BioWorld MedTech

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Habib EndoHPB probe; Emcision Ltd., acquired by Boston Scientific Corp.

Device for bile duct blockages

Boston Scientific acquires endoscopic coagulation device maker Emcision

By Katie Pfaff, Staff Writer

Boston Scientific Corp. has acquired private company Emcision Ltd., bringing the firm's Habib EndoHPB probe under its endoscopy division. The Habib endoscopic bipolar radiofrequency device is used to coagulate tissue in the gastrointestinal tract (GI) in treatment of patients with pancreaticobiliary cancers. Financial details of the transaction were not disclosed.

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Inside

Owlstone Medical raises $15M to advance commercialization of VOC breath biopsy tech

By Nuala Moran, Staff Writer

LONDON – Owlstone Medical Ltd. has raised $15 million to advance commercialization of its volatile organic compound (VOC) breath biopsy technology, providing the means to launch a lung cancer diagnostic and to develop other

See Owlstone, page 4

Predicting cognitive problems in the elderly with retinal imaging of blood vessels

By Stacy Lawrence, Staff Writer

Current brain imaging techniques are unable to visualize small vessels, but researchers have taken a systematic look at what could be the next best thing: retinal images. Vascular disease has long been known to contribute to cognitive decline

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AdvaMed says regulated digital products need streamlined review

By Mark McCarty, Regulatory Editor

The FDA's two-day workshop on the digital health pre-certification pilot was directed principally toward the agency's approach to certification of vendors rather than software products, but Zachary Rothstein of the Advanced Medical

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Australia builds national database to chart the course of new health technology

By Tamra Sami, Staff Writer

PERTH, Australia – Australia is launching an online "innovation showcase" that aims to catalogue and track the progress of innovations in the pharmaceutical, medical technology and digital health space across Australia in real time on a public platform open to investors, health practitioners and the public.

The National MedTech, Pharmaceutical and Digital Health Showcase (MTPD Showcase) is the first of a milestone project funded by the Australian government's Medical Technology and

See Australia, page 7

Indian pharma companies urged to team up with digital tech, data firms

By T.V. Padma, Staff Writer

HYDERABAD, India – Indian pharmaceutical companies are taking baby steps toward a greater collaboration with digital tech firms and data analytics, but they may not be moving fast enough. Delegates at the BioAsia 2018 conference

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BioWorld MedTech's Cardiology Extra

Staff Writer Katie Pfaff
on one of med-tech's key sectors

Read this week's edition

Other news to note

Tel Aviv, Israel-based **Cynerio** reported that Rambam Health Care Campus, also in Israel, will pilot its cyber-security technology to protect its medical device ecosystem from cyber threats. Cynerio's technology was developed for health care connected devices, and will provide continuous and automated device discovery and classification, full visibility of device activity on the network and associated risks, and detection of anomalous activity and stoppage of a threat to ensure patient safety and data protection. The platform is available for rollout evaluation the U.S. and will launch at the HIMSS conference in Las Vegas.

Renovacare Inc., of Pittsburgh, developer of a technology for spraying a patient's own skin cells onto burns and wounds, reported it has received video evidence showing what appears to be predatory trading practices of several FINRA member firms in its stock. The company has informed investigative agents about the practices, which it believes are extensive, illegal and ongoing by certain FINRA member firms. These firms may be covertly collaborating with the short seller syndicate targeting the company, according to Renovacare, and they are filing of a formal complaint regarding these "bear raid" trading practices with both FINRA and the SEC and will explore all potential private legal remedies. "As reported to stockholders on Feb. 12, 2018, a known "short and distort" syndicate has engaged in an ongoing smear campaign of disseminating grossly misleading, inaccurate and distorted facts and misinformation, including false allegations of insider selling," according to Renovacare. The company confirms none of its officers and directors have ever sold any company shares, and the majority stockholder, Kalen Capital Corp., has not sold any company shares since 2008. "Renovacare strongly believes that it has an obligation to protect its stockholders from adverse financial and reputational harm caused by these unfounded and potentially illegal activities," stated the company, which also suggested if the alleged actions were left unaddressed, the company and ability to commercialize its products in the future could be impacted.

Daily M&A

Bioduro LLC, a San Diego-based life sciences contract research and development organization, reported the acquisition of **Molecular Response LLC**, also of San Diego, and its translational oncology research platform, including its biobank of more than 100,000 viable tumor specimens. Bioduro customers can now access this platform to support a range of drug discovery oncology and immuno-oncology studies – from immunophenotyping screens to xenograft pharmacology studies. As part of the acquisition, Molecular Response CEO, Thomas Broudy, will assume the role of executive vice president of translational sciences and strategy. Bioduro will maintain Molecular Response as a wholly owned subsidiary, growing its ongoing operations in Shanghai, Beijing and San Diego with new service offerings using the biobank platform. Molecular Response will continue all business development efforts to sell biospecimens to strategic partners interested in tissue acquisition to support internal capabilities.

Medeon Biodesign Inc., of Taipei, Taiwan, said it entered a definitive asset purchase agreement with Tokyo-based **Terumo Corp.** for its large bore vascular closure system, Xpro. The transaction consists of an up-front payment of $20 million and milestone payments. Medeon will continue to provide its strong expertise in product innovation in collaboration with Terumo for future technical, clinical and regulatory developments of the closure system. The Xpro system is an automated suture-mediated closure device to simultaneously deliver two pairs of sutures, specifically targeting percutaneous large bore procedures, including transcatheter aortic valve replacement, endovascular aneurysm repair, thoracic endovascular aneurysm repair and percutaneous balloon aortic valvuloplasty procedures.

