Curetis Publishes Full-Year 2017 Financial Results and Updated Guidance For 2018

- Received U.S. FDA clearance for Unyvero System and Unyvero LRT Cartridge; commercial U.S. roll-out initiated

- Launched two novel CE-IVD marked Unyvero Applications

- Strengthened global commercial footprint; expanded installed base

Amsterdam, the Netherlands, and Holzgerlingen, Germany, April 30, 2018 – 01:00 am EDT-- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced financial results for the twelve months ended December 31, 2017 and provided an updated guidance for 2018.

Operational Highlights 2017 up to and including April 2018

- *De Novo* request for Curetis' Unyvero System and Unyvero LRT Application granted by U.S. FDA on April 3, 2018;
- Completed build-out of commercial team and initiated commercial roll-out of Unyvero LRT Application in the U.S.;
- Launched novel CE-IVD marked Unyvero Application Cartridges for Intra-Abdominal Infections (Unyvero IAI) and, most recently, Urinary Tract Infection (Unyvero UTI);
- Established U.S. Scientific Advisory Board to provide scientific counsel on advancing the development of pipeline programs for the U.S. market;
- Raised additional capital of EUR 4.1 million via private share placements and with access to additional USD 10 million in equity over 36 months;
- Received approval from the Singapore Health Science Authority for the Unyvero HPN and BCU Application Cartridges;
- Signed strategic agreement in form of a memorandum of understanding with MGI (a BGI Group company, China) to leverage Curetis' sample preparation technology and to enable short-term commercialization of NGS-based molecular microbiology;
- Awarded grant funding commitment from Austrian Research Promotion Agency (FFG) for Ares Genetics' project 'The Digital Microbe' with total project volume of EUR 1.6 million;
- Increased global installed base of Unyvero Analyzers by 33 to 175 by year-end of 2017, a 23% growth rate from 142 Analyzers at the end of 2016.[1] With completion of a pharmaceutical partners' clinical trial, the Company has in Q1-2018 bought back Unyvero Systems deployed in this clinical trial and has continuously taken a stronger focus on higher priority accounts and conversion efficiency, which led to a re-deployment of Unyvero Systems resulting in a temporary decrease to 167 Analyzers by the end of the first quarter 2018;
- Initiated second U.S. FDA study to obtain clearance for the Unyvero IJI Invasive Joint Infections Application Cartridge;

[1] as previously announced on February 5, 2018

- Partnered with Biotest to support academic PEPPER Pentaglobin® Peritonitis trial with Unyvero IAI Application Cartridge;
- Strengthened Supervisory Board with the appointment of Dr. Nils Clausnitzer, MD, MBA, elected at the 2017 AGM;
- Founded wholly-owned subsidiary Ares Genetics in Vienna, Austria, to advance the business building on the GEAR database asset acquired form Siemens in September 2016.

2017 Key Financials

- Revenues: EUR 1.2 million (EUR 1.3 million in 2016). [1]
- Expenses: EUR 20.1 million total cost of sales, distribution costs, administrative expenses and research & development expenses (EUR 16.7 million in 2016).
- Operating loss: EUR -18.6 million in 2017 due to the costs of the commercial expansion, R&D and pipeline expansion efforts (EUR -15.2 million in 2016).
- Net loss: EUR -19.3 million (EUR -15.2 million in 2016).
- Cash & cash equivalents: EUR 16.3 million as of December 31, 2017 (EUR 22.8 million as of December 31, 2016).[1]
- Net cash burn from operating activities: EUR -15.7 million in 2017 (EUR -15.7 million in 2016).
- Net cash burn from investing activities: EUR -0.4 million in 2017 (EUR -7.4 million in 2016), mainly resulting from the acquisitions of the GEAR database and Gyronimo platform in 2016.

Commenting on Curetis' 2017 results, Curetis´ CEO Oliver Schacht, stated: "In 2017, we believe we have paved the way for accelerated future growth and expansion of Curetis' capabilities. This includes the completion of our integration of the GEAR and Gyronimo (now ARES*db* and Unyvero A30 *RQ,* respectively) asset acquisitions to build a truly versatile 'any-plex' platform, which covers a broad range of infectious disease diagnostics. Moreover, we have focused on the clearance of our Unyvero Platform and Unyvero LRT Cartridge in the U.S. and invested in qualified and experienced personnel to initiate the commercial U.S. roll-out of these products immediately following their clearance. The recent U.S. FDA clearance marks a major milestone in expanding our global commercial footprint into one of the largest and most important diagnostics markets worldwide. We are confident in our U.S. roll-out strategy and remain dedicated to achieving a number of additional milestones throughout the year."

