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Cepheid's GeneXpert rapid MRSA test wins FDA approval

By LYNN YOFFEE

Medical Device Daily Staff Writer

There is light at the end of the infection control tunnel – particularly when it comes to the growing incidences of methicillin-resistant *Staphylococcus aureus* (MRSA) infections – with the FDA's clearance this week of **Cepheid's** (Sunnyvale, California) GeneXpert MRSA/SA Skin and Soft Tissue Infection (SSTI) test, which can provide clinicians with results in less than a hour, compared to traditional cultured tests which can take days.

"This is the first FDA-cleared test to go straight to a clinical specimen and diagnose the presence of staph and MRSA," David Persing, MD, PhD, executive VP, chief medical & technology officer, told *Medical Device Daily*. "It's the only polymerase chain reaction [PCR] system that allows stat tests to be performed in the lab. Samples can be run as they come in and delivered in a time frame that's action-

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Aethlon starts human study of Hemopurifier in HIV/AIDS

By OMAR FORD

Medical Device Daily Staff Writer

The number of med-tech companies that could possibly rival the patience of **Aethlon Medical** (San Diego) might be few and far between. Since 2001, the company has held its hopes on its Hemopurifier being used to treat HIV Infection.

Most recently, the company began inching towards turning that hope into cold, hard reality when it reported that it planned to initiate a first-in-man clinical study of the device (*Medical Device Daily*, June 25, 2008). The company said it initiated the study in September.

The device is said by Aethlon to have the potential to extend the lives of HIV patients by removing HIV strains that cause drug failure and reducing the presence of viral proteind that kill off immune cells.

The HIV treatment studies are being conducted at **Jat-**
See Aethlon, Page 7

Report from Europe

bioMérieux in accord with ProteoSys on prostate test

A Medical Device Daily Staff Report

bioMérieux (Marcy l'Etoile, France) reported signing a license and development agreement with **ProteoSys** (Mainz, Germany) for Annexin 3, which will be used to develop a urine-based, confirmatory diagnostic test for prostate cancer.

After a research phase, the new test should be developed on the VIDAS platform, which is one of the most widely installed automated immunoassay instruments in the world.

Financial details of the agreement were not disclosed.

"It was an obvious choice to partner with bioMérieux because of its strategic focus on oncology, the market leadership of its VIDAS platform and its extensive commercial network," said André Schratzenholz, chief scientific officer of ProteoSys.

bioMérieux CEO Stéphane Bancel said, "We are . . . pleased to work with ProteoSys to bring such an innovative

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Radiologists urged to pick a specialty as field advances

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Technology has been a wonderful friend to the medical community, and the imaging sector is no exception. But one radiologist, Barry Pressman, MD, says that technology is driving the need for radiologists to choose a subspecialty in order to keep up with the continuous change in the field.

"As technology advances your ability to keep up with it diminishes and the only way to survive is to choose your area, or limit your areas," Pressman told *Medical Device Daily*.

Pressman addressed the changing field of radiology and the need for subspecialization in his speech, "Presidential Address: Distinction or Extinction," which he delivered at the **American College of Radiology's** (Reston, Virginia) annual meeting in May. The speech also appears in the October issue of the *Journal of the American College of Radiology*.

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 **AHC Media LLC**

*Washington roundup***Covidien gets warning for technetium production**By **MARK McCARTY****Medical Device Daily Washington Editor**

The recent news of the shutdown of a reactor in the Netherlands that was producing molybdenum-99, a precursor agent for the anticarcinogenic technetium-99 (*Medical Device Daily*, Sept. 17, 2008) jangled a few nerves among radiation oncologists, especially given a previous decision on the part of Canadian authorities to end development of a new reactor for this application. This medical radioisotope is now back in the news with the release of a warning letter to **Covidien** (Mansfield, Massachusetts) addressing the company's processing of molybdenum-99 into technetium-99.

The Aug. 12 warning letter, which FDA posted early last week, addressed a March inspection of the firm's medical radioisotope plant in Maryland Heights, Missouri. The lead citation was for failure of the company's release limits for production of molybdenum-99 to "assure that the specification would be met." Molybdenum is a precursor material for technetium-99, which is used for treatment of a variety of cancers.

The agency said that the company's response to this finding indicated that Covidien had opted to deal with the related requirement by using a standard test method to predict the ratio of molybdenum to technetium, but FDA inquired as to "why you have chosen to set the limit in this manner versus setting a maximum limit that cannot be exceeded."

The letter cited Covidien for lack of established controls for "backwashing, column assembly and column activation . . . to assure that the molybdenum adsorbs and remains adsorbed to the column," a failure of which was said to open the door to "molybdenum breakthrough effect." The agency said that the company's generator "is not a new product or process," but pressed Covidien to explain the source of

Today's MDD food for med-tech thought

"This product deals with the issue of getting an answer back to the clinicians so that they can make appropriate treatment decisions quickly."

