device assembly utilizing our proprietary component," said Mauricio Arellano, senior VP of Medical Solutions for Greatbatch. "This will enable us to work in conjunction with our customer's design teams to build more sophisticated devices."

Greatbatch is a developer of critical components used in implantable medical devices and other technically demanding applications.

In other dealmaking news:

· **Uroplasty** (Minneapolis) reported that it has closed on the previously reported agreement to purchase from **CystoMedix** (Andover, Massachusetts) certain intellectual property assets related to its Urgent PC neuromodulation system (*MDD*, March 19, 2007). The agreement also provided for the termination of the April 2005 exclusive manufacturing and distribution agreement with that company.

In consideration, Uroplasty issued CystoMedix 1,417,144 shares of Uroplasty common stock. With the issuance of the shares to CystoMedix, Uroplasty will have 13 million common shares outstanding.

Uroplasty develops products for the treatment of voiding dysfunctions.

· **Synovis Life Technologies** (St. Paul, Minnesota) reported the completion of its acquisition of the 4Closure Surgical Fascia Closure System from privately-held **Fascia Closure Systems** (Santa Ana, California).

The 4Closure system is a device and operating method for closure of punctures in the fascia, a layer of connective tissue on the inner surface of the chest or abdominal wall, following laparoscopic procedures which use larger diameter operating ports or trocars. The device is authorized for sale in the U.S. and has a patent pending.

"With this acquisition, our direct sales force has a new product to sell and another entry point to bariatric and general surgeons, as well as other surgical specialists who utilize laparoscopic techniques," said Richard Kramp, president/CEO of Synovis Life Technologies.

Synovis Life Technologies develops medical devices for the surgical and interventional treatment of disease.

· **Medwave** (Arden Hills, Minnesota) reported that its board of directors has decided to begin a process to explore strategic alternatives to enhance shareholder value, including but not limited to the raising of capital through the sale of securities or assets of the company, a recapitalization, strategic acquisitions, and the combination, sale or merger of the company with another entity.

Medwave is engaged in the development of noninvasive, blood pressure measurement and monitoring systems.

· **Delcath Systems** (Stamford, Connecticut) reported that it has entered into a modification agreement with Laddcap Value Partners, Laddcap Associates, and Laddcap Value Associates to amend the Oct. 8, 2006 settlement agreement between Delcath and Laddcap (*MDD*, Oct. 11, 2006). The key terms of the modification agreement will allow Laddcap to increase its position in Delcath, if it so chooses, through open market purchases of Delcath shares beyond the previous 14.9% limitation established by original settlement agreement to just under 20%. Additionally, Delcath will no longer be required to elect two directors nominated by Laddcap or to appoint at least one Laddcap nominee to each of its committees as stipulated in the original agreement. The board of Delcath also voted unanimously to increase the threshold level for triggering the shareholder rights plan from 15% to 20%, effective immediately.

Delcath Systems is a developer of percutaneous perfusion technology for organ or region-specific delivery of therapeutic and chemotherapeutic agents. ■

eHealth

Continued from Page 3

Angela Merkel in February and signed into law the week of the Barcelona conference, calls for a full capitation of the healthcare system by 2009 through a central insurance fund. That has created tension with the 250 insurance companies gathering and distributing funds.

"Yes, it is true," said Amelung, "but there will be an election before that. Healthcare is a topic that loses elections, a great way to burn your fingers as a politician."

"The health system in Germany is in a major period of reform," said Dr. Hans Jürgen Ahrens, chairman of **AOK-Bundesverband** (Bonn, Germany), who said that he welcomed the reform law, saying it "creates new spaces for insurers, creating a wider playing field to offer different incentives and pricing."

Meanwhile, Spain is inspiring European ministries with diverse approaches to reforming healthcare delivery among the 17 autonomous regions. Catalonia and Andalusia are references for e-health initiatives on the leading edge of the federally endorsed roadmap, Plan Avanza, developed within the framework of the EU action plan i2010.