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Our newsroom

Lynn Yoffee (News Director), Holland Johnson (Executive Editor), Mark McCarty (Regulatory Editor), Andrea Applegate (Production Editor)

Staff writers: Katie Pfaff, Bernard Banga, John Brosky, David Godkin, Stacy Lawrence, Alfred Romann, Tamra Sami

Business office

John Borgman, Director of Commercial Competitive Intelligence,
Donald R. Johnston, Senior Marketing Communication Director, Life Sciences

Contact us

newsdesk@bioworldmedtech.com

John Borgman, (831) 462 2510 | Donald R. Johnston, (678) 641-0970 | Lynn Yoffee, (770) 361-4789 | Holland Johnson, (470) 252-8448 | Andrea Applegate, (470) 236-3994 | Mark McCarty, (703) 966-3694 | Katie Pfaff, (267) 270-7054

Practical information

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Boston Scientific

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Marlborough, Mass.-based Boston Scientific did not disclose specifics of the transaction, apart from the acquisition was "expected to be immaterial to earnings per share in 2018 on an adjusted and GAAP basis and accretive thereafter." U.K. and Canada-based Emcision's FDA-approved and CE marked Habib EndoHPB probe will be added to its endoscopy business, which currently includes diagnostic, treatment, and management devices for GI and pulmonary ailments.

Fits into endoscopy portfolio

"The integration of the Emcision business is underway, and we expect it to be fully integrated over the course of the next year," Art Butcher, president and SVP, endoscopy, Boston Scientific told *BioWorld MedTech*. "The Emcision portfolio is a natural complement to our current portfolio of pancreaticobiliary devices and solutions, which help physicians diagnose cancer and treat the symptoms that patients experience during treatment for cancer."

Emcision's portfolio is expected to be sold under the Boston Scientific name. Boston Scientific also is developing devices to address the need for greater minimally invasive options in endoluminal surgery as a method to remove precancerous tissue and tumors of the GI system.

Patients with pancreaticobiliary cancer can experience blocked bile ducts and eventual jaundice due to tissue growth impeding the ducts and natural outflow. Habib can improve the ability to drain fluid by coagulating tissue blockages. Stents are sometimes placed in the GI area to ensure continual drainage, improving quality of life. Stents often are placed during palliative care.

"As we continue to search for ways to treat pancreaticobiliary cancers, we also seek to improve the quality of life for patients living with a cancer diagnosis today," said Butcher. "We are committed to exploring options to help increase the chance of early diagnosis, improve treatment and advance the ability to remove cancers located in challenging areas of the GI tract. The Habib Endo HPB probe is used with patients who are not candidates for surgery and helps improve a patient's quality of life by coagulating tissue that causes blockages in the GI tract. Approximately 20 percent of patients with pancreatic cancer and 40 percent of patients with cholangiocarcinoma are candidates for surgery."

Stent and ablation approach

A combination of stent placement for continued drainage and radiofrequency ablation (RFA) directly to tissues may have an enhanced effect, according to a 2014 *Digestive Diseases and Sciences*-published study examined stenting in GI cancers in comparison to stenting and RFA. "Comparison of metal stenting with RFA versus stenting alone for treating malignant biliary strictures: is there an added benefit?"was published online July 18, 2014. The authors concluded, "Our study confirms that RFA in combination with stent placement is a safe and effective technique for biliary decompression in patients with malignant biliary strictures."

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>
> Art Butcher
> President and SVP, endoscopy, Boston Scientific Corp.

Success in decompression and stent patency were equivalent, though the research found "RFA appears to improve survival in patients with malignant biliary stricture," according to the article.

Endoscopy portfolio

Boston Scientific's endoscopy division includes its Spyglass DS direct visualization system, a single use digital cholangioscope that can provide color viewing of the biliary, hepatic and pancreatic ducts. The system was launched in 2007 and can be used in conjunction with the Spybite forceps to obtain tissue for biopsy. Its Axios stent and electrocautery enhanced delivery system also provides an endoscopic option for transduoendal and transgastric drainage related to pancreatic pseudocysts. In late 2016, Boston Scientific also bought Endochoice Holdings, based in Alpharetta, Ga., for $210 million. Prior to that deal, Boston Scientific picked up private company, Cosman Medical Inc. The Burlington, Mass.-based firm makes radiofrequency ablation systems. Boston Scientific made another acquisition around the same time when its snapped up Distal Access LLC, adding Distal's gynecology and urology holdings into the company's pelvic health and urology business. Distal created its single use Resectr tissue resection device for removal of uterine polyps. (See *BioWorld MedTech*, Sept. 28, 2016.)

Several years back, Emcision had entered a global license agreement with Rita Medical Systems, of Freemont, Calif., for its Habib sealer disposable radiofrequency resection device to coagulate and allow for quick tissue removal. That agreement launched with a $50,000 initial payment, payment of $200,000 when the product received 510(k) clearance, and additional royalty and revenue target-based payments. The device, created by Nagy Habib, a professor of surgery at Imperial College London/Hammersmith Hospital and founder of Emcision, can be used with radiofrequency ablation systems and generators. (See *BioWorld MedTech*, May 27, 2005.) ♦

Appointments and advancements

Intuitive Surgical Inc. of Sunnyvale, Calif. said it has appointed Phil Bradshaw as its first general manager for the company's operations in the U.K. and Ireland. Intuitive said Bradshaw will direct business strategy and operations in those nations. He most recently served as strategic alliance director for EMEA at Medtronic of Dublin. He previously spent time at Stryker UK and Synthes. Intuitive develops, manufactures and markets the Da Vinci surgical system for robotic-assisted, minimally invasive surgery.

