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SALE DETAILS STILL BEING NEGOTIATED

Toshiba selling medical systems unit to Canon for estimated $6B

By Cornelia Zou, Staff Writer

Three months after the Japanese conglomerate Toshiba Corp. decided to cut loose of its health care and services unit, industry giant Canon Inc. is likely to scoop it up for $6 billion.

Toshiba announced on March 9 that it granted exclusive negotiating rights to Canon, among other bidders, for the sale of its Toshiba Medical Systems Corp. (TMSC) unit which manufactures diagnostic imaging systems including MRI, X-ray and ultrasound equipment.

"Toshiba has carried out a close evaluation of the overall proposals received from companies that expressed an interest in acquiring TMSC, including their appraisal of

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EXOSKELETON MARKET TO REACH $2.1B BY 2021

PH scores FDA nod for exoskeleton, Rewalk stumbles with warning letter

By Omar Ford, Staff Writer

Parker Hannifin Corp. said it has been given FDA clearance to sell its exoskeleton for clinical and personal use and plans to launch the device in the coming months. The Cleveland-based company said Indego, which is a powered

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REGULATORY

FDA gives its blessing to OSMA petition for class II for cervical screws

By Mark McCarty, Regulatory Editor

The FDA has announced that posterior cervical screw systems will henceforth be deemed class II devices, applying a designation to previously unclassified device type per the request of a trade association and a recommendation by an

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ONE STEP AT A TIME

Mayo, UCSF moving pharmacogenomics to front-line care

By Michael Fitzhugh, Staff Writer

Two major medical centers chasing some of the multi-faceted rewards of genomic sequencing – better informed prescribing decisions and potentially lower medical costs – are making slow but steady strides in rolling out nascent infrastructures for the project, according to key players in the initiatives who spoke

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Sientra reports losses, may shed Silimed as Brazilian manufacturer

By Sergio Held, Staff Writer

BOGOTA, Colombia — Troubled Santa Barbara, Calif.-based breast implants maker Sientra Inc. reported an expected drop in fourth quarter results even as it floated the possibility of moving on without relying on Silimed, its scandal-ridden Brazilian supplier.

During a results call on Wednesday, Sientra executives reported results that reflected the impact of a year-old crisis

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DIAGNOSTICS EXTRA

Staff Writer Omar Ford on one of med-tech's key sectors

Read this week's Friday Special

OTHER NEWS TO NOTE

A Worcester, Mass.-based startup, **Interscope, Inc.**, has received approval from the European Union to market its Endorotor system, an endoscopic device that streamlines interventional gastrointestinal procedures used to manage colon and esophageal cancer. Additionally, the U.S. Patent Office has awarded Interscope five patents for the medical device. Interscope's Endorotor system is a single resection tool to remove mucosal lesions (i.e., polyps) and Barrett's esophagus. According to the American Cancer Society, while a majority of mucosal disease is benign, patients with polyps and/or Barrett's have an increased risk for cancer. Interscope used this early-stage support to advance its business, which included selecting Boston Engineering to develop the product. Boston Engineering drove the product development and design for manufacturing process including feasibility and analysis; industrial design; rapid prototyping; and product engineering.

Newark, Calif. company **Magnetic Insight Inc.,** a maker of diagnostic imaging technologies, reported a collaboration with the **Stanford School of Medicine** around magnetic particle imaging for solving challenges in cell therapy and vascular imaging with magnetic particle imaging. The pediatrics, radiology, bioengineering and microbiology & immunology department will lead an effort to better understand early disease states in cancer and new therapeutic paths. In addition, the chief of radiology and neuroradiology at Stanford health care will also use the new imaging technology to perform quantitative cerebral perfusion and vascular studies in a variety of disease states, including stroke, traumatic brain injury and brain cancer, with the goal to eventually improve diagnosis and care in patients affected with these conditions.

The collaboration will focus on methods involving magnetic particle imaging to: track cells *in vivo* to study early and minimal residue disease states of cancer; develop therapies targeting breast tumors; and study inflammation response in stroke, traumatic brain injury and tumor. Magnetic Insight's Momentum Imaging system will be used in combination with Stanford's capabilities in optical, nuclear, CT and MRI imaging systems at the Clark Center.

