

MEDICAL DEVICE DAILY

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PAGE 1 OF 9

With initiation of coverage . . .

BMO: Masimo's opportunities buoyed by 'better mousetrap'

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Citing multi-billion-dollar market opportunities, a "tried and true" patent portfolio and a strong platform technology, **BMO Capital Markets** (New York) initiated coverage Tuesday of **Masimo** (Irvine, California) with a \$44 price target.

Masimo makes devices for the non-invasive measurement of pulse rate, arterial oxygen saturation and other blood constituents such as carbon monoxide levels and total hemoglobin. The company went public last August.

BMO med-tech analyst Joanne Wuensch told investors during a conference call yesterday that Masimo is one of the more unique companies that BMO has run across in medical technology.

"If anyone has been in the hospital, or knows some-
See Masimo, Page 5

1-size-fits-all blood pressure cuff launched by Welch Allyn

By OMAR FORD

Medical Device Daily Staff Writer

Navigating the waters of having a safe blood pressure cuff is problematic for most medical practitioners. The problems stem from the same cuff being used on multiple patients, which leads to the spread of disease; different connection points for blood pressure cuffs; and multiple cuffs being used in each department, which have a hand in jacking up supply costs.

Studies show that more than 99,000 deaths occur each year in the U.S. that are a result from infections garnered from the hospital.

The major way to eliminate this problem: create a cuff that would stay with the patient from admission to omission, thus eliminating the spread of harmful bacteria or general confusion clinicians might have over which cuff to use, according to Lisa Riggs, a clinical nurse specialist at **St.**
See Welch Allyn, Page 6

International report

Israeli firm completes trial of device for treating lupus

A Medical Device Daily Staff Report

Hadasit Bio-Holdings (HBL; Jerusalem, Israel), a subsidiary of **Hadasit**, the technology transfer company of the **Hadassah-Hebrew University Medical Center**, reported that one of its portfolio companies, **Verto** (in which it has a 75% stake), has completed a human clinical trial of a device for treating patients who suffer from systemic lupus erythematosus.

The goals of the trial at the **Hadassah Medical Center** (Ein Kerem, Israel) – in which 10 lupus patients took part – were to demonstrate the safety and efficacy of the **Lupusorb**, developed by Verto. The treatment was successful and achieved the goals.

Verto, established to commercialize the research of Professor Yaakov Naparstek, the head of the department of internal medicine at the Hadassah Hospital in Ein Kerem, is developing the **Lupusorb** for the treatment of systemic lupus erythematosus.

See International, Page 7

Deals roundup

Roche to add Arius for \$191M; CCH eyes MDA Holdings buy

A Medical Device Daily Staff Report

Roche (Basel, Switzerland) and **Arius Research** (Toronto) reported signing a definitive agreement for Roche to acquire Arius in an all-cash transaction of nearly \$191 million.

Arius is the developer of a proprietary antibody platform called **FunctionFirst** which rapidly identifies and selects antibodies based on their functional ability to affect disease before progressing into clinical development. The **FunctionFirst** platform will allow Roche to further strengthen its developmental portfolio, initially within the areas of oncology and inflammatory diseases where this new technique offers potentially broad therapeutic applications.

"Arius' promising platform and early pipeline of new antibody candidates represent an excellent fit with our own progressing research in the fields of cancer and immunology," said Lee Babiss, head of global research at
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INSIDE: CCS RAISES \$600,000 TO FURTHER DEVELOP TUBE CLEARANCE SYSTEM2
MONOGRAM WINS U.S. IP PROTECTION COVERING VERATAG3

AHC Media LLC

*Financings roundup***CCS raises \$600,000 to further develop tube clearance system**By **AMANDA PEDERSEN****Medical Device Daily Staff Writer**

Clear Catheter Systems (CCS; Bend, Oregon), formerly named **PleuraFlow**, an early stage device company developing a catheter clearance platform, reported the completion of a \$600,000 financing round.

X Gen (Cleveland, Ohio), a family venture fund, led the financing. The funding also includes a grant from the **Cleveland Clinic Global Cardiovascular Innovation Center** (GCIC) initiative, which is backed by \$60 million from the state of Ohio's Third Frontier Project, a program to promote technical innovation and commercialization. BVC.CC, an angel group, also participated in the funding.

The funding will support CCS's development of its lead tube clearance product, the PleuraFlow system. The system will be used as an improved method for preventing the obstruction of surgical drainage tubes inserted after heart, lung and trauma surgery.

Edward Boyle, MD, CEO of CCS, told *Medical Device Daily* that patients who require heart surgery or lung surgery all have to have a chest tube placed after surgery and these tubes – which are the same type that hospitals have used for the last 40 to 50 years, he said – tend to clot. Because surgeons are aware that the tubes clot, they tend to put in larger tubes to reduce the clotting risk, Boyle said.

