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DEVICE HAS EAP DESIGNATION

New financing pumps \$113M into Cvrx to support FDA approval of Barostim Neo

By Amanda Pedersen, Senior Staff Writer

A private company using the brain to treat the heart has attracted \$113 million in new financing to support a device that the FDA has designated for the expedited access pathway (EAP) program. Minneapolis-based [Cvrx Inc.](#) said \$93 million of the new funding will come from a completed \$57.7 million equity financing and another \$35.3 million from the same investors that will be based on operational milestones. The other \$20 million will come from a new \$20 million debt facility.

Nadim Yared, president and CEO of Cvrx, told *Medical Device Daily* the company will use the proceeds to complete its phase III U.S. clinical trial, the results of which are expected to support FDA approval of the company's Barostim Neo device for [heart failure](#).

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FIRM UNDERPERFORMS BY \$65M-\$75M

Davita sees bright spot in dialysis, while medical group is underwhelming

By Liz Hollis, Staff Writer

Denver-based [Davita Healthcare Partners Inc.](#), (NYSE: DVA) is lowering its guidance, citing the underperformance of its medical group.

"Unfortunately, year-to-date, we have financially underperformed relative to plan, and we expect this gap to increase in the second half of the year," Vijay Kotte, chief financial officer of Davita

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REGULATORY

Medicare contractor proposes coverage of NSCLC gene testing

By Mark McCarty, Regulatory Editor

A Medicare administrative contractor has drafted a proposed coverage memo for comprehensive genetic testing for patients with non-small cell lung cancer (NSCLC), a move that would expand coverage to a number of states, including Florida, where four million Medicare beneficiaries constitute a potentially

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BIG DATA RISING

Biopharma looks to big data for the next big breakthrough

By Marie Powers, News Editor

The big data revolution is all around us, from politics to power plants, manufacturing to multimedia content, Wall street to Main Street. Small wonder that big data also is driving radical change in health care and therapeutic development.

"We live and die by big data," said Nick

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MARKET TO GROW TO \$48B BY 2020

Nimble challengers erode fortunes of major ortho players

By John Brosky, Contributing Writer

PARIS – Recent multi-billion dollar mergers and acquisitions among orthopedic companies might give the impression that this industry segment has a bright future.

In fact, external acquisition is the only way for major companies to show robust revenue growth as they watch prices for

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ONCOLOGY EXTRA

Regulatory Editor Mark McCarty and Senior Science Editor Anette Breindl on one of med-tech's key sectors

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Orthopedics

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products decline steadily, and scrappy local competitors erode market share in nearly every geography.

These were top line conclusions delivered by Ali Madani, president of the Paris-based consulting company Avicenne Medical, at the start of the company's 12th Annual Implants Conference in Paris.

The bottom line is that the global orthopedic market will grow steadily with a 4.4 percent compound annual growth rate (CAGR) through 2020, from \$39 billion in 2015 to what Madani estimates will be \$48 billion.

The overall orthopedic market is sliced into highly competitive segments that in 2015 generated \$8.9 billion for knee procedures, \$8.3 billion for spine hardware and \$6.5 billion for hip replacement products.

The remaining \$15.3 billion in orthopedic sales fall into categories for trauma, extremities or ortho-biologics. The global orthopedic sales figures from Avicenne do not include sales of power instruments, nor procedures for arthroscopy and soft tissue repair, sports medicine nor neuro-stimulation.

The United States accounts for 56 percent of sales in knee implants, 46 percent for hip prostheses and 64 percent in spine, "due to historical trends, and of course, the higher prices," said Madani.

The 17 strongest European economies included in the analysis account for 19 percent, 23 percent and 18 percent in the categories for knee, hip and spine, respectively, though Europe is now surpassed by the vast collection of geographies grouped under the category rest-of-world.

Orthopedic manufacturers attending the conference looked back with fond memories as Madani recalled the era of double digit growth for all product categories during the first decade of this century.

From 2000 through 2010 the CAGR across the total market was 11.4 percent. A precipitous drop in sales revenues followed, and CAGR has crawled at an average 4 percent since then, and will continue to do so for the foreseeable future.

The only double digit growth since 2010 for orthopedics is seen in the segment for extremities that peaked by 2012 at 14 percent and has slacked to 11.3 percent. The \$2 billion in sales in this market for extremities devices makes up just 5 percent of the total orthopedics market.

Looking to the fortunes of the newly hyphenated major players in the market, Madani reported that 20 percent of global orthopedic sales were claimed by Depuy Synthes Companies, created in 2011 with the acquisition of West Chester, Pa.-based Synthes Inc. by Johnson & Johnson in New Brunswick, N.J. and the subsequent merger with its Depuy orthopedics subsidiary.

Warsaw, Indiana-based Zimmer Biomet Inc, created in a 2015

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How Davids can win against Goliaths

Collectively, challenger companies in orthopedics are steadily gaining up to 2 percent of the total market each year, stealing it away from multi-nationals with 10 to 50 times greater revenues.

According to Ali Madani, president of Paris-based Avicenne Health Consulting SA, there are three different types of challengers.

The country leader typically generates well over \$100 million annually thanks to export sales in several developed countries that are added to the national base. San Diego-based Nuvasive Inc. is an example of such a challenger in the U.S. while Aesculap AG from Tuttlingen would be the native leader for Germany, and in Italy the national champion is Lima Corporate based in Villanova di San Daniele del Friuli.