San Francisco-based **McKesson Corp.** will consolidate and expand its operations in the Dallas metro area and open a new regional office in Irving. McKesson's expansion is projected to create at least 975 new jobs and $157 million in capital investment in Texas. A Texas enterprise fund grant offer of $9.75 million has been extended to McKesson, which is purchasing an existing 525,000 square foot office building in Irving as the location for their latest expansion. McKesson's Irving facility will perform vital functions including information technology, finance and accounting, administration and support, purchasing, and project management. The Irving facility will be in addition to McKesson's specialty pharmaceutical business that is headquartered in The Woodlands, Texas.

Amsterdam-based **Royal Philips N.V.** reported that its digital pathology solutions are among the first pathology IT systems and equipment to be certified for compliance with the U.S. Department of Defense (DoD) security requirements, under its DoD information assurance certification and accreditation process (DIACAP). As part of this certification, the Netherlands-based company says it will follow the DoD's risk management framework (RMF) and use industry best practices for security across all of its digital pathology solutions. Stringent security

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Toshiba

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TMSC's value and the feasibility of successfully completing the transaction, and determined that the proposal from Canon Inc. is superior to that of the other companies," said Toshiba in a stock market notice.

"We closely evaluated the overall proposals received from companies that expressed an interest in acquiring TMSC, including their appraisal of TMSC's value, the feasibility of successfully completing the transaction and the contribution the transaction would make to Toshiba's shareholders' equity," Midori Hara from Toshiba's communications division told *Medical Device Daily*. "We cannot comment on the details of the proposal as it is confidential."

"Details of acquisition are under negotiation, and we cannot comment on it now," Hara added.

Toshiba first disclosed its decision to invite third party companies to become the majority shareholders in TMSC in its Toshiba Rebuilding Initiative published at the end of December 2015. The company said it hopes this change will ensure sufficient support and generate resources for the health care business and improve Toshiba's financial position.

Toshiba will keep negotiating with Canon until March 18 to map out the final agreement.

The sale of the Toshiba business unit has drawn much attention in the med-tech industry. Toshiba was screening buyers including other leading technology companies such as Fujifilm Holdings Corp. and a joint bid by Konica Minolta Inc. and U.K. private equity fund Permira.

COMPANY LOOKING TO REBOUND FROM SCANDAL

Back in 2015, the revelation of irregularities in Toshiba's financial earning results sent the company into a tailspin.

Toshiba inflated its profits by ¥155 billion (US$1.38 billion) from fiscal year 2008 (Japanese fiscal years end in March the next year). The company's stock price nosedived from ¥501.1 (US$4.45) to ¥203.6 (US$1.81) in April 2015 when the scandal first surfaced.

"Toshiba's accounting scandal has damaged investor and consumer confidence, leading to widespread restructuring efforts aimed at rebuilding trust," noted industry intelligence company BMI Research in a report.

Several executives have resigned as a result of the scandal, the damage has also been reflected in the company's financial results. Toshiba now forecasts losses of ¥550 billion (US$4.6 billion) for fiscal year 2015.

"Toshiba is prioritizing the short-term in looking for a quick cash sale to boost its balance sheet," noted BMI Research. "The revitalization strategy is designed to offload underperforming assets, but the healthcare systems and services unit has reported reasonable financial performance in recent quarters and does not necessarily deserve to be weakened."

Canon, on the other hand, is boosting its presence in the med-tech sector as a part of its future expansion plans. The push can be seen from a series of investments and acquisitions in the field in recent years.

In February 2010, Canon acquired 90 percent of Polish ophthalmic diagnostic equipment maker Optopol Technologies S.A. in the hopes of becoming a world leader in that segment.

In May 2011, the Clinical Research Center for Medical Equipment Development was established at Kyoto University with funding from Canon. The company plans to accelerate clinical research into the use of optical ultrasound mammography systems.

In February 2012, Canon acquired Dutch company Delft Diagnostic Imaging B.V. that focuses on medical picture archiving and communication system software solutions, digital X-ray imaging systems and system integration.

In March 2015, Canon established Canon Biomedical, a wholly owned subsidiary, in New York. Canon Biomedical serves as a global headquarters for Canon's biomedical business including its life science and molecular diagnostics platform.

