Medical Device Daily™
The Daily Medical Technology News Source
Thursday, December 8, 2011 Vol. 15, No. 234 Page 1 of 9

First patient treated in IDE trial of AeroForm device

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

AirXpanders (Palo Alto, California) reported that the first patient has been treated in the AirXpanders Patient Activated Controlled Tissue Expander System for Breast Reconstruction(EXPAND trial. XPAND is a prospective, randomized, controlled, open-label pivotal study of the company's AeroForm breast tissue expansion device in mastectomy patients undergoing breast reconstruction.

The first patient that received the AeroForm device was implanted in New York on Nov. 30. An additional three patients have been enrolled in the trial and are awaiting treatment.

FDA granted the company an IDE to conduct the trial a few months back (*Medical Device Daily*, Sept. 1, 2011). Participating sites include hospitals in Boston, New York, St.

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Amp Orthopedics initiates OARS clinical trial for PFR technology

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

Osteoarthritis (OA) is an irreversible joint disease characterized by progressive loss of articular cartilage resulting in crepitus, pain, and joint dysfunction and affects 27 million adults in the U.S. It's the leading cause of disability in middle-aged and older adults and is the 6th leading cause of non-fatal burden worldwide.

Despite the numerous treatments that are available for management of knee OA symptoms, no known therapy can alter the natural history of this disease.

But **Amp Orthopedics** (Seattle), a privately held medical device company, has started the OARS clinical trial targeting adults with mild-to-moderate knee osteoarthritis (OA) to determine the safety and effectiveness of its non-thermal pulsed radio frequency (PRF) technology to

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International report

CMT's shares fall on fraud allegations from short seller

A *Medical Device Daily* Staff Report

Shares of **China Medical Technologies** (CMT; Beijing) lost more than 25% of their value on Tuesday to hit a lifetime low, after an online research firm alleged that the Chinese company had defrauded investors.

In a report on its website, California-based research firm **Glaucus Research Group** alleged that China Medical's CEO "orchestrated an acquisition to embezzle roughly $20-$23 million from the public company."

The firm disclosed that it held a short position in China Medical shares and stood to gain from a decline in the stock's price.

Glaucus's report is the latest in a string of fraud allegations against Chinese companies listed in the

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Aethlon's Hemopurifier is focus of exosome study

By ROBERT KIMBALL
***Medical Device Daily* Staff Writer**

Aethlon Medical (San Diego), a maker of therapeutic filtration devices to address infectious disease and cancer, reported a cancer research study to test the *ex vivo* effectiveness of the Aethlon Hemopurifier to capture tumor-secreted exosomes from the blood of advanced-stage cancer patients has received institutional review board approval to begin studies at the **Sarcoma Oncology Center** (Santa Monica, California). The study will enroll up to 25 patients with metastatic cancer, including those with non-small cell lung cancer, prostate cancer, melanoma, head and neck cancer, and sarcoma. Testing of blood samples provided by three enrolled sarcoma patients has already been initiated. The study goal is to establish the first

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Don't miss today's MDD Extra: Orthopedics

INSIDE:

AHC Media

Financings roundup

Celsion closes sale of $15M of its securities

A *Medical Device Daily* Staff Report

Celsion (Lawrenceville, New Jersey) reported the closing of its previously announced sale of $15 million of its securities to leading life science institutional investors in a private placement offering (*Medical Device Daily*, Dec. 2, 2011).

The company received about $13.9 million in net proceeds from the offering, after deducting placement agent fees and estimated offering expenses. The company intends to use the net proceeds from the offering for general corporate purposes, including the funding of the clinical development of its Phase III HEAT Study, a multinational, double-blind, placebo-controlled, pivotal study of ThermoDox in combination with radio frequency ablation (RFA) for hepatocellular carcinoma (HCC) or primary liver cancer.

In connection with the offering, institutional investors and two members of the company's board received 6,486,488 shares of the company's common stock at a price of $2.3125 per share and warrants potentially exercisable for up to 3,243,244 additional shares of its common stock at an exercise price of $2.36 per share. The warrants are immediately exercisable and will expire five years from the date of issuance.

Rodman & Renshaw, a wholly owned subsidiary of Rodman & Renshaw Capital Group, acted as the exclusive placement agent for the offering.

In other financings activity:

• **Small Bone Innovations** (New York), a privately held orthopedics company focused exclusively on technologies and treatments for the small bones and joints, has closed on a $43 million credit facility to help further accelerate sales of its flagship Star total ankle replacement technology, upper and lower limb portfolio and to refinance existing indebtedness.

The senior, secured credit facility was provided by New Health Capital Partners Fund I LP and affiliated private equity funds managed by New Health Capital Partners. New Health is focused on investing throughout the capital structure of life sciences companies, including senior secured loans, royalty monetizations, control equity investments and other structured financings.

The new credit facility has enabled SBi to repay its previous credit facility and provide working capital to continue to drive growth in the STAR ankle and its upper and lower limb product portfolio. The facility will also support a more aggressive buildup of SBi's direct sales organization in the U.S.

• **Merge Healthcare** (Chicago), a provider of enterprise imaging and interoperability solutions, said that it has completed the exchange offer of its 11.75% senior secured notes due 2015.

The old notes were issued in a private placement in June 2011 to finance Merge's redemption of the Series A Preferred Stock issued by Merge in connection with its acquisition of **Amicas** (Boston) in April 2010 (*Medical Device Daily,* April 30, 2010).

• **Tenet Healthcare** (Dallas) reported the completion of its previously disclosed cash tender offer to purchase any and all of the $714.012 million aggregate principal amount outstanding of its 9.0% senior secured notes due 2015. The tender offer expired at midnight, EST, on Dec. 5.

