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J.P. Morgan Healthcare Conference

Private ophthalmic companies make pitches to audience

By LARRY HAIMOVITCH
***Medical Device Daily* Contributing Writer**

SAN FRANCISCO — Private companies continued to be of great interest at this conference and one of the most keenly anticipated presentations was from **Bausch + Lomb** (B + L; Rochester, New York). B + L, which was founded in 1853, is one of the oldest continuous operating companies in the U.S. and has one of the best-known healthcare brands in the world.

B + L was a public company for many years until it was acquired and taken private by private equity firm **Warburg Pincus** (New York) in October 2007 for $4.25 billion (*Medical Device Daily*, Oct. 29, 2007).

Prior to its acquisition by Warburg, B + L had suffered myriad setbacks and was floundering. It had fallen behind

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OneMedForum 2013

Emerging companies on the hunt for angel and other funding

By RONALD TRAHAN
***Medical Device Daily* Contributing Writer**

SAN FRANCISO — **Cognoptix** (Acton, Massachusetts) CEO Paul Hartung believes that med-tech companies must have a global perspective on fundraising and suggests that angel investors have become "much more of a success factor" for emerging companies. "They get it."

Hartung, who orchestrated the first-ever Series A syndicated angel deal in the Northeast United States, led by **Launchpad Venture Group** (Boston), has also closed Series B and C rounds of financing for Cognoptix with an international angel and VC syndicate. The company's biggest investor is **Inventages Venture Capital** (London), one of the world's largest VC funds with $15 billion under management exclusively for life-sciences, nutrition and wellness.

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Report from Europe

Ramsay extends imaging fleet with new MR system

A *Medical Device Daily* Staff Report

Ramsay Diagnostics, a division of **Ramsay Health Care** (both London), has extended its mobile imaging fleet with the addition of a mobile Magnetom Avanto Tim and Dot MR system from **Siemens Healthcare** (Malvern, Pennsylvania). The new mobile system is to be operated by Ramsay's mobile radiography team and is expected to deliver high quality, rapid imaging services across the UK.

The mobile trailer has been specifically tailored to meet patient needs with a changing cubicle and relaxed clinical environment featuring scenes from nature. In order to maximise workflow, the Magnetom Avanto Tim and Dot system features the same day optimizing throughput benefits available on its sister scanner, the Magnetom Aera. It

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Washington roundup

CBO: tax system prods U.S. firms into locating overseas

By MARK McCARTY
***Medical Device Daily* Washington Editor**

U.S. corporate income tax rates will be under the microscope for quite a bit of this year, and the Congressional Budget Office (CBO) has added to the discussion with a paper claiming that the current tax system "provides incentives for U.S. firms to locate their production facilities in countries with low taxes as a way to reduce their tax liability at home." The CBO paper comes at an interesting time with the onset of the 2.3% medical device tax in the U.S., especially given that CBO claims that current tax policy costs jobs and reduces the collection of tax in the U.S., a series of claims that will put more pressure on policymakers to re-examine the 35% tax rate currently in effect.

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Don't miss today's MDD Extra: Cardiology

INSIDE:

AHC Media

Financings roundup

MID secures $3.5 million of its $5 million Series B funding round

A *Medical Device Daily* Staff Report

Micro Interventional Devices (MID; Bethlehem, Maryland), an emerging cardiovascular company, said it has secured $3.5 million of its expected $5 million Series B financing. The initial tranche was led by Originate Ventures with existing investor, Battelle Ventures, LP, also participating in the round. In conjunction with the financing Mike Gausling, Managing Partner of Originate Ventures, will join the MID board.

The funding will be used to support the ongoing development of the Permaseal product, advance the STASIS clinical study (Sutureless Transapical Access and Closure Study) and obtain CE mark approval for Permaseal. The funding will also support MID's research and development initiatives focused on developing its percutaneous transapical and large bore femoral access and closure devices.

"The market for transcatheter aortic valve implantation is expected to grow rapidly over the next several years as innovation continues to improve and simplify the procedure," said Mike Gausling, Managing Partner of Originate Ventures. "Originate Ventures believes that Permaseal represents a significant opportunity given these market dynamics. I am excited to be joining MID's board and to work with management to ensure the successful clinical and commercial development of this revolutionary access and closure technology."

Permaseal is the first transapical access device to enable true "self-sealing," sutureless cardiac access and closure, the company said. The device is designed to enable a range of structural heart repair procedures including transcatheter aortic valve implantation (TAVI) and mitral valve replacement and repair.

"Closing the first tranche in our Series B, and the addition of Mike Gausling to MID's board, are key milestones in the growth of MID and ongoing development of Permaseal," stated Michael Whitman, president/CEO of MID. "As TAVI becomes more widespread there is a critical need for efficient cardiac access and closure devices. We believe the Permaseal platform is a true game-changing technology, and we look forward to completing the STASIS trial and securing CE mark in order to fulfill this unmet therapeutic need."

In other financings activity; **ArthroCAD** (Ayer, Massachusetts) said that it has closed the first tranche of its Series A financing with secured commitments for additional funding. The proceeds of the Series A round will be used to develop ArthroCAD's lead product for the Total Hip Arthroplasty market.

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Coming Wednesday in *MDD Perspectives*

The device tax repeal effort: RIP

The device tax has been one heck of an effort. Industry continues to assert it will do everything it can to peel this tax monkey off its back, but there are a number of reasons it just doesn't look like it's going to happen. For more on this question, see tomorrow's edition of *MDD Perspectives*, an op-ed e-zine that provides fresh commentary from the *MDD Perspectives* blog, http://mdd.blogs.medicaldevicedaily.com. Plus, you'll have access to free reprints from *Medical Device Daily* and *Biomedical Business & Technology*. If you don't already receive this complimentary e-zine, go to medicaldevicedaily.com to opt in.

