



## Curetis Publishes First Quarter 2016 Business and Financial Update

- ***Worldwide commercial expansion and US FDA trial on track***
- ***Installed base of Unyvero Analyzers increased to 107 devices***

**Amsterdam, the Netherlands and Holzgerlingen, Germany, May 20, 2016** -- Curetis N.V. (the "**Company**") and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today published its business update for the quarter ended March 31, 2016, and confirmed its outlook for the full year 2016.

### First Quarter 2016 Operational and Business Highlights

#### Unyvero US FDA trial

- The **US FDA** trial for the **Unyvero LRT Application** in lower respiratory tract infections is nearing completion, with expected enrolment targets to be reached by mid-year. At the end of March 2016, more than 1,600 patient samples had been enrolled, with over 2,000 prospective and retrospective patient samples enrolled to-date;
- Curetis anticipates completing the contrived specimen study, molecular composite comparator testing for all samples and ancillary preclinical work packages in the second half of 2016, with top line data expected to be available upon unblinding, not before fall 2016;
- The submission of 510(k) data package to the US FDA is expected before year-end 2016.
- The Company also continues to prepare for the **second Unyvero Application Cartridge to enter US FDA trials** in the second half of 2016. Further details will be announced later this year.

#### Commercial Expansion

- The Company has **hired Willem Haagmans as Head of Sales EMEA**. He brings a strong track record and extensive leadership experience with both large and small-to-medium sized molecular diagnostics companies. Prior to joining Curetis, he worked as General Manager Benelux at Beckman Coulter. Previously, Haagmans held international management positions at Roche, Nimblegen, and Vela Diagnostics. In addition, the Company has hired key **commercial staff** in the **UK, France and Benelux**, significantly strengthening its direct commercial footprint and positioning the Company to accelerate new Unyvero installations in these key markets.
- Curetis has established a **wholly owned sales subsidiary** in the UK (Curetis UK Ltd, London, UK) at the beginning of May 2016 and anticipates to incorporate further subsidiaries in France (Curetis France SARL) and the Netherlands (Curetis Benelux BV) in the coming months.

### Product Development

- Curetis has successfully completed the CE performance evaluation study and subsequently **launched its Unyvero BCU Blood Culture Application Cartridge** during ECCMID 2016 in Amsterdam in April. The CE-marked BCU application is designed for diagnosing infections spreading through the blood stream in positively flagged blood cultures. The comprehensive panel covers 87 of the most relevant pathogens, including Gram negative and Gram positive bacteria, and 16 related resistance markers.
- The Company has advanced the development of a **second-generation Unyvero ITI Application Cartridge** (expected European launch in mid-2016) and **IAI Intra-Abdominal Infection Cartridge** (expected development completion by year-end 2016). In addition, the partnered **Sepsis Host Response program** (anticipated completion in late 2017) is progressing according to plan.
- Curetis has established a Medical Advisory Board with experts from the US (Robin Patel, MD, Mayo Clinic), Belgium (Jean-Louis Vincent, MD, Erasme University Hospital), Switzerland (Reno Frei, MD, University Hospital Basel), and Germany (Mathias Pletz, MD, Jena University Hospital). The advisors bring strong expertise in intensive care, clinical microbiology, sepsis and prosthetic joint infections. Recently, Curetis added Dr. Laurent Poirel (University of Fribourg, Switzerland), an expert in antibiotic resistance markers, to its MAB. Dr. Poirel has a long-standing scientific career at the French National Institute of Health and Medical Research (INSERM) in Paris / France with a focus on the genetics, biochemistry and epidemiology of antibiotic resistance determinants. In addition, he and his team have jointly developed a variety of rapid diagnostic tests for the detection of extended-spectrum  $\beta$ -lactamases and carbapenemases.

### Installed Base

- Curetis has **expanded the installed base of Unyvero Analyzers** to 107 at the end of the first quarter 2016 (vs. 58 at the end of the first quarter 2015).
- The Company reiterates its guidance of an expected global installed base of 150 to 200 Unyvero Analyzers by year-end 2016.

