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J.P. Morgan Healthcare & OneMedForum 2012 Conferences

Diagnostic companies display wares to highly receptive audience

By HOLLAND JOHNSON
***Medical Device Daily* Managing Editor**

SAN FRANCISCO — Just a couple of blocks away from the shoulder-to-shoulder crowds at the J.P. Morgan Healthcare Conference, the much smaller OneMedForum conference on healthcare was moving along at the Sir Francis Drake Hotel. A Tuesday morning track on diagnostics held attendees in thrall, with several intriguing private companies vying for the affections, and potentially, funding from investors.

First up to bat was Scarlett Spring, the CEO for **VisionGate** (Phoenix), a company developing a non-invasive test for the early detection of lung cancer and other applications. Scarlett noted that lung cancer, the world's number one deadliest form of cancer, is often detected too late to save a patient's life. "We want to change that," she

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Biotech Diaries: Sernova cutting through 'valley of death' at JPM

By JENNIFER BOGGS
***Medical Device Daily* Contributing Writer**

SAN FRANCISCO — On the periphery of the 30th annual J.P. Morgan Healthcare Conference, with its 8,000 registered attendees and crowded hallways at the Westin St. Francis hotel, another tier of activity reigns: the small and medium-sized life sciences companies hoping to gain an audience with the right investor or partner to bolster shrinking cash balances and propel R&D work to the next levels.

One such firm is **Sernova** (London, Ontario), a regenerative medicine cell therapy firm. The small Canadian company, which re-invented itself in 2006 with a listing on the Toronto Venture Exchange (SVA.V) and an approach for improving the islet transplantation space, has remained largely under the radar. But, in June 2009, Sernova appointed

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Lack of funding, FDA burdens threaten industry growth

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Growth and innovation in the biomedical industry is in serious trouble and, according to a recent CEO survey, problems at the FDA and lack of funding (which lead back, at least in part, to problems at the FDA) are largely to blame.

Access to capital, a burdensome and uncertain regulatory environment and lack of innovation and productivity in R&D are the biggest threats to the biomedical industry's growth over the next five years, according to company CEOs surveyed by the **California Healthcare Institute** (CHI; La Jolla, California), **BayBio** (South San Francisco), and **PwC US** (New York).

Nearly three quarters (74%) of biomedical industry CEOs surveyed said their companies have had to delay

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Washington roundup

AHRQ backs knee replacement, tallies increased use by Boomers

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

It's no surprise to hear that a cohort of nearly 80 million is having an effect on the volume of a surgical procedure, but Carolyn Clancy, MD, director of the Agency for Healthcare Research and Quality, let it be known in a Jan. 3 posting at the AHRQ website that despite the scare over implants in other parts of the body, data from a government study suggests that knee implant procedure "give[s] a better quality of life that makes it worth the cost." Clancy also said the benefits of the procedure "are even better if the surgery is done at a hospital that does a large number of knee replacement procedures."

Clancy said data obtained by AHRQ indicated that those

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Don't miss today's MDD Extra: Oncology

INSIDE:

AHC Media

International report

Qiagen's EGFR detection kit receives Japanese approval

A *Medical Device Daily* Staff Report

Qiagen (Hilden, Germany) reported regulatory approval of its therascreen EGFR Mutation Detection Kit RGQ in Japan. EGFR, the epidermal growth factor receptor, has been shown to play an important role in certain cancers and is the target of many new anticancer drugs.

The company says this approval is a milestone in its personalized healthcare strategy, as Japan is one of the world's largest markets for companion diagnostic tests. In April 2011, Qiagen's therascreen KRAS Mutation Detection Kit was approved in Japan, targeting a different biomarker that is also used to guide cancer treatment decisions. The potential patient population alone in Japan for EGFR and KRAS testing is estimated at almost 100,000 per year.

"Greater use of companion diagnostic tests such as our EGFR and KRAS assays may help overcome significant challenges by maximizing the efficacy and safety of therapies and improving patient outcomes," said Stephen Little, VP of global personalized healthcare at Qiagen. "Japanese and other East Asian populations generally have a higher rate of EGFR mutations than other groups, and non-smoking East Asian women are the largest potential market for EGFR-inhibitor anticancer drugs. This approval allows QIAGEN to market our companion diagnostic along with major pharmaceutical companies offering certain EGFR-inhibitor drugs. The approval of therascreen EGFR exemplifies our strategy of driving dissemination of molecular technologies by creating innovative test content and providing efficient, automated platforms for hospitals and laboratories to use these tests."

Companion diagnostic tests targeting EGFR, like QIAGEN's therascreen EGFR Mutation Detection Kit RGQ, determine the presence or absence of an EGFR mutation in a patient's tumor. Individuals, for whom treatment decisions are made following determination of EGFR mutation status, can experience 60% response rates to EGFR-inhibitor drugs, a much higher success rate than with traditional chemotherapy, studies show. Conversely, other patients can be unresponsive to EGFR-inhibitor drugs. Using the companion diagnostic not only may improve therapeutic outcomes, but also save patients and healthcare systems a significant amount of money since the newer classes of drugs can cost tens of thousands of dollars. By determining EGFR mutation status, doctors can prescribe the relevant drugs only to patients who are expected to benefit from them.

Japanese cardiologist uses RenalGuard for CIN

PLC Systems (Milford, Massachusetts) reported that Ichiro Michishita, MD, a leading Japanese cardiologist, has completed two cases using RenalGuard for the prevention of Contrast-Induced Nephropathy (CIN) at **Yokohama Sakae Kyosai Hospital** (Yokohama, Japan). This is the first step in the process to secure regulatory approval for RenalGuard in Japan.

"I am very pleased that the very first cases utilizing RenalGuard in Japan to prevent CIN were successful. I am very impressed with the ease of use of the system, and how it works to maintain the fluid balance of the body. Once it is approved by the MHLW, I believe that RenalGuard will be a great benefit for patients undergoing PCI requiring contrast media," said Michishita.

Artimplant shifts focus of Artelon to U.S.

