



Curetis Announces Financial Results for the First Six Months of 2017

- Further advancement of product pipeline and integration of GEAR and Gyronimo platforms

- Expansion of global installed base to 161 as of June 30, 2017; 42.5% increase over prior year

Amsterdam, the Netherlands, and Holzgerlingen, Germany, August 16, 2017; published at 08:00 am CET -- Curetis N.V. (the "**Company**" and, together with Curetis GmbH, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today reported its financial results for the first six months ended June 30, 2017, and provided an update on its financial and business guidance for the second half of 2017 and beyond.

Operational and Business Highlights 2017 to Date

Unyvero U.S. FDA Trials

- On January 5, 2017, Curetis submitted a **510(k) application** to the U.S. Food and Drug Administration (FDA) for its Unyvero Platform and the Unyvero LRT Lower Respiratory Tract Infection Cartridge. The LRT panel includes up to 36 analytes for all key pathogens and antibiotic resistance markers across which it has demonstrated an overall weighted average sensitivity of 91.4% and an overall weighted average specificity of 99.5%.
- In March of 2017, Curetis received a letter from the FDA with questions relating to details on pathogens, antibiotic resistance markers, sample types and other items. To **clarify remaining open issues**, a meeting with the FDA was held on April 21, 2017. Based on the outcome of this meeting and further discussions with the reviewers, Curetis has made the strategic decision to initially focus on securing clearance of the Unyvero Platform and LRT Application for use with **tracheal aspirate samples**. Originally, Curetis had filed for both bronchial lavage (BAL) and tracheal aspirate sample types in its *de novo* submission. With this phased approach, Curetis aims to pursue the most expeditious regulatory pathway.
- Curetis expects to continue its interactive review of the *510(k)* submission with the FDA. The Company aims to complete its responses and data package for final submission in the coming weeks, and expects a **subsequent clearance decision from the FDA later in the latter parts of the second half of 2017**. In addition, Curetis will continue working closely with the FDA reviewers to identify the most appropriate path to develop or augment the BAL data package, which it intends to submit as part of a proposed future label claim expansion as soon as practicable following the potential initial clearance of Unyvero LRT for tracheal aspirates.
- After the recent successful completion of a clinical feasibility study evaluating 80 synovial fluid samples, the Company continues to prepare for its **next FDA trial** for potential U.S. clearance of the **Unyvero IJI (invasive joint infections) Application**.

This product, a derivative of the European CE-marked Unyvero Implant and Tissue Infection (ITI) Application, is tailored to U.S. clinical and market needs.

Corporate Growth

- In April 2017, Curetis established **Ares Genetics GmbH** as a **wholly-owned subsidiary** headquartered in Vienna, Austria. Ares Genetics was founded to leverage the **GEAR GENetic Antibiotic Resistance and Susceptibility Database** and associated assets acquired from Siemens in 2016. Ares Genetics is seeking to collaborate on the **identification of potential novel biomarkers, biomarker combinations, and algorithms predicting antibiotic resistance**, as well as potential novel targets for antimicrobial drugs. Negotiations with various potential partners in the diagnostic and pharma industry, the public health space, as well as academic institutions are ongoing. GEAR may also be leveraged to generate fully genetic antibiograms and provide a reference for NGS-based clinical diagnostics. In June 2017, GEAR was recognized in the innovation contest '**Landmarks in the Land of Ideas**'. This prestigious award has been granted for the past twelve years through the "Germany – Land of Ideas" program and Deutsche Bank.
- Curetis has drawn down the **first tranche of EUR 10 million of the non-dilutive debt financing facility** provided through the **European Investment Bank (EIB)** in April 2017 to further advance its R&D and product platform.
- Recruiting activities for selected key positions of the **commercial team in the U.S.** are underway. Further expansion of the team is expected in H2-2017, to better synchronize the hiring of the sales force with the anticipated FDA clearance decision.
- To strengthen its **EMEA marketing** efforts, the Company recently **hired Riwat Lim, MSc, as its Director Marketing & Scientific Affairs EMEA and Managing Director Curetis UK Ltd.** Mr. Lim brings 15 years of sales and marketing experience in the pharmaceutical and diagnostic industries, including senior positions with large industry players like Proctor & Gamble and Pfizer as well as small innovative companies like Cellestis, which was acquired by Qiagen. He joins Curetis from Qiagen, where he was responsible for developing the market for Qiagen's QuantiFERON tuberculosis test in Northern Europe. Mr. Lim will directly report to Dr. Achim Plum, CBO of Curetis N.V.
- Curetis recently announced a **partnership with Biotest** for the use of Unyvero in the **clinical trial PEPPER** (**P**ersonalized Medicine with **P**entaglobin® after surgical source control in **p**atients with **p**eritonitis). The clinical trial is a multicentric, two-arm Phase IIb study to test the immune-modulating effect of Pentaglobin®, an IgM enriched immunoglobulin marketed by Biotest, in patients with secondary peritonitis. The clinical trial is being sponsored by RWTH Aachen and conducted in 12 centers across Germany and Austria. Curetis' services will comprise testing 200 native ascites samples and an equal number of matched positive blood culture samples from the same patients for microbial pathogens (bacteria and fungi), toxins, and antibiotic resistance markers using its Unyvero IAI Application for severe intra-abdominal infections. Following the clinical trial partnerships with Sanofi Pasteur, Cemptra and an undisclosed major pharma company, PEPPER is the fourth third-party clinical trial with Unyvero.