As previously reported, Tenet received tenders and consents for proposed amendments to the related indenture governing the notes from the holders of about $712.968 million (nearly 99.85%) aggregate principal amount of the outstanding notes prior to the consent payment deadline of 5 p.m., EST, on Nov. 18. After the consent payment deadline, but prior to the expiration of the tender offer, Tenet received additional tenders of $22,000 aggregate principal amount of the outstanding notes. ■

Medical Device Daily™ (ISSN# 1541-0617) is published every business day by AHC Media, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305, U.S.A.

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AHC Media

Deals roundup

Humana acquires Anvita for undisclosed amount

A *Medical Device Daily* Staff Report

Humana (Louisville, Kentucky) said it has acquired **Anvita Health** (San Diego), a healthcare analytics company. Financial terms of the deal were not disclosed.

Anvita, founded in 2000, provides analytics solutions that produce clinical insights for companies that want to improve the quality and lower the cost of healthcare for their members and clients. According to the company, the Anvita Insight engine analyzes health data from more sources than any other analysis engine, and is highly scalable.

"We've been partnering with Anvita since 2010 to enhance Humana's health care analytics performance, and we're excited about what this acquisition will mean for Humana health plan members, health care providers and employer-customers," said Michael McCallister, Humana's chairman/CEO. "Anvita helps its clients improve health care quality while also identifying cost savings for individuals and populations."

Humana already uses the Anvita Insight engine to identify members' gaps in care and drug-safety concerns. Based on insights generated by Anvita, Humana initiates automated messaging to members, healthcare providers and its own service associates to help ensure that members and their care providers are getting information they need when they need it, the company said.

"Anvita's purpose is to transform enormous volumes of clinical data into actionable intelligence for the benefit of all of Humana's constituencies, as well as across the healthcare system," said Ahmed Ghouri, MD, co-founder and chief medical officer of Anvita Health. "Humana is concerned not only with helping its own members and customers but also with helping the overall health system work better for everyone's benefit. We can help them do that."

Anvita Health will continue to operate independently as a subsidiary of Humana, serving customers at all points in the healthcare ecosystem, Humana noted. The acquisition is not expected to have a material impact on Humana's financial earnings guidance for either of the years ending Dec. 31, 2011 or Dec. 31, 2012.

"As Humana seeks to optimize the ways the company touches all levels of the healthcare system, it's increasingly necessary to implement an even broader set of clinical outreach efforts and to deploy stronger analytical tools," said Paul Kusserow, Humana's chief strategy and corporate development officer. "Anvita will help Humana strengthen its clinical management across a broad array of company initiatives."

In other dealmaking activity, **Streamline Health Solutions** (Cincinnati), a provider of enterprise and departmental document management solutions and business process workflows for healthcare, said it has signed a definitive asset purchase agreement with **Interpoint Partners** (Atlanta). Streamline will acquire Interpoint for a combination of cash and a convertible subordinated note totaling $5 million. Additionally, the agreement provides for a contingent earn out payment in cash or convertible subordinated notes based on Interpoint's financial performance for the 12 month period beginning six months after closing and ended 12 months thereafter. Closing is subject to standard closing conditions, including closing of a financing transaction, the company said.

Interpoint delivers healthcare information technology-driven solutions designed to simplify, facilitate, and optimize a healthcare provider's operating and financial performance with real-time access to financial data and a robust reporting engine coupled with an agile workflow management system. ■

Agreements/contracts

Boston-area care centers to provide network coverage

A *Medical Device Daily* Staff Report

Blue Cross Blue Shield of Massachusetts (BCBSMA), **Tufts Medical Center** and **New England Quality Care Alliance** (NEQCA; all Boston) said that they have agreed to a new three-year contract. The agreement ensures that BCBSMA members who receive care at Tufts Medical Center, Floating Hospital for Children or from a NEQCA community physician can continue to do so without any interruption. BCBSMA members who would like to be new patients of NEQCA, Tufts Medical Center and Floating can receive care as well.

Under the agreement, the Tufts Medical Center and NEQCA network will receive an annual network-wide average increase of 3%. In addition, Tufts Medical Center and NEQCA, who were early participants in BCBSMA's Alternative Quality Contract (AQC), have agreed to join the newest version of the contract known as AQC 2.0. The main feature of the new model is that participating organizations are required to outperform the rest of BCBSMA's provider network in managing the growth in health care spending.

Eric Beyer, president/CEO of Tufts Medical Center, said, "The relationship between physicians and patients is extremely important and we are pleased that an agreement has been reached with BCBSMA that supports our patients and their members. Caring for our patients is our first priority and this contract will allow us to continue to deliver the exceptional care our patients appreciate and deserve. We realize the public nature of these negotiations caused anxiety for BCBSMA members and our patients, and we thank them for their understanding and patience as we worked to reach an agreement that supports their healthcare needs."

The organizations have agreed to not publicly discuss other details of the contract terms. ■

HIT roundup

Teradici launches secure patient information system

A *Medical Device Daily* Staff Writer

Teradici (Burnaby, British Columbia), a developer of a PC-over-IP (PCoIP) protocol that enables a PC experience for desktop virtualization, and **Imprivata** (Lexington, Massachusetts), a provider of access management for healthcare, reported the availability of a joint solution that delivers strong authentication as well as single sign-on access from PCoIP zero clients. The solution, which combines Teradici PCoIP Firmware release 3.5.0 and Imprivata OneSign Virtual Desktop Access with VMware View, is compatible with a broad range of access cards and ID badges and provides PCoIP zero client users with fast and secure access to their roaming desktops from any location with a simple tap of their badge.

