Curetis Publishes Full-Year 2018 Financial Results and Updated Guidance for 2019

- Launched Unyvero System and Unyvero LRT Cartridge in the U.S.

- Increased revenues to EUR 1.4 million in 2018

- Raised EUR 19.5 million additional funding

- Revised focus and strategy

Amsterdam, the Netherlands, and Holzgerlingen, Germany, April 11, 2019 – 08:00 am CET -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced the financial results for the twelve months ended December 31, 2018, and provided an updated guidance for 2019.

Key Events 2018 and Year-to-Date 2019

- Received U.S. FDA clearance for Curetis' Unyvero System and Unyvero LRT Application on April 3, 2018, and launched Unyvero LRT in the U.S. at ASM Microbe in June 2018;
- Signed strategic pan-European distribution agreement with A. Menarini Diagnostics for the Unyvero A50 Platform and Application Cartridges initially covering eleven countries, including all European markets that have so far been served directly by Curetis;
- Progressed Unyvero A30 *RQ* platform to fully functional prototype stage and engaged in multiple strategic partnering and licensing negotiations for this platform in all key global geographies and multiple indication areas;
- Significantly expanded strategic collaboration with Beijing Clear Biotech for greater China and filed for Unyvero System and HPN Application approval in China;
- Expanded geographical presence in Northern Africa and Latin America with three new distribution partnerships in Egypt, Mexico and Uruguay and entered into a new distribution agreement for Ireland;
- Received several approvals for Unyvero Application Cartridges in countries of the ASEAN region;
- Launched novel CE-IVD-marked Unyvero UTI Application Cartridge for critical urinary tract infections;
- Raised EUR 4.1 million in PIPE transaction;
- Signed financing facility of up to EUR 20 million of convertible notes with Yorkville, accessed first EUR 3.5 million tranche;
- Closed follow-on offering with EUR 8.9 million gross proceeds;
- Sharpened focus on near-term strategic value drivers and reduced headcount by approximately 25%, targeting reduction of cash burn by up to 50% in 2019;
- Curetis´ wholly-owned subsidiary Ares Genetics
    - entered into bioinformatics partnership with QIAGEN to create a bioinformatics community platform for antimicrobial resistance research,
    - launched ARES & CO pharma partnering program and teamed up with Sandoz to develop digital anti-infectives platform,
    - initiated feasibility study with an undisclosed global IVD player,

- secured public co-funding of R&D projects with project volumes totaling approximately EUR 3 million.

Installed Base

Upon completion of a pharmaceutical partner's Phase III clinical trial, Curetis in Q1-2018 exercised an option to buy back multiple Unyvero systems deployed in this clinical trial and has increasingly focused on higher priority accounts and conversion efficiency throughout 2018. This led to a re-deployment of Unyvero Analyzers and a temporary decrease in the installed base of Unyvero Analyzers to 167 Analyzers as of the end of 2018, down by a net of 8 Analyzers compared to 175 Analyzers at year-end 2017.

2018 Key Financials

- Revenues: EUR 1.4 million (EUR 1.2 million in 2017).
- Expenses: EUR 25.1 million total cost of sales, distribution costs, administrative expenses and research & development expenses (EUR 20.1 million in 2017).
- Operating loss: EUR -22.9 million in 2018 due to the commercial expansion and U.S. launch, R&D and pipeline expansion efforts including the Unyvero A30 *RQ* program and Ares Genetics (EUR -18.6 million in 2017).
- Total comprehensive loss: EUR -24.0 million (EUR -19.3 million in 2017).
- Cash & cash equivalents: EUR 10.3 million as of December 31, 2018 (EUR 16.3 million as of December 31, 2017).
- Net cash burn from operating activities: EUR -22.0 million in 2018 (EUR -15.7 million in 2017).
- Net cash flow from investing activities: EUR -0.8 million in 2018 (EUR -0.4 million in 2017), mainly resulting from the operating loss.