"I'm a cardiothoracic surgeon myself, so I identified this problem and started working on some inventions to improve this and it turns out some cardiothoracic surgeons at the Cleveland Clinic were working on something similar, so I approached them and we agreed to form a company," Boyle said. "Our ultimate goal is to make heart surgery safer, less invasive and less painful, and we think we can do this by making these tubes that are less prone to clogging so they can be smaller."

Today's MDD food for med-tech thought

"... a platform technology, a tried and proven patent portfolio, and new market opportunities knocking on its door."

Key attributes of pulse oximetry firm Masimo, cited by BMO analyst Joanne Wuensch as reasons for creating the company's highly desirable position in the med-tech universe. "BMO: Masimo's big opportunities launched by 'better mousetrap,'" pp. 1, 5.

Boyle said patients often describe the current plastic tubing as more like a garden hose, about 36 Fr (or 11 mm, the size of an index finger tip). The new tubing comes in three sizes, he said, 15 Fr, 20 Fr and 32 Fr.

Boyle said this round of financing would hopefully carry the company far enough to have a product that is FDA cleared and ready to be used in humans. Once the PleuraFlow system is FDA cleared and ready for human use, CCS will start gaining its initial clinical experience, Boyle said. "At that point I think we'll be poised to scale up for a much broader market launch," he said.

CCS plans to go out for a full venture capital round for \$4 million to \$5 million once the product is FDA cleared, Boyle said.

The company raised its first seed-round of financing in August 2007, Boyle said. He said the company's most likely exit strategy would be a merger and acquisition.

"I've had patients say to me that the most memorable and painful part of heart surgery was the day their drainage tubes were pulled out," said Marc Gillinov, MD, the Cleveland Clinic cardiothoracic surgeon who helped develop the PleuraFlow system. "We need to develop smaller tubes that drain the wound effectively, but don't hurt as much." Gillinov serves as chairman of CCS's scientific advisory board and as a consultant to the company.

The company also said it is in the process of opening a
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Patent watch

Monogram wins U.S. IP protection covering its VeraTag technology

A Medical Device Daily staff report

Monogram Biosciences (South San Francisco, California) reported winning three U.S. patents (Nos. 7,402,397; 7,402,398 and 7,402,399) for its VeraTag technology.

The company said that the patents relate to the VeraTag technology for methods of detecting and profiling protein complexes, including protein homodimers and heterodimers. A European patent (No. 1278760) has also been issued for these claims, Monogram said.

The company says that being able to detect and profile protein complexes is important because proteins achieve their biological function when they interact, form protein complexes, and thereby trigger cellular signaling processes. In this way, protein complexes are pivotal in regulating cellular survival and proliferation in normal and cancer cells.

Examples of these protein complexes are those involving the same proteins pairing up to form “homodimers” and

different proteins pairing up to form “heterodimers.” Being able to detect and profile normal and aberrant protein complexes, such as homodimers and heterodimers, is believed to be important for predicting patient prognosis and response to therapy, Monogram said.

The patent claims cover all types of protein complexes, including homodimers and heterodimers, detected with the VeraTag method.

“The latest issued patents provide patent protection for some of the most important applications of our VeraTag technology – those related to the identification of protein complexes,” said William Young, Monogram’s CEO. “We believe that determining the status of particular protein complexes, such as homodimers and heterodimers, will be important for determining whether a patient’s tumor will respond to certain drugs.”

Monogram reports its worldwide patent portfolio including 78 issued and pending patents and patent applications related to its VeraTag technology, 102 issued and pending patents and patent applications related to its virology technology, and 101 issued and pending patents and patent applications related to its microfluidics technology. ■

MED - TECH NEWS AND NOTES

Greenway participates in Health IT week

Greenway Medical Technologies (Carrollton, Georgia) said it participated in the recent National Health IT Week’s Capitol Hill Technology Showcase, held in Washington. The showcase marked one of the healthcare IT industry’s first real-time demonstrations of ambulatory software providers exchanging healthcare data between disparate EHR systems.

Greenway, NextGen Healthcare Information Systems, IBM and Initiate Systems all took part in the demonstration. During National Health IT Week, public and private entities collaborated to advance health IT adoption with “one voice, one vision.”

“Greenway is excited with the success and collaboration achieved by two of the HIT industry’s leading EHR providers,” said Justin Barnes, VP of marketing and government affairs for the company. “The showcase effectively demonstrated the reality of data sharing from one ambulatory product to another and the call to action is clear, it is time we bring interoperability from a concept into a practical working exchange that will improve the quality of healthcare across the board and afford EHR adoption incentives such as the Stark relaxation to increase EHR availability.”

