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Aethlon to start 1st human study of Hemopurifier for HIV/AIDS

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Since 2001 **Aethlon Medical** (San Diego) has bannered its Hemopurifier as potentially the first device that could be used to treat HIV infection. Now, seven years later, the company is on the brink of turning that potential into reality as it plans to initiate the first-in-man clinical study of the device to treat HIV.

The Aethlon Hemopurifier is created to provide real-time therapeutic filtration of infectious viruses and immunosuppressive proteins. According to the company, the Hemopurifier holds promise to extend the lives of AIDS patients by removing HIV strains that cause drug failure and reducing the presence of viral proteins that kill off immune cells. The clinical study was approved by the Institutional Ethics Committee at the **Jattinder Gambhir Hospital** (J.G. Hospital; Punjab, India) and is expected to begin in September.

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Questionnaire, blood test offer early detection of ovarian cancer

By OMAR FORD

Medical Device Daily Staff Writer

Initial results of a new pilot study show that four symptoms, combined with the CA125 blood test, can greatly improve the early detection of ovarian cancer by 20%.

The study was conducted by researchers at **Fred Hutchinson Cancer Research Center** (Seattle) and published this week online in *Cancer*.

Research has found that when used alone, the CA125 ovarian-cancer blood test and a simple four-question, symptom-screening questionnaire asking if abdominal or pelvic pain, difficulty eating or feeling full quickly and abdominal bloating are present, each detect about 60% of women with early-stage ovarian cancer and 80% of those with late-stage disease.

The study found that when used together, the questionnaire and blood test may boost early detection rates

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Report from Europe

French health minister hails Varian radiotherapy system

By JOHN BROSKY

Medical Device Daily European Editor and Staff Reports

Finally some good news in radiotherapy for French Health Minister Roselyne Bachelot.

With the first year of her administration marked by revelations of thousands of patients burned by radiotherapy (*Medical Device Daily*, Dec. 14, 2007), Bachelot went out of her way to lead the inauguration of an advanced image-guided radiotherapy suite installed at the **Georges-François Leclerc Cancer Center** (Dijon, France) recently.

In addition to standard radiation therapies, the Trilogy linear accelerator from **Varian Medical Systems** (Palo Alto, California) offers stereotactic radiosurgery as an alternative treatment for cancers that are either inoperable or can not be treated by chemotherapies.

Combining conventional and stereotactic therapies in a single unit with on-board imaging to plan and guide

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MDD's State of the Industry book offers sector overview

The latest version of our annual overview of the med-tech industry, the *Medical Device Daily State of the Industry Report 2008*, is now available.

The book, which totals just over 500 pages, includes an introductory section featuring chapters dealing with regulatory, legislative and executive branch actions affecting the industry, along with looks at the most significant dealmaking and financing activities of the past year.

Those are followed by the heart of our look at this industry – just under 300 pages devoted to 15 chapters ranging from “Biomaterials” to “Women’s Health.” In those sections, we take a broad look at some of the key companies and developments shaping particular segments.

To obtain your copy of this important report, call MDD's customer service representatives at 1-800-688-2421 or 1-404-262-5476.

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*Washington roundup***GAO, CMS butt heads over providers' unpaid tax debts**By **MARK McCARTY****Medical Device Daily Washington Editor**

Mark Twain is credited with having said that he would never use profanity "except in discussing house rent and taxes." If a recent report by the Government Accountability Office is any indication, he has a lot of company among healthcare providers, given that the June 13 posting at the GAO web site shows that Medicare providers are not always in a hurry to pay taxes.

On the other hand, the Centers for Medicare & Medicaid Services has a few problems with some of the math used by GAO.

According to the GAO report, an audit of 2006 data of more than 27,000 providers disclosed that those providers owed Uncle Sam more than \$2 billion. That figure is up substantially from an earlier report filed by GAO, which indicated a tax debt of better than \$1 billion owed by roughly 21,000 providers (*Medical Device Daily*, March 23, 2007). As was the case last year, CMS at present has no policy for mandating that Medicare providers be screened via public records for unpaid taxes. Providers are also not required to allow CMS to inquire with IRS about unpaid debts.

Among the more egregious cases is that of a nursing home that took in \$7 million in Medicare monies in 2006, but owes the federal government \$13 million. GAO says that the company "has a history of not paying all payroll taxes owed since the early 2000s" and that the company was the subject of an IRS investigation into offshore accounts.

Part of the full report was a copy of a May 19 letter signed by IRS commissioner Douglas Shulman, which states that the agency is able to provide CMS with the relevant data upon request, but also noted that the two agencies will roll out a pilot program in October that will chan-

Today's MDD food for med-tech thought

"What we're trying to do is mimic the natural immune response of clearing infectious viruses and toxins before cells and organs can be infected."