Commenting on Curetis' 2018 results, the Company´s CEO Oliver Schacht, stated: "In 2018, a major step for Curetis has been the granting of the *De Novo* request by the FDA in April and the subsequent U.S. launch of the Unyvero Platform and Unyvero LRT Cartridge for pneumonia. While this milestone has enabled us to raise an additional EUR 19.5 million funding during the course of 2018 in multiple transactions, the overall financing goals were not fully reached. We have therefore taken decisive action in December 2018 to focus on key value drivers and made significant changes to our strategy, commercial channels and R&D pipeline priorities. The necessary re-organization has led to a workforce reduction by approximately 25%. Re-prioritizing several R&D programs and a more partnering-driven strategy should allow us to reduce cash burn significantly in 2019. In light of available financial resources and funding for Curetis, we have also made the strategic decision to streamline our European commercial operations by moving from a direct sales model in key European markets towards an external distribution model in 2019. With A. Menarini Diagnostics, we have found an ideal partner to execute this strategy."

Anticipated 2019 Milestones and Guidance

Commercial Operations and Business Development

- Building on a solid funnel of sales opportunities, which have been developed in the U.S. since the launch of the Unyvero LRT cartridge in mid-2018, the first installations of Unyvero Analyzers in fall of 2018 and numerous commercial evaluations ongoing, Curetis expects multiple accounts to become buying customers of Unyvero LRT during the course of 2019. Taking into account the smaller-sized U.S. commercial organization as a consequence of the overall restructuring of the Curetis Group completed in early 2019, the Company expects to more than double the overall installed base of Unyvero A50

Analyzers in the U.S. from 15 to 30-40 devices by year-end 2019, with a continuously growing number of Analyzers starting to generate revenues as commercial accounts in H2-2019.

- Commercial operations throughout 2019 in EMEA will focus on the hand-over of the markets so far served directly or by other smaller regional distributors to A. Menarini Diagnostics, Curetis' new pan-European partner for the commercialization of the Unyvero A50 product portfolio. While this may temporarily lead to a further consolidation of the installed base of Unyvero Analyzers in such markets, the Company expects to offset such potential effect over the course of 2019.

- In total, Curetis expects to grow the global installed base of Unyvero A50 Analyzers from 167 at year-end 2018 to more than 200 by year-end 2019.

- With the strategic focus on near-term value drivers announced in December 2018, Curetis has significantly ramped up its business development activities for key assets such as the Unyvero A30 *RQ* Platform in development, ARESdb and the ARES Technology Platform. With validating partnerships signed with QIAGEN and Sandoz and numerous ongoing strategic partnering and licensing discussions for such assets, the Company expects to enter into further agreements over the course of 2019. These partnerships are expected to contribute significantly to 2019 cash inflow and revenue generation in 2019 and beyond.

- In total, revenues from commercial operations, licensing and collaborations are expected to more than double from EUR 1.4 million in 2018 to over EUR 3 million in 2019. Revenue recognition under IFRS 15 will depend on the exact nature and details of commercial and partnering or licensing deals and contracts.

Research & Development

- To further expand its offerings in the U.S. market, Curetis intends to submit for the clearance of an additional Unyvero LRT Application Cartridge specifically optimized for the use with bronchoalveolar lavage (BAL) samples, the second most commonly obtained sample type in the diagnostic work-up of patients with suspected lower respiratory tract infections. A 510(k) filing and submission is planned for mid-2019, with an expected clearance decision in H2-2019.

- Subject to identifying a suitable partner providing co-funding for late-stage clinical development and collaborating on the future commercialization, Curetis would be in a position to finalize the development and clinical trials of its Unyvero IJI Application Cartridge for invasive joint infections for the U.S. market and file a subsequent submission to the U.S. FDA for this product.

- Further U.S. FDA trials for Unyvero A50 applications are expected to follow in 2020 and beyond, continuing the expansion of the portfolio of differentiated testing applications in the U.S., subject to the availability of additional capital or partnerships to fund such trials.

- The Company also expects its Chinese partner BCB to complete further steps potentially required by the Chinese NMPA (formerly CFDA) to support the submission for approval of the Unyvero HPN Cartridge in China that was filed in February 2019, with an expected clearance decision in 2020.

- For the Unyvero A30 *RQ* mid-plex PCR platform in development, Curetis expects to complete the development of small series manufacturing prototypes ready for verification and validation studies with application cartridges of future partners by mid-2019. The

further development timelines and potential future product launches will depend on Curetis entering into agreements with suitable diagnostics industry partners for the final stages of platform and product development (based on partners' content and menu or application choices) and commercialization.

