



Curetis Reports Financial Results for the First Six Months of 2016

- *Key business and commercial milestones and goals met*
- *Global presence further strengthened with subsidiaries in the U.S., UK, France and the Netherlands*

Amsterdam, the Netherlands, and Holzgerlingen, Germany, August 19, 2016 -- 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, 2016, and provided an update on its financial and business guidance for the second half 2016 and beyond.

Operational and Business Highlights 2016 to Date

- In April 2016, Curetis successfully completed the CE performance evaluation study and subsequently **launched its Unyvero BCU Blood Culture Application Cartridge** during ECCMID 2016 in Amsterdam. The CE-marked BCU Application is designed for diagnosing infections spreading through the blood stream in positively flagged blood cultures. The comprehensive panel covers 87 of the most relevant pathogens, including Gram negative and Gram positive bacteria, and 16 related resistance markers. Interim data from a prospective multicenter evaluation showed 98% concordance with conventional microbiology and Unyvero results were on average available 24 hours earlier than results obtained by routine diagnostic methods.
- The **U.S. FDA trial for the Unyvero LRT Application** in lower respiratory tract infections is almost completed. Prospective and retrospective sample enrolment has been successfully concluded on schedule in the first half of 2016. In less than a year, a total number of more than 2,250 samples including approximately 1,700 prospective and over 550 retrospective patient samples, have been enrolled at nine clinical trial sites across the U.S., including, amongst others, Mayo Clinic, Northwestern University, Johns Hopkins Hospital, UCLA and Columbia University Medical Center.
- Curetis has continued its commercial expansion in both the United States and Europe. In the U.S., the Company has appointed **Christopher M. Bernard** as **President and Chief Executive Officer** of the newly-formed North American subsidiary **Curetis USA, Inc.** Christopher Bernard is a seasoned executive with significant expertise in sales, marketing and commercialization of in-vitro diagnostic platforms. Prior to Curetis, he has worked in several executive management roles at Epic Sciences, Metabolon, Inc., Abaxis, Inc. and Cytoc Corporation (Hologic, Inc.). At Curetis, he will be responsible for the development of the new subsidiary and will lead the marketing and sales initiatives of Curetis in the U.S..

In Europe, the Company has hired **Willem Haagmans** as **Head of Sales EMEA**. He brings a strong track record and extensive leadership experience with both large and small-to-medium sized molecular diagnostics companies. Prior to joining Curetis, he worked as General Manager Benelux at Beckman Coulter. Previously, he held

international management positions at Roche, Nimblegen, and Vela Diagnostics.

In addition, the Company has hired **key commercial staff** in the **UK, France** and **Benelux** that is currently on boarded. This new staff will significantly strengthen Curetis' direct commercial footprint and position the Company to accelerate new Unyvero installations in these key markets.

Curetis has also established **wholly owned sales subsidiaries** in the **UK** in May and in **the Netherlands** for the Benelux area in June and is in the process of setting up an additional subsidiary in France.

- In June 2016, the Company signed an exclusive, three-year **distribution agreement** with **Axon Lab AG** for Curetis' Unyvero products in Central and Eastern European countries, including Austria, the Czech Republic, Slovakia, Slovenia and Croatia.
- The Company is in the final stage of completing the development of a **second-generation Unyvero ITI Application Cartridge** and is progressing the development of its **IAI Intra-Abdominal Infection Cartridge**. In addition, the partnered **Sepsis Host Response program** is progressing according to plan.
- Curetis has continued to expand the **installed base** of Unyvero Analyzers to 113 as of June 30, 2016 (vs. 70 instruments as of June 30, 2015).
- During the Annual Shareholder Meeting held on June 16, 2016, **Dr. Prabhavathi Fernandes**, CEO of Cempra Pharmaceuticals Inc., Chapel Hill, NC, USA, has been elected as a **member of the Curetis N.V. Supervisory Board**. Dr. Prabhavathi Fernandes has profound knowledge in infectious diseases and antibiotics as well as experience in successfully founding, building and leading several biotech companies and taking one public on Nasdaq, raising more than half a billion U.S. dollars. Moreover, Dr. Holger Reithinger and Dr. Rudy Dekeyser were re-elected for another one-year term, respectively. In addition, the proposed resignation of Dr. Frank Muehlenbeck, the creation of a new Stock Option Program for the Company and associated changes to the Supervisory Board remuneration policy as well as changes to the Management Board's Remuneration Policy and Stock Option grants were also approved by the shareholders.
- Additionally, Curetis has established a **Medical Advisory Board** with experts from the US (Robin Patel, MD, Mayo Clinic), Belgium (Jean-Louis Vincent, MD, Erasme University Hospital), Switzerland (Reno Frei, MD, University Hospital Basel, as well as Laurent Poirel, MD, University of Fribourg), and Germany (Mathias Pletz, MD, Jena University Hospital). The advisors bring strong expertise in intensive care, clinical microbiology, sepsis, prosthetic joint infections, and antibiotic resistance.