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Deals roundup

ART to acquire AccuBoost installations held by Elekta

A *Medical Device Daily* Staff Report

Advanced Radiation Therapy (ART; Tyngsboro, Massachusetts), manufacturer of the AccuBoost System for radiation therapy of partial breast and **Elekta** (Stockholm, Sweden), a developer of cancer management systems and software, reported executing an agreement whereby ART acquires the assets of all AccuBoost installations held by Elekta, its worldwide distribution partner. As part of the transaction, ART has purchased the assets and the operating agreements for more than 20 installations in the U.S.

The transaction is designed to enable both companies to focus on their core competencies, and serves AccuBoost user groups by allowing ART to increase its support to these installations.

"The support of Nucletron/Elekta has been helpful for the growth of the AccuBoost product to become an established treatment option for partial breast radiation therapy in the United States," said Piran Sioshansi, PhD, president/CEO of ART. "With this agreement, AccuBoost will resume its lead position in support of the treatment centers and concentrate on future growth of the technology and accelerate the introduction of new treatment options."

In other dealmaking activity:

• **7 Medical Systems** (Minneapolis), a developer of in on-demand digital imaging, electronic medical records (EMR) and revenue cycle management (RCM) solutions for healthcare, reported the closing of its acquisition of **HealthLink Minnesota Management Group**, (Minneapolis), a company providing strategic advisory, business office, operational management and IT services to clinics in the Twin-Cities area.

• **Accellent** (Wilmington, Massachusetts) completed the sale of its facility located in Watertown, Connecticut to Utitec (Watertown, Connecticut). The vast majority of the Facility's employees became employees of Utitec on January 1, 2013.

"We are very excited to begin a new era for the Watertown facility, and we believe our focused efforts and planned improvements will bring added value and greater opportunity to our customers," said Carl Contadini, executive chairman of Utitec. "We are in the process of making this transition as smooth and seamless as possible for our customers, vendors and employees. We are taking great effort to ensure that our customers will continue to be able to order and receive the highest quality products from the Watertown facility."

• **Accelrys** (San Diego), a provider of scientific innovation lifecycle management software, said it is solidifying its market leadership in the laboratory informatics space with the acquisition of its long-time partner **Vialis AG** (Liestal, Switzerland), a systems integrator serving the pharmaceutical, biotechnology, chemicals, and agro-science industries. Vialis' deep experience implementing and supporting paperless laboratory solutions further strengthens Accelrys' position in the laboratory informatics software market and expands the company's capabilities in the downstream analytical development, quality control, and quality assurance and manufacturing areas.

Accelrys has purchased all of Vialis' outstanding stock for about $5 million in cash. The acquisition includes potential for additional incentive consideration of up to about $5 million in cash, contingent upon meeting specified growth objectives over the next three years.

In addition to its systems integration services, Vialis' business process consultancy delivers process improvements in lab data management. Employing a proprietary approach to analyzing existing lab processes, Vialis' business process consultancy services help customers optimize efficiency, enhance quality by design efforts, increase compliance, maximize knowledge re- use and reduce cycle times. ■

Agreements/contracts

Infosys to help transform NovaSom's OSA testing

A *Medical Device Daily* Staff Report

Infosys (Bangalore, India) has partnered with **NovaSom** (Glen Burnie, Maryland), a maker of home testing for obstructive sleep apnea (OSA), to significantly improve the efficiency of administering and analyzing results of home tests.

Infosys has designed a cloud-based user portal, Meditrack, on Salesforce.com to broaden the reach and efficiency of NovaSom's diagnostic solution suite. The new portal provides physicians with a single, easy-to-use interface that speeds up the order-to-delivery of devices, processing of diagnostic data and management of insurance claims.

Meditrack provides web interfaces with third-party applications to access and analyze patient data immediately upon wireless receipt of the completed home sleep test. The portal, launched earlier this year, enables NovaSom to shorten the time from test completion to report generation by two days. This capability helps NovaSom's sleep specialist customers deliver faster diagnoses to patients and speed their paths to treatment.

The NovaSom diagnostic solution also leverages AccuSom, an FDA-cleared wireless home sleep testing device. With more than 18 million moderate to severe cases of OSA in the U.S., NovaSom's suite of accurate, cost-effective home sleep testing solutions is delivering new

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HIT roundup

FACES Foundation selects SOAPware for EHR service

A *Medical Device Daily* Staff Report

Through their recent procurement of the **SOAPware** (Fayettville, Arkansas) electronic health record, non-profit medical care organization, **FACES Foundation** (Fayettville, Arkansas), said that it seeks to provide high-quality care for its medically underserved clients with a new level of coordination. Electronic healthcare solutions provider, SOAPware will work closely alongside FACES to deliver a solution which can accommodate the Foundation's needs for individual patient follow-up and collaboration with numerous local community resources.

Dedicated to offering comprehensive care beyond surgery alone for indigent, medically isolated patients with cleft lip and palate deformities, the FACES Foundation has transformed hundreds of lives by performing corrective surgeries in conjunction with their individualized and holistic follow-up services. The Foundation has long used a unique, internet-based model to connect with their international patients, and looks forward to integrating their current capabilities with those an EHR can provide.

As FACES Foundation President Thomas Albert MD, DMD, maintains, "Having a reliable, flexible EHR allows for much better follow up and data collection. It is a crucial part of trying to provide the same level of care as we do for patients in the US. The generous contribution from SOAPware will help tremendously in our mission."

In other HIT news; Six San Diego County locations of **Valley Radiology Consultants** (Escondido, California) are now using PACS, RIS and Breast Imaging PACS from the international medical imaging IT company, **Sectra** (Shelton, Connecticut). These integrated IT solutions will assist the group to improve workflow, report turnaround and service to its referring physician community.

Sectra PACS allows reading from any site, regardless of imaging location, and provides referring physicians the ability to view images and reports on their tablet devices.

Sectra RIS, a CCHIT certified EHR module, is designed to grow with Valley Radiology Consultants as they expand their practice and allows them to qualify for funding by supporting the Stage 1 meaningful use measures in the US. Sectra Breast Imaging PACS enables radiologists to efficiently review all modalities from the same workstation, while taking advantage of important features such as breast density measurement. ■

Agreements

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benefits to patients, health insurers, and specialty and primary care physicians.