Product Development

- In April 2017, Curetis successfully completed the CE performance evaluation study and subsequently launched its **Unyvero IAI Intra-Abdominal Infections (IAI) Cartridge to the European market** during ECCMID. The CE-IVD marked IAI application supports the fast and reliable diagnosis of various severe conditions

related to the intra-abdominal tract, including peritonitis, cholecystitis and acute pancreatitis. The comprehensive panel covers up to 130 diagnostic targets, comprising 92 bacteria, 13 fungi, 3 toxins and 22 antibiotic resistance markers. In the prospective multi-center study, the IAI panel demonstrated 93.8% overall weighted average sensitivity and 99.7% overall weighted average specificity.

- In the U.S., Curetis has finalized the specifications of the **Invasive Joint Infections (IJI) Application** in collaboration with KOLs and clinical experts. The Company continues related application development efforts in preparation for the planned U.S. clinical trial.
- All other **R&D programs and product development projects** continue to **progress on track** and in line with guidance provided during the most recent earnings call in April 2017.

Installed Base

- Curetis' **global installed base** of Unyvero Analyzers reached 161 at the end of the first half of 2017; representing a 42.5% increase compared to 113 devices as of June 30, 2016.
- In addition to recent placements at key customer sites in Europe, Curetis GmbH received the first bulk order for 18 Unyvero Analyzers from its Curetis USA Inc. subsidiary in July 2017. Delivery and first installations with U.S. beta test sites under an IUO (investigational use only) label are expected to take place throughout H2-2017. These **Unyvero installations in the U.S.** are very likely to contribute towards the targeted installed base growth in H2-2017. A further Curetis USA Inc. bulk order of Unyvero Analyzers is expected later in 2017, ahead of the anticipated commercial launch following potential FDA clearance of the Unyvero Platform and Unyvero LRT Cartridge.
- Based on these orders and several recent shipments to key EMEA sites, the Company **maintains its target for a global installed base of 200+ Unyvero Analyzers** by year-end 2017, subject to the timing of a final FDA clearance decision.

New Patents and Clinical Data

- Curetis has **further expanded its international patent portfolio**. The Company was recently granted a key patent for its *"Universally Applicable Lysis Buffer And Processing Methods For The Lysis Of Bodily Samples"* in Europe, the U.S. and Japan. In Australia and Singapore, the patent had been granted in 2015. Therefore, this core patent is effective in all key markets.
- In addition, Curetis was granted another core patent, *"Reaction Vessel for PCR Device and Method for Performing PCR"* in China, Singapore, Japan and the U.S. This patent is pending in Europe.
- Curetis was also granted an important patent, *"Apparatus and Method for a Lysis of a Sample"* in Australia (2016) and Japan (2017).
- In addition, **new clinical data** that underscores the value of Curetis' Unyvero Solution and product portfolio have been **presented at several major scientific conferences in the U.S. and Europe**, including ECCMID 2017, the 5th Joint Conference of the DGHM & VAAM / VAAM Annual Meeting 2017, the American Thoracic Society International Conference, and ASM Microbe 2017.