The country player is typically a company with more than \$10 million in annual sales and a robust share of market, ranking among the top 20 providers in their home market offering a complete range of products for hip and knee replacements and a stand out flagship product. They also have export sales to emerging markets.

One of the top challengers cited by Madani with a CAGR of 24.5 percent was Austin-based LDR Holding Corp., a spine specialist acquired in June 2016 by Zimmer Biomet Holdings Inc. (See *Medical Device Daily*, Jun 8, 2016.)

The second type is a country player with more than \$10 million in annual sales and a robust share of market, ranking among the top 20 providers in their home market offering a complete range of products for hip and knee replacements and a stand out flagship product. They also have export sales to emerging markets.

Finally there is the regional player within the home country with less than \$10 million in annual sales and no significant export revenues.

Whatever their flavor, challengers are growing more rapidly, on average by 15 percent per year by hitting where the major players are not playing.

While major companies standardize products, the challengers multiply customization. Major players reduce their product range while challengers extend it.

Major companies are cutting costs in sales channels while the challengers are attracting new sales people to reinforce local presence and increase the local level of service.

And where the majors are interested only in surgeons with high activity, the challengers nurture relations with all surgeons regardless of the intensity of their practice. //

- John Brosky, Contributing Writer

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fusion of the two companies, held a 16 percent share of the global orthopedics market in 2015, according to Avicenne.

Then-Minneapolis-based Medtronic Inc was only marginally boosted in 2015 orthopedic sales by its acquisition of Dublin, Ireland-based Covidien Ltd, holding an 8 percent market share. Kalamazoo, Mich.-based Stryker held a 13 percent share of the market, while Smith & Nephew held a 5 percent share.

“Together, these five companies control more than 60 percent of the worldwide market, yet have continuously lost market share to challengers,” Modani said.

Over the past two years, the burgeoning category of challengers had expanded from a 33 percent share of the total market to almost 38 percent.

In 2014 alone, gains made by challengers at the expense of major players represented a \$2 billion value, Madani noted.

Stepping back for a longer perspective, Madani showed the challengers are gaining consistently in every category. Zooming in closer on the hip market he showed the share for major players has remained relatively flat since 2008 while the challengers have gained steadily, climbing from 32 percent to 47 percent in 2015.

“The majors have saved their margins, yet it is the challengers who are getting the growth. The majors have saved big market shares but are only seeing low growth,” he said.

Challengers and majors alike face three formidable limitations in the orthopedic market moving forward.

First is no end in sight for declining prices. The sudden shift in the fortunes of companies in 2010 came precisely as health care payers and hospital groups scrambled to cut costs and stabilize spending in the wake of the financial meltdown in 2008.

“This is the main limiter of the orthopedic market. We do not expect a major shift, but some countries will suffer a more significant price decrease than others,” said Madani.

Closely linked in squeezing margins is the rise of group purchasing.

“Group purchasing in Germany drove down implant prices and is widely seen as a success, serving as a model in lot of other European countries,” he stated in his conclusions, giving the example of a basic knee product that was priced at €1,350 (\$1,500) and that a major company recently proposed for just €900 (\$1,000).

Then there is the shared burden of increasing regulatory requirements that result in longer time to market for products and higher development costs.

“This is one of the greatest concerns everywhere,” he said.

“Cost has increased dramatically, and to see the number of people now working in regulatory service in these companies, it is huge. The number of people in regulatory exceeds the

number of people working in R&D.” //

Data

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Twoxar Inc., a 2014 start-up, is exploiting big data and proprietary algorithms to uncover new drugs without using a wet lab, potentially shaving years off development timetables and slashing associated R&D costs. The computational drug discovery firm uses its cloud-based platform, called Duma, to draw insights from a variety of independent data sources. The platform can interrogate public and private datasets to identify and prioritize drug candidates against specific disease targets. The method is designed to predict whether or not a drug will be successful in preclinical and, ultimately, in clinical studies.

Meanwhile, Dundee University spinout Exscientia Ltd. last year showed that its automated medicinal chemistry technology cut the time and cost to design and optimize a drug by 75 percent while improving the quality of the resulting molecule. In 12 months, Exscientia delivered to partner Sumitomo Dainippon Pharmaceutical Co. Ltd., of Osaka, Japan, a pipeline-ready, bispecific, dual agonist compound that selectively activates G protein-coupled receptors from two distinct families.

Starting from product concept, Exscientia synthesized fewer than 400 compounds to shape a molecule that matched Sumitomo’s development criteria, compared to several thousand compounds typically synthesized in a standard project. The partners worked together closely, with Sumitomo chemists conducting rapid synthesizing and assaying so that Exscientia could continually refine its algorithms and evolve the drug design. Exscientia also has alliances with Eli Lilly and Co. and Johnson & Johnson unit Janssen Pharmaceutical Co.

BIOPHARMA ‘RAPIDLY COMING UP TO SPEED’

X-Chem Inc., founded in 2010 around a small-molecule discovery platform, is another that has embraced the potential of big data. Last month, the Waltham, Mass.-based company expanded a global drug discovery collaboration with Bayer AG, initiated in 2012, to encompass the entire bandwidth of therapeutic areas and target classes from the R&D pipeline at the Leverkusen, Germany-based pharma.

The sweetened arrangement came after swift progress during a pilot deal between the companies in which Bayer licensed an early stage drug discovery program against an undisclosed epigenetic drug target and a second drug discovery program against a cardiovascular drug target.

And the Bayer deal wasn’t a fluke. X-Chem has licensed more than 20 programs, according to Rick Wagner, co-founder and

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