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FDA ADVISORY COMMITTEE

Watchman wins at advisory, but post-approval issues lurk

Mark McCarty, Washington Editor

GAITHERSBURG, Maryland — **Boston Scientific** (BSX; Natick, Massachusetts) scored a resounding 13-1 victory in the second advisory panel for the Watchman left atrial appendage closure device in a hearing that drew 10 respondents for the open public hearing. The vote came with a strong recommendation for a heftier post-approval study recommendation than the firm had proposed, which was a single-arm, five-year study of 1,000 existing and new patients. The big question is whether the company will have to foot the bill for a post-approval study and participate in the build-out of a registry.

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REPORT FROM EUROPE

St. Jude's 25 mm Portico valve approved in Europe for TAVR

Staff Report

St. Jude (St. Paul, Minnesota) has received European CE mark approval for its 25 mm Portico transcatheter aortic heart valve implantation system. The approval expands the number of patients who can be treated using the Portico heart valve during transcatheter aortic valve replacement (TAVR) procedures. TAVR is an option for patients with symptomatic severe aortic stenosis (a narrowing of the aortic heart valve that obstructs blood flow from the heart). These patients are considered high-risk for conventional open-heart valve replacement surgery.

Made of bovine pericardial tissue attached to a self-

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Cook initiates its study for Evolution Esophageal stent

Omar Ford, Staff Writer

Cook Medical (Bloomington, Indiana) is aiming toward getting its metal removable stent approval in the U.S. The firm took tremendous steps in achieving this goal when it reported that it has initiated a clinical study to evaluate the removability of its new Evolution Esophageal fully covered stent. The stent design used in the study has been modified to accommodate retrieval. The study will also evaluate the use of the device in esophageal conditions, including strictures, fistulas, perforations or leaks.

The company said that the Evolution Esophageal study will be conducted at up to 15 sites across the U.S. and will enroll 130 patients. Patients will be followed for the duration of stent

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New residency program requirements create opportunities for companies

Ronald Trahan, Contributing Writer

The Physician Payments Sunshine Act (Sunshine Act) requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals. So, how can med-tech companies win the hearts and minds of potential customers without breaking the law? Here's one idea.

On the third Friday of every March approximately 30,000 newly 'white coated' medical school graduates are matched to their residencies. 'The Match' is highly competitive in desired specialties such as orthopedics, surprisingly subjective, and determines the formative 5-6 years of a doctor's career. These

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INSIDE

FINANCINGS ROUNDUP

Avinger reports completion of 'signifcant' new financing round

Staff Report

Avinger (Redwood City, California) producer of therapeutic devices incorporating intravascular imaging and pioneer of the lumivascular approach to treating vascular disease, reported the closing of what it said is a "significant funding round." Both new as well as existing investors participated in the financing.

"This funding represents an additional important milestone for Avinger, and brings us another step closer to a life-long dream of mine to provide practitioners with the first-ever image-guided atherectomy device, helping the millions of patients suffering from PAD"

"We are very pleased with the outcome of this recent capital raise, to support what we anticipate to be a very successful clinical trial of Pantheris, the first-ever peripheral atherectomy catheter that also incorporates intravascular imaging technology using Optical Coherence Tomography (OCT)," said Kenneth Novack, chairman of Avinger's board. "We are increasingly confident that Avinger's Lumivascular Platform is well positioned to radically change the treatment of vascular disease.

"This funding represents an additional important milestone for Avinger, and brings us another step closer to a life-long dream of mine to provide practitioners with the first-ever image-guided atherectomy device, helping the millions of patients suffering from PAD, " said Dr. John Simpson, CEO/founder of Avinger.

In conjunction with the financing Avinger has added three individuals to its board of directors. They are: James Muzzy, co-founder of PIMCO, John Delfino, president of Concorde Capital, and Donald Lucas, founder of Lucas Venture Group.

Avinger's global product portfolio has helped physicians treat more than 15,000 patients suffering from PAD. Often dismissed as normal signs of aging, symptoms of PAD include painful cramping, numbness, or discoloration in the legs or feet. Hospitalization costs of PAD alone are estimated to exceed $21 billion annually, largely due to late detection and patients experiencing a decreased quality of life from invasive bypass surgery or amputation. To learn more about PAD, visit http://avinger.com/patients.

Avinger seeks to radically change the treatment of vascular disease through the development of new technology and a new approach called lumivascular (lumi = light, vascular = artery). Lumivascular procedures use an interventional catheter system that incorporates light-based, radiation-free, intravascular imaging technology within the actual therapeutic device. This provides physicians with live, real-time, video-rate images of the inside of an artery during treatment, offering a variety of benefits for patients, physicians and hospitals. Ocelot, the first line of devices using lumivascular technology, has been commercially available since late 2012. This system is used to open totally occluded arteries in the legs.

In other financings news:

▪ **Thoratec** (Pleasanton, California) revealed that its board authorized the repurchase of up to $200 million of the company's common stock till 2015 as its prior repurchase authorization will expire at the end of this year. However, following the announcement, shares of the company slipped 1.1% to $38.

The previous share repurchase program was initiated on Nov 26, 2012, when the board of directors authorized the repurchase of shares worth up to $150 million. At that time, THOR entered into an Accelerated Share Repurchase with an investment bank and agreed to repurchase $75.0 million of its common stock.

In the third quarter of 2013, Thoratec again entered into an

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AGREEMENTS/CONTRACTS

Tissue Regenix to distribute dCELL in new U.S. markets

Staff Report

Tissue Regenix Group (York, UK) has signed seven independent regional sales distribution agreements in the U.S. The regional distributors' represent more than 40 sales representatives that will actively promote DermaPure, Tissue Regenix's dCELL human dermis into acute care hospitals, Veteran Affairs (VA) Hospitals and institutions as well as Long Term Acute Care hospitals (LTACs) in the U.S.

With the aim of targeting all the states within the U.S., Tissue Regenix intends to sign further distribution agreements to ensure sales coverage exists in all U.S. metropolitan areas by the end 2014. DermaPure also remains on course for its commercial launch in the U.S. during the first three months of 2014.

The distribution agreements will now allow Tissue Regenix to promote DermaPure in the following states: Alaska, Washington, Oregon, Idaho, Utah, Montana, New Mexico, Arizona, Minnesota, North Dakota, South Dakota, Wisconsin, Illinois, Texas, Pennsylvania, New York, Maryland, New Jersey, Delaware, Massachusetts, Connecticut, Rhode Island, Vermont, Maine and New Hampshire.