In what it calls a focus on establishing itself in the U.S. market, **Artimplant** (Vastra Frolunda, Sweden) said it will take over responsibility for sales of Artelon CMC Spacer, previously handled by the licensee **Small Bone**

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Grants roundup

GQ doles out more than $120K in software, services for labs

A *Medical Device Daily* Staff Report

GenomeQuest (Westborough, Massachusetts), a provider of large-scale genomic software applications, said it has awarded six grants totaling more than $120,000 in software and services to help six laboratories facilitate the transition from multiple Sanger-based gene tests to consolidated next generation sequencing (NGS) based tests.

"As a clinician, I am intrigued by the potential benefits of NGS for the long-term and the practical benefits in the near-term," said Roberta Pagon, a professor in the Department of Pediatrics at **University of Washington** and principle investigator of GeneTests and GeneReviews. "At this point it appears that the entry path to NGS for a number of labs listed in the GeneTests Laboratory Directory will be through consolidation of existing single gene testing into multi-gene panels – such panels will benefit many patients whose physicians are seeking to identify the genetic basis of an inherited disorder. The GenomeQuest Lab Grant program offers a complete NGS bioinformatics solution that promises to help labs advance to NGS and next generation testing services."

GenomeQuest will provide the software, annotation data, and infrastructure required to process and store NGS data, produce diagnostic reports, and perform follow-up research on individual and aggregate results. Recipients will use the resources to more quickly and cost-effectively perform a variety of diagnostics for rare genetic disorders, autism, cystic fibrosis, congenital heart disease, muscular dystrophy, and harmful bacterial pathogens.

"We look forward to collaborating with the six grant recipients who were selected from a competitive field of applicants based on their clear, actionable vision for utilizing NGS-based diagnostics in the clinic," said GenomeQuest CEO Richard Resnick. "Lab directors are recognizing the enormous opportunity to improve patient care by screening larger and larger regions of the genome while simultaneously lowering costs and turn-around times with next generation sequencing. This program supports GenomeQuest's commitment to empowering laboratories with the knowledgebase and interpretation tools they need to bring new NGS-based diagnostics to the clinic." ■

Agreements/contracts

Orthofix to develop bone grafting technology for MTF

A *Medical Device Daily* Staff Report

Orthofix (Lewisville, Texas) has reached an agreement with **Musculoskeletal Transplant Foundation** (MTF; Edison, New Jersey) to both co-develop and commercialize a new technology for use in bone grafting applications and to expand MTF's Trinity Evolution processing capacity. MTF and Orthofix have also extended the initial term of their existing agreement for an additional five years.

"Our collaboration with Orthofix has been highly successful, and we are excited to expand our partnership through the development of this innovative new tissue form for the benefit of surgeons and patients," said Bruce Stroever, CEO of MTF. The new tissue form incorporates all three properties necessary to facilitate bone growth, enables excellent handling characteristics, and is complementary to Trinity Evolution.

"Together with the expanded capacity for Trinity Evolution, we are adding to our biologic pipeline and are very well positioned to help MTF fulfill its mission and meet the market's increased demand for novel bone grafting solutions," said Vaters. The parties plan to introduce the new tissue form in 2013.

Orthofix is focused on innovative repair and regenerative technologies to the spine and orthopedic markets. The Musculoskeletal Transplant Foundation is a full service tissue organization dedicated to providing quality tissue through a commitment to excellence in education, research, recovery and care for recipients, donors and their families.

In other agreements/contracts news:

• **Applied BioCode** (Santa Fe Springs, California) has signed a license and supply agreement with **Hologic** (Bedford, Massachusetts), a maker of diagnostics products, medical imaging systems and surgical products. Under the agreement. Hologic may purchase barcoded magnetic beads with digital multiplex capabilities for up to 128-plex testing from Applied BioCode. Hologic plans to use the barcoded magnetic beads in conjunction with Hologic's proprietary Invader chemistry to create highly multiplexed nucleic acid based tests for the agriculture market.

"Our partnership agreement with Applied BioCode enables us to address the growing need for increased throughput and cost containment through highly multiplexed testing in the agricultural testing market," said Rohan Hastie, VP/GM, Hologic Molecular Diagnostics. "Our combined technologies should offer a powerful solution for our customers."

Applied BioCode makes highly multiplexed (128-plex and 4,096-plex) products to assist those focused on the molecular diagnostics, bioresearch, and biomarkers validation.

• **Teleflex** (Limerick, Pennsylvania), a provider of medical devices for critical care and surgery, reported a new agreement with **Novation** (Irving, Texas) for Teleflex's Arrow Dialysis Access products. The agreement begins April 1 and extends through March 31, 2015. Novation is the

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HIT roundup

HealthEdge, Keane deliver BPO software services

A *Medical Device Daily* Staff Report

HealthEdge (Burlington, Massachusetts), a provider of enterprise-class software platforms for healthcare payors, has entered into a strategic partnership with **Keane** (Boston), an NTT DATA company, to provide enterprise software that will deliver performance-based business process outsourcing (BPO) services to the healthcare payor community. By combining HealthEdge's HealthRules product suite with Keane's ability to improve operational and technology performance, payors will have the opportunity to predictably and cost-effectively manage current delivery while supporting new and emerging healthcare models and initiatives.

The performance-based BPO offerings from Keane will offer payors transparent solutions that align customer expectations with quantified outcomes. This new alternative will allow payor organizations to address many of the critical business imperatives facing today's healthcare economy, including value-based and consumer benefits, healthcare and payment reform, and evolving initiatives surrounding Accountable Care Organizations. In addition, payors that leverage the new Keane BPO offerings will have a partner that can immediately support the increased workload expected from implementing new standards like ICD-10 and HIPAA 5010.

"Our partnership with HealthEdge will allow Keane to deliver compelling value to our customers by offering solutions that optimize operational performance while reducing administrative cost," said Michael Ragan, senior VP, Life Science and Healthcare, for Keane. "By combining Keane's proven ability to deliver value to our market, with the flexibility and unique capabilities of the HealthRules products, we can now offer payors a wide array of BPO services that not only reduce costs but introduce new levels of transparency and predictable performance that will allow them to compete more effectively in their markets."