Anticipated Milestones and 2018 Guidance

Commercial Operations

- Curetis plans to continue its EMEA commercial conversion campaign and to roll out new products (e.g. the recently launched Unyvero UTI Cartridge for urinary tract infections and the A30 *RQ* Platform, which will be further developed in 2018 and which is expected to be marketed under CE-mark in 2019) and plans to grow the installed base of Unyvero Analyzers and, upon commercial conversion of accounts, cartridge utilization on such installed base.

- Following the clearance of the Unyvero System and the Unyvero LRT Application Cartridge by the U.S. FDA in April 2018, the Company has initiated the commercial launch of the products in the U.S. in Q2-2018, with the goal of increasing the global installed base of Unyvero Analyzers. Based on an expected U.S. sales cycle of six to nine months, sales of the LRT Application Cartridge are anticipated to ramp up by the end of 2018. In this

context, Curetis expects to experience positive revenue effects towards the end of 2018 and going forward.

- The Company also strives to continuously evolve and expand its commercial distribution network across those EMEA markets that are not covered by direct sales and marketing teams. To that end, Curetis has recently hired Eneko Goya as Global Commercial Partner Manager, who has longstanding experience in sales and business development, to manage and expand the global commercial partner distribution channel.

- In line with the geographic expansion, in particular to the U.S. market and the further commercial roll-out in the markets covered directly or through distribution partners, the Company expects to significantly increase its global installed base of Unyvero Analyzers throughout 2018 and beyond. Starting from 175 Analyzers installed as of December 31, 2017, Curetis in Q1-2018 exercised a buy-back option for several Analyzers previously used in a by now successfully completed clinical trial (Amikacin Phase III trial) by a pharmaceutical industry partner. Further, under new commercial leadership in the EMEA region, the direct sales strategy has taken a reinforced focus on higher priority accounts and commercial conversion effectiveness, which led to a temporary re-deployment and a temporary decreased number of the global installed base to 167 Analyzers by the end of Q1-2018. Building on this consolidated installed base, the Company is targeting to grow its total installed base to around 250 to 300 analyzers by the end of 2018. Of these, a growing number is expected to be placed in the U.S. following the clearance of the Unyvero System and the Unyvero LRT Application Cartridge by the U.S. FDA in April 2018. Hence, Curetis USA Inc. within the next six to nine months targets the installation of around 40 to 50 Unyvero Analyzers across the U.S. and an increase to around 60 to 80 Analyzers within the first year following full commercial launch (i.e. Q2-2019).

Research & Development

- To further advance its U.S. product portfolio, Curetis expects to initiate sites for prospective patient sample enrollment into its second U.S. FDA clinical trial for the Unyvero IJI Invasive Joint Infection Application Cartridge beginning in H2-2018, with the aim of completing this trial in 2019. Curetis will also in the coming months initiate a dialogue with the U.S. FDA on the data requirements for a label claim expansion of its current Unyvero LRT Cartridge to also include bronchoalveolar lavage (BAL) as a sample type and the potential expansion of its panel to include one further microorganism and certain additional resistance markers to further strengthen the clinical utility of this first-in-class application. Further U.S. FDA trials are expected to follow, subject to access to additional funding, thus continuing the portfolio expansion of available differentiated testing applications in the U.S.

- The Company also anticipates that its Chinese partner Beijing Clear Biotech (BCB) is to complete all steps required by the Chinese regulatory agency CFDA in terms of analytical testing needed to initiate prospective clinical trials in China in the second half of 2018. The objective is to complete the first trials in 2019, with subsequent CFDA submission and approvals required for launch and commercialization in the Chinese market.

- With the recent launch of the Unyvero UTI Application Cartridge for severe urinary tract infections, the Company has further expanded its offering of Unyvero A50 high-multiplex syndromic panels for hospital-acquired infections. The Company expects to further develop and expand its Unyvero A50 application portfolio through stringent life-cycle management of its existing applications as well as through development of selected novel applications.

- In 2018, Curetis expects to work on further expanding the Unyvero platform beyond the core Unyvero A50 high-multiplex Analyzer and Unyvero A50 syndromic testing panels by advancing the development of the Unyvero A30 *RQ* Analyzer and additional application cartridges for this rapid, low- to mid-plex module to complement the Unyvero product offering as a broader platform in hospital infections. The Company expects to receive CE-IVD marking for the Unyvero A30 *RQ* Analyzer as well as first A30 *RQ* Application Cartridges during the course of 2019.