Owlstone

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cancer tests, while expanding the precision medicine arm of its business.

The new money will allow the company to reach a number of milestones, said co-founder and CEO, Billy Boyle. "[They] include bringing our lung cancer breath biopsy test to market, deepening our early detection pipeline – with ongoing trials across multiple cancers – and to further grow our existing precision medicine business," he told *BioWorld MedTech*.

The round was co-lead by a new investor Horizons Ventures, the private investment arm of Hong Kong business magnate Li Ka-shing, with existing investor Aviva Ventures as co-lead.

Other investors also followed on in the financing, which brings the amount raised by Owlstone Medical since it spun out of its parent Owlstone Inc. in August 2016 to $40.5 million.

Owlstone Medical's diagnostics depend on measuring VOCs in exhaled breath. In the first part of an ongoing lung cancer study funded by the U.K. National Health Service, it was shown that the company's Field Asymmetric Ion Mobility Spectrometry (FAIMS) technology could detect VOCs at thresholds 10 times lower than previously reported with other gas chromatography techniques.

Building on this, the second part of the study aims to validate lung cancer breath biomarkers from samples collected with Owlstone's breathalyzer, Reciva (Respiration collection for in vitro analysis), in 3,000 patients thought to have lung cancer and who have been referred for diagnostic tests.

Samples collected with the Reciva device are processed in Owlstone's central laboratory at its base in Cambridge.

That part of the study is ongoing. If successful, Owlstone plans to conduct a population-based screening trial.

Proving breath biopsy is a suitable tool for population screening in lung cancer will open the way for similar tests for the early detection of a range of cancers.

Owlstone is working with the charity Cancer Research UK to determine the VOC fingerprints for cancers including bladder, head and neck, kidney, pancreatic, breast and prostate cancer (See *BioWorld MedTech*, July 27, 2017.)

In addition to VOCs in breath, Owlstone is using FAIMS to measure VOCs in urine as the basis of an early diagnostic for colorectal cancer. The company says the kidney's role in filtering waste products from the blood makes it a good medium for detecting VOC disease markers.

Preliminary data from a study in colorectal cancer has shown the VOC signature in urine of patients with cancer can be distinguished from healthy controls, with sensitivity of 88 percent and specificity of 60 percent.

That is not as good as colonoscopy, but compares with fecal immunochemical testing (FIT) in use in national screening programs.

Research also has been carried out on noninvasive diagnosis of pancreatic cancer through VOCs in urine. In addition, the technology has been assessed as the basis for diagnosing pediatric inflammatory bowel disease by analyzing fecal VOCs.

Owlstone claims the advances it has made in standardizing the collection and analysis of breath samples will create a new diagnostic modality. "Since the founding of the company, we have established breath biopsy as a new industry category and are confident that the funding will allow us to demonstrate the significant value we can deliver," Boyle said.

The robustness and accuracy of FAIMS has been established over more than a decade by the parent Owlstone company, which markets the technology for applications including detection of chemical warfare agents, explosives, narcotics and toxic industrial chemicals, and for quality control in food and beverages, pharmaceuticals and water supply industries.

Given that, the main task for Owlstone is to demonstrate the VOC fingerprints of different diseases can be defined and distinguished one from the other, and that the metabolites from which they are generated are consistent across patient populations.

Breath biopsy captures VOCs released by the lungs that are a direct reflection of pulmonary disease. But because the lungs are very effective at exchanging chemicals with the blood, breath also provides a snapshot of all the metabolites being released from the bloodstream.

Owlstone says that capturing exhaled breath over one minute, the time taken for the blood to circulate all the way around the body, gives a complete metabolic picture.

In addition to cancer, Owlstone is involved in a study where breath biopsy is being used to stratify asthma patients into different subtypes, to inform treatment.

There is evidence that different VOC profiles correlate to different inflammatory subtypes, and also that VOC profiles can be used to tell whether a viral or a bacterial infection is the cause of an asthma exacerbation.

VOC analysis is being applied by Glaxosmithkline plc in a phase II study of the anti-inflammatory drug danirixin in the treatment of chronic obstructive pulmonary disorder. In addition to patient stratification, VOC breath biopsy will be used in the assessment of treatment effects.

Owlstone now plans to expand the use of breath biopsy in drug development and precision medicine, where it says the technology can provide dynamic information about disease activity and response to therapy. ♦

Appointments and advancements

Nephcure Kidney International, a non-profit based in King of Prussia, Pa., has appointed Joshua Tarnoff as the organization's CEO, a position Tarnoff assumes after serving as president/CEO of Complexa Inc. of Pittsburgh. Tarnoff's 30 years of experience includes stops at Astrazeneca and Viropharma. He said his move from the world of corporate pharmaceuticals to a patient advocacy group is timely. "It's the right time to build on the tremendous accomplishments that Nephcure has achieved to date and be able to work directly with patients to help advance cures" for various kidney diseases.

Retinal imaging

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in older adults, but a recent study published in the journal *Neurology* aimed to define that relationship more precisely.

In a longitudinal study, researchers found that people who presented with moderate to severe retinopathy in fundus photographs at about age 60, were much more likely to having thinking and memory problems by age 80. The researchers have incorporated more precise retinal imaging technology in a subset of patients in the study in an effort to understand even better how well the retina functions as a window into the brain.

Microvascular changes

"We know that vascular disease contributes to cognitive decline in older adults. So, we were really trying to get an idea of the relative contribution of microvascular disease. That would be the very, very small blood vessels and, unfortunately, with current standard-of-care imaging techniques like MRI, we can't see those very small vessels," Jennifer Deal, an assistant scientist at the Johns Hopkins Bloomberg School of Public Health, told *BioWorld MedTech*.