Factors such as the HITECH Act's incentives for the use of electronic medical records (EMR), the mobile nature of healthcare workers, the requirement to secure patient information and the need to reduce desktop maintenance and increase availability at point-of-care are all driving the swift adoption of desktop virtualization in healthcare. With this integrated solution, clinicians now have streamlined No Click Access to secure data from their zero client devices.

PCoIP zero clients virtually eliminate the need for desktop management because they have no CPU, application OS, device drivers, fan or hard drive. Compatible and integrated with VMware View, the benefits of PCoIP zero clients for IT in healthcare include low operational cost, increased security capabilities, a rich user experience and future-proof desktop scalability.

In other HIT news:

• **Capario** (Santa Ana, California), a provider of revenue cycle management solutions that connect healthcare payers and providers nationwide, reported the launch of a new enrollment service that enables providers to enroll with payers faster and easier, streamlining the entire process.

The new service was developed based on Capario customer feedback, which reflected that reimbursement could be accelerated if the revenue cycle service included a solution to streamline the payer enrollment process. Customers benefit from a number of features.

• **ExteNet Systems** (Lisle, Illinois) said it has been awarded the rights to enable advanced indoor wireless network connectivity at 15 healthcare facilities owned and operated by **Banner Health** (Phoenix).

The indoor distributed antenna system (DAS) networks will give patients, visitors and medical and professional staff access to robust wireless services provided by carriers that use these DAS networks to enhance their coverage and capacity within the facilities.

"Reliable wireless connectivity inside our facilities is in big demand for physicians and staff, as well as for visitors with mobile devices such as smartphones," said Michael Warden, Banner Health's CIO and Senior VP of Information Technology. "A key advantage of this arrangement is that multiple wireless carriers can be added to the distributed networks, which potentially benefits everyone using a mobile device, regardless of their chosen service provider."

• **BodyMedia** (Washington), the developer of wearable body monitors, plans to collaborate with **Qualcomm Life**, a wholly owned subsidiary of **Qualcomm** (San Diego) to utilize the new 2net Platform for its BodyMedia FIT LINK Armband. The wireless health collaboration will enable BodyMedia Armband users to share wireless health data, such as calorie expenditure, activity, and sleep patterns, with designated healthcare providers and service companies through the 2net Platform as part of a broad initiative to help improve health outcomes.

Initially, data will be available from the BodyMedia FIT LINK Armband, a Bluetooth-enabled on-body wellness monitor that tracks calories burned, physical activity levels, steps taken and sleep efficiency using a proprietary four-sensor system to capture more than 5,000 data points per minute for proven accuracy. With the consumer's permission, that data – currently delivered to the user's smartphone via Bluetooth and available on the BodyMedia web interface via USB upload – will soon also be enabled for wireless transmission onto the 2net Platform.

Additional BodyMedia-collected wellness data is expected to be made available as the company introduces new types of body monitors and expands its support for machine-to-machine (M2M) connectivity. Future applications will address a broad range of therapeutic conditions and special populations.

• **Texas Instruments** (Dallas) reported the MSP430F563x and MSP430F663x families adding more performance and features to its ultra-low-power 16-bit microcontroller portfolio. Developers can immediately take advantage of the microcontrollers' larger memory, display capacity and analog peripherals, which enable high precision measurement and connectivity. The F563x and F663x devices meet the needs of portable measurement applications, including blood glucose meters, pulse oximeters, blood pressure monitors, electrocardiograms (ECG), activity monitors and sensor hubs. Home automation and industrial applications requiring a user interface such as utility meters, remote sensing and thermostats also benefit from the ultra-low-power, high-performance capabilities of these MSP430 families. ■

AirXpanders

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Louis, San Diego, Sacramento, San Jose and Durham, North Carolina.

"Given the data collected in the recently-published PACE feasibility trial, the AeroForm device has the potential to offer breast cancer patients a needle-free and more convenient tissue expansion process as part of breast reconstruction following a mastectomy," said Leroy Young, MD, **Mercy St. Louis Cancer and Breast Institute**, principal investigator of the XPAND trial. "This study will compare the patient-controlled, carbon-dioxide-based AeroForm device to the standard saline injection method, an often arduous process that has historically been a major deciding factor against breast reconstruction for many women."

The tissue expansion process is often required after mastectomy to stretch the skin and the muscle of the chest wall so a permanent breast implant can be inserted. Traditionally, surgeons implant a saline tissue expander under the skin and pectoral muscle at the site of the mastectomy. During subsequent weekly office visits, the surgeon will insert a needle through the skin into the tissue expander's port and inject as much saline into the temporary implant as the woman can tolerate.

AirXpanders designed the AeroForm tissue expander system to address the limitations of traditional saline expanders. The system consists of a technologically advanced self-contained tissue expander and a small hand-held wireless remote control. The AeroForm system eliminates the need for invasive saline injections by using compressed carbon dioxide that is gradually released through a small internal valve to fill the expander. Following a standard implant procedure, the patient can use the remote control at home to perform the expansion process as directed by the surgeon.

Young told *Medical Device Daily* that another advantage to the AeroForm procedure, from a surgeon's perspective, is being able to remove those subsequent office visits related to the procedure, which the surgeon does not get reimbursed for. He also noted that if the patient undergoes a standard saline expansion procedure later in the year and the follow-up visits roll into the new year, that patient has to meet their insurance deductible again.

Although infection is rare with the traditional saline expansion method, Young noted that the new procedure does reduce the risk of infection from repeated needle injections.