Greenway Medical Technologies provides ambulatory healthcare business solutions and services.

LCA-Vision opens Nashville LasikPlus store

LCA-Vision (Cincinnati), a provider of laser vision correction services under the LasikPlus brand, reported the opening of its 77th LasikPlus vision center in Nashville,

Tennessee. This opening marks the fifth LasikPlus vision center the company has opened this year, and is the first LasikPlus first vision center located in the state of Tennessee.

Merge regains Nasdaq compliance

Merge Healthcare (Milwaukee) it has received notification from the Nasdaq stock market that the company had regained compliance with Nasdaq marketplace rule 4450(a)(5) and that Nasdaq now considers the matter closed.

The company was notified on April 2 that it was not in compliance with the minimum bid price rule because

shares of its common stock had closed at a bid price of less than \$1 for 30 consecutive business days. At that time, in accordance with marketplace rule 4450(e)(2), the company was provided with 180 calendar days, or until Sept. 29, to regain compliance. Since then, the company’s common stock maintained a closing bid price at \$1 or greater for at least 10 consecutive business days.

Merge Healthcare makes medical imaging software.

*Grants/contracts***Greiner to pay MedPro \$57.8M in a pair of supply accords****A Medical Device Daily Staff Report**

MedPro Safety Products (Lexington, Kentucky) said it has entered into two manufacturing supply agreements with **Greiner Bio-One**, a division of **Greiner Bio-One International** (Kremsmuenster, Austria), valued at \$57.8 million.

The two agreements grant Greiner the right to manufacture, market and distribute MedPro's tube-activated and skin-activated blood collection systems and its winged "butterfly" safety needle system. Each agreement extends for a six-year term from the commencement of initial manufacturing of the applicable products.

Greiner agreed to pay MedPro a production per-unit royalty on a minimum volume of units of each product plus additional cash to acquire the production lines for the products.

The agreement with Greiner for the exclusive right to manufacture and distribute MedPro's tube-activated blood collection system and its skin-activated blood collection device supersedes and replaces a prior distribution agreement with Greiner for the system.

Greiner agreed to pay MedPro a capital amount not to exceed \$8.6 million for the rights to MedPro's tube-activated and skin-activated blood collection system. Additionally, Greiner is obligated to pay a minimum production royalty of \$33 million for its commitment of a minimum of 275 million pieces during the initial five years of the agreement.

Greiner also entered into an agreement for the exclusive right to manufacture and distribute MedPro's winged "butterfly" safety needle system on similar terms. Greiner will pay MedPro an amount not to exceed \$5 million in exchange for the production of this product. Greiner will make an initial payment of \$1 million upon acceptance of the initial design plan by Greiner on or before Oct. 1, 2008. Additionally, Greiner is obligated to pay a minimum royalty of \$10.8 million for its commitment of a minimum of 75 million pieces during the agreement's initial five years.

In other contracts:

Palomar Medical Technologies (Burlington, Massachusetts) reported a new agreement with **Astron Clinica** (Cambridge, UK) to distribute aesthetic imaging products in the U.S. and Canada.

Palomar will have exclusive rights to sell Beau Visage, a skin imaging and consultation system. Palomar's customers can use Beau Visage during initial client meetings to visualize and measure blood, pigment, and wrinkles before recommending cosmetic treatments using Palomar's StarLux Laser and Pulsed Light System.

Palomar also will sell Astron Clinica's Physiometrics photographic imaging system which captures a library of images of the body. This new technology will allow for

visual documentation of the benefits that will be seen using the recently introduced Palomar Aspire SlimLipo laser-assisted lipolysis system.

DataCore Software (Fort Lauderdale, Florida) said that its SANmelody software is serving as the foundation of a replication and disaster recovery (DR) plan at **Alameda County Medical Center** (ACMC; Oakland, California) orchestrated by DataCore partner **Entisys** (Concord, California). The IT environment at ACMC was based upon products from Dell and EMC, as well as virtual machines from VMware.

BayCare Health System (Tampa) and **PeaceHealth** (Bellevue, Washington) healthcare system have selected real-time electronic surveillance and expert clinical decision support systems provided by **TheraDoc** (Salt Lake City).

TheraDoc says that its interoperable Expert System Platform is a standards-based, scalable solution providing hospitals with real-time surveillance, management, prevention and reporting of patient safety problems, such as hospital-acquired infections and adverse drug events.

Orchestrate Healthcare (Greenwood Village, Colorado), a provider of healthcare IT integration consulting services, said that **St. Vincent's HealthCare** (SVHC; Jacksonville, Florida) has contracted with it to provide Sun Java CAPS training to its team of IT professionals.

