

### The first connected all-in-one Diabetes Management System

Press release

# Cellnovo reports Q3 sales and cash position at September 30, 2017

Sales remain impacted by production constraints Solid net cash position

Paris, France, October 25, 2017 – Cellnovo Group ("Cellnovo" or "the Company" — CLNV: EN Paris), a medical technology company marketing the first mobile, connected, all-in-one diabetes management system, today publishes its sales for the first nine months and third quarter ended September 30, 2017.

	Jan Sept 9 months		Quarterly - 3 months	
(In €K)	2017	2016	Q3 2017	Q3 2016
Sales	689,533	1,053,591	218,408	301,218

Over the first nine months of 2017, and in line with the Company's strategy to limit sales of systems for new patients until the full ramp-up of insulin cartridge production takes place, Cellnovo generated sales of €689,533, a reduction compared to 2016. During the third quarter of the year, sales totalled €218,408, compared with €301,218 for the same period in 2016. This decrease is entirely attributed to the reduction in new systems sold. As such, over the course of the third quarter, Cellnovo sold 38 new devices compared to 68 in Q3 2016, bringing the total number of systems sold since launch to 774.

As of September 30, 2017, Cellnovo had a net cash position of €18.7 million. Cellnovo confirms that there has been no drawdown of the equity line agreed with Kepler Cheuvreux since the end of June 2017 and, given the Company's net cash position following the funds raised in July 2017, the use of this facility has been suspended.

Sophie Baratte, Chief Executive Officer of Cellnovo, commented: "We are working closely with our partners to accelerate the full commercialisation of our unique micro-pump so that patients are able to benefit from our intuitive, connected device as soon as possible. The demonstrated benefits of our product for people with type 1 diabetes remain strong, reinforcing our confidence in the Company's midterm and long-term growth prospects. Furthermore, we are well-positioned to advance one or several artificial pancreas solutions, which will revolutionise the management of this chronic condition and reinforce our competitive advanctage on the insulin pump market."

### Third quarter operational highlights

# A rigorous optimisation of the large-scale production process, ensuring the Company's long-term sucess

### Successful transfer of production

As previously announced, the transfer of insulin cartridge production from Cellnovo to Flex was confirmed in early summer with the production of three consecutive commercial validation batches. This marked the completion of a comprehensive industrialisation process and included the manufacture of precision moulding tools for the production of plastic parts at Flex's specialised centre in Switzerland, as well as the development of custom robots and the formation of an automated production line in Austria. The validation batches met regulatory requirements and Cellnovo's criteria for performance and quality, confirming Flex's ability to successfully produce insulin cartridges for the Cellnovo System.

An optimisation phase necessary for a successful ramp-up to large-scale production



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In August, Flex began large-scale production to assess how the process performs when operating at high throughput and volumes. During this assessment, Flex identified certain parameters in the production process that need optimising. These adjustments are not unusual at this stage of industrialisation and an immediate action plan is currently underway to achieve large-scale production targets. An update on the progress of this plan is scheduled for January 2018.

### Flex, an expert in industrialisation, ensuring long-term success

Flex has extensive experience, a proven expertise garnered through numerous production transfers and a track record of success. Cellnovo believes Flex is well-equipped and that its skill and commitment are a guarantee of quality and reliability that will support Cellnovo's long-term success.

The Cellnovo System remains in high demand, allowing the Company to anticipate strong, sustained sales growth once large-scale production begins.

### 510(k) application for clearance from the FDA

In November 2016, Cellnovo filed for 510(k) approval to market the Cellnovo System in the United States. The FDA raised questions that were answered by Cellnovo within the required time frame. The FDA has since sent the Company further questions requesting additional details on certain answers already provided (for example, in regard to the biocompatibility of materials in the pump.) Cellnovo plans to meet with the FDA representatives reviewing its submission in order to ensure that its proposed answers are fully in line with the US regulatory authority's expectations.

Cellnovo is working closely with its US advisory team in order to ensure a positive outcome. The Company is taking advantage of this additional time to establish more in-depth dialogue with its local partners to ensure a successful launch in the US.

As announced on September 8<sup>th</sup>, Cellnovo remains confident in its ability to obtain the FDA clearance in 2018 and will be able to communicate a more precise timeline after its meeting with the FDA.

# Cellnovo's artificial pancreas programmes to improve quality of life for people with type 1 diabetes

Cellnovo is positioned as an important player in three flagship projects to develop artificial pancreas solutions: Pepper, a collaborative project supported by the European Union's H2020 programme; a strategic collaboration with the US market leader TypeZero; and the French Diabeloop project.

A clinical trial is in progress for the project in collaboration with Diabeloop. The first part of the trial has been completed and received "very positive feedback from investigator sites" (Diabeloop, August 20, 2017). At the same time, Cellnovo and Diabeloop are discussing the terms of a commercial agreement that has not yet been signed.

The project with the US company TypeZero is also progressing well. In April 2017, the two companies have signed a global commercial agreement. Integration of the Cellnovo System and the TypeZero artificial pancreas software is currently being finalised, which paves the way for a pilot study for validation of the system with a limited number of patients.

More generally, Cellnovo's aim is to be able to offer an artificial pancreas solution coupled with its system to ensure the best experience for patients and maximise the value created for the Company.

### Continuous improvement of the Cellnovo System

Cellnovo's R&D teams are finalising the development of the next generation of the Cellnovo System using Bluetooth protocol as the means of communication between the pump and the touchscreen handset. This will allow for an enhanced user experience thanks to faster communication and will open



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the system's platform to other devices that can be connected by Bluetooth, in particular, continuous glucose monitoring systems (CGM), as part of an artificial pancreas system.

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### **About Cellnovo (Euronext: CLNV)**

An independent medical technology company specialising in diabetes, Cellnovo has developed and markets the first mobile, connected, all-in-one diabetes management system that helps make life easier for patients. Compact, intuitive and entirely connected, Cellnovo's insulin pump comprises a mobile touchscreen controller with an integrated blood-glucose meter. This unique device allows optimal management of insulin injections whilst ensuring extensive freedom of movement and peace of mind for patients. Thanks to the automatic transmission of data, it also allows the patient's condition to be continually monitored by family members and healthcare professionals in real time. Cellnovo is currently participating in several major Artificial Pancreas projects with Diabeloop, TypeZero and Horizon 2020 to develop automated insulin delivery systems.

For more information go to www.cellnovo.com

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Cellnovo is listed on Euronext, Compartment C ISIN: FR0012633360 – Ticker: CLNV)



# Cellnovo

Chief Executive Officer Sophie Baratte investors@cellnovo.com

#### **NewCap**

Investor Relations
Tristan Roquet Montégon
+ 33 1 44 71 00 16
cellnovo@newcap.eu

#### **NewCap**

Media Relations in France Nicolas Merigeau + 33 1 44 71 94 98 cellnovo@newcap.eu