Curetis Reports Financial Results for the First Six Months of 2019

- Strategic transaction to combine businesses with OpGen Inc.

- Revenues increased by approximately 35% year-on-year

- Progressing regulatory product approvals in the U.S. and China

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, September 18, 2019, 08:00 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 six months ended June 30, 2019, and provided a business update for 2019 year-to-date and its outlook for the future.

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 company's 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 business. 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).

- Following the closing, the combined company´s U.S. headquarters will be in Gaithersburg, MD, while the company's European operations will be run from Holzgerlingen, Germany. Ares Genetics GmbH ("Ares Genetics"), a subsidiary of Curetis GmbH, will continue its bioinformatics and NGS service laboratory operations in Vienna, Austria.

- The combined companies will have a broad commercial-stage diagnostics portfolio of CE-IVD-marked and U.S.-FDA cleared products and platforms, as well as a proprietary NGS-based and AI-powered technology and knowledgebase for the rapid molecular prediction of AMR. The initial two main focuses for the company will be (a) rapid diagnostics for lower respiratory infection and urinary tract infection and (b) bioinformatics and NGS services for AMR prediction by Ares Genetics as well as bioinformatics services based on the Acuitas Lighthouse® AMR kowledgebase by OpGen.

- Key elements of the combined company's strategy include: continuing to gain regulatory clearances and approvals, establishing a stronger market position for proprietary molecular diagnostic tests and platforms, capitalizing on unique technology

platforms, leveraging global commercial capabilities and partnerings, pursuing development collaborations, and capitalizing on the financial leverage and operational and research synergies to improve return on capital and achieve future profitability.

- The implementation agreement has been approved by both companies' Boards of Directors. Curetis will seek approval 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 end of the fourth quarter 2019. Subject to receipt of shareholder approvals and satisfaction of other closing conditions, as detailed below, the transaction is expected to close by early 2020. For more information on the transaction, please visit: https://curetis.com/investors/

Key Operational and Business Updates 2019 Year-to-Date

U.S. Commercialization of Unyvero System and LRT Cartridge

- Following the re-organization of Curetis USA Inc. in January 2019, which has reduced the size of the team in the USA to currently 10 full-time staff with the majority being based in the field, the expectation for 2019 is to **increase the installed base of Unyvero Analyzers** with a continuously growing proportion of installations at commercial accounts towards the end of 2019.

Commercial Development EMEA

- On March 26, 2019, Curetis and **A. Menarini Diagnostics (Menarini)** announced an exclusive strategic **pan-European commercial distribution collaboration**. Initially, this agreement covers 11 countries including key markets such as Germany, France, UK, Italy, as well as Spain and 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 has 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.
- At the key European conference for microbiology, **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.

Installed Base

- The **worldwide installed base of Unyvero A50 Analyzers as of June 30, 2019, was 170**, compared to 162 as of June 30, 2018. This figure includes a significantly sized pool of Analyzers now managed by Menarini Diagnostics in EMEA (9 new installations have already been identified by Menarini for H2-2019) as well as 37 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 10 refurbished Unyvero Systems were ordered by various international distribution partners with most of them expected to be sold and shipped in H2-2019.

Product Launches and Regulatory Approvals

- 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 meeting 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 now expects a near-term clarification on potential requests for ancillary data or any required edits to the original application and any potentially required additional clinical data generated in a Chinese population. Assuming a final submission in 2019 and an **NMPA approval in 2020**, Curetis 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.

Business Development

- Following the strategy change announced in December 2018, H1-2019 saw 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.

Product Development

- The **Unyvero A30 *RQ* Platform**, which is now targeted for strategic partnering and licensing later in 2019, has seen excellent R&D progress in H1-2019. First fully functional instrument system prototypes have been available since Q4-2018 and first multiplex real-time PCR assays have been successfully transferred onto the A30 *RQ* cartridges and successfully benchmarked against their performance on standard PCR instruments. The goal is to have the A30 *RQ* platform ready for potential partnering and 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 filed for the 510(k) clearance of an LRT Application Cartridge optimized for use with bronchoalveolar lavage (BAL) as additional sample type on July 23, 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 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. An initiation of the prospective arm of the trial will

depend on Curetis partnering for the further development as well as the commercialization of this unique application cartridge.