In other HIT news:

• **Zynx Health** (Los Angeles), a maker of evidence-based and experience-based clinical decision support (CDS) solutions, reported the release of a new software enhancement designed to improve productivity for joint Meditech and Zynx Health clients. The company's Export Validation provides an efficient integration of content into the electronic health record (EHR) system for Meditech clients, facilitating a more streamlined approach to delivering evidence-based CDS to the point of care.

These latest Zynx Health software enhancements will enable hospitals and healthcare systems to smoothly integrate CDS into health information technology and enable hospitals in meeting meaningful use standards for EHRs.

The Zynx Health Export Validation tool is a content development functionality that allows joint Zynx Health and Meditech subscribers to expedite integration of their ZynxOrder evidence-based order sets into the Meditech computerized provider order entry (CPOE) system and accelerate speed to go-live. Export Validation identifies potential integration barriers, deploying warning and error icons that provide the opportunity to address any issues during the order set development phase. Efficient global mapping enables the removal of integration errors caused by unmapped terms across all order sets using the same term.

• **Medsphere Systems** (Carlsbad, California) and **Midland Memorial Hospital** (Midland, Texas) said that Midland Memorial has met the requirements for Stage One Meaningful Use with Medsphere's OpenVista system, the company's EHR, and has received an initial reimbursement from the federal government. According to Midland Memorial administrators, the hospital has received initial disbursements of $2.3 million from the Medicare side of the program and $1 million in Medicaid compensation.

Having gone live in early 2006, well before the federal reimbursement program was established, Midland Memorial is Medsphere's long-standing partner and a true pioneer in the adoption of open source EHRs derived from the U.S. Department of Veterans Affairs' VistA EHR system. The 320-bed West Texas hospital will ultimately receive in excess of $7 million, significantly more than the initial investment cost of OpenVista, from the federal government over the life of the meaningful use reimbursement program established by the American Recovery and Reinvestment Act (ARRA).

Medsphere's subscription-based pricing model enables hospital, clinic and integrated delivery network customers to pay for OpenVista from their operating budget with no upfront costs or back-end balloon payments.

• **iHealth Lab** (Mountain View, California), a maker of mobile personal healthcare products for iPod Touch, iPhone, and iPad, unveiled three new additions to its suite of devices: iHealth Smart GlucoMeter, iHealth Wireless Body Fat Scale, and iHealth Wireless Blood Pressure Monitor.

The iHealth Smart GlucoMeter lets users test blood glucose levels and test, graph and share blood glucose results. The system uses industry standard test strips and a specially designed iHealth test strip reader that attaches to an iPod touch, iPhone, or iPad. The iHealth Wireless Blood Pressure Monitor lets users test, track and share their blood pressure – wirelessly. Using their iPhone, iPod touch or iPad, they can connect their iOS device via Bluetooth technology to a comfortable, soft blood pressure cuff. The iHealth Wireless Body Fat Scale reads and records vital body composition components such as weight, body fat, and muscle mass directly on an iPod touch, iPhone, or iPad. A unique design based on human body engineering automates user identification so that multiple users on multiple mobile devices can share a single scale. ■

Patent watch

Saladax Biomedical gains six immunoassay patents

A *Medical Device Daily* Staff Report

Saladax Biomedical (Bethlehm, Pennsylvania), a privately held company developing and commercializing novel diagnostic assays to achieve the promise of personalized medicine for new and existing therapeutics, reported that it has been issued six patents within the last 12 months, bringing the company's total to 15 issued U.S. patents, all of which contain broad claims in the immunoassay space.

The issued patents are as follows:

- Busulfan Immunoassay: U.S. Patent No. 7,893,220
- Stabilized Standards for Busulfan Immunoassay: U.S. Patent No. 8,039,220
- Doxorubicin Immunoassay: U.S. Patent No. 8,053,205
- Imatinib Immunoassay: U.S. Patent No. 8,076,097
- Doxorubicin Immunoassay: U.S. Patent No. 8,084,586
- Resperidone Immunoassay: U.S. Patent No. 8,088,594

"The issuance of these patents in the U.S. positions Saladax as the leader in chemotherapy dose management and we believe that Saladax has been issued more patents in the therapeutic dose management (TDM) space than any other diagnostic company," said Salvatore Salamone, founder and CSO of Saladax. "Of particular note, our patent for Resperidone marks a significant milestone for Saladax as this is our first patent in the CNS field."

• **American Shared Hospital Services** (San Francisco), a provider of turnkey technology solutions for advanced radiosurgical and radiation therapy services, said that a U.S. patent has been allowed on a variety of technologies jointly owned by AMS and NBBJ LP, a leading global architecture and design firm, that are designed to increase efficiency and improve patient outcomes in the operating room.

"These technologies have applications ranging from novel operating room lighting systems to innovative operating table design," said Ernest Bates, MD, chairman/CEO of AMS.

• **Argentum Medical** (Chicago) reported the issuance of US 7,989,674, US 8,093,444, and allowed claims for U.S. Application 11/930,541. All cover Silverlon antimicrobial wound, burn and surgical dressings. These patents not only clarify and expand patent protection to double layer fabrics, non- woven materials such as silver calcium alginates, but also include conductive gels.

"The USPTO has, once again, recognized our technological advancements in the art and granted us new patent protections," said Gregg Silver, CEO of Argentum Medical. "Over the past 10 years we have lead the market in developing a comprehensive silver nylon based product portfolio to harness the Safe. Strong. Simple antimicrobial powers of pure silver." ■

Agreements

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healthcare industry's supply contracting company for the members of VHA, UHC and Provista.

Teleflex offers a full line of dialysis access products. The Arrow brand of dialysis access products includes the Arrow NextStep, Arrow Cannon and Arrow Edge chronic hemodialysis catheters, the Arrow PTD declotting device and micropuncture introducers.

Novation is a supply contracting company, serving members and affiliates of VHA, UHC, and Provista.

• **CJPS Healthcare Supplies & Equipment** (Auburn Hills, Michigan) has been awarded a 36-month group purchasing agreement with the **Premier** (Charlotte, North Carolina) healthcare alliance, for its vital signs monitors and its telemonitoring equipment. Effective Feb. 1, the new agreement allows Premier members, at their discretion, to take advantage of special pricing and terms pre-negotiated by Premier for VitalPoint Home, VitalPoint Pro, and their respective peripherals.