Management Board

- **Andreas Boos**, CTO and co-founder of Curetis, today has resigned from the Management Board of Curetis N.V. effective August 31, 2017, to focus on his role as the group's CTO and program director for Gyronimo platform development. Andreas will continue to serve as one of the managing directors of Curetis GmbH. This move is part of the continuing evolution of Curetis' organization towards a more commercially-driven enterprise.
- Effective August 16, 2017, **Chris Bernard**, President and CEO of Curetis USA Inc., has been appointed Executive VP of Global Sales and will assume direct management responsibility for the EMEA sales organization. He will report directly to Curetis' CEO Oliver Schacht and will advise the Supervisory Board on all sales-related matters.
- Additionally, **Dr. Achim Plum** has assumed the role of CBO (Chief Business Officer) for Curetis N.V. In this function, he will continue to head all EMEA marketing, customer service & support, scientific affairs and global business development efforts. This allows him to dedicate more time on market development and expansion for Unyvero and – as one of the managing directors of Ares Genetics GmbH in Vienna - on accelerating the partnering and development activities of GEAR-related programs.

Supervisory and Medical Advisory Boards

- At this year's Annual General Meeting in June, Dr. Nils Clausnitzer was elected to **Curetis N.V.'s Supervisory Board** for a three-year term. Dr. Clausnitzer is Senior Vice President and President, EMEA-APAC Lab and Distribution Services of VWR International llc. / VWR GmbH, a position he has held since January 2016. Furthermore, Dr. Holger Reithinger and Dr. Rudy Dekeyser were each re-elected for another one-year term.
- Curetis' **Medical Advisory Board** has been expanded to six internationally renowned experts. Dr. Melissa Miller, Ph.D., Professor of Pathology and Laboratory Medicine and Director of the Clinical Molecular Microbiology Laboratory at Chapel Hill Medical School at University of North Carolina, has joined the MAB. Her research focuses on health economic evaluations of the implementation of new molecular technologies.

Financial Highlights, First Half-Year 2017

- **Revenues:** EUR 594.8 k (vs. EUR 654.7 k in the first half-year 2016).
- **Expenses:** EUR 9.9 million (vs. EUR 7.5 million in the first half-year 2016).
- **Gross loss:** EUR 457.3 k (vs. EUR 9.0 k in the first half-year 2016).
- **Net loss:** EUR 9.7 million (vs. EUR 6.7 million in the first half-year 2016).
- **Cash and cash equivalents:** EUR 25.4 million (vs. EUR 22.8 million as of December 31, 2016).

Anticipated Milestones

- **Curetis continues to expect an FDA clearance decision on the Unyvero System and Unyvero LRT Cartridge** for tracheal aspirates in the U.S **later in the second half of 2017**. Within 6 to 9 months following a potential U.S. launch, the Company

targets a U.S. installed base of 25 to 40 Unyvero Analyzers the Company **plans to expand its U.S. team by 20+ new hires** in sales, applications, field service and operations just ahead of the expected FDA clearance decision.

- Curetis is preparing to initiate its second prospective clinical, multi-center FDA trial of the **Unyvero IJI (invasive joint infections) Application** in the U.S. with the goal of enrolment completion in 2018.
- Curetis and its subsidiary Ares Genetics are actively pursuing **multiple partnering opportunities for GEAR**, providing for potential upside in the Company's business in the coming quarters.
- The **CFDA trial** carried out by Curetis' Chinese partner, Beijing Clear Biotech, is not expected to be completed before end of 2018. Based on this anticipated timing, the Chinese market is unlikely to have any significant commercial impact before 2019.
- **The development of Gyronimo continues to progress on track**, with expected completion by end of 2018 and commercial launch planned not before early 2019. Gyronimo is expected to accelerate Curetis' product pipeline over time, giving customers broader menu faster.
- The Company will **add further differentiated Unyvero Cartridges to the pipeline**, with the next cartridges for urinary tract infections (UTI) and sepsis host response (SHR) already in development. In addition, life cycle management of selected applications will be a continuous effort.

"In the first half of 2017, we continued to accelerate our corporate, commercial and product development initiatives," said Oliver Schacht, Chief Executive Officer of Curetis. "Most notably, we are looking forward to a FDA decision on potential U.S. clearance of the Unyvero Platform and LRT Application for tracheal aspirates in late 2017. This decision is expected to be a key value inflection point for Curetis, and we have already begun establishing the foundation for an impactful U.S. launch. We are also working to expand the Unyvero Platform's potential utility in the U.S. through development of a second Unyvero Application addressing invasive joint infections. We recently completed a clinical feasibility study of 80 samples and are preparing for a U.S. clinical trial, whose enrolment we aim to complete in 2018. Moreover, we are excited about the multitude of potential partnering opportunities currently being evaluated for our GEAR platform."