Tissue Regenix's DermaPure works by taking human donor skin and removing the DNA and cells, using the patented dCELL process to leave a natural biological scaffold that can be placed in the wound to aid natural healing by attracting the patient's own cells to the wound area.

A recently completed trial in the UK by NHS Blood and Transplant with the University Hospital of South Manchester has shown that patients who have had chronic wounds for an average of 4.5 years and who were treated with a single application of Tissue Regenix' DermaPure have seen an 87% reduction in the size of all wounds, while 60% of patients were completely healed, with virtually no recurrences.

Greg Bila, president of Tissue Regenix Wound Care said, "We are delighted to have signed these seven regional distribution agreements, allowing us to dispense DermaPure to 25 states in the U.S. These agreements allow us to launch our institutional sales strategy, and we are working hard with the distributors to bring the product to market. With a significant distribution footprint now in place across the U.S., we remain steadily on course for the North American commercial launch of DermaPure in 2014."

Tissue Regenix is a medical devices company in the field of regenerative medicine. The company's decellularization (dCELL) technology removes DNA and other cellular material from animal and human tissue leaving an acellular tissue scaffold which is not rejected by the patient's body which can then be used to repair diseased or worn out body parts. The potential applications of this process are diverse and address many critical clinical needs such as vascular disease, heart valve replacement and knee repair.

In other agreements/contracts news, **Median Technologies** (Sophia Antipolis, France), a medical imaging software solutions developer and a service provider for image interpretation and management in oncology clinical trials, has been selected to provide imaging solutions and services in a new phase II clinical trial for Non-Small Cell Lung Cancer. The study is sponsored by a major global biopharmaceutical company.

Within the framework of the project, imaging data will be acquired from 20 clinical sites worldwide. Anticipated total enrollment is 50 patients with a forecasted start date early 2014. Median will provide on-site reading services based on the deployment of its Median LMS – Lesion Management Solutions – application software. Median LMS is a suite of software modules for the automated detection, quantification, and tracking of tumors in 3D medical images. It provides unique features for the review of images and quantitative assessment of response to therapy in clinical trials. Within the frame of the trial, response evaluation to therapy will be assessed using RECIST criteria and tumor volume growth, an advanced imaging biomarker. Median will also supply a set of services including clinical site training, as well as collection and quality control of image interpretations performed by the sites involved in the study. //

PEOPLE IN PLACES

• **Alere** (Waltham, Massachusetts) has named Regina Benjamin, MD, to the company's board. From 2009-2013, Benjamin served as the 18th Surgeon General of the U.S. and chair of the National Prevention Council – 17 cabinet-level Federal agencies that developed the road map for the Nation's health – the National Prevention Strategy. Alere makes new capabilities in near-patient diagnosis, monitoring and health information technology.

• The **Diabetes Research Institute Foundation** (DRIF; Hollywood, Florida) has named Joshua Rednik as its new president/CEO effective Jan. 6, 2014. Rednik recently served for nearly six years as executive director of The Jewish Community Foundation of Greater MetroWest in Whippany, New Jersey. The Diabetes Research Institute Foundation's mission is to provide the Diabetes Research Institute with the funding necessary to cure diabetes.

CLARIFICATION

In the 12/6 issue of *Medical Device Daily*, we inadvertently gave the wrong name of the new Edwards Lifesciences CFO. The company has named Scott Ullem as corporate VP/CFO. We regret the error.

DEALS ROUNDUP

Centene acquires majority Interest in U.S. Medical Management

Staff Report

Centene (St. Louis) reported that it has signed a definitive agreement to purchase a majority interest in **U.S. Medical Management** (USMM; Troy, Michigan), a management services organization and provider of in-home health services for high acuity populations, for about $200 million.

USMM provides a continuum of in-home services including primary care, health risk assessments, home health, hospice, podiatry, radiology, DME, lab and pharmacy, the company noted. Centene said the investment underlines its commitment to provide integrated care for the aged, blind and disabled (ABD), long-term care (LTC), dual–eligible, and Medicare populations. Centene will acquire about a 68% interest in USMM. Mark Mitchell, the company's founder/CEO, will continue to lead USMM and retain his existing management team.

"The partnership with USMM is the next step in Centene's strategy to provide a continuum of high quality services that allow us to effectively manage the complex needs of our growing high acuity populations. The integrated, home-based primary care model is a capability expansion for Centene. This will allow us to offer quality healthcare services and programs for an aging population in the comfort of their own homes," said Michael Neidorff, chairman/CEO of Centene. "We believe that there is significant opportunity to enhance access to health services and quality of life for complex populations by removing barriers to receiving care in the home. We are pleased to partner with USMM to assist in the build out of a national platform that will improve quality and reduce medical costs for Centene and USMM's other managed care partners."

In conjunction with the investment in USMM, Centene is announcing the formation of a new healthcare enterprise holding company. This new independent enterprise will connect Centene and other health solution providers while preserving the entrepreneurial spirit and innovation which has led to improved health outcomes, development of a more efficient care model and the facilitation of sales to third party companies.

The transaction is expected to close in the first quarter of 2014, subject to customary closing conditions.

In other dealmaking activity, **Kindred Healthcare** (Louisville, Kentucky) has acquired real estate associated with seven leased nursing centers from **HCP** (Long Beach, California) for about $61 million.

The company previously agreed to acquire the real estate associated with two other nursing centers from HCP. The company expects to close on the acquisition of those two properties in the first quarter of 2014, subject to customary conditions to closing. The annual lease payments for the seven nursing centers and the two under contract are nearly $9 million. Kindred anticipates that the transactions with HCP will be slightly accretive to earnings in 2014. //

GRANTS ROUNDUP

ZetrOZ gets NIH support for osteoarthritis study

Staff Report

ZetrOZ (Trumbull, Connecticut) has been awarded a Phase I Small Business Innovation Research (SBIR) grant totaling $397,000 from The National Institute on Minority Health and Health Disparities of the U.S. National Institutes of Health to evaluate the effectiveness of its long-duration wearable ultrasound therapy technology for pain management in osteoarthritis. The milestones of the project include refinement of the device for the treatment of knee osteoarthritis and clinical evaluation of daily treatment to improve patient quality of life and alleviate arthritis pain. Preliminary studies conducted by the investigative team suggest that daily wearable ultrasound treatment provides an effective non-pharmaceutical approach to arthritis pain management.