— David Persing, MD, PhD, of Cepheid, discussing the firm's new GeneXpert MRSA/SA Skin and Soft Tissue Infection test, which delivers results in less than one hour, "Cepheid's GeneXpert rapid MRSA test wins FDA approval," pp. 1, 6.

"new unexplained variability in component quality and/or the manufacturing process," to which FDA chalked up a "recent increased number of molybdenum breakthrough complaints." The letter also stated that at the time of the inspection, Covidien had not studied "among other things, the washing process and particle size as well as how they impact product quality and function."

The company's responses apparently included reference to an investigation into the adsorption of molybdenum "onto the column," but FDA did not indicate the start date or projected duration of that investigation.

The warning letter also stated that the company's quality control unit missed on several points, including the molybdenum adsorption and the validation of "all key process variables." FDA said that while Covidien commenced with the related investigation in 2007, follow-up "did not occur until our representatives inspected your facility in March" and that the quality control unit had previously "failed to prevent the distribution of defective products." The agency also indicated that similar problems had shown up "in other product areas during previous inspections."

At press time, Covidien had not responded to calls for comment.

Pedicle screw maker hit with warning

Allez Spine (Irvine, California) also was the recipient of an August warning letter that surfaced at the FDA web

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EDITORIAL
Holland Johnson, **(404) 262-5540**
Fax: **(404) 814-0759**

SVP/GROUP PUBLISHER
Donald R. Johnston,
(404) 262-5439

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Agreements/contracts**Q-Med, Medy-Tox to terminate botulinum collaboration accord****A Medical Device Daily Staff Report**

Q-Med (Stockholm, Sweden) and **Medy-Tox** (Seoul, South Korea), a pharmaceuticals company, have decided to terminate their collaboration agreement that was entered into in 2007 (*Medical Device Daily*, Feb. 12, 2007).

The collaboration comprised the development and commercialization of new products based on botulinum toxin and potential for Q-Med to distribute Medy-Tox's existing botulinum toxin type A product.

The parties have both signed a separation agreement, amongst other things, where they agree to a financial settlement which entails Medy-Tox repaying the majority of the loan that Q-Med has given the company up until the present date. Further details concerning the repayment will not be made public, however.

The parties' original agreement included Q-Med giving Medy-Tox a loan of up to \$3 million for the adaptation of facilities and manufacturing processes, and paying up to \$8 million on condition that certain commercial objectives were achieved.

Q-Med said it still aims to continue work on the development and commercialization of products within the botulinum toxin area.

In other agreements/contracts news:

- **Zotec Partners** (Indianapolis), a provider of medical billing, practice management and radiology information systems software, reported that New Jersey-based **Atlantic Medical Imaging** (AMI) has licensed the company's Electronic Billing Center suite, which includes the RIS, EZ Med Portal and Decision Support tools. Zotec said its software suite will enable the AMI to accomplish better patient care while enhancing workflow management.

AMI is a full service, outpatient imaging practice operating seven offices throughout New Jersey and providing professional services to three area hospitals.

- **Instrumentation Laboratory** (IL; Lexington, Massachusetts) reported that it has been awarded a three-year contract for its critical care portfolio with **Premier Purchasing Partners** (San Diego), the group purchasing unit of the Premier healthcare network. This is the fifth contract Premier has awarded IL since 1998.

"Our relationship with IL enables Premier members to access high-quality, cost-effective blood gas products and services. We look forward to offering those benefits for another three years," said Barbara Maillet, Sr. Director of Laboratory Services for Premier's Group Purchasing Services.

The contract covers IL's portfolio of critical care analyzers, reagents, consumables and service, including IL's flagship product, the GEM Premier 4000 analyzer for blood gas, electrolyte and metabolite and integrated CO-Oximetry testing. ■

Washington

Continued from Page 2

site only last week. FDA cited the maker of pedicle screws for a number of citations indicating a lax quality control system, but the warning letter also indicated that Allez did not report to FDA several instances in which a failure of pedicle screws to fixate to the bone.

According to the warning letter, three complaints indicated that "your device failed to seat properly during initial implantation" and "the devices were therefore immediately explanted." FDA indicated that the company's investigation into the matter unearthed "evidence of cross threading and other distortions of the components in the returned devices," and the warning letter argued that these should have been forwarded as medical device reports (MDRs) because of the potential "to cause or contribute to a death or serious injury."

The company's response to this finding was deemed inadequate because "your files do not provide adequate documentation to support the reasonableness" of the initial conclusion that the events were not reportable. The company was said to have later reviewed and reported the events based on "unspecified information."