Valencia is attacking problems for public health financing directly by forming partnerships with private sector insurers. The Denia district in Valencia has granted a 15-year concession to **Deutsche Krankenversicherung** (DVK, Frankfort), a German health insurance company, for managing public health facilities and delivering health services for the 160,000 inhabitants. Denia is the third district in Valencia to grant management to DVK. In Alzira, where the model was tested in 1997, DVK took on the responsibility for building a needed hospital.

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UK's information tech showing lead in patient empowerment

By JOHN BROSKY
***Medical Device Daily* Contributing Writer**

BARCELONA — Ironically, the most headstrong and sometimes nettlesome member state of the European Union, the United Kingdom, has emerged as the key reference for overhauling a national system of care.

"Six years ago no one would have dared let the British speak at a healthcare congress," Volker Amelung, managing director of the **German Managed Care Association** (Berlin), said during the recent World Health Care Congress Europe. "Their system was a case study for disaster, with terrible infrastructure and delivery. Today they have a tremendous experience and knowledge that is showing everyone the importance of information technology, and for empowering patients within the system. It is impossible to have a conference without them."

David Nicholson, chief executive for the UK's **National Health Service** (NHS), said, "Anyone reading an English newspaper will see daily the pain and anger of the transformation of our system."

Nicholson said the NHS "massively invested in capacity, which has meant more doctors, more nurses and new and better hospitals and clinics," but he added: "This investment alone, capacity alone, is not enough."

The boldness of the British e-health program, Connecting for Health, shows the kind of courage needed in Europe, according to keynote speaker Viviane Reding, the EU commissioner responsible for the EU Directorate for the Information Society.

"We need a greater sense of urgency to attack health budgets to prepare for the crisis that is coming," she said. "Spending is growing faster than gross domestic product and only IT can help to keep down the costs and to help reorganize the delivery of services. The Commission believes profoundly in IT and we have set ambitious goals."

Reding added, "My frustration with e-health is that we are seeing great results but on a limited scale, with limited prospects for a wide-scale deployment anytime soon."

Despite the widespread admiration for British pluck in using a nationwide IT structure to force upon the entire healthcare system, no other European nation is following the lead.

The only European nation with the political structure to mandate national change is France, which presented at the World Health Care Congress Europe here, a carefully designed plan for outflanking the expected resistance from the healthcare establishment to any large-scale change.

The head of IT development for the French Ministry of Health, Jacques Sauret, told the conference the long-delayed dossier médical personnel (personal medical record, or DMP) would go public in 2008, though he said the request for proposals from network hosts for constructing the infrastructure is not expected before mid-April.

The France-based operations of IBM, Atos Origin, Bulle and Thales are the probable bidders for the project, Sauret told *Medical Device Daily*.

France will select three providers, with one required to serve as a back-up service capable of recovering the files of the other two in the event of a system failure.

In the end the DMP will not be an electronic health record (EHR) but instead will be issued as a "service." The 60 million smart cards to be carried by French citizens starting in 2008 will serve as a key to unlock a file managed by the patient providing information for urgent care, medications, potentially medical imaging and documents, but not clinical data

"We are thinking big regarding the needs but acting small to avoid unpilotable projects," Sauret said. "Phasing the project is essential because it is not possible to get everything done at the same time the way the English are trying it."

3M

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if a patient is a "known carrier," she said, upon readmission that patient is tested again to determine if he or she had cleared the infection.

"There are several places they are tested in the body, but [clinicians] are not looking for active infections," she said. "They're looking for carriers."

One of the "most common" locations on the body is in the nose, she said.

3M said that the new 3M BacLite Rapid MRSA Test will help clinicians quickly identify MRSA-colonized patients so they can proactively manage carriers. Importantly, the company said, a confirmed negative test result is available within five hours, and a confirmed positive result is available in 24 hours.

Currently, a typical culture test would take two to three days to provide a result, Dillow said.