According to George Lewis, Jr, PhD, company chief scientific officer and co-founder, and principal investigator for the grant, the study will be designed to increase scientific understanding of long-duration low-intensity therapeutic ultrasound for the treatment of musculoskeletal pain resulting from osteoarthritis, as well as its impact on mobility and joint stiffness. The U.S. Center for Disease Control and Prevention estimates that 50 million adults in the U.S. have some form of arthritis, and that approximately 1 in 2 people will develop symptomatic knee osteoarthritis in their lifetime. "Persistent pain whether from arthritis or other pain-producing conditions is the number-one reason that patients access the healthcare system, according to the National Institutes of Health," said Lewis. "Pain seriously affects a patient's quality of life. While medications are often the first-line treatment for pain, they're not without side effects such as nausea, stomach pain, diarrhea and drowsiness. The ZetrOZ device does not negatively affect patients in these ways."

For the study, the device will be clinically evaluated on subjects diagnosed with osteoarthritis of the knee. Over the multi-week, outpatient study, patients will be monitored for reductions in pain and joint stiffness, increased mobility, improved quality of life and their use of pharmaceuticals for pain control.

The ZetrOZ ultrasound delivery system relies on aggressive miniaturization and integration of the ultrasound transducer, electronics, and power supply to produce a smaller, low-intensity ultrasound system that can deliver portable, convenient, and effective therapy for long durations. It is currently CE marked and cleared in Europe for sale, and under FDA review for market clearance in the U.S.

ZetrOZ is a medical device maker that provides ultrasound technology. //

FDA

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BSX presented data from three sources; the Protect AF study, a continued access protocol (CAP) for Protect AF patients, and Prevail, a Bayesian-structured study that incorporated data from Protect AF. FDA went out of its way to suggest that advisory committee panelists consider "the totality of the data" in its executive summary released Dec. 10 (*Medical Device Daily,* Dec. 11, 2013) despite that Prevail came up slightly short in one of the three endpoints.

The votes that the data supported a reasonable expectation of both safety and efficacy matched the 13-1 final tally for the vote on whether the benefits outweigh the risks, but the proposed indication for use statement seems up in the air. Panel chairman Clyde Yancey, MD, of **Northwestern University's Feinberg School of Medicine** (Chicago) offered a few cautionary remarks to physicians to close the hearing. Yancey said, "our discipline has shown very little regard for filters, limits and advisories" regarding novel medical technologies, adding that physicians "need to work collaboratively" to deploy the device appropriately. A failure to do so, he said, "would be tragic."

During the open public hearing. Karen Carruth, executive director of the atrial fibrillation patient group **Mended Hearts** (Dallas), said that afib "affects 5 million worldwide," and noted that such patients are five times more likely to experience stroke. She remarked that stroke is "the number one cause of disability in afib patients," and advised the panelists, "it is universally accepted that afib is on the rise."

Some members of the panel were satisfied with BSX's proposal for a post-approval study (PAS), but Bram Zuckerman, MD, chief of the cardiology devices branch at FDA's Office of Device Evaluation, said FDA and the company were "quite far apart" on the PAS question. Michael Slotwiner, MD, of the **Long Island Jewish Medical Center** (New Hyde Park, New York), seemed to up the ante, stating that in his view, a registry should be paired with the PAS. He suggested an effort to get medical societies involved, stating, "I think we need to consider both types of data" to evaluate the device's performance in real-world use.

Among those who seconded the notion of at least a larger PAS was panel chairman Yancey, who noted that the use of novel oral anticoagulants (NOACs) is a contraindication, but that maintaining a barrier to NOAC use with the device in place may be futile. "We should have a much larger sample size" than proposed by the firm, Yancey argued.

Steering a different tack was Jeffrey Borer, MD, of the **Downstate Medical Center** (New York), who remarked, "I think the sponsor's proposal is reasonable," although he said, "the proposed sample size is relatively small" given the objectives. He recommended an enrollment of 2,000 in the PAS, which he said "would get us the data we want to get." He explained, "the new oral anti-coagulants have never been studied with this device," and mused that there are possible adverse interactions in the offing.

Yancey concluded with the observation that the panel collectively believe "it is reasonable for this to be a single-arm study," and said there is "unanimous opinion that the sample size would be larger," with consecutive enrollment and a more representative population.

As has been widely reported, Prevail missed on one of the three co-primary endpoints, which was for both types of stroke, systemic embolism, and both cardiovascular and unexplained death. Yancey made note of "several panel members . . . who harbor ongoing concerns" on this first endpoint even after removing fatalities. He summarized, "we had a mixed response, but the response is largely in favor of the totality of the data," adding, "the totality of the data are persuading the totality of this panel" that the data are acceptable despite a failure to demonstrate non-inferiority on this measure.

FDA hinted at concerns regarding BSX's planned indications for use (IFU) statement (*Medical Device Daily*, Dec. 11, 2013), which BSX had proposed as prevention of thrombus embolism from the left atrial appendage in high-risk patients with non-valvular atrial fibrillation. The proposed indication includes a notation regarding patient eligibility for warfarin therapy, but noted that the risks should outweigh the benefits for this patient population.

During the panel discussions on the IFU predicament, several voiced an interest in a more prescriptive IFU statement, but Yancey said he believed "the amount of editing can be minimal and doesn't have to be totally reconstructive." John Somberg, MD, of **Rush University Medical Center** (Lake Bluff, Illinois) suggested the IFU should state that the patient should have to have been on warfarin for some time, but he said the IFU should also remind that "it's not a casual decision and you really should have a reason not to be on warfarin."

Yancey concluded that the consensus, to the extent that there was one, was that the IFU should "establish they're warfarin eligible, indicate the importance of" the patient's score under the Chads2 scoring system, and a personalized approach "so that it's in keeping with the patient's wishes" regarding lifestyle considerations related to the bleeding issues associated with warfarin.

IS AN LAA CLOSURE REGISTRY ON THE WAY?