FDA also said that Allez had no PMA or 510(k) for the company's Laguna polyaxial pedical screw system, a citation apparently based on several changes made to the device. These included a change from "a two-piece press-fit locking nut to a two-piece welded locking nut" and "several revisions of to the thread profile of the locking nut." The agency made the case that such changes "raise the risk of decreased biomechanical performance, which could in turn lead to adverse events."

Among the more routine citations covering good manufacturing processes was a failure to validate changes to the design of an unspecified item "from a welded two-piece locknut to a one-piece locknut." At press time, Allez had not responded to a call for comment.

FDA hits firm with detention

The Aug. 20 warning letter addressed to **Suarez Corp/dba Biotech Research** (Canton, Ohio) led off by notifying the company that it had neither PMAs or 510(k)s for several of the firm's offerings, which includes the PainNOT heating pad. The letter also said that the company failed to file MDRs for two instances of burns associated with the use of the PainNOT. In one case, a user received third-degree burns "because he was not warned that the device used infrared heat," and in the other instance, a user received second-degree burns on his upper back, for which he went to an emergency room for treatment.

The letter notes seven other instances in which the company failed to file MDRs, and followed with a citation for lack of procedures for filing MDRs with the agency. FDA

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Patent watch**New U.S. patent protects Cytori's Celution System****A Medical Device Daily Staff Writer**

Cytori Therapeutics (San Diego) said it has received U.S. Patent No. 7,429,488, which broadly protects its Celution system-based methods of generating adipose tissue-derived stem and regenerative cell-enhanced fat grafts. According to the company, cell-enhanced fat grafts may be used in a variety of cosmetic and reconstructive surgery applications, including breast reconstruction following partial mastectomy, breast implant salvage, as well as facial and other cosmetic applications. The Celution 800/CRS system is currently sold in Europe and parts of Asia.

Cytori said the patent, which runs until at least January 2024, is important to the company "because it further strengthens the Celution system's competitive position within the cosmetic and reconstructive surgery market." Part of Cytori's strategy to create greater barriers-to-entry is to protect distinct applications of the Celution System, the company said. This allows Cytori to build additional layers of protection around U.S. Patent No. 7,390,484, which was recently issued to Cytori and covers the Celution system's core technology. Additional patents have been filed around other Celution system applications, including cell banking, cardiovascular disease, spine and orthopedic

repair, among others, Cytori said.

According to the company, the new patent broadly protects its system, which is designed to automate the method of creating a cell-enhanced fat graft. First, the system processes stem and regenerative cells from a small amount of adipose tissue. Next, it mixes these cells with liposuctioned fat tissue, Cytori said. This forms the cell-enhanced fat graft, which may be used as a natural filler to reconstruct soft tissue defects, the company noted. ■

Washington*Continued from Page 3*

noted that Suarez was in the process of developing such procedures, but that they were incomplete as of the date of the warning letter.

The company apparently sent letters to owners of the Foot Choice infrared heat massager to urge the customers to "check the skin in contact with the heated area . . . frequently to reduce the risk of burns or blistering," in 2006. FDA noted that the company failed to inform the agency of this action.

FDA also cited the company's PainNOT patch as a new drug for which the company had no new drug application, and informed the company – which is said to import at least most of its products from its overseas locations – that its products would be detained. At press time, the company had not responded to calls for comment. ■

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Grants roundup**Susan G. Komen organization doles out \$100M for research****A Medical Device Daily Staff Report**

Susan G. Komen for the Cure (Dallas) organization reported distributing \$100 million in grants to American and International Scientists this year.

This marks the largest commitment of breast cancer research funding by a single nonprofit organization, targeted to 81 universities and hospitals in 27 states and five countries. These grants represent research with the highest likelihood of producing results for patients during the next decade.

"There's a tremendous urgency to translate what we're learning in the lab into treatments for patients, particularly patients with very aggressive cancers who don't have years to wait," said Eric Winer, MD, chief scientific advisor to Susan G. Komen for the Cure and director of the Breast Oncology Center at **Dana-Farber Cancer Institute** (Boston).

He added: "The grants we are funding focus on safely and effectively bringing treatments to cancer patients in a more timely way than we have been able to in the past."

During the past 25 years, Komen for the Cure has raised and distributed \$1.2 billion for research and community health programs. And Komen is pledging to invest another \$2 billion during the next 10 years.

This year, Komen introduces new research programs called Promise Grants, which are worth millions of dollars and last for five years. They are designed to get scientists and doctors to work together in new ways to bring treatments out of the laboratory to patients as quickly as possible. Komen also is funding new and bigger grants to attract and retain young cancer researchers.

In other grants:

- The National Institute of Child Health and Human Development division of the National Institutes of Health (NIH) has awarded Michelle Williams a \$2.9 million grant for a five-year research project to examine possible linkages between the serious pregnancy complication known as preeclampsia and migraine.