VitalPoint Home is a remote patient monitor; VitalPoint Pro is a vital signs monitor.

Premier maintains a repository of clinical, financial and outcomes information and operates a healthcare purchasing network.

• **Conmed Healthcare Management** (Hanover, Maryland) has signed an agreement with Galveston, Texas, to provide correctional healthcare services for the County of Galveston Jail. The initial 20-month contract, which is effective Feb. 1, is expected to generate revenues for Conmed of roughly $5.8 million during its initial term. The contract has the option, at Galveston's request, for three additional one-year renewals, with medical services CPI increases in renewal years for a total aggregate value of about $16.2 million.

The contract includes a full suite of medical and mental health services for Galveston detainees, including: physicians, nurses, medication aides and paramedics; a dentist and dental assistant; a psychiatrist and mental health professionals; emergency department and hospitalization; management of pharmacy services; x-ray; and laboratory services. The average daily population of the facility is approximately 1,000 detainees.

Conmed has provided correctional healthcare services since 1984. ■

Diagnostics

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said, adding, "We have the technology to actually bring a screening test to market."

The company's 3-D cell imaging platform, dubbed Cell-CT, is capable of generating high resolution 3-D biosignatures from intact cells through a technique called Optical Projection Tomography, which enables early lung cancer screening for symptomatic and high-risk populations through the Lung Cancer Early Detection Test. A cell is transported through the Cell-CT's glass micro-capillary by applying pressure to a gel that embeds cells. As the capillary spins, the cell is scanned from multiple perspectives to yield a set of pseudo-projection images that are combined using filtered back-projection, which produces the final 3-D cell volume.

Scarlett estimated that the opportunity in this space as somewhere between $7 billion to $9 billion. She also noted that the company already has 60 patents worldwide for the technology, with another 50 pending. The company is pursuing a 510(k) de novo application using the technology as an adjunct to the more traditional CAT scan that is used to detect lung cancer. "That should give us the pathway into the FDA," she said, adding that the company expects to submit the application in October 2012.

Scarlett said that the company is not out to disenfranchise any area of the pathology or radiology community. "This is actually a brand new revenue stream, whether you be a physician, whether you be a lab that might test for this condition, or whether you might be a diagnostic company." She added that while the company is initially coming to market as an adjunct technology to CAT scan, "we do believe our rightful place is first-line screening."

Earlier this week, the company reported that it had achieved full automation of its Cell-CT system (*Medical Device Daily*, Jan. 9, 2012). Development of the fully automated system was funded in part by a $2.6 million grant from the National Institutes of Health's (NIH) BRDG-SPAN program (Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies).

Providing a potential new technology for the early detection of breast cancer is **Life Medical Technologies** (Hopewell Junction, New York) The company's main offering is the BreastCare DTS (Differential Temperature Sensor), a device for mammography and other procedures for the detection of breast diseases, including breast cancer. The system is a noninvasive device that enables women to screen for breast cancer in conjunction with annual or biannual mammography and clinical breast examination.

Company President/CEO Carol Fitzgerald said the device already has FDA 510(k) clearance as an adjunct to mammography and other procedures for the detection of breast disease, including breast cancer. She noted that the early detection of breast cancer is critical, with only 20% of patients surviving when the cancer has reached Stage 4.

The device is designed to detect the increased heat given off during angiogenesis, the process whereby tumors in the breast are fed via newly formed capillaries. During the procedure, sensors are applied to a women's breasts and the heat from the skin is conducted to three foil sensors on each breast. After 15 minutes, the sensors display a pattern of blue and pink dots. The pink dots indicate the temperatures of the three regions of each breast.

"If there is a difference of four columns or 2 degrees temperature difference, it's been shown in clinical studies to be a very strong risk indicator for breast cancer," Fitzgerald said.

More than 5,000 women have been evaluated thus far in clinical trials, and while Fitzgerald noted that no detection method is 100% accurate, "by using something as inexpensive as our device as an adjunct to the other detection methods, we're able to give women an earlier chance to find breast cancer when it's more treatable." She said that the sensitivity of the test was between 71% and 90%, and has a U.S. retail price of $39.95. Importantly, Fitzgerald also pointed out that the BreastCare DTS works well in pregnant and lactating women "that can't have radiation from mammography."

Pitching for **GlySure** (Abingdon, UK), a developer of in-hospital continuous blood glucose monitoring systems, was CEO Chris Jones. GlySure has developed an intravascular glucose monitoring system that enables effective clinical implementation of tight glycemic control (TGC) in hospital ICUs. Jones said that research has demonstrated that tightly controlling glucose levels in the ICU can siginificantly reduce mortality. However, contemporary methods of glucose monitoring remian both time-consuming and expensive, which results in far less frequent monitoring than is needed by these patients.

The company's sensor, Jones said, "is designed with the nurse in the ICU in mind and to integrate easily into their everyday practice."

The company said that its trials in human serum, plasma, and whole blood confirmed that the sensor can measure glucose levels across the entire human physiological range with a very high degree of accuracy.

Jones said the real-time feedback that the sensor provides will have a great impact in the ICU, "and gives physicians the type of control that they're looking for."

Earlier this week, the company reported the close of its $10.9 million Series C financing round (*Medical Device Daily*, Jan. 10, 2012). The company will use this funding to complete clinical trials to support regulatory approval in the U.S. and Europe.

The financing round was supported by Morningside Venture, as well as existing investors Amadeus Capital Partners, Chester Investments and Delta Partners. Since its foundation in May 2006, GlySure has secured a total of $19.5 million in venture capital funding. ■

Sernova

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new CEO Philip Toleikis, and in the last two and a half years, his team has completed the preclinical package needed to launch the first clinical study in Canada later this year.

"We have money in the bank to get the clinical study up and running," Toleikis told *Medical Device Daily*. Over the last two and a half years, he has gone to the firm's retail investors and obtained government grants, pulling in about $4.5 million in funding altogether. As the company looked ahead past the planned 20-patient Phase I/II trial, however, it was clear more money would be needed. "We're crossing that valley of death between a preclinical- and clinical-stage company," he said, adding that Sernova is looking for around $5 million to $10 million.