The AeroForm method should offer several patient benefits as well, he added. "Not every patient complains of pain from having the saline injection, but some do [experience discomfort]," Young said. "Like any shot, no one looks forward to getting stuck with a needle."

The new procedure also is considerably quicker than the standard saline expansion method, Young said. "This allows you to complete reconstruction quicker and I believe . . . it is more comfortable for the patient and it'll be more convenient."

The only added inconvenience associated with the AeroForm method that Young noted was that the patient is not allowed to fly while they have the device implanted.

"This is a momentous occasion for the company, as we begin collecting the data that will be submitted to the FDA in support of our 510(k) application," said Scott Dodson, president/CEO of AirXpanders. "Each year 250,000 women undergo a mastectomy, and for those women who choose reconstruction, we believe that the AeroForm will prove to be an empowering device that will allow these patients to move on with their lives, have more control during the tissue expansion process and have the potential to avoid disruptive weekly doctor's visits."

During the company's feasibility trial in Australia, the average expansion time associated with the AeroForm remote-controlled tissue expander was 15 days, a fraction of the time typically required using traditional saline expanders.

The trial is designed to directly compare the outcomes of tissue expansion of the traditional saline expansion method to the investigational AeroForm, remote-controlled, needle-free tissue expander. Enrollment will continue until a total of 92 AeroForm devices and 46 saline expanders have been implanted in patients.

AirXpanders is backed by GBS Venture Partners, Prolog Ventures, Heron Capital and Shalon Ventures. The company has previously raised $8 million through a $5 million Series C financing led by GBS Ventures in April 2010 and an additional $3 million working capital line from Oxford Finance in February. ■

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Med-Tech Notes

Kindred Healthcare opens new hospitals

Kindred Healthcare (Louisville, Kentucky) reported the opening of a new hospital in Seattle, and the relocation of an existing hospital in the Las Vegas market.

In downtown Seattle, Kindred has opened Kindred Hospital Seattle-First Hill, a 50-bed freestanding long-term acute care (LTAC) hospital with six intensive care unit beds in all private, state of the art rooms.

Kindred also recently opened Kindred Hospital-Las Vegas at St. Rose Dominican Hospitals-Rose de Lima Campus in Henderson, Nevada, a suburb of Las Vegas. The LTAC hospital replaces a hospital that was located in Desert Springs Hospital in Las Vegas. The new hospital has 28 LTAC beds and six private rooms dedicated to intensive care.

Kindred Healthcare is a healthcare services company.

Amp

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ameliorate pain from the debilitating joint disease.

"Our parent company **Ivivi Health Sciences** [San Francisco] has a pulsed radio-frequency device they've been marketing commercially to primarily control post operative pain in edema after plastic surgery procedures," Eric Dremel, Amp Orthopedics CEO, told *Medical Device Daily*. "What we're trying to do is migrate that technology to orthopedics."

The Amp PRF technology induces an electrical field to create a specific biological effect in tissue by increasing the binding kinetics of intracellular calcium to calmodulin (a first-order signaling molecule), which accelerates calmodulin-dependent biochemical cascades that are involved in tissue repair and regeneration. Electromagnetic field therapy has successfully been utilized for treatment of delayed-union fractures, chronic wounds, and postoperative pain and edema, as well as for the management of knee OA symptoms.

The company said that the OARS trial is a randomized, sham-controlled, double-blind study utilizing standardized pain indices to measure changes in pain scores and compare pain reduction and duration of clinical benefit between the treated and control groups.

According to the company, the 150-patient study will take about 12 months to complete, with a six-month enrollment period, one-week run-in period and an eight to 26-week treatment period. The primary endpoint of the trial is a comparison of changes in current knee pain severity at four weeks over baseline. A between-group difference of at least 25 percentage points will be considered clinically significant. Secondary endpoints include measures of knee pain severity, quality of life based on patient assessment instruments and reduction in use of concomitant pain medications and modalities.

But it isn't being conducted like traditional clinical trials. To keep costs down and ensure greater results the firm said that it was conducting the trial virtually, with the help of its partner **Mytrus** (San Francisco), a clinical technology and services company utilizing a novel, Internet-based, direct-to-patient recruitment methodology.

"The methodology for this clinical trial is a little different," Dremel said "It's really a virtual site. There are three investigators . . . the patients are recruited online – they actually don't go into a traditional brick & mortar study site. They're screened using Mytrus' technology and we're able to verify their identity online. The patients also go through informed consent online."

The Mytrus approach uses an array of online social media and data management tools, and enables patients to safely participate in clinical trials from their own homes, thereby enhancing patient accessibility and convenience as well as improving trial cost-effectiveness.

"The Amp OA pain trial is well-suited for a direct-to-patient clinical recruitment methodology," said Nancy Lane, MD, Endowed Professor of Aging, Medicine and Rheumatology and Director of the Musculoskeletal Diseases of Aging Research Group at the **University of California, Davis Medical School** (Sacramento, California), in a release. "Unlike traditional trials, patients can more easily participate and sponsors can save considerable costs in setting up and managing multiple brick and mortar study sites. Patients are routinely using the Internet to research and manage their medical conditions, as well as using convenient devices, including mobile phones, iPads and other web-enabled devices that can connect the patient to medical staff without requiring a site visit. This approach also leverages multi-media and online learning tools to bring patients a much better informed consent process. It may have the added benefit of providing better safety data. Because patients need not wait several weeks for the next visit to report issues, we can potentially get more accurate day-to-day details of their adverse events."