Hospitals would be required to buy 3M's instrument system to run the assay, but more tests are planned as applications for the instrumentation in the future, Dillow said.

The BacLite test requires 45 minutes total hands-on time for 45 specimens, which 3M said helps the laboratory's efficiency and productivity. Also, the company said it is an easy system to implement, because it does not require a high level of skill to operate.

"It also has an objective endpoint, which means that the opportunity for error is reduced," the company said.

Dillow said that molecular testing is another alternative to culture, but those tests tend to be more complex and more expensive than culture-based tests.

3M's Director of Microbiology at the diagnostics unit, Steve O'Hara, said, "The BacLite MRSA test represents a revolutionary step in microbiology testing. It is quick and simple to use due to its accelerated culture-based detection of micro-organisms direct from clinical specimen."

MRSA is one of the most common hospital-acquired infections in Europe. Among Germany, UK, France, Italy and Spain, prevalence rates range from 21% to 44%, according to the company. It said that in some European countries, the proportion of MRSA infection in patients in intensive care units is more than 60%.

In the UK, for example, it is estimated that MRSA infections are costing €1.5 billion ($2 billion) a year.

Dillow said that Europe is not homogeneous and due to this diversity, "parts of Europe have been tackling the problem many years in advance of what we have in the States and in other European countries." However, while some EU countries are "further along in thinking about this problem," MRSA is "not any less or more of a problem than in the U.S."

The expectation is that earlier screening will result in less spread of the infection and lower costs associated with isolating patients suspected of carrying the bacteria, because typically the wait is about 48 hours until confirmatory tests are obtained.

When the organization of 3M Diagnostics was first reported by the company last month, Dillow told *MDD* at the time that she expected three tests in the U.S. to be launched later this year, although they still require approval from the FDA.

In addition to tests for MRSA, 3M expects to develop tests of influenza A and B, along with its initial strategy to provide products in the area of infection control.

"MRSA is the top antibiotic-resistant pathogen of concern, so it's considered a great first step into the marketplace," Dillow said. ■

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The Lombardy region of Italy is that country's showcase for e-health, with 5,000 general practitioners connected and 9.2 million users of the Carta Regionale de Servizi (health cards).

Walter Bergamaschi, IT director at the Italian Health Ministry, said the Lombardy program is a cornerstone for the federal architecture.

"We are watching the UK with great interest," he said, "but a central, federal database for Italy could only serve as an index. The big deal for Italy is creating a federation of regional databases. Each region has started something and the question is whether they are interoperable. Right now we are identifying standards."

Sweden is also broken into 21 regional and municipal authorities, each responsible for healthcare service delivery, and each of which is running relatively advanced e-health programs.

Kalmar County, with 238,000 inhabitants on the east coast of Sweden, was presented at the conference as a case study and the district's chief information officer, Peter Alvinsson, reported over €9 million in annual savings "that we measured ourselves, without consultants."

Despite the relative maturity of programs in Sweden, health executives from Europe took note that it is only recently, according to Alvinsson, "that for the first time we have a solid commitment to one national strategy for healthcare IT."

Anita Eriksson Pallinder, CEO of **CareLink** (Stockholm), an association of Swedish local governments, is charged with pulling together the diverse Swedish local programs into a national system and assure interoperability between regions and communities.

"We are now in the midst of procurement for a national patient record to include critical data such as lab results, medications, or a family doctor contact," she told *MDD*.

The long-term commitment of Denmark to an e-prescription service is now delivering tangible benefits for the

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PRODUCT BRIEFS

• **Ethicon Endo-Surgery** (Cincinnati) reported submitting a premarket approval application with the FDA for its adjustable gastric band, an implantable device intended to treat morbid obesity. The device is a soft, adjustable band that is fitted around the uppermost part of the stomach during laparoscopic surgery, creating a small pouch and restricting food consumption. Ethicon Endo-Surgery, a J&J company, makes devices for minimally invasive and open surgical procedures.