The question of whether FDA will push for a registry for left atrial appendage (LAA) devices is technically up in the air, but there are those who believe the agency will insist on it. Michael Mack, MD, of **Baylor Health Systems** (Plano, Texas) is not necessarily sold that FDA will require a registry, but he said any such registry could leverage existing registries in a way to make it more economical than one built from scratch.

Mack, who chairs the committee at the **Society of Thoracic Surgeons** (STS; Chicago) that deals with the TVT registry for

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transcatheter aortic valves, told *Medical Device Daily* the size of an LAA registry would ultimately depend "upon what size of a PAS surveillance study FDA would be interested in" for the Watchman. He noted that the TVT registry, operated jointly by STS and the **American College of Cardiology** (ACC; Washington) "captures all the devices implanted in the U.S."

"Part of the vision of FDA is that device registries would become the de facto PAS and this was the first step" toward that, Mack remarked. He said the TVT registry will be used for the MitraClip by **Abbott Vascular** (Temecula, California) in addition to the **Medtronic** (Minneapolis) CoreValve, whenever it hits the market. The first-to-market Sapien, made by **Edwards Lifesciences** (Irvine, California) is also the first device to appear in the TVT registry.

Mack said he cannot say for certain whether LAA closure devices are part of FDA's plan for a series of comprehensive registries, but said, "I can't imagine they're not envisioning a similar setup." Such a registry "wouldn't be an STS database per se, but it would be in the family of registries" ACC and STS are cobbling together, Mack remarked.

"I think you'll end up seeing a portfolio of society-based clinical registries designed specifically for post-market approval surveillance that will all be nested together," Mack commented, adding, "I see that as an appropriate fit for a device such as this one."

Given the family registry notion, Mack said it may be more economical than a stand-alone registry. "You would hope there would be some economies of scale," if only because of "the infrastructure that's in place for data collection and analysis."

Financing is a question, however, as registries are not inexpensive. Mack said TVT and Intermacs each charge hospitals a $10,000 annual fee for participation. "What makes this work is the national coverage determination that mandates participation," he observed. Device makers benefit "so industry supports the registries to the degree that they receive work value from it," Mack stated.

Mack said he understood that the TVT registry ran up a tab of at least $2 million on the front end, but he noted that 250 sites have signed on, which generates roughly $2.5 million annually. "This is probably the right price [for ongoing financing] at least at this stage of things," he said.

"It will be interesting to see what the ultimate FDA decision is" for the Watchman, Mack commented. He noted that the agency passed in 2009 despite the 7-5 vote for approvability, but predicted a different outcome thanks to the 13-1 vote in affirmation. "With such a strong vote this time I cant see that they won't" approve the device, he said. Still, Mack said, "I think they will clearly mandate a strong post-approval study that will essentially be every device implanted. That's what's happening with the MitraClip," he added, noting that an LAA registry would likely require data for on- and off-label use.

Post-approval studies and registry studies may be functionally converging, suggesting the notion that the two will merge at some point. "That's ultimately FDA's vision," Mack said, stating, "how fast they get there remains to be determined. If you have a robust registry format, then MDR reporting could conceivably go away, and formal PASs go away because you're collecting everything," he said. However, Mack acknowledged this calls for a more exhaustive use of electronic heath records than is currently the case.

Boston Scientific did not respond to contacts for comment on whether the Watchman was the subject of a parallel FDA/CMS review or other coverage/reimbursement matters. //

PRODUCT BRIEFS

• **ICU Medical** (San Clemente, California) said two new studies presented at the American Society of Health-System Pharmacists (ASHP) Midyear Meeting and Exhibition in Orlando demonstrated that the company's newly launched ChemoLock closed system transfer device (CSTD) prevents hazardous drug surface contamination while eliminating leakage and providing a completely dry disconnect. ChemoLock is the first and only needlefree CSTD to receive FDA clearance for pharmacy applications (product code ONB), as well as patient administration applications (product code FPA) and was officially launched this week at the ASHP meeting. The studies, performed by researchers at Nebraska Methodist Hospital and University of Nebraska Medical Center, are the first independent studies to verify the efficacy of the ChemoLock system. ChemoLock is designed to provide a new standard of safety for hazardous drug preparation, transportation, administration and disposal. The system prevents the escape of hazardous drug or vapor concentrations outside the system, blocks the transfer of bacteria and other environmental contaminants into the system, and eliminates needlestick injuries while keeping patients and clinicians safe from hazardous drug exposure. The ChemoLock system consists of easy to use needlefree components that connect with an audible click, cannot be deactivated, and will passively aid in preventing both needlestick injuries and exposure to cytotoxic medications. No complex assembly is required prior to usage and the system remains completely closed throughout the entire safe handling process – including preparation, transportation, administration, and disposal – assuring both patient and caregiver safety as well as the sterility of the prepared medication.

Europe

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expanding stent frame, the Portico valve is the first transcatheter aortic heart valve that can be completely resheathed (the process of bringing the valve back into the delivery catheter), repositioned at the implant site, or retrieved before being released from the delivery system.

"The Portico valve is an important part of our growing portfolio of products that treat valvular disease and heart failure. The approval of this 25 millimeter valve size will allow us to expand our footprint in the global TAVR market and provide a promising solution for patients with severe aortic stenosis," said Frank Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division.

The 25 mm Portico valve supports a patient's native annulus (a ring-shaped supporting structure in the heart) with diameters ranging from 21 mm to 23 mm. With the addition of the 25 mm valve, the Portico platform can now treat patients with an annulus ranging from 19 mm to 23 mm. In 2014, St. Jude expects to add two additional valve sizes to the Portico line, which will expand the eligible range of patients to those with annulus sizes ranging from 19 mm to 27 mm.

During an implant procedure, the Portico valve is delivered through a catheter after a small incision is made to the femoral artery in the leg. Positioned while the patient's heart continues to beat, use of the Portico valve alleviates the use cardiopulmonary bypass, which involves a machine taking over a patients' heart and lung function during surgery.

Aortic stenosis is the most prevalent form of cardiovascular disease in the Western world after hypertension and coronary artery disease, the company noted. Roughly 25% of people 65 and older, have aortic valve thickening and 3% age 75 and older have severe stenosis.

The Portico 23 mm and 25 mm transcatheter aortic heart valves continue to be evaluated in a non-randomized, multi-center study, the Portico TF CE trial.