### Supervisory Board

- Curetis announced the **nomination of Dr. Prabhavathi Fernandes**, CEO of Cempra Pharmaceuticals Inc., Chapel Hill, NC, USA, as a candidate for Curetis N.V.'s **Supervisory Board**. The election is to be held during the upcoming Annual General Meeting on June 16, 2016. Further important resolutions in the agenda are the resignation of Dr. Frank Mühlenbeck, and the re-election of Dr. Holger Reithinger and Dr. Rudy Dekeyser for another one-year term.

### **First Quarter 2016 Financial Highlights**

- **Revenues:** EUR 132.8 k (vs. EUR 228.4 k in the first quarter 2015). In general, revenues are expected to remain volatile from quarter-to-quarter, as early-stage instrument sales to distribution partners are unevenly spread throughout the year.
- **Expenses:** EUR 3.3 million (vs. EUR 2.7 million in the first quarter 2015). The increase is in line with the operational and organizational growth, and driven by higher R&D expenses, distribution costs as well as G&A costs only partly compensated by less cost of sales.
- **Gross loss:** EUR 30.1 k (vs. EUR 54.2 k in the first quarter 2015). This is mainly due to IFRS accounting requiring idle capacity of manufacturing line and facility to be allocated to cartridge output.

- **Net loss:** EUR 3.2 million (vs. EUR 2.6 million in the first quarter 2015).
- **Cash and cash equivalents:** EUR 43.2 million (vs. EUR 46.1 million as of 31 Dec 2015). Net cash burn in the first quarter 2016 was EUR 2.9 million.

#### Key non-audited financials as of March 31, 2016

Curetis N.V.		
consolidated numbers in '000 Euros		
	<b>For the three months ended March 31, 2016</b>	<b>For the three months ended March 31, 2015</b>
Revenues	133	228
Operating loss	(3,125)	(2,461)
Total comprehensive income	(3,169)	(2,588)
	<b>March 31, 2016</b>	<b>December 31, 2015</b>
Cash and cash equivalents	43,190	46,060

„We are very pleased with the operational progress in the first quarter of 2016. Year-to-date, we have successfully tested more than 2,000 patient samples in our FDA trial, with enrolment for prospective and retrospective sample testing nearing completion. This progress keeps us on-track to report top-line data from the trial during the latter part of 2016 and submit our 510(k) package to the FDA by year-end," said Oliver Schacht, CEO of Curetis. "In addition to advancing our U.S. trial, we have strengthened our commercial infrastructure through key sales hires in the UK, France and Benelux, and additions to our application specialist and marketing teams in Germany."

"The expansion of our direct sales organization in Western Europe is fully on track, and we continue to pursue strategic distribution partnerships aimed at providing Unyvero access to additional markets and potentially bolstering our presence in existing markets," he added. "The successful launch of our Unyvero BCU Blood Culture Application Cartridge adds a third comprehensive syndromic panel to the Unyvero Platform in Europe, further strengthening our product portfolio. With several other cartridges in development and expected to launch in the coming years, we believe that Curetis is optimally positioned to succeed in the global MDx market."

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## About Curetis

Founded in 2007, Curetis is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. The diagnostic solutions of Curetis enable rapid multi-parameter pathogen and antibiotic resistance marker detection in only a few hours, a process that today can take up to days or even weeks with other techniques.

To date, Curetis has raised EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 million. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical and Cempira Inc. as well as several international distribution agreements covering many countries across Europe, the Middle East and Asia.

**For further information, please visit [www.curetis.com](http://www.curetis.com).**

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According to §§ 190 ff. German Reorganization Act (UmwG) and by way of enrolment in the commercial register at district court Stuttgart on March 15, 2016 Curetis plc (AG) changed its legal form into Curetis Ltd. (GmbH).

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