"But what's really unique and so wonderful about the eye is that it's anatomically and physiologically related to what's going on in the brain. So we think that by actually looking at the back of the retina, we can visualize those very small blood vessels and that gives us kind of an idea of what's going on in the brain," she continued. "So, that was really our goal. We wanted to try to estimate what the contribution of vascular disease might be to cognitive decline in older adults."

A prior study had looked at a similar question in this study population, but this time around researchers were able to examine all the patients rather than a sub-group and to have a longer time period of follow-up. With the larger population and longer follow-up, the results were heightened with the relationship between retinopathy at age 60 and later cognitive issue found to be even stronger than it had been previously.

In a longitudinal study of 12,317 people, about three years into the study when the participants had an average age of 60, a fundus photograph was taken with a retinal camera. At that time, 11,692 people had no signs of retinopathy, while 365 people displayed signs of mild retinopathy and another 256 people showed moderate to severe damage.

Those patients with moderate to severe retinopathy at about age 60 were found to have had much bigger drops in scores on memory and thinking tests that had been conducted over time through at least about age 80.

The scores of these patients declined by 1.22 standard deviation units over 20 years. In contrast, people who had healthy eyes had a decline of 0.91 standard deviation units. When adjusted for missed tests, the difference between the two groups was found to be 0.57 standard deviation units.

The association of cognitive decline with prior retinopathy, and the microvascular problems in the brain that this indicates, is actually stronger than the association with diabetes. A prior study using the same methods found that the difference in cognitive decline scores between healthy adults and those with diabetes was equal to 0.21 standard deviation units. Diabetes is known to be associated with cognitive decline, so the fact that microvascular issues are an even stronger indicator is significant.

OCT advances

"If our study results can be confirmed, differences in retinal integrity could provide reasonable estimates of how much small blood vessel damage in the brain is contributing to cognitive decline," said Deal.

Confirmation is expected to come with the inclusion of a subset of patients that are examined with a more precise kind of imaging of the eye: optical coherence tomography (OCT). Deal anticipates that the use of OCT could lead to the clinical use of a retinopathy diagnosis as a predictor of the risk of cognitive decline.

"Another type of eye imaging, OCT, may be more sensitive than the retinal fundus photography that we used. So, we're very interested in thinking about the association between OCT measures and what's going on in the brain with cognitive decline, as well. It may be that, eventually, that could be something that could be useful for clinical practice, just because it does have more sensitivity than the fundus photograph," said Deal.

Summed up the study, "Retinopathy was associated with accelerated rates of 20 year cognitive decline. These findings support the exploration of more sensitive measures in the eye such as optical coherence tomography angiography, which may provide surrogate indexes of microvascular lesions relevant to cognitive decline in older adults."

Biomarker complications

This research did not address any specific diseases related to cognitive decline, such as dementia or Alzheimer's disease. But Deal expects that OCT retinal images could offer a preclinical biomarker for dementia. Microvascular disease in the brain has been found on autopsy in dementia patients. Alzheimer's disease is one kind of dementia.

With its latest updated guidance on the topic, the FDA is encouraging drug developers to target Alzheimer's disease patients via biomarkers before they develop symptoms. The theory is that symptomatic patients are too far along in the disease process to be aided by drug candidates. But early identification of an at-risk population, without any accompanying meaningful treatments to offer those patients, carries its own risks as well when it comes to patient treatment.

"Any time when you think about screening in a population, we have to demonstrate the validity of the tool. We need to know who actually has the disease and to be able to correctly identify people who don't have the disease. So, we need to do both. And, ideally, we would have some sort of intervention," noted Deal.

She concluded, "If we were able to screen someone and tell them that they have a disease, but we are not able to do anything for them, that can be tough. That's why groups like the United States Preventive Services Task Force have not recommended for dementia screening in routine clinical care." ♦

AdvaMed

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Technology Association said digital health products that will have to go through the PMA and 510(k) channels should enjoy a streamlined review process as well.

The FDA workshop provided feedback from participants in the digital health pre-cert program, which the agency launched in July 2017 in the anticipation that a company's demonstration of a commitment to quality would suffice to demonstrate safety and effectiveness in lieu of traditional premarket review mechanisms. The concept was part of the agency's action plan on digital health, although not all the agency's moves in this area have been well received, including the draft guidance for clinical decision support systems. (See *BioWorld MedTech*, March 1, 2018.)

Rothstein, who leads the digital health effort at AdvaMed, acknowledged that the pre-cert program could reduce the demands on FDA's resources and cut regulatory red tape for developers. He said, "We believe the pre-cert program should apply broadly" to include software as a medical device (SaMD) and software embedded in a medical device. Artificial intelligence should likewise be eligible for a pre-cert program in the future, Rothstein said, adding that any such programs "should be software- and platform-agnostic."

Program eligibility and certification criteria should be constructed such that developers of all sizes "have the same opportunities to participate," Rothstein said, adding that large firms with established key performance indicators and development practices "should be held to the same eligibility criteria as a small firm that may have fewer internal software development KPIs." In short, Rothstein said, "the playing field for eligibility must be level."

Rothstein said that the program "should right-size the premarket process so it is better aligned with software development practices," relying on the risks associated with that product type along with that developer's demonstrated excellence. He said software subject to review under the 510(k) program "should at a minimum be provided an exemption or a streamlined premarket review," while programs currently requiring a PMA should be "offered a streamlined premarket process" as well.