BIOCARTIS, VIB, IN LICENSE DEAL

Biocartis (Lausanne, Switzerland) and **VIB** (Mechelen, Belgium) reported an exclusive license agreement on a panel of new microsatellite instability (MSI) biomarkers for several cancers, in particular colorectal cancer (CRC). This agreement will enable Biocartis to develop a unique and user-friendly assay, whereby MSI biomarkers can simply and rapidly be detected by Biocartis' molecular diagnostics platform Idylla.

MSI is one of the premier molecular markers in CRC but is also important in ovarian, endometrial and gastric cancers. MSI evolves as a result of inactivation of the DNA mismatch repair (MMR) system and can be found in about 15% of all CRCs.

Biocartis will develop a new CRC assay for MSI biomarker detection. Today, MSI-testing is vastly underused due to the technical complexity of the current laboratory-developed assays, the company noted.

Financial details of the license agreement were not disclosed.

CORMEDIX NEUTROLIN CATHETER LOCK APPROVED IN GERMANY

CorMedix (Bridgewater, New Jersey) reported that it has received approval to sell its Neutrolin catheter lock solution in Germany. The company says it has already received orders from several dialysis centers.

In conjunction with ongoing sales and marketing of Neutrolin in Germany, the company's 2014 strategic plan includes expanding Neutrolin sales into other targeted EU countries and other markets. Additionally, CorMedix will pursue label expansion for Neutrolin beyond its primary indication of hemodialysis, oncology, ICU, total parenteral nutrition and peritoneal dialysis.

The Neutrolin solution, which received CE mark approval as a Class III device, includes the standard of care concentration of an anti-coagulant and a highly potent, very broad-spectrum antimicrobial (antibacterial and antifungal) combination that is active against common microbes including antibiotic-resistant strains and inhibits the formation of biofilm. As a catheter lock solution, Neutrolin was designed to significantly reduce the incidence of catheter related bloodstream infections (CRBIs) as well as maintain catheter patency by inhibiting thrombosis, reducing the need for systemic antibiotics and prolonging central venous catheter life.

EOS INSTALLS SYSTEM AT MVZ

EOS imaging (Paris) reported the installation of its EOS system at the private **Medical Center MVZ Bad Sobernheim**, Germany. Medical Center MVZ Bad Sobernheim doctors specialize in orthopedic surgery, physical and rehabilitative medicine and more generally the medical care of musculo-skeletal pathologies. A section of MVZ specializes in the diagnosis and conservative treatment of spinal deformities, primarily scoliosis.

Marie Meynadier, CEO of EOS imaging, said this is the company's first private EOS imaging installation in Germany. "Conservative treatment of scoliosis with bracing was recently highlighted by a major study as beneficial for patients at risk of progression. Such treatments require frequent monitoring for which EOS provides the right low dose solution," Meynadier said. "We are also eager to help brace manufacturers and technicians design the most efficient bracing solutions based on EOS 3-D information."

SEQUENOM REPORTS LAUNCH OF PRENATAL TEST

Sequenom (San Diego), a life sciences company providing testing and genetic analysis solutions, reported that **Laboratoire Cerba** (St. Ouen L'aumone, France) has launched its validated

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placement up to six months. After endoscopic stent removal, specified patients will have a 30-day follow-up that will complete his or her enrollment.

"The version of the stent that we're doing in the clinical trial is approved in Europe," Angela Wiant, the product manager for the Evolution Esophageal stent, told *Medical Device Daily*. It is CE marked for removability and so that's what we're working on obtaining with this clinical trial. We estimate study enrollment to be completed by the end of 2014 and then we would expect data follow up and enrollment follow up to be completed by 2015."

She added, "We could see some initial study results at some point next year in 2014 or early 2015."

Evolution could appeal to patients suffering from benign strictures.

"A benign stricture could be a couple of examples," Wiant said. "It could come from post radiation. So maybe the patient had radiation therapy to treat the cancer and it caused a stricture in their esophagus so this stent would be placed to allow the esophagus to open up and then be removed once it is open enough for a patient to swallow their food orally. That's one example. In this clinic trial, we're also looking at using this stent for sealing a leak. So there could be a post surgical leak that needs to be sealed off and healed, and then it can be removed once that healing process is complete.

The study, led by Principal Investigator John Vargo MD, MPH and chairman of Gastroenterology and Hepatology at the **Cleveland Clinic**, is a prospective, single-arm study. Patients can be enrolled in the study when they require a stent for an obstruction that is caused by an intrinsic or extrinsic malignancy or a refractory benign esophageal stricture. Also, patients that have an esophageal fistula, perforation or leak can be included in the study. There are additional eligibility criteria for the study.

"Defining the role of removable stents in benign and malignant esophageal disorders is still a quandary for clinicians," said Vargo. "This multicenter study which involves many of the leading centers in therapeutic endoscopy, should help answer this question."

The firm said that it has seen strong uptake of the device in Europe.

"We've seen an increase in the need for a stent that can be removed after placement," Wiant said. "Today there is only one stent cleared in the FDA for removability and it is a plastic stent. [Based on its performance in Europe] we have a fully covered metal stent that offers some advantages clinically to patients that need a stent for just a few weeks. The stent can go and do its job and help the patient and be removed once the stricture area has been resolved. It's a big advantage to patients that currently today do not have a really good option for managing a benign stricture. We do see it performing very well in Europe where its being used today."

"We are very excited to see where this study takes us," said Barry Slowey, global leader of Cook Medical's Endoscopy division. "We hope that the results of this study will allow for some expanded treatment options for malignant and benign esophageal diseases." //

Europe

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noninvasive prenatal test (NIPT) to healthcare providers and patients in France, Belgium, Luxembourg and portions of the Middle East and Africa. Laboratoire Cerba's test utilizes technology licensed from Sequenom to analyze the relative amounts of chromosomes 21, 18 and 13 in cell-free fetal DNA obtained from a maternal blood sample.

"We are excited that Laboratoire Cerba has been able to develop and validate a noninvasive prenatal test using our ground-breaking patented technology," said Dirk van den Boom, executive VP, R&D and CTO, Sequenom. "This is a process that we are able to replicate with other laboratories around the world, and we look forward to continuing to establish meaningful partnerships and drive continued access to our patented technology internationally."

As part of the process of developing its test, Laboratoire Cerba performed its own blinded validation study to confirm the test's accuracy.

