

# Curetis Announces Preliminary, Unaudited 2019 Condensed Combined Key Financials and Provides Business Update

- Revenue increases by 64% to EUR 2.3 million, up from 1.4 million in 2018
- More than tripled total contract order volume received yearover-year to about EUR 3.4 million 2019
  - Curetis N.V. shareholders to vote on March 10, 2020 on planned business combination with OpGen, Inc.

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, February 20, 2020, 08:00 am CET -- Curetis N.V. (the "Company" and, together with its subsidiaries, "Curetis"), a developer of next-level molecular diagnostic solutions, today announced preliminary. unaudited condensed combined key financials for the fiscal year 2019 and provided a business update for 2020 year-to-date.

Revenue of the Curetis business in 2019 amounted to EUR 2.3 million, up by 64% compared to EUR 1.4 million in 2018. This revenue was realized from a total contract order volume of about EUR 3.4 million received in 2019, up by a factor of more than three comparted to contract order volume in 2018 (EUR 1.1 million). Revenue growth in 2019 was primarily driven by partnering projects of Curetis Group Company Ares Genetics as well as increasing uptake of Curetis' Unyvero product line. Preliminary, unaudited operating loss of the condensed combined business for fiscal year 2019 was approximately EUR 17.2 million compared to EUR 21.6 million in 2018, an improvement of about 21%. This improvement is mainly driven by significant reductions in operating costs for R&D as well as distribution (marketing and sales) and comes despite significantly increased G&A costs that were driven by one-off transaction-related expenses for the preparation and implementation of the proposed business combination.

Key accomplishments of the Curetis business in 2020 year-to-date include:

- Curetis' launch of the Unyvero LRT Panel for BAL specimens in the U.S. following receipt of 510(k) clearance by the U.S. FDA in December 2019. The panel includes atypical pathogens such as *Pneumocystis jirovecii* important for immunocompromised patients and is commercially available to Curetis' U.S. customers since end of January 2020. The LRT BAL panel is expected to substantially increase the total addressable market for the Unyvero System in the U.S.
- Curetis GmbH's subsidiary Ares Genetics' collaboration with BGI Group to offer Next-Generation Sequencing (NGS) and PCR-based Coronavirus (2019-nCoV) testing in Europe.
- Curetis GmbH and Quaphaco entered into an exclusive distribution partnership for Vietnam for an initial term of three years with Quaphaco committing to a minimum purchase totaling approximately EUR 1.9 million during such initial term.

## **Business combination with OpGen Inc.**

The Company also announced the following updates relating to the planned business combination with OpGen, Inc., Gaithersburg, MD, USA (OpGen):

- OpGen's preliminary unaudited total revenue for 2019 increased by 18.7% to US\$3.5 million, up from US\$3.0 million in 2018. Such revenue growth was driven by Acuitas AMR Gene Panel and Acuitas® Lighthouse revenue, which increased 147% to approximately \$1.4 million while revenues from OpGen's rapid FISH products decreased approximately 12% to \$2.1 million.
- OpGen's preliminary, unaudited operating loss for fiscal year 2019 was approximately \$12.4 million compared with \$13.4 million in 2018.
- Patient accrual is underway since December to support FDA submission for the OpGen's lead rapid molecular diagnostic test, the Acuitas® AMR Gene Panel Urine for the Acuitas AMR Gene Panel (Urine) FDA De Novo clearance clinical trial;
- OpGen is working interactively with the FDA to provide final responses to Additional Information Request Letters for the Acuitas AMR Gene Panel (Isolates) pending FDA 510(K) submission. The response process to the FDA is anticipated to be completed in February to be followed by formal response filings; and
- OpGen achieved the planned program milestone under the New York State Infectious Disease Digital Health Initiative demonstration project.

Evan Jones, Chairman & CEO of OpGen, commented, "We were pleased with the initial results from fiscal year 2019 and we look forward to further progress following the expected first FDA clearance of our AMR Gene Panel products. Our teams have been working closely with Curetis to complete the planned business combination of our two companies. Together we have exciting prospects for growth from our combined product portfolios."

Oliver Schacht, CEO of Curetis, commented, "We are encouraged by the significant progress of our business in 2019 and of our planned business combination with OpGen. The initial launch of the new Unyvero LRT BAL panel opens a significant additional opportunity in the U.S. market. Several prestigious medical centers, including a major cancer center and a large academic institution, have already committed to evaluate the Unyvero LRT BAL panel for routine use in patients hospitalized for suspected pneumonia. The Unyvero LRT BAL application is the first and only FDA-cleared molecular diagnostic pneumonia panel that includes *Pneumocystis jirovecii*. This difficult to diagnose pathogen is a leading cause of pneumonia in immunocompromised individuals."

The preliminary financial results of Curetis and OpGen are estimates prior to the completion of the companies' financial closing procedures and audit procedures by its external auditors and therefore may be subject to adjustment when the actual results are available.

OpGen and Curetis entered into a definitive agreement to combine businesses on September 4, 2019. The closing of the transaction under such definitive agreement has not yet occurred and is subject to a number of significant closing conditions, including receipt of approval from the stockholders of OpGen, Inc. and the shareholders of Curetis, N.V. To this end, OpGen filed and furnished to its stockholders a proxy statement/prospectus and a notice of special meeting of OpGen stockholders to be held on March 10, 2020 to approve the business combination with Curetis. On the same day at 1:00pm CET, Curetis will host its extraordinary shareholder meeting with the objective of seeking approval from its shareholders for the planned business combination with OpGen.

Until the closing occurs, each of OpGen and Curetis are operating as stand-alone businesses.

#### **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 <u>www.curetis.com</u> and <u>www.ares-genetics.com</u>.

# **About OpGen**

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures. For more information, please visit <a href="https://www.opgen.com">www.opgen.com</a>.

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc.

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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," "targets," "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.

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