In 2012, NovaSom expanded its product suite, launching AccuSom Deliver, a customized turnkey solution allowing sleep specialists to use high-quality, at-home sleep testing into their practices on a larger scale. AccuSom Safe Recovery was also launched this year, which leverages AccuSom's wireless functionality to complete home sleep testing prior to surgery. The new portal from Infosys has helped NovaSom scale operations to meet the expanded solution portfolio more effectively. Sleep specialists, surgeons, and anesthesiologists can now develop a patient management plan that further minimizes the risk of adverse respiratory events and other OSA-related complications during and after surgery.

"A quicker OSA diagnosis is critical to helping sufferers get the therapy they need sooner, and we are achieving that goal with the help of Infosys," said Richard Hassett, MD, CEO, NovaSom. "The customized MediTrack portal enables us to complete tests quickly and accurately. NovaSom's cloud-based infrastructure allows us to partner with providers to improve access to care, reduce cost and address this undiagnosed epidemic."

Infosys is a consulting, outsourcing and technology solutions company.

In other agreements/contracts news:

• **Opko Health** (Miami) has expanded its diagnostic test technology collaboration with Bristol-Myers Squibb (New York) to include Opko's technology in areas beyond Alzheimer's research.

In December 2010, the two companies entered into a multi-year collaboration agreement to investigate the utility of Opko's novel technology for the diagnosis of Alzheimer's and for identifying individuals with early stage cognitive impairment that are likely to progress to Alzheimer's (*Medical Device Daily*, Jan. 11, 2011).

Under the expanded collaboration, work will continue on the Alzheimer's project and additional investigations will use Opko's technology in an attempt to identify biomarkers that are predictive of drug response(s) in several therapeutic areas.

• **DMS Health Technologies** (Fargo, North Dakota), a mobile diagnostic imaging services provider, signed a three-year contract with **Via Christi Hospital Pittsburg** (Pittsburg, Kansas), to provide mobile PET/CT services to their facility every Tuesday and Thursday. The Joint Commission accredited mobile PET/CT unit offers patients a clean, clinical setting for their PET/CT scan, which is conducted by a professional PET/CT technologist.

DMS Health Technologies specializes in delivering products and services to the healthcare industry. DMS Health Technologies is a distributor of Philips Healthcare diagnostic imaging equipment and patient monitoring equipment in the upper Midwest; sells supplies and accessories, and reconditioned equipment, ultrasound and biomedical and diagnostic imaging parts. ■

Patent watch

CardioLogical Soultions gets coverage for aortic devices

A *Medical Device Daily* Staff Report

CardioLogical Solutions (Los Altos, California), an emerging cardiovascular device company formed by the recent merger of **Emboline** and **VasoStitch** (*Medical Device Daily*, Jan. 3, 2013), has been issued an additional patent for its family of aortic embolic protection devices that are designed to prevent stroke and other ischemic complications.

The aortic embolic protection technologies of Emboline and the large-hole access and closure technologies of VasoStitch form the initial core of a suite of accessory devices offered by CardioLogical Solutions to address the clinical needs of emerging interventional cardiology procedures. Added to these is a novel approach to preventing contrast nephropathy during cardiovascular procedures.

"This new issued patent affords CardioLogical Solutions additional IP protection for the most comprehensive range of accessory products aimed at the TAVR community today," said David Smith, CEO. "Indeed, our three platforms of procedural accessory devices address the three most pressing clinical needs in the rapidly growing evolution of transcatheter aortic valve replacement (TAVR) therapies: specifically, (1) a dire need for nonsurgical, large-hole (>12 Fr) access and closure technologies, (2) aortic embolic protection devices for prevention of stroke and other ischemic complications, and (3) prevention of contrast nephropathy. The combined potential of these markets where there exists now a strong clinical need is estimated at $2 billion to $3 billion per year, and this is where CardioLogical Solutions is focused."

In other patent news:

• **Hygieia** (Ann Arbor, Michigan) received a notice of allowance from the U.S. Patent and Trademark Office for core patent claims broadly covering the company's Diabetes Insulin Guidance System (DIGS) technology. The patent application titled "System for Optimizing a Patient's Insulin Dosage Regimen" relates to Hygieia's unique methods of automatically adjusting a diabetic patient's insulin dosage as needed to achieve a better glycemic balance of lowered hemoglobin A1C, as well as reduced hypoglycemia frequency.

"DIGS is the first technology to uniquely provide insulin users with the means to attain good blood glucose control along with the important safety requirement of avoiding hypoglycemia," said Eran Bashan, Hygieia's CEO. "This patent allowance greatly strengthens Hygieia's commercial position and boosts our roll out efforts in the United Kingdom, where our d-Nav Diabetes Insulin Guidance System product is currently available."

In Fall 2012, the d-Nav Diabetes Insulin Guidance System, Hygieia's first commercial product to incorporate DIGS technology, was granted a CE mark (*Medical Device Daily*, Oct. 9, 2012).

• **DR Systems** (San Diego), the provider of medical imaging and information systems, said the U.S. Patent and Trademark Office has issued to the company a new patent, relating to a system and method for viewing medical images at full resolution.

U.S. Patent No. 8,019,138 describes systems and methods for viewing medical images. For certain medical images, it is important and/or required that a user view all of a medical image at full resolution so that minute, but important, indicia in the medical image are not missed.

A computing system monitors the portions of the medical image that are displayed on the displayed device, notates those portions that have been displayed at full resolution (or other user-defined display parameters), and provides the user with information indicating portions that have not been viewed at full resolution and/or provides information indicating for which images of a multiple image examination full pixel display has been accomplished. The process reduces the possibility of missing an abnormality in a medical image due to the viewer not viewing a portion of the image at full resolution or using other user-defined display parameters. ■

J.P. Morgan

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its competitors in many of its key markets. Since Warburg took control in late 2007, numerous changes have been made and the company has regained its momentum. Brent Saunders, who became CEO nearly three years ago, characterized the company's recent performance as a "profound transformation" from its troubled past and provided a compelling argument that the company is now thriving.