"We are pleased to now offer prenatal testing through our network with the use of Sequenom's patented technology," said Sylvie Cado, COO of Laboratoire Cerba. "We are continuously trying to improve our service and offerings for patients and healthcare providers, and we believe our physician customers and the expectant families they work with will be thrilled to have access to this important information in an accurate, safe and efficient method."

Under the license from Sequenom, Laboratoire Cerba has the right to market its noninvasive test in multiple countries, including France, Luxembourg, Belgium, Lebanon, Morocco, Algeria, Tunisia, Libya, Senegal, Ivory Coast, Burkina Faso, and Cameroun. Laboratoire Cerba will process test samples at laboratory facilities in Paris and will also have the option to send samples to Sequenom Laboratories in the U.S. for testing. //

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Residency

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new clinicians-in-training will learn in a different environment than that of their faculty, one characterized not just by high-tech diagnosis, prevention and therapy but also by cost-efficiency, patient-involved multidisciplinary care, and measured outcomes, all desired hallmarks of a newly efficient U.S. healthcare model.

The increasingly diverse skill and temperament sets required for success mean that resident training gets more and more difficult, and that matching the right candidates to a residency program is more and more critical. New tools are needed to select, train and coach young physicians for success.

The Accreditation Council for Graduate Medical Education (ACGME), responsible for setting all guidelines and requirements for residency training programs since 1981, has been anticipating training changes for years. In 2009, recognizing a need for new competencies in the 21st century, it began a multiyear process of examining and updating its accreditation system. With little fanfare, ACGME launched in July 2013 its Next Accreditation System (NAS) www.acgme-nas.org in 7 of its 26 accredited core specialties including Orthopaedics and Neurological Surgery.

Key in the Next Accreditation System is new emphasis on educational outcomes ('competency') that are measured against an extensive new set of Milestones that were determined by a Working Group in each of the 26 accredited core specialties.

Joseph Zuckerman, MD is Chairman of Orthopaedic Surgery at **NYU Langone - Hospital for Joint Diseases**, past president of AAOS, has a well-known passion for orthopedic education and was the long-time Residency Program Director of the highly acclaimed HJD Orthopedic Residency program, which boasts 12 residency positions matched annually. He has written extensively on orthopedic resident training and was one of the NAS Orthopedic Advisory Group that created the orthopedic Milestones just implemented. "A difference with the New Assessment System is that we will be evaluating expertise instead of checking off the required periodic accomplishments on the way to residency completion," Zuckerman told *Medical Device Daily*. "Residents' requirements will be more detailed and specific, right down to needing a specified number of certain procedures types. The idea generally is to make evaluation more objective, less subjective."

Some see NAS as a mixed bag. Steve Paragioudakis, MD, is the Residency Program Director of the Orthopedic Surgery Residency Program at **Monmouth Medical Center** in New Jersey, a program affiliated with The **Drexel University** (Philadelphia) College of Medicine. "While NAS has many great concepts, parts of it are essentially unfunded mandates; we are asked to do more, with less resident hours, on an already stretched budget," Paragioudakis told *MDD*. "Where will the money come from?"

Jeff White believes he knows where the money will come from. "Isn't education one of the very few avenues left for med-techs to ingratiate themselves with their customers in the hope – but, by law, not the promise – of securing more sales? There is a business opportunity here for med-techs, certainly," says White, a 35-year veteran of the surgical and orthopedics industries who is currently an independent advisor to early-stage med-tech companies.

"As U.S. healthcare moves to improve efficiency, implicit is objective reporting of outcomes and accurate measurement of the cost of achieving them. Incentivized (or penalized) by payer directives and increasingly, by their hospital or corporate employers, clinicians are being forced to account for their decisions, actions and outcomes. While this could be seen simply as learning the lessons implemented in corporate America to achieve continuous, measurable improvements in quality and efficiency, it can be a difficult pill for many providers, including residency faculty, to swallow, accustomed as they may be to practicing their 'medicinal art' as they see best. Previously unavailable tools and training – and apparently, funding – are needed to train the next generations of American clinicians," White told *MDD*.

Enter **Residency Select** (Manalapan, New Jersey), a firm whose goal, like that of ACGME's NAS, is to improve the residency training 'product' by injecting measureable, objective 'order' into a subjective, poorly measured experience. But Residency Select has taken the opportunity to another level: in addition to optimizing resident training using proven educational management and scientific methods to help meet the new Milestones, its mantra is "Let's use the same proven methods for selection."

Residency Select uses psychometric testing tools proven extensively in industry to provide objective selection tools for residency programs. The firm is the product of an exclusive partnership between Alan Friedman, entrepreneur and spine industry alumnus, and Hogan Assessment Systems, the prominent behavioral assessment firm used by Fortune 500 firms to predict employee match, performance and fit. One of many talented Synthes executives who departed upon the **Johnson and Johnson** (New Brunswick, New Jersey) merger, Friedman completed his Master's degree in Organizational Psychology at Columbia University where he furthered his interest in organizational behavior. His close ties to several residency programs led him to believe that there were missed opportunities for organizational excellence that could be enhanced with selection and training methods commonly used in business. Residency Select's goal is to enable programs to improve resident success, initially by making sure the correct individuals are in the right position in the first place.

Residency Select's program uses the flagship Hogan Personality Inventory used by many Fortune 500 firms, plus

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Residency

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additional custom assessments to perform the key affective domain evaluation of residency candidates against a profile created by the company and the residency program directors and leaders. The process augments traditional residency candidate selection process with objective, proven and data-driven analysis.

For its part, Hogan is excited to be entering this segment. "Success in the medical field takes not only the proper skills and training, but also the right personality," Hogan Partner and VP of Global Alliances, Ryan Ross, told *MDD*. "The combination of Residency Select's expertise in merging commercial, medical, and resident training with the power of Hogan's personality assessments will better position candidates for success in their residency program."

Residency Select is finalizing its multi-site pilot launch under IRB and has already completed data collection with 280 resident and 167 faculty/subject matter expert surveys from 11 programs. Leading orthopedic programs have signed on to Residency Select's pilot launch including NYU Langone Medical Center Hospital for Joint Diseases, The Cleveland Clinic, Rush University Medical Center, The University of Miami, The University of Maryland, Virginia Commonwealth University, University of California, San Diego, Harbor UCLA and Monmouth Medical Center. "Once the pilot study for Orthopaedics is complete, we already have pilot sites identified within Neurological Surgery, Emergency Medicine and General Surgery and will eventually expand to every medical/surgical specialty," Friedman told *MDD*.