— James Joyce, CEO/chairman of Aethlon Medical, discussing the initiation of a first-in-man study in India of the company's Hemopurifier device for the treatment of HIV/AIDS, "Aethlon to start first human study of Hemopurifier for HIV/AIDS," pp. 1, 6.

nel some portion of payments to fee-for-service providers to the IRS for payment of tax liabilities under the federal levy payment program (FPLP).

In a May 29 letter, acting CMS administrator Kerry Weems reiterates the point that IRS cannot disclose tax liabilities without the provider's consent and acknowledges that CMS has no policy for checking for tax liens levied against a provider.

However, Weems takes exception to some of the GAO report. He says that the GAO report "suggests that CMS has not incorporated most of its debt into the FPLP since the passage of the Taxpayer Relief Act of 1997," which authorized the program. Weems rebuttal is that at present, "more than \$11 billion in payments per month are subject to the FPLP, representing 30% of Medicare monthly payments." This ratio will rise to 60% with the commencement of the Healthcare Integrated General Ledger Accounting System (HIGLAS), which Weems says will replace the 75 different accounting systems that currently make up the agency's accounts payable system.

Weems also says that the GAO calculation that the 27,000 providers make up 6% of all participating Part A and Part B providers does not match up well with the fact that "there are approximately one million Part B providers and suppliers alone," let alone the total when Part A providers are tallied.

After detailing a few other objections, Weems writes
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Grants/contracts**IDC to provide technology to HealthPartners Medical Group****A Medical Device Daily Staff Report**

Imaging Dynamics (IDC; Calgary, Alberta), a developer of digital radiography (DR), reported that **HealthPartners Medical Group** of Indiana and Michigan has purchased IDC's 1600 Plus X-Series DR system.

HealthPartners is a multi-specialty physician group with facilities in Michigan City, Chesterton, LaPorte and Westville, Indiana, and New Buffalo, Michigan. The IDC system will be installed in the group's new orthopedic facility in its Michigan City location.

IDC is collaborating with its regional partner, **RPS Imaging**, on installation and ongoing service of the contract with HealthPartners Medical Group. According to RPS sales rep Kathy White, "Our close working relationship with IDC, consistent success with IDC products, and our combined commitment to service excellence were important factors in winning this account."

Since its inception in 1977, RPS has grown to be the second-largest independent radiology sales and service provider in the Midwest and 12th-largest in the country.

In other grants/contracts news:

- **Swissray International** (East Brunswick, New Jersey) said that it has been awarded purchase orders for several Veterans Affairs medical centers and the Navy base at Balboa, California for their flat panel DR systems.

John Monahan, SVP of strategic accounts for Swissray, said, "We are proud to have been selected by both the U.S. Navy and several VA medical centers to place our digital radiographic systems into their facilities. Their product evaluation process is quality driven and quality is where Swissray DR Systems excel."

Swissray said its DR systems enable the provider to "significantly decrease cost and increase staff efficiency and job satisfaction, while improving the delivery of patient care without expanding space. With our automated positioning system, Swissray's DR solutions offer the fastest patient throughput in the industry at the lowest radiation dose."

- **Intronis Technologies** (Boston), a provider of online data backup, archiving and recovery services, has partnered with **CRC Technologies** (Seattle) to address the need for business continuance in the northwestern health-care market. CRC Technologies provides IT support to professional offices, with a focus on the dental community.

CRC Technologies' interest in Intronis was sparked after hearing from industry colleagues about the company's business model and eSureIT partner enablement program.

"I had heard about Intronis and their partner-centric program from a variety of people while attending several local trade shows," said James Cosgrove, president/CEO of

CRC Technologies. "We were looking to complement our service offerings with an online backup solution and after our due diligence, Intronis and its eSureIT program proved to be the ideal platform to help ensure our customers' business continuance."

By providing partners with the flexibility to refer, resell or rebrand its eSureIT online backup service to suit individual business needs, the Intronis partner program adds value to its partners' bottom line. The partner enablement program also is designed to help its partners move through the certification and training processes quickly and efficiently, while offering a variety of marketing and support tools on the back-end once certified.

Intronis Technologies specializes in data backup, archiving and recovery for the entire range of consumers, SMBs and large enterprises. ■

Washington

Continued from Page 2

that CMS "would like to again acknowledge our appreciation to the GAO for its efforts."

Two-man firm gets warning

Who says the ultra-small device business is dead?