Williams is a co-founder and co-director of **Swedish's Center for Perinatal Studies** (Seattle) and one of the world's leading authorities on preeclampsia and other pregnancy concerns. She is also a professor of Epidemiology at the **University of Washington**.

The goal of the research is to evaluate whether, and to what extent, a maternal pre-gestational history of migraines and migraine symptoms during early pregnancy are associated with the risk of preeclampsia.

Preeclampsia is a vascular disorder characterized by high blood pressure and the presence of protein in the urine starting around mid-pregnancy. It occurs in up to 8% of all pregnancies and, in addition to other hypertensive

disorders, is the leading global cause of maternal and infant illness and death.

Migraine is a common chronic-episodic disorder characterized by severe, debilitating headaches. It is often accompanied by nausea and sensitivity to activity and/or external stimuli. Between 14% to 25% of women suffer from some form of migraine, which is more common during childbearing years.

Starting this fall, Swedish will enroll approximately 2,000 women who are in their first trimester of pregnancy from obstetrics clinics affiliated with the medical center. As part of the study protocol, women who screen positive for migraine or indicate they have experienced it will have a follow-up interview to confirm the diagnosis, and then be interviewed about their medical history. Enrolled women will be followed through to delivery and information will be collected during in-person interviews using study questionnaires.

Earlier this year, Williams was awarded a \$495,554 grant from the March of Dimes Foundation to fund a three-year research project to identify pre-conceptual risk factors and biological markers of preeclampsia and preterm delivery in China.

- **GeneGo** (St. Joseph, Michigan) provider of databases, tools and services in systems biology, reported that they were awarded with a Phase I SBIR grant from the National Cancer Institute (NCI) for the development of a platform for understanding the influence of nutrients on cancerogenesis and cancer prevention. GeneGo will collaborate with FDA investigator, Jim Kaput Director of Personalized Nutrition and Medicine, on the project.

The new platform will include a comprehensive manually curated database on nutrition, an OMICs data repository, advanced search and statistical modeling tools.

GeneGo develops systems biology technology such as compound based pathway analysis, cheminformatics & bioinformatics software for life science research. ■

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Cepheid

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able to the clinician right away.”

The test, which requires just a swab of the infected wound site, runs on Cepheid's GeneXpert system.

In less than one hour, Cepheid's GeneXpert processes specimens from the swabs to determine if a patient is infected with MRSA or *S. aureus*, giving physicians and surgeons a new tool to aid in selecting the most effective antibiotic therapy to improve patient management.

There are an estimated 292,000 hospitalizations with a diagnosis of *S. aureus* infection annually in U.S. hospitals. Of these, approximately 126,000 hospitalizations are related to MRSA.

Last year Cepheid received FDA clearance to market its GeneXpert MRSA test for infection control surveillance purposes (*Medical Device Daily*, April 19, 2007).

“Not every hospital has a program for surveillance, but every hospital does deal with MRSA,” Persing said. “This product deals with the issue of getting an answer back to the clinicians so that they can make appropriate treatment decisions quickly. Most of the time, patients are treated with the wrong drugs for MRSA [because it takes days to get test results back].”

Each GeneXpert test will cost \$75 while the system to run the tests, GeneXpert costs \$20,000 or more. Prices are higher for systems that have the capacity to run more tests simultaneously.

While the testing system may be costly, the operator does not have to be specially trained.

“Any lab tech can run this test,” Persing said. “They don't have to be molecular diagnostics specialists. Because it's so easy to perform, it can be run around the clock. There are no special skill requirements that would prevent someone from doing the tests.”

Globally, Cepheid has already sold and installed more than 700 GeneXpert systems, mostly in North America.

“The value of the technology will be especially recognized among surgeons, intensive care unit specialists and emergency room physicians who need information on the right treatment strategy,” Persing said. “We think that the drivers will be the end users: surgeons and surgical directors of intensive care units.”

Persing also said that he believes that this is a critical test for drugs companies selling MRSA therapies. “We think a lot of pharmaceutical companies are interested in this as the test to make a treatment decision between one pharmaceutical agent or another,” he said, adding that Zyvox from **Pfizer** (New York) is one of the few drugs that effectively treats MRSA.

“So there are a lot of treatment algorithms spurred by these test results and we think co-marketing deals with pharmaceutical companies are possible. In general, we're seeing a trend to target therapy and bring diagnostic testing into the treatment algorithms.”

The **Centers for Disease Control and Prevention** (CDC; Atlanta) reports approximately 12 million patient visits in the U.S. each year for skin infections. MRSA is a bacterium that has become resistant to multiple antibiotics including penicillin and cephalosporins. Current culture-based lab testing methods require up to 72 hours to determine if a skin or soft tissue infection is caused by MRSA or *S. aureus*. As a result, physicians and surgeons often prescribe broad-spectrum antimicrobial therapies while awaiting culture results.