Business Development

- Following the broad strategic Memorandum of Understanding (MoU) signed with MGI (a BGI Group company, China) in September 2017 and the further collaboration and commercialization agreements under this MoU signed in January 2018, Curetis expects first results and initial product launches from this collaboration in the 2018 and 2019 timeframe. Importantly, Curetis expects to continue to grow, broaden and deepen this strategic partnership with the BGI Group moving forward and to apply the Unyvero as well as Ares Genetics' bioinformatics competencies and assets to their NGS platform to fuel future growth. Curetis expects that the Companies will also explore further options for strategic and commercial collaborations in China and beyond.

- Curetis also aims to enter into additional value-adding R&D and commercial partnerships with well-known players in the relevant industries that are based on the ARES AMR Database, ARES*db*, and the ARES Technology Platform and/or the Unyvero A30 *RQ* Analyzer and further elements of the Unyvero Platform.

Financial Position and Financing

- Building on stable year-over-year revenue in Q1-2018, a solid sales funnel in the EMEA region, the ongoing commercial launch in the U.S. and other developments described above, the Company aims to at least double its revenue year-over-year in 2018.

- With the expansion of the U.S. commercial organization in December 2017 and Q1-2018 and the initiation of the U.S. commercial roll-out of the Unyvero System and the Unyvero LRT Application Cartridge as well as the continued development of the Unyvero A30 *RQ* Analyzer and further Unyvero Application Cartridges, in particular for the U.S. market (e.g. the Unyvero IJI Application Cartridge incl. clinical trials), the Company expects the net cash-burn from operating and investment activities for 2018 to be around 30 million EUR, an anticipated significant increase over cash burn of 15.7 million EUR in 2017.

- Curetis will continue to assess all tactical and strategic financing options in the debt and equity capital markets globally. With the cash available at year-end 2017 (plus VAT receivable of EUR 0.3 million) in combination with up to EUR 15 million of additional debt financing from the EIB that may become available for draw-down by Curetis upon it meeting several agreed upon milestones (including an additional EUR 3 million EIB debt tranche which became available immediately upon the April 2018 FDA clearance), and the EUR 4.1 million from the recent private share placements and access to additional USD 10 million in equity mentioned above, Curetis aims to raise additional growth capital as either equity or debt in 2018 to secure appropriate funding and cash for continued operations for at least 12 months to ensure it has the financial resources to continue as a going concern. Depending on commercial success and financing availability, Curetis also expects to further grow its employee base at its various international sites and operations in the coming years.

- Curetis also plans to pursue non-dilutive financing sources such as government grants or

licensing and partnering models (e.g. for the Ares AMR Database and Unyvero A30 *RQ* Platform) to partially fund some of its operations in 2018 and 2019.

Full-Year 2017 Financial Results

For the twelve months ended December 31, 2017, revenues were EUR 1.2 million, as compared to revenues of EUR 1.3 million in 2016.

Gross loss for the year totaled EUR -462 thousand, compared with a gross loss of EUR -290 thousand in 2016, as under IFRS accounting the cost of goods for the Unyvero Application Cartridges still includes significant elements of as-yet unutilized capacity to allow for future expansion in manufacturing output. The full-year 2017 gross margin was –38.9%, compared with -22.2% for 2016.

Operating loss in 2017 totaled EUR -18.6 million, compared with EUR -15.2 million in 2016.

Net loss for the year was EUR -19.3 million compared with a net loss of EUR -15.2 million in 2016 due to expenses related to the commercial expansion, R&D and pipeline expansion efforts.

On December 31, 2017, Curetis Group's cash, cash equivalents and financial assets amounted to EUR 16.3 million (including the proceeds from an EIB loan facility drawn-down in April 2017 of EUR 10 million) compared with EUR 22.8 million as of December 31, 2016.

The financial statements 2017 have been prepared on a going concern basis despite the fact that as of December 31, 2017, remaining cash reserves were insufficient to cover at least 12 months after the signing date of the auditor's report. This determination was based on work conducted by the auditors PwC including detailed scenario analysis and risk assessments, incl. assessment of all strategic and tactical financing options with several additional cash inflows based on potential debt or equity financings and various cost reduction and cash preserving measures identified for implementation during 2018. Please also refer to Note 3.27 on 'Going Concern' of the Group's audited 2017 consolidated financial statements.

