



Curetis Publishes Business and Financial Update for the First Nine Months 2016

- ***U.S. FDA trial completed with excellent top-line data***
- ***Leading position in genetic antimicrobial resistance biomarker testing strengthened by GEAR acquisition***

Amsterdam, the Netherlands, and Holzgerlingen, Germany, November 18, 2016 -

Curetis N.V. (the "**Company**") and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today published a business and financial update for the first nine months ended September 30, 2016 and provided an outlook to coming months.

Recent Operational and Business Highlights

Unyvero US FDA Trial

- Curetis **successfully completed** the **U.S. FDA trial** for the Unyvero Platform and its LRT Application in lower respiratory tract infections and reported positive top-line data in October 2016. The prospective and retrospective study met its primary endpoint by demonstrating an overall weighted average sensitivity of 90.2% and an overall average weighted specificity of 99.3%. These data are fully consistent and in line with the performance evaluation previously conducted by Curetis for CE IVD marking in Europe, as well as published data from various European KOLs and customer sites.
- The submission of Curetis' (de novo) **510(k) data package** to the **U.S. FDA** is expected in due course. FDA feedback and the potential clearance for Unyvero and start of commercialization are expected in the first half of 2017.
- Curetis is preparing **to enter U.S. FDA trials** for its next U.S. product. To that end, the Company has submitted a so-called pre-submission package to the FDA for a U.S. version of its **Unyvero ITI Cartridge**. Based on the FDA's feedback and additional market research data that are expected in Q4-2016, Curetis will determine appropriate next steps and timelines for a U.S. FDA trial for this second product. Further details will be announced in 2017.

Acquisition of NGS Database GEAR and IP from Siemens

- Curetis has acquired sole commercial rights from Siemens Technology Accelerator to the **GEAR (GEnetic Antibiotic Resistance and Susceptibility)** platform and database with all its content, numerous GEAR-related patents and patent applications, as well as all corresponding know-how. The deal gives Curetis sole worldwide product development and commercial rights, including the right to sublicense assets in human and animal diagnostics as well as food safety testing. Furthermore, Curetis has secured the sole rights to leverage the GEAR assets in collaboration with

pharmaceutical companies for the development of novel antimicrobial drugs for human and animal health.

- The state-of-the-art bioinformatics database comprises more than **11,300 bacterial strains** that have been collected at more than **200 sites on 5 continents over 30 years**. The next gene sequencing (NGS) data with 0.4 trillion reads is a wealth of comprehensive and internationally relevant **information** amounting to **30 terabytes** in total.
- GEAR allows Curetis to rapidly identify potential novel biomarkers, biomarker combinations, and algorithms predicting antibiotic resistance, as well as potential novel targets for antimicrobial drugs. The acquisition of the GEAR database and patent estate adds significantly to the **leading position** that Curetis has established in the area of genetic antimicrobial resistance biomarker testing with its Unyvero Cartridges. Curetis intends to further expand and mine the GEAR database in collaboration with leading academic institutions as well as pharmaceutical and diagnostics companies and leverage those into commercial products on its Unyvero Molecular Diagnostics platform and beyond.

Commercial Expansion

- **United States**
Following the appointment of **Christopher M. Bernard as President and Chief Executive Officer of Curetis USA, Inc. in La Jolla, San Diego, CA**, the Company has been building its senior leadership and U.S. commercial core team for the North American market during the second half of 2016. The U.S. subsidiary has been founded to drive the future commercial development and sales of the Company's Unyvero Platform in North America. Curetis is planning direct commercialization of all Unyvero Products in the U.S. hospital market.
- **Europe**
The Company has made excellent progress in expanding its commercial footprint in its direct sales territories. To this end, Curetis has established four new wholly owned commercial subsidiaries in Europe covering the UK, the Netherlands for the Benelux area, France and Switzerland and has hired senior market development managers and key account managers from industry leaders such as Roche, Cepheid, Abbott and others.

