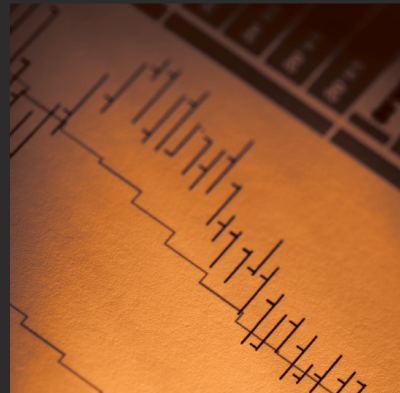
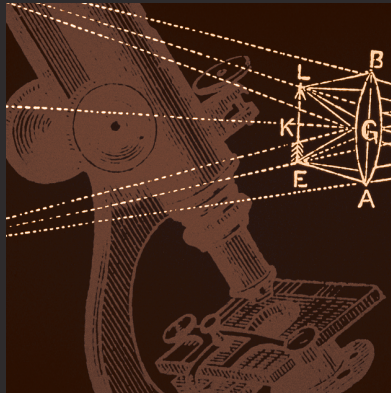
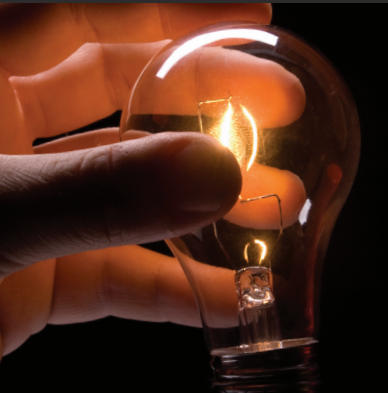


MEDICAL DEVICE DAILY

# STATE OF THE INDUSTRY REPORT 2013

INSIGHTS AND INNOVATIONS FROM INDUSTRY LEADERS



**MEDICAL DEVICE DAILY™**

**2013 STATE OF THE INDUSTRY REPORT**

**INSIGHTS AND INNOVATIONS FROM INDUSTRY LEADERS**

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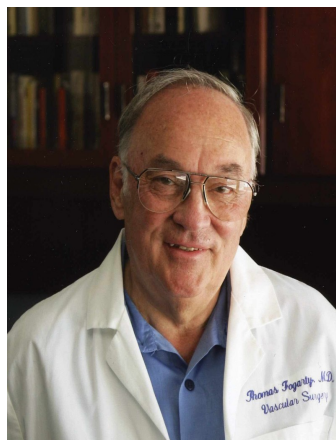
*The MDD Interview***Innovators see both obstacles and opportunities as they assess the condition of medical innovation in the U.S.****Interview by JIM STOMMEN, MDD Contributing Writer**

As part of *Med-Tech on a Mission: Strategies to Drive Innovation*, a special edition of the MDD Interview was put together, with the focus on the state of medical innovation in the U.S.

A panel of entrepreneurs and innovators in the medical field shared their thoughts on a wide variety of issues related to where innovation is in this country today and where it seems to be headed in the future.

The participants include:

Thomas Fogarty, MD, PhD, president of **Fogarty Research & Development** (Portola Valley, California). A renowned cardiovascular surgeon, successful entrepreneur and investor, and an award-winning vintner, he is perhaps best known for inventing and patenting the Fogarty Balloon Catheter, a device which has revolutionized not only vascular surgery but the medical field overall. He has been the founder/co-founder and chairman of the board of more than 33 business and research companies, all of which are based on devices designed and developed by Fogarty Engineering Inc. In 1993, Fogarty founded Three Arch Partners, a venture capital firm that invests in new healthcare companies.

**Fogarty**

Pharmaceuticals in 1999).

Josh Makower, MD, founder and CEO of **ExploraMed Development** (Mountain View, California), a medical device incubator. He also is a venture partner with New Enterprise Associates, where he supports the investing activity in the medical device arena, and is a consulting associate professor of medicine at Stanford, where he co-founded the university's Biodesign Innovation Program.

**Genova**

Perry Genova, PhD, founder and CEO of medical device start-up firm **Oncoscope** (Durham, North Carolina), a maker of optical imaging systems for tissue sampling. A biomedical professional with expertise in medical and pharmaceutical product innovation and development. Previously, he previously served with GlaxoSmithKline and Kos Pharmaceuticals, and has also been involved in a number of successful start-up ventures, including Quill Medical (acquired by Angiotech in 2006) and IEP Pharmaceutical Devices (acquired by Kos

Arlen Meyers, MD, president/CEO of the **Society of Physician Entrepreneurs** (SoPE; Denver). He also is professor of otolaryngology, dentistry and engineering at the University of Colorado Denver. The founder or co-founder of several companies, he is a consultant to life science, IT and investment firms.

