
Cellnovo 3Q17 - Revenue of €218,408 declines 28% YOY and 24% sequentially; 38 new devices shipped on continued manufacturing delays; FDA clearance now expected in 2018; AID updates - October 30, 2017

Executive Highlights

- **Revenue** declined 28% year-over-year (YOY) and 24% sequentially to just €218,408, the third consecutive quarter with a YOY decline.
- **Cash** stood at €18.7 million at quarter's end, presumably enough to last into mid-2019 (per [2Q17](#)).
- **Manufacturing delay** - Due to another delay in the insulin cartridge manufacturing hand-off to Flex, Cellnovo shipped just 38 new pumps this quarter. The manufacturing process requires further optimization.
- **FDA delay** - Cellnovo now anticipates receiving FDA clearance in 2018, after the Agency requested additional information on the submission (e.g., regarding biocompatibility of pump materials). A US launch was previously expected by the end of 2017.
- **Automated Insulin Delivery** - The first arm of the [Diabeloop CE Mark trial](#) is complete; no data has been shared but Diabeloop says feedback has been "very positive" and an "early 2018" launch is still expected. Integration of Cellnovo's pump with TypeZero's software is being finalized, which will pave the way for a small pilot study (we imagine the expected "2018" launch could be pushed back). Cellnovo is also participating in the EU Horizon 2020-funded PEPPER project.

Cellnovo announced 3Q17 financial results in a [press release](#) last week, reporting modest sales of €218,408, which dropped 28% YOY and 24% sequentially. Pump sales were down 44% YOY and 36% sequentially, with only 38 new devices shipped (despite reported "high demand"), bringing the total shipped since launch to 774. The [press release](#) cites this decrease in shipments as wholly responsible for the company's sales decline. As of September 30, Cellnovo still has €18.7 million (~\$21.8 million) in cash - presumably still providing runway through mid-2019.

As has been common in recent quarters, Cellnovo announced another delay in the manufacturing transition to Flex. Per [the 2Q17 update](#), full production was slated to occur by end of August (also a delay), but further optimization is needed. A progress update is now expected in January 2018, meaning this plan is now running over a year behind [3Q16 expectations](#). Oddly, a handout at [EASD](#) claimed "large-scale, automated production" of the cartridges was now available, which does not appear to be true. The company's execution continues to be disappointing, though fortunately it does have a lot of cash in the bank and several AID projects in the works.

In [November 2016](#), Cellnovo submitted a 510(k) to the FDA, and has since been asked to [provide](#) additional details to the Agency (e.g., in regard to issues of biocompatibility). Cellnovo plans to meet with FDA reviewers to ensure that its answers are adequate and expects to obtain FDA clearance in 2018. A more specific update will be shared after the FDA meeting. A US launch was [previously expected](#) by the end of 2017. We're not sure if the company will commercialize with a partner or raise money to do so on its own in the highly competitive US market.

