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FINANCINGS

OrbiMed raises $924M in fund, exceeds target in single closing

By Amanda Pedersen, Senior Staff Writer

OrbiMed (New York), an investment firm focused on the healthcare sector, reported the closing of its second healthcare royalty and credit opportunities fund, OrbiMed Royalty Opportunities II, LP, with $924 million in commitments, including $24 million from the General Partner. Investors in the fund include a broad range of premier endowment, foundation, pension and other institutional investors.

Consistent with its predecessor, the new fund will acquire healthcare royalty streams and provide tailored debt capital solutions to healthcare companies and institutions worldwide.

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MDD INTERVIEW, 1ST OF 2 PARTS

SpineJack sales surge 69% on the back of EU sales network

By John Brosky, Europe Editor

Vexim has been advancing steadily since Vincent Gardès took the helm as CEO three years ago. The company went public six months after he joined, providing the support for an ambitious expansion of its direct sales footprint across Europe. Vexim surged ahead in 2014, reaping the fruits of this long labor, reporting it had sold as many SpineJack prosthesis in one year as it had since winning the CE mark in 2011. SpineJack implants enable a mechanical lift between vertebrae to achieve an optimal anatomy for the spinal column. Gardès spoke with *Medical Device Daily* from his office near Toulouse, France.

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INSIDE THE BELTWAY

Ten-year ONC interoperability plan sees basic interop functions by 2017

By Mark McCarty, Washington Editor

The Office of the National Coordinator has released a plan for healthcare record interoperability that sets out ambitious goals given the pace of progress to date. The interoperability roadmap, a subset of the December 2014 healthcare IT roadmap, suggests that electronic health records should demonstrate some baseline interoperability by 2017, but vendors and providers have to be prepared to deploy a health IT system that can support a "learning health system" by 2024.

The Department of Health and Human Services announced the interoperability roadmap in a Jan. 30 statement describing

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2016 budget busts spending caps; will boost FDA, NIH funding

By Mari Serebrov, Regulatory Editor

Calling for an end to the "mindless austerity of sequestration," the White House submitted a nearly $4 trillion budget to Congress Monday, exceeding the spending caps mandated by the 2011 Budget Control Act by 7%. Among the spending increases are several health-related initiatives, a 9% increase in FDA funding and a 3% bump for the National Institutes of Health (NIH).

Under the president's budget, the FDA would receive $4.93 billion in federal funding and new and existing user fees. The budget includes $2.7 billion to advance the agency's drug and device activities, with $1.372 billion for the Center for Drug Evaluation and Research (CDER), $456 million for the Center for Devices and Radiological Health (CDRH) and $351 million for

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INSIDE

Vexim

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MDD: Sales surged by 69% in 2014, doubling the number of implantations of SpineJack. Is this a one-shot wonder?

Vincent Gardès: In three years the company's revenue has grown from practically nothing to €10 million. It is a strong, sustained growth, a very nice ramp-up. We really launched SpineJack in 2011 and the first year had $1 million in revenue, then €2.7 million the next year and €6.1 in 2013. Now in 2014 we reached €10 million.

We are seeing a steady adoption of SpineJack in Europe where we have been focused. This is a direct result of the strategy we described when we did the IPO in 2011. We have created five subsidiaries in Germany, France, the United Kingdom, Spain and Italy. There are now about 30 people, direct employees whose only focus is to promote and distribute our products. Last year we really began to see very nice results of this distribution strategy. Most of our competitors decided to lay off people and concentrate their sales efforts for their European operations, giving to a single rep many products. They have appointed distributors in different markets. We took a different approach. I believe very much in focus and dedication. By hiring and training 30 reps we have made our people truly expert in the space of trauma spine. We are now seeing the productivity per rep increasing.

MDD: The announcement mentions only SpineJack as the driver of growth. What role did other Vexim products play in the sales surge?

Gardès: We do have other products now, but it is SpineJack that accounts for about 90% of our revenues. So it is the adoption of SpineJack in Europe that is driving our sales revenue.

MDD: What changed? What lit a fire under adoption and sales?

Gardès: We received a CE mark extension a year ago for trauma indications and trauma has absolutely been a big growth area with strong adoption. We also launched in the spring a new generation of our SpineJack that while it did not change the fundamental design, it streamlined the instrument kit and ancillaries to make it easier and smoother to use. The feedback over the past eight months has been great.

These have been key contributors to the growth. And the third factor driving the business are the people, all the investments we have made putting more feet on the street with direct sales reps in the big markets is now paying back on that investment.

MDD: So you have seen your market expand significantly with trauma. Do you see extensions to other indications?

Gardès: In the beginning, we saw SpineJack as a therapy mainly for the elderly osteoporotic fractures. But the anatomical restoration that we are seeing with SpineJack is proving so effective that surgeons are using it on more severe fractures, which has allowed our CE mark to be extend to these types of fractures.

VINCENT GARDÈS
Vexim CEO

Still, Vexim remains focused only on vertical compression fractures (VCF). I don't want the company to become another small spine supermarket, so we are not serving degenerative scoliosis, disc prosthesis, or whatever. We want to stay specialized, and VCF is a very nice market at $1 billion. In Europe it is €150 million. All the products we bring to the market and all the products we will be launching are related to fractures of the spine.

SpineJack can treat the problems of VCF where we are competing primarily with a balloon kyphoplasty technology. But we have also seen that SpineJack can treat much more acute and severe fractures. Actually today 50% of our revenue comes from people who never used the balloon before. This means they are using SpineJack instead of traditional fusion devices where they place four pedicle screws and two metal rods. Surgeons are finding they can treat these injuries, that traditionally they have done in a very invasive manner, in a much more minimally invasive, percutaneous approach with a lighter, safer and effective surgery that last about 30 minutes.

When there are young adults who have suffered a sport or traffic accident, the surgeons can tell them they have a choice for a simpler SpineJack procedure, or they can have a more invasive therapy. And they tell them that if SpineJack is not effective, they can always return for the more invasive spine surgery.

For balloon kyphoplasty surgeons, the sequence of the surgical technique is very well known. It falls pretty much into the routine that people have learned with balloon kyphoplasty. We are able to use in some markets the same DRG (diagnostic-related group) and the reimbursement codes as kyphoplasty. //

Financings

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to repay some of its existing indebtedness and any remaining net proceeds will be used for working capital and general corporate purposes.

J.P. Morgan Securities, BofA Merrill Lynch and Barclays Capital are acting as lead joint book-running managers in the proposed offering. Evercore Group, Goldman, Sachs & Co. and Citigroup Global Markets are acting as book-running managers in the proposed offering and BMO Capital Markets and TPG Capital BD, are acting as co-managers in the proposed offering.

IASIS is a healthcare services company that delivers healthcare through a broad and differentiated set of capabilities and assets that includes acute care hospitals with related patient access points, and a diversified and growing managed care risk platform. //