Bausch + Lomb is a "160 year old iconic brand that is the only global company focused on caring for the world's eyes," Saunders said. His company participates in a global eye care market which approximates $29.5 billion. The largest sector is pharmaceuticals, which accounts for roughly 60% of the total, while contact lenses (including lens care products) and surgical products account for roughly 25% and 15% respectively.

Having turned B + L around, Saunders said that his company is now in the "acceleration phase" of it life cycle and in his opinion has become an "exciting, sustainable growth story." Estimated financial results for the company, which were provided here and at last year's J.P. Morgan conference, are presented below.

Its highly profitable and "double digit growth" pharmaceutical business, which accounts for about 42% of its worldwide sales, was bolstered by the mid-2012 acquisition of **ISTA Pharmaceuticals** (Irvine, California) for $500 million in cash. Saunders called ISTA the "locomotive for growth," with rapid gains from its four approved ophthalmic compounds. He also mentioned three new agents that are expected to reach the commercial stage and are expected to contribute significantly to future growth.

Bausch's Vision Care unit, accounting for 41% of sales, is "back in the game, and growing nicely" according to Saunders. A key addition to its product line is Biotrue ONEday, a premium daily disposable contact lens, which was approved in the U.S. in mid-2012. Biotrue ONEday is made from HyperGel, an innovative, next generation of daily disposable material that Saunders termed a "biomimetic material."

"It has the best features of conventional hydrogels and silicone hydrogels," he said.

The Surgical Division, which accounts for only 17% of global sales, has been hampered in the past with a mediocre product portfolio and management turnover, made major strides in 2012. He cited the new enVista intraocular lenses (IOLs), which are "the only FDA approved glistening free IOLs," as an example of innovation in that unit.

Saunders is also very ebullient about the prospects for its Victus laser, which will be acquired with the purchase of **Technolas Perfect Vision** (Munich), a leading ophthalmology laser company. This deal is expected to close in the next few weeks.

This acquisition brings femtosecond (FS) laser technology to B + L, allowing it to enter the burgeoning FS laser-assisted cataract surgery (FLACS) market. Saunders described this product as "best in class" and said that FS lasers represent a "huge advancement" in the field in cataract surgery. Indeed, in October 2012, the Cleveland Clinic cited FLACS as one of the "Top 10 Medical Innovations for 2013" (*Medical Device Daily*, Nov. 2, 2012).

B + L has been in the news of late, with several rumors that Warburg has put the company up for sale. Following his presentation here, Saunders told reporters that his company is "aspiring to return to public markets." Additionally, he declined to comment on reports that Warburg is looking for buyers willing to pay more than $10 billion for the eye care company.

Privately-owned, venture capital-backed **OptiMedica** (Sunnyvale, California), presenting for the first time at this conference, is a pure play in the FLACS market and is showing robust growth since shipping its first Catalys system in late-February 2012. CEO Mark Forchette said that this was an "incredibly exciting time" for his company, now that it is fully commercialized. He proudly pointed to the installation of more than 40 systems, which *Medical Device Daily* estimates were sold for about $500,000 each. In addition, this installed base performed more than 10,000 procedures, which are priced to the cataract surgeon at about $375 per procedure.

Based in Silicon Valley, OptiMedica's system features several unique and "high tech" features that enable its FLACS procedure to be "an order of magnitude" more precise than conventional, manual cataract surgery. He cited clinical data showing that OptiMedica's device performs a capsulotomy (removal of the natural lens) far more precisely than a manual procedure and even better than its FLACS competitors. These include the LenSx laser from the **Alcon** (Fort Worth, Texas) division of **Novartis** (Basel, Switzerland) and the LensAR system from privately-owned **Lensar** (Orlando, Florida), who are also FDA-approved for sale.

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Bausch + Lomb Operating Results 2007-2012 ($ in millions)

	Revenue	Gross Margin	EBITDA
2012	$3,050	63%	$640
2011	$2,850	62%	$548
2010	$2,570	60%	$472
2009	$2,510	59%	$410
2008	$2,450	58%	$389
2007*	$2,449	58%	$375

* Estimated by *MDD*.

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Hartung has Cognoptix (formerly Neuroptix) poised to deliver the world's first in-office, drug/device diagnostic system to aid in the early detection of Alzheimer's disease. Previously, at Summit Technology, he was a member of the management team that developed the LASIK laser-based eye procedure; and after a successful IPO, Summit was eventually acquired by **Alcon** (Fort Worth, Texas). At Winphoria Networks, he participated in a successful acquisition by Motorola, and led the integration of operations of the companies post-acquisition. While at **3Com**, he played a leadership role in the integration of large acquisitions, including **Palm Computing**, **US Robotics**, and **Chipcom**, pioneering a "design anywhere/build anywhere" strategy to reduce time-to-market globally. Now, at Cognoptix, he is the inventor on issued and pending patents, has raised $17 million to date, and has secured R&D collaborations with **Pfizer** (New York) and **Merck** (Darmstadt, Germany).

Hartung told investors at last week's OneMedForum conference in San Francisco that the ability of the Cognoptix drug/device combination product, SAPPHIRE II, to easily identify and qualify patients for clinical study inclusion, as well as accurately and inexpensively track patient disease progression, could provide pharma companies with a significant competitive advantage in securing new Alzheimer's drug approvals.

"Cognoptix will change the way Alzheimer's is detected and managed, and we are the only com-pany positioned to make this happen soon," insists Hartung. He adds that the Alzheimer's pharmaceutical market is estimated at well over $8 billion and growing rapidly.

"Earlier diagnosis of AD will enable earlier drug intervention and titration, which will not only significantly increase the treatable AD patient base but also will provide for superior therapeutic outcomes, improving patients' lives," Hartung says.