SVHC said it recently formed a team of five IT professionals with Java CAPS experience. ■

Financings

Continued from Page 2

Cleveland office to better facilitate its collaboration with the clinic, and to access other resources available to companies in the Ohio medical device community.

"Clear Catheter Systems is doing exciting work, and we are pleased to be involved in the continued development of the PleuraFlow System," said Mark Low, GCIC managing director. "Cleveland Clinic and GCIC are committed to expanding Ohio's economy, and we welcome this growing company to Northeast Ohio." ■

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Masimo

Continued from Page 1

body who has been in the hospital lately, you will notice that the patient will have on a sensor usually on the finger, sometimes on a toe or a ear lobe to help monitor blood oxygenation level . . . it is fairly dominating in the hospital," Wuensch said.

"What Masimo did," she said, was to create "a better mousetrap. They created filtering algorithms, which allowed for a more direct and clean, if you will, read of the pulse oximetry signal so that the patient could be read continuously, non-invasively if the patient happens to be being moved, if the patient happens to have a cold and be shaking, so it is clearly a better mouse trap.

"What's also interesting is the technology can be applied to multiple applications. So while the first application was pulse oximetry, it has added since then other measurements, such as carbon monoxide or carboxyhemoglobin or methemoglobin."

Wuensch cited Masimo's "huge" market opportunities as another decider in BMO's decision to initiate coverage of Masimo. She said that the company's Signal Extraction Technology (SET), introduced in 1995, addresses many of the limitations of conventional pulse oximetry devices, tapping the \$1 billion worldwide pulse oximetry market, which BMO said is growing 6% to 8% a year.

Masimo's technology began to expand in 2005, BMO noted, with the introduction of the measurement carboxyhemoglobin, methemoglobin in 2006, pleth variability index last year, and with total hemoglobin in March.

Frost & Sullivan has estimated that Masimo shipped 38% of the pulse oximetry systems into the U.S. market in 2006. Based on the company's growth rates, BMO estimates its share of annual U.S. shipments is now well into the 40% range – and increasing.

"This is a tried and true patent portfolio," Wuensch said.

Masimo holds more than 444 patents in that portfolio, which has been extensively tested against Nellcor/Tyco (now **Covidien** [Hamilton, Bermuda]), Wuensch said.

She noted the companies' settlement of patent litigation in January 2006 that resulted in Covidien paying \$263 million and royalties to Masimo through March 2011. Covidien agreed to pay Masimo a royalty equal to 20% of its U.S. pulse oximetry sales in 2006 (\$69.2 million) and 15% in 2007 (\$56.6 million), and that it will continue to pay about 13% at least through March 14, 2011, according to BMO.

Wuensch said Masimo is using the money from Covidien to ramp up its direct sales effort.

The market opportunity for Masimo's products is expected to increase over the fairly near term from about \$1 billion in 2007 to about \$4 billion in 2010, Wuensch estimated.

In 3Q09, Masimo is expected to launch another measurement, BMO said, this time for acoustic respiration monitoring (ARM).

"The ARM technology measures patient respiration, an important feature for the general floor of the hospital, an area that is estimated to have 450,000 beds, creating an incremental \$1-billion opportunity to Masimo, assuming it taps only a quarter of the beds in the U.S. alone," Wuensch said in a research report.

"[Masimo] is a unique franchise within our medical technology universe, with a platform technology, a tried and proven patent portfolio, and new market opportunities knocking on its door," Wuensch said in the note. "As such, we would argue that it should receive a premium multiple, and it has."

Applying a forward P/E multiple of 50x leads to a price target of \$40, she said. In a similar vein, using an EV/revenue multiple of 7x on 2009 revenue leads to a price target of \$43, she noted. Finally, BMO conducted a DCF analysis, resulting in a price target of \$47.

Triangulating these methodologies and their results, "we arrive at a \$44 price target, or 21.6% upside," Wuensch said. ■

M E D - T E C H N E W S A N D N O T E S

BSD Medical delivers response to FDA

BSD Medical (Salt Lake City) said that a formal response has been delivered to the FDA pertaining to the BSD-2000 hyperthermia system submission that is currently in review by the agency.

The response followed an in-person meeting with the FDA management and reviewers in which the company's response strategy was discussed before the company made its formal response.

BSD Medical makes systems used to deliver hyperthermia therapy for the treatment of cancer.

Life Recovery Systems moves HQ

Life Recovery Systems HD (Waldwick, New Jersey), a maker of products for the emergency medical care market, has moved to a larger space in the Hopper Technology Center, 150 Hopper Avenue, Waldwick. The company had been headquartered in Kinnelon, New Jersey.