So Toleikis arrived in San Francisco Sunday, armed with a three-day schedule of one-on-one meetings with prospective investors, partners and consultants. And, on Monday, he let *Medical Device Daily* tag along.

9 a.m. I met with Toleikis in the lobby of Hotel Nikko, just a few blocks from the Parc 55 Wyndom hotel, which is hosting the simultaneous Biotech Showcase. An earlier meeting with a prospective investor was rescheduled. We had a couple of hours before Toleikis was slated to give a 30-minute presentation at the Showcase, so I took that opportunity to get a little background on the company – and on Toleikis.

The Sernova CEO started as a scientist and eventually worked his way up into senior management at **Angiotech Pharmaceuticals** (Vancouver), the firm that helped pave the way for drug-device combos with its drug-eluting coronary stents. By figuring out a way to add drugs to the bare metal stents, Angiotech grew the stent market "from $500 million to a $4 – $5 billion market," Toleikis said. "That's the kind of thing I'd like to do here" with the islet transplantation space.

Using islet transplantation to get diabetics off the daily insulin injections is not a new idea. For the past few years, a process called the "Edmonton protocol" has been available, a treatment method that involves the use of donor islet cells infused into the portal vein – usually from two to four pancreata – transplanted into diabetic patients. It works – at least to some degree – and lasts for a few years.

The problem is that the majority of islet cells end up dying in the process – they don't like being bathed in blood, Toleikis said. There also is a limited number of donor islet cells. Plus, patients receiving islet transplant must stay on anti-rejection pills for the rest of their lives.

Sernova's approach involves the transplantation of islet cells via the Cell Pouch System, a scalable polymer medical device about the size of a business card that can be implanted in an outpatient procedure under the skin. At implantation, the device would hold removable plugs, around which tissue and micro-vessels would form to create a natural environment. After a few weeks, the plugs would be replaced with the donor islet cells – and eventually with Sernova's cell-based technology Sertolin to provide immune protection, Toleikis said.

Those cells would then be capable of reading insulin levels in the blood and releasing insulin as needed, eliminating the need for insulin injections. Animal data have been strong, he added. If Sernova can confirm those results in humans, the Cell Pouch could mark a potentially disruptive treatment in the diabetes space.

10:15 a.m. We headed over to the Parc 55 hotel – after making a quick Starbucks run – and made our way to the fourth floor meeting rooms. We caught the tail end of another firm's presentation before Toleikis took the podium. During his presentation, he stressed the benefits of the Cell Pouch System, such as the fact that it requires only 10% to 25% of the islet cells required under the Edmonton protocol.

Toleikis also noted that the product already captured the attention of James Shapiro, the physician from the **University of Alberta, Edmonton**, who developed the Edmonton protocol. Shapiro has since signed on as the lead investigator for the upcoming Phase I/II trial, expected to start in the first half of this year.

As Sernova CEO, Toleikis does hundreds of these types of presentations a year. But he tries to never let it seem by rote. He takes a similar approach to dealing with existing and potential investors. "I always take their calls," he said. "You never know if they're going to invest a million dollars or two dollars."

At the end of the presentation, a few prospective investors wanted to chat, so we headed to the breakout room down the hall. After a brief conversation, during which one of the investors advised Toleikis to emphasize the lack of available donor islet cells as a major selling point for the Cell Pouch System, the Sernova CEO agreed to a follow-up phone call and meeting after the conference to start the due diligence process.

2 p.m. Following a lunch break, Toleikis and I ended up back in the meeting rooms at Parc 55, where Toleikis spent a few minutes talking to a contract research organization (CRO) that also made equity placements. The CRO seemed interested in the technology's potential, and they agreed to talk later about potential regulatory strategies and possible funding opportunities.

Sernova has decided to launch the upcoming trial in Canada first, where the regulatory path is clearer. Canadian authorities accepted the firm's suggestion to seek clearance of the Cell Pouch System as a medical device – the therapeutic cells are approved separately. That means development of the Cell Pouch should move rapidly. Sernova anticipates, pending positive data from the Phase I/II study, to go straight into pivotal testing pending regulatory approval.

Getting the program through the FDA as a medical

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Funding

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a research or development project in the past year. Lack of funding was the top reason for project delays cited by private company CEOs, and accounted for more than one-third (40%) of delays by all public and private companies in the survey. Eight in 10 CEOs surveyed agreed or strongly agreed that the current FDA regulatory approval process has slowed the growth of their organization.

Findings of the CEO survey reflect issues being discussed throughout the biomedical industry by executives gathering in San Francisco this week for the 30th annual J.P. Morgan Healthcare Conference and the 5th annual OneMedForum meeting. The survey was conducted in November and targeted about 100 companies that conduct business in California in the areas of pharmaceuticals, biotechnology, medical devices, diagnostics or medical equipment. The findings also provide an early glimpse into the 2012 California Biomedical Industry Report, due in February.

"As the center of biomedical innovation in the U.S, California's biomedical industry is a national treasure," said Gail Maderis, president/CEO of BayBio. "But the pace of R&D productivity and its global leadership position hang on the availability of capital to fund future innovation and a regulatory framework that is based on consistency and innovative technologies."

Leaders from CHI, BayBio, PwC, and the CEOs of **NuVasive** (San Diego), **Omniox** (San Francisco), and **Theravance** (San Francisco) discussed the findings during a press briefing Tuesday in San Francisco.

"These major concerns of our companies are in fact having an impact on the ability to move projects forward," Maderis told reporters during the briefing.

The CEO survey found that biomedical companies in California have been resourceful over the past year in seeking diverse funding sources, divided almost evenly among government grants, angel investors, venture capital and licensing agreements and partnerships.

"Biomedical companies have long relied on government grants and venture capital to finance innovation, but funding sources are shifting and companies will need to adapt to a new reality," said Tracy Lefteroff, national life sciences partner at PwC US. "While venture capitalists and angel investors will continue to be an important source of funding, it has become increasingly difficult for biomedical companies to gain access to them. Alternative sources of funding are emerging, which highlight shifting opportunities and dynamics in life sciences innovation."