Cognoptix has a strong and comprehensive patent portfolio covering diagnosis of beta amyloid-based diseases via ophthalmic imaging. Exclusive licenses have been acquired from **Mass General Hospital** (Boston), **UC San Diego**, and **Brigham and Women's Hospital** (Boston)**.**

Also presenting to investors in San Francisco at 'OneMedForum' last week was **ExThera Medical** (Berkeley, California) CEO Dr. Robert Ward, who was bullish about his company's Seraph device designed to eliminate bacteremia and prevent sepsis at point-of-care. Like Paul Hartung of Cognoptix, Ward encourages other emerging company CEOs to look globally in seeking funding.

For example, his first start-up — **Polymer Technology Group** (Berkeley) — earned a 555X return for investors upon its sale in 2008 to **DSM** (Heerlen, the Netherlands), the global life sciences and materials company. Now, Dr. Ward believes he has another homerun in ExThera, whose scientific origins were at the Karolinska Institute (Stockholm, Sweden). Using its patented 'Seraph' technology, ExThera intends to provide the critical care medical community with an important new therapy that quickly and safely reduces the blood's bacterial and/or viral load. At the same time it removes pathogens, 'Seraph' can also reduce circulating levels of many of the factors that initiate a patient's extreme inflammatory response, including bacterial toxins, pro-inflammatory cytokines, harmful proteins, and other virulence factors.

Ward told OneMedForum investors that ExThera Medical's Seraph device is unique in its broad-spectrum ability to safely remove harmful substances from the blood. "No other single technology is known to sweep all of these agents from the blood of bacteremic and septic patients in a single course of treatment," he says. Ward believes that ExThera's disposable device may even be able to forestall, or prevent, a patient from slipping into a full systemic inflammatory response: sepsis. "Our story is one that appeals to a global audience, which is why we chose to present at OneMedForum."

ExThera was self-funded by its initial stakeholders and has just completed its first round of outside funding. The company expects to close a second round of financing in mid-2013.

(Ronald Trahan is president of Ronald Trahan Associates, which has been providing public and investor relations services to big and small companies, private and public, since 1992. rctrahan@ronaldtrahan.com) His firm provides professional services to Cognoptix and ExThera. ■

Financings

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Surgical morbidity is a focal point for patients, physicians, regulators, and device companies. In recent years, patient awareness of morbidity following THA has dramatically increased due to popular press reports, medical litigation, and device recalls. The number of THAs performed in the US was estimated to be more than 350,000 in 2007. The magnitude of the problem is projected to increase dramatically since this number is expected to double by 2030.

Foley Hoag LLP, led by Life Sciences Practice chair Jeffrey Quillen, represented ArthroCAD in the financing. Quillen has represented ArthroCAD since its founding in 2011. ■

Europe

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also includes AudioComfort functionality taking advantage of magnet suspension, special casting for gradient coils and a unique MR sequence design to keep noise levels to a minimum, further enhancing patient comfort within the mobile unit.

Ramsay says the Avanto's wide selection of applications and high density coil configuration allows radiologists to diagnose a range of conditions such as stroke, spinal abnormalities and heart disease, as well as providing routine high quality musculoskeletal imaging. The system also has an accessible low-to-the-floor table position of just 47 cm that can support patients of up to 250kg and enables feet first examinations to be conducted for most MR procedures.

"Ramsay Diagnostics is pleased to take delivery of the mobile MR system. The scanner is a valuable addition to our mobile imaging fleet and demonstrates our ongoing commitment to delivering top quality services to NHS and private patients," said Andy Spellman, head of diagnostics at Ramsay Health Care. "The advanced Siemens system, operated by our experienced mobile radiography team, will undoubtedly deliver high quality and efficient scanning services."

BSD reports sale of MicroThermX in Turkey

BSD Medical (Salt Lake City), a provider of medical systems that use heat therapy to treat cancer, said it has sold multiple MicroThermX Microwave Ablation systems and antennas to **ADA Medikal** (ADA; Izmir, Turkey), pursuant to their exclusive distribution agreement signed in October 2012 for the MicroThermX in Turkey. ADA is a medical specialty distributor in Turkey with offices in the major metropolitan areas. ADA represents a number of major medical device companies and sells strategically adjacent products to the same clinicians targeted for the MicroThermX

ADA projects that they will need to order a significant number of systems to address the market for the MicroThermX in Turkey. Turkey's location at the crossroads of Europe and Asia and its growing economy have led to its recognition as a regional power in the Middle East.

The MicroThermX is a system that includes a microwave generator, single-patient-use disposable antennas, and a thermistor-based temperature monitoring system. The innovative design of the MicroThermX is the first of its kind that allows delivery of higher power levels using a single generator. The MicroThermX uses synchronous phased array technology that was developed and patented by BSD to provide larger and more uniform zones of ablation during a single procedure.

BSD makes systems to treat cancer and benign diseases using heat therapy, which is delivered using focused radio frequency and microwave energy. ■

People in the News

• **AtriCure** (West Chester, Ohio) reported three promotions of personnel into key leadership positions. Douglas Seith has been promoted to senior VP of sales and marketing. Seith has spent nine years at AtriCure and has more than 25 years of cardiac surgery, cardiology and general surgery sales and sales leadership experience. Michael Rogge has been promoted to VP of marketing, and has more than 22 years of medical device experience. Andrew Wade has been promoted to VP and chief financial officer. Wade has more than 15 years of financial experience, the past five with AtriCure building the finance and accounting team. AtriCure specializes in cardiac ablation systems for the treatment of atrial fibrillation, or AF, and systems for the exclusion of the left atrial appendage.

• Mark Smith, MD, who has led the **California HealthCare Foundation** (CHCF; Oakland) since its founding, plans to step down as president/CEO at the end of year. Smith, a physician and expert on state and national health policy, will continue his work as a member of the clinical faculty at the University of California, San Francisco, and as an attending physician at the Positive Health Program for AIDS care at San Francisco General Hospital, where he has practiced since 1992, including during his tenure at CHCF. The California HealthCare Foundation works as a catalyst to fulfill the promise of better healthcare for Californians.