Kevin Schulman, MD, professor of medicine in the **Duke University School of Medicine** (Durham, North Carolina), where he also serves as the director of the Center for Clinical and Genetic Economics and as an associate director of the Duke Clinical Research Institute. He holds a joint appointment as a professor of business administration in Duke University's Fuqua School of Business, where he is the director of the Health Sector Management Program.

They chatted with MDD Contributing Writer Jim Stommen on





**Makower**

issues impacting the present and future of medical innovation.

***MDD: What's the state of medical device innovation in the U.S. today, and where do you see it headed?***

Makower: I fundamentally believe that regardless of the downward pressure on healthcare cost, that Americans will continue to value their health above other needs and thus there is a future for medical innovation in the U.S. That said, the hurdles associated with reimbursement, certain government policies/taxes, regulatory challenges and access to capital will limit which projects can succeed and thus we must continue to evolve our thinking about which business models and technologies we can and should pursue. In all likelihood there will be a redistribution of focused effort as entrepreneurs adapt to these changes. Certainly government policies with respect to how new technologies are paid for and taxed could dramatically propel or depress innovation in our sector.

Schulman: That's a really challenging question. I think we're in transition between models. The need for new technology, for new medical devices, is great, but the customer in terms of the payer or the hospital is becoming increasingly challenging and that's putting a lot of pressure on the business model, at least in the U.S. And then we have an explosion of what we consider medical devices, from implantable devices to information technology systems to all kinds of new opportunities for sensors for remote monitoring. So I think the technology that enables us to do new things and exciting things is there and increasing in development, but the payer makes the reimbursement model and the business model around devices, and that's really challenging.

Genova: Personally, I believe the U.S. is still extremely innovative and creative as a nation and, more specifically, within the medical device sector. We have an abundance of people who are creative and understand the entrepreneurial model and the risks and rewards that are associated with it, and are willing and able to take these risks. However, I am concerned about the significant challenges ahead of us. The problem isn't fundamentally with our creative genius, but, rather, with the lack of a receptive environment on the back-end for that creativity. For innovation to thrive we must warmly embrace, on a national level, medical device innovation and reward innovation and innovators rather than hobbling them through regulatory complexity or by associating innovation with increased costs. I fear that the medical device innovation model in the U.S. may follow the outsourced manufacturing model for consumer products where we setup manufacturing somewhere else in the world and subsequently established engineering services to be proximal to the manufacturing centers. In a way, it's already begun. For some time now, medical device companies have launched products in Europe or Asia first and leveraged some of the revenue from those exercises to fund U.S. regulatory filings and commercialization. So, like the aforementioned outsourcing model, if we are focusing on commercializing outside of the U.S., it wouldn't be unusual to consider that innovation centers may follow.

Meyers: Overregulated, overtaxed and still mostly run by the combination of payers, industry and the government. Doctors and patients, the two most important ingredients in the innovation formula, are still on the margins.

Fogarty: It's an important issue, probably more important in this day and age than it has ever been. It's in trouble today, and right now it's not headed in a very good direction. An even more unfortunate thing is that many physicians really don't know that, and even fewer patients know that. But if you look at the facts, if you look at the reports being made at major medical meetings, probably a third of the information being presented is being presented by people from offshore. When I first entered this field 40 years ago, probably 90% of what was presented in the way of valuable new information came from the United States. Not anymore, and I don't think that is a welcome direction by any means. I think patients are not getting the care they should get, are not getting the care at the price they should get. Its multi-factorial, but a major reason is that medicine

# **NEW COs ON THE GO**



## AirXpanders gets IDE to study AeroForm

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

There has to be a better way.

That sentiment is what inspired the development of a new breast tissue expansion device for mastectomy patients undergoing breast reconstruction. The device, called AeroForm, was developed by **AirXpanders** (Palo Alto, California), which recently received an investigational device exemption from FDA to move forward with a clinical trial evaluating the technology.

The prospective, randomized, controlled, open-label pivotal study, XPAND (AirXpanders Patient Activated Controlled Tissue Expander System for Breast Reconstruction), will be conducted at multiple centers across the U.S. AirXpanders said the results will be used as the basis for its AeroForm 510(k) filing with the FDA.