Canon's medical device business accounted for about 11 percent of its overall sales in fiscal year 2014. Sales grew 6.4 percent year on year to ¥400 billion ($3.4 billion) in the same period. Its medical device business focuses on key areas such as digital radiography systems, ophthalmic diagnostic systems, medical IT solutions and general diagnostic technologies. Its medical device products fall into two groups: ophthalmic and X-ray. The company produces X-ray cameras, ophthalmic refractometers, keratometers, fundus cameras, tonometers and laser imagers. //

Exoskelton

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lower limb exoskeleton enabling people with spinal cord injuries to walk and participate in over-ground gait training, is already commercially available in Europe, having received the CE mark late last year.

FDA clearance gives the company an opportunity to take a greater share of the exoskeleton sector, which is set to reach $2.1 billion by 2021, according to a December 2015 report from Wintergreen Research Inc.

"The most important part of this approval is that it allows the individual to take these exoskeletons home and use these devices in the community," Achilleas Dorotheou, head of the human motion and control business unit for Parker, told *Medical Device Daily*. "What you see in this device is really the tip of the iceberg."

Patients will have to be approved for the device and there is some level of training that goes along with using it, Dorotheou said. Indego was evaluated in the 40-patient Indego Exoskeleton; Assessing Mobility for Persons With Spinal Cord Injury study.

TROUBLE WITH REWALK

Indego's approval comes on the heels of FDA recently disclosing that Parker Hannfin's chief rival in the exoskeleton space, Rewalk Robotics Ltd.,received a warning letter from the regulatory agency for failing to comply with a requirement to conduct a post-market study plan and failing to disclose the letter on its annual financial statement.

Issues between the Yokneam,Israel/Marlborough, Mass.-based company and the agency bubbled up two years ago, when the FDA notified Rewalk that the post-market study plan it had proposed was defective. The FDA said the required information had to be completed within 30 days, which did not happen. After FDA said Rewalk's answer arrived late, the agency notified the company that particulars were still lacking.

Rewalk said it had responded to FDA and that it was working to resolve the issue.

"Rewalk Robotics responded within 15 business days to the FDA warning letter dated Sept. 30, 2015, and the company has been in regular communication with the FDA in the intervening months to resolve all issues tied to the post-market study, said Rewalk CEO, Larry Jasinski. "Restructuring the format of the study has raised additional conversations, and Rewalk is confident we will be able to reach a resolution that meets the requirements of the FDA 522 order."

PLAYERS IN THE EXOSKELETON SPACE

Up until now, Rewalk, which was formerly known as Argo Medical Technologies Ltd., has been relatively unchallenged in the U.S. home market for the robotic exoskeleton sector. The company received FDA clearance back in June 2014 (*Medical Device Daily*, June 30, 2014).

Rewalk also scored a huge victory when the U.S. Department of Veterans Affairs issued a national policy for the evaluation, training and procurement of the Rewalk Personal exoskeleton systems for all qualifying veterans (*MDD*, Dec. 21, 2015).

But the extra lead time Rewalk has had in the market only gave time for companies like Parker Hannifin to refine exoskeleton technology. Dorotheou said Parker Hannifin's expertise in engineering helped it design a more competitive device.

Dorotheou noted that Indego had a weight advantage over Rewalk's technology.

"The Indego is only 26 pounds and the Rewalk personal device is 66 pounds," Dorotheou said. "It's a pretty big difference. Indego is less than half the weight of Rewalk's device."

He added that the technology was also modular and could perfectly fold up into five separate components for the patient.

So far, there are two other players in the space other than Indego and Rewalk that are making an impact. These are Richmond, Calif.- based Ekso Bionics and Auckland, New Zealand-based, Rex Bionics. //

Other news to note

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and privacy requirements apply to all IT systems that operate on a DoD network. The DIACAP certification and authorization to operate allows the Philips Intellisite pathology solution, including the image management system, pathologist suite and scanner, to be deployed across global DoD sites.

Biocept Inc., a molecular diagnostics company from San Diego, which makes liquid biopsies to improve the detection and treatment of cancer, said Tel Aviv, Israel's **Progenetics LTD** will market and distribute Biocept's portfolio of Target Selector liquid biopsy assays in Israel. Terms of the transaction were not disclosed.

Regulatory

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advisory panel convened in 2012.

The March 10 *Federal Register* notice stated that the Orthopedic Surgical Manufacturers Association (OSMA) had made the request for a class II designation for posterior cervical screw systems. The agency reminded that these devices, a pre-Amendments device the agency had not formally classified until now, emerged from pedicle screw spinal systems, which had been deemed class II devices in 1998. The agency separated posterior cervical screw systems from the pedicle screw category three years later, although such devices have been reviewed under the 510(k) program in the interim.