• **EndoGastric Solutions** (EGS; Redwood City, California) reported two additions to the company's management team – Pat Crilly, as VP, human asset development and Lilip Lau as senior VP, R&D. Prior to EGS, Crilly was president of Performance Solutions International. Lau most recently was senior VP, chief technical officer and director at Paracor Medical. EndoGastric Solutions makes products for the endoluminal treatment of GERD.

• **Fluidigm** (South San Francisco, California) has named Gerhard Burbach to Fluidigm's board. Burbach serves as president/CEO and director of Thoratec. Fluidigm makes microfluidic systems consisting of instruments and consumables, including integrated fluidic circuits, assays and other reagents.

• **Highmark** (Pittsburgh) has named Jayanth Godla as executive VP and chief strategy officer. Since 2011, Godla served as head of enterprise strategy at Aetna. Highmark is a national health and wellness company specializing in health insurance, dental insurance, vision care, information technology and integrated healthcare delivery.

• **Seegene** (Gaithersburg, Maryland) has named John Hurrell as its new senior executive VP. Most recently, Hurrell was the president and GM of Focus Diagnostics. Seegene makes multiplex molecular technologies and multiplex molecular diagnostic tests.

Washington

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CBO notes that the U.S. corporate tax rate is 39% when computed for state and local taxes, which is "higher than that in any of the other 34 member countries" of the **Organization for Economic Cooperation and Development** (OECD). While there are deductions and exemptions for U.S. tax filings, a weighting of taxes against GDP for the various OECD nations puts the average statutory tax rate in all OECD nations at 19% in 2011, CBO said.

The summary from the Jan. 8 report said that 12% of all federal revenues collected in 2008 came from corporate income taxes, about half of which were paid by multi-national corporations (MNCs) that had income from nations outside the U.S. CBO pointed out that the U.S. government taxes "both the domestic and the foreign income[s]" of businesses that are incorporated in the U.S., but that corporations can take a credit from their OUS tax obligations against domestic taxes, although this is limited to the amount owed the U.S. government. American firms can also defer their U.S. taxes from overseas income pending repatriation of the income.

The summary notes that the U.S. tax system is more of a worldwide than a territorial system of taxation, but that a purely worldwide tax system "would ensure that firms faced the same tax rate no matter where they operated." Between this exception to an entirely worldwide tax system and the fact that firms can defer U.S. taxes on foreign incomes, MNCs have incentives to locate factories and other production facilities in other nations. CBO argues that such conditions tend to promote economic inefficiency and can "reduce the income of shareholders and employees in the United States." The summary notes further that a loss of federal tax revenue is another consequence, and the full report said that OUS corporate revenues deferred for tax reasons came to $16 billion in fiscal 2012.

CBO said that several attempts have been made to delineate a relationship between U.S. corporate income tax rate changes and corporate investment, with one such effort concluding that an increase in the U.S. rate of 1% compared to another nation was associated with an increase of employment and sales in the other nation of 1.6% and 2.9%, respectively. However, this study, said to have appeared in the *National Tax Journal* in 2009, also deduced that "both the assets and the gross income" of the entities in those other nations rose by proportionally greater amounts, which suggests "that firms respond to differences in tax rates by shifting reported profits as well as by relocating business activities."

The report broaches a shift from a worldwide to a territorial U.S. tax system, which CBO said would eliminate deductions for OUS operations. CBO said that the congressional Joint Committee on Taxation (JCT) has made the argument that a corporation's taxable income would increase sufficiently "to more than offset the Treasury's loss from not taxing foreign income" in this scenario.

One alternative scenario would be to maintain a worldwide tax system, but to eliminate or at least curtail deferral of U.S. tax liabilities for income earned in other nations. CBO acknowledged that such a move would bolster the incentives to "incorporate or register abroad or to be acquired by or merge with foreign companies." Still, CBO claims that this approach would boost tax collections by more than $100 billion over 10 years, an estimate provided by JCT. This, CBO said, "would be the largest revenue increase attributable to any of the options discussed in this report."

The **Advanced Medical Technology Association** (AdvaMed; Washington) was unable to comment for this story, but a Feb. 7, 2012, statement by the association indicates a preference for "adoption of a territorial tax system consistent with other advanced economies" along with "a reduction in the overall corporate tax rate." AdvaMed also advocated an "innovation box" in the tax code designed to spur the formation of high value-added industries.

The **U.S. Chamber of Commerce** (New York) did not respond to contact for comment.

St. Jude says warning letter out for Sylmar

St. Jude Medical (St. Paul, Minnesota) said it has received a warning letter for operations at the firm's plant in Sylmar, California. The FDA inspectional form 483 from the September-October 2012 inspection emerged late last year (*Medical Device Daily*, Dec. 12, 2012) detailing a number of compliance issues associated with the company's production of electrophysiology leads.

Among the citations appearing in the 483 was a problem associated with a process validation protocol that failed to control for the differences between several manufacturing machines, but FDA also cited St. Jude for failure to validate three test methods associated with design input verification for the Durata lead.

The company said in a Jan. 11 8-k filing that the warning letter addresses only the Sylmar plant and does not affect any of the company's other facilities. St. Jude said the letter did not "identify any specific concerns regarding the performance of, or indicate the need for any field or other action regarding" the Riata ST Optim or Durata leads "or any other St. Jude Medical product." Hence, the firm indicates it will continue to manufacture and ship product from Sylmar.

The statement notes that St. Jude "takes this matter seriously and has already begun to respond to the FDA's requests," and that the warning letter "can be resolved without a material impact on the company's financial results." A fourth quarter earnings call is scheduled for Jan. 23. ■

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Forchette, an ophthalmic industry veteran, noted that there were nearly 20 million cataract procedures performed worldwide in 2012 and that this creates a FLACS market opportunity that he believes will ultimately exceed $1 billion. In addition to the opportunity to replace manual cataract procedures with FLACS, Forchette noted several other allied areas where his company might prosper. These include:

- As a centerpiece of a new ultrasound-free "no phaco" procedure
- New IOL designs synergistic with precisely machined capsulotomies
- Viscoeleastics optimized for no ultrasound use
- New irrigating solutions and concepts
- Disposable, packs and handpieces optimized for lens nuclear removal

Closing his upbeat presentation, Forchette said "we plan to challenge the status quo of the ophthalmic landscape."