Life Recovery makes the ThermoSuit System, a non-invasive hypothermia device, which reduces core body temperature in a patient to between 33 degrees centigrade and 37 degrees centigrade in a matter of minutes. The system continuously pumps a thin film of ice water around the patient's body until the temperature reaches a preset level. This technology cools patients at a rate of one degree centigrade for every seven minutes of treatment. The duration of cooling treatment required to achieve target temperature is typically 20 to 30 minutes.

Welch Allyn

Continued from Page 1

Luke's Hospital (Chesterfield, Missouri).

On Tuesday, **Welch Allyn** (Skaneateles Falls, New York) introduced such a solution through its FlexiPort blood pressure cuffs to its U.S. market – what it calls the first cuffs designed to work with devices in any patient care area. The nearly century-old-company held a press conference to discuss the device and how it could revolutionize the way hospitals use blood pressure cuffs in the future.

“The real problem is that there are compatibility issues and practitioners are forced to make it work,” said Sean Karla, global category manager of Welch Allen, during a press conference touting the devices. What we’ve developed is a unique fitting that will go under the device tube . . . so that the cuff can stay with the patient throughout their [stay in the hospital].”

FlexiPort cuffs connect to virtually any manual or electronic blood pressure device, so patients can be freely moved from room to room, floor to floor and department to department without forcing clinicians to find new cuffs for each different device.

“FlexiPort cuffs make finding, ordering and using cuffs as simple as it should be,” Karla said. “There is currently incredible variability with all the different tube, connector, and cuff styles out there, which causes a tremendous amount of caregiver confusion and leads to excess inventory. By providing a single common connection point between the device and cuff, FlexiPort cuffs can eliminate much of that variability.”

Facility standardization with FlexiPort blood pressure cuffs can reduce the typical hospital’s cuff part numbers by up to 60%. The reduced part numbers mean a reduction in inventory levels – so blood pressure cuffs are easier to find for clinicians and easier to order for purchasing managers.

“If hospitals were to simply open new cuffs every time they used one on a patient, then they would significantly run up costs,” Karla said during the conference.

The FlexiPort connection is built into every new FlexiPort cuff. When a facility standardizes with FlexiPort cuffs, it attaches FlexiPort fittings to every device tube it has in-house. The fittings, which vaguely resemble extension cord endings, can then snap directly into the FlexiPort connection to eliminate traditional tubes and connectors from their cuffs, while making every cuff work like a one- or a two-tube cuff.

“Clinicians face enough challenges when they’re at work, so we designed a cuff option that actually makes caregivers’ lives easier,” Karla said. “FlexiPort removes one of the many problems caregivers face on a daily basis so they can focus on what matters most – their patients.”

FlexiPort also helps cut down the risk of spreading infectious diseases through cuffs by enabling a single cuff to be used on multiple devices. Assigning a FlexiPort cuff to a patient when he or she is admitted to the hospital allows

the patient to move freely throughout the facility without having the cuff changed every time the patient is hooked up to a new device, which reduces waste as well as exposure to other hospital-borne illness, the company said.

The FlexiPort feature was available for both reusable and disposable cuffs and approved for sale throughout Europe and the Middle East in November 2007. The feature is now approved for sale and available in the U.S.

Welch Allen was founded in 1915 when Dr. Francis Welch and William Noah Allyn built the world’s first hand-held, direct-illuminating ophthalmoscope. It has since expanded its operations to include therapeutic devices, cardiac defibrillators, patient monitoring systems and miniature precision lamps. ■

M E D - T E C H N E W S A N D N O T E S

Theragenics reports favorable Medicare news

Theragenics (Buford, Georgia) reported favorable developments in Medicare reimbursement policies related to brachytherapy. On July 15, the Medicare Improvements for Patients and Providers Act of 2008 was enacted into law.

The new law extends Medicare’s longstanding reimbursement safeguards (originally enacted in 2003) for brachytherapy seeds administered in the hospital outpatient setting through Dec. 31, 2009, ensuring that the Medicare program does not implement potentially restrictive caps on reimbursement during that period. The longstanding policy actually expired after June 30, 2008, but the new Act is retroactive to July 1.

“Theragenics has worked diligently for many years to ensure prostate cancer patients have access to all treatment options,” said Christine Jacobs, chairman/CEO of Theragenics, the manufacturer and marketer of the TheraSeed and I-Seed brachytherapy devices.

Interventional Spine surpasses 400 physicians

Interventional Spine (Irvine, California) said that it has surpassed the 400-physician milestone in delivering training on its percutaneous spine therapy technologies since introducing its product line less than two years ago. Of this group, 150 physicians have completed such training in the past six months, illustrating the increasing pace at which the company is expanding its presence in the spine treatment market.