In response to OSMA's 2011 petition for a class II designation, the FDA had convened a Sept. 21, 2012, advisory committee that recommended class II for posterior cervical screw systems, although that recommendation was limited to the use of such devices as adjuncts to fusion in the cervical spine and in the cranio-cervical junction. The proposed class II order sustains the adjunct-to-fusion recommendation by the panel, although the agency did not directly address several recommendations regarding indications for use made by the panel. Among these are use in traumatic spinal fractures/dislocations, failed previous fusions, and degenerative disease, including facet disease with demonstrated instability.

Also among the indications the 2012 panel had recommended were for temporary restoration of stability in patients with advanced stage tumors, assuming the patient's life expectancy was insufficient to achieve fusion, but pediatric use was also recommended by the advisory committee.

Among the special controls the FDA has proposed is the use of CT or MRI imaging to discern the location of the transverse foramen and the vertebral arteries. The agency said that only three devices, made by two manufacturers, are affected by the classification under product code NKG.

OSMA told *MDD* that the organization is "very pleased that FDA has finally published the *Federal Register* notice announcing the proposed rule." The OSMA added that it will "be carefully reviewing the document and plan on submitting comments to the docket."

The American Academy of Orthopedic Surgeons was unable to provide a spokesperson for comment.

FDA SLAPS MD BIOSCIENCES FOR ZIKA TEST

The FDA has never shied away from clamping down on marketing of unapproved or un-cleared tests for pathogens that are the subjects of emergency use authorizations, and MD Biosciences of St. Paul, Minn. found itself in the agency's crosshairs. The company received an untitled letter stating that the company's marketing of a real-time polymerase chain reaction test for the Zika virus is violative due to the lack of a regulatory filing, but the company's press statement touting the test was still available as of the afternoon of March 10.

The company's Feb. 29 statement claims that the Zika nucleic acid test is not confounded by other pathogens such as Dengue and West Nile, known to be species that cross-react for Zika, but the FDA was unimpressed. The agency said that the urgency of the Zika predicament made it "particularly important" that the FDA have access to information on the test's design, validation and performance characteristics.

GRASSLEY, WARREN PROD CMS ON UDI

Sens. Elizabeth Warren (D-Mass.) and Chuck Grassley (R-Iowa) have penned a March 8 letter to acting CMS administrator Andy Slavitt and two other officials at the Department of Health and Human Services, asking when unique device identifiers will finally appear in Medicare claims. The letter is the latest salvo in a series of proddings that the CMS has yet to act on due to what the agency is said to believe are insuperable technological challenges.

The senators' interest in this area dates back to at least 2014, when the duo inked a letter to then-CMS administrator Marilyn Tavenner inquiring into the matter, and the Office of Inspector General weighed in with a Sept. 1, 2015, letter to the senators. The OIG letter stated that Medicare likely incurred costs in excess of $1 billion associated with the recall of Medtronic's Sprint Fidelis leads. However, the OIG letter indicated that arriving at a precise estimate of the potential savings associated with incorporation of UDI data was difficult due to difficulties associated with working back from the then-currently available data.

Warren and Grassley acknowledged that the next revision of Medicare claims forms is not due until 2021, but remarked that "the window to make changes (to those forms) is rapidly closing."

AETNA SAYS YES TO CRYO FOR AFIB

Aetna of Hartford, Conn., indicated it will cover cryoablation for atrial fibrillation in a recent clinical policy bulletin citing appearances in the literature that for the most part were at least a decade old.

The bulletin stated that two medical societies, including the American College of Cardiology, offered a class I recommendation for ablation for atrial fibrillation, a recommendation said to have made no distinction between radio-frequency and cryoablation. The most recent journal entry cited is Blomström-Lundqvist, et al, from the 2007 edition of the *European Heart Journal*. All the other citations date back at least as far as 2005.

UHG COVERS SINUS SURGERY

Unitedhealthcare has published its monthly coverage bulletin for the month of March, stating that functional endoscopic sinus surgery (FESS) is now covered. The coverage applies to patients with chronic rhinosinusitis of at least 12 weeks

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Pharmacogenomic

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at the Molecular Medicine Tri-Con meeting this week.