Another privately-owned, venture capital backed company appearing at the conference was **Glaukos** (Laguna Hills, California). The company, which has raised $126 million in venture financing since its founding in 2001, was the first to achieve FDA clearance (June 2012) for a new category of glaucoma devices called MIGS (minimally invasive glaucoma surgery).

Glaucoma afflicts three million Americans and is the second leading cause of blindness in the U.S., trailing only diabetic retinopathies. It affects an estimated 70 million persons worldwide. Glaucoma, particular the mild to moderate varieties, is typically managed with eye drops but their efficacy is modest and many patients require multiple regimens. Non-compliance is well documented and is "rampant" according to CEO Tom Burns.

Conversely, the iStent, a snorkel-like device, is implanted in a straightforward surgical procedure in a combined cataract-IOL exchange procedure. It is easy to implant and takes just a few minutes of the surgeon's time. According to Burns, the device, which is selling for $1000 at ambulatory surgical centers during the introductory launch phase, is the smallest implanted product ever placed in the human body. It creates a channel to allow the aqueous fluid to pass through the clogged trabecular meshwork in the front of the eye, thus lowering intraocular pressure (IOP). Myriad clinical trials have shown that the iStent consistently lowers IOP and either reduces or eliminates the need for glaucoma medications.

Glaukos is now fully commercial in the U.S., with a 12 person direct sales force in the U.S. selling its iStent to both cataract and glaucoma surgeons. Burns indicated that he plans to expand this direct sales force to 24 during 2013. The initial target market is the 650,000 patients in the U.S. who are having a cataract removed and also have concomitant glaucoma. It is specifically targeting 500 glaucoma specialists and 2500 cataract surgeons. The company has attained excellent surgeon and device reimbursement, indeed Burns noted that "it occurred faster than we had hoped for."

In addition to its efforts to sell the iStent, Glaukos has a robust pipeline of second and third generations products that are in advanced stages of clinical trials. It has 18 clinical pivotal and post-market trials underway globally, gathering data on the iStent injectable device as well as the iStent Supra, which will be implanted in a different location in the eye.

Burns noted that Glaukos has significant regulatory leads over several privately-owned, venture-financed companies, which he believes may be four-to six years away from FDA approval.

"We have a wide berth over our competition," he said. ■

Product Briefs

• **Blockade Medical** (Irvine, California) said more than 100 patients have been successfully treated with the Barricade Coil System. The patients treated, presented with a wide range of cerebral aneurysms and peripheral lesions. All treated patients had positive clinical outcomes without any reported complications. The Barricade Coil System is an embolization coil line which is designed to endovascularly occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. The Barricade Coil System is a comprehensive bare platinum coil line available in framing, filling and finishing shapes. Blockade Medical is a privately held medical device company focused on expanding the endovascular management of hemorrhagic stroke and related disease of the neurovascular system.

• **CardioFocus** (Marlborough, Massachusetts) maker of the HeartLight Endoscopic Ablation System for the treatment of atrial fibrillation (AF), said that a U.S. pivotal trial evaluating the safety and efficacy of the HeartLight system is approximately half enrolled. The study, initiated in 2012, is on track to complete enrollment this year. HeartLight is the first catheter ablation system to incorporate an endoscope for direct visualization of the beating heart, a laser energy source and a compliant balloon catheter. The HeartLight pivotal trial is randomizing the HeartLight system against Biosense Webster's Thermocool Catheter, and will randomize an estimated 350 patients in this multi-center U.S. trial. The HeartLight Endoscopic Ablation System for catheter ablation uses an endoscope to provide physicians with the capacity to see within the heart, and for the first time, visually direct the application of laser energy to achieve durable pulmonary vein isolation.

MDD's Cardio Extra

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

Tuesday, January 15, 2012

Keeping you up to date on recent developments in cardiology

Babies and kids capable of generating new heart muscle cells . . .

Researchers at **Boston Children's Hospital** have found, for the first time that young humans (infants, children and adolescents) are capable of generating new heart muscle cells. These findings refute the long-held belief that the human heart grows after birth exclusively by enlargement of existing cells, and raise the possibility that scientists could stimulate production of new cells to repair injured hearts. Findings of the study, "Cardiomyocyte proliferation contributes to post-natal heart growth in young humans," were published in *Proceedings of the National Academy of Sciences*, online edition last week. The study was led by Bernhard Kühn, MD, of the department of cardiology at Boston Children's. Beginning in 2009, Kühn and his team looked at specimens from healthy human hearts, ranging in age from 0 to 59 years. Using several laboratory assays, they documented that cells in these hearts were still dividing after birth, significantly expanding the heart cell population. The cells regenerated at their highest rates during infancy. Regeneration declined after infancy, rose during the adolescent growth spurt, and continued up until around age 20. The findings offer the strongest evidence to date that proliferation of cardiomyocytes (the cells making up heart muscle) contributes to growth in healthy young human hearts. "For more than 100 years," Kühn says, "people have been debating whether human heart muscle cells are generated after birth or whether they simply grow larger." Kühn points out that research in the 1930s and 1940s suggested that cardiomyocyte division may continue after birth, and recent reports about myocardial regeneration in zebrafish and neonatal mice suggest that some young animals regenerate heart muscle by using mechanisms of muscle cell division. Still, for many years, the accepted belief in the scientific community was that human hearts grow after birth only because cells grow larger. Kühn's work challenges the accepted wisdom and offers hope for new heart failure treatments. Babies and children may be able to increase heart muscle cell proliferation and regenerate damaged parts of their heart muscle. In addition, the study points to new research directions by suggesting that abnormal cardiomyocyte proliferation may be involved in diseases of the heart muscle (cardiomyopathy) that affect young humans, and that cardiomyocyte proliferation could be stimulated in young humans for the treatment of heart failure. The findings, according to Kühn, help to create a "cellular blueprint for how the human heart grows after birth." Using this blueprint, treatment strategies could be developed to treat heart failure in children.