Lefteroff told reporters during the briefing that venture-backed biomedical companies likely have a rough couple of years ahead of them. "When you go out and talk with venture capitalists today they will tell you that the number one concern on their plate is how much money they are going to need to fund a young company because they don't know what the pathway to FDA is," he said.

According to the survey results, 44% of biomedical CEOs said they will look to licensing agreements and corporate partnerships as a source of finance in the next 12 months, double the number of CEOs who last year said their companies are using this avenue for finance.

Corporate venture funding, the investment of corporate funds into external endeavors, is expected to become a much more crucial source of funding to the industry, with 30% of CEOs surveyed saying they will tap corporate venture capital as a finance source in the next 12 months, versus only 10% who did so in the past 12 months.

Though still only a small contributor to the finance equation, disease foundations/non-governmental organizations are growing as a funding source for 11% of CEOs who plan to use these funds in the next 12 months, versus only 4% who did last year.

Access to capital is seen by CEOs as the most influential state policy issue to keep biomedical research, innovation and investment in California. Nearly three-quarters (72%) of CEOs said that access to capital is extremely important, followed by tax incentives for innovation (60%), corporate taxation (51%), workforce preparedness (47%) and duplicative regulation among various state and federal agencies (37%).

According to CEOs surveyed, FDA and regulation are the key issues affecting R&D, with 81% noting that coverage and reimbursement issues are extremely important to the industry's ability to advance biomedical research, innovation and investment in California.

In addition, 80% of CEOs surveyed do not believe that FDA has the best regulatory approval process in the world, and three-quarters believe that within five years, another country could conceivably recreate the ecosystem that has made the U.S. the leading biomedical region in the world.

"Sound public policy and managerial and operational improvements at FDA, along with responsible congressional oversight, will encourage biomedical innovation and, ultimately, job growth here in California," said David Gollaher, PhD, president/CEO of the California Healthcare Institute. "Working collaboratively with other stakeholders, Congress, FDA and the biomedical industry can maintain the high standards of safety and effectiveness that address patients' need, while improving our ability to attract investment and grow in 2012 and beyond."

NuVasive Chairman/CEO Alex Lukianov told reporters during the briefing that his company, which is just over a decade old, has noticed a "huge slow down" in the time it takes to get a product approved by FDA and released to the market. "We continue to see ongoing challenges with regard to FDA . . . really significant delays," he said. "Last year the delays cost our company $70 million in lost revenue in 2011 and pouring over into 2012 as well as having to reduce our headcount growth plans . . . because of products that were backed up at FDA."

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Washington

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between the ages of 45 and 64 " were more than twice as likely to have had knee replacement surgery in 2009 than in 1997," adding the observation that knee replacement surgery "is most common in people whose knees have been damaged by osteoarthritis, rheumatoid arthritis, or injury." The Boomers' fondness for sports puts them "neatly into each category," Clancey continued, and she made note of some none-surgical options for heading off problems with knee degeneration, including the use of supplements of glucosamine and chondroitin as well as joint lubricant shots. Of this latter approach, Clancy said, "studies have found that most people who get the shots do not improve very much."

AHRQ offered a set of data from the Hospital Cost and Utilization Project (HCUP) comparing the rates of knee arthroplasty procedures for men and women in 2009. The text from the report states that the aggregate rate of knee arthroplasty for women and men aged 45-64 "was about 2.5 times higher in 2009 than in 1997." For men, the rate increased 144%, from 11 stays per 10,000 persons in 1997 to 28 in 2009, while the rate for women rose by 157%, from 16 stays per 10,000 in 1997 to 42 in 2009.

The parents of Boomers also experienced a higher rate of knee arthroplasty procedures according to AHRQ, which states in the text that the rate increased by 69% for women between the ages of 65 and 84, jumping from 72 stays per 10,000 in 1997 to 122 stays in 2009. Men of this generation, however, exhibited a much less pronounced increase of 55% (58 stays per 10,000 population in 1997 to 90 stays in 2009).

AHRQ's numbers indicate that hip implants underwent a similar increase in the 46-64 cohort. Hip replacements for women of this generation are said to have gone up by 81% (10 per 10,000 population in 1997 to 17 in 2009), but this time men needed more than women. The rate for men is said to have "nearly doubled, from 10 per 10,000 population in 1997 to 19 per 10,000 population in 2009." However, the Boomers' antecedents needed fewer hip implants in 2009 compared to 1997, decreasing by 17% for women (139 to 116 stays per 10,000) and by 12% in men from 100 stays in 1997 to 88 in 2009).

AdvaMed to boost small company presence

The **Advanced Medical Technology Association** (AdvaMed; Washington) announced Jan. 10 it will "strengthen its commitment to small companies by reorganizing and expanding" its Emerging Growth Company Council, known by the acronym EGCC. The move is intended to give the 70% of AdvaMed members whose receipts total less than $100 million a greater voice in the organization's policy focus.

AdvaMed's President/CEO Steve Ubl said the decision, which was endorsed by the association's board in a December meeting, "will bring greater focus to issues facing" smaller firms. Ubl also remarked that emerging growth firms "are drivers of medical innovation, economic growth and job creation," and that AdvaMed is committed to ensuring that their perspective "is always heard by policymakers."

The new EGCC will consist of a 15-member board of directors and a five-member executive committee, which will be populated by CEOs from small companies. Among these are Michael Minogue, CEO/President of **Abiomed** (Danvers, Massachusetts), who will chair the executive committee. Among the other four are Nadim Yared, CEO of **CVRx** (Minneapolis), which like Abiomed is a known innovator in the cardiovascular space, while CEO Stuart Randle of **GI Dynamics** (Lexington, Massachusetts) will offer a focus on devices intended for use in gastro-intestinal applications.

AdvaMed indicates that the EGCC will emphasize policy development to help drive capital formation and innovation and will advocate "for domestic and international payment and regulatory policies that are favorable to emerging companies." The panel will also provide educational meetings and opportunities for emerging growth company leaders and professionals," the statement notes."