FDA yesterday posted an April 10 warning letter to **Don Tay Industries** (New Berlin, Wisconsin) for deviations from the quality systems regulations in the firm's production of Softy Trode disposable electrocardiogram electrodes. Don Tay is owned and operated by the company president and his father, the founder, and they are the only employees of the company at present.

The warning letter stated that Don Tay had no design history files documenting design controls, validation or risk analysis, and that the company lacked documentation of verification and validation of changes to the company's electrodes.

The agency cited Don Tay for lack of a device master record that describes "specifications for the non-woven fabric component" or testing of that component, and for lack of a quality system for several QSR requirements, including complaint handling and medical device reporting.

The company's president, Jeffrey Arndt, told *Medical Device Daily* that Don Tay is "in the process of sending a response" and that the company is not shipping electrodes at present. However, Arndt said "we're definitely going back into that" as soon as he can get a quality system in place. He said he expects to hear from FDA on the corrections by year's end.

Arndt said "the issues were on bookkeeping and tracking items," and that the company has been making the electrodes "for about 25 years." However, he and his father are not eager to ship to Europe, given the burden of dual certification. "At this time, it's really not a cost effective thing we'd like to get into," he said. ■

*Deals roundup***Tenet selling its interest in Broadlane for \$155 million****A Medical Device Daily Staff Report**

Hospital operator **Tenet Healthcare** (Dallas) reported that it will sell its entire interest in healthcare services company **Broadlane** (also Dallas) to TowerBrook Capital Partners for proceeds of about \$155 million in cash.

The sale is part of a deal for TowerBrook to acquire a majority stake in Broadlane, Tenet said.

Ten percent of the proceeds will be held in escrow and distributed over about six years. Tenet said expects to record a gain on the deal, which will be substantially offset for tax purposes by existing net operating loss carryforwards. The deal is expected to close in 3Q08.

Broadlane originated as the materials management department of Tenet and later became an independent company. Broadlane's senior management team will continue to retain a significant ownership interest in the company.

Dr. Charles Saunders, Broadlane's CEO/chairman, will step down from those positions once the transaction closes and will be succeeded by David Ricker, the company's founder, president/COO.

"Over the past several years, we have successfully grown and diversified Broadlane's business from its roots as a division of Tenet Healthcare," said Saunders. "Having achieved this strategic goal, I will be stepping down upon the closing of the transaction and will be succeeded by David Ricker, who has grown from one of the company's initial founders to become our president/COO. I have full confidence in David's ability to assume the CEO role and lead Broadlane into the future."

"In looking for a new equity partner, we were attracted to TowerBrook's significant expertise in the healthcare industry," said Ricker. "The senior management team is excited to work with TowerBrook to fulfill Broadlane's tremendous growth potential."

Trevor Fetter, Tenet's president/CEO, said, "We have confidence in Broadlane and its management team, and we look forward to continuing a productive and close relationship with Broadlane under its new ownership."

In other dealmaking news, **Trustmark Mutual Holding Co.** (Lake Forest, Illinois) has acquired **Health Contact Partners** (HCP; Wheeling, Illinois), a privately held company specializing in contact and call center services to the healthcare industry. HCP will operate as a stand-alone subsidiary of Trustmark.

Details of the transaction were not disclosed.

Founded in 2001, HCP provides telephonic and live chat services, including a 24/7 nurse line, health and member advocacy, customer service, and disease management enrollment services. In addition, HCP provides online services that include a consumer health portal –

www.healthyliving247.com.

Deb Leong, HCP founder, will remain as president of HCP, reporting to Trustmark executive VP Chris Martin. The company said the acquisition by Trustmark will not impact HCP's current call center operations or clients. ■

*Patent watch***AMO, Alcon in \$40 million cross-licensing accord****A Medical Device Daily Staff Report**

Advanced Medical Optics (AMO; Santa Ana, California) reported that it has entered into a patent cross-licensing agreement with **Alcon** (Huenenberg, Switzerland) relating to lubricious coatings for intraocular lens (IOL) inserters and one-piece IOL haptic designs.

AMO is granting a license to Alcon to AMO's U.S. patent nos. 5,803,925, titled "IOL Insertion Apparatus with Covalently Bonded Lubricant," and 5,716,364, titled "IOL Insertion Apparatus and Method for Making and Using Same," and related foreign patents.

Alcon is granting AMO a license to Alcon's U.S. patent No. 5,716,403, titled "Single Piece Foldable Intraocular Lens," and related foreign patents, insofar as they relate to AMO's newly-launched Tecnis One-Piece Intraocular Lens.

As part of this cross-license agreement, Alcon will make a payment to AMO of \$31 million and AMO will make a payment to Alcon of \$10 million. All other terms of the agreement are confidential.