Patel notes program viability by end of 2018

Several FDA officials were on hand for the event, including Bakul Patel, the CDRH associate director for digital health. Patel said the pre-cert concept assumes that a review process, driven at least in part by feedback derived from real-world evidence sources, is still essential. Patel indicated that the FDA intends to expand the pre-cert pilot into a full-fledged program in short order. "We are hoping by the end of this year to get to a minimum viable program (MVP) that we can then move forward next year" out of the pilot stage and into a full-fledged program.

This MVP, Patel stated, will require that stakeholders come to agreement on several crucial points, starting with a more or less final version of an excellence appraisal model. Following this, stakeholders have to come up with a streamlined review approach, and subsequently, the best methods of real-world data access and analysis. Patel noted that each step will include a public feedback loop, adding that much of the effort up to now has revolved around development of a common vocabulary.

"We will get it right to some degree, we will get it wrong to some degree. The key point is that we need your help and input . . . to make sure we get it right," Patel said.

Jeff Shuren, director of the Center for Devices and Radiological Health, briefly addressed the gathering, stating that digital health technologies challenge the incremental changes to the device regulatory framework as originally spelled out in the 1976 Medical Device Amendments, largely because the software device is more rapidly iterative than a hardware device.

Shuren said simplicity is a priority for the agency's regulatory effort going forward, the pursuit of which requires that CDRH will be "continually streamlining" policies and programs. He said the 2011 mobile medical apps guidance was focused on functionality and agnostic about the platform, and said a "massive de-regulatory effort" accompanied the guidance.

Shuren said the agency will continue to emphasize the formation of collaborative communities in order to keep pace with technological change, vowing that such efforts will not revert to "collaboration on our terms." He pointed to a similar effort for development of standards for next-generation DNA sequencing systems, adding, "we think in moving forward . . . we should be establishing one or more of these collaborative communities" for many of the regulatory tasks that lay ahead. "Whatever we build, we will do this together," he concluded.

Data quality an issue

There are those who wonder how manageable large volumes of data are, but John Birch of the investment firm Mid-America Angels in Kansas City, Kan., said the quality of those data are less than ideal. Birch said, "We hear pitches from software entrepreneurs all the time," and he predicted "there's going to be a flood of software of all kinds" once the FDA digital health program matures.

Birch said the quality of data that is collected from sources external to a software device, such as the data fed into electronic health records, "is really lousy. Its inconsistent and it's dangerous," he said, citing a recent report that artificial intelligence will be stymied "until the data problem has been solved. Just a cascade of errors is going to result," he predicted.

"Patient registries are booming right now," Birch said, adding that predictions are that investment in patient registries will rise from about $300 million in 2017 to more than $2 billion in five years. He concluded remarks by asking, "Can registries be the solution to the data quality problem?" ♦

Australia

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Pharmaceutical Industry Growth Center (MTPConnect).

The health innovation showcase was developed by Canberra-based start up Health Horizon, which led the applications for the second round of MTPConnect's Project Fund Program, MTPConnect CEO Sue MacLeman told *BioWorld MedTech*.

The Health Horizon showcase is one of 19 projects to receive investment from the 2017 MTPConnect Project Fund Program, a dollar-for-dollar matched grant program that invests in "big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector," MacLeman said.

Open to investors, health practitioners and the public, the showcase will be a place for anyone to make sense of, and support the diverse and rapidly evolving health innovation ecosystem.

"The number of health innovations being developed is astonishing," MacLeman said, "but, it is becoming harder and harder to keep on top of innovations and for those innovations to be found by the right people for collaboration and investment."

"Not only will it provide greater visibility of what is available or in development, it will help to drive greater collaboration between innovators who may be working to the same goal."

Bridging the disconnect for patients

Matthew McGann, co-founder of Health Horizon, said the genesis of the project came from the idea that people are keen to learn about what is new in health and to invest, but there's a disconnect between hearing about new discoveries and the 10-year window to commercialize them.

"That time span loses people, so now the public can watch the progress transparently," he said.

"For example, patients can see a clinical trial in the context of the journey of that innovation, so it provides a bit of context, and consumers can sign up to the platform to receive updates on certain trials or therapy areas."

"We want to be a place where practitioners and consumers and investors all use the platform on the same playing field. It's one massive network where they can all visit and track progress."

Health Horizon has two rules to list innovations on its platform: The technology needs to be an improvement over existing products, and there needs to an intent to spread the technology globally.

The medical innovation space was more clear-cut years a few years ago, McGann said, but in the last five or so years, the number of technologies has exploded, and "the journey through the ecosystem is really unclear. It's quite a confusing time," he said, noting that there's a feeling that health research and the commercialization of medical technology is a "separate world."

"But consumers are demanding more control, and they could pull innovation through the system that otherwise may not have survived," he said.

"We see that as trend where health will become more like any other industry, and the innovators will benefit from the increased transparency, and the entire ecosystem will benefit from knowing the progress of these innovations."

The project includes a consortium of national organizations to help support it, including the Medical Technology Association of Australia, Health Informatics Society of Australia, ANDHealth, Novartis Pharmaceuticals, Queensland University of Technology, the University of Newcastle and others.

ANDHealth CEO Bronwyn Le Grice said ANDHealth supported Health Horizon's MTPConnect industry application because "we were excited by the opportunity to use machine learning and artificial intelligence to support a living database and to help train that algorithm on innovations across the sector on a living basis."

"Our approach to digital health is the collision of IT and health care – from pharmaceuticals to apps to devices to digital therapeutics to electronic health records – and the best way of sourcing these is to see what is competitive and what is collaborative and where the opportunities lie."

