Curetis Publishes Business and Financial Update for the First Quarter 2018

- Received U.S. FDA clearance for Unyvero System and LRT Cartridge

- Grew revenues in EMEA direct selling markets by 518% vs Q1 2017

- Closed EUR 4.1 million equity offering and gained access to additional USD 10 million equity facility

Amsterdam, the Netherlands, Holzgerlingen, Germany and San Diego, CA, USA, May 18, 2018; published at 01:00 a.m. EDT - Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today published a business and financial update for the three months ended March 31, 2018.

Operational and Business Highlights 2018 YTD

Unyvero System and Unyvero LRT Cartridge cleared by U.S. FDA

- On April 3, 2018, the Unyvero System and the Unyvero Lower Respiratory Tract Infection (LRT) Cartridge received ***De Novo*** **clearance from the U.S. FDA** with 29 assays cleared, including 19 of 20 pathogen assays originally submitted plus 10 antibiotic resistance marker assays. Commercial launch in the U.S. has been initiated in Q2 2018.

Commercial Development

- In EMEA direct selling markets under the new leadership of Director of Commercial Operations EMEA, Riwat Lim, the focus on the commercial conversions of high priority accounts has resulted in **revenues from cartridges and instruments growing by 518%** compared to Q1 2017. Revenue growth from cartridges was 79% year-on-year in EMEA direct selling markets.
- To expand its commercial reach, Curetis is further evaluating multiple **distribution partnering** opportunities, which would allow it to enter into new geographies and could also potentially contribute positively to system and cartridge sales over time.

Business Development and Market Expansion

- In January 2018, Curetis and **MGI** (a BGI Group Company, Shenzhen, China) **signed an R&D collaboration** and supply agreement focused on the **Unyvero Lysator technology** and instruments. Going forward, Curetis is focused on entering into further value-generating R&D and commercial partnerships with well-known industry players around ARES*db* and the ARES Technology Platform, as well as the Unyvero Platform.
- The **Unyvero Hospitalized Pneumonia (HPN) and Blood Culture (BCU) Applications** were **approved by the Singapore Health Sciences Authority (HSA)** and fully registered as a Class C IVD medical device with the Singapore Medical Device Register. The

approval allows for a more comprehensive roll-out in Singapore as a bridgehead to additional markets in the ASEAN region.

- Working towards **Chinese market clearance** by the Chinese Food and Drug Administration (CFDA), analytical testing of the Unyvero HPN Cartridge by Curetis' partner Beijing Clear Biotech (BCB) in China was initiated in Q4 2017 and was nearing completion in Q1 2018 under the auspices of the Beijing Institute of Medical Device Testing. Regulatory submission of CFDA clinical trial data is expected in 2019.

Global Installed Base

- Following the completion of a pharmaceutical partner's phase III clinical trial, Curetis exercised a very attractive option to buy back multiple Unyvero Systems deployed in this clinical trial at a discounted price in Q1 2018. Additionally, Curetis has increased its focus on higher priority accounts and conversion efficiency, which has led to a re-deployment of Unyvero Systems resulting in a short-term decrease of the global installed base from 175 Analyzers by year-end to **167 Analyzers** at the end of the first quarter 2018.
- With the launch of Unyvero in the U.S. and the ongoing and anticipated commercial uptake in non-U.S. territories, the Company reiterates its target of an **expected global installed base of 250 to 300 Unyvero Analyzers by year-end 2018**. Of these, Curetis aims at placing 40 to 50 Analyzers in the U.S. by year-end and 60 to 80 Analyzers within the first twelve months of full commercial launch in the U.S.