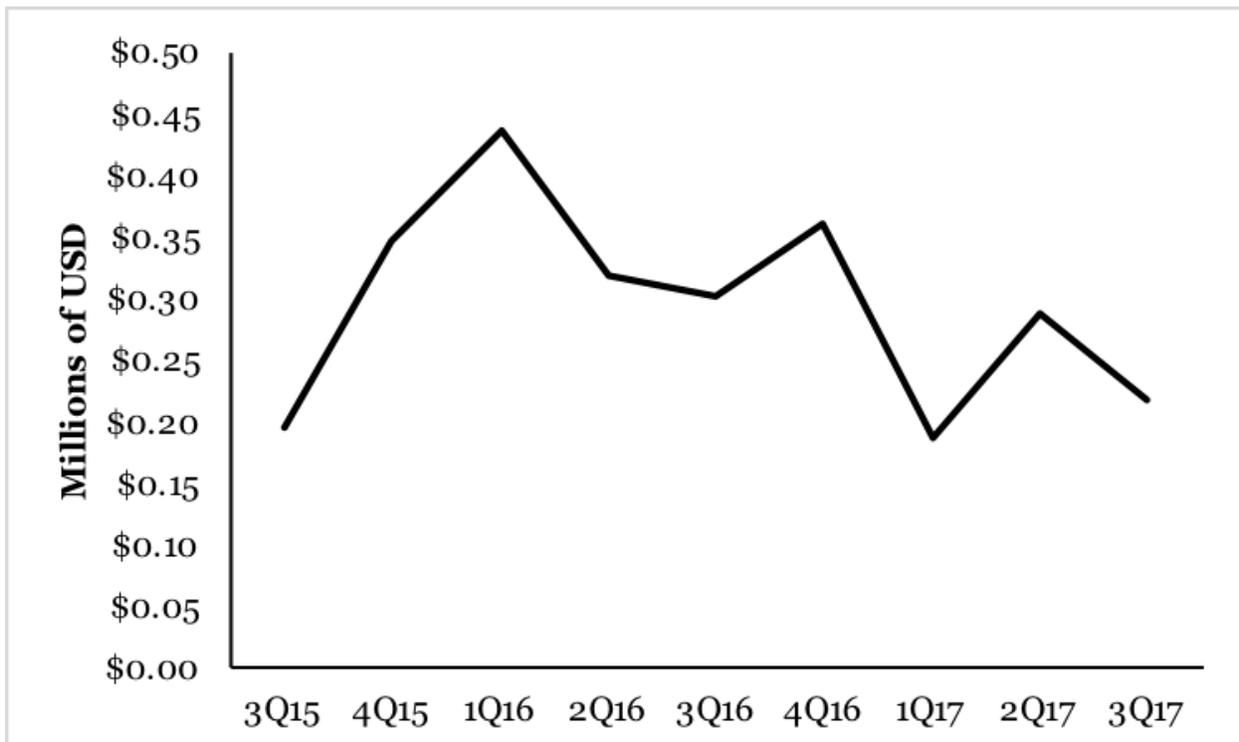
As for the company's automated insulin delivery bets, there are now three moving along - a smart strategic play to leverage the pump in multiple programs. Updates:

- **The first arm of [Cellnovo's trial with Diabeloop](#) has been completed** - data has not yet been shared, but a [Diabeloop press release](#) notes "very positive feedback." The two companies are

discussing the terms of a commercial agreement, and Diabeloop still ambitiously [anticipates](#) a launch in early 2018, after the second arm reportedly started in early September. [CT.gov](#) indicates that the trial will actually wrap up in February-March 2018.

- **Integration of the Cellnovo system and TypeZero artificial pancreas software is "currently being finalized,"** which paves the way for a "pilot study...with a limited number of patients." The two companies signed a global licensing agreement [earlier this year](#), and this is the first mention of a pilot study. We're assuming that the [previous expectation for a 2018 launch](#) might have to be revised, though the press release maintains that the project is "progressing well."
- **The [press release](#) also mentioned Cellnovo's participation in PEPPER,** an artificial pancreas and decision support project supported with 4 million euros the European Union's Horizon 2020 program (see a [Cellnovo press release from 2016](#) for details). We don't know much about this, including timing or the path to market.
- **In other pipeline news, Cellnovo is finalizing development of its next generation system equipped with Bluetooth connectivity,** a clear move to stay competitive with where all pumps are heading (e.g., Tandem's t:slim X2, Insulet's Omnipod Dash, Medtronic's future pumps, Bigfoot's smartloop, Beta Bionics' iLet, etc.). There were no updates on the remote-upgradable Android handset slated to launch in October as per [EASD](#).
- **Cellnovo's execution will need to be spot on to compete in the already-fragile, highly competitive pump market.** Can the company build a market in Europe? What is true demand right now? Can it compete with Insulet? Can the manufacturing and customer support scale? Can Cellnovo reach sustainable margins? Can it meaningfully differentiate from larger players with more resources? Will its automated insulin delivery pipeline come to fruition?

Quarterly OUS Sales (3Q15-3Q17)



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