"We're seeing a blurring of the boundaries between what's med-tech, what's digital health and what's pharma, and these living ecosystem maps are really important because you can't put things in clear-cut boxes anymore," Le Grice stressed.

Enabling national action

The initiative enables national action on key issues such as collaboration, commercialization, international engagement, skills and regulation reform. "It drives excellence, not dependence, and will create an economy that ensures Australia's ongoing prosperity," MacLeman said

"As with all of MTPConnect projects, the showcase aligns with one or more of our seven sector growth priorities," she said. Projects must be collaborative and industry-led, developed by consortia to creatively address barriers to growth and deliver results on a national scale with sector-wide impact.

MTPConnect was established as part of the Australian government's Industry Growth Centers Initiative, an industry-led approach driving innovation, productivity and competitiveness by focusing on areas of competitive strength and strategic priority.

This year, MTPConnect has selected 20 national MTP projects to receive $7.385 million in funding over two years with proposed matched funding of $15.2 million coming from the sector.

Last year, the launch of the program saw 14 projects receive $7.4 million in funding over two years, with matched funding of $15.6 million. ♦

BioAsia

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said such collaborations should speed up to tap into that significant innovation potential.

"Technologies can help analyze and compare data from clinical trials conducted under highly controlled conditions with data from the real world, which factors in socioeconomic conditions of the patients, physicians' outreach and patients' access to health care professionals," said Shreeram Aradhye, chief medical officer at Novartis Pharmaceuticals Corp. "Such collaborations help in advancing a digital transformation from discovery to engaging with health care professionals."

That, in turn, can help improve the lives of patients and health outcomes. For example, in patients with heart failure, digital tech can help in remote patient monitoring, enable an early warning system mechanism for patients not responding to treatment or developing any reactions, and aid in a more personalized, integrated health care model.

The potential that India holds to develop those collaborations has been an increasingly important focus of discussion in the country.

"We are in an era of Amazon and Google. India's experience in IT [information technology] could revolutionize drug discovery," Sridharan Natesan, head of strategic initiatives and scientific relations (North America R&D) at Sanofi SA, said during a session on how life sciences companies are bolstering the R&D pipelines through dealmaking.

With the emergence of digital IT startups in life sciences and health care, there are a number of models for pharma companies to collaborate with new businesses, said panelists at a session on collaboration between pharma companies and health tech companies.

"We need to work with startups working on next-generation technologies," said Subodh Deshmukh, senior vice president and head of global drug development, at Novartis India. Startups in the IT sector can help drive and improve operational efficiency in the pharma sector by helping mine and compile data, he added.

Similarly, New Delhi-based 1MG started with a drug discovery search engine and has now evolved to providing integrated care.

"Health care will be more personalized and more data-driven," said Vikas Chauhan, co-founder of the company, whose app offers personalized online assistance on health issues.

Apart from personalized medicine and patient-centric services models, big data have other uses for pharma companies. A 2017 report of Indian IT giant Infosys noted that pharma companies increasingly are deploying big data analytics programs. "Pharmaceutical companies are being inundated with data that most firms are simply not capable of leveraging. As a consequence, most companies have vast amounts of unleveraged and underleveraged data. Big data analytics provide a way to harness the unleveraged and underleveraged data and gain timely insights for making better business decisions."

The rise of big data

The report also cited how big data analytics can be used in the pharma industry.

Big data analytics "can simultaneously process clinical trial, molecular and publicly available data to either discover or rule out associations between molecules and targeted diseases." Similarly, predictive modeling can help predict outcomes such as efficacy and side effects.

Big data analytics can also help pharma wholesale distributors understand customers better and develop precise customer segmentation, the Infosys report said.

And given that in the global pharmaceutical chain, major suppliers, be it of bulk drugs or generics, are mostly located in Asia, big data analytics can help predict disruptions in supply chains to the U.S. market, due to, for instance, a natural disaster or geopolitical upheaval.

There are other areas that offer scope for collaboration.

Alok Ramgarhia, senior manager at Deloitte's India office in Guragon, near New Delhi, said that in the last four to five years, digital companies worldwide have been entering the health care sector, along with health insurance companies, launching their health apps for diagnosis and adherence to treatment.

For example, Dr. Reddy's Foundation for Health Education (DRFHE), an arm of the Indian generics major Dr. Reddy's Laboratories, based in Hyderabad, has launched several programs to improve the soft skills of doctors. Those include the Abhilasha program for nurses that aims to impart soft skills necessary for effective patient management and enhanced service orientation; and Sarathi, a soft skills program for physicians' assistants and front office, said Karunakar Reddy, IT manager at Dr. Reddy's.

A 2017 report of Research and Markets projected that in 2017, big data vendors would pocket nearly $4 billion from hardware, software and professional services revenues in the health care and pharmaceutical industry. Those investments are further expected to grow at a compounded annual growth rate of more than 15 percent over the next three years, eventually accounting for more than $5.8 billion by the end of 2020.

The Research and Market report also said that through the use of big data technologies, hospitals and other health care facilities have reduced costs by more than 10 percent, improved outcomes by 20 percent for certain conditions, boosted revenues by 30 percent, and increased patient access to services by more than 35 percent.

It said that big data technologies are helping to accelerate the transition "towards accountable and value-based care models, by enabling the continuous collection, consolidation and analysis of clinical and operational data from health care facilities and other available data sources."