In addition, Alcon will receive paid-up, non-exclusive, worldwide licenses under two families of patents owned by AMO. The licenses assure Alcon of freedom to operate with respect to the subject AMO patents, relative to the coating systems currently utilized in its Monarch and Acrysert brand IOL insertion devices, as well as any future coating systems of a similar type that Alcon may develop.

AMO expects to receive the net cash proceeds of \$21 million in 2Q08.

In other patent news, **Hyaluron Contract Manufacturing** (HCM; Burlington, Massachusetts) reported the grant of a patent and the registration of a trademark for its proprietary process for aseptic online vacuum filling and online vacuum stoppering of low viscosity liquids in syringes. Bubble-Free Filling enhances product stability for oxygen sensitive compounds where dissolved oxygen negatively impacts solution stability. The process also provides additional assurances of sterility by reducing stopper movement as well as creating an unfavorable environment for the growth of aerobic micro-organisms.

HCM said it was able to develop the Bubble-Free Filling method by re-engineering standard syringe filling equipment and creating a unique fluid handling and transfer process. HCM has another patent pending for a proprietary aseptic processing method for non-destructive testing of container/closure integrity. ■

MED - TECH NEWS AND NOTES

WorldDoc combines with HealthVault

WorldDoc (Las Vegas) reported the integration of its consumer care management systems with Microsoft HealthVault, Microsoft Corp.'s consumer health platform. Now users of WorldDoc's systems will be able to pull data from their personal HealthVault record into WorldDoc's systems, as well as make updates to their HealthVault record from within the WorldDoc system. The enhanced accessibility and portability of health information resulting from this coordination opens new possibilities for improved and personalized health management.

HealthVault is a free, web-based platform designed to put individuals in control of their health data. It helps them collect, store and share health information with family

members and participating health care providers. HealthVault provides a privacy- and security-enhanced foundation that providers of wellness and care management solutions, such as WorldDoc, can connect to in order to synchronize health data. The individual consumer determines what information is stored in the HealthVault record and who is allowed access to that information.

The core component of WorldDoc's consumer care management systems, WorldDoc 24/7, is an interactive personal health management application that assists users to evaluate symptoms, understand their health issues, assess health risks and take steps to decrease those risks.

WorldDoc provides consumer care management systems to health plans, third party administrators and employers.

Navigators Group establishes life science unit

The **Navigators Group** (New York) said that its principal underwriting agency subsidiary, Navigators Management, has established the Life Sciences business unit. This business unit will focus on underwriting specialized property/casualty products for the life sciences industry on a global basis, as well as help to deliver the company's existing portfolio of relevant products.

Christopher Duca, president of the company's Naviga-

tors Pro division, said: "The mapping of the human genome has accelerated drug discovery that is in part driving the growth of the life sciences sector. Navigators has responded to the needs of life science companies and their directors and officers, who face complex management liability exposures, with our breakthrough coverage InNAVation line of products. We are pleased to strengthen our solid market position in the life sciences sector with a complete suite of innovative insurance solutions."

DRS introduced to imaging industry

Diagnostic Radiology Services (DRS; Roseville, California), a provider of a range of tailored consulting services for the diagnostic imaging, radiation oncology fields said that it is introducing its practice to the imaging industry. DRS was created to assist radiology groups, hospitals, publicly traded imaging companies, senior executives of equipment manufacturers and large-scale lending institutions with the development and management of outpatient imaging centers and radiation treatment centers.

DRS was formed to address the changing needs of the imaging and radiology markets and to help providers face recent challenges stemming from the aftermath of the

Deficit Reduction Act of 2005. The tailored services offered by DRS include, among others, development and implementation of initiatives that address revenue opportunities, cost management, workflow processes, technology appropriation and implementation, clinical and service excellence, turn-key management, mergers and acquisitions consulting and due diligence, facility design and construction and financial and business development.

DRS is lead by Steven Renard, an imaging executive who serves as chairman, president/CEO. Renard brings more than 15 years of healthcare experience to the new business, most of which have been spent within the diagnostics imaging arena.

Freedom2 Holdings expands into skin industry

Freedom2 Holdings (Cherry Hill, New Jersey), makers of inks for the purpose of permanent but more easily removable tattoos today announces its expansion into the \$250 billion worldwide skin care industry through the application of the company's Patented Particle Encapsulation Delivery System (PEDS).

PEDS is a patented and patent-pending technology that encapsulates matter, such as pigments, dyes and pharmaceuticals in a biocompatible microscopic polymer bead.

The polymers used allow for different bead size and construction. The biocompatible beads can be erodible (biodegradable) or non-erodible.

