Curetis Publishes Business and Financial Update for the First Nine Months of 2017

- Preparing for expected U.S. FDA clearance decision on Unyvero System and Unyvero LRT Application

- Second U.S. FDA trial initiated for Unyvero IJI Application

Amsterdam, the Netherlands, and Holzgerlingen, Germany, November 16, 2017; published at 02:00 a.m. EDT - 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, 2017, and provided details on its outlook for the coming months.

Recent Operational and Business Highlights

U.S. FDA Trials with Unyvero LRT and IJI Application Cartridges

- Curetis continues to work closely with the U.S. FDA in the **interactive review of the *510(k)* submission** for its Unyvero Platform and the Unyvero LRT Lower Respiratory Tract Infection Cartridge.
- Recently, Curetis **completed all agreed upon work packages**, wet-lab testing and risk & benefit analysis. In early November, Curetis also provided all of its responses to the original AI (Additional Information) request letter to the U.S. FDA's questions. Subject to completion of the interactive review and subsequent final review, Curetis **expects an FDA clearance decision in due course**.
- The Company continues to **prepare for the commercial launch of Unyvero in the U.S.** in 2018, with recruiting activities underway for additional commercial and operations positions, including clinical application specialists and field service engineering support. A further expansion of the team is in progress with the hiring of the sales force in the field expected in the coming months.
- As Curetis recognizes the importance of antibiotic stewardship programs, and the goal of limiting inappropriate use of antibiotics, Curetis USA Inc. hosted a KOL roundtable discussion with PharmD Infectious Disease specialists in the U.S. in San Diego during IDWeek.
- Curetis has **initiated a U.S. FDA trial for its second U.S. product**, the Unyvero Invasive Joint Infections (IJI) Application Cartridge. Following Institutional Review Board (IRB) approvals, Curetis has initiated sample collection for its second multicenter FDA study. The IJI Cartridge represents a newly developed U.S. version of the CE-IVD marked Unyvero ITI Cartridge. The ITI Implant and Tissue Infection Application is commercially available in Europe and other parts of the world.
- Among the **sites that have already entered the trial** for sample collection of microbiology-positive synovial fluid patient samples are sites that previously participated in the Unyvero LRT trial (e.g. Beaumont Hospital, Royal Oak, MI), as well as new sites (e.g. Froedtert Hospital and the Medical College of Wisconsin,

Milwaukee, WI), med fusion, (Lewisville, TX) and a leading reference lab in the Southwestern United States. The Company is expecting further expansion of the network to include additional sites in the coming months.

- The overall **trial design** is similar to the Unyvero LRT study. Following FDA guidance, the IJI clinical trial is expected to enroll more than 1,500 prospective test samples, complemented with archived microbiology-positive specimens to reach significant numbers for each of the analytes in the IJI panel, as well as a comprehensive analytical testing data package. The Company expects availability of the cartridges and the **initiation of the prospective arm of the FDA trial to begin in 2018**.

Business Development and Market Expansion

- Following the announcement of a strategic **memorandum of understanding and initial R&D collaboration between MGI (a BGI Affiliate) in China** and Curetis / Ares Genetics in September 2017, MGI has commenced a feasibility study for Next-Generation Sequencing in-vitro diagnostic assays for microbial infections. Together with MGI, Curetis attended a major conference in China. Discussions and negotiations between Curetis and MGI regarding future expansion of their strategic collaboration are ongoing.
- Ares Genetics GmbH, a wholly owned subsidiary of Curetis, has **advanced additional partnering discussions pertaining to the genetic antibiotic and susceptibility database GEAR** to term sheet stage(s). Additional GEAR related partnering activities are anticipated in the coming quarters.
- Curetis' partner **Biotest to enroll the first patient into the PEPPER clinical trial**. This is the fourth pharma partnership supported by Curetis. The Company continues to explore further pharma clinical trials that might benefit from the use of Unyvero.
- The Unyvero System and its application cartridges for pneumonia (HPN), implant and tissue infections (ITI) and bloodstream infections (BCU), have recently been **cleared by the regulatory authorities for commercial use in Israel**.
- Working toward a **potential Chinese market clearance**, analytical testing of Unyvero HPN Cartridges by BCB in China is progressing as expected. Analytical testing is a key requirement and precondition to Curetis' partner initiating the prospective Chinese FDA clinical trials in 2018.
- The **regulatory review of the Unyvero submission in Singapore is in progress** and it is anticipated that a clearance decision will be made in the coming months.

Commercial Development

- Following the **shift of global sales responsibility to Chris Bernard** (announced in August 2017), there have been changes to the team composition and organization in Curetis´ EMEA direct selling markets. **Riwat Lim** has joined Curetis from QIAGEN as Managing Director of Curetis UK Ltd. and Head of Marketing and Scientific Affairs. To maximize synergies across all customer-facing teams and given Riwat's deep expertise and strong leadership capabilities, he has recently been appointed as **Director of Commercial Operations EMEA**.
- In his new role, Riwat leads and oversees all EMEA commercial operations including Sales, Customer Support and Services, Scientific Affairs and Marketing. Riwat will continue shaping and evolving the EMEA commercial team.