The report also cautioned about the need to address privacy and security concerns to fully leverage the benefits of big data in the health care and pharmaceutical industry, which, in turn, necessitates significant investments in data encryption and cybersecurity: adopting defensible de-identification techniques and implementing strict restrictions on data use. ♦

Product briefs

Biotricity Inc., of Redwood City, Calif., reported the commercial availability of Bioflux, a real-time, high-precision mobile cardiac telemetry solution for customers. The Bioflux system is designed to be a complete solution for cardiac monitoring and diagnosis, consisting of the Bioflux device, proprietary software and a 24/7 monitoring center that merges with physicians' existing platforms and workflows. The device monitors a patient's ECG in near real time, constantly analyzing and collecting data on the device and periodically uploading to the cloud via embedded cellular technology. Both symptomatic and asymptomatic patient symptoms are reviewed and triaged for each patient throughout the monitoring period.

Calcivis Ltd., of Edinburgh, Scotland, launched its imaging system in the U.K. The Calcivis imaging system is designed for the assessment and management of dental caries and erosion. It involves a photoprotein that reacts directly with the calcium ions released from the tooth surface in the early stages of demineralization. Calcivis plans to launch its imaging system in the U.S. The company filed a PMA application with FDA in October 2017. The company anticipates launching the Calcivis imaging system in the U.S. in 2019, subject to the successful review of its PMA by FDA.

Corindus Vascular Robotics Inc., of Waltham, Mass., received 510(k) clearance from the U.S. **FDA** for the first automated robotic movement designed for the Corpath Grx platform. The software feature, named "Rotate on Retract," is the first automated robotic movement in the Techniq Series for the Corpath Grx platform. It allows the operator to quickly navigate to a targeted lesion by automatically rotating the guidewire upon joystick retraction. The software received CE mark approval in January 2018.

Irvine, Calif.-based **Endologix Inc.** said the first patient was treated in the EVAS2 IDE-approved confirmatory clinical study of the investigational Nellix Endovascular Aneurysm Sealing (EVAS) system by Sajjad Hussain at the St. Vincent Heart Center of Indiana. The Nellix system is an endovascular abdominal aortic aneurysm therapy designed to seal the entire aneurysm and has received a CE mark. The EVAS2 trial is designed to evaluate the safety and effectiveness of the second-generation Nellix system and the refined indications for use. The study is approved to enroll up to 90 primary patients at 28 U.S. centers, with one-year follow-up data required for the premarket approval application.

Nihon Kohden Corp., of Tokyo, reported the commercial launch of its NK-Hiq wireless patient monitoring system, a smart, secure data acquisition and management platform that leverages Wi-Fi technology to provide safe continuous patient monitoring in the hospital setting. The system captures and manages patient data from admission to discharge, seamlessly throughout the enterprise. The company will showcase its NK-Hiq system at HIMSS18 in Las Vegas, March 5-8.

Reshape Lifesciences Inc., of San Clemente, Calif., said results from a study examining real-world safety and efficacy of the Reshape Balloon were published in the February issue of *The Journal of Clinical Gastroenterology and Hepatology*. The article, titled "Real-world safety and efficacy of fluid-filled dual intra-gastric balloon for weight loss," discusses a retrospective, physician-sponsored study of data collected on 202 adults at two academic centers and five private practices in which all patients paid for the Reshape Balloon procedure and follow-up visits out of pocket. All patients had the Reshape Balloon inserted for weight loss therapy and the Balloon was removed from each patient after six months. Patients also received counseling on lifestyle modifications focused on diet and exercise. Primary outcomes were percent total body weight loss (%TBWL) and percent excess weight loss (%EWL) at one, three, six, nine and 12 months after the procedure. Mean %TBWL was 11.4 percent and 14.7 percent at six and 12 months, respectively. Also, 60.4 percent of patients achieved more than 10 percent TBWL and 55.4 percent had more than 25 percent EWL. The study investigators concluded that the Reshape Balloon is a safe and efficacious endoscopic method for producing weight loss, with most patients achieving greater than 10 percent TBWL at six months.

Sensus Healthcare Inc., a Boca Raton, Fla.-based developer of superficial radiation therapy (SRT) systems for the noninvasive treatment of non-melanoma skin cancers and keloids, reported the launch of the Sensus laser systems, a multiplatform line of dermatological lasers to compliment Sensus' existing SRT system. Sensus laser systems includes applications for hair and tattoo removal, acne lesion correction, skin rejuvenation and pigmentation/large pore treatment.

Triple W Japan K.K., Tokyo-based developer of Dfree, a connected wearable device that can track the progression of bladder movements using noninvasive ultrasonic sensors, said its product will be released in the U.S. later this year. The device will help elderly and disabled people who suffer from incontinence by notifying when they will need to go to the bathroom. Dfree is placed on the lower abdomen and monitors the change in bladder size. The data collected is then sent to a server where it is analyzed using a patented algorithm. The notification is then sent to a smartphone or tablet used by the patient, nurse or caregivers, to inform when it is necessary to go to the bathroom.

Shefayim, Israel-based **Zebra Medical Vision Ltd.**, reported the CE regulatory approval of its newest algorithm to be included in its growing Deep Learning Imaging Analytics platform. The algorithm is capable of detecting intracranial hemorrhages and broadens Zebra-Med's AI1 "All-In-One" Imaging Analytics package, which includes algorithms that automatically detect low bone mineral density, vertebral fractures, fatty liver, coronary artery calcium and emphysema.