Ares Genetics GmbH

- Ares Genetics signed an exclusive global bioinformatics licensing and collaboration agreement with **QIAGEN** in February 2019. This constitutes the third strategic collaboration agreement following the deals with Sandoz and an undisclosed global IVD corporation in Q4-2018.
- In Q1-2019, Ares Genetics also announced the **co-funding of a EUR 1.3 million project** to advance AI powered NGS testing called Triple-A (Assay Development and Artificial Intelligence to Diagnose Antibiotic Resistant Infections) by the Vienna Business Agency.
- In collaboration with the Curetis team, Ares Genetics in April 2019 released a beta-testing version of the **AMR Atlas**, a knowledge base on 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.
- In July 2019, Ares Genetics has received a notification from the **European Patent Office (EPO)** on the decision to grant the **European Patent No. 3 099 813 titled "Genetic Resistance Testing"**. The patent broadly covers biomarkers and biomarker combinations indicating resistance of the pathogen *Escherichia coli* to numerous classes of antibiotics and the use of such genetic biomarkers and biomarker combinations to predict resistance based on DNA testing. The patent is the first that was granted from a series of eleven similarly structured patent applications for different pathogen/drug combinations owned by Ares Genetics.
- On August 8, 2019, Ares Genetics has **opened a specialized service laboratory called ARESlab** 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. All services are based on Next Generation Sequencing (NGS) 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 worldwide. First customer orders have been successfully completed.
- On September 16, 2019, Ares Genetics has entered into a **multi-phase partnership 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. The companies signed an R&D and option agreement for the first phase of the partnership. The partnership 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). 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 for pathogen drug combinations relevant for a first undisclosed clinical application. Furthermore, in return for an undisclosed up-front option fee, the Partner obtained a 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.

Annual General Meeting (AGM) and Supervisory Board

- At the **Annual General Meeting ("AGM")** held in Amsterdam on June 27, 2019, the Company's shareholders **approved all proposed resolutions** and items on the agenda of the AGM.
- **Johannes Bacher, COO of Curetis**, has been re-elected as Curetis N.V. Management Board member for a period of three years. In addition to this management board appointment, the supervisory board members **William E. Rhodes III, Mario Crovetto and Prabhavathi Fernandes, Ph.D.** were re-elected for a further term of two years, respectively. **Dr. Rudy Dekeyser** was re-elected to the supervisory board for another one-year term.
- Furthermore, the management board was designated as the company body authorized to **issue new shares** or to **grant rights to subscribe for shares** in relation to strategic capital raising(s) and to not limit or exclude pre-emption rights on these shares. The Curetis N.V. 2019 AGM meeting minutes, detailed voting results as well as further information are available on Curetis' website at: https://curetis.com/investors/

Financing

- On May 21, 2019, Curetis reported that under the **EIB debt financing facility** dated December 2016, Curetis would now **receive another EUR 5.0 million** tranche of non-dilutive debt financing. This tranche, which was provided in June 2019, 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 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), 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 May 2019 received access to another EUR 1.5 million gross in funding. Net proceeds from this tranche, which was provided in June 2019, 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. For further details on the Yorkville convertible notes facility, please also see the "Convertibles" section under: https://curetis.com/investors/#corporate-governance.

Key Financials H1-2019

- **Revenues:** EUR 1.09 million (up by almost 35% compared to EUR 807k in the first half-year 2018).

- **Expenses:** EUR 11.49 million total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 12.44 million in the first half-year 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.These expenses in H1-2019 include EUR 1,242k in write-downs on inventory in Unyvero systems which had no cash flow impact.

- **Operating loss:** EUR 10.28 million (vs. EUR-11.37 million in the first half-year 2018).
- **Net loss of the period:** EUR -11.08 million (vs. EUR-11.56 million in the half-year 2018).
- **Cash and cash equivalents:** EUR 7.81 million of June 30, 2019 (vs. EUR 10.28 million as of December 31, 2018).
- **Net cash burn** in the first six months ended June 30, 2019, was EUR -2.49 million - i.e. a reduction by 47.5% compared to the first six months 2018.