- For Ares Genetics, Curetis expects the further development of NGS service offerings for pharma and the public health sector with an anticipated launch by mid-2019. Moreover, Ares Genetics is expected to drive the further development of its ARESupa diagnostic test for initial deployment as a laboratory-developed test through its own laboratory as well as partner laboratories.

Financial Position and Financing

- Curetis will continue to evolve its shareholder base and gradually reduce the venture capital ownership and allow for a more diversified blue-chip, long-term institutional investor base. With the recent financing transactions and Yorkville convertible notes financing, Curetis also aims to further improve liquidity and free float of its stock.

- Given the negative cash flow pattern of an early-stage commercial MDx company, Curetis continues to assess all tactical and strategic options available to access capital markets and potential strategic partners globally.

- With EUR 10.3 million cash available at year-end 2018 (plus VAT receivable of EUR 0.4 million) in combination with a clear path to access the next EUR 5.0 million debt financing tranche from the European Investment Bank (EIB) with an agreed equity-based component upon maturity of such tranche in 2024 or later as well as potential future access to further tranches under the Yorkville convertible notes facility, Curetis expects to raise additional growth capital by 2020 to secure appropriate funding and cash for continued operations for the coming at least 12 months to ensure continuing as going concern. The Company will continue to assess all available strategic and tactical financing options going forward, including raising equity capital funding directly into Ares Genetics to accelerate the development of NGS-based infectious disease diagnostics.

- Given available funding, the Company has also significantly reduced its headcount globally from 127 staff at the end of Q3-2018 to approximately 95 staff (i.e. approximately 87 full-time equivalents - FTEs) at the beginning of Q2-2019. Corresponding cash burn is expected to be reduced from EUR 22.7 million in 2018 towards approximately 12.5 to 15 million in 2019.

- Curetis also expects to pursue various non-dilutive financing options such as government grants or licensing and partnering models (e.g. for the Unyvero A30 *RQ* Platform, ARES AMR Database and Technology Platform, Unyvero portfolio) to partially fund some of its operations in 2019 and 2020.

Full-Year 2018 Financial Results

For the twelve months ended December 31, 2018, revenues amounted to EUR 1.4 million, as compared to revenues of EUR 1.2 million in 2017.

Gross loss for the year totaled EUR -814 thousand, compared with a gross loss of EUR -462 thousand in 2017 due to higher write-downs on Unyvero systems to reflect marketability discounts. The full-year 2018 gross margin was -57.4% compared with -38.9% for 2017.

Operating loss in 2018 totaled EUR -22.9 million compared with EUR -18.6 million in 2017.

Total comprehensive loss for the year was EUR -24.0 million compared with a total comprehensive loss of EUR -19.3 million in 2017 due to expenses related to the commercial expansion, R&D and pipeline expansion efforts.

On December 31, 2018, Curetis Group's cash, cash equivalents and financial assets amounted to EUR 10.3 million (including the EIB loan facility drawdown of EUR 3 million in 2018, the drawdown of the first tranche of the Yorkville convertible notes totaling EUR 3.5 million and the equity financings closed in April and November 2018, respectively) compared with EUR 16.3 million as of December 31, 2017.

The financial statements 2018 have been prepared on a going concern basis despite the fact that as of December 31, 2018, remaining cash reserves were insufficient to cover at least 12 months after the sign-off date from the full-year 2018 report. However, detailed scenario analysis risk assessments were conducted as well as all strategic and tactical financing options assessed with several additional cash inflows such as another EUR 5.0 million EIB debt tranche available upon the waiver of condition precedent, potential Yorkville convertible notes tranche, possible future PIPE financing transactions based on authorized share capital and various cost reduction and cash preserving measures identified and implemented in Q4-2018 and Q1-2019, respectively.

Earnings Conference Call and Webcast

Curetis will host a public earnings conference call and webcast today, April 11, 2019, at 03:00 pm CET / 09:00 am EST to discuss the financial results of 2018, highlight the most important events and provide an outlook for 2019 and beyond.

For participating in the earnings conference call, please access the presentation at:
https://webcasts.eqs.com/curetis20190411/no-audio

To access the call, please dial the following numbers:

Belgium:	+3224019516
Germany:	+4969201744220
The Netherlands:	+31207168020
UK:	+442030092470
US:	+18774230830

When instructed, please use the passcode 46052411#

For further international dial-in numbers, please open the following link:
http://events.arkadin.com/ev/docs/International%20Access%20Numbers_%20UKFELBRI1_SU7.pdf

The conference webcast can be accessed after completion of the call at:
https://curetis.com/investors/#financial-reports

The full annual financial report 2018 is available as of today, April 11, 2019, at:
https://curetis.com/investors/#financial-reports

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 is developing next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines the presumably 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.