Earnings Conference Call and Webcast

Curetis will host a public earnings conference call and webcast today, April 30, 2018, at 03:00 pm CET / 09:00 am EST to discuss the financial results of 2017, highlight the most important events and provide an outlook for 2018 and beyond.

For participating in the earnings call conference please access the presentation at https://webcasts.eqs.com/curetis20180430/no-audio

To access the call, please dial the following numbers using the passcode 93120684#

Belgium: +3211500307
Germany: +49 69 222229043
The Netherlands: +31107137273
UK: +44 20 30092452
US: +1 855 4027766

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

The full annual financial report 2017 will be available as of today, April 30, 2018, at http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html

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

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 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.

Legal Disclaimer

This document constitutes neither an offer to buy nor an offer to subscribe for 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," "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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CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

in kEuro	2017	2016
Revenue	1,187	1,306
Cost of sales	-1,649	-1,596
Gross loss	**-462**	**-290**
Distribution costs	-7,302	-5,091
Administrative expenses	-3,755	-3,024
Research & development expenses	-7,362	-7,027
Other income	314	198
Operating loss	**-18,567**	**-15,234**
Finance income	21	101
Finance costs	-1,004	-30
Finance result - net	**-983**	**71**
Loss before income tax	**-19,550**	**-15,163**
Income tax expenses	52	-10
Loss for the period	**-19,498**	**-15,173**
Other comprehensive income for the year, net of tax	171	-28
Total comprehensive income for the period	**-19,327**	**-15,201**

Loss per share attributable to the ordinary equity holders of the company	**2017**	**2016**
Basic	-1.26	-0.98
Diluted	-1.26	-0.98

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Assets

in kEuro	31 December 2017	31 December 2016
Current assets	**24,009**	**30,272**
Cash and cash equivalents	16,311	22,832
Trade receivables	200	101
Inventories	6,946	5,870
Other current assets	552	1,469
Non-current assets	**11,506**	**12,514**
Intangible assets	7,524	7,520
Property, plant and equipment	3,566	4,466
Other non-current assets	182	212
Other non-current financial assets	156	316
Deferred tax assets	78	-
Total assets	**35,515**	**42,786**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Liability & Equity

in kEuro	31 December 2017	31 December 2016
Current liabilities	**2,926**	**2,384**
Trade and other payables	928	721
Provisions current	124	51
Tax liabilities	24	10
Other current liabilities	1,226	1,120
Other current financial liabilities	624	482
Non-current liabilities	**10,385**	**41**
Provisions non-current	43	41
Other non-current financial liabilities	10,342	-
Total liabilities	**13,311**	**2,425**
Equity	**22,204**	**40,361**
Share capital	155	155
Capital reserve	152,793	152,793
Other reserves	8,527	7,360
Currency translation differences	143	-29
Retained earnings	-139,414	119,918
Total equity and liabilities	**35,515**	**42,786**

CONSOLIDATED STATEMENT OF CASH FLOWS

in kEuro	2017	2016
Profit before income tax	-19,498	-15,172
Adjustment for:		
- Net finance income / costs	983	-71
- Depreciation, amortization and impairments	1,327	1,744
- Gain on disposal of fixed assets	2	2
- Changes in provisions	75	23
- Changes in equity settled stock options	1,167	767
- Changes in the PSOP-liability	0	-367
- Net exchange differences	371	-30
- Changes in deferred tax assets and liabilities	-78	0
Changes in working capital relating to:		
- Inventories	-1,076	-3,083
- Trade receivables and other receivables	1,008	201
- Trade payables and other payables	911	270
Effects of exchange rate differences not realized from consolidation	-199	2
Income taxes received (+) / paid (-)	-52	0
Interest paid (-)	-622	-10
Net cash flow provided by operating activities	**-15,681**	**-15,724**
Payments for intangible assets	-111	-7,025
Payments for property, plant and equipment	-320	-456
Interest received	10	51
Net cash flow used in investing activities	**-421**	**-7,430**
Proceeds from other non-current financial liabilities	10,000	0
Payments for finance lease liabilities	-48	-105
Net cash flow provided by financing activities	**9,952**	**-105**
Net increase in cash and cash equivalents	**-6,150**	**-23,259**
Net cash and cash equivalents at the beginning of the year	22,832	46,060
Net decrease in cash and cash equivalents	-6,150	-23,258
Effects of exchange rate changes on cash and cash equivalents	-371	30
Net Cash and cash equivalents at the end of the period	**16,311**	**22,832**