



Curetis Announces Financial Results for the First Three Months of 2019

- Total year-on-year revenue growth of approximately 45%**
- Successful implementation of corporate re-organization and significant reduction of cost base**
- Exclusive pan-European distribution partnership with A. Menarini Diagnostics**

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, May 17, 2019, 07:00 am CET -- Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today reported its financial results for the first three months ended March 31, 2019, and provided a business update for 2019.

Key Operational and Business Updates

Commercial Development

- **Total global revenue was up by approximately 45%** compared to the first three months of 2018.
- **The total installed base of Unyvero Analyzers at the end of Q1-2019 has increased to 172 Analyzers** compared to 167 at year-end 2018, following a temporary decrease in global installed base in 2018 due to various factors, e.g. repurchased units due to the completion of a pharma project and efficiencies in working capital deployment.
- As of March 31, 2019, Curetis USA Inc. had an **installed base of 15 Unyvero Analyzers across the USA** in different types of hospitals and laboratories. Clinical and commercial evaluations are ongoing at multiple of these accounts.
- Following the re-organization of Curetis USA Inc. in January 2019, which has reduced the size of the team in the USA to currently 11 full-time staff primarily based in the field, Curetis USA Inc. is building on a **solid funnel of target accounts and opportunities** and expects to **increase the installed base of Unyvero Analyzers in the U.S. to about 30 to 40 by year-end 2019**, with a continuously growing proportion of installations at commercial accounts in the second half of 2019.
- On March 26, 2019, **Curetis and A. Menarini Diagnostics (Menarini) announced an exclusive strategic pan-European commercial distribution partnership**. Initially, this partnership covers 11 countries, including key markets such as Germany, France, UK, Italy, Spain, Portugal, Switzerland, Benelux and Sweden.
- Following the successful re-organization of Curetis GmbH initiated in December 2018 and largely completed at the end of Q1-2019, Curetis will maintain a **strong and highly**

experienced commercial partner support team and customer service. This team will support Menarini as well as all other international distribution partners in EMEA, Asia, and Latin America in broadly commercializing the Unyvero A50 product line.

Market Access Asia

- Beijing Clear Biotech (BCB), Curetis' distribution partner for the Unyvero A50 System and Application Cartridges in **Greater China**, in Q1-2019 **submitted an application for the Unyvero System and HPN Application Cartridge to the Chinese NMPA (formerly CFDA)**. The submission follows the successful completion of analytical testing in 2018 and the **expansion of the strategic collaboration between Curetis and BCB** in October 2018. In an initial response, the NMPA has proposed an expert panel discussion for the HPN pneumonia product to be convened in summer 2019. Assuming that any potential further data requirements by NMPA can be satisfied in 2019 and will allow for an NMPA approval in 2020, **Curetis anticipates initial revenues from commercial sales in China starting in 2020.**
- Curetis' partner for the **ASEAN region**, Acumen Research Laboratories, in Q1-2019 obtained **regulatory approvals** for the Unyvero System and HPN as well as BCU Application Cartridges in **Malaysia and Thailand.**

Business Development

- Following the strategy change announced in December 2018, business development in Q1-2019 focused on a **broad range of business discussions, technical feasibility demonstrations, licensing negotiations, and due diligence procedures around the Unyvero A30 RQ Platform.** These ongoing discussions with numerous interested parties span all key geographies in Europe, the USA and Asia and cover various clinical indication areas such as infectious diseases and oncology.
- **Menarini and Curetis are also foreseeing a further expansion of the existing collaboration** to potentially include additional EMEA markets that might become available for distribution in the future.

Product Development

- The **Unyvero A30 RQ Platform** is aimed at strategic partnering and licensing later in 2019 and has made **excellent R&D progress** in Q1-2019. First fully functional instrument system prototypes have been available since Q4-2018. Also, first multiplex real-time PCR assays have been successfully transferred onto the A30 RQ Cartridges and successfully benchmarked with regards to their performance against standard PCR instruments. The goal is to have the **A30 RQ Platform ready for partnering** as well as verification and validation testing with assays **by first licensing partners from H2-2019 onwards.**
- With the current Unyvero LRT Application Cartridge for lower respiratory tract (LRT) infections being cleared for the use with tracheal aspirates as a sample type, Curetis plans to file for the clearance of an **LRT Application Cartridge optimized for use with bronchoalveolar lavage (BAL) as additional sample type.** BAL is another common sample type for the diagnosis of lower respiratory tract infections. It is estimated that BAL samples account for half of the samples obtained for the diagnosis of lower respiratory tract infections and Curetis believes that a clearance of an Unyvero LRT Application Cartridge for this additional sample type would increase the total addressable market for Unyvero in the U.S. accordingly. In Q1-2019, Curetis **successfully completed the analytical testing and significantly progressed the clinical validation testing of the LRT BAL Application Cartridge.** Clinical data are

