Curetis Provides Business Update for the First Nine Months of 2019

- Signed IVD partnership for Ares Genetics

- Progressed implementation of the Curetis - OpGen business combination with S4 filing

- More than tripled total contract order volume received year-over-year to EUR 3.4 million in 9M-2019

- Revenue growth of approximately 16%

- ***Near-term FDA decision on clearance of Unyvero LRT for BAL specimen expected***

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, November 14, 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 provided a business update for the first nine months ended September 30, 2019, including key financial results. Due to the ongoing implementation of the business combination with OpGen, Curetis expects to issue the voluntary full 2019 third quarter and nine months business and financial report at a later point in time.

Key Operational and Business Updates

Combination of Businesses with OpGen Inc.

- On September 4, 2019, Curetis and OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, announced the entry into a **definitive agreement to combine the two companies' businesses**, subject to approval by both companies' respective shareholders, regulators and Curetis' debt financing providers as well as additional equity financing being raised by OpGen. The transaction is structured as an acquisition by OpGen of Curetis GmbH, a wholly-owned subsidiary of Curetis which owns all of the Curetis Group businesses. The combination will create a transatlantic, U.S.-headquartered and Nasdaq-listed company with an innovative commercial-stage molecular diagnostics and bioinformatics franchise and a strong pipeline focusing on infectious diseases and antimicrobial resistance (AMR).
- Prior to the announcement, the **implementation agreement had been approved by both companies' Boards of Directors**. Further, Curetis' largest debt holder, the European Investment Bank (EIB), **formally approved the transaction** subject to customary closing conditions on October 15, 2019.
- Another **major milestone and prerequisite for closing the transaction** was met on October 28, 2019, when OpGen announced the **successful closing of a $9.4 million**

underwritten public offering. As per the implementation agreement between Curetis and OpGen, part of the proceeds from this transaction will be used to (1) complete the business combination with Curetis GmbH; (2) provide short-term funding to Curetis GmbH under an interim facility to fund current operations of Curetis' business. That interim financing facility agreement was signed on November 12, 2019.

- Also on November 12, 2019, another key step has been taken towards completing the transaction with OpGen filing an S4 with the SEC. Review and approval of the S4 filing are expected in the coming weeks and will be one of the last critical steps before inviting for the shareholder meetings and seeking their approval for the transaction.
- In the further process, Curetis will seek approval from its remaining debt holder and from its shareholders at an extraordinary general meeting and OpGen will seek approval from its stockholders at a special meeting. It is expected that both meetings will be scheduled for the early first quarter of 2020. Subject to receipt of shareholder and all debt holder approvals and satisfaction of other closing conditions, the transaction is expected to close in Q1-2020.
- For more information on the transaction, please visit: https://curetis.com/investors/

Commercial Development

- **The total installed base of Unyvero Analyzers at the end of Q3-2019 was 165 Analyzers** compared to 166 at the end of Q3-2018. This figure includes a significantly sized pool of Analyzers now managed by Menarini Diagnostics in EMEA as well as 35 Analyzers installed in the USA (including 20 for current and future clinical trials). Furthermore, as part of a campaign performed towards the end of Q2-2019, a total of 4 refurbished Unyvero Systems were sold and another 6 systems ordered for expected shipping in Q4-2019 by various international distribution partners in H2-2019 to date.
- As of September 30, 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 or have been successfully completed at multiple of these accounts. The expectation for 2019 is to increase the installed base of Unyvero Analyzers further by year-end 2019 with a continuously growing proportion of installations at commercial accounts towards the end of 2019 and into 2020.
- On March 26, 2019, **Curetis and A. Menarini Diagnostics (Menarini) announced an exclusive strategic pan-European commercial distribution partnership**. As of September 30, 2019, this partnership covers 11 countries, including key markets such as Germany, France, UK, Italy, Spain, Portugal, Switzerland, Benelux and Sweden. Menarini and Curetis in the initial agreement are also **foreseeing a further expansion of the collaboration** to potentially include additional EMEA or other global markets that might become available for distribution from time to time.
- In July 2019, the Company announced that it had entered into **two distribution agreements with the Bosnian and Serbian branches of AKO MED**, a manufacturer and distributor of medical products, AKO MED d.o.o., Banja Luka, Bosnia Hercegovina, and AKO MED d.o.o., Beograd, Serbia, respectively. Under the terms of the agreements, AKO MED has the exclusive right to commercialize Curetis' Unyvero A50 instrument system and application cartridges for the diagnosis of severe infections in hospitalized patients in Serbia, North Macedonia, Bosnia Hercegovina and Montenegro. With the regulatory filing process under way in all of these markets, the first Unyvero System orders are expected in the coming months.