The scalable PEDS technology platform uses three methods of encapsulation: single-emulsion solvent evaporation, double-emulsion solvent evaporation, and spray dry solvent evaporation. Freedom-2 has developed pilot-scale processes (up to 100 gram/batch) and is rapidly developing (under ISO 9001:2000 controls) commercial scale capabilities.

Aethlon

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"The Hemopurifier provides a unique strategy to prolong the lives of AIDS patients who are increasingly becoming resistant to their drug regimens," James Joyce, Aethlon's CEO/chairman, said. "In the absence of a curative vaccine, the largest void in HIV care remains a method to slow the proliferation of drug resistant strains produced by the constantly mutating AIDS virus. Clinical validation that the Hemopurifier can fill this void would also establish the opportunity to enhance and extend the benefit of both established and candidate drug therapies."

The J.G. Hospital study will evaluate the treatment effectiveness of the Hemopurifier during single-use treatments lasting up to four hours as well as sustained benefit resulting from intermittent treatments administered thrice weekly during extended treatment periods.

"This is a very crucial study for us . . . we believe we have developed methodologies that will allow real-time therapeutic filtration methods to transcend from dialysis into the disease and cancer world," Joyce told *Medical Device Daily*.

Aethlon introduced the Hemopurifier device seven years ago at the 7th annual National Blood Product Safety Conference in Washington (*Medical Device Daily*, Feb. 9, 2001). The system is a hollow-fiber dialysis cartridge that reduces viral load through the direct physical removal of the HIV in circulation. It is designed for use within an established infrastructure of dialysis machines in hospitals and clinics worldwide.

"What we're trying to do is mimic the natural immune response of clearing infectious viruses and toxins before cells and organs can be infected," Joyce said.

Aethlon says its Hemopurifier provides real-time therapeutic filtration of infectious viruses and immunosuppressive particles, and is positioned to address the treatment of drug and vaccine-resistant viruses. Additionally, the device holds promise in cancer care, as research studies have verified the Hemopurifier is able to capture immunosuppressive particles secreted by tumors, Aethlon noted.

If successful, the first-in-man study would provide Aethlon with an early commercialization opportunity in India, Joyce said, where there are an estimated 5.7 million people living with HIV/AIDS, giving India as an individual country the highest predominance of HIV.

"There is obviously a very significant opportunity both to help people, but at the same time to enroll patients at a level that will allow us to show clinical benefit," Joyce said.

He said it is difficult in the U.S. to find large populations of HIV/AIDS patients who are not already on drug therapy.

"So India certainly offers an opportunity to treat people that are progressing in the disease but who have not yet experienced the use of drug protocols," Joyce said. "We look at this as an opportunity to demonstrate performance without taking into account the use of drugs . . . to see what this can do on its own."

The next step for the company, Joyce said, will be the transition to initiating human studies in the U.S. He said Aethlon has an IDE application on file with FDA related to a safety study that looks very similar to studies the company has been running overseas in India.

Aethlon also reported that two candidates remain to be enrolled and treated to complete human safety studies currently being conducted at the **Fortis Hospital** (Delhi, India). Completion of the study is anticipated, but not required to occur, in advance of the HIV treatment studies to be conducted at the J.G. Hospital. Aethlon previously demonstrated treatment safety of the Hemopurifier in a 24-treatment study conducted at the **Apollo Hospital** (also Delhi).

The Hemopurifier is designed to act both as a stand-alone therapeutic, and as an adjunct treatment to enhance clinical benefit of established therapies.

Earlier this month the company said that the Hemopurifier has proven effective in capturing the reconstructed Spanish Flu of 1918 (1918rv). During *in vitro* testing, high concentrations of 1918rv were rapidly depleted from cell culture fluid when circulated through the device. The Hemopurifier also has demonstrated effectiveness in capturing H5NI avian influenza (bird flu), the company said (*MDD*, June 4, 2008).

Aethlon is conducting studies to support the use of the Hemopurifier as a broad-spectrum treatment countermeasure against bioterror threats, including Smallpox, and Ebola, Marburg, and Lassa hemorrhagic fever. Regulatory and commercialization initiatives in the U.S. are presently focused on bioterror threats, while international initiatives are directed toward naturally evolving pandemic threats, and chronic infectious disease conditions including HIV and hepatitis C. The company said it has submitted an IDE to FDA to advance Hemopurifier as a broad-spectrum treatment countermeasure against category "A" bioterror threats. ■

Financings roundup

EpiCept aims to get \$1.9M in offering of about 8M shares

A Medical Device Daily Staff Report

EpiCept (Englewood Cliffs, New Jersey) reported the pricing of a public offering of about 8 million shares of its common stock for 25 cents a share and five-year warrants to buy up to roughly 8 million shares of common stock at 39 cents a share. EpiCept will receive roughly \$1.9 million in net proceeds from the offering.