Financial Development and Guidance

For the six months ended June 30, 2017, revenues were EUR 594.8 thousand, as compared to EUR 654.7 thousand in the same period 2016. In general, revenues are expected to remain volatile from quarter-to-quarter, as early-stage instrument sales are unevenly spread throughout the year.

Expenses in the first six months of 2017 amounted to EUR 9.9 million (vs. EUR 7.5 million in the first half-year 2016). The increase is in line with the operational and organizational growth, and driven by higher distribution costs as well as G&A costs and cost of sales. The increase is also related to non-cash expenses accounting for the newly implemented equity settled stock option program 2016. This has resulted in expenses of EUR 0.8 million in H1-2017 (no such expense in the first half-year 2016).

Gross loss for the first six months of 2017 totaled EUR 457.3 thousand, compared with a gross loss of EUR 9.0 thousand in the same period 2016.

Net loss for the first six months of 2017 was EUR 9.7 million compared with a net loss of

EUR 6.7 million in the same period in 2016.

As of June 30, 2017, the Company had a strong cash position of EUR 25.4 million (vs. EUR 22.8 million as of December 31, 2016). The net cash increase in the first half-year 2017 was EUR 2.8 million. The net cash outflow from operating and investing activities was EUR 7.2 million (vs. EUR 6.2 million in H1-2016). This was more than offset by the EUR 10.0 million cash inflow from financing activities following the drawdown of the first tranche of EUR 10.0 million from the EIB debt financing facility (senior unsecured debt, 5 years to maturity from drawdown of each tranche, 5 years interest only, no warrants attached).

Earnings Conference Call and Webcast

Curetis will host a public earnings conference call and webcast today, August 16, 2017, at 03:00pm CET / 09:00am EST to discuss the financial results of the first six months 2017, highlight the most important events and provide an outlook for the second half 2017 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> (participants' passcode curetis0817).

A slide presentation accompanying the earnings conference call will be accessible at <http://www.audio-webcast.com/> using the passcode curetis0817.

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

BEL: +32 11500307
D: +49 69 222229043
NL: +31 1071 372 73
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_%20UKFELBRI1SU7.pdf

The first half-year financial report 2017 will be available as of today, August 16, 2017, at <http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html>

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About Curetis

Founded in 2007, Curetis is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. The diagnostic solutions of Curetis enable rapid multi-parameter pathogen and antibiotic resistance marker detection in only a few hours, a process that today can take up to days or even weeks with other techniques.

To date, Curetis has raised EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 million. Furthermore, Curetis has entered into a debt financing facility with EIB for up to EUR 25 million. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis collaborates with Heraeus Medical, pharmaceutical companies, and has entered into several international distribution agreements covering many countries across Europe, the Middle East and Asia.

In 2017, Curetis established Ares Genetics GmbH, a wholly-owned subsidiary of Curetis GmbH in Vienna, Austria. Ares Genetics is dedicated to maximizing the R&D and related scientific and business opportunities of the GEAR assets acquired in 2016 for the entire Curetis Group.

For further information, please visit www.curetis.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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CURETIS N.V.
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER
COMPREHENSIVE INCOME (UNAUDITED)

For the periods ended June 30

in Euro	Six months ended June 30, 2017	Six months ended June 30, 2016
Revenue	594,800	654,682
Cost of sales	1,052,070	663,657
Gross loss / gross margin	-457,270	-8,975
Distribution costs	3,845,547	2,095,227
Administrative expenses	1,847,996	1,406,161
Research & development expenses	3,161,438	3,301,211
Other income	49,766	85,976
Operating loss	-9,262,485	-6,725,598
Finance income	19,601	61,343
Finance costs	405,471	41,127
Finance costs - net	-385,870	20,216
Profit / loss before income tax	-9,648,355	-6,705,382
Income tax expenses	14,242	-
Profit / loss for the period	-9,662,597	-6,705,382
Other comprehensive income for the year, net of tax	117,015	6,044
Total comprehensive income for the period	-9,545,582	-6,699,338
Earnings / loss per share	Six months ended June 30, 2017	Six months ended June 30, 2016
Basic	-0.61	-0.43
Diluted	-0.61	-0.43

CURETIS N.V.
CONSOLIDATED STATEMENT OF FINANCIAL POSITION –
ASSETS (UNAUDITED)