Market Access Asia

- Following the successful completion of analytical testing in 2018 and expanded strategic collaboration between Curetis and BCB for the Unyvero A50 System and Application Cartridges in Greater China, BCB has **submitted the Unyvero System and HPN Application Cartridge to the Chinese NMPA (formerly CFDA) in Q1-2019**.
- On July 26, 2019, the **NMPA held a panel hearing** to discuss the application with local clinical experts and gave Curetis an opportunity to comment on various aspects of the application. As a result, Curetis expects a clarification on potential further requests for ancillary data and any required edits to the original application and potentially some limited set of additional clinical data to be generated in China in the near term.
- Curetis and its partner BCB expect an NMPA approval in 2020, Curetis also **anticipates initial revenues from commercial sales in China starting in 2020.**
- Curetis' partner **Acumen Research Laboratories obtained regulatory approvals for the Unyvero System and HPN as well as BCU Cartridges in Malaysia and Thailand** in Q1-2019. Order volumes and commercial use of Unyvero Systems in Singapore continue to grow significantly.

Business Development

- Following the strategy change announced in December 2018, the Company in 2019 has seen a **broad range of business development discussions, technical feasibility work, negotiations, and due diligence** around the Unyvero A30 *RQ* Platform. These discussions spanned all key geographies in Europe, the USA and Asia as well as various clinical indication areas such as infectious diseases and oncology. However, to best leverage the value of this state-of-the-art multiplex PCR platform and in the context of the business combination with OpGen**, Curetis will advance the development of Unyvero A30 *RQ* in the remainder of 2019 and in 2020** before entering into initial partnering deals for this asset anticipated later in 2020.

Product Development

- The development of the **Unyvero A30 *RQ* Platform** has made **excellent progress** in 2019. First fully functional instrument system prototypes have been available since Q4-2018, and by October 2019 first fully integrated sample-to-answer assays have been transferred onto the A30 *RQ* Cartridges and successfully benchmarked with regards to their performance against standard laboratory methods. 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 in the course of 2020.**
- With the current Unyvero LRT Application Cartridge for lower respiratory tract (LRT) infections being cleared by the U.S. FDA for the use with tracheal aspirates as a sample type, Curetis in July 2019 has filed for the 510(k) clearance of an **LRT Application Cartridge optimized for use with bronchoalveolar lavage (BAL) as additional sample type**. In Q3-2019, Curetis received an additional information request letter by the FDA and has provided answers to all of the agency's questions to date. A near-term FDA decision on the clearance of Unyvero LRT (BAL) is expected in the coming weeks. The submission builds on analytical and clinical performance data obtained with more than 5,500 BAL Cartridges. 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 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. A multi-center study on the stability of synovial fluid samples has been successfully completed in the first nine months of 2019. However, the potential future initiation of the prospective arm of the trial will depend on Curetis partnering for the further development as well as the commercialization or otherwise raising the capital needed to fund such a trial of this unique application cartridge.

Ares Genetics

- On September 16, 2019, Ares Genetics has entered into a **multi-phase collaboration with an undisclosed leading global in-vitro diagnostics corporation** (the "Partner") to jointly develop diagnostic solutions for infectious disease testing based on next-generation sequencing ("NGS") technology. Following the agreement with QIAGEN in February 2019 and the deals with Sandoz and an undisclosed global IVD corporation in Q4-2018, this is the fourth major strategic collaboration agreement Ares signed since 2018.
- The Companies signed an R&D and option agreement for the first phase of the collaboration. The collaboration follows the successful completion of a feasibility study in which Ares Genetics correctly identified 100% of the pathogen species and successfully predicted antibiotic resistance for over 50 drug/pathogen combinations in line with FDA requirements (<1.5% very major error, i.e. misclassification of resistant isolates as susceptible and <3% major error, i.e. misclassification of susceptible isolates as resistant). Under the initial agreement, the Partner will fully fund Ares Genetics' research and development activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predictive antibiotic resistance testing. Furthermore, in return for an undisclosed **up-front option fee**, the Partner obtains a 3-months right of first negotiation for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform for the term of the agreement plus three months.
- In August 2019, Ares Genetics has **opened a specialized service laboratory offering next-generation molecular antimicrobial resistance (AMR) testing services** with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D. The services are largely based on next-generation sequencing (NGS) with Ares Genetics' first generation ARESupa Universal Pathogenome Assay and the Company's proprietary, AI-powered antimicrobial resistance database ARESdb. The newly opened laboratory is located at the Vienna Biocenter Campus in Vienna, Austria, and will serve researchers, hospitals, public health institutions, and pharmaceutical companies world-wide. First commercial orders have been successfully processed and data delivered to customers.
- In October 2019, Ares **Genetics launched an early access program for an advanced version of ARESupa**, an artificial intelligence (AI) powered, next-generation sequencing (NGS) based molecular antibiotic susceptibility test (AST). Compared to the first generation, this second generation of ARESupa is capable of also **accurately predicting antibiotic susceptibility** via AI- powered interpretation of high-throughput DNA sequencing data. ARESupa is initially offered to AMR researchers, hospitals, public health institutions, and pharmaceutical companies for non-human diagnostic use. With ARESupa, Ares Genetics aims at supporting the cost-effective analysis and management of outbreaks of multidrug-resistant bacterial pathogens in hospitals and care facilities as well as facilitating molecular epidemiology by public health institutions and hospitals and antimicrobial drug development and AMR research. Ares Genetics' R&D programs for the development of ARESupa are