Out of the more than 1.3 million people provided direct care by Mayo Clinic in 2015, it sequenced the genomes of about 600 individuals in 2015, said Keith Stewart, director of the clinic's Center for Individualized Medicine. Growing the number of individuals sequenced from that relatively small number to the clinic's goal of having 50,000 patients sequenced annually instead will take a leap of automation though. "We can't have PhD post-docs sitting, pouring over genomes for two days each. It needs to be fully automated to be done at scale," said Stewart.

Furthermore, the out-of-pocket price point will need to fall. People tend to be comfortable with a sequencing service in the $500-range while, as of today, patients pay $9,500 to get their whole genome sequenced by way of Mayo's executive health program.

To close the gap, Mayo made a strategic investment in Helix, a San Francisco-based company that has a neutral platform offering genetic sequencing using Illumina's existing technology and database services for consumer samples brought through third party partners. Illumina joined New York-based private equity firm Warburg Pincus and venture capital firm Sutter Hill ventures to seed Helix with $100 million last summer. (See *Medical Device Daily*, Aug. 20, 2015.)

In the name of building a strong infrastructure to support its practice, the center has launched a biobank consisting of tissue samples for 50,000 primary care patients who've had an average of 10 years follow-up at the clinic in their medical records – an average of 27 doctor visits. It just started sequencing the biobank's samples and expects to have the first 1,000 patients sequenced with whole genome sequencing soon.

The technical infrastructure required to support the project has been substantial. Mayo has already partnered with the University of Illinois, Urbana-Champaign and Oracle Corp. as well as storage management providers. It has also had to hire a biomedical informatics team to help it help it with analysis and bioethicists to guide them in the data's use. Even more work is being done to address a gap in terms of educating patients, providers and payers about the potential value of the program.

One of the many practical applications that have arisen from Mayo's efforts to date is the implementation of 20 pharmacogenomic rules in its medical records system, said Stewart. Alerts suggest to doctors that they run a genetic test when it might impact their prescribing decisions or instruct them on how to apply existing test results to directing drug choices. Still, "we're currently a little dissatisfied with the evidence in favor of pharmacogenomics, particularly when it comes to getting payer reimbursement," said Stewart.

To address that issue, Mayo is making a big bet on a trial called TAILOR-PCI, for "Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response After Percutaneous Coronary Intervention." While the current standard of practice is to prescribe clopidogrel (Plavix) for one year, up to 30 percent of those who undergo angioplasty have a genetic variation in the CYP2C19 liver enzyme that interferes with clopidogrel metabolization. TAILOR-PCI is designed to determine whether moving those poor metabolizers of clopidogrel to an alternative antiplatelet medication, such as Brilinta (ticagrelor, Astrazeneca plc), may be more effective, have fewer side effects, and reduce repeat hospital and clinic visits – thus lowering the overall cost of care.

The ongoing 6,000-patient study, now about half enrolled via 25 global hospitals, is using rapid genotyping to identify the poor metabolizers of clopidogrel. Its primary endpoints are non-fatal myocardial infarction, non-fatal stroke, cardiovascular death, severe recurrent ischemia, or stent thrombosis in 12 months.

"This is the kind of evidence we're going to need to get widespread reimbursement for these kind of tests," said Stewart. The clinic should see a readout for the trial within the next couple years.

RESISTANCE AND PROGRESS AT UCSF

"The acceptance of pharmacogenetic testing requires cooperation between three groups:

patients, first and foremost; providers, because they have to be able to prescribe, understand, and react to it; and payers, because if your payers aren't going to reimburse for it, it's not going to be done," said Joshua Galanter, an assistant professor at the University of California, San Francisco School of Medicine and a member of the school's pharmacogenetics implementation committee.

Although his committee arrived at a similar conclusion to Mayo regarding the potential value of CYP2C19 testing for Plavix, instead of facing reimbursement issues, his team ran up against a lack of provider buy-in when it sought to convince UCSF cardiologists. Those doctors write about 6,000 prescriptions for clopidogrel each year. Research findings applied to the demographics of UCSF's patient population suggesting that a CYP2C19 testing program could potentially avert two to three deaths by stroke per year.

"It seemed like a slam dunk," he said. Alas, when the committee approached UCSF's cardiologists, "they basically said no thank you," he said. Objections ranged from skepticism about the data around CYP2C19 and familiarity with clopidogrel to steadfast belief in clopidogrel's efficacy and the higher costs of alternative medicines. Since then, the committee has found some traction in talking to neuro-interventional radiologists.