Scott Dodson, president/CEO of AirXpanders, told *Medical Device Daily* that the current method for undergoing breast reconstruction following a mastectomy is a procedure during which the surgeon creates a space for a permanent implant. To do this, the surgeon makes a small incision into the woman's pectoral muscle, inserts a silicone bag. Then, during weekly office visits, the surgeon inserts a needle through the skin into the tissue expander's port to inject saline into the temporary implant. These weekly injections continue for upwards of four months, Dodson said.

So Daniel Jacobs, MD, a practicing plastic surgeon and one of the co-founders of AirXpanders, decided there had to be a better way.

What AirXpanders ended up coming up with was a breast tissue expansion device that would address the limitations of traditional saline expanders. The AeroForm tissue expander consists of a technologically advanced self-contained tissue expander and a small hand-held wireless remote control. Dodson said the system uses compressed carbon dioxide that is gradually released through a small internal valve, in place of invasive saline injections, to fill the expander. After a standard procedure to implant the expander, the patient is able to inflate the expander herself at home using the remote control, eliminating the need for weekly doctor visits and needle-based saline injections.

The patient can inflate the expander up to three times a day with a three-hour lock-out between doses. "We thought if we could expand the patient on a gradual daily basis we could get her there quicker," Dodson told *MDD*.

The way the remote control part of the system works is that the patient waves it over the implant area to allow it to communicate with the implant.

"It's like using a stud finder on the wall to find out where a stud is," Dodson said. "This dose controller communicates when it is over the implant . . . once you're in the sweet spot you simply press the button and immediately a 10 cc dose is delivered."

He said the company recently completed its feasibility trial in Australia which showed that the implant was able to reach full expansion in about two weeks using the new device.

"This is a significant event in the fact that women want to get on to the recovery phase after they've gone through this horrible ordeal with cancer . . . we validated that we can help get them there quicker," Dodson said. AirXpanders noted that the randomized, controlled clinical trial is designed to directly compare the outcomes of tissue expansion using the traditional saline expansion method to the investigational AeroForm, remote-controlled, needle-free tissue expander. Enrollment will continue until a total of 92 AeroForm devices have been implanted and 46 saline expanders have been implanted. Dodson said the company expects the trial to take six to eight months to complete.

Participating sites include hospitals in Atlanta, Boston, New York, St. Louis, San Diego and other cities across the U.S., the company noted.

"We're very blessed to have some great sites on board with this study, we have not been told no by anyone, there has been great physician receptivity to this trial, which in my 25 years of working

## Apollo Endosurgery raises \$47.6M in Series B round

By AMANDA PEDERSEN

*Medical Device Daily* Senior Staff Writer

**Apollo Endosurgery** (Austin, Texas) raised \$47.6 million in its Series B financing round in February 2012. New investors Novo A/S, Remeditex Ventures, and CPMG joined existing investors PTV Sciences and H.I.G. BioVentures in the round. Proceeds were targeted for the commercial launch of the second generation OverStitch endoscopic suturing system and other Apollo endosurgery flexible surgical tools designed to allow surgeons and interventional endoscopists to perform numerous procedures without making incisions into the patient's skin.

As part of the financing, Jack Nielsen of Novo A/S, John Creecy of Remeditex and Kent McCaughy of CPMG will join Apollo's board.

"We are pleased to have this strong financial support from both our new and existing investors, which will enable a successful launch of the OverStitch platform and the broader adoption of flexible surgical approaches for numerous medical conditions," said President/CEO Dennis McWilliams. "This new financing will enhance Apollo's leadership position as an innovator and a driving force in advancing this new class of less invasive therapies."

McWilliams told *Medical Device Daily* that being able to raise such a significant round of funds in the current financial environment is a testament to Apollo's technology, the OverStitch, as well as the size of the opportunity the company is targeting. The company has been fortunate to have the continued support it has received from its existing investors, he noted.

"The past three years have been very challenging in the fundraising environment ... and that's constrained a lot of companies to build their businesses and grow," McWilliams said. "We put our heads down and focused on preserving our cash and continuing to hit the milestones, but we maintained our vision to develop the OverStitch." He added that the current financing is a testament to the size of market the company is going after.

"There are huge opportunities that have not been very well tapped," he said. This latest round, combined with Apollo's earlier round of \$11.7 million, adds up to a total raised of \$59.3 million.