Installed Base

- Curetis has **continued to expand the installed base** of Unyvero Analyzers to 165 as of September 30, 2017 (vs. 121 as of September 30, 2016), an increase of 36.4% year over year. During Q3, 2017, a total of 9 new Analyzers were installed and 5 were brought back following completion of the demo and evaluation phase.
- As expected, **system placements** during the summer months have been slow. Also, during the third quarter, Curetis has experienced some prolonged customer discussions and contracting in Germany, France and the UK. Therefore, several new system placements expected in the third quarter have been postponed into Q4.
- Furthermore, in the U.S., paperwork has been signed for **multiple Unyvero Analyzers to be installed in the U.S.** in Q4-2017 under an Investigational Use Only (IUO) labeling. The U.S. impact on the overall installed base will be relatively limited in FY 2017, but is expected to accelerate significantly upon the planned commercial launch following the anticipated FDA clearance decision.
- Curetis USA Inc. is expected to place a significant initial stocking order with Curetis GmbH in late Q4-2017 for inventory purposes ahead of an anticipated U.S. launch and commercial roll-out. Given the timing of this anticipated order, the Company now expects to reach its installed base target of **200 Unyvero Analyzers** in Q1-2018 rather than by 31 December 2017.

Product Development

- Development of the **Unyvero UTI Urinary Tract Infection Cartridge has been completed** and is pending verification and validation. Curetis aims to **launch** this as a CE-IVD marked product at a major European conference **in Q2-2018**.
- Curetis has **finalized the specifications of the Invasive Joint Infections (IJI) Application** in collaboration with KOLs and clinical experts. As detailed above, the Company has continued related application development efforts in preparation for the second U.S. clinical trial.
- All other **R&D programs and product development projects continue to progress on track** and in line with Curetis' guidance. These projects include the completion of development of a Unyvero Sepsis Host Response Cartridge (SHR) which will be provided under an IUO (Investigational Use Only) label for further clinical validation and testing.
- Curetis has integrated the former **Gyronimo platform** into the Unyvero suite of products as the future **Unyvero A30 RQ Analyzer**, which will add rapid and where needed quantitative testing capabilities. The development program is on track for completion by the end of 2018.

Financial Highlights for the First Nine Months 2017

- **Revenues:** EUR 0.83 million (vs. EUR 1.08 million in the nine months ended September 30, 2016). As outlined above, a number of placements expected in Q3 have been postponed to Q4-2017. 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 14.8 million (vs. EUR 12.0 million in the nine months ended September 30, 2016). 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. The increase is also due to non-cash expenses accounting for the newly implemented equity settled stock option program 2016. This has resulted in expenses of EUR 946k in the first nine months of 2017 (EUR 363k in the first nine months of 2016).

- **Gross loss:** EUR 0.66 million (vs. a gross loss of EUR 0.11 million in the nine months ended September 30, 2016). The key driver of the higher COGS was depreciation on Unyvero Systems by way of marketability discounts totaling EUR 521k in the first 9 months of 2017 (EUR 268k in the first nine months of 2016) as well as increased costs.
- **Net loss**: EUR 14.6 million (vs. a net loss of EUR 10.7 million in the nine months ended September 30, 2016).
- **Cash and cash equivalents**: EUR 21.6 million as of September 30, 2017 (vs. EUR 22.8 million as of December 31, 2015) and a net cash decrease of EUR 1.2 million during the first nine months of 2017. The net cash outflow from operating and investing activities was EUR 10.9 million (vs. EUR 10.5 million in the first nine months of 2016) with EUR 10.0 million cash inflow in Q2-2017 from the EIB debt financing tranche draw-down.

Key non-audited financials as of September 30, 2017

Curetis N.V.		
consolidated numbers in ´000 Euros		
	For the nine months ended September 30, 2017	**For the nine months ended September 30, 2016**
Revenues	831	1,077
Operating loss	(13,865)	(10,760)
Total comprehensive income	(14,452)	(10,731)
	September 30, 2017	**September 30, 2016**
Cash and cash equivalents	21,561	35,415

„While we are awaiting the FDA clearance decision for our Unyvero System and the LRT cartridge, we are busy preparing for the commercial roll-out in the U.S.," said Dr. Oliver Schacht, CEO of Curetis. "We have therefore realigned our global commercial organization, which has also had a short-term impact on sales and revenues in the EMEA region. However, we expect to be able to partially offset the temporary decrease in system placements in the fourth quarter this year and into early 2018. We are also very confident that the market launch in the U.S. will be a major value inflection point and key milestone for the company. Given our level of confidence, we have initiated an FDA clinical trial of a second U.S. product for the detection of invasive joint infections. Looking ahead, we believe that both the continued commercial expansion and the integration of last year´s GEAR and Gyronimo acquisitions will have an increasing impact on Curetis´ long-term growth prospects."

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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. Furthermore, Curetis has entered into a debt financing facility with EIB for up to EUR 25 million. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis collaborates with Heraeus Medical, pharmaceutical companies, and has entered into several international distribution agreements covering many countries across Europe, the Middle East and Asia.

In 2017, Curetis established Ares Genetics GmbH, a wholly-owned subsidiary of Curetis GmbH in Vienna, Austria. Ares Genetics is dedicated to maximize the R&D and related scientific and business opportunities of the GEAR assets acquired in 2016 for the entire Curetis Group.

For further information, please visit www.curetis.com**.**

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