AAMI urges action on device reprocessing

The Association for the Advancement of Medical Instrumentation released a report Jan. 10 on device reprocessing in healthcare facilities, urging those facilities in an accompanying Jan. 10 statement to "take action" on improving their reprocessing work.

AAMI states that the 40-page publication "summarizes the priorities and challenges identified at a two-day" meeting between the association and FDA last year, and lists seven "clarion themes" that emerged at the Oct. 11-12 summit. These themes are "broad goals," including development of a consensus on how "clean is clean" and creating "standardized and clear instructions" on how to maximize the cleanliness of reprocessed devices. AAMI states that the report "also lists 10 immediate steps a facility can take to help solve the problem" of unsafe reprocessing.

The statement notes that nearly 300 stakeholders attended the summit, a list that includes "regulators, sterilization experts, industry experts, clinicians, and sterile processing staff." AAMI also remarked that reprocessing of instruments such as endoscopes and forceps "is a routine procedure in healthcare, but it has come under increased scrutiny in the wake of reports of patients getting sick after being exposed to contaminated devices." The association indicated that "various AAMI standards committees will create an action plan to address the summit's themes and priorities." ■

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Sernova

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device rather than drug-device combo might prove trickier. Sernova plans to wait until there is interim data from the Phase I/II trial before approaching the agency to expand testing in the U.S.

3 p.m. We left the Parc 55 and headed down the street to another Union Square hotel to meet with a consultant, who was interested in hearing about Sernova's plans for reaching U.S. investors.

The company has returned to its retail investor base in Canada to raise money in small bursts over the past few years, but Toleikis said the firm had been considering a move to a larger exchange as it moves further into the clinic. "We've been thinking about the OTCQX right now," he said.

5 p.m. We returned to the Parc 55 meeting rooms to meet with an investment banker, who was most interested in applications of Sernova's technology beyond islet cells.

Toleikis said the Cell Pouch System could be used with any protein or hormone, including parathyroid hormone, Factor X for hemophilia and could even be a way to transplant stem cells. Those possibilities make the firm ripe for a potential partnership, which also could help shore up its cash position, and Toleikis said he's eager to discuss collaboration opportunities this week as well.

That meeting marked the end of the day for me. For Toleikis, Tuesday and Wednesday would be much the same, with back-to-back meetings with potential investors, though he said he tried to aim for quality rather than quantity. The connections made at J. P. Morgan might not immediately translate into a financing round or partnership, but each one increases the firm's chances of striking a deal.

That makes pounding the pavement in Union Square during J.P. Morgan well worth it, Toleikis said. "We only need one good meeting to lay the groundwork for future financing that could launch the company to the next stage." ■

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Stephen Cary, PhD, CEO and co-founder of Omniox, recalled that the FDA process went through a robust period during the early '90s but then events that happened with certain products earlier in the past decade led to a change in the ecosystem at FDA. "My company has had challenges, we've overcome some of those but it did lead to reductions in jobs and reductions in the number of employees we've had . . . I hope that we are sort of through this period and that we're on the path to reducing regulatory uncertainty."

Lukianov said that these prior issues, primarily devices that have been recalled, have led to a "cultural tone at the FDA of over-correction." He noted that when a device that has been approved is recalled – which usually has to do with a manufacturing problem – Congress "slams FDA pretty hard for that." That has led to the somewhat-misguided belief that "there's just not enough science out there," which trickles down to the reviewer, who in turn thinks he/she should ask for more information. This request for additional information is, at least in some cases, unnecessary, Lukianov said.

There are some changes happening at the agency on this front, Lukianov acknowledged, but he says "we've not seen it get down to the reviewer level and impact our companies in a favorable way." ■

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International

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Innovations (SBi; New York).

Since December 2011, Artimplant has had a stronger sales organization in place in the U.S., which it is felt will contribute positively to the company's presence and sales volumes. By assuming responsibility for sales of Artelon CMC Spacer and other products for restoring joint surfaces, Artimplant says it will have a more complete product offering on the U.S. market.

The former licensee, SBI, will cease sales of Artimplant products for restoring joint surfaces in conjunction with Artimplant taking back the sales rights for these products.

Artimplant is focused on solutions to problems in orthopedic and oral surgery.

InSite Vision gets Japan patent

InSite Vision (Alameda, California) said the Japanese Patent Office has issued a Notice to Patent with claims covering the formulation of azithromycin alone or combined with an anti-inflammatory agent, including dexamethasone, in an aqueous topical opththalmic suspension. The patent will expire on March 31, 2019. Japan is the third largest ophthalmic market in the world after the U.S. and the EU.

"We are thrilled that the Japanese Patent Office has awarded us this very broad patent covering our AzaSite family of products," said Timothy Ruane, InSite Vision's CEO. "We believe that the issuance of this patent will greatly enhance our ability to partner our AzaSite product candidates in Japan."

InSite Vision's product portfolio uses the company's DuraSite bioadhesive polymer core technology, a platform that extends the duration of drug retention on the surface of the eye, thereby reducing frequency of treatment and improving the efficacy of topically delivered drugs. ■

MDD's Oncology Extra

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

Wednesday, January 11, 2012

Keeping you up to date on recent developments in oncology

Photoacoustics may provide the next melanoma detection device . . .

The different energies that can be applied to diagnostics and therapeutics is amazing and seems to be growing every day, and the **University of Missouri-Columbia** (UMC; Columbia, Missouri) has announced an invention that could train laser-induced ultrasound energies on blood samples to detect melanomas before they become unmanageable. According to a Jan. 5 statement at the university's website, the invention entails the emission of laser light into a blood sample whereupon melanin within any cancer cells will absorb the light and "then expand as the lasers rapidly heat and then cool the cancer cells," making them visible. The device would also be equipped to capture the cancer cells, and thus identify the type of cancer. John Viator, PhD, an associate professor of biomedical engineering and dermatology in the Christopher S. Bond Life Sciences Center at UMC, said in the statement, "we compare the detection method to watching an eight-lane highway full of white compact cars. In our tests, the cancer cells look like a black 18-wheeler." Viator also remarked that the device will need only "a small blood sample," and "will provide an earlier diagnosis for aggressive melanoma cancers." The statement indicates that Viator recently inked a commercialization license that will allow others to conduct research with his invention, but Viator and his team are also said to be ramping up for clinical trials toward FDA approval for clinical use, an effort the statement indicates will take only "approximately two to three years." The finished devices is expected to "look similar to a desktop printer, and the costs to run the tests in a hospital would be a few hundred dollars," the statement notes. Viator said the intent is to "provide a faster and cheaper screening method, which is ultimately better for the patient and the physician." However, he also remarked that the combination of "several melanoma drugs on the horizon" and the new device will allow doctors "to use targeted therapies and personalized treatments, changing the medical management of this aggressive cancer." Viator also brashly predicted that if the test proves as accurate "as we believe it will be, our device could be used as a standard screening in targeted populations."