The company said it would use the proceeds to meet its working capital needs and general corporate purposes through July and to pay certain fees owed to its senior secured lender. Rodman & Renshaw, a subsidiary of Rodman & Renshaw Capital Group, acted as the exclusive placement agent for the offering.

EpiCept says it is focused on unmet needs in the treat-
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Ovarian

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to more than 80% and late-stage detection rates to more than 95%.

"The results are highly encouraging," Robyn Andersen, PhD, an associate member of the Public Health Sciences Division at the Hutchinson Center and lead author of the study, told *Medical Device Daily*. "Cure rates for those diagnosed when the disease is confined to the ovary are approximately 70% to 90%. However, more than 70% of women with ovarian cancer are diagnosed with advanced-stage disease, when the survival rate is only 20% to 30%."

Andersen and other researchers administered the symptom questionnaire to 75 women about to undergo surgery for pelvic masses who were later diagnosed with ovarian cancer (the case group), and 254 healthy women at high risk for ovarian cancer due to a family history of the disease (the control, or comparison, group).

The cases were recruited through Pacific Gynecology Specialists at **Swedish Medical Center** (Seattle) and the controls were recruited through the Ovarian Cancer Early Detection Study, a joint project of the Hutchinson Center and the **Marsha Rivkin Center for Ovarian Cancer Research** (also Seattle).

Initially the questionnaire had 22 symptoms, which included fatigue. But the focus was significantly narrowed to four symptoms after many women with ovarian cancer reported exhibiting these four main symptoms the most.

"This research suggests that if a woman has one or more symptoms that are new for her, having begun within the past year, and if the symptoms happen nearly daily or at least 12 times a month, that may well be a signal to go in and discuss those symptoms with her doctor," Andersen said. "It's probably not going to be ovarian cancer, just as most breast lumps are not breast cancer, but it's still a sign that it might be worth checking with her doctor to see if a CA125 blood test and transvaginal ultrasound may be appropriate."

She stressed that just the CA125 blood test isn't very reliable for pre-cancer detection and to fill out the complete pre-cancer detection picture the questionnaire was needed.

CA-125, cancer antigen-125, is a protein that is found at levels in most ovarian cancer cells that are elevated compared to normal cells. CA-125 is produced on the surface of cells and is released in the blood stream.

The symptom-screening index was developed in 2006 by paper co-author Barbara Goff, MD, professor and director of gynecologic oncology at the **University of Washington School of Medicine** (Seattle).

Researchers are now looking toward a clinical study with 4,000 patients.

"If the results of this pilot study replicate in the clinical study, then we would look at a randomized trial," Andersen told *MDD*. "If the findings were positive then ultimately this

questionnaire coupled with the CA-125 test could become the standard testing procedure for identifying ovarian cancer in women."

She added, "In the immediate future the blood test and questionnaire could be used for patients with a high risk of ovarian cancer."

Assessing the symptoms included in the symptom-screening index may already be done by some doctors based on a consensus statement issued last year by the National Institutes of Health. The researchers hope their symptom index will help doctors know which among their patients who complain of symptoms such as abdominal swelling and pelvic pain might have cancer.

Ovarian cancer is the fifth-leading cause of cancer deaths in women, the leading cause of death from gynecological malignancy and the second-most-commonly-diagnosed gynecologic malignancy.

Because ovarian cancer is so hard to detect initially, it often isn't caught until months after it has moved into advanced stages, significantly reducing patient survival.

"And those months are months wasted for ovarian cancer treatments," Andersen said. ■

Financings

Continued from Page 6

ment of pain and cancer. The company's portfolio of pharmaceutical product candidates, includes several pain therapies in clinical development and a lead oncology compound for acute myeloid leukemia with demonstrated efficacy in a Phase III trial. In addition, EpiCept's ASAP technology, a proprietary live cell high-throughput caspase-3 screening technology, is designed to efficiently identify new cancer drug candidates and molecular targets that selectively induce apoptosis in cancer cells. Two oncology drug candidates currently in clinical development that were discovered using this technology have also been shown to act as vascular disruption agents in a variety of solid tumors.

In other financing activity, **CardioNet** (Conshohocken, Pennsylvania), a wireless med-tech company with an initial focus on the diagnosis and monitoring of cardiac arrhythmias, said it has filed a resale registration statement with the Securities and Exchange Commission related to the shares that were underlying the convertible preferred stock issued in March 2007. The shares being registered remain subject to lock-up agreements entered into in connection with CardioNet's IPO, pursuant to which the holders have agreed not to sell such shares until at least Sept. 15 of this year, the company said.

