MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWS SOURCE

FRIDAY, AUGUST 26, 2016 VOLUME 20, NO. 166

WAS FDA THE STRAW THAT BROKE EVAR'S BACK?

Lombard to exit U.S. market as it eyes potential sale in the wake of latest regulatory setback

By Liz Hollis, Staff Writer

Irvine, Calif.-based Lombard Medical Inc. (NASDAQ: EVAR) has hit the pause button on its U.S. operations, company executives confirmed this week, citing an unexpected roadblock erected by the FDA. In addition, Lombard, which focuses on the minimally invasive treatment of abdominal aortic aneurysms (AAAs), is mulling strategic alternatives, including a sale.

Despite its success in Europe, where in June it secured the CE mark for its Intelliflex delivery system to use with the Aorfix endograft system, Lombard has faced a number of hurdles in the U.S. market.

The final straw seems to have been the FDA's request for additional clinical data

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MYLAN BLAMES INSURANCE CHANGES

Public scrimmage over Epipen pricing now tackling FDA barriers

By Mari Serebrov, Regulatory Editor

The Mylan NV pile-on over the U.S. pricing of its life-saving Epipen is putting other players, including the FDA, on the defensive in a Senate investigation, while unintentionally showcasing the importance of a delivery device.

In the opening play of a bipartisan investigation into a 480 percent pricing increase, over several years, of the auto-

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25 FDA-APPROVED DEVICES

3-D printing comes online for orthopedic implants makers

By John Brosky, Contributing Writer

PARIS – Innovation delivers, according to Kalamazoo, Mich.-based Stryker Corp. CEO Kevin Lobo.

In December, he reported during an earnings call that the introduction of titanium 3-D printed products boosted sales growth above industry averages. He also revealed that a large part of a

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DIVIDE & CONQUER PRIORITIES

Past acquisitions, lighter tax burden boost Medtronic's quarterly revenue

By Omar Ford, Staff Writer

Medtronic plc saw its 1Q17 profits rise, mostly aided by a lighter tax burden and a drop in expenses. The amount the Dublin-based company set aside for income tax was more than halved to $59 million, from a year earlier. Medtronic's relocation from Minneapolis, via its $43

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REGULATORY

Patient preference final issued with new risk-benefit guidance

By Mark McCarty, Regulatory Editor

The FDA has issued a final guidance for the inclusion of patient preference information in a variety of regulatory filings, but the agency has also re-issued the final risk-benefit determination guidance from 2012 in order to align it with the patient preference final.

The agency noted that both final

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$450 million capital expenditure plan for this year is dedicated to building a second 3-D printing facility in Cork, Ireland where ground has already been broken.

"We're seeing it to have an impact on two different divisions, our knee business as well as spine, and we have a huge lineup of other divisions with ideas and prototypes to get into 3-D printer titanium product," Lobo said.

According to orthopedics market specialist Ali Madani, managing partner of Paris-based Avicenne Medical, the industry forecast of market growth for 3-D printing through 2021 range from 18 percent to 30 percent and orthopedic applications are expected to be the most dynamic segment.

During the annual Implants conference in Paris in June 2015, Madani reported that by the end of 2015 almost 300 machines were installed for 3-D printing of implantable prostheses.

In 2010 there were just four 3-D-printed implantable devices approved by the FDA, he noted. By 2014, 25 FDA-approved products were created through what is informally called 3-D printing and officially designated as additive manufacturing, because metal is progressively added to create the device, as opposed to traditional milling and machining of metal, which is a subtractive process.

On what is called a build plate, micro layers of titanium powder are progressively laid down and then burned with a laser to solidify the powder into a metal with nano-precision according to the design model.

The pioneer in additive manufacturing applied to orthopedic devices is Warsaw, Ind.-based Zimmer Biomet Holdings Inc., which began developing products 15 years ago.

Yet, Madani noted that Italy is the most advanced market where challengers like Lima Corporate Spa, of San Daniele del Friuli, and Milan-based Adler Ortho Srl, have invested massively in the technology and each year sell thousands of hip cups, shoulder implants, knee tibial plates, or mini-hip stems.

Currently spinal cages made by additive manufacturing processes is the most dynamic orthopedic segments, and Madani correlated the steady erosion of market share for polyetheretherketone cages to the growth of 3-D printed titanium cages in the five major markets of Europe. He expects the porosity of trabecular cages produced by additive manufacturing, which encourages in-bone growth for superior fixation, will drive a 19-percent growth to achieve 61,000 units in 2018.

The planned porosity of 3-D printed devices is the must-have feature for implantable prostheses that is winning adoption by orthopedic surgeons, according to Robin Stamp, associate manager for advanced technology at Stryker, who presented at the Implants conference.

Where traditional implants use cement to fuse the metal with the native bone, porous materials encourage bone growth directly into the implant to create a vascularized bonding.

For more than 20 years, Stryker has milled and machined metal to create in-growth devices – a complicated, multi-step manufacturing process based on coating materials with rigid requirements that limit design options, Stamp said.

"What 3-D printing does is give design freedom, an ability to put porous structures where we need porous structures for creating a biologic bond. We can go to exotic designs, build channels into the surface, create roughness, give a product any feature needed for essentially the same cost as building a standard model," he said. "Where we are really seeing a difference is in the speed of design iterations."

Instead of a product development cycle of 18 months to two years with a high cost for making changes, Stamp said additive manufacturing enables his group to produce a design and, within one week, give the part to a surgeon panel. Then the engineers can rapidly iterate and further develop the design.

"This is phenomenally powerful," he said. "We are capable of doing so many more iterations, putting much more functionality and creativity into products."