Apollo's OverStitch platform combines the flexibility of endoscopy with the precision of surgical suturing, allowing physicians to access, manipulate and suture internal tissue without making incisions through the skin, the company says. The platform therefore allows physicians to develop less invasive options for the patient.

Ted Stephens, global marketing director at Apollo, told *MDD* that the second generation OverStitch is clinically very similar to the first generation of the device. "The second generation device was really designed to allow much easier, improved experience from the clinician's perspective,"

Stephens said. "It's much easier to use, it allows for more precision in placing sutures than the first generation device." McWilliams added that Apollo built the OverStitch device to commercial scale, which is unique these days among medical device companies, he said. "Not many companies take that approach out of the gate, which is a testament to new times in medical devices," McWilliams said.

With exit margins not being very solid in the industry over the last few years, McWilliams says companies need to build their businesses to have products built to scale from the start. With that in mind, he said Apollo has been built to be a self sustaining company because the traditional model of building a prototype device, running a clinical trial, and getting acquired is no longer as easy as it once was. "They really want to see traction in the market place and you really have to build your company like that from the start," he said, referring to companies looking at acquiring smaller start-ups.

Apollo also recently received FDA clearance for its SuMO platform designed to help surgeons remove large, flat pre-cancerous gastrointestinal lesions and polyps. The company now has 11 products cleared by FDA, McWilliams said. In general, this new class of flexible surgery procedures

## Auxogyn aims to improve IVF outcomes with Eeva

By AMANDA PEDERSEN

*Medical Device Daily* Senior Staff Writer

The field of assisted reproduction is one that is highly subjective using today's technology. The challenge embryologists are faced with during *in vitro* fertilization (IVF) procedures is to look at embryos under a microscope and decide, based on limited information, what the chances are that the embryo is viable enough to result in a successful pregnancy and decide the fate of that embryo.

"The ultimate objective of IVF procedures is to transfer one embryo that will result in one healthy baby," Lissa Goldenstein, president/CEO of **Auxogyn** (Menlo Park, California), told *Medical Device Daily*.

The company's first product, the Early Embryo Viability Assessment System (Eeva), was developed based on science and technology that started at **Stanford University** (California). Eeva brings the IVF field closer to its goal by providing solid data for the selection of embryo(s) to transfer, Goldenstein said. The noninvasive system is designed to provide IVF clinics and patients with objective information regarding embryo viability.

"We believe it will revolutionize the field of assisted reproduction because of the fact that it brings scientific rigor and objectivity to the selection of embryos," Goldenstein said. "We believe that Eeva's predictive capabilities will help guide the treatment path decisions for women pursuing IVF."

Eeva's software is designed to automatically analyze embryo development against scientifically and clinically validated cell-division parameters. With Eeva's quantitative data for each embryo's potential development, according to Auxogyn.

The company was initially funded in May 2010 by Kleiner Perkins Caufield & Byers, TPG Biotech and Merck Serono Ventures.

Last week Auxogyn reported raising \$18 million in a Series B financing round, which included new investor SR One.

"We believe that we've been able to attract a new high quality investor and secure participation from all existing investors due to the fact that Eeva brings scientific rigor and objectivity to the field of assisted reproduction, a field that is largely subjective today," Goldenstein told *MDD*. "We believe the addition of SR One is a validation of the importance of our technology, the strong science behind Eeva, and also our ability to move this test quickly toward commercialization."

The company has also recently completed a multicenter, 160-patient study to validate the safety and efficacy of Eeva, and plans to introduce the system to the European market later this year. The results of its clinical study are expected to support regulatory filings both in Europe and in the U.S.

"We are very excited to bring Eeva to the market, and we are absolutely committed to furthering research for women and their families pursuing assisted reproduction," Goldenstein said.