co-funded by non-dilutive public grants provided by the Vienna Business Agency, the Austrian Research Promotion Agency (FFG), and other institutions with a total co-funded volume of up to more than EUR 3 million from 2017-2021.

Financing

- In June 2019, **Curetis received another EUR 5.0 million tranche of non-dilutive debt financing from the European Investment Bank (EIB)**. This tranche will also have a five-year term to maturity and will require interest-only payments during that five-year term. In line with all prior tranches, the majority of interest is also deferred into the bullet repayment structure upon maturity. In return for the EIB waiving certain conditions precedent to disbursing this EUR 5 million tranche, the parties have agreed on a 2.1% participation percentage interest (PPI). Upon maturity of the tranche, i.e. not before around mid-2024 (and no later than mid-2025), the EIB will be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis. All other terms and conditions of the EIB financing contract with Curetis remain unchanged.
- Under the up to EUR 20 million Yorkville convertible notes financing facility that was originally implemented in October 2018, **Curetis in Q2-2019 received another EUR 1.5 million gross in funding**. Net proceeds from this tranche were EUR 1.36 million. As with the prior tranche, Yorkville is expected from time to time to convert such notes into equity and Curetis will then issue new shares. However, given the fact that Curetis N.V. does not have any available shares anymore under any of the current authorizations for issuing additional shares, there will not be any option for Yorkville to convert any of the remaining EUR 1.3 million in unconverted notes. As part of the business combination with OpGen, it has been agreed that OpGen will assume the liability and future conversions will be into new OpGen shares.
- In 2019 year-to-date, Yorkville has **converted a total of EUR 3.7 million notes into equity. A total of 4,780,552 new shares have been issued in 2019 year-to-date**. Under the terms of the agreement with Yorkville, the number of shares to be issued upon conversion of all convertible notes of the first tranche should initially not exceed 2.75 million shares. Any excess entitlement on the basis of the conversion ratio will be settled in cash unless the Company elects to settle such excess in shares. On July 31, 2019, the limit of 2.75 million shares was exceeded by a further conversion note by Yorkville. On August 1, 2019, the Company opted to settle its obligations resulting from this conversion notices fully in shares, thereby exercising its right under the agreement with Yorkville to settle the excess beyond the First Tranche Share Issue Cap in shares. The Company also intends to elect settlement fully in shares with respect to any further conversion of the remaining notes held by Yorkville. For further details on the Yorkville convertible notes facility, please also see the “Convertibles” section under: https://curetis.com/investors/#corporate-governance

Preliminary First Nine Months 2019 Key Financials

- **Revenues:** EUR 1.38 million (growing by approximately 16% compared to EUR 1.19 million in the nine months ended September 30, 2018).
- **Order Volume: Almost EUR 3.4 million in commercial order volume committed and received by Curetis and Ares Genetics** in 2019 year-to-date, including orders for Unyvero instruments and cartridges, Ares Genetics’ laboratory and advanced bioinformatics services, as well as compensations for access to certain rights. Therefore, order volumes have **more than tripled** compared to EUR 1.1 million in the

same period of 2018.

- **Cash and cash equivalents:** EUR 3.05 million as of September 30, 2019 (vs. EUR 10.28 million as of December 31, 2018). Net cash burn in the first nine months ended September 30, 2019, was EUR -7.23 million, i.e. a reduction by about 34.7% compared to a cash burn of EUR 11.07 million in the first nine months 2018. This was mainly the result of the successful implementation of the restructuring measures as well as financing cash inflows from EIB and Yorkville. Curetis will now have access to at least US$ 4 million under the interim financing facility in the coming months towards the closing of the business combination.

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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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