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Sientra

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that came to a head at the end of 2015 with suspended licenses for its supplier and a fire at a manufacturing site. Total net sales for the fourth quarter of 2015 were just $1.5 million, a decrease of $10.6 million from the same period in 2014.

"The past five months have been enormously challenging for Sientra and all our stakeholders, including customers, employees and investors and I'm sure you are all aware of it," said Sientra CEO Jeffrey Nugent.

On Oct. 9, 2015 Sientra placed a voluntary hold on the commercialization of its products in the U.S., following the suspension of the CE certificate of Silimed, from Rio de Janeiro, Brazil, their manufacturer and breast implants provider. On Oct. 22, 2015, a fire broke out in the Brazilian company's plant, destroying the manufacturing site of Sientra´s products (*Medical Device Daily*, Nov. 4, 2015).

"Our organization faced these challenges head on acting honestly and responsibly and we made difficult decisions in order to protect the most valuable asset that we have: the trust of our board certified plastic surgeon customers," explained Nugent, who assumed the direction of the company five months ago, right after the crisis started.

But despite the company's response, its financings were seriously hit during the fourth quarter, as Sientra confirmed this week. Sientra´s gross profit for the quarter was $1 million, a decrease of 64.4 percent compared to the same period a year earlier.

Sierra's stock (NASDAQ: SIEN) traded up 1.77 percent on Wednesday to close at $8.07, well below a 12-month high of $26.67 but also much higher than the lows of $2.78.

The company is now moving forward and trying to get over a crisis that undermined its shares and placed it in a challenging position. During the company's most recent call, Nugent was reluctant to discuss details about the manufacturing alternatives open to Sientra but he did confirm that a high level team is working on the issue.

"Our primary objective is to develop a manufacturing capability that is consistent with our current product specifications," said Nugent. "So, while the first objective is to enter into a confident high quality resupply, we are also looking at the ability to bring innovations into the market," he said. "But the first priority is to take what we've manufactured in the past with Silimed. And to be able to have multiple sources, and a level of confidence associated with these alternatives is frankly what we just learned, is critical to meeting the objectives that we have."

Sientra´s priority is to design the manufacturing process and make it as efficient as possible, so they can maintain their gross margin.

"And the second part is to do that job so well, that the FDA certification process skews toward the shorter end of the spectrum than the longer, and we believe that we have a high level of credibility with the FDA, so frankly that is one of the variables that causes us not be able to be more forthcoming," he said.

When asked about a possible change of location, Nugent declined to talk about Silimed.

"I can't comment on Silimed," he said.

Announcements regarding a new manufacturing site, either with or without Silimed, should be expected for June or July 2016, according to Nugent.

When asked for a possible relocation of the manufacturing site to the U.S., Nugent just said that manufacturing and re-entering the supply chain is one of the company's top priorities.

"I want to remind everyone that we had taken the initiative some time ago to establish a redundant and duplicate source of supply and those aggressive plans are on schedule and moving on well," he said.

During 2015´s fourth quarter, the company spent $29.2 million in operating expenses. The figure is an increase of $17.8 million or 157.2 percent compared to operating expenses of $11.4 million for the same period in 2014.

"The increase is primarily due to the goodwill impairment of $14.3 million. Further increases were due to an increase in product development costs, transition costs for certain former executives and outside legal counsel costs," the company said.

On Wednesday, Sientra reported the acquisition of the exclusive U.S. rights to biocorneum, an advanced silicone gel scar management products line, in a transaction with Enaltus LLC, from Suwanee, Ga. The deal was worth $7 million in cash. //

Regulatory

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duration, although the insurer will not cover implant of drug-eluting stents for maintenance of sinus patency.

The bulletin includes updates for a number of coverage matters, including for epidural steroid injections for spinal conditions and bariatric surgery. //

Pharmacogenomic

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Happier outcomes have followed since then, including successes around the implementation of a program that has implemented reminders to doctors around testing for HLA-B*5701 prior to prescription for the antiretroviral Ziagen (abacavir). The test can help head off a potential hypersensitivity reaction that occurs in about 3.7 percent of patients given the drug.

A program around testing for CYP2D6, a polymorphism that leads patients to have trouble with weak opioids, is also making progress, said Galanter, though reimbursement issues mean that patients need to pay for the test out of pocket. UCSF is exploring the potential of paying for the tests itself if data suggest that they ultimately boost patient satisfaction and reduce follow-up visits.

