



Curetis Provides Business and Financial Update for the First Quarter 2017

- *First quarter 2017 revenue increases 2.6-fold year over year*
- *Successful completion of CE performance evaluation study and launch of Unyvero IAI Intra-Abdominal Infections (IAI) Cartridge*
- *Incorporation of wholly-owned subsidiary Ares Genetics to accelerate commercialization of GEAR database*

Amsterdam, the Netherlands, and Holzgerlingen, Germany, May 24, 2017 – 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 quarter ended March 31, 2017, and provided details on its outlook for the remainder of the year.

Recent Operational and Business Highlights

Unyvero U.S. FDA Trials

- In January 2017, Curetis **filed a 510(k) application** with the U.S. Food and Drug Administration (FDA) to obtain clearance for its Unyvero Platform and LRT Application Cartridge. The submission is based on clinical data from the Company’s U.S. FDA trial comparing the performance of the Unyvero LRT Lower Respiratory Tract Cartridge in detecting respiratory pathogens to microbiology culture, the current diagnostic standard of care.
- In March 2017, Curetis received a letter from the FDA requesting additional details on pathogens, antibiotic resistance markers, sample types etc. To clarify the remaining open issues, a so-called “**Submissions Issues**” meeting was held on April 21, 2017. Following this meeting, Curetis has submitted draft minutes to the FDA, continues to respond to the Agency’s requests during interactive review, and expects to provide complete responses on remaining open items in the coming months. Curetis expects a **clearance decision from the FDA** in the second half of 2017.
- In addition, Curetis continues to prepare for its **second FDA trial** with the goal of clearing the second Unyvero Cartridge in the U.S. This Unyvero Cartridge is expected to be a U.S. version of the **Unyvero Implant and Tissue Infection (ITI) Cartridge**, which is tailored to specific U.S. customer and market needs and focuses on (prosthetic) joint infections (PJI).
- Curetis has recently **successfully completed a clinical feasibility study** for the U.S. version of the PJI / ITI panel. Having run over 80 synovial fluid patient samples with available clinical microbiology data, the **overall weighted average sensitivity after discrepant result resolution was 93.5%** at an **overall weighted average specificity of 99.8%**. The panel identified several anaerobic pathogens otherwise missed by standard of care microbiology. Next steps will be finalization of

specifications for a U.S. panel of pathogens and resistance markers to be included and the completion of development. The PJI cartridge is expected to be ready for the **start of clinical trials in the U.S. later this year.**

Corporate Growth

- Curetis has established a new **wholly-owned subsidiary - Ares Genetics GmbH** - in Vienna, Austria. Ares Genetics was founded to leverage the **GEAR GENetic Antibiotic Resistance and Susceptibility Database** and associated assets acquired from Siemens in 2016. The Company will use GEAR to investigate the genetic foundations of antibiotic resistance and to develop and subsequently **commercialize novel approaches to improve the rapid detection of antibiotic resistance** in patients with microbial infections as well as tools to accelerate antibiotic research.
- Via its subsidiary Ares Genetics, Curetis will use GEAR as a **biomarker engine to rapidly identify potential novel biomarkers, biomarker combinations, and algorithms predicting antibiotic resistance**, as well as potential novel targets for antimicrobial drugs. In the future, GEAR may also pave the way towards fully genetic antibiograms and provide a reference for NGS-based clinical diagnostics.
- Curetis has drawn down a **first tranche of EUR 10 million of the non-dilutive debt financing facility** provided through the **European Investment Bank (EIB)** in April 2017 to further advance its R&D and product platform.

Product Development

- In April 2017, Curetis **successfully completed the CE performance evaluation study** and subsequently launched its **Unyvero IAI Intra-Abdominal Infections (IAI) Cartridge** at ECCMID 2017 in Vienna. The CE-IVD marked IAI application aims to support clinicians in the fast and reliable diagnosis of various **severe conditions related to the intra-abdominal tract, including peritonitis, cholecystitis and acute pancreatitis**. The comprehensive panel covers up to 130 diagnostic targets, comprising 92 bacteria, 13 fungi, 3 toxins and 22 antibiotic resistance markers. In the prospective multi-center study, the IAI panel demonstrated 93.8% overall weighted average sensitivity and 99.7% overall weighted average specificity.

Installed Base

- Curetis' global **installed base of Unyvero Analyzers** totaled 151 at the end of the first quarter 2017 (vs. 107 at the end of the first quarter 2016 and compared to 142 at year-end 2016).
- During the first quarter of 2017, over a dozen new Unyvero Analyzers were shipped and several Analyzers were brought back in following successful completion of customer evaluations. Placements were made at key sites in France and the UK, regions in which the Company has seen increased momentum since the establishment of dedicated local sales teams in 2016. Several accounts have been advanced from successful product evaluation to contract negotiation stage.
- Customers have finalized several studies providing the basis for additional publications demonstrating the value of Unyvero, further supporting sales efforts going forward.
- Based on the installed base approaching 160 Unyvero Analyzers during the course of Q2 with several recent shipments to key sites in the UK, the Company reiterates its **guidance of an expected global installed base** of 200 to 240 Unyvero Analyzers by year-end 2017.