The Mytrus methodology complies with all FDA-required clinical trial practices and regulations, including informed consent. Amp said that it believes that the patient-focused Mytrus approach can be particularly effective for this trial in accelerating and streamlining recruitment and ensuring compliance and retention. Patients interested in screening for the study can start here: kneepain.mytrus.com/home.

"We're expecting the OARS trial to be completed in 3Q12," Dremel told *MDD*.

Results from the trial are anticipated in 2012, and could become the basis for market clearance of the Amp device in the OA pain reduction indication.

Dremel said that the company would be seeking out additional funding to get the device to market under this indication. He added that Amp Orthopedics would probably seek no more than $10 million in this endeavor. He added the company was hoping to have the product on the market in 2013.

Last month, Amp Orthopedics was selected as the new corporate name for Ivivi Orthopedic Health. The selection of the name Amp Orthopedics reflects the company's therapeutic and commercial focus on the growing field of orthopedic specialties, including post-operative indications and musculoskeletal diseases *(Medical Device Daily*, Nov. 18, 2011). ■

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International

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North America, and are often made by investors who are simultaneously shorting the stocks on which they comment.

In 2007, China Medical acquired Beijing Bio-Ekon Biotechnology Co. for $28.8 million.

Glaucus said it believes that the medical device maker overpaid for the acquisition from an entity it thinks is secretly related to CMT's CEO Xiaodong Wu.

The firm also alleged that China Medical sold its biggest revenue generating segment – high intensity focused ultrasound business that develops products used to treat solid cancers and benign tumors – to Wu, to conceal that the unit was worthless.

CMT's shares were down 17% at $2.81 in Tuesday morning trading on Nasdaq. They touched a low of $2.46 earlier in the session. On Wednesday afternoon, the stock had rallied, trading at $3.08, after opening at $2.70.

The company furnished a lengthy rebuttal of the Glaucus report, maintaining that the allegations concern matters which have long been disclosed in the company's annual reports and press releases, misrepresent the information they present and attribute motives to management that are "based on innuendo and fail to take into account business and commercial considerations relevant to the matters discussed in the report."

CMT is an advanced IVD company using molecular diagnostic technologies including fluorescent *in situ* hybridization (FISH) and Surface Plasmon Resonance (SPR) and an immunodiagnostic technology, Enhanced Chemiluminescence Immunoassay (ECLIA), to develop, manufacture and distribute diagnostic products used for the detection of various cancers, diseases and disorders as well as companion diagnostic tests for targeted cancer drugs. The Company generates all of its revenues in China through the sale of diagnostic consumables including FISH probes, SPR-based DNA chips and ECLIA reagent kits to hospitals which are recurring users of the consumables for their patients.

Quest launches Simplexa dengue test in Brazil

Quest Diagnostics (Madison, New Jersey) reported that the Simplexa Dengue molecular test kit developed by its Focus Diagnostics products business has been registered for distribution in Brazil. The test kit, from the Simplexa product line on the 3M Integrated Cycler, is the first commercial real-time polymerase chain reaction (RT-PCR) test to be approved for use by Brazil's public and private health laboratories for testing for Dengue viruses.

Dengue, a virus transmitted by the Aedes mosquito, is endemic throughout the tropics and subtropics. Brazil has the greatest number of dengue infections in the Americas, with nearly a million cases annually accounting for 60% of the region's dengue infections.

"Dengue is a major source of illness in Brazil and a burden on the country's healthcare system," said John Hurrell, PhD, vice president and general manager, Focus Diagnostics. "Public health and private clinicians in Brazil now have, for the first time, a registered commercial molecular-based tool for testing specimens in their own molecular laboratories. A reliable solution that can quickly identify patients with primary or secondary dengue infections will help physicians improve clinical management of patients in dengue-endemic areas."

Simplexa tests on the 3M Integrated Cycler employ RT-PCR to qualitatively and quantitatively detect viruses, bacteria and other agents. The dengue test is performed on whole blood specimens to quantitatively detect and differentiate between the four dengue serotypes (viruses DEN1-4). Results can be provided in as few as 60 minutes following sample extraction.

Dengue symptoms range from mild fever to severe headaches with muscle and joint pain. Dengue hemorrhagic fever is a potentially fatal complication primarily affecting children. Although there are no specific antiviral medicines for dengue, "early clinical diagnosis and careful clinical management by experienced physicians and nurses increase survival of patients," according to the World Health Organization (WHO). The use of RT-PCR for dengue detection and differentiation allows clinicians to identify the presence of the virus, potentially enhancing clinical outcomes.

Focus Diagnostics, a wholly-owned business of Quest, develops the Simplexa line of molecular test products operating on the 3M Integrated Cycler, a compact, portable testing platform, as part of an exclusive collaboration with **3M** (Maplewood, Minnesota).

Dfine receives device licenses in Canada, Mexico

Dfine (San Jose, California), a developer of minimally invasive radio frequency (RF) targeted therapies for the treatment of vertebral pathologies, reported that it has received Medical Device License from Health Canada and the Secretaria de Salud (Ministry of Health) in Mexico to sell its StabiliT radiofrequency targeted vertebral augmentation (RF-TVA) system throughout Canada and Mexico, respectively.

"StabiliT represents a significant advance in the treatment of osteoporotic compression fractures. The ability to target access and cement delivery while sparing valuable cancellous bone in patients who already have compromised bone structure due to osteoporosis is significant. I'm very pleased that we will now have access to this technology in Canada," said Kieran Murphy, MD, deputy chief of radiology at **University Health Network** (Toronto).