The **Institute of Healthcare Improvement** (Cambridge, Massachusetts) reports that about 800,000 surgeries are complicated by infections annually. Cost to the healthcare system to treat these infections is estimated at \$9.5 billion, largely due to extended hospital stays following surgery.

The GeneXpert system is a closed, self-contained, fully-integrated and automated platform. It combines on-board sample preparation with real-time PCR amplification and detection functions for automated nucleic acid analysis. The system is designed to purify, concentrate, detect and identify targeted nucleic acid sequences thereby delivering answers directly from unprocessed samples. ■

MED - TECH NEWS AND NOTES

Orthovita submits response to FDA

Orthovita (Malvern, Pennsylvania), a spine and orthopedic biosurgery company, said that it recently submitted its response to the initial set of comments received from the FDA to its 510(k) application for the use of Cortoss bone augmentation material in vertebral augmentation.

After receiving the FDA's initial comment letter in March, Orthovita requested a 180-day extension from the FDA for its response in order to collect and submit additional two-year follow-up patient data from its pivotal U.S. Cortoss clinical study that was conducted under an FDA Investigational Device Exemption (IDE).

FDA granted Orthovita's request and Orthovita submitted its response to the FDA within the extension period. This response increases the number of patients in the pivotal study for whom two-year follow-up data has been submitted to approximately two-thirds of the original pivotal IDE study cohort. This data is in addition to the long-term follow-up data from Orthovita's earlier pilot studies and European investigations that was previously submitted as part of the Cortoss 510(k) application.

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Aethlon

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tinder Gambhir Hospital (J.G. Hospital; Punjab, India) and **Bhvani Hospital** (Bihar, India).

According to Aethlon, up to six HIV-infected patients will be administered daily Hemopurifier treatment for a period of up to nine consecutive days.

"Right now we're in the process of looking at the data for four different patients who might be eligible for the process," Jim Joyce, chairman/CEO of Aethlon, told *Medical Device Daily*. "We expect to treat the first patient in the next few weeks.

"Based on our recent hepatitis C treatment observations, I am increasingly confident that our Hemopurifier will demonstrate similar effectiveness in HIV studies," he said. "If correct, the Hemopurifier will advance HIV care by offering a treatment option that extends life for patients no longer responsive to drug therapy, and enhances the benefit of drug regimens by inhibiting the proliferation of HIV strains that cause drug resistance."

The device provides a mechanism which to mimic the natural immune response of clearing infectious viruses and toxins before cells and organs can get infected.

The goal of Hemopurifier treatment is to inhibit viral replication through the rapid clearance of all strains of infectious HIV, and to augment the immune response by eliminating circulating gp120, a protein that sheds from the surface of HIV to kill-off immune cells necessary to fight infection.

The company said the study is expected to be completed in 1Q09.

"If studies go well we would expect commercialization in India in 2009, with commercialization in the U.S. and [Europe] in late 2010 and early 2011," Joyce said.

On Sept. 17, Aethlon disclosed preliminary data resulting from hepatitis C (HCV)-infected patients being treated with the Hemopurifier (a separate matter, yet related). The HCV-treated patients were among end-stage renal disease patients enrolled in human safety studies being conducted at the **Fortis Hospital** (Delhi, India). In the HCV studies, an average viral load reduction of 82% was observed in patients after just three Hemopurifier treatments.

The study data documented that two of three patients infected with HCV responded with measurable viral load reductions during the course of three 4-hour Hemopurifier treatments.

The three treatments were administered during scheduled dialysis therapy every other day over the span of five days. The third patient showed both increases and decreases in viral load during the course of treatment, but demonstrated significant overall reduction of viral load in follow-on tests. Given the small sample size, viral load data was averaged for all three patients. Average initial HCV viral load was 3.13×10^8 viral units per ml of blood. After completion of three Hemopurifier treatments, viral load

was reduced an average 57%.

The stepwise drop in HCV viral load averaged 36% per treatment. Follow-on testing indicated that HCV viral load was 60% lower than initial viral load values when measured three days after final Hemopurifier treatment, and at seven days post-treatment, viral load declined to 82% below starting viral load values.

None of the patients were being treated with antiviral drug therapy. Viral load measurements were performed with real-time quantitative polymerase chain reaction (RT-PCR). Control samples were measured in duplicate while treatment samples were generally measured in triplicate.

The company first introduced the device seven years ago during the annual **National Blood Safety Conference** in Washington (*MDD*, Feb. 9, 2001). The device is a hollow-fiber dialysis cartridge and can reduce the viral load through the direct physical removal of the HIV in circulation.

Since the device's inception, Aethlon has retooled it and filed for patents to seek its improvement. One such modification stems from the filing for a provisional patent submission titled, "Method and Apparatus for Increasing Contaminant Clearance Rates during Extracorporeal Fluid Treatment," with the U.S. Patent and Trademark Office (*MDD*, March 8, 2007).