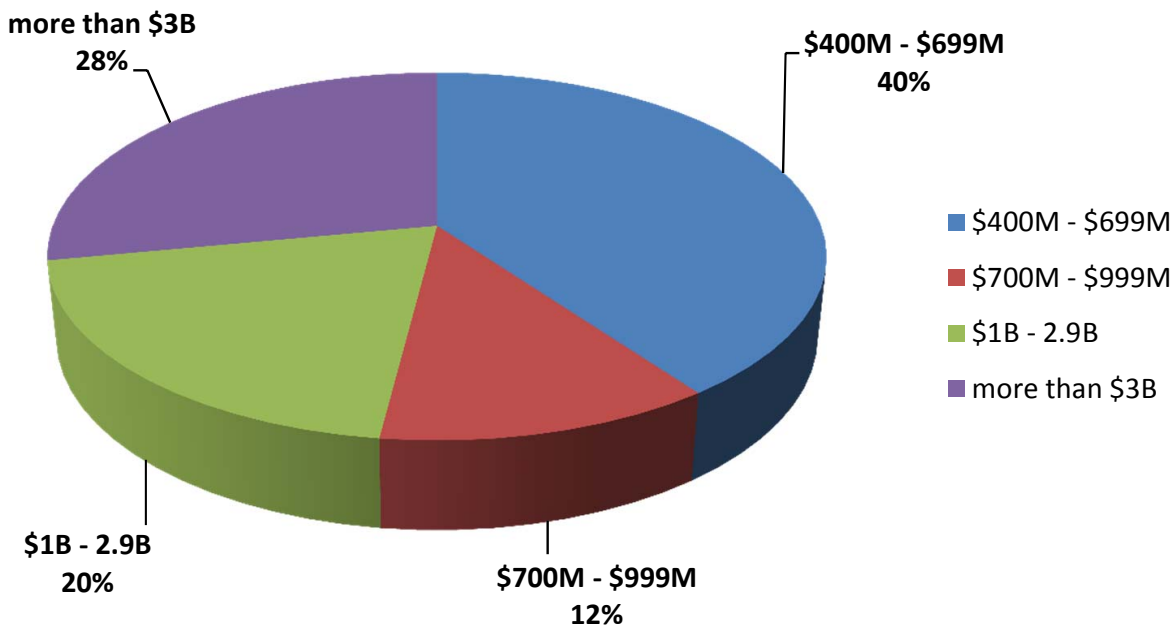
In addition to Eeva, Auxogyn says it intends to develop other products to address infertility.

The company joins several others working on medical technology to address this need, including **OvaScience** (Cambridge, Massachusetts), **INVO Bioscience** (Beverly, Massachusetts), **Incept BioSystems** (Ann Arbor, Michigan), and **Intimate Bridge to Conception** (Ib2c; Pittsburgh), among others.

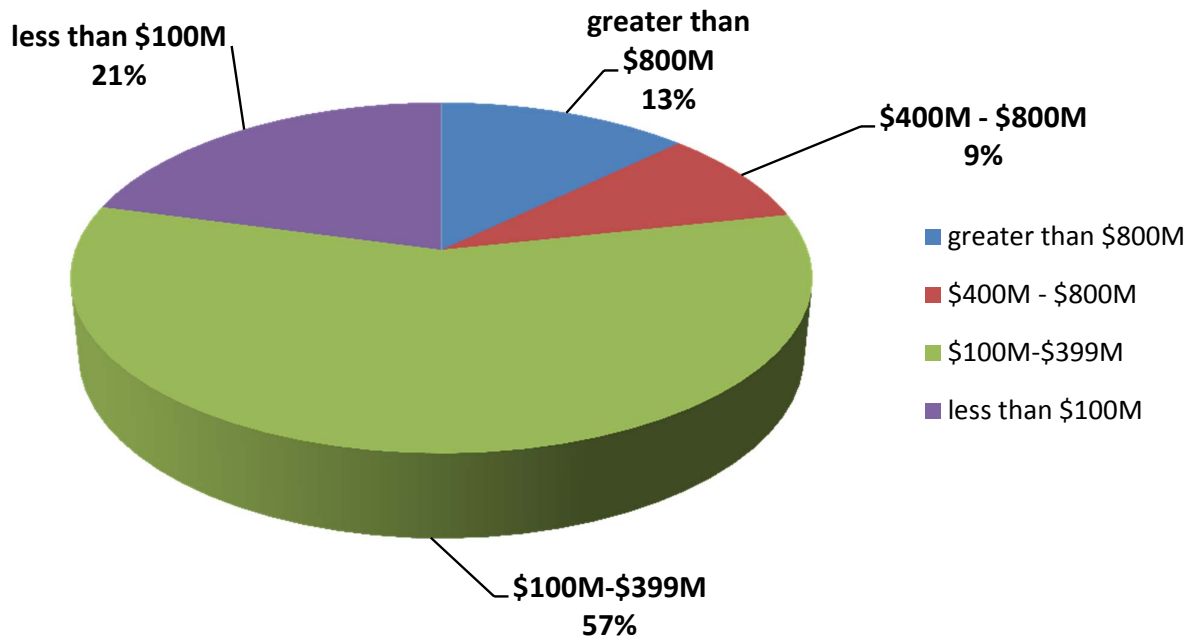
OvaScience, which was launched in 2011, recently completed a \$37 million Series B financing. That company is developing a method of capturing mitochondria from a mother's own ovarian stem cells and injecting them along with sperm into eggs for IVF.