• **Millipore** (Billerica, Massachusetts) reported the availability of the new BioPak C disposable ultrafiltration cartridge. This in-line cartridge is designed to minimize alkaline phosphatase (ALP) released by bacteria that may be present in immunoassay and clinical analyzer feed water used to prepare buffers, make blanks and rinse tubing and probes. The cartridge is delivered decontaminated by beta irradiation at 15 kGy and can be stored for two years before usage. The filter allows flow rates up to 3 L/min at 1.5 bar and ensures up to 120 days of continuous operation. Millipore specializes in improving productivity in laboratory research and bioprocessing manufacturing.

• **Masimo** (Irvine, California) reported that three new independent studies concluded that Masimo acoustic respiratory monitoring technology (ARM) is "at least as accurate as capnometry" and "significantly more reliable" for monitoring respiration in spontaneously breathing patients." The study released at the recent IARS showed that "premature cannula dislodgement occurred in 14 patients [treated with ARM]" in less that 20 minutes, while "in no patient was the bioacoustic sensor dislodged before the end of the stay in the PACU." Two studies released in January at the 2007 Society for Technology in Anesthesiology annual meeting, concluded that Masimo's new bioacoustic respiratory sensor "demonstrates accuracy for respiratory rate monitoring as good as capnometry" and that the device "offers multiple benefits over existing devices and has a potential to improve monitoring in a general care setting." Masimo makes monitoring products.

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healthcare system, according to Niels Kristensen, president of the **Danish Pharmaceutical Association**.

Kirstensen reported that the Danish Pharmacy Server went live in January, creating the world's first national database for medication, including a registry of all prescriptions and all medications dispensed. With a central national server, prescription information can now be registered to any citizen's medical profile, he said, "making the patient record more complete."

A tour of Europe is not complete until the Dutch, often the earliest adopters of change, have spoken. Cor Spreeuwenberg , dean of health sciences at the **University of Maastricht**, told conference participants, "Nationalization doesn't seem to matter, there are many helpful decentralized initiatives, and, personally, I like the mentality of managed competition. Encouraging managed competition between regional providers may contribute to effectiveness and quality of care." ■

PEOPLE IN PLACES

• Matthew Hill has resigned as VP/CFO of **EP MedSystems** (West Berlin, New Jersey), and the company has named James Caruso as interim CFO. Caruso was EP MedSystems' CFO from 1995 to 1999 and managed the company's IPO in 1996. EP MedSystems makes cardiac electrophysiology products used in visualizing, diagnosing and treating cardiac rhythm disorders.

• Hugh Levaux has been named VP of product strategy for **Medidata Solutions** (New York). Levaux previously was CEO at Ninaza. Medidata is a provider of electronic clinical data capture, management and reporting solutions.

• **MIV Therapeutics** (Atlanta) reported the addition of the Biosync Scientific management team, comprised of authorities in the interventional cardiology industry. Among this group is Biosync founder Rajesh Vaishnav, an authority in the Indian interventional cardiology industry, who will join MIVT as CEO of Biosync. MIVT develops biocompatible coatings and drug delivery systems for cardiovascular stents and other implantable medical devices.

• David Mayfield has been named senior VP of sales and marketing for **Sharps Compliance** (Houston). Mayfield comes to Sharps from Valeant Pharmaceuticals International, where he was director of strategic markets and national sales director. Sharps is a provider medical waste disposal solutions.

• David Mazepink has been appointed director of sales and marketing for **SpectraScience** (San Diego). Mazepink formerly worked for Endoscopy Centers of America and its affiliates. SpectraScience makes minimally invasive devices used to distinguish between normal, pre-cancerous and cancerous tissue.

• Bruce Keyt has been named chief technology officer and VP of research for **Trellis Bioscience** (South San Francisco). Most recently, Keyt was VP of R&D at Abmaxis prior to its acquisition by Merck. Trellis' proprietary CellSpot platform employs the convergence of nanotechnology, software, digital microscopy and biology, enabling a parallel evaluation of millions of cells along more than 15 desired parameters.