expected in Q2-2019 and the FDA submission for a 510(k) is anticipated in mid-2019.

- In addition, Curetis has continued the collection of retrospective samples for its U.S. trials for the **Unyvero IJI Invasive Joint Infection Cartridge** to augment the future prospective arm of the clinical trial. Moreover, a sample stability testing study has been initiated at multiple U.S. sites in Q1-2019. An initiation of the prospective arm of the trial, however, will depend on the closing of a **development and commercialization partnership** for this cartridge.
- At ECCMID 2019 in Amsterdam (April 13-16, 2019), a total of **nine clinical data sets and studies with Unyvero applications** across many different indication areas such as pneumonia, joint infections, blood stream infections, and intra-abdominal infections were presented.

Ares Genetics

- Ares Genetics signed an **exclusive global bioinformatics licensing and collaboration agreement with QIAGEN** in February 2019. This is the third strategic collaboration agreement following the deals with Sandoz and an undisclosed global IVD corporation in Q4-2018.
- Ares Genetics announced the **expected mid-2019 launch of its next-generation sequencing (NGS) lab service offering**. To that end, Ares has begun building its lab infrastructure and operations team in Vienna, Austria.
- In Q1-2019, Ares also **received co-funding by the Vienna Business Agency for a EUR 1.3 million project** to advance AI-powered NGS called “Triple-A” (Assay Development and Artificial Intelligence to Diagnose Antibiotic Resistant Infections).
- In collaboration with the Curetis team, Ares Genetics released a beta testing version of the **AMR Atlas**, a knowledge base of antimicrobial resistance markers specifically designed to support users of the Curetis Unyvero Platform. The initial focus of the Unyvero AMR Atlas is on antibiotic resistance markers detected by the Unyvero HPN Application Cartridge in pneumonia patients.

Financing

- Following the financing in November 2018, **Curetis continues to explore additional strategic and tactical financing options**. In Q1-2019, the Company primarily focused on finding an agreement with EIB for the next EUR 5.0 million debt financing tranche.
- In 2019 year-to-date, Yorkville has converted a total of EUR 1.5 million in notes into equity. A total of 1,290,726 new shares have been issued in 2019 so far and Curetis expects to also access a further EUR 1.5 million (gross) tranche of the Yorkville convertible notes facility in 2019.

First Three Months 2019 Key Financials

- **Revenues:** EUR 708 thousand (growing by approximately 45% compared to EUR 490 thousand in the three months ended March 31, 2018).
- **Expenses:** EUR 5,180 thousand total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 6,081 thousand in the first

three months of 2018). The decrease is mainly based on the successful implementation of the recent re-organization and reduction in organizational size, complexity and staffing levels as well as R&D pipeline and commercial channel partnering and revised commercial strategy.

- **Operating loss:** The operating loss in Q1-2019 has been reduced by approximately 19% to EUR -4,413 thousand (vs. EUR -5,412 thousand in the first three months of 2018).
- **Total comprehensive loss for the period:** EUR -4,746 thousand (vs. EUR -5,701 thousand in the first three months of 2018).
- **Cash and cash equivalents:** EUR 6,158 thousand as of March 31, 2019 (vs. EUR 10,279 thousand as of December 31, 2018). Net cash burn in the first three months ended March 31, 2019, was EUR -4,326 thousand.

Non-Audited Key Financials as of March 31, 2019

Curetis N.V.		
consolidated numbers in thousand Euros		
	For the three months ended March 31, 2019	For the three months ended March 31, 2018
Revenues	708	490
Operating loss	-4,413	-5,412
Total comprehensive loss	-4,746	-5,701
	March 31, 2019	December 31, 2018
Cash and cash equivalents	6,158	10,279

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About Curetis

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis' wholly owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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