Two studies say protons good for prostate cancer . . .

The clash of treatment modalities continues with a Jan. 5 statement by the **American Society for Radiation Oncology** (ASTRO; Fairfax, Virginia) indicating that two studies give proton beam therapy a thumbs-up for treatment of prostate cancer. The statement notes that these two new studies, which appear in the January edition of ASTRO's official journal, the *International Journal of Radiation Oncology·Biology·Physics*, includes a study of 211 men at the **University of Florida Proton Therapy Institute** (Jacksonville, Florida), whose prostate cancers ran the gamut from low- to high-risk cases. The statement indicates that two years of follow-up have been completed and that the results indicate "that the treatment was effective and that the gastrointestinal and genitourinary side effects were generally minimal." Nancy Mendenhall, MD, of the Proton Therapy Institute said in the statement that the study "is important because it will help set normal tissue guidelines in future trials." The second study, conducted at three institutions including **Massachusetts General Hospital** (Boston), consisted of "a case-matched analysis comparing high-dose external beam radiation therapy using a combination of photons (X-rays) and protons with brachytherapy (radioactive seed implants)." Over a span of three years, 196 patients underwent this treatment regime, and those data were matched against data for 203 men of similar disease progression who concurrently received brachytherapy. The data for biochemical failure rates, described as "a statistical measure of whether the cancer relapses," indicated that proton/photon therapy exhibited the same rate of recurrence as brachytherapy. John Coen, MD, a radiation oncologist at Massachusetts General, said the data lend credence to the notion that men with prostate cancer "can reasonably choose either treatment for localized prostate cancer based on their own concerns about quality of life without fearing they are compromising their chance for a cure."

New year cheer for red wine lovers . . .

Alcoholic beverages have a bad reputation among MDs, but oenophiles – or those who are into red wine, anyway – can now defend their modest con-

sumption of red wine with a Jan. 5 statement posted by the **Cedars-Sinai Medical Center** (Los Angeles) that describes a study suggesting that moderate consumption of red wine "may help cut women's breast cancer risk." This study, which will appear in the online edition of the *Journal of Women's Health* in April, offers some rebuttal to the notion that alcohol inevitably boosts estrogen levels, which is thought to amplify the growth of cancer cells. The study randomized 36 women to drink either Cabernet Sauvignon or Chardonnay each day for nearly a month, but the participants had to switch to the other wine halfway through. The researchers collected blood twice each month to measure hormone levels in an effort to determine "whether red wine mimics the effects of aromatase inhibitors, which play a key role in managing estrogen levels," the statement notes (aromatase inhibitors are currently used to treat breast cancer according to the statement). The results of the study are that "chemicals in the skins and seeds of red grapes slightly lowered estrogen levels while elevating testosterone among pre-menopausal women who drank eight ounces of red wine nightly for about a month," although the data also suggest that white wine "lacked the same effect." Chrisandra Shufelt, MD, assistant director of the Women's Heart Center at the Cedars-Sinai Heart Institute and one of the study's co-authors, offered no advice on food-wine pairings, but said in the statement, "if you were to have a glass of wine with dinner, you may want to consider a glass of red." Co-author Glenn Braunstein, MD, said the data offer no indication that white wines elevate breast cancer risk, but he remarked, "there are chemicals in red grape skin and red grape seeds that are not found in white grapes," a difference in chemistry that may influence more than just the choice of protein one serves with dinner.

Runyon, Sohn join forces to boost pediatric research . . . Cancer is less common in children than adults, a state of affairs that in some minds has led to a paucity of resources for research into pediatric cancer. However, the **Sohn Conference Foundation** (New York) has earmarked $15 million to amend this oversight, according to a Jan. 5 statement by the **Damon Runyon Cancer Research Foundation** (New York). The statement notes that the National Cancer Institute applies "only 4% of its budget" to pediatric cancer research, adding that the biopharmaceutical industry has not applied much effort toward this end, either, and "as a result, there have been limited advances in recent years in treating these cancers, and fewer scientists are working in this field." The $15 million grant "will provide funding to basic scientists and clinicians who conduct research with the potential to significantly impact the prevention, diagnosis or treatment of one or more pediatric cancers," the statement notes. Lorraine Egan, president/CEO of Runyon, said in the statement, "as in the technology world, where transformative innovation most often comes from young minds, the most brilliant and audacious young scientists drive breakthroughs in biomedical research." Egan remarked further, "we are confident that by getting them to focus on childhood cancers, we can cure children and prevent the long-term side effects that result from today's treatments." The objective of the award "is to recruit the top young minds to research childhood cancers," and that the award "leverages the success of the internationally-renowned Damon Runyon Fellowship Award, which has an unparalleled track record for identifying future breakthrough scientists." Runyon will publish a national call for proposals, after which a selection committee chaired by William Carroll, MD, director of the **New York University Cancer Institute** (New York), will choose among the applicants. This, the statement indicates "is being launched as a pilot project with the potential for expansion if successful." The interest of the Sohn Foundation is simple. The foundation is named for Ira Sohn, a Wall Street stock trader who died of cancer in the mid-1990s. Ira's brother Evan said in the statement, "ever since my brother Ira died from cancer at age 29, the Sohn Conference Foundation has been committed to finding cures for cancer affecting kids and young adults. By partnering with Damon Runyon, we hope to encourage the best young scientists to focus on childhood cancers," Evan Sohn said.

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