As of 30 June 2017 and 31 December 2016

in Euro		June 30, 2017	December 31, 2016
Current assets		32,284,377	30,272,260
	Cash and cash equivalents	25,400,949	22,832,117
	Trade receivables	197,685	101,398
	Inventories	6,206,633	5,870,167
	Other current assets	479,110	1,468,578
Non-current assets		11,844,994	12,514,826
	Intangible assets	7,518,963	7,520,048
	Property, plant and equipment	3,975,692	4,466,462
	Other non-current assets	192,514	211,870
	Other non-current financial assets	157,825	316,446
	Deferred tax assets	-	-
Total assets		44,129,371	42,787,086

CURETIS N.V.
CONSOLIDATED STATEMENT OF FINANCIAL POSITION –
LIABILITY & EQUITY (UNAUDITED)

As of 30 June 2017 and 31 December 2016

	in Euro	30 June 2017	31 December 2016
Current liabilities		2,350,146	2,384,156
	Trade and other payables	482,710	721,113
	Liability PSOP	-	-
	Provisions current	86,000	51,000
	Tax liabilities	22,677	10,128
	Other current liabilities	1,118,731	1,120,299
	Other current financial liabilities	640,028	481,616
Non-current liabilities		10,140,846	40,522
	Provisions non-current	40,522	40,522
	Other non-current financial liabilities	10,100,324	-
	Deferred tax liability	-	-
Total liabilities		12,490,992	2,424,678
Equity		31,638,379	40,362,408
	Share capital	155,384	155,384
	Capital reserve	152,793,347	152,793,347
	Other reserves	8,181,376	7,359,821
	Currency translation differences	89,277	-27,736
	Retained earnings	-129,581,005	-119,918,408
Total Equity and liabilities		44,129,371	42,787,086

CURETIS N.V.

CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

For the periods ended June 30

in Euro	Six months ended June 30, 2017	Six months ended June 30, 2016
Profit before income tax	-9,662,597	-6,705,382
Adjustment for:		
- Net finance income / costs	385,870	-20,216
- Depreciation, amortization and impairments	694,338	897,324
- Gain on disposal of fixed assets	0	1,550
- Changes in provisions	35,000	-26,998
- Changes in equity settled stock options	821,555	0
- Changes in the PSOP-liability	0	0
- Net exchange differences	217,095	39,316
Changes in working capital relating to:		
- Inventories	-336,466	-1,608,393
- Trade receivables and other receivables	1,071,158	756,373
- Trade payables and other payables	93,822	547,066
Effects of exchange rate differences not realized from consolidation	-100,082	6,044
Income taxes received (+) / paid (-)	-14,242	0
Interest paid (-)	-174,625	-41,127
Net cash flow provided by operating activities	-6,969,174	-6,154,443
Payments for intangible assets	-50,955	-3,524
Payments for property, plant and equipment	-151,528	-147,008
Proceeds from sale of property, plant and equipment	0	0
Interest received	5,850	61,343
Net cash flow used in investing activities	-196,633	-89,189
Proceeds from borrowings	10,000,000	0
Payments for finance lease liabilities	-48,266	-69,304
Net cash flow provided by financing activities	9,951,734	-69,304
Net increase (decrease) in cash and cash equivalents	2,785,927	-6,312,936
Net cash and cash equivalents at the beginning of the year	22,832,117	46,060,397
Net increase (decrease) in cash and cash equivalents	2,785,927	-6,312,936
Effects of exchange rate changes on cash and cash equivalents	-217,095	-39,316
Net Cash and cash equivalents at the end of the period	25,400,949	39,708,145

CURETIS N.V.
CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY
(UNAUDITED)

As of June 30, 2017

In Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at January 1, 2016	155,384	152,793,347	6,592,372	0	-104,746,112	54,794,991
Loss of H1-2016					-6,705,382	-6,705,382
Other comprehensive income				6,044		6,044
Balance as of June 30, 2016	155,384	152,793,347	6,592,372	6,044	-111,451,494	48,095,653
in Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at January 1, 2017	155,384	152,793,347	7,359,821	-27,736	-119,918,408	40,362,408
Loss of H1-2017					-9,662,597	-9,662,597
Equity settled ESOP			821,555			821,555
Other comprehensive income				117,013		117,013
Balance as of June 30, 2017	155,384	152,793,347	8,181,376	89,277	-129,581,005	31,638,379