Incept BioSystems has developed a device with the intention of enabling a continuous, refreshable culture microenvironment while using industry-standard IVF culture medium.

## Top 25 Med-Tech Deals: Aug. 2011 - Aug. 2012



## All Med-Tech Deals: Aug. 2011 - Aug. 2012



<b>Top 25 Med-Tech Financings: Aug. 2011 - Aug. 2012</b>				
<b>Rank</b>	<b>Company</b>	<b>Value</b>	<b>Notes</b>	<b>Date</b>
1	<b>Bristol-Myers Squibb</b>	\$3.000B	increased its repurchase authorization	6/28/12
2	<b>Baxter</b>	\$2.000B	authorized share repurchase program for up to 2 billion	7/26/12
3	<b>Community Health Systems</b>	\$1.200B	aggregate principal amount	7/20/12
4	<b>Health Care REIT</b>	\$1.100B	20.7 million shares in public offering	2/29/12
5	<b>Cowen Healthcare Royalty Partners</b>	\$1.000B	Cowen Healthcare Royalty Partners II	1/6/12
6	<b>Quest Diagnostics</b>	\$1.000B	increased share repurchase authorization	1/25/12
7	<b>Community Health Systems</b>	\$1.000B	Senior notes due 2019	3/9/12
8	<b>Hologic</b>	\$1.000B	private placement of 6.25% senior notes	7/20/12
9	<b>Biomet</b>	\$1.000B	completed previously reported offering of senior notes due 2020	8/9/12
10	<b>DaVita</b>	\$1.000B	offering to help with HealthCare Partners buy	8/15/12
11	<b>LabCorp</b>	\$1.000B	priced offering of notes in two tranches	8/22/12
12	<b>Healthcare REIT</b>	\$963M		2/23/12
13	<b>Community Health Systems</b>	\$850M		4/6/12
14	<b>Health Care REIT</b>	\$811M	total proceeds of stock sale	8/14/12
15	<b>Stryker</b>	\$750M	offering of senior unsecured notes	9/15/11
16	<b>Medtronic</b>	\$650M	offering of senior notes	3/15/12
17	<b>Health Care REIT</b>	\$632.5M	public offering of stock	11/11/12
18	<b>OrbiMed</b>	\$600M	creation of a new Investment Fund	9/1/11
19	<b>Canaan Partners</b>	\$600M	mostly goes to tech investments	1/11/12
20	<b>Health Care REIT</b>	\$600M	notes due 2019	3/29/12
21	<b>Ventas</b>	\$600M	public offering of notes	4/16/12
22	<b>Covidien</b>	\$600M	senior notes	5/23/12
23	<b>Riverside Partners</b>	\$ 561M	committed capital	5/15/12
24	<b>Biomet</b>	\$550M	aggregate principal amount	7/26/12
25	<b>Perkin Elmer</b>	\$500M	offering of aggregate principal amount of 5% senior notes	10/24/11

# **CONFERENCE COVERAGE**

## Medtronic CEO: ‘business model has to be adjusted’

By **AMANDA PEDERSEN**

**Medical Device Daily Senior Staff Writer**

In an economy where people are more careful with their money than ever before, even the big guys in the industry have to take a disciplined approach with their business model. That was the take-home message from **Medtronic** (Minneapolis) CEO Omar Ishrak Monday at the 30th annual J.P. Morgan Healthcare Conference in San Francisco.

“The business model has to be adjusted without compromising the need for, and the desire for, higher standard of care,” Ishrak told his audience during a presentation that was also webcast.

Ishrak said Medtronic has identified three key imperatives to improve its growth: improved execution; optimizing innovation; and globalization.

“We want a business that moves quickly and is agile,” he said in explaining the first of these three imperatives, improved execution.

Doing so requires a business alignment “so that everyone is moving in the same direction,” he added. Things like quarterly assessments and constant market connection are examples of this, Ishrak said, noting that he makes a point to meet in person with customers in the U.S. a few days a month. “Me and my management team want to stay in touch with customers,” he said.