The patent describes technical improvements to the Aethlon Hemopurifier that increase the rate of capture of undesirable blood contaminants including viruses, toxins and immunosuppressive particles associated with cancer.

The company said the device also holds promise in cancer care, as research studies have verified the Hemopurifier is able to capture immunosuppressive particles secreted by tumors. ■

MED - TECH NEWS AND NOTES

Encision gets Amex delisting notice

Encision (Boulder, Colorado) said it received notice from the American Stock Exchange (Amex) indicating that, due to Encision's continued failure to comply with certain of the Amex's continued listing standards, the exchange intends to immediately file a delisting application with the Securities and Exchange Commission to drop Encision's common stock from the exchange.

The Amex's notice indicates that, based on a review of the company's Form 10-KSB for the year ended March 31, Form 10-Q for the period ended June 30 and information provided by the company, the exchange has determined that the company has not made progress consistent with its plan of compliance and that there is no basis for the Amex to conclude that the company could regain compliance by the Jan. 16, 2009, deadline. The company does not intend to appeal the delisting.

Europe

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biomarker to urologists around the world. This agreement is yet another building block in our high-medical-value test strategy.”

Annexin 3, also known as ANXA 3, was discovered by ProteoSys. Studies have shown that ANXA 3 quantification in urine is a novel, non-invasive test with high specificity for prostate cancer. The ANXA 3 test is expected to be used to provide better identification of patients with a high probability of prostate cancer, thereby reducing the number of unnecessary biopsies.

The first phase of research is beginning at bioMérieux, which will be followed by the development of a diagnostic test for the VIDAS platform. While the confirmatory diagnostic application on VIDAS will be the initial focus, bioMérieux said it also is considering the development of treatment decision and prognostic applications for ANXA 3.

The ANXA 3 test will be complementary to the tPSA and FPSA tests available on the company's VIDAS platform.

CardioWest training for Italian hospital

Professor Francesco Musumeci, director of the cardiovascular department, cardiothoracic surgeon Antonio Loforte, MD, and the cardiac surgery team from **Azienda Ospedaliera San Camillo Forlanini** (Rome) completed the first phase of certification training for **SynCardia's** (Tucson, Arizona) CardioWest temporary Total Artificial Heart (TAH-t) in Berlin last month.

Originally designed as a permanent replacement heart, the CardioWest artificial heart is currently approved as a bridge to human heart transplant for patients dying from end-stage biventricular failure.

Italy's first implant of the CardioWest artificial heart was performed in December 2007 at **Azienda Ospedaliera di Padova** in Padova. The patient was discharged from the hospital on the European portable driver on Feb. 4 and is at home while he waits for a matching donor heart.

The European portable driver received CE-mark approval in July 2006. “It allows stable CardioWest patients to recover at home while they wait for a donor heart,” said SynCardia. “Discharge drivers allow stable artificial heart patients to shop, travel and enjoy a quality of life comparable to people with human hearts.”

The company said it will submit an application to the FDA in 4Q08 to conduct an IDE clinical study of the Companion Driver System at 22 U.S. CardioWest certified centers. The Companion Driver is designed for use in both the hospital and for discharge.

Azienda Ospedaliera San Camillo Forlanini will become the 36th hospital in the world and the third in Italy to complete CardioWest certification training. The 270-bed Roman hospital performed 26 heart transplants last year and had performed 19 this year as of Aug. 31.

UK fellowships eye patient benefits

A new research fellowship program unveiled in the UK last month will provide £4 million in funding over the next three years for healthcare scientists to undertake research to improve patient services and treatment.

Funded by the UK Department of Health and supported by the **National Institute for Health Research** (NIHR), the effort will fund areas of research that will have direct patient benefit.

Research projects may include helping patients to self-care and self-manage, developing diagnostic tests, enhancing therapeutic services or improving the NHS's ability to monitor disease.

For this program, National Health Service scientists are invited to develop a research project that could both address a patient care issue and promote links between the NHS and university research groups.

Successful applicants will be selected by a panel, including representatives from the Department of Health, the NIHR and the NHS. Funding will be awarded for up to two years on a full-time or proportionate part-time basis.

Chief Scientific Officer Professor Sue Hill, who led the initiative, said, “These fellowships . . . build on the aptitude and dedication of thousands of NHS healthcare scientists. I hope the new opportunities offered to them will help to support the research capabilities of NHS departments by further encouraging scientists to undertake translational research within health to improve care for patients.” ■

MED - TECH NEWS AND NOTES

Zila completes 1-for-7 stock split

Zila (Phoenix) said it has completed a 1-for-7 reverse stock split. Accordingly, every seven shares of the company's common stock have been combined into one share of common stock. Fractional shares will be issued to Zila's shareholders to the extent required by the impact of the reverse stock split.