Legal Disclaimer

This document constitutes neither an offer to buy nor to subscribe securities and neither this document nor any part of it should form the basis of any investment decision in Curetis.

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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", "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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CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

in kEuro	2018	2017
Revenue	1,419	1,187
Cost of sales	-2,233	-1,649
Gross loss	**-814**	**-462**
Distribution costs	-8,155	-7,302
Administrative expenses	-4,095	-3,755
Research & development expenses	-10,568	-7,362
Other income	721	314
Operating loss	**-22,911**	**-18,567**
Finance income	406	21
Finance costs	-1,204	-1,004
Finance result - net	**-798**	**-983**
Loss before income tax	**-23,709**	**-19,550**
Income tax expenses	-36	52
Loss for the period	**-23,745**	**-19,498**
Other comprehensive income for the period, net of tax	-283	171
Total comprehensive loss for the period	**-24,028**	**-19,327**

Loss per share attributable to the ordinary equity holders of the company	2018	2017
Basic	-1.41	-1.26
Diluted	-1.41	-1.26

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Assets

in kEuro	31 December 2018	31 December 2017
Current assets	**18,095**	**24,009**
Cash and cash equivalents	10,279	16,311
Trade receivables	323	200
Inventories	6,734	6,946
Other current assets	759	552
Non-current assets	**11,012**	**11,506**
Intangible assets	7,425	7,524
Property, plant and equipment	3,196	3,566
Other non-current assets	162	182
Other non-current financial assets	158	156
Deferred tax assets	71	78
Total assets	**29,107**	**35,515**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Liability & Equity

in kEuro	31 December 2018	31 December 2017
Current liabilities	**6,064**	**2,926**
Trade and other payables	957	928
Provisions current	65	124
Tax liabilities	22	24
Other current liabilities	1,235	1,226
Other current financial liabilities	3,785	624
Non-current liabilities	**13,993**	**10,385**
Provisions non-current	44	43
Other non-current financial liabilities	13,949	10,342
Total liabilities	**20,057**	**13,311**
Equity	**9,050**	**22,204**
Share capital	209	155
Capital reserve	162,967	152,793
Other reserves	9,176	8,527
Currency translation differences	-143	143
Retained earnings	-163,159	-139,414
Total equity and liabilities	**29,107**	**35,515**

CONSOLIDATED STATEMENT OF CASH FLOWS

in kEuro	2018	2017
Loss after income tax for the period	-23,745	-19,498
Adjustment for:		
- Net finance income / costs	798	983
- Depreciation, amortization and impairments	1,256	1,327
- Gain on disposal of fixed assets	0	2
- Changes in provisions	-60	75
- Changes in equity settled stock options	649	1,167
- Net exchange differences	-375	371
- Changes in deferred tax assets and liabilities	7	-78
Changes in working capital relating to:		
- Inventories	212	-1,076
- Trade receivables and other receivables	-312	1,008
- Trade payables and other payables	659	911
Effects of exchange rate differences not realized from consolidation	89	-199
Income taxes received (+) / paid (-)	36	-52
Interest paid (-)	-1,173	-622
Net cash flow used in operating activities	**-21,959**	**-15,681**
Payments for intangible assets	-118	-111
Payments for property, plant and equipment	-669	-320
Interest received	0	10
Net cash flow used in investing activities	**-787**	**-421**
Proceeds from other non-current financial liabilities	3,000	10,000
Proceeds from current financial liabilities	3,109	0
Payments for finance lease liabilities	0	-48
Proceeds from issue of ordinary shares	13,200	0
Payments for financing costs for issue of ordinary shares	-2,972	0
Net cash flow provided by financing activities	**16,337**	**9,952**
Net decrease / increase in cash and cash equivalents	**-6,409**	**-6,150**
Net cash and cash equivalents at the beginning of the year	16,311	22,832
Net decrease in cash and cash equivalents	-6,409	-6,150
Effects of exchange rate changes on cash and cash equivalents	377	-371
Net Cash and cash equivalents at the end of the period	**10,279**	**16,311**