In order to optimize innovation, Ishrak said the company will aim to improve its R&D spend and “optimize” its capability. “This is not about going and getting engineers to work harder, nor is it about improving our technical capability,” he said. “It really is more about what we work on and how we work on it . . . working on things that don’t have an effective value proposition has to be de-focused. If there is no value proposition the innovation is not going to succeed.”

Doing this means providing economic value to customers, Ishrak said, adding that the company aims to develop products that either improves the hospital’s standard of care, increases procedure volumes, or improves quality of care so that the hospital’s quality metrics go up. “All of this will provide more revenue to a hospital,” he said.

Products that improve workflow for hospitals is another way the company strives to add value for its customers, Ishrak noted. “Reducing ICU stays . . . moving the shift of care from one type of physician to another or moving the care from the hospital to home,” are examples of innovation that improves hospital workflow, he said.

Finally, Ishrak noted, Medtronic will optimize product prices by providing better value for the same price.

“Customer economics is something that is going to be a screen for all of our new products,” Ishrak said.

Of course the company also recognizes the need to reach emerging markets for future growth. “Contrary to popular perception, our margins in emerging markets are actually as good if not better than . . . other markets,” Ishrak said.

Also, going forward, Ishrak told the audience that Medtronic will have to be more disciplined in its approach to acquisitions – as it will be for new product development and existing products – by first asking: Is it a growth market? Can Medtronic win in that market? And finally, can Medtronic add value to that market.

During another webcast presentation from the J.P. Morgan conference, the CEO of a considerably younger company, **CareFusion** (San Diego), offered his perspective on how companies like CareFusion can turn the current challenges in healthcare into opportunities.

“As all of you know, this is certainly not new news in this room today, this is certainly a challenging environment in healthcare markets in various parts of the globe,” CareFusion CEO Kieran Gallahue said. Specifically, he noted that “30% of U.S. hospitals are running at negative operating margins . . . they understand that they need to make some fundamental changes” including capturing efficiencies in their supply chain, primarily in the areas of pharmaceuticals and medical devices.

So while there is a lot of “doom and gloom” out there where healthcare is concerned, Gallahue



# **REGULATORY**

## Patent reform may prompt more filings, does little for pendency

By MARK McCARTY

*Medical Device Daily* Washington Editor

The U.S. Senate passed a long-awaited patent reform bill in September 2011, avoiding a showdown with the House over the lower chamber's version of H.R. 1249 (the America Invents Act) by taking an up-or-down vote on the House version. President Obama signed the bill without delay as expected, but opinions diverged from there as to the value of the legislation for med-tech firms in the U.S.

Tony Shaw, counsel at the law firm of **Arent Fox** (Washington) and an adjunct professor of law at the **Georgetown University Law Center** (Washington), told *Medical Device Daily* that once the law goes into effect, inventors may conclude they "have to file preemptively even if [they] haven't quite perfected the invention" because of the imposition of the first-to-file (FTF) paradigm embodied in the bill. Shaw also remarked that inventors in other nations are more savvy about the FTF approach and hence "we sort of put ourselves at a competitive disadvantage by adopting their system."

On the other hand, JC Scott, senior executive VP for government affairs at the **Advanced Medical Technology Association** (AdvaMed; Washington), said in a statement e-mailed to *Medical Device Daily* that modernizing the patent process "is an important element of making sure that America's medical device companies continue to be the world leaders." Scott said FTF will "promote international harmonization and create efficiencies throughout the system."

Not all the associations were as optimistic, however. Tom Novelli, VP for government affairs at the **Medical Device Manufacturers Association** (MDMA; Washington) said in a statement e-mailed to *Medical Device Daily* that the bill, "while not perfect, is a positive step towards updating the current patent system," although Novelli expressed concern that the establishment of a new post-grant review process "may overburden PTO and provide a potential vehicle for abuse by some parties."

The debate over the America Invents Act covered several amendments addressing issues such as business method patents, but the most important amendment in terms of the U.S. Patent and Trademark Office's operations was offered by Sen. Tom Coburn (R-Oklahoma). Coburn's amendment would have removed the patent fee diversion written into H.R. 1249, a feature that will send some patent fees to the general treasury fund, which would then be repatriated to PTO upon Congressional approval. The Senate voted 50-48 to table Coburn's amendment.