“I am very pleased that the holders of 73% of our shares participated in the reverse stock split decision, with 93% of those that participated voting in favor of the reverse split,” said Chairman/CEO David Bethune. “The company will continue with its efforts to reduce expenses and improve revenues over the coming months.”

The reverse stock split affects all of Zila's outstanding common stock, as well as the number of shares issuable upon the exercise or conversion of the company's outstanding warrants, convertible notes, options and other similar rights. In addition, the number of shares of common stock that Zila is authorized to issue was reduced to 30 million in connection with the reverse stock split.

Zila is an oral diagnostic company focused on the prevention, detection and treatment of oral cancer and periodontal disease.

Radiology

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"Specialization is the wave of the future but it's not just the wave of the future, it is now," Pressman said. "I just felt it was important to address the issue in my speech because the American Board of Radiology, which does our board exams, has made some announcements changing their structure, such that subspecialization is not only available, it's encouraged."

This has caused subspecialization to become a hot topic in the radiology community, Pressman told *MDD*, because while there are many radiologists switching over to a subspecialty, there are also a significant number of them resisting it.

"So I just took an issue that was sort of smoldering and hopefully lit a fire to it."

Pressman has been a neuroradiologist for 35 years. When he became a subspecialist in 1973, he said, subspecialists were a minority. Now, he believes, they are a majority. "But not an overwhelming majority, we still have a large number of people who trained in my generation or half a generation later, who try to do the entire watershed of imaging," he said.

Pressman told *MDD* he was approached by one of his colleagues, a radiologist just a few years younger than himself, before delivering his speech who asked him, "are you going to piss me off?"

"And afterwards he said 'you pissed me off' because I addressed the issue head on . . . I have more people thinking about it, hopefully young people thinking about it. There's no way to stop progress and subspecialization is progress."

As with anything, the big driver behind progress, of course, is technology.

"As technology advances and we become more sophisticated in its use and its abilities you need people who are more and more expert in applying those new procedures and interpreting those new procedures," Pressman said.

In his article Pressman points out that in 1970, when he was beginning his residency, ultrasound was in its infancy. "We couldn't even spell CT, let alone MR," he wrote.

He elaborated on this point during a phone conversation yesterday with *MDD*: "We did plain X-rays . . . we couldn't see the brain itself as we could with CT and now with MR we can not only see the brain, but we can see the functioning of the brain."

That's why he believes it is so important for radiologists – especially those just entering the field – to choose a subspecialty rather than trying to "do it all."

"The things we can do now are so sophisticated compared to what we could do before . . . its hard for any one person just to keep up with all of that and I don't do it all."

Pressman's speech also points out other challenges that radiologists have faced over the years as technology has progressed.

"Too often, especially recently, while the science of radiology has been moving forward, we radiologists have been pushed back," Pressman said.

Just one of several examples he used is the advance of radiation therapy: "We advance radiation therapy, only to hear every Tom, urologist, and Harry, declare himself a radiation oncologist."

Pressman also urges radiologists to take the lead in combating commoditization by continuing to deliver value to the healthcare system through frequent patient and referring physician interactions, initiating research opportunities, and delivering quality interpretive consultations, rather than just a list of findings, through their reports. ■

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

Playtex launches VentAire advanced bottle

Playtex Products (Westport, Connecticut), a subsidiary of Energizer Holdings, and the maker of Playtex Infant Care products, said it is launching the VentAire advanced bottle, in a bisphenol-A (BPA)-free material, which will begin shipping in October.

The new VentAire advanced bottle is made out of BPA-free clarified polypropylene, a durable and translucent plastic. The bottle design offers superior benefits for infants as it has been clinically shown to reduce colic, gas and spit-up better than competitors, as shown in a clinical study of over 11,000 feedings. In fact, 8 out of 10 moms in the study confirmed that their baby showed fewer signs of colic using the VentAire advanced system versus three leading brands.

"The VentAire advanced bottle was designed with a unique micro-channel bottom vent to prevent air from mixing with the liquid ensuring that infants don't ingest excess air," said John Rousso, director of research and development for Playtex Infant Care. "And its unique angled shape supports a semi-upright feeding position, which is recommended by pediatricians to help prevent ear infections."

PPD to amend cash dividend

PPD (Wilmington, North Carolina), a contract research organization, said its board of directors has amended the company's annual cash dividend policy to increase the annual dividend rate by 25%, from \$0.40 to \$0.50 per year, payable quarterly at a rate of \$0.125 per share. PPD expects the new dividend rate will be effective beginning in 4Q08.

