



Curetis Announces Financial Results for the First Nine Months of 2018

- Total year-on-year revenue growth of 43% globally, 207% in EMEA direct selling markets**
- Initial traction in U.S. market after Unyvero launch**
- Strategic collaboration with BCB in Greater China expanded**
- Commercial reach expanded to Northern Africa, South America and Asia**

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, November 23, 2018, 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 nine months ended September 30, 2018, and provided a business update for the third quarter of 2018.

Operational and Business Highlights

U.S. Launch of Unyvero System and LRT Cartridge

- Curetis **launched the Unyvero System and the Unyvero LRT Application Cartridge** for lower respiratory tract infections in the U.S. in June 2018 after receiving U.S. FDA clearance in April 2018.
- To drive the commercial roll-out of the Unyvero System and the Unyvero LRT as a first application cartridge in the U.S., the Company in the first half of 2018 **completed the operational set-up of its subsidiary Curetis USA Inc.** in San Diego, CA, USA, and its field-based commercial team across the U.S. Since the launch, the U.S. commercial team has qualified about 140 accounts in the top 1,000 hospitals initially targeted with about 80 being deeply vetted. Several accounts have **entered into clinical and commercial evaluation agreements** and, with a dozen Unyvero Analyzers placed beyond FDA trial sites, have since then started the on-site evaluation of the Unyvero System and the LRT Application Cartridge. These and many further of the vetted accounts are expected to be converted to commercial accounts over the next several quarters, with about a dozen accounts constituting near-term opportunities currently at the contract negotiation stage. These initial accounts on average are expected to have **Unyvero LRT cartridge volumes of 700 to 800 annually** once they become commercial customers, with some accounts having significantly higher total potential annual testing volumes.

Commercial Development

- In all EMEA direct markets, combined **revenues from cartridges and instruments grew by more than 207%** year-on-year. **Total global revenue was up by 43%** compared to the first nine months of 2017.
- In August 2018, Curetis expanded its **geographic presence into the Northern African and Latin American markets** by signing exclusive distribution partnerships with Future Horizon Scientific for Egypt, with Quimica Valaner S.A. for Mexico and with Biko S.A. for Uruguay. Each of the three new distribution partners intends to commercialize all five Unyvero Application Cartridges (HPN, ITI, BCU, IAI and UTI) that are currently CE-IVD-marked. These partners in total have **committed to purchasing a minimum of 45 instrument systems** at Curetis' typical distributor transfer prices over the respective three-year contractual terms. In addition, they have committed to minimum purchases of **several thousand Unyvero application cartridges** over the terms of the agreements.
- Including these additional distribution partnerships, Curetis to date has **17 distribution partners covering 29 countries**. With a strong pipeline of further potential distribution partners covering additional markets, Curetis expects to sign further near-term distribution agreements.

Global Installed Base

- Upon completion of a pharmaceutical partner's phase III clinical trial, Curetis in Q1-2018 had exercised an option to buy back multiple Unyvero Systems deployed in this clinical trial and due to financing availability has concurrently taken a cautious working capital management approach with much stronger focus on higher priority accounts and conversion efficiency throughout Q3-2018, which has led to a re-deployment of Unyvero Analyzers resulting in a temporary decrease in the installed base of Unyvero Analyzers to **166 Analyzers as of the end of the first nine months 2018**, down by a net of 9 Analyzers compared to 175 Analyzers at year-end 2017. The Company expects to offset this decrease through additional future U.S. placements and by entering into additional distribution partnerships and has also identified a significant number of EMEA direct market opportunities for new Unyvero placements.

China Market Access

- In October, **Curetis and BCB expanded their strategic collaboration for the Unyvero A50 System and Application Cartridges in Greater China**, including an extension of their exclusive Unyvero A50 distribution agreement to eight years. This minimum commitment would indicate potential revenues to Curetis of over EUR 30 million annually in years six through eight of commercialization in China, in addition to potential cumulative revenues of more than EUR 60 million for years one through five of commercialization in China as agreed upon previously. Assuming a final submission in 2019 and a CFDA approval in late 2019 or early 2020, **Curetis anticipates initial revenues from commercial sales in China starting in 2020**.