CardioNet provides ambulatory, continuous, real-time outpatient management solutions for monitoring relevant and timely clinical information regarding an individual's health. CardioNet's initial efforts are focused on the diagnosis and monitoring of cardiac arrhythmias with a solution that it markets as the CardioNet system. ■

Europe

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dosage, Varian positions Trilogy as a versatile and high-throughput radiotherapy system.

Radiotherapies to be offered at the Dijon clinic include intensity-modulated radiotherapy treatments (IMRT), image-guided radiotherapy (IGRT) and whole-body stereotactic radiosurgery (SRS).

Professor Philippe Maingon, head of radiation oncology at the Dijon center, said the first application for the new Trilogy unit will be prostate cancer treatments using the system's advanced cone-beam CT imaging capabilities to validate the accuracy of patient set-up positioning prior to treatment in a dose-escalation program.

Five prostate cancer patients died and another 495 were severely burned in radiotherapy administered by technicians who had tampered with the settings at **Jean-Monnet Hospital** in Epinal, which is within the 200-kilometer service area of the Dijon clinic.

The Dijon clinic also will participate in a national clinical research trial involving hypo-fractionated stereotactic treatment of lung tumors.

Steerable pill camera demonstrated

Pill cameras are proven diagnostic tools for the colon and points south in the body, where the capsule moves slowly through the natural digestive processes, sending images at the rate of two frames per second for several hours.

But because the capsule passes through the esophagus in less than five seconds and the 5-gram imaging device drops quickly to the bottom of the stomach, pill cameras have been impractical for reliable images of affected tissue in these regions.

The first control system for a camera pill, using a hand-held magnet the size of a bar of chocolate, has been developed through a research collaboration led by the **Fraunhofer Institute for Biomedical Engineering** (Sankt Ingbert, Germany) and involving **Given Imaging** (Yokneam, Israel), **Israelite Hospital** (Hamburg, Germany) and **Royal Imperial College** (London).

The physician holds the magnet during the examination, moving it up or down and the camera capsule follows the motion precisely, according to Dr. Frank Volke of the Fraunhofer Institute.

The prototype of the steerable camera pill passed its first practical test in the human body in early June with the researchers conducting a "self-experiment" demonstrating the camera can be held in the esophagus for almost 10 minutes, even when the patient was sitting upright.

"In the future, doctors will be able to stop the camera in the esophagus, move it up and down and turn it, and thus adjust the angle of the camera as required," said Volke. "This allows them to make a precise examination of the junction between the esophagus and the stomach and we can even scan the stomach walls."

CE mark for GTX bare-metal stent

Global Therapeutics (Broomfield, Colorado), the cardiology unit of **Cook Medical** (Spencer, Indiana), has received CE-mark approval for a new cobalt chromium bare-metal coronary stent that the company believes will fill a demand for non-drug-eluting coronary stents among interventional cardiologists.

The Global Therapeutics GTX Coronary Stent System is available immediately in the European Union.

"Ever since the issue of late-stage thrombosis associated with drug-eluting coronary stents (DECS) came to light, interventional cardiologists have been re-examining the valuable role bare metal stents can play in treating coronary artery disease in many patients," said Joe Horn, president of Global Therapeutics.

He added, "Not only do our bare-metal stents eliminate the concerns associated with potential delayed reactions from DES in certain coronary patients, our bare-metal cobalt chromium stent has advanced features designed to improve clinical performance of BMS in coronary arteries."

Horn said the GTX stent has been engineered to eliminate such technical challenges, as recoil, stent balloon retention and stent spring-back – all of which have been associated with earlier cobalt chromium stent designs currently on the market.

Global Therapeutics also is developing a DES technology using the GTX platform and an improved application of antisense gene therapy — developed by its partner, **AVI BioPharma** (Corvallis, Oregon) — to inhibit the proliferation of a gene known to induce the restenosis process.

The clinical trial for that stent is expected to begin in Europe in 3Q08.

MarrowXpress System gets CE mark

ThermoGenesis (Rancho Cordova, California), a supplier of products and services to process and store adult stem cells, said its European Notified Body, TUV, has issued CE-mark certification to the company for the MarrowXpress (MXP) system.

The MXP device is used to process bone marrow in a laboratory setting.

The MXP is a derivative of the company's approved AutoXpress (AXP) Platform, which is used to volume reduce and collect stem cells from umbilical cord blood. Earlier in June, ThermoGenesis reported that it had submitted a 510(k) pre-market approval application to the FDA seeking regulatory clearance in the U.S.