Clinical Studies

- Several presentations at ECCMID 2017 demonstrated the **advantages of rapid diagnostic testing** with the **Unyvero Implant and Tissue Infection Cartridge (ITI)** in Prosthetic Joint Infections, specifically its **clinical and health economic benefits**. Rapid testing of sonication fluid from explanted joint prostheses demonstrated a shortened length of hospital stays and average savings of EUR 2,040 per patient. In addition, two studies on the first generation of Unyvero ITI by Charité - University Medicine Berlin showed that its **performance was similar to culture** for sonication fluids and synovial fluids, with the advantages of shorter processing time and full automation of the Unyvero System. One of the aforementioned studies calculated the **advantage of time-to-result** as 5 hours versus 6.8 days.
- Researchers at the Institute of Medical Microbiology, University Hospital Essen (Essen, Germany), published data on Unyvero P55 concluding that the "Unyvero Application is a useful diagnostic tool for the early and rapid detection of pathogens in respiratory specimens". They reported a **significantly higher detection rate when using Unyvero** as compared to culture methods and a **considerably reduced time-to-result**, from a median of 48h to a median of 7.5 hours. The team has tested the Unyvero P55 Pneumonia Cartridge in daily clinical routine with 439 respiratory specimens from 342 patients. Results from the European Study were presented during the 5th Joint Conference of the DGHM & VAAM / VAAM Annual Meeting 2017.

Supervisory and Medical Advisory Boards

- **Dr. Nils Clausnitzer** has been nominated for Curetis N.V.'s **Supervisory Board**. The election for a three-year term is part of the agenda of the upcoming Annual General Meeting on June 23, 2017. Nils Clausnitzer is Senior Vice President and President, EMEA-APAC Lab and Distribution Services of VWR International llc. / VWR GmbH. Furthermore, Dr. Holger Reithinger and Dr. Rudy Dekeyser will run for re-election for another one-year term.
- **Dr. Melissa Miller, Ph.D.**, Professor of Pathology and Laboratory Medicine and Director of the Clinical Molecular Microbiology Laboratory at Chapel Hill School of Medicine at The University of North Carolina, U.S., has joined Curetis' **Medical Advisory Board**. Her special research focus is on the health economic evaluation of new molecular technologies for detecting viral infections and drug resistant organisms.

Financial Highlights for the First Three Months 2017

- **Revenues:** EUR 347.2 k (growing 2.6 times vs. EUR 132.8 k in the first quarter 2016). 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 4.7 million (vs. EUR 3.3 million in the first quarter 2016). The increase is in line with the operational and organizational growth, and driven by higher distribution costs as well as G&A costs.
- **Gross loss:** EUR 175.7 k (vs. EUR 30.1 k in the first quarter 2016).
- **Net loss of the period:** EUR 4.4 million (vs. EUR 3.2 million in the first quarter 2016).
- **Cash and cash equivalents:** EUR 19.3 million (vs. EUR 22.8 million as of December 31, 2016). Net cash burn in the first quarter 2017 was EUR 3.5 million. In April 2017, the company has drawn down EUR 10.0 million from the EIB debt financing facility.

Key non-audited financials as of March 31, 2017

Curetis N.V.		
consolidated numbers in '000 Euros		
	For the three months ended March 31, 2017	For the three months ended March 31, 2016
Revenues	347	133
Operating loss	(4,303)	(3,125)
Total comprehensive income	(4,378)	(3,169)
	March 31, 2017	December 31, 2016
Cash and cash equivalents	19,310	22,832

“During the past several months, we have laid the foundation for accelerating Curetis’ pipeline, further expansion and corporate growth,” said Dr. Oliver Schacht, CEO of Curetis. “The incorporation of Ares Genetics will enable us to access new market segments in infectious disease testing. The launch of the Unyvero IAI Cartridge is another key milestone in building a highly attractive, value generating product portfolio. In addition, we continue to progress with our U.S. market launch preparations and have successfully completed a clinical performance evaluation study for the second potential U.S. product in our pipeline. Following the 510(k) application, we have been in a continuous dialogue with the U.S. FDA in order to obtain clearance for our Unyvero System and LRT Application Cartridge.”

###

Disclaimer

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on the Curetis Unyvero technology is currently available for sale in the United States of America or Canada. The analytical and clinical performance characteristics of any Curetis Unyvero product which may be sold at some future point in time in the U.S. have not yet been established.

###

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 maximizing 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.

Legal Disclaimer

This document constitutes neither an offer to buy nor to subscribe securities and neither this document nor any part of it should form the basis of any investment decision in Curetis.

The information contained in this press release has been carefully prepared. However, Curetis bears and assumes no liability of whatever kind for the correctness and completeness of the information provided herein. Curetis does not assume an obligation of whatever kind to update or correct information contained in this press release whether as a result of new information, future events or for other reasons.

This press release includes statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes”, “estimates”, “anticipates”, “expects”, “intends”, “may”, “will”, or “should”, and include statements Curetis makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Curetis’ actual results may differ materially from those predicted by the forward-looking statements. Curetis undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

Contact details

Curetis
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com or ir@curetis.com
www.curetis.com - www.unyvero.com

International Media & Investor Inquiries

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68

U.S. Media & Investor Inquiries

The Ruth Group
Lee Roth
lroth@theruthgroup.com
Tel. +1 646 536 7012