“This performance and achievement is indicative of the accelerating interest by physicians in being able to offer their patients treatment alternatives with Interventional Spine’s products, which are aimed at eliminating open back surgery when conservative care fails to mitigate chronic, debilitating back pain,” said CEO Walter Cuevas.

International

Continued from Page 1

The device is a filter column that can be incorporated into the standard process of plasmapheresis, in which the blood is removed from the patient's body, cleansed of immune-system compounds, and returned to the body, for lupus patients.

The column contains a peptide (short protein), designated VRTI01, which specifically binds a subgroup of auto-antibodies that the body has developed against itself, and which cause the disease. At the end of the process the blood is returned to the body with all the vital components intact, except for the auto-antibodies, which have been bound to the peptide in the column.

During the trial, 10 patients underwent plasmapheresis. Over the next two months they came in for regular check-ups, which included blood and urine tests and medical examinations.

The results indicated a statistically significant decrease in the level of disease-related antibodies in the patients' blood (anti-VRT). The antibody level remained low for three weeks and only then returned to its pre-treatment levels (increased four weeks into the trial) but there was no rebound effect (in which the antibody level exceeds that before treatment), as is usually found in routine plasmapheresis.

Improvement also was seen in other components of the immune system that bolster the body's resistance to the disease. No significant harmful side-effects associated with use of the device were observed.

Ophir Shahaf, CEO of Hadasit Bio-Holdings, said, "We are proud of the results of the trial, which represent a breakthrough in the treatment of lupus, given that until now there has been no treatment specific to the disease and the standard approach has been based on the use of steroids and chemotherapy that suppresses the immune system, with severe side-effects. Lupusorb has been found safe and effective in removing harmful antibodies from patients. The decline in the plasma antibody level is statistically significant after the first week and at week three."

He added, "Based on these encouraging results, we have scheduled a series of meetings with potential strategic partners who can cooperate with us in developing the device. As a medical device, it is attractive with regard to the odds for quick regulatory approval to market."

ColonSentry launched in Canada

GeneNews (Richmond Hill, Ontario), focused on developing blood-based biomarker tests for the early detection of diseases and personalized health management, reported the launch of ColonSentry, billing it as the world's first blood-based molecular test for colorectal cancer screening.

ColonSentry assesses a patient's current risk of having colorectal cancer, identifying those in the asymptomatic general population with increased risk who might benefit from further more invasive diagnostic testing such as colonoscopy.

The company said this risk stratification approach allows for a more targeted application of colonoscopy, which could increase the detection rate of colorectal cancer by as much as threefold in the general population.

The test requires a simple blood sample. The mRNA expression of a panel of seven specific genes is measured at the molecular level by quantitative RT-PCR, which results in an assessment of the patient's current risk.

ColonSentry will be performed at the company's laboratory facilities in Richmond Hill, and the company said it is the first in a series of blood-based molecular tests based on its platform technology, the Sentinel Principle.

"Each year thousands of Canadians die from colorectal cancer, the No. 2 cause of death among all cancers in both men and women. This is a tragedy because colorectal cancer is a preventable and curable disease, but only when detected early," said Lawrence Cohen, MD, director of gastroenterology at **Sunnybrook Health Sciences Center** and associate professor of medicine at the **University of Toronto**.

"The launch of ColonSentry represents a leap forward in the way we currently screen for colorectal cancer," he said. "By using this risk assessment tool as the first step in a regular screening program, information obtained with ColonSentry will result in better decision-making by doctors and their patients regarding next steps in the colorectal cancer screening process."

Barry Stein, president of the **Colorectal Cancer Association of Canada**, said, "A patient-friendly blood test like ColonSentry . . . can certainly contribute to increased compliance with screening programs. This will facilitate earlier detection and treatment of the disease, resulting in improved outcomes for patients with colorectal cancer."

Singapore lab opened by AMRI

AMRI (Albany Molecular Research; Albany, New York) reported the opening of its first *in vitro* biology laboratory in Singapore and also the completion of a 10,000-square-foot laboratory expansion for medicinal chemistry discovery services, more than doubling the capacity of its Science Park III facility.

AMRI said that the establishment of *in vitro* biology testing services, coupled with expanded chemistry capabilities, increases its ability to execute integrated drug discovery projects of increasing complexity with reduced cycle time. The *in vitro* biology group will test compounds synthesized by AMRI's Singapore-based medicinal chemistry teams to deliver high-quality potency data using cell-based or biochemical assays.