"We have had very encouraging feedback from a number of European centers at which bone marrow clinical trials are either underway or planned. With this approval, we can now ramp up those discussions and initiate a formal launch for the MXP in Europe," said CEO William Osgood. ■

PRODUCT BRIEFS

- **Octagon Research Solutions** (Wayne, Pennsylvania) reported the introduction of a new service offering, CheckPoint. This service provides over 300 separate validation checks of electronic clinical study data to ensure compliance with the CDISC SDTM. CheckPoint is a three-tiered offering that enables clients to choose basic validation services, which include the same 105 validation checks that the agency runs once submission data is received, and also includes an additional four checks for JANUS. Enhanced validation includes the basic checks plus an additional 200 checks that confirm SDTM compliance. These checks have been developed as a result of Octagon's extensive experience converting over 250 studies and 3,500 datasets to SDTM-compliant format.

- **Orfit Industries America** (Jericho, New York) reported the expansion of its North American operations to give hospital-based and freestanding cancer centers faster access to their high-precision patient immobilization systems, which use Efficast thermoplastic masks. Efficast head, neck, and shoulder masks feature a thermoplastic anchored with multiple, independent fixation points. This design offers stability, reducing movement to less than 2 mm for improved treatment accuracy. The silky, non-stick material enhances patient comfort, ensures an excellent skin sparing effect, while providing high-precision immobilization. Orfit makes thermoplastic materials for the physical rehabilitation (splinting)

Enrollment ends in firm's M6-C cervical disk study

A Medical Device Daily Staff Report

Spinal Kinetics (Sunnyvale, California), a maker of artificial disc technology, said that it has successfully completed patient enrollment in its M6-C artificial cervical disc U.S. feasibility study.

A total of 30 patients, with either single- or two-level degenerative disc disease, were implanted with the M6-C cervical disc.

The M6-C is the company's first motion preservation product to treat degenerative diseases of the spine. The M6-C is an artificial disc designed to replace an intervertebral disc damaged by cervical disc degeneration.

The disc's compressible polymer nucleus is designed to simulate the function of the native nucleus, while the surrounding multi-layer, high-tensile-strength fiber annulus is intended to facilitate a controlled range of motion in multiple directions.

The M6-C is implanted with surgical instrumentation that was designed with surgeon feedback.

"Overall, we were extremely pleased with the intra-operative performance of the M6-C cervical disc, as well as the simplicity and ease of implanting the device during the study," said Thomas Dimmig, MD, principal study investigator from **Triangle Orthopedic Associates** (Durham, North Carolina).

and technical orthopedics (orthoses, prosthetic sockets) markets.

PEOPLE IN PLACES

- Yi Zhu was named clinical research manager for **ACR Image Metrix** (Philadelphia). Previously, Zhu led global trial initiation with Sanofi Aventis. ACR Image Metrix is a research unit of the American College of Radiology.

- Brian Jaffee was named executive VP of marketing for **AFP Imaging** (Elmsford, New York). Jaffee previously was senior VP of marketing for Suni Medical Imaging. AFP Imaging is a diagnostic supplier for dental, medical and veterinary professionals.

- **Bausch & Lomb** (Rochester, New York) has named Joseph Barr, OD, as VP of global clinical & medical affairs and professional services, vision care. Barr joined B&L in July 2007 as VP of global research and development, vision care. Bausch & Lomb is an eye health company.

- Hans de Haan, MD, PhD, has joined **Bio-Path Holdings** (Houston) as medical officer. Most recently, de Haan was medical director for Pharmion. Bio-Path Holdings is a

drug-development biotech.

- Michael Cooreman, MD, was named VP of transitional medicine at **Ikaria Holdings** (Clinton, New Jersey). He most recently was a senior translational medicine expert, autoimmune diseases and transplantation, exploratory clinical development at Novartis. Ikaria Holdings is a critical care biotherapeutics company.

- **Quality Systems** (Irvine, California) reported that President/CEO Lou Silverman has resigned, effective Aug. 16. The company said it anticipates having a replacement in place before Silverman's departure. Quality Systems and its NextGen Healthcare Information systems subsidiary make computer-based practice management, patient records, and connectivity and other applications and services for medical and dental group practices.

- **Thomas Weisel Partners Group** (San Francisco) reported the hiring of Jason Moran and Ralph Sutton as managing directors focused on the healthcare sector. Moran previously was managing director at Piper Jaffray & Co., while Sutton was a managing director at Bear Stearns. Thomas Weisel Partners Group is an investment bank focused on growth sectors of the economy.