Cardiology Extra

Keeping you up to date on recent developments in cardiology

By Katie Pfaff, Staff Writer

Study shows both Mediterranean and vegetarian diets are heart healthy

A vegetarian diet, which includes dairy and eggs though not fish and meat (lacto-ovo-vegetarian), may be as effective as Mediterranean diet at reducing heart disease risk and stroke, suggested a study published in *Circulation,* a journal of the American Heart Association. The study included 107 participants aged 18 to 75 who were overweight though healthy, and were randomly picked to follow a low calorie vegetarian diet with eggs and dairy for three months, or a low calorie Mediterranean diet for three months. Participants then switched to the opposite diet. Researchers reported both groups were able to lose about three pounds of fat and four pounds of weight total, and had similar changes in body mass index. However, a vegetarian diet was more effective at decreasing LDL while a Mediterranean diet resulted in reduced triglycerides. The study, "Low-calorie vegetarian versus Mediterranean diets for reducing body weight and improving cardiovascular risk profile: CARDIVEG study (cardiovascular prevention with vegetarian diet)," was published online Feb. 26, 2018. Limitations were that participants were considered low risk for heart disease.

Heart attack linked to waist and hip circumference rather than obesity

Carrying weight at the waist and hip is more strongly tied to risk of heart attack than obesity overall, according to a study in the open access *Journal of the American Heart Association*, and suggesting the distribution of fat plays a role. The link between an increased waist and hip measurement and heart attack is more pronounced among women. "Our findings support the notion that having proportionally more fat around the abdomen (a characteristic of the apple shape) appears to be more hazardous than more visceral fat, which is generally stored around the hips (i.e., the pear shape)," said lead author Sanne Peters, Research Fellow in Epidemiology at the George Institute for Global Health at the University of Oxford in the United Kingdom. The study included 500,000 U.K. adults between ages 40 and 69 from the Biobank. Authors suggested that general obesity and weight around the abdominal area had a detrimental effect on heart attack risk. Women were most affected by increased waist circumference and increased waist to hip ratio. Additional study may provide treatment strategies. The study, "Sex differences in the association between measures of general and central adiposity and the risk of myocardial infarction: results from the U.K. Biobank," was published online Feb. 28, 2018.

Heartflow entered licensing agreement with Cedars-Sinai for plaque technology

Heartflow Inc., of Redwood City, Calif., has entered a licensing and technology transfer agreement with Cedars-Sinai in Los Angeles for a software system to detect and characterize coronary artery plaque. The Autoplaque technology uses coronary computed tomography angiography (CCTA) images to illuminate plaques and allow for better diagnosis and planning in treatment for patients with coronary artery disease (CAD). Such assessment of plaques that may rupture, referred to as vulnerable plaques, and lead to acute coronary syndrome is being researched as a method of determining which plaques are most at risk. A recent study, EMERALD (Exploring the MEchanism of the plaque Rupture in Acute coronary syndrome using coronary CT angiography and computationaL fluid Dynamics) indicated Heartflow FFRct (fractional flow reserveCT) analysis with coronary plaque assessment may pinpoint which plaques are at greatest risk of rupturing. FFRct is a noninvasive method that creates a 3-D model of a patient's heart to look at blockages as well as blood flow to determine treatment options and the greatest possible effectiveness. "In addition to assessing lesion-specific physiology, understanding and characterizing coronary artery plaque is important in determining the most appropriate treatment path for patients with suspected CAD. The power of utilizing the Autoplaque tool in the Heartflow analysis may accelerate our ability to analyze and characterize plaque in coronary arteries," said John Stevens, president and CEO, Heartflow. "Heartflow is committed to looking beyond our initial FFRct offering to additional novel products that can help clinicians address other important clinical factors in the diagnosis and treatment of CAD and develop solutions that we believe will benefit patients who may be most at risk for acute coronary syndrome." CAD occurs as a result of narrowed arteries and can result in chest pain, myocardial infarction and death. Acute coronary syndrome results from decreased blood flow in the heart, possibly due to ruptured plaque in a coronary artery.

Opt-out vs. opt-in increases cardiac rehab referral rate: study

Taking the simple action of setting the default option for patients as "opt-out" as opposed to "opt-in" for cardiac referral increased rates significantly, according to a study presented at the American College of Cardiology. Patients who are recovering after heart attack, heart failure, angioplasty or heart surgery have been known to benefit from medically supervised cardiac rehab, including reduced readmission rates, reduced deaths and increased quality of life. However, not all patients complete the exercise counseling and education, smoking cessation and other guidance provided in cardiac rehab. In the study, care teams were informed of the benefits of rehab and provided information to patients at discharge. More than 40 cardiac rehab locations in the area were chosen and confirmed to take patients and participate in the re-ferral process. Staff helped patients chose the facility and program

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and sent the referral to that facility. A transition coordinator then followed up with patients a week after discharge. In the 21 months preceding the program, the cardiac rehab referral rate was about 12 percent on average. That rate jumped to 75 percent for the next three quarters after the program began. Patients who were discharged from hospitals that had not participated in the full program but were simply provided more information on cardiac rehab also saw referral rates increase from 4.2 percent to 24.8 percent, and 4 percent to 25.4 percent at two separate hospitals. “Cardiac rehab gives patients an opportunity to get back to or begin exercising safely under the guidance of a specialist and helps them understand medications they’ve been placed on,” said lead researcher Elizabeth Jolly, interventional cardiology transitions coordinator at the Hospital of the University of Pennsylvania in Philadelphia. “If a provider thought a patient would benefit from cardiac rehab, they would hand the patient a handwritten prescription but didn’t have the tools to get them there,” Jolly said. “At a big institution like ours, we have so many patients that it’s not always evident who qualifies for cardiac rehab. Now we know in real time. We started bringing cardiac rehab into our conversations with patients and adding it to discharge documentation and conversations following discharge as well. Now this is part of our daily workflow.”