As of today, 137 FDA-approved drugs feature pharmacogenetic information on the labels, including nine instances in which the information has made it into a "black box" warning. In light of the large number of potential opportunities for better tailoring medication though, spending six months developing individual programs for every drug that has a potentially significant pharmacogenetic component is unsustainable, said Galanter.

In an effort to take the next big step for integration of genomic sequencing and pharmacogenetic testing into medical practice, both UCSF and Mayo are taking part in the Institute of Medicine's DIGITizE initiative, short for Displaying and Integrating Genetic Information Through the EHR. "The idea is to establish connectivity in clinical decision support that's common for everybody so that each institution doesn't have to reinvent the wheel."

UCSF is also preparing for the flood of information that it expects to begin seeing in coming years. Patients will at some point start arriving with their entire genome either genotyped or sequenced. "They're going to have pharmacogenetic tests done for everything, and we're going to have to be able to look at them for all drug, simultaneously, the second they arrive," he said. "Right now, we're getting a drip, drip, drip of genetic testing. But in the future, it's going to be like drinking out of a fire hose," he said. **//**

APPOINTMENTS AND ADVANCEMENTS

Saratoga, Calif.-based **Visioncare Ophthalmic Technologies Inc.**, the developer of the implantable miniature telescope for end-stage age-related macular degeneration (AMD), reported the appointment of ophthalmic industry veteran, Thierry Clidiere, to its board. Clidiere joined Alcon Laboratories in 1983, where he spent the next 28 years in executive management positions.

PRODUCT BRIEFS

Avita Medical Ltd., of Northridge, Calif., a company which makes regenerative medicines for wounds and skin defects, reported positive results from the company's multicenter clinical trial of Regenercell in the treatment of chronic venous leg ulcers. The company claims the positive results indicate that the cellular suspension delivered by Regenercell shows great promise as an effective treatment for healing chronic wounds that have resisted other approaches in this sizable area of unmet medical need, and that a statistically-powered pivotal trial is now justified.

Boston Scientific Corp., of Marlboro, Mass., has received FDA approval for the Blazer Open-Irrigated (OI) radiofrequency ablation catheter. The Blazer OI catheter has been approved to treat Type I atrial flutter, an abnormal rhythm of the upper chambers of the heart. The approval of the Blazer OI catheter marks the first time Boston Scientific will offer an open-irrigated catheter to the U.S. market.

Oakland's **Dictum Health Inc.**, has unveiled it virtual exam room (VER), the centerpiece of its telehealth system. The VER is private, uses clinically accurate medical devices while providing patients with real-time access to their physicians. Patients can use the VER to see a physician, share real-time vital signs, cardiopulmonary data and medical images. Patients can create their personal exam rooms using the company's IDM100 integrated medical tablet, and physicians enter the VER using the care central web interface from their laptop or tablet.

Rheonix Inc., of Ithaca, N.Y., has completed development and testing of a microfluidic system and assay to simultaneously detect host anti-HIV antibodies and viral RNA in a single specimen of saliva or blood. The company's findings are outlined in the recently published research article, "A Rapid, Self-confirming Assay for HIV: Simultaneous Detection of Anti-HIV Antibodies and Viral RNA" in the *Journal of AIDS & Clinical Research*. The assay is performed on the Rheonix CARD (Chemistry and Reagent Device). Once a raw sample is placed on the Rheonix CARD, the automated platform runs with no user intervention through the process of sample extraction, purification, amplification and detection.

St. Jude Medical Inc., based in St. Paul, Minn., reported CE mark approval for magnetic resonance conditional labeling for 1.5 T scans for the company's Nanostim leadless pacemaker. This approval will allow patients with this pacemaker to safely undergo a full-body MRI diagnostic scan. The Nanostim is less than 10 percent the size of a conventional pacemaker and designed to be implanted directly in the heart without the need for a surgical pocket or lead. Implanted via the femoral vein with a leadless technology delivery system, the device is designed to be fully retrievable so that it can be readily repositioned throughout the implant procedure and later retrieved if necessary.