Blueberries and strawberries may reduce heart attack risk in women . . .

Eating three or more servings of blueberries and strawberries a week may help women reduce their risk of a heart attack by as much as one-third, researchers reported in *Circulation*. Blueberries and strawberries contain high levels of naturally occurring compounds called dietary flavonoids, also found in grapes and wine, blackberries, eggplant, and other fruits and vegetables. A specific sub-class of flavonoids, called anthocyanins, may help dilate arteries, counter the buildup of plaque and provide other cardiovascular benefits, according to the study. Blueberries and strawberries were part of this analysis simply because they are the most-eaten berries in the U.S. Thus, it's possible that other foods could produce the same results, researchers said. Scientists from the **Harvard School of Public Health** (Boston) and the **University of East Anglia** (Norwich, Norfolk, UK) conducted a prospective study among 93,600 women ages 25 to 42 who were registered with the Nurses' Health Study II. The women completed questionnaires about their diet every four years for 18 years. During the study, 405 heart attacks occurred. Women who ate the most blueberries and strawberries had a 32% reduction in their risk of heart attack compared to women who ate the berries once a month or less – even in women who otherwise ate a diet rich in other fruits and vegetables. The findings were independent of other risk factors, such as age, high blood pressure, family history of heart attack, body mass, exercise, smoking, caffeine or alcohol intake.

Non-use of donor livers up due to complications following cardiac death . . .

A new study published in the January issue of *Liver Transplantation*, a journal of the American

Association for the Study of Liver Diseases (AASLD), found that the non-use of donor livers climbed through 2010 due to a worsening of donor liver quality, primarily from donation following cardiac death. donor age, and body mass index were also linked to a decrease in use of organs. "For patients with end-stage liver disease, transplantation is the only option for extending life, but organ availability places constraints on the transplant community," said Eric Orman, MD, with the **University of North Carolina School of Medicine** (Chapel Hill). "One of the methods to increase the donor pool is to include donors with less than ideal health status - those with fatty livers, older donors, and donation after cardiac death." In an attempt to increase available livers for transplant, the transplant community has gradually extended donation criteria. However, previous research shows that poor outcomes may occur following transplant of more inferior organs. In fact, studies have shown an increased recipient morbidity and mortality risk with donation after cardiac death (when circulation ceases) than with standard donation following brain death in which donor circulation is sustained. For the present study researchers used data from the Organ Procurement and Transplantation Network (OPTN) to indentify 107,259 deceased donors in U.S. between 1988 and 2010. Donors were 18 years of age and older who had a least one organ (liver, heart, intestine, kidney, lung or pancreas) used for transplantation. The mean donor age was 44 years; 41% were female and 68% were white. Split liver donations and donors with BMI less than 14 kg/m2 or more than 50 kg/m2 were excluded. Analysis indicates that 41,503 donations occurred after June 30, 2004 with 82% of livers used for transplant and 18% unused. The number of unused livers decreased from 1,958 (66% of donors) in 1988 to 841 (15%) in 2004, and then increased to 1,345 (21%) in 2010. Liver non-use was independently linked to older donor age, greater BMI, diabetes prevalence and donation after cardiac death - all of which are on the rise in the U.S. Researchers reported a four-fold increase in the odds of non-use of livers from donation following cardiac death donors between 2004 and 2010, with the proportion of nonuse climbing from 9% to 28% during the same time period. "Our findings show nonuse of livers for transplantation is steadily rising, and is primarily due to donation after cardiac death," Orman said. "If these trends continue, a significant decline in liver transplant availability would be inevitable."

Metabolic stress increases onset of arrhythmias, researchers find

. . . Researchers have found new evidence that metabolic stress can increase the onset of atrial arrhythmias, such as atrial fibrillation, a common heart condition that causes an irregular and often abnormally fast heart rate. The findings may pave the way for the development of new therapies for the condition which can be expected to affect almost one in four of the UK population at some point in their lifetime. The British Heart Foundation study, led by **University of Bristol** scientists and published in *Circulation: Arrhythmia and Electrophysiology*, found that metabolic stress - a condition induced by insufficient oxygen supply to the heart (e.g. following blockage of a coronary artery) - caused marked changes in the electrical activity of the heart's atria (the upper chambers of the heart). While it has been recognized for many years that metabolic stress causes ventricular arrhythmias - abnormal heart rhythms that originate in the two lower chambers of the heart (the ventricles) and which form the basis to heart attacks- it is the first time it has been demonstrated for arrhythmias in the atria. The researchers examined the contribution of a particular kind of protein underlying the electrical activity of the atria during metabolic stress. These proteins, known as KATP channels enable cells to respond to changes in metabolism. ATP (adenosine triphosphate) is a small molecule that represents the 'energy currency' for cell metabolism and when ATP levels inside cells fall, KATP channels are activated. For example, KATP channels in the pancreas are involved in the regulation of insulin secretion and drugs targeting these channels are used to treat Type 2 diabetes mellitus. The findings show that metabolic stress caused marked changes in the electrical activity of the atrium consistent with the activation of KATP channels. Electrical stimulation was applied to try to evoke atrial arrhythmia. It was possible to induce atrial arrhythmia during, but not before, metabolic stress. Importantly, blockade of KATP channels with drugs used to treat patients with Type 2 diabetes (glibenclamide and tolbutamide), completely reversed the effects of metabolic stress on the electrical activity of the atrium and prevented the induction of atrial arrhythmia. The anti-diabetic drugs were without effect in the absence of metabolic stress. The findings represent a 'proof-of-principle' (the stage at which any new drug must undergo before full-scale clinical trials can begin) that atrial KATP channels can be activated by metabolic stress and facilitate atrial arrhythmias. Thus, atrial KATP channels may represent a target for drugs for the treatment of atrial arrhythmias, such as atrial fibrillation.

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