"Approvals in Canada and Mexico are significant milestones for Dfine and the StabiliT system. With the North American market established, we will continue to execute our broader global expansion strategy, which will focus on potential growth markets including South America, Asia Pacific and the Middle East," said Kevin Mosher, CEO of Dfine. ■

Aethlon

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validation that a medical device, the Aethlon Hemopurifier, can effectively capture tumor-secreted exosomes from the blood of cancer patients.

James Joyce, CEO of Aethlon Medical told *Medical Device Daily* that "this study would be the first validation of a device to selectively remove tumor-secreted exosomes from the blood of cancer patients. This validation would then provide a basis for human treatment studies in actual cancer patients."

The Aethlon Hemopurifier is a first-in-class medical device with broad-spectrum capabilities against viral pathogens, including HIV and Hepatitis C virus (HCV). The device has also demonstrated the ability to capture tumor-secreted exosomes from cell culture and human ascites fluids. Tumor-secreted exosomes, which are not addressed by drug therapy, assist cancerous tumors in evading the immune response and are implicated in the survival, growth, and metastasis of cancer.

Exosomes are vesicles secreted by most cells, including tumors, which induce T-cell apoptosis (programmed cell death), and block T-cell signaling, proliferation, and cytokine production in cancer patients. The Hemopurifer is effective in capturing and removing these particles. Joyce said the attention given to these particles has increased over time. "When we first started doing research into tumor-secreting exosomes underlying different types of cancer, the consensus of the medical community was that exosomes didn't have any real function. They more or less operated as 'cellular garbage bags;' but over the last two years, that viewpoint within the medical community has changed drastically. These particles are now considered to be extremely immunosuppressive, and are indicated in the spread of metastases, and contribute to angiogenesis in cancer," he said.

Researchers have also identified that cancer-released exosomes assist tumors in evading the response of the immune system. Joyce said that it has become "evident these particles have a prominent role in cancer survival; so the hope would be that if we remove [the exosomes] it would help patients become more responsive to the cancer therapies. Our initial response from the medical community has been positive."

The Hemopurifer device is also the subject of a human clinical study in India to evaluate its ability to accelerate viral load depletion when used in combination with HCV standard of care drug therapy (*Medical Device Daily*, March 10, 2011). An investigational device exemption (IDE) to initiate clinical studies in the U.S. is pending with FDA.

Joyce is optimistic about the potential for new findings in this study. "It's going to be a very valuable study. We also believe there is something compelling about exosomes and their role in helping cancer survive. We have found that the quantity of exosomes in circulation seems to be in direct correlation to the progression of cancer. When you don't have cancer, you have no instances of these particles in circulation, when you have advanced stage cancer, there are massive amounts of these particles present. If we can remove these particles that would be beneficial to patients," he said.

The Sarcoma Oncology Center's practitioners are board certified in internal medicine, hematology and medical oncology. The hospital claims to be one of the most sought after research centers for the treatment of sarcomas and provide the newest investigational protocols for our patients. The hospital has several ongoing phase I and phase II studies. Sant Chawla, MD, a recognized authority in the sarcoma oncology field, will lead the study.

The company hopes to have generated sufficient data from this study for publication of results by mid-2011.

The company's ADAPT System is a revenue-stage technology platform that provides the basis for a new class of therapeutics that target the selective removal of disease enabling particles from the entire circulatory system. The Aethlon ADAPT product pipeline includes the Aethlon Hemopurifier to address infectious disease and cancer; HER2osome to address HER2+ breast cancer, and a medical device being developed under a contract with the Defense Advanced Research Projects Agency (DARPA) that would reduce the incidence of sepsis in combat-injured soldiers and civilians (*MDD*, Oct.4, 2011). ■

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Court report

Exactech enters into amendment on surgeon consultation DPA

A *Medical Device Daily* Staff Report

Exactech (Gainesville, Florida), a maker of bone and joint restoration products for hip, knee, shoulder, spine and biologic materials, has agreed to enter into an amendment to its deferred prosecution agreement (DPA) with the U.S. Attorney's Office for the District of New Jersey (USAO) that extends the term of the DPA for three months, ending on March 8, 2012. Exactech entered into the DPA in December 2010 (*Medical Device Daily*, Dec. 9, 2010) in connection with the resolution of the investigation commenced by the USAO in December 2007 into the company's consulting arrangements with orthopedic surgeons relating to its hip and knee products in the U.S.

In accordance with the DPA, an independent monitor was appointed to review and evaluate Exactech's compliance with its obligations under the DPA, and the company agreed to extend the term of the DPA, at the request of the USAO, in order to allow the monitor additional time to further test the implementation of compliance systems. The USAO has not alleged any breach by Exactech of any of the terms of the DPA, and, other than extending its term, the amendment makes no other changes to the DPA. ■

Product Briefs

• **DePuy Spine** (Raynham, Massachusetts) reported the launch of the Expedium Neuromuscular System, a new modular system of pre-contoured rods and proximal connectors, open and closed iliac screw designs and wires, designed to help surgeons address spinal and pelvic deformity in patients with neuromuscular scoliosis. "The modularity of the Expedium Neuromuscular System allows for easy fixation to the pelvis without the need for intra-operative modification of implants or complex rod bending. It also allows for the cantilever correction of severe pelvic obliquity and spinal deformity that was previously corrected with the unit rod," said Kirk Dabney, MD, orthopedic surgeon and associate director of the Cerebral Palsy Program at the Alfred I. duPont Institute in Wilmington, Delaware.

