

CLOSING THE LOOP

Cellnovo investors pump \$6 million into artificial pancreas efforts

By John Brosky, Contributing Writer

PARIS – Cellnovo Group SA raised €5.4 million (US\$6 million) in a fundraising round dedicated exclusively to putting its artificial pancreas program on a fast-track to commercialization.

European and U.S. institutional investors participated in the capital increase.

Cellnovo's insulin pump is being used by several academic-driven programs to develop an artificial pancreas, a closed-loop system for automated delivery of insulin.

Paris-based Cellnovo said it will also use the funding to license rights from a partner to close the loop for its insulin micro-pump and mobile diabetes management system.

The company's current collaborations include the International Diabetes Closed Loop (IDCL) trial in the United States that gathers nine academic centers and is being conducted by Charlottesville, Va.-based Typezero Technologies LLC and is funded by the National Institutes of Health. (See *Medical Device Daily*, Feb. 18, 2016.)

In July, Typezero said it would license its technology to San Diego, Ca.-based Tandem Diabetes Care Inc. to integrate the artificial pancreas into the Tslim insulin pump.

Cellnovo was also the insulin pump of choice for the artificial pancreas being developed by Diabeloop SAS, of Grenoble, France, a spin out of a consortium of French research institutes, which was created in 2015 to commercialize the final device, with a goal of reaching the market by the end of 2017.

Over the next 18 months, Cellnovo's new funds are also expected to support the development of a new patient interface and clinical portal for the company's web-based applications, and additional trials to for regulatory submissions.

Cellnovo CEO Sophie Baratte told *Medical Device Daily* the Diabeloop and Typezero programs are the most advanced in the company's collaborations, and that very good outcomes have been reported for IDCL, with Diabeloop trial results currently in publication. As a result of these existing programs, she said the key resources for the company's accelerated development program are already in place.

The funding is expected to carry the program through to a commercial launch in Europe.

The urgency of the medical need is so great that some type 1 diabetics, frustrated by the slowness of industry to put the pieces of the system together, have built their own kits and shared tutorials about it online.

At the annual meeting of the American Diabetic Association (ADA) in June in New Orleans, the patient-driven Open Artificial Pancreas System project, featured in a late-breaking poster session, reported quantitative and qualitative measures of 40 do-it-yourself diabetes patients.

As of May, there were six commercial automated insulin delivery systems advancing on clinical and regulatory pathways, according to The Diatribe Foundation, of San Francisco. All of these systems are projected to hit the market no later than 2018.

Dublin, Ireland-based Medtronic plc is closest to commercialization with the Minimed 670G pump, expected to be submitted to the FDA in the third quarter and a U.S. launch targeted for next April.

The Tandem Tslim pump is expected to complete a pivotal trial this year and potentially launch in the second quarter of 2017. Beta Bionics Inc. is developing the Ilet pump, a dual-chamber device designed to inject controlled doses of either insulin or the hormone glucagon.

CEO Ed Damiano, a professor of biomedical engineering at Boston University, spun his research into Beta Bionics and structured the company as a benefit corporation.

At ADA, Beta Bionics demonstrated that glucagon injections can play a critical role in helping to control glucose levels, reporting results of a randomized, placebo-controlled, 22-patient study in which hypoglycemia reduced by 75 percent during the day and 91 percent at night.

According to Diatribe, two other companies shooting for FDA approval in 2017 are Bigfoot Biomedical Inc., of Milpitas, Ca., and Chesterbrook, Pa.-based Animas Corp., a unit of Johnson & Johnson Diabetes Care. //

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