"This expansion continues AMRI's investment in building out a worldwide drug discovery and development platform. Along with parallel investments in the U.S., India and Hungary, AMRI's global footprint is gaining a critical mass," said Thomas D'Ambra, PhD, president/CEO and chairman of the company. ■

Deals

Continued from Page 1

Roche. "The FunctionFirst approach provides us with a large library of antibodies from which we can identify the best new drug candidates for the development of clinically differentiated medicines."

Roche will pay C\$2.44 for each common share of Arius Research. This price represents a 15% premium to the closing price on July 22, 2008 and a 44% premium to the 20-day volume-weighted average closing price. Roche will also acquire all of the issued and outstanding warrants of Arius. Roche will pay C\$1.44 for each Class F warrant and C\$1.78 for each Class G warrant.

The acquisition of Arius will be completed by way of a statutory plan of arrangement under Canadian law. In addition to the approval of Arius' shareholders and warrant holders, the transaction will require court approval.

As part of the transaction, shareholders, warrant holders and management representing 54.3% of outstanding shares and 72.3% of outstanding warrants have entered into an agreement to support the transaction at the shareholder meeting. The acquisition, which is subject to customary closing conditions including regulatory approvals, is expected to close in 3Q08.

Roche said that the Arius site will remain open and serve as a centre for the discovery of innovative biotherapeutics, initially focusing on the areas of oncology and inflammation.

Aquilo Partners, Reedland Capital Partners and Dundee Securities acted as financial advisors to Arius in connection with this transaction.

Arius is focused on discovering and developing the next wave of antibody therapeutics to treat cancer and other diseases.

Roche made ripples earlier this week when it offered **Genentech** (South San Francisco, California) a proposal to acquire all of the outstanding shares of Genentech's stock, not already owned by Roche, at a price of \$89 in cash a share (*Medical Device Daily*, July 23, 2008). Roche is a research-focused healthcare group that develops products in the fields of pharmaceuticals and diagnostics.

Cross Country Healthcare (CCH; Boca Raton, Florida) reported that it has entered into an agreement to acquire substantially all of the assets of privately held **MDA Holdings** (MDA; Norcross, Georgia) and its subsidiaries for \$112.3 million in cash, plus additional earn-out payments based on 2008 and 2009 performance criteria.

The transaction is subject to certain approvals and closing conditions. CCH said it anticipates closing the transaction by the end of 3Q08. The company expects this acquisition to be accretive to its 2008 earnings by roughly 2 cents a diluted share, subject to the timing of the closing of the transaction.

Cross Country Healthcare entered into a fully underwritten \$200 million financing commitment with Wachovia

Capital Markets and certain of its affiliates, and Banc of America Securities. Pursuant to this commitment, the company will amend and keep in place its existing \$75 million revolving credit facility and also enter into a \$125 million five-year term loan, with the proceeds used to finance the acquisition and for general corporate purposes.

MDA provides multi-specialty physician and allied staffing services to the healthcare industry in all 50 states.

Cross Country is a provider of nurse and allied staffing services in the U.S., a provider of clinical trials services to global pharmaceutical and biotechnology customers, as well as a provider of other human capital management services focused on healthcare.

In other dealmaking activity:

HLTH (Elmwood Park) reported that it has completed the sale of its ViPS segment to **General Dynamics Information Technology**, a business unit of **General Dynamics** (both Providence, Rhode Island), for \$225 million in cash. The transaction was announced on June 3.

HLTH owns 84% of **WebMD Health** (New York). WebMD is a provider of health information services, serving consumers, physicians, healthcare professionals, employers and health plans through its public and private online portals and health-focused publications.

Air Products (Lehigh Valley, Pennsylvania) reported that it is planning to sell its U.S. Healthcare business and will record an impairment charge of roughly \$315 million (\$237 million after-tax) in its 3Q08 results, ended June 30.

The company plans to report the U.S. Healthcare business as a discontinued operation beginning in the fiscal fourth quarter and will continue to operate and serve patients until the business is transitioned to a new owner.

In 2007, the company implemented a number of actions to improve the performance of its U.S. Healthcare business, including changes in management, a product and service offering simplification program, and other measures to drive earnings growth and improve profitability, but the business has continued to underperform this year.

As a result, Air Products disclosed in April that it was evaluating its strategic options for the business. Based on a review of the market and competitive conditions, the company determined that the U.S. Healthcare business no longer fits its business portfolio. At its July meeting, the company's board of directors authorized management to pursue the sale of the business, and the company is in discussions with potential buyers.