Despite reassurances from many on Capitol Hill, Shaw echoed some of the widespread skepticism regarding Congress's ability to keep its hands off PTO's fees. "I don't think anyone thinks Congress will behave itself" on this score, he said. "I think everyone recognizes the need to stop fee diversion, and it didn't happen," he shrugged.

Regarding the pendency/patent backlog problem, Shaw remarked, "you see articles by people who think throwing more money at PTO won't solve the problem," but he noted that the Board of Patent Appeals and Interferences at PTO is also working under a backlog. "There's nothing in this legislation that's going to address that," he said.

Shaw seemed appreciative of the efforts by PTO's management to streamline operations at the agency, but he said PTO director David Kappos may have "used all the tools in his toolkit to this point" to clear out the backlog. "I'm not sure how much more he can drive those numbers down," and the new law may fuel "a huge surge of patent applications" 18 months after passage.

As for the prior user rights issue, Shaw remarked that the intent is "to avoid snaring people who didn't steal it from the inventor," and "the reason we didn't have that before is that we wanted to encourage people to file" so as to disseminate technological and methodological advances.

Among the things the bill does not do, Shaw said, is it does not affect eligible subject matter a la *Prometheus v. Mayo*. "There didn't seem to be much push to do that," he observed. He did not forecast much of an impact on lab-developed tests, however, at least not a negative effect.

"The big thing is that you develop some proprietary method of interpreting test results and you

# **INDUSTRY INTERVIEWS**

## Aspinall says diagnostics assure effective treatment

By JIM STOMMEN, MDD Contributing Writer

Mara Aspinall is president of **Ventana Medical Systems** (Tucson, Arizona), a maker of tissue-based cancer diagnostics and a member of the Roche Group. Prior to joining Ventana in September 2011, she was founder, president/CEO of **On-Q-ity**, a start-up diagnostics company focused on circulating tumor cell technology. Prior to that, Aspinall spent 12 years with Genzyme, where she held senior leadership roles as president of Genzyme Genetics and president of Genzyme Pharmaceuticals.

A frequent industry speaker, she has spearheaded industry-wide outreach initiatives to better educate the healthcare community and policymakers about the importance of diagnostics, genomics, and personalized medicine. Aspinall is a founder of DxInsights, a new organization focused on education regarding the importance of diagnostics in healthcare today and into the future.

### **MDD: What was the genesis of the DxInsights organization?**

Aspinall: It started three years ago when a number of political and healthcare-related events occurred and the diagnostics community either did not get a full seat at the table or the industry was not fully understood by the key stakeholders. The diagnostics industry has become an order of magnitude more important over the last decade. This increased significance has happened as a result of new technologies that allow us to use diagnostics much more effectively, and the combination of diagnostics with specific therapeutics.

As a result of the coming together of the increasing importance of diagnostics and the increasing sophistication of diagnostics technology, we believed there was a need to set a foundational education around diagnostics across the broad healthcare industry. That was why we believed it was important to start a non-profit, independent, technology-agnostic, business model-agnostic organization that can provide that core education on diagnostics.

**MDD: I would add as an outside observer, I too have thought that diagnostics has gotten short shrift from the policy perspective over the years, and I also agree with your view on how diagnostics has grown in importance over the past decade.**

Aspinall: It is a great time to be in diagnostics. Many people believe they understand diagnostics today, but diagnostics has taken on a very different persona over the last decade. Diagnostics has moved from important but basic tests that analyze serum for single analytes to highly complex assays that identify and analyze genes, proteins and other markers from the smallest samples of tissue, blood and saliva.

Diagnostics now has the ability to do much more than just diagnose. It's now about monitoring. It's now about prediction. It's now about prognosis. The dimensions for which diagnostics can add value has increased consistent with the changes and improvements in the technologies available.

**MDD: The two words that really jumped out at me from that comment were "monitoring" and "prediction" or "prognosis." What a different role for diagnostics today. Personally I think those have moved ahead of pure diagnosis in terms of the importance.**

Aspinall: I don't know if they have moved ahead, but they certainly have become at least as important.

### **MDD: All right, co-equals then.**

Aspinall: Right. Many ask if diagnostics today is all about personalized medicine – I would argue that personalized medicine is critical and growing, but it's still just a piece of the broader diagnostics industry. But if we are to make life-threatening diseases such as cancer into chronic diseases, it is no longer possible to say, we're diagnosing them on Day One and you're done – we must continue to monitor and assess patients through diagnostics.

AIDS is the best example. We don't make one single diagnosis of AIDS and then treat the patient.

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