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### Looking to take bigger bite of \$2.2B market

## Cellnovo ramps up manufacturing for breakthrough in insulin delivery

By John Brosky, Contributing Writer

PARIS – The news flow could not be better for Paris-based Cellnovo, which reported an 11-fold increase in sales over the past year and powerfully convincing results for its insulin micropump against a direct competitor's product.

Yet CEO Sophie Baratte remains cautious, telling *Medical Device Daily*, "we are still dealing with small numbers."

Entering an addressable market for insulin pumps that the dominant competitor, Dublin-based Medtronic plc, estimated will reach \$2.2 billion annually, Cellnovo generated in the first half of this year €752,373 (US\$826,668).

And as for the publication of a peer-reviewed clinical study that showed the Cellnovo pump to be far more accurate in insulin delivery than the next-generation wearable pump, the Omnipod from Insulet Corp., based in Billerica, Mass., Baratte preferred to praise Insulet for its pioneering device.

The restraint imposed on enthusiasm for Cellnovo is based on the company's continuing struggle against constrained production of its device, which is currently assembled manually in Swansea, Wales.

Demand for the Cellnovo pump is far outstripping supply, to the point that the company limited the number of new patients using the system in order to ensure that the requirements of all current patients can be met.

Less than 500 patients are currently using the device, compared to approximately 35,000 Type 1 diabetes patients in France who currently use some kind of insulin pump.

Ramping up production has been the primary focus for Baratte since she took over as CEO in October 2015.

The technology transfer, the tooling and design of the robotic assembly line has taken nine months she said, "and now that is behind us."

In 3Q16 the Swansea operation will be able to step up moderately its production with sub-assembly parts produced by Singapore-based Flextronics Manufacturing Ltd., and by 4Q16 she expects automated mass production will begin.

"One year from now Cellnovo will be a very different company," she said.

Over the coming weeks she said a series of commercialization agreements will be announced with Paris-based Air Liquide SA, which has identified diabetes as a growth area for extending its

international footprint in home care that currently is built around chronic respiratory diseases.

Tapping on the Air Liquid network is critical for commercialization success against competitors in this field, which include Medtronic, Insulet, Animas Corp. based in West Chester, Pa., that is a division of New Brunswick, N.J.-based Johnson & Johnson Inc., as well as Tandem Diabetes Care Inc., from San Diego, and Cellnovo's partner for its integrated glucose monitoring system, Roche Diabetes Care, which is part of the Roche Diagnostics division of Hoffmann-La Roche, based in Basel, Switzerland.

While Cellnovo sales may be small for the moment, Baratte said, "the market potential is huge. In Europe alone where the penetration of insulin pumps is on the order of 10 percent, in the United States it is around 30 percent, which shows there is a potential in Europe for another 20 percent among Type 1 patients waiting for something that is wearable and easy to integrate into their day-to-day life."

Beyond ramping up production to meet the demand, the second objective for Cellnovo is positioning its wearable micropump for artificial pancreas programs that Baratte said represents the true break-through for insulin-dependent people.

Cellnovo has been selected as the partner company for four leading artificial pancreas programs including the prestigious International Diabetes Closed Loop Trial (IDCL) in the United States funded by the National Institute of Health that is being conducted by Typezero Technologies LLC from Charlottesville, Va.

Cellnovo is also the insulin pump of choice for the Diabeloop closed-loop diabetes management project being conducted by the Center for Studies and Research for Diabetes Treatment Intensification in Evry, France that is enrolling 240 patients at 10 sites in France and six in the United States.

"The artificial pancreas is the future, and it is going to come a lot faster than people think," said Baratte.

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# Cellnovo

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"For those patients with Type 1 diabetes who are technology adverse, there is such a great benefit from an artificial pancreas, a patient well-being that can be felt, that it will be compelling for them to adopt the technology," she said.

"The Cellnovo micropump is so wearable, so convenient that it can set them free even further from their disease, which is why this is an area of extreme focus for us," she said.

Funding for research and development in partnerships with artificial pancreas programs has taken up the largest share of spending by Cellnovo from the €31 million (US\$34 million) raised in an initial public offering on the Paris Euronext stock exchange in July 2016.

The company reported a cash position of €26.5 million at the end of 2015.

The technical advantages that build preference for the Cellnovo pump are based on it being smaller, lighter and using a patch approach that does not require a tube to deliver insulin, making the device more wearable.

Instead of tubing-and-needle, a micro-needle mounted on the Cellnovo patch pump pierces the dermis for a subcutaneous delivery of insulin.

The key innovation in the Cellnovo technology are the microfluidics built around a micro-actuator that is a piston with no moving parts, driven by the expansion and contraction of paraffin wax against a membrane using ultra low-energy heating.

This development allows a miniaturization of the components and low-cost manufacturing with a disposable insulin reservoir.

In June 2016 the peer-reviewed journal *European Endocrinology* published the results from an *in vitro* study comparing the pulse accuracy of the Cellnovo micropump with the only other commercially available patch pump, the Omnipod.

Measuring the the percentage of pulses delivered outside of the accuracy threshold showed a significant difference of 7.3 percent for Cellnovo against 37 percent for Omnipod at 10 pulses. Both pumps improved as the observation window increased to 40 pulses with Cellnovo delivering just 0.4 percent outside the accuracy threshold while Omnipod delivered 25.9 percent outside the threshold.

"This study showed that not all patch pumps are the same," the authors concluded, adding that, "the pumping mechanisms employed in these pumps play a significant role in the accuracy and precision of such devices."

In announcing the results, Baratte stated, "These data, obtained following an established methodology, demonstrate that the miniaturization of the pump has not been achieved to the detriment of accuracy."

"What the study clearly says to the pharma industry is that the Cellnovo micropump is ready to embark in clinical trials with concentrated insulin," Baratte told *Medical Device Daily*.

"Clearly the more concentrated insulin becomes, the accuracy in delivery is going to matter enormously," she said. //