Business Development

- In January 2018, **Curetis and MGI** (a BGI Group Company, Shenzhen, China) **signed R&D collaboration and supply agreements focused on the Unyvero Lysator technology and instruments**. Under the agreement, MGI can utilize Curetis' Lysator technology to develop and commercialize a universal automated solution for next generation sequencing (NGS)-based microbiology that can process any sample type routinely obtained from patients for microbiological analysis. With the feasibility phase recently completed and all pre-defined performance criteria met, the collaboration has

now entered into the development phase for a first integrated product. Study data resulting from the collaboration were presented at the ICG-13 Conference in Shenzhen, China, on October 24-28, 2018. Further potential collaboration areas, including the development and near-term commercialization of an NGS-based microbiology application, are currently being discussed.

- Going forward, Curetis aims to enter into further value-adding R&D and commercial partnerships with well-known industry players around the Unyvero Platform and the ARES Technology Platform.

Product Development

- To expand the label claim of its recently U.S. FDA cleared Unyvero LRT Application Cartridge for lower respiratory tract infections, Curetis plans to **file for the clearance of bronchoalveolar lavage (BAL) as a second sample type**. In a **pre-submission meeting with the U.S. FDA** at the end of September 2018, the Agency has confirmed the suitability of the 510(k) clearance pathway for Curetis' Unyvero LRT Application Cartridge specifically optimized for the detection of microbial pathogens in bronchoalveolar lavage ("BAL") samples. The U.S. FDA further confirmed that data required for the submission could be largely based on clinical samples previously collected during the original Curetis U.S. FDA trial for the Unyvero LRT Application Cartridge. Overall, the Company **believes that U.S. FDA feedback has substantially de-risked the planned submission of the Unyvero LRT Application Cartridge for BAL** and that the requirements agreed upon with the U.S. FDA should allow Curetis to accelerate generating the required data for an early submission, with an expected clearance decision in 2019.
- BAL is another common sample type for the diagnosis of lower respiratory tract infections. It is estimated that half of the samples obtained for the diagnosis of lower respiratory tract infections are BALs and Curetis believes that a clearance for this additional sample type would **increase the total addressable market for the Unyvero LRT Application Cartridge in the U.S.** accordingly.
- Curetis also expects to include data on an **assay for one additional pathogen, *Pneumocystis jirovecii***, as part of the 510(k) submission. This fungus is particularly prevalent in lower respiratory tract infections in patients with compromised immune status, such as transplant recipients or AIDS patients.
- In addition, Curetis has continued the collection of retrospective samples for its U.S. trials for the **Unyvero IJI Invasive Joint Infection product** to augment the future prospective arm of the clinical trial.
- Curetis expects to provide a more detailed update on its R&D pipeline and priorities following the most recent financing around the J.P. Morgan Healthcare Conference in early 2019.

Ares Genetics

- In July 2018, Ares Genetics launched the **ARES & CO (Antibiotic REsistance Solutions by COoperative R&D) pharma partnering program**, a program supported and largely funded by the Vienna Business Agency. It aims to establish an alliance for antibiotic stewardship with pharmaceutical companies and contract research organizations by offering advanced data-driven solutions to antimicrobial drug development and life cycle management of existing antimicrobial drugs.
- Ares Genetics also initiated the development of its **ARESupa Universal Pathogenome Assay**. The assay for the diagnosis of microbial infections and

antimicrobial drug response is based on the Company's proprietary ARES Technology Platform and genetic antimicrobial resistance database ARESdb. While planning to launch the test as a laboratory-developed test first, Ares Genetics ultimately aims to seek regulatory approval as an in vitro diagnostic test for broad and scalable commercialization. Ares Genetics is further exploring fast-track options to launch ARESupa as a laboratory-developed test in the U.S., once development of a first-generation ARESupa has been completed.