• **Echo Therapeutics** (Philadelphia), the maker of the Symphony tCGM System – a non-invasive, wireless, transdermal continuous glucose monitoring (tCGM) system – and the Prelude SkinPrep System for transdermal drug delivery, reported positive results from its clinical study of its Symphony tCGM System in patients with Type 1 and Type 2 diabetes. Data from the study confirm that Symphony monitors the broad range of blood glucose values seen in people with diabetes. Echo also reported that it plans to conduct a study in critical care patients in the near term.

• **Patient Engagement Systems** (PES; Burlington, Vermont) has introduced the Chronic Kidney Patient Engagement System (CKPES). This system helps primary care providers identify patients at risk for chronic kidney disease (CKD), manage treatments to recommended guidelines, and reduce avoidable costs and inconsistencies in patient care. CKPES increases communication between patients and their healthcare providers, supports physician decision making through advanced analytics, and promotes provider interaction through a distributed web-based solution. "It is difficult for providers to recognize early-stage CKD without the right analytical support, yet early identification and intervention are essential to slowing disease progression, maintaining quality of life, and improving outcomes. CKPES automatically identifies and stages CKD, giving primary care providers a decision-support tool to help them effectively manage patient care, and bring patients into the care dialogue through targeted personalized content," said Stanley Goldstein, CEO for Patient Engagement Systems.

• **Varian Medical Systems** (Palo Alto, California) said its Clinac and Trilogy medical linear accelerators have been updated to deliver higher doses up to two times faster than was previously possible. They can now also better facilitate treating breast cancer patients on their stomachs (in the prone position) rather than their backs – an approach that can reduce the volume of lung and heart tissue exposed to radiation during treatment. Updated control software adds a High Intensity Mode to the Clinac and Trilogy machines, enabling dose delivery rates of up to 2400 monitor units per minute – double their former highest output, the company said.

People in the News

• **Brain Resource** (San Francisco) has named Gregory Bayer, PhD, CEO of its U.S. operations. Previously, Bayer was CEO of OptumHealth Behavioral Solution, a subsidiary of United Health Group. Brain Resource translates new findings about the brain into products for consumers, employers and clinicians to improve cognition and brain function.

• **TrovaGene** (San Diego) has named Antonius Schuh, PhD, as CEO. Schuh previously was chairman/CEO of Sorrento Therapeutics. Schuh also was the founding CEO of AviaraDx. TrovaGene makes molecular diagnostics for the oncology market.

• **Quest Diagnostics** (Madison, Wisconsin) said its board has elected Timothy Ring to serve as a director. Ring is chairman/CEO of C. R. Bard. Ring joined Bard in 1992, and was named chairman/CEO and joined Bard's board in 2003. Quest is a provider of diagnostic testing, information and services.

Med-Tech Notes

Alliance continues NYSE listing

Alliance HealthCare Services (Newport Beach, California) reported receipt of notice that the New York Stock Exchange has accepted the company's plan for continued listing and, pursuant to such plan, has granted the company an 18-month extension until March 28, 2013 to regain compliance with the NYSE continued listing standards subject to ongoing oversight.

Alliance's common stock will continue to be listed on the NYSE, subject to quarterly reviews by the NYSE to ensure Alliance's progress toward its plan to regain compliance with the market capitalization standard.

Alliance HealthCare Services is a provider of advanced outpatient diagnostic imaging and radiation therapy services based upon annual revenue and number of systems deployed.

MDD's Ortho Extra

Additional Developments in One of Med-Tech's Key Sectors

Thursday, December 8, 2011

Keeping you up to date on recent developments in orthopedics

Spatiotemporal signals guide stem cell changes enabling engineering of cartilage replacements . . . A lab discovery is a step toward implantable replacement cartilage, holding promise for knees, shoulders, ears and noses damaged by osteoarthritis, sports injuries and accidents. Self-assembling sheets of mesenchymal stem cells permeated with tiny beads filled with growth factor formed thicker, stiffer cartilage than previous tissue engineering methods, researchers at **Case Western Reserve University** (Cleveland) have found. A description of the research is published in the *Journal of Controlled Release*. "We think that the capacity to drive cartilage formation using the patient's own stem cells and the potential to use this approach without lengthy culture time prior to implantation makes this technology attractive," said Eben Alsberg, associate professor in the departments of Biomedical Engineering and Orthopaedic Surgery, and senior author of the paper. Alsberg teamed with biomedical engineering graduate students Loran Solorio and Phuong Dang, undergraduate student Chirag Dhami, and Eran Vieregge, a student at Case Western Reserve School of Medicine. The team put transforming growth factor beta-l in biodegradable gelatin microspheres distributed throughout the sheet of stem cells rather than soak the sheet in growth factor. The process showed a host of advantages, Alsberg said. The microspheres provide structure, similar to scaffolds, creating space between cells that is maintained after the beads degrade. The spacing results in better water retention – a key to resiliency. The gelatin beads degrade at a controllable rate due to exposure to chemicals released by the cells. As the beads degrade, growth factor is released to cells at the interior and exterior of the sheet, providing more uniform cell differentiation into neocartilage. The rate of microsphere degradation and, therefore, cell differentiation, can be tailored by the degree to which the microsphere are cross-linked.