Air Products also reported that it has reached preliminary agreement to sell its U.S. Healthcare businesses in the metropolitan New York area and in New Jersey, including its A&J Care locations in Glendale and Peekskill, New York, and its COPD Services locations in Runnemede, Cape May Courthouse and Cedar Grove, New Jersey. This sale is expected to be completed by the end of the fiscal year. ■

PRODUCT BRIEFS

Canon U.S.A. (Lake Success, New York) reported expansion of its line of digital radiography (DR) systems with the introduction of the Canon CXDI-60G portable flat panel detector. The CXDI-60G succeeds the CXDI-31, which the company calls the world's first portable cassette-type DR system. Features include low power consumption and a detachable sensor cable for maintenance and installation. The model's detachable sensor cable, which provides power to the unit and transfers data, enables room-to-room installation from multiple locations such as the patient's bedside or wheelchair, trauma or intensive care unit (with an optional power box and PC) and fits into most neo-natal incubator trays. Canon U.S.A. develops imaging solutions.

Pioneer Surgical Technology (Marquette, Michigan) reported the availability of the SlimFuse anterior cervical plate system, designed to optimize anterior cervical fusion procedures while addressing the needs of anterior cervical discectomy and fusion (ACDF) surgery. Pioneer says that SlimFuse provides surgeons "the flexibility to choose between a rigid, semi-rigid, or translationally dynamic system without additional instrumentation." And SlimFuse's narrow plate width and scalloped cutouts provide improved interoperative visualization. Pioneer Surgical is a develops motion preservation devices.

Tecan (Durham, North Carolina) has introduced the new Cavro Omni Robot, a general purpose OEM liquid handling robot for a wide range of applications within clinical

diagnostics, life sciences and analytical chemistry. The robot's closed-loop positioning system provides assurance of knowing exactly where the pipetting probe is located at all times, while its high payload opens up a broad range of capabilities for automation solutions. Using the Cavro Integration Kit, any Tecan Cavro pump or robot can be set up for evaluation in a matter of minutes. The Cavro Fusion Software included in the Cavro Integration Kit automatically recognizes the device, and pumps and robots can even be operated simultaneously via an intuitive graphical user interface.

Electronic payment solutions from **Vanco Services** (Minnetonka, Minnesota) are now integrated into practice management software from Ortho II. This new integration allows Ortho II users to process credit card, debit card and direct debit transactions through Vanco Services. The integration eliminates the dual entry of payment information. Vanco Services makes payment solutions to businesses and organizations of every size. Vanco is a payment card industry level 1 compliant service provider. Ortho II is a provider of practice management, imaging and communication solutions for orthodontists.

Zeus Scientific (Raritan, New Jersey) said it will offer a rapid nasal screening test for methicillin-resistant *Staphylococcus aureus* (MRSA), based upon the company's own technology, using the enrichment and nucleic acid amplification of a target pathogen. The new test will enable identification of the carriers of this pathogen within two hours. The company noted that studies "have shown that time to results is critical in demonstrating a reduction in MRSA hospital infection rates." Zeus makes clinical diagnostics.

PEOPLE IN PLACES

Agustin Gago has been named VP of international IRE sales for **AngioDynamics** (Queensbury, New York). Gago was recently VP of global business for E-Z-EM. AngioDynamics makes products used by interventional radiologists, nephrologists and surgeons for the minimally invasive treatment of cancer and peripheral vascular disease.

Brett Scott was named CFO of **North American Scientific** (Chatsworth, California). Previously, Scott was CFO of Alsius. North American Scientific is focused on making products to deliver local, controlled radiation therapy for cancer.

Karen McRae, RN, has joined the sales team of the European subsidiary of **Pioneer Surgical Technology** (Marquette, Michigan) in Driebergen, Netherlands. Previously, McRae worked for Surgical Dynamics, and is a former member of the World Health Organization and a charter member of the Spine Arthroplasty Society. Pioneer Surgical's European subsidiary was established in the Netherlands in August 2006 following the introduction of the NuBac Disc Arthroplasty system in Europe.

FDA Inspections in China: Are You Ready?

In spite of the multiple deaths from the Heparin catastrophe discovered in March, the FDA has been working to place inspectors on the ground in China. A permanent office is scheduled to open in October. So what does this mean for your operations in China? Are your manufacturing facilities in compliance? Will your staff even be able to communicate with inspectors?

In a new *Medical Device Daily* audio conference, speaker Joan McEntee, Shareholder and Chair of the China Group at Baker, Donelson, Bearman, Caldwell & Berkowitz, provides strategic guidance on the changing face of FDA-regulated manufacturing in China.

"FDA Inspections in China: Your Manufacturing Operations Are in the Crosshairs—Be Ready" is just \$349 per listening site. Scheduled for August 5th, from 1-2:30 p.m., it includes presentation handouts and a half-hour Q&A session with the speaker. A conference CD (MP3) is available. Please call 800-688-2421 or 404-262-5474 and mention conference code T08505.