Product Development

- After launching the BCU Blood Culture Application Cartridge in Q2-2016, Curetis has **launched its second Unyvero Test this year** with its **next generation Unyvero ITI Cartridge** for Implant and Tissue Infections in September 2016. The CE performance evaluation study was successfully completed and demonstrated an overall average sensitivity for all pathogens of 86.9% and an overall average specificity for all pathogens of 99.2% in a total of 1,100 samples. The next-generation cartridge now covers a total of 102 (up from 80 in first generation) diagnostic targets: 85 of the most clinically relevant pathogenic microorganisms, including Gram positive and Gram negative bacteria, several fungi, and 17 related antibiotic resistance markers.
- The Company has furthermore progressed the development of the **IAI Intra-Abdominal Infection Cartridge**, its **fourth Unyvero Application**, towards completion by the end of this year. In addition, the partnered **Sepsis Host Response program** (anticipated completion not before the end of 2017) is progressing according to plan.

Installed Base

- Curetis has continued to expand the **installed base** of Unyvero Analyzers to 121 as of September 30, 2016 (vs. 79 instruments as of September 30, 2015, i.e. an increase by 53% year over year).

Financial Highlights for the First Nine Months 2016

- **Revenues:** EUR 1.1 million (vs. EUR 0.9 million in the nine months ended September 30, 2015). Overall revenues were up by 21.7% year over year. While revenues in the first half of 2015 had included EUR 297 thousand generated by Unyvero Systems sales to a pharma partner, revenues in the same period in 2016 did not include any such system sales to pharma. 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 12.0 million (vs. EUR 9.6 million in the nine months ended September 30, 2015). The increase is in line with the operational and organizational growth strategy and driven by higher R&D expenses, distribution costs as well as G&A costs.
- **Gross loss:** EUR 0.1 million (vs. a gross loss of EUR 0.5 million in the nine months ended September 30, 2015). The relatively low gross margin is significantly impacted by the mix of systems sales to cartridge sales and by IFRS accounting requiring excess capacity of the cartridge manufacturing line and facility to be allocated to actual period cartridge output.
- **Net loss:** EUR 10.7 million (vs. a profit of EUR 13.5 million in the nine months ended September 30, 2015). The profit in the nine months ended September 30, 2015 was due to 23.6 million financial income resulting from a one-time accounting-effect due to the revaluation of preferred and common shares under IFRS.
- **Cash and cash equivalents:** A strong cash position of EUR 35.4 million as of September 30, 2016 (vs. EUR 46.1 million as of December 31, 2015) and a **net cash burn** of 10.6 EUR million during the nine months of 2016 for all operating, investment and financing activities combined.

Key non-audited financials as of September 30, 2016

Curetis N.V.		
consolidated numbers in '000 Euros		
	For the nine months ended September 30, 2016	For the nine months ended September 30, 2015
Revenues	1,077	885
Operating loss	(10,760)	(8,676)
Total comprehensive income	(10,731)	13,493
	September 30, 2016	December 31 2015
Cash and cash equivalents	35,415	46,060

Comparative figures for the nine months ended September 30, 2015, are those of Curetis GmbH (former AG).

„We are very happy with the operational development,” said Dr. Oliver Schacht, CEO of Curetis. “We completed the U.S. FDA study on time and as planned. We are now using the outcome, a very strong and comprehensive data set, for compiling the final submission documents and look forward to receiving feedback from the FDA. In addition, we launched

the next-generation Unyvero ITI Cartridge for Implant and Tissue Infections and submitted the pre-submission package to the FDA for a U.S. version of the Unyvero ITI Cartridge.”

“Furthermore, the GEAR acquisition allows us to significantly expand the scale and scope of the Unyvero Platform and complement it with NGS-based knowledge,” he added. “GEAR will allow us to stay on top of the development of cutting-edge molecular diagnostic products for critical hospital infections as it will serve as an engine for even more comprehensive and differentiated content of antibiotic resistance biomarkers in our Unyvero Products. Last but not least, the commercial expansion is also progressing in both Europe and the U.S., where we have built a senior leadership and U.S. commercial core team for the North American 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 Cembra 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.

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