Zuckerman is optimistic about Residency Select's ability to positively impact resident selection. "This pilot program, which NYU's Hospital for Joint Diseases is leading, will give us a nice profile for values and drivers that help make a successful orthopedic resident. I suspect we will find strong correlation between our current resident assessments and their 'fit' as projected by Residency Select. I believe it has great potential to deliver better success by the residents and the residency programs."

Friedman told *MDD* he believes strongly that this is an opportunity for medtech industry companies to offer Residency Select's programs to its customers as value-add components of an overall offering.

"We need this help," Monmouth's Paragioudakis told *MDD*. "Particularly with the NAS mandates we have less time to hold residents' hands so we really need to be sure that we select residents who will be successful in our program. They are all hugely qualified on paper but we lack the skills to evaluate things like ethics, values and other attributes commonly known as 'psychological profile' that are so successfully used by American businesses." //

Financings

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Accelerated Share Repurchase agreement with an investment bank and agreed to repurchase another $40.0 million of its stock under the same program. As of Sep 28, 2013, $35 million worth of shares was available for repurchases under the November 2012 program.

· **Vestagen Technical Textiles** (Orlando, Florida) reported that it raised an additional $7.3 million in an extension of its recent financing round. Existing investor Advent Life Sciences was joined in the extension by new investors Sofinnova HealthQuest Capital and the Clearwell Group. The extension brings the total raised by Vestagen in this financing round to $15.5 million; the company raised $8.25 million earlier this year. In conjunction with the financing extension, Randy Scott, partner at Sofinnova HealthQuest Capital, is joining the Vestagen board.

The company said the additional funds will support expanded commercialization of Vestex, the first in a new class of active barrier protective fabrics for everyday use that are clinically proven to prevent or reduce the acquisition and retention of microbes and other contaminants. Vestex is engineered to have robust liquid repellency and embedded antimicrobial properties, along with enhanced breathability, good durability and affordability. The company's initial focus is on medical scrubs and other protective apparel for healthcare workers, who are at daily risk of exposure to dangerous contaminants and who can unknowingly spread these contaminants to other workers, patients and family members.

Vestagen makes performance textile products and technologies.

· **Physicians Realty Trust** (Milwaukee) reported the completion of its public offering of 9,545,000 common shares of beneficial interest, including 1,245,000 shares issued pursuant to the exercise of an option to purchase additional shares granted to the underwriters to cover over-allotments, at a price to the public of $11.50 per share.

Wunderlich Securities, and KeyBanc Capital Markets served as joint book-running managers for the offering, Oppenheimer & Co. and Janney Montgomery Scott served as co-lead managers for the offering, and Compass Point Research & Trading, J.J.B. Hilliard, W.L. Lyons, and B.C. Ziegler and Co. served as co-managers for the offering.

Physicians Realty Trust is a self-managed healthcare real estate company organized to acquire, selectively develop, own and manage healthcare properties that are leased to physicians, hospitals and healthcare delivery systems. The company invests in real estate that is integral to providing high quality healthcare. The company intends to elect to be taxed as a real estate investment trust (REIT) for U.S. federal income tax purposes. //

DIAGNOSTICS EXTRA

Keeping you up to date on recent developments in diagnostics

By Omar Ford, Staff Writer

Clinical waste may prove valuable for monitoring treatment response in ovarian cancer . . . A microchip-based device developed by **Massachusetts General Hospital** (MGH; Boston) investigators may greatly simplify the monitoring of patients' response to treatment for ovarian cancer – the most lethal form of gynecologic cancer – and certain other malignancies. The team from the MGH Cancer Center and the Center for Systems Biology reports using their device to isolate and identify tumor cells from ascites, an accumulation of fluid in the abdomen that often occurs in abdominal cancers. The *PNAS Early Edition* paper also describes development of a panel of four protein markers to accurately identify ovarian cancer cells in ascites. "We were able to demonstrate that simply squirting small amounts of otherwise discarded ascites fluid into our device allowed us to quantify tumor cells and explore mechanistic markers of tumor progression without the need to process liters of ascites with advanced instrumentation not readily available in many community hospitals," says Cesar Castro, MD, MMSc, MGH Cancer Center and Center for Systems Biology, co-lead author of the PNAS paper. "Moreover, achieving point-of-care readouts of tumor cell markers from repeatedly collected ascites at different time points, could allow for frequent monitoring of treatment response without having to wait for the next imaging scan." The ability to reliably track treatment response essentially lets caregivers know whether a particular anticancer drug should be continued or if another option should be tried. Tumor recurrence begins before metastases become visible on imaging studies, so several options for non-invasive "liquid biopsies" are being investigated, including analysis of circulating tumor cells and other factors found in the blood. Since ovarian cancer metastases are usually confined to the abdominal cavity and ascites commonly form in advanced disease, the research team theorized that ascites fluid could be an alternative, if not better, option than blood for treatment monitoring. Isolation of ascites tumor cells (ATCs) has been challenging, since they constitute less than 1 percent of the cells in ascites fluid. ATCs themselves vary greatly in size, and other fluid contents – inflammatory and blood cells, cells from the abdominal lining and additional debris – often form large clumps that would clog typical microfluidic devices. Along with removing the non-tumor-cell components of ascites fluid, the team also needed a way to accurately identify ovarian cancer cells and analyze their molecular properties. Through a lengthy process that involved laboratory work comparing ovarian cancer cells with benign cells and ascites samples from ovarian cancer patients with those from individuals with noncancerous conditions like cirrhosis, the investigators uncovered a panel of four protein markers that specifically identified ATCs from ovarian cancer patients. They confirmed the accuracy of the panel, called ATCDX, in two separate sample sets, comparing ascites fluid from ovarian cancer patients with either noncancerous fluid or with ascites from patients with other types of cancer.