- With initial seed funding of Ares Genetics provided by Curetis and non-dilutive funding through grants, **Ares Genetics is currently identifying U.S. strategic partners and exploring options for accessing U.S. venture capital funding** to accelerate the further development, particularly for the ARESupa Universal Pathogenome Assay and its commercial deployment.

Financing

- In October 2018, **Curetis secured up to EUR 20 million in growth capital** through the issuance of convertible notes with share subscription warrants to YA II PN, LTD., an investment fund managed by Yorkville Advisors Global LP, a U.S. based management firm. To date, Curetis has drawn down EUR 3.5 million of the first tranche.
- In November, **Curetis raised EUR 8.9 million through private placements to institutional investors in Europe and the U.S.** In this transaction, 4,450,000 out of 7,085,546 offered new ordinary shares were placed at an offer price of EUR 2.00 per share, resulting in additional available funds of EUR 7.3 million. The Company intends to use the proceeds from the sale of the Offer Shares for (i) funding the commercialization of its Unyvero Platform and LRT Application Cartridge in the U.S., (ii) its European commercialization activities, (iii) working capital requirements, (iv) research and development programs and (v) for general corporate purposes. Curetis will re-assess the priorities and allocation of proceeds to fund these activities in the light of the lower than expected proceeds from this offering and will inform its shareholders on such priorities as well as any potentially required changes to its guidance once this assessment has been completed.
- Curetis will continue to **assess all tactical and strategic options and operational requirements** to secure appropriate funding and cash for its continued operations for at least the next 12 months and to ensure it has the financial resources to continue as a going concern.

First Nine Months 2018 Financial Highlights

- **Revenues:** EUR 1,191k (growing by about 43 % compared to EUR 831k in the nine months ended September 30, 2017). EMEA direct sales have grown by 207 % year-on-year.
- **Expenses:** EUR 18,774k total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 14,771k in the first nine months of 2017). The increase is in line with the operational and organizational growth, and driven by higher distribution costs, higher research & development expenses as well as G&A costs.
- **Operating loss:** EUR -17,237k (vs. EUR -13,865k in the first nine months of 2017).
- **Net loss for the period:** EUR -17,719k (vs. EUR -14,574k in the first nine months of 2017).

- **Cash and cash equivalents:** EUR 5,541k as of September 30, 2018 (vs. EUR 16,311k as of December 31, 2017).
- **Cash Burn and Financing:** Net cash burn in the first nine months ended September 30, 2018, was EUR -11,066k. In April 2018, Curetis had raised EUR 4.1 million in a private equity placement and issued 854,166 new shares and signed an additional USD 10 million equity facility offered by Global Corporate Finance (GCF) New York, NY, USA. In October, Curetis secured up to EUR 20 million in growth capital through the issuance of convertible notes with share subscription warrants to YA II PN, LTD., an investment fund managed by Yorkville Advisors Global LP, a U.S. based management firm. To date, Curetis has drawn down EUR 3.5 million of the first tranche. In November 2018, Curetis raised EUR 8.9 million through private placements of 4,450,000 new ordinary shares to institutional investors in Europe and the U.S. resulting in additional available funds of EUR 7.3 million. Cash outflow from operations and investments totaled EUR 17,846k in the first nine months 2018.

Key non-audited financials as of September 30, 2018

Curetis N.V.		
consolidated numbers in '000 Euros		
	For the nine months ended September 30, 2018	For the nine months ended September 30, 2017
Revenues	1,191	831
Operating loss	-17,237	-13,865
Total comprehensive loss	-17,854	-14,451
	September 30, 2018	December 31, 2017
Cash and cash equivalents	5,541	16,311

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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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