Product Development

- In April 2018, Curetis **launched** the **CE-IVD marked Unyvero Urinary Tract Infection (UTI) Cartridge** at ECCMID 2018. The UTI panel covers 103 diagnostic targets, including 88 pathogens and 15 resistance markers.
- With regard to **Unyvero LRT,** Curetis plans to file for the additional clearance of **bronchoalveolar lavage (BAL**) as a second sample type at a later stage.
- In addition, Curetis has started its **second FDA trial** for its next U.S. product, the **Unyvero Invasive Joint Infection (IJI) Cartridge** for severe invasive joint infections, a variant of its Unyvero Implant and Tissue Infections (ITI) Cartridge specifically designed and developed for the U.S. market. Curetis has submitted a presubmission package to the FDA, and aims to finalize the U.S. clinical trial for Unyvero IJI in 2019.
- **All other R&D programs** and product development projects remain **on track** and in line with guidance. In particular, Curetis has advanced the development of its new analyzer module, Unyvero A30 *RQ,* and expects CE-IVD marking in 2019.

U.S. Scientific Advisory Board

- In April 2018, Curetis established a dedicated U.S. Scientific Advisory Board (SAB) with five renowned U.S. infectious disease experts. With the formation of this SAB, Curetis' scientific network and clinical expertise will support U.S. adoption of the recently cleared Unyvero System and LRT Cartridge.

Financing

- In April 2018, Curetis raised **EUR 4.1 million in an equity offering of** 854,166 newly-issued shares. In addition, Curetis secured **access to an additional USD 10 million** equity facility offered by Global Corporate Finance (New York City, NY, USA), allowing the Company solely at its request to raise additional equity over a period of up to 36 months, subject to certain pre-determined floor pricing.
- Curetis' subsidiary Ares Genetics received a **funding commitment** for its project "Digital Microbe" with a total project volume of **EUR 1.6 million** by the Austrian Research

Promotion Agency (FFG).

Supervisory Board

- Dr. Holger Reithinger, General Partner at Forbion Capital Partners, has resigned from Curetis' Supervisory Board effective April 30, 2018. The Supervisory Board now consists of six members.
- Dr. Werner Schaefer and Dr. Rudy Dekeyser will run for re-election for another two-year and one-year term, respectively, at the Annual General Meeting 2018 in Amsterdam on June 21, 2018.

Financial Highlights for the First Three Months 2018

- **Revenues:** Total revenues for Q1 2018 were EUR 490 thousand and grew by 41% (vs. EUR 347 thousand in the three months ended March 31, 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 6,081 thousand (vs. EUR 4,675 thousand in the three months ended March 31, 2017). The increase is in line with the operational and organizational growth strategy and driven by higher R&D expenses, distribution costs as well as general and administrative expenses.
- **Gross loss:** EUR -331 thousand (vs. a gross loss of EUR -176 thousand in the three months ended March 31, 2017).
- **Net loss**: EUR -5,786 thousand (vs. EUR -4,351 thousand in the three months ended March 31, 2017).
- **Cash and cash equivalents**: EUR 11,367 thousand as of March 31, 2018 (vs. EUR 16,311 thousand as of December 31, 2017) and a net cash decrease of EUR -4,825 thousand during the first quarter 2018. The net cash outflow from operating and investing activities was EUR -4,685 thousand (vs. EUR -3,371 thousand in the first three months of 2017).

Key Non-Audited Financials as of March 31, 2018

Curetis N.V.		
Consolidated numbers in ´000 Euros		
	For the three months ended March 31, 2018	**For the three months ended March 31, 2017**
Revenues	490	347
Operating loss	-5,412	-4,302
Total comprehensive loss	-5,701	-4,338
	March 31, 2018	**December 31, 2017**
Cash and cash equivalents	11,367	16,311

„In April, we reached a key corporate milestone with the U.S. FDA clearance for our Unyvero System and the LRT Cartridge. It is exciting to enter the U.S. market with a first-in-class-product with no direct competition in the U.S.," said Dr. Oliver Schacht, CEO of Curetis. "In our EMEA direct selling markets, we have increased systems and cartridge revenues by more than 500%. We expect to continue executing on our commercial conversion campaign, expand our commercial distribution partner network and launch new and updated Unyvero applications. Looking ahead, we believe that continued commercial expansion, new cartridge launches, platform expansion and value-creating partnerships will provide long-term growth prospects."

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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 diagnosing 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, and thereby facilitates 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 Curetis believes to be the world's most comprehensive database on the genetics of antimicrobial resistances, ARES*db*, with advanced bioinformatics and artificial intelligence.

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

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