DIAGNOSTICS EXTRA

Keeping you up to date on recent developments in diagnostics

By Omar Ford, Staff Writer

Nanostring, CST reach agreement to create protein assays

Nanostring Technologies Inc., of Seattle, a provider of life science tools for translational research and molecular diagnostic products, and **Cell Signaling Technology Inc.** (CST), of Danvers, Mass., a provider of antibodies, have reached an agreement to use highly validated antibodies from CST in Nanostring's 3-D Biology Protein Profiling Panels. 3-D Biology applications enable researchers to simultaneously measure combinations of up to 800 DNA, RNA and protein targets in a single experiment. The agreement brings together leaders in the fields of multiplexed genomic profiling and antibody development to create new protein-based assays that will expand Nanostring's 3-D Biology product offerings. CST will supply antibodies for use in Nanostring assays which will be marketed by Nanostring for use with its nCounter Analysis System. These assays will provide investigators with powerful tools to uncover the molecular mechanisms of disease and enable the development of more comprehensive treatment strategies.

Sensitive biosensor opens door for on-the-spot diagnostics

A compact optical device that can rapidly and sensitively detect biomarkers in urine has been developed by researchers at Agency for Science, Technology and Research. It has promise for developing simple point-of-care diagnosis of cancer and other diseases MicroRNAs are a newly discovered class of short (about 19 to 24 nuclides in length) fragments of noncoding RNAs that are useful biomarkers for diagnosing various diseases, including cardiac disease and some cancers. Since they are surprisingly well preserved in fluids such as urine and blood, their detection is well suited to a rapid, point-of-care method. Researchers at the A*Star Institute of Microelectronics and have devised a silicon photonic biosensor that can detect tiny changes in the phase of a light beam caused by hybridization between an immobilized DNA probe and target microRNAs in a sample.

Diagnostic liquid can detect tooth decay

The days of the dreaded dental drill-and-fill as the standard solution for tooth decay may be numbered if a discovery by a Creighton University School of Dentistry professor continues to advance. Douglas Benn has created a simple diagnostic liquid solution that can be applied to the surface of a patient's teeth prior to a dental X-ray and which will help show dentists whether a tooth has cavitated decay or is pre-cavity. The diagnostic liquid will help dentists to more readily see cavitated decay on a standard X-ray and will also allow the dentist to use recently developed topical products to arrest tooth decay at an early stage, thereby preserving healthy tooth structure and utilizing a simple, pain-free method of detection and treatment, without anesthesia or drilling. Dental caries - otherwise known as tooth decay - is the most common infection in the world and probably the one producing the most anxiety in potential dental patients. Caries goes through two stages: an initial non-cavitated state where decay can stop and no filling is needed, and a later cavitated state where a filling is often needed to stop decay from progressing. Currently, dentists do not have a test to determine the difference between the two states, and this leads to the standard treatment: a drilling and a filling. But decay doesn't automatically mean a cavity, and the filling cure can often be more trouble than it's worth. Benn said American Dental Association data indicate some two-thirds of fillings are replacements, meaning the treatment, historically, needs to be repeated, and can cost a patient an average of $2,000 per filled tooth over a lifetime. With the use of the diagnostic liquid solution, he estimated 50 percent of cases resulting in dental fillings today could be delayed or avoided, with other recently developed treatments deployed to stave off cavities.

Chronic conditions may be common at MS diagnosis

People newly diagnosed with multiple sclerosis (MS) may often have other chronic health conditions as well, according to a study published in the March 9, online issue of *Neurology*, the medical journal of the *American Academy of Neurology*. For the study, researchers examined how common several chronic conditions were in 23,382 people with MS at the time of their diagnosis and 116,638 people of the same age and sex without the disease. The conditions included high blood pressure, diabetes, high cholesterol, heart disease, chronic lung disease, epilepsy, fibromyalgia, inflammatory bowel disease, depression, anxiety, bipolar disorder and schizophrenia. The people with MS had higher rates of all of the conditions except high cholesterol. The rates were especially high for mental illness. The most common condition was depression. At least 19 percent of those with MS had depression compared to 9 percent of those without the disease. As depression and anxiety can affect quality of life and can increase the risk of hospitalization, the ability of people to be adherent to their medication regimens is important. Marrie said these conditions should be closely monitored. For many of the conditions, the rates differed for men and women with MS. For men with MS, the rate of high blood pressure was 48 percent higher than for men without the disease: 22 percent of men with MS versus 15 percent of men without MS. For women with MS, the rate was 16 percent higher than for women without the disease: 14 percent of women with MS vs. 12 percent of women without MS.