"PPD's board of directors, management team and employees are delighted to reward our shareholders with the third consecutive annual increase in our cash dividend rate since the adoption of the dividend policy in 2005," said CEO Fred Eshelman. "We remain firmly committed to generating long-term shareholder value through the delivery of high-quality services and the advancement of our compound portfolio strategy, and returning value to our shareholders."

PRODUCT BRIEFS

• **ArthroCare** (Austin, Texas) reported results from a study showing that Coblation-assisted procedures eliminated the risk of airway fires, and Coblation-Assisted Sinus Surgery (CASS) procedures lowered the risk of blood loss in nasal polypectomy/endoscopic sinus surgery (ESS). The study compared the risk of airway fire for an electrosurgical device (Bovie) and a bipolar radiofrequency ablation wand (Coblator) in a mechanical chicken cavity model. The study found that the risk of airway fire appeared to be eliminated with Coblation, while electrosurgical devices present a risk of fire during open cavity surgery in oxygen-enriched environments. All experimental conditions were tested for four minutes, or until a positive result was achieved and were repeated in another model to ensure accuracy.

• **ArthroSurface** (Franklin, Massachusetts) said that its HemiCAP toe hemiarthroplasty product is now approved for reimbursement by Aetna and other major insurance carriers. Metatarsal head resurfacing with the HemiCAP implant provides a treatment approach for patients with Grade II and early Grade III MTP changes. This intermediate patient population can be served with a motion-preserving surgical alternative for providing pain relief and functional improvement. The metatarsal phalangeal joint or great toe is considered one of the most common osteoarthritic joints and the often painful condition of *hallux rigidus* is reported to be present in females at a rate of 2:1 over males. The underlying disease process of *hallux rigidus* is not fully understood but it is believed to be associated with joint impingement diseases and previous traumas such as sports or occupational injuries.

• **Biolmagene** (San Diego) has launched iLearn – a new online educational offering for pathologists, in partnership with i-Path Diagnostics – a UK-based biomedical software company. iLearn provides educational modules for histopathology and cytopathology for residents and experienced pathologists. The company says that iLearn brings

internet technology and the convenience of online education into pathology training, supplementing the traditional learning methods of trainee pathologists. Digital images, e-learning tools and streaming video are used to deliver virtual case material in pathology

• **Guided Therapeutics** (GT; Norcross, Georgia) reported completion of its FDA trial for the LightTouch non-invasive cervical cancer detection device. The GT LightTouch technology systematically scans the cervix to identify cancers and pre-cancers painlessly and non-invasively by analyzing the wavelengths of light reflected from cervical tissue. The LightTouch uses technology to identify cancers and pre-cancers painlessly and non-invasively by analyzing light reflected from the cervix. The technology distinguishes between normal and diseased tissue by detecting biochemical and morphological changes at the cellular level. Unlike Pap or HPV tests, the non-invasive test does not require a tissue sample or laboratory analysis, and results are available immediately.

• **HeartWare** (Framingham, Massachusetts) said that it has received full approval from the FDA of an investigational device exemption for the HeartWare Left Ventricular Assist System (LVAS). HeartWare said in May that it had received conditional approval from the FDA for a U.S. clinical trial of the HeartWare LVAS for use as a bridge to cardiac transplant in patients suffering from end-stage heart failure (*Medical Device Daily*, May 18, 2008). This conditional approval permitted the company to start its U.S. trial, but included several conditions which HeartWare was required to address to the FDA's satisfaction.

• **OBS Medical** (Carmel, Indiana) reported FDA clearance for its Visensia Alert (VitalAlert) in the U.S. Formerly known as BioSign, Visensia's automated early warning technology fuses up to five vital signs – heart rate, respiration rate, body temperature, oxygen saturation and blood pressure – into a numerical index. The Visensia Index is an indication of a patient's wellness and can enable significant improvement in clinical outcomes and optimization of hospital resource utilization. When the Index reaches and/or surpasses the default threshold, the VitalAlert is triggered.

PEOPLE IN PLACES

• Steven Young has been named president of the **Addario Lung Cancer Medical Institute** (ALCMI; San Francisco). Former president Tony Addario has assumed the role of CEO. Most recently Young was the executive director of the Multiple Myeloma Research Consortium.

• Peter Benton has been named president of the Phoenix Data Systems division of **Bio-Imaging Technologies** (Newtown, Pennsylvania). Most recently, he was COO

of an eClinical technology services company.

• Steven Schaefer has been promoted to president of **CSA Medical** (Baltimore). He has been CFO since November 2006.

• **Mindray Medical International** (Shenzhen, China) said that Peter Wan and Kern Lim have been named the company's board. Lim and Wan both are independent directors and will serve on the audit, compensation and corporate governance and nominating committees. Wan is a former partner of PricewaterhouseCoopers and is a Hong Kong-based CPA. Lim is VP of finance of the Venetian Macao-Resort-Hotel.