Converging 3-D design flexibility with the company's expanding library of patient-specific CT imaging means that instead of going to a locker for a piece of bone or a design template, designers can now iterate a product across eight variations adapted to populations that surgeons will encounter in the real world.

The significance of the new 3-D printing facilities for Stryker, Stamp said, is that the production can run 24/7 with non-specialized operators, people with undergraduate-level education.

Mark Morrison, the lead research scientist for London-based Smith & Nephew Plc, said his company first applied 3-D printing processes to patient-specific instruments to reduce time spent on surgeries by moving the procedure planning upstream. The Visionaire cutting guides that are patient-matched using pre-operative medical imaging were first used in September 2009 and by 2014 had reached 100,000 procedures.

Last November, Smith & Nephew won FDA approval for the Redapt Revision acetabular hip cup produced with additive manufacturing technology.

Charged with providing an overview of 3-D printing for the Implants conference, Morrison noted that while the technology will prove disruptive for the industry, it is still early days with significant challenges ahead.

"Although we know a lot about additive manufacturing, there is not yet an in-depth understanding," he said. "The process is not perfect with variations in surface treatments compared to milled and machined standards, or for dimensional accuracy, and quality control is an issue."

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Medtronic

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billion acquisition of Covidien, is being credited for the tax burden reduction. (See *Medical Device Daily*, June 17, 2014.)

In addition, the company said its earnings for the quarter rose to $929 million, or 66 cents per share, from 2015 earnings of $820 million, or 57 cents per share. The company beat analysts' expectations, earning $1.03 a share compared to $1.01 a share. A year ago, Medtronic took in about $1.02 a share.

"In the U.S., we continue on an upward trajectory delivering another quarter of sequential improvement in our growth rate," said Omar Ishrak, chairman and CEO of Medtronic, during a Thursday call.

Ishrak pointed to Medtronic's diabetes group as sign of successful growth. Revenue for the group increased 2 percent to $452 million. Recently, Medtronic's diabetes group submitted a premarket approval application for a hybrid closed-loop system, a device designed to measures blood glucose levels in real time and automatically adjust the amount of insulin it delivers. (See *Medical Device Daily*, July 1, 2016.)

Medtronic first gained access to the artificial pancreas technology through its $3.7 billion acquisition of Minimed Inc. nearly 15 years ago.

While the diabetes group was a strong performer for the company, quarterly sales fell in most other segments. The cardiac and vascular Group (CVG), minimally invasive therapies group, and the restorative therapies group all saw revenue fall between 1 percent and 3 percent. Medtronic's stock (NYSE: MDT) took a 1.45 percent dip Thursday, after the company forecast growth at the lower end of expectations for 2017. Shares closed at $85.39, down $1.26, on above average trading volume.

STAYING AHEAD OF THE PACK

Medtronic finds itself in a position similar to other companies in the medical device space. Hospital customers are now approaching prices for devices with more scrutiny - having a bit more leverage over what they are willing to pay. Device companies have had to develop stronger products at a more reasonable price to foster sales growth. Medtronic has looked toward acquisitions in unique spaces to keep up its growth pace.

On Tuesday, Medtronic closed on the $1.1 billion acquisition of heart pump maker Heartware International Inc. The Heartware deal was originally estimated to close by October. The addition of Heartware expands Medtronic's portfolio of heart failure technologies and "is expected to add meaningful revenue to the CVG group throughout the balance of the fiscal year and beyond," Ishrak said. (See *Medical Device Daily*, Aug.24, 2016.)

The deal should also give the company more firepower to compete against the combined might of the Abbott-St. Jude Medical entity in the cardiovascular space.

St. Jude boosted its own position in the heart failure space when it acquired Heartware's rival, Pleasanton, Calif.-based Thoratec, for $3.4 billion last year. (See *Medical Device Daily*, July 23, 2015.)

In July, Medtronic continued to strengthen its presence in the robotic surgery space and invested an additional $20 million in Israeli med-tech company Mazor Robotics Ltd. Two months earlier, Medtronic agreed to make up to $52 million in total potential investments and laid claim to exclusive distribution rights for new Mazor spine products.

During Thursday's call, Ishrak said Medtronic's partnership with Mazor is generating "significant surgeon interest," and that both companies are set to debut the Mazor X, a robotically-assisted spine surgery system, at the North American Spine Society conference later this year.

While Heartware and the Mazor partnership will surely impact Medtronic in the future, Covidien has been the company's most beneficial acquisition by far.

Joshua Jennings, an analyst with Cowen and Co. Inc., said results of Medtronic's most recent earnings, "should give investors further conviction that the Covidien integration has been seamless and led to better-than-expected post-merger performance."

Ben Andrew, of William Blair & Co. LLC, agreed that the Covidien integration will help expand operating margin potential and bolster Medtronic's earnings in coming quarters. In a research note, the analyst also applauded the company's approach of dividing growth priorities into three buckets – new therapies, emerging markets, and service and solutions – to achieve consistent revenue growth in the mid-single digits. //

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According to Stryker CFO William Jellison, speaking to analysts during the December conference call, the company's focus for at least the next few years is on new products, not replacing existing products with 3-D printed products. "Over time, 10 years from now, that could be the case," he said. //

APPOINTMENTS AND ADVANCEMENTS

Pulse Biosciences Inc., of Burlingame, Calif., appointed Edward Ebbers as VP and GM of its dermatology products. Most recently he served as chief commercial officer and vice president of marketing at Capnia. Pulse Biosciences is developing a therapeutic tissue treatment platform based on Nano-Pulse Electro-Signaling, a bioelectronics cell signaling technology.