Outlook

Going forward, Curetis expects to focus on the execution of the transaction to combine its business with OpGen and on securing funding of the combined operations for at least the next twelve months. The transaction is expected to close in early 2020. In the meantime, Curetis will continue its regular business activities and expects to:

- convert the **U.S. and EMEA pipeline of commercial opportunities** for Unyvero into near-term deal closures and revenue contribution;
- expand its **global Unyvero distribution network** and commercial reach through further partnerships with suitably positioned distributors;
- continue to work with BCB to obtain **NMPA approval** for Unyvero HPN to gain market access in China;
- execute on all **R&D programs** including the Unyvero A30 *RQ* development with a focus on partnering readiness from H2-2019 onwards, and the further development of ARES*db* and the ARES Technology Platform;
- enter into further **value-adding R&D and commercial partnerships** with well-known industry players around ARES*db* and the ARES Technology Platform as well as the Unyvero Platforms.

"In 2019, we have advanced our commercial roll-out in the U.S. and progressed the anticipated regulatory approvals in the U.S. and in China. We have also made tremendous progress in advancing Ares Genetics from a bioinformatics start-up to an increasingly self-sustained NGS and AMR data intelligence operation with very significant partnerships both in the IVD and pharma space," said Oliver Schacht, Chief Executive Officer of Curetis. "The strategic transaction and business combination with OpGen will allow Curetis to access U.S. capital markets, which we believe is essential to accelerate the development of our proprietary molecular diagnostic platforms and solutions for microbiology."

Conference Call and Webcast

Curetis will host a public conference call and webcast on September 18, 2019, at 15:00 pm CET / 09:00 am ET to present the H1-2019 financial results, highlight the most important events and provide an outlook for the second half of 2019 and beyond.

The conference call will be supplemented by a presentation, which can be accessed during the call at:
http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html

For participating in the earnings conference call, please access the presentation at
https://webcasts.eqs.com/curetis20190918

To access the call, please dial the following numbers using the passcode 28653292#:

NL:	+31 107137273
BE:	+32 11500307
DE:	+49 6922 222 9043
UK:	+44 2030 092 452
US:	+1 855 4027766
China:	+86 4006815483
Hong Kong:	+852 30773565

Further country-specific dial-in numbers can be found at:
http://events.arkadin.com/ev/docs/International Access Numbers_UKFELBRI1_SU7.pdf

The full H1-2019 Report will be available as of September 18, 2019, at:
http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html

The live webcast and a replay will be available at:
https://webcasts.eqs.com/curetis20190918

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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, 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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CURETIS N.V.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME (UNAUDITED)

For the periods ended 30 June 2019 and 30 June 2018

in kEuro	Six months ended 30 June 2019	Six months ended 30 June 2018
Revenue	1,088	807
Cost of sales	-2,027	-1,435
Gross profit / gross loss	-939	-628
Distribution costs	-3,306	-4,214
Administrative expenses	-1,976	-2,111
Research & development expenses	-4,181	-4,683
Other income	121	271
Operating loss	-10,281	-11,365
Finance income	7	274
Finance costs	-747	-496
Finance results - net	-740	-222
Loss before income tax	-11,021	-11,587
Income tax expenses	-56	26
Loss for the period	-11,077	-11,561
Other comprehensive income for the period, net of tax*	16	-171
Total comprehensive loss for the period**	-11,061	-11,732

Loss per share attributable to the ordinary equity holders of the company	Six months ended 30 June 2019	Six months ended 30 June 2018
Basic	-0.51	-0.73
Diluted	-0.51	-0.73

* Relates to exchange differences on translation of foreign operations, which may be recycled through profit and/or loss in the future

** Total comprehensive loss is solely attributable to owners of the company

CURETIS N.V.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) - ASSETS

As of 30 June 2019 and 31 December 2018

in kEuro	30 June 2019	31 December 2018
Current asset	13,926	18,095
Cash and cash equivalents	7,809	10,279
Trade receivables	196	323
Contractual assets	215	-
Inventories	4,715	6,734
Other current assets	991	759
Non-current assets	12,785	11,012
Intangible assets	7,354	7,425
Property, plant and equipment	3,738	3,196
Right of use assets	1,298	-
Other non-current assets	222	162
Other non-current financial assets	158	158
Deferred tax assets	15	71
Total assets	26,711	29,107

CURETIS N.V.