Swallowing a diagnostic pill . . . A tiny capsule that can carry out a chemical analysis of the contents of one's stomach could identify the presence of so-called "occult" blood at very low levels. The data is automatically broadcast to an external monitoring device for detection of early stage stomach cancer by one's physician. Details of the invention and initial trials are described in a forthcoming issue of the *International Journal of Biomedical Engineering and Technology*. Hongying Liu, Panpan Qiao, Xueli Wu, Lan Zhu, Xitian Pi and Xiaolin Zheng of **Chongqing University**, in China, have adapted capsule endoscopy to allow them to detect tiny quantities of blood that might be present in a patient with the earliest signs of stomach cancer. The capsule is encased in non-toxic and acid-safe polycarbonate. It carries inside it a detector, power supply, and wireless transmitter. The device has a detection limit of 6 micrograms per liter of fluid and laboratory tests demonstrate its simplicity as well as its reliability. Once its task is complete the tiny pill-like device would be disposed of through the usual route without harm to the stomach or intestine. This approach thus avoids the uncomfortable and risk retrieval of such a device via the oral route. Occult bleeding is usually first identified in patients who have given a stool sample in which blood is found. However, it is important to identify the source of such blood, whether intestine or stomach. The detection of occult blood is indicated as one method of early diagnosis and so reduction of mortality from gastrointestinal cancers given the availability and adoption of suitable treatment by the patient. The next step is to take the patent-pending device to clinical safety testing and then to in patients. It is so far likely to prove safe to use, less invasive than other endoscopic technology and devices.

An eye test for MS . . . As you step outdoors into the bright sunshine, your pupils automatically contract. Scientists from the **Australian Centre of Excellence in Vision Science** (ACEVS; Canberra, Australia) based at The **Australian National University** (ANU) are making use of how this 'pupil reflex' is connected to the brain as a potential new way of testing the severity of multiple sclerosis (MS). Dr. Eman Ali and her ACEVS colleagues have used an instrument they are developing to accurately measure the pupil responses of MS patients and have found that the pupils of MS sufferers respond appreciably

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slower. The finding opens the door to a simple and quick way of tracking the severity of MS over time: the slower the response, the worse the MS. "Our instrument uses special patterns of flashing lights that the patient looks at for four minutes," says Professor Ted Maddess, a vision scientist at ANU who is head of the ACEVS team. "We use infrared cameras to measure light-induced changes in the diameters of both pupils, and with computer tracking we can measure the diameter to within a micrometre 30 times a second. "We have just published the results of our study of 85 MS patients, and we find that in MS patients the pupil response is about 25 milliseconds slower than in our control group. Although the study is preliminary, we believe the test has good potential in individual patients because it can precisely measure the speed of their response to within a millisecond. "So instead of an expensive MRI to track the condition, the new method gives an accurate readout after just a few minutes. That quick and easy test might, in the future, allow MS patients to be assessed on the spot and have their medication adjusted accordingly," he says. MS is a potentially devastating neurological condition affecting the myelin sheath of nerve fibres, leading to sensory disturbances and muscle weakness. Vision, speech, and walking are most often affected, and pain can occur. Puzzlingly, MS affects different people in different ways, but the condition inexorably gets worse with age and there is currently no cure. Some patients experience acute, inflammatory attacks while others don't. "MS is the most common neurological disability in adults, with about 12,000 sufferers in Australia," says Professor Maddess. "Although it seems to be some sort of immune disorder, its cause is still obscure."There are many puzzling aspects to MS, and there are many theories," he says. "But our main aim in this work was just to find a way of accurately monitoring the progression of the disease, a single measure that relates to the degree of disability. MRI is good for giving insight into the inflammation associated with episodic attacks, but it's not so good at monitoring the chronic decline that's always going on. TrueField has already received American FDA clearance, and Professor Maddess is hopeful it might, after some more research, also find a role in monitoring MS. He believes it has good prospects of reducing the high treatment costs associated with the disease.

Home testing devices could monitor epilepsy, drug levels, reduce clinical visits

. . . Medications remain the mainstay of epilepsy treatment, and to date there are no FDA-approved devices that provide an accurate means of detection for generalized tonic-clonic seizures (GTCS), or convulsions, during activities of daily living. Two new studies presented at the **American Epilepsy Society**'s 67th Annual Meeting in Washington D.C. provide data that warrants the development of non-invasive devices with the capability to signal the onset of an epileptic seizure and could be crucial to optimal patient dosing. Interim analysis that aims to validate a seizure detection software algorithm was presented to support the development of a non-invasive detection device with the ability to measure electromyography (EMG) signals. Patients in this study were asked to wear an arm-device that detected all GTCS within 30 seconds of arm motor action. Twenty-nine patients with a history of seizures were enrolled in the study while in the hospital Epilepsy Monitoring Unit for routine EEG monitoring. "Our study demonstrates the feasibility to detect generalized tonic-clonic seizures with an arm device analyzing muscle activity during daily living. We were able to capture the GTCS through analysis of EMG signals and confirmed these seizures using video-EEG (VEEG) recordings. The software algorithm was optimized using baseline measurements of maximum voluntary muscle contraction (MVC). In every instance that a GTCS was recorded by vEEG, it was also captured by EMG," said Akos Szabo, MD, the lead researcher of the study. The results determined that the seizure detection algorithm appeared superior to the other devices currently under investigation or currently commercialized. No false alarms were triggered during activities of normal living. In a related study conducted by an interdisciplinary team that includes clinician and research experts in epilepsy from the **University of Texas Houston,** and bioengineers from **Rice University** (Houston), programmable Bio-Nano-Chips (p-BNCs) are presented here in their first application as a non-invasive, repeatable and adaptable alternative to serial serum antiepileptic drug measurements. This study provides a report on progress towards the development of a realistic saliva-based BNC system demonstrating proof of concept of simultaneous detection and quantitation of two commonly used antiepileptic drugs – phenytoin (PHT) and phenobarbital (PHB). Advantages offered by this technology include the potential for the patients or their caregiver to monitor the levels of antiepileptic drugs in their system, always in a non-invasive, cost effective manner outside the doctor's office. "These bio-nano-chips, or "labs on a chip" as we like to call them, are a new generation of compact, programmable chemical processors that will satisfy the urgent need for non-invasive, adaptable and cost effective alternatives to blood test," said Giridhar Kalamangalam, MD. The BNC calibration signals are robust and provide ultra-low reliable limits of detection, and compare favorably to the in-lab reference or gold standards. Further work aims to produce a practical point of care diagnostic, eventually a hand-held device hosting a disposable, credit card-sized lab card that will empower patients to monitor drug intake on their own.