3-D printer makes bone-like material . . . It looks like bone. It feels like bone. For the most part, it acts like bone. And it came off an inkjet printer. **Washington State University** (WSU; Pullman) researchers have used a 3-D printer to create a bone-like material and structure that can be used in orthopedic procedures, dental work, and to deliver medicine for treating osteoporosis. Paired with actual bone, it acts as a scaffold for new bone to grow on and ultimately dissolves with no apparent ill effects. The authors report on successful *in vitro* tests in the journal *Dental Materials* and say they're already seeing promising results with in vivo tests on rats and rabbits. It's possible that doctors will be able to custom order replacement bone tissue in a few years, says Susmita Bose, co-author and a professor in WSU's School of Mechanical and Materials Engineering. "If a doctor has a CT scan of a defect, we can convert it to a CAD file and make the scaffold according to the defect," Bose says. The material grows out of a four-year interdisciplinary effort involving chemistry, materials science, biology and manufacturing. A main finding of the paper is that the addition of silicon and zinc more than doubled the strength of the main material, calcium phosphate. The researchers also spent a year optimizing a commercially available ProMetal 3-D printer designed to make metal objects. The printer works by having an inkjet spray a plastic binder over a bed of powder in layers of 20 microns, about half the width of a human hair. Following a computer's directions, it creates a channeled cylinder the size of a pencil eraser. After just a week in a medium with immature human bone cells, the scaffold was supporting a network of new bone cells.

Soft-tissue sarcoma: Unlocking the genetic and molecular mystery of soft-tissue sarcoma . . . Scientists at **Joslin Diabetes Center** (Boston) have uncovered important molecular and genetic keys to the development of soft-tissue sarcomas in skeletal muscle, giving researchers and clinicians additional targets to stop the growth of these often deadly tumors. Published in the *Proceedings of the National Academy of Sciences*, the study identified two major molecular signaling pathways (the Ras and mTOR pathways) that are common in tumor growth and development. These molecular pathways regulate cell growth and division, two cellular properties whose over-activation are hallmarks of cancer biology. "In humans, some sarcomas respond to chemotherapy," says lead author

Amy Wagers, PhD, an associate professor of stem cell and regenerative biology at **Harvard Medical School** (Boston) and Joslin Diabetes Center, "but many don't. With these findings, we have vetted a list of new candidate targets whose inhibition may lead to regression of these tumors." Many soft-tissue sarcomas, which develop in certain tissues such as bone and muscle, carry specific genetic mutations or unique gene signatures, which can allow scientists to develop more precise, targeted therapies. Wagers and her colleagues engineered a tumor system in mice by introducing into mouse skeletal muscle a cancer-carrying gene, or oncogene, known to cause tumors in humans. They used this engineered system to identify a small set of genes that are active in sarcoma tumors. There are many different types of soft-tissue sarcomas, which develop in tissues that connect, support or surround other structures and organs, including muscle, tendons, nerves, fat and blood vessels. If diagnosed early, treatment, primarily through surgical removal of the tumor, radiation therapy or chemotherapy, can be effective. If the tumor has spread, however, the tumor can be controlled only for a period of time, but treatment does not often cure the disease. By inducing these tumors in mice, Wagers says the scientists knew when the tumors would form in the mice and where in the body they would develop, which helped them better understand the molecular and genetic pathways underlying the disease. With this knowledge, researchers may be able to develop new intervention strategies that interfere with these genetic activities and stop the growth of this type of tumor. "With the engineered system we developed, we can find new fragile points in the tumor to target," says first author Simone Hettmer, MD, a pediatric oncologist at the **Dana-Farber/Children's Hospital Cancer Center** (Boston), who treats children with these tumors. In addition, she adds, the system allows scientists to look at the genetic changes in sarcomas and how they interact with the development of tumors and can be applied to sarcomas in tissues other than skeletal muscle. Surprisingly, says Wagers, the researchers found they could induce tumors using several different "beginning" cells.

Physical fitness more important than body weight in reducing death risks . . .

If you maintain or improve your fitness level – even if your body weight has not changed or increased – you can reduce your risk of death, according to research reported in *Circulation*. In a study of 14,345 adult men, mostly white and middle or upper class, researchers found that: Maintaining or improving fitness was associated with a lower death risk even after controlling for Body Mass Index (BMI) change. Every unit of increased fitness (measured as MET, metabolic equivalent of task) over six years was associated with a 19% lower risk of heart disease and stroke-related deaths and a 15% lower risk of death from any cause. Becoming less fit was linked to higher death risk, regardless of BMI changes. "This is good news for people who are physically active but can't seem to lose weight," said Duck-chul Lee, PhD, the study's lead researcher and physical activity epidemiologist in the Department of Exercise Science at the **University of South Carolina**'s (Columbia) Arnold School of Public Health in Columbia. "You can worry less about your weight as long as you continue to maintain or increase your fitness levels." Results of the study underscore the importance of physical inactivity as a risk factor for death from heart disease and stroke, said researchers. Researchers also found no association between changes in body fat percentage or body weight and death risk. Participants, who were an average 44 years old, were part of the long-term, large-scale Aerobics Center Longitudinal Study. They underwent at least two comprehensive medical exams. Researchers used maximal treadmill tests to estimate physical fitness (maximal METs), and height and weight measurements to calculate BMI. They recorded changes in BMI and physical fitness over six years. After more than 11 years of follow-up, researchers determined the relative risks of dying among men who lost, maintained or gained fitness over six years. They accounted for other factors that can affect outcomes, including BMI change, age, family history of heart disease, beginning fitness level, changes in lifestyle factors such as smoking and physical activity, and medical conditions such as high blood pressure or diabetes. One possible explanation for these results: about 90% of the men were either normal weight or overweight at the beginning of the study. Among obese people, changes in BMI might have a significant effect on death risks. So it's unclear whether these results would apply to severely obese people, Lee said. A BMI score under 25 is considered healthy, 25 to less than 30 is overweight, and 30 or greater is obese. Because the study was mostly done in white middle and upper class men, it's difficult to know whether the results apply to other racial and socioeconomic groups. Women would likely have similar results as the men in the study, Lee said.

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