STATEMENT OF FINANCIAL POSITION (UNAUDITED) - EQUITY AND LIABILITIES

As of 30 June 2019 and 31 December 2018

in kEuro	30 June 2019	31 December 2018
Current liabilities	6,150	6,064
Trade and other payables	853	957
Provisions current	130	65
Tax liabilities	2	22
Other current liabilities	1,370	1,235
Other current financial liabilities	3,362	3,785
Current lease liabilities	433	-
Non-current liabilities	20,539	13,993
Provisions non-current	44	44
Other non-current financial liabilities	19,623	13,949
Non-current lease liabilities	872	-
Total liabilities	26,689	20,057
Equity	22	9,050
Share capital	226	209
Capital reserve	164,661	162,967
Other reserves	9,499	9,176
Currency translation differences	-128	-143
Retained earnings	-174,236	-163,159
Total Equity and liabilities	26,711	29,107

CURETIS N.V.
STATEMENT OF CASH FLOWS (UNAUDITED)

For the periods ended 30 June 2019 and 30 June 2018

in Euro	Three months ended 30 June 2019	Three months ended 30 June 2018
Profit after income tax	-11,077	-11,561
Adjustment for:		
- Net finance income / costs	740	222
- Depreciation, amortization and impairments	825	618
- Gain on disposal of fixed assets	5	0
- Changes in provisions	65	-70
- Changes in equity settled stock options	323	427
- Changes in deferred tax assets and liabilities	56	-45
Changes in working capital relating to:		
- Inventories	2,019	55
- Trade receivables and other receivables	-380	-1,050
- Trade payables and other payables	314	612
Income taxes received (+) / paid (-)	56	-26
Interest paid (-)	-530	-471
Net cash flow provided by operating activities	-7,584	-11,289
Payments for intangible assets	-31	-67
Payments for property, plant and equipment	-1,054	-163
Interest received	1	0
Net cash flow used in investing activities	-1,084	-230
Proceeds from other non-current financial liabilities	5,000	3,000
Proceeds from current financial liabilities	1,385	0
Proceeds from issue of ordinary shares	1,711	4,100
Repayment of convertible loan	-1,711	0
Payments for financing costs of issue of ordinary shares	0	-320
Principle elements of leases paid	-203	0
Net cash flow provided by financing activities	6,182	6,780
Net increase (decrease) in cash and cash equivalents	-2,486	-4,739
Net cash and cash equivalents at the beginning of the year	10,279	16,311
Net increase (decrease) in cash and cash equivalents	-2,486	-4,739
Effects of exchange rate changes on cash and cash equivalents	16	74
Net Cash and cash equivalents at the end of the period	7,809	11,646

CURETIS N.V.

CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 30 June 2019 and 30 June 2018

in kEuro	Share capital	Capital reserve	Other reserve	Currency translation difference	Retained earnings	TOTAL equity
Balance at 1 January 2018	**155**	**152,793**	**8,527**	**143**	**-139,414**	**22,204**
Loss of the period					-11,561	-11,561
Other comprehensive income				-171		-171
Total comprehensive income	**0**	**0**	**0**	**-171**	**-11,561**	**-11,732**
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	**9**	**4,091**				4,100
Transaction costs for the issue of ordinary shares		**-319**				-319
Equity stock option program 2016			427			427
Balance as of 30 June 2018	**164**	**156,565**	**8,954**	**-28**	**-150,975**	**14,680**

in kEuro	Share capital	Capital reserve	Other reserve	Currency translation difference	Retained earnings	TOTAL equity
Balance at 1 January 2019	**209**	**162,967**	**9,176**	**-143**	**-163,159**	**9,050**
Loss of the period					-11,077	-11,077
Other comprehensive income				15		15
Total comprehensive income	**0**	**0**	**0**	**15**	**-11,077**	**-11,062**
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	17	1,694				1,711
Equity stock option program 2016			323			323
Balance as of 30 June 2019	**226**	**164,661**	**9,499**	**-128**	**-174,236**	**22**