Financial Highlights, First Half-Year 2016

- **Revenues:** EUR 655 thousand (vs. EUR 742 thousand in the first half-year of 2015).
- **Expenses:** EUR 7.5 million (vs. EUR 6.4 million in the first half-year of 2015).
- **Gross loss:** EUR 9 thousand (vs. a gross profit of EUR 77 thousand in the first half-year of 2015).
- **Net loss:** EUR 6.7 million (vs. EUR 12.4 million in the first half-year ended June, 30 2015).
- **Cash and cash equivalents:** EUR 39.7 million as of June 30, 2016 (vs. EUR 46.1 million as of December 31, 2015).
- **Net cash burn** in the first half-year 2016 was EUR 6.4 million.

Anticipated Milestones

- For the **U.S. FDA trial** with the **Unyvero LRT Application** in lower respiratory tract infections, Curetis targets completion of the contrived specimen study, molecular composite comparator testing for all samples and ancillary preclinical work packages in the second half of 2016, with top line data expected to be available after unblinding.
- The submission of Curetis' (de novo) **510(k) data package** to the **U.S. FDA** is anticipated by year-end 2016 with the goal of achieving FDA clearance for Unyvero and starting commercialization in the first half of 2017.
- The Company has begun preparing to enter **U.S. FDA trials** for its next U.S. product. To that end, Curetis has already submitted a so-called pre-submission package to the U.S. FDA in which the Company has outlined the intended use claims and a proposed study design for a U.S. version of its **Unyvero ITI Cartridge**. Depending on the FDA's feedback later this year, the Company will determine appropriate next steps and timelines for a U.S. FDA trial for its second U.S. product. Further details will be announced later this year.
- The Company and its partner BCB are progressing the regulatory trials for **product clearance in China** with important data and preclinical parts of the trial expected to be run in H2-2016 under the auspices of the Beijing Institute of Medical Device Testing of the Beijing Center for Medical Device Quality Supervision and Testing of the Chinese State Food and Drug Administration (CFDA). BCB has expressed its goal to obtain CFDA clearance in 2017 and to begin commercialization in mainland China thereafter. **Commercial efforts in Hong Kong and Taiwan**, which are not subject to first obtaining CFDA approval, have already begun with a first commercial installation at a major hospital in Hong Kong successfully completed in July.
- Curetis' partner **Acumen** has recently submitted a filing to the regulatory authorities in **Singapore** with the goal of achieving regulatory clearance for the **Unyvero HPN (Hospitalized Pneumonia) Application** which is equivalent to the current EU P55 Pneumonia cartridge. Acumen has also started preparing respective filing documents for the **Unyvero BCU Blood Culture Application** and plans to apply for the **ITI Application** once the second-generation has been CE-IVD marked in Europe. Regulatory approval for the Unyvero Platform and Products is expected not before 2017.
- The **Japanese Patent Office** has decided to grant a **key patent for the Unyvero Platform** combining PCR amplification and array-based detection in the Unyvero Cartridges. The patent will become effective with the issuance of an official note by the Japanese patent office.
- The European launch of the **second-generation Unyvero ITI Application Cartridge** is expected in Q3-2016. Completion of development of the **IAI Intra-Abdominal Infection Cartridge** is planned by year-end 2016. Moreover, the partnered **Sepsis Host Response program** is anticipated to be completed not before the end of 2017.
- Together with its **Medical Advisory Board**, the Company is in the process of defining and prioritizing multiple additional **new infectious disease indication areas** of high unmet medical need for further Unyvero Cartridge developments and will update its product pipeline shortly.
- With the commercial teams in all **European direct selling markets** now in place and getting up to speed, the Company believes that there are several dozen well-qualified Unyvero placement opportunities for H2-2016. Therefore, the Company reiterates its guidance of an expected **global installed base of 150 to 200 Unyvero Analyzers**

by year-end 2016.

- Following the formation of **Curetis USA, Inc.** in San Diego, CA, and the start of recruitment of a core team of senior U.S. marketing and sales leadership, the Company is planning direct commercialization of all Unyvero products in the U.S. hospital market.
- Further **Curetis subsidiaries** are to be incorporated in **France** and **Switzerland** in Q3-2016.

"We are very satisfied that we could meet our key corporate milestones in the first six months of 2016," said Oliver Schacht, Chief Executive Officer of Curetis. "As our product and commercial development is progressing well, we are convinced that we can continue to deliver on the anticipated milestones communicated during our IPO. The market launch of our BCU Cartridge and the expected roll-out of our second-generation ITI and the new IAI Application Cartridges provide opportunities for further commercial upside. With our EMEA team fully built out by mid-year, we are now looking forward to accelerating our commercial momentum in the second half of 2016."

Financial Development and Guidance

For the six months ended June 30, 2016, revenues were EUR 655 thousand, as compared to revenues of EUR 742 thousand in the same period 2015. While revenues in the first half of 2015 included EUR 297 thousand Unyvero Systems sales to a pharma partner, revenues in the same period in 2016 did not include any such system sales to pharma. In general, revenues are expected to remain volatile from quarter-to-quarter, as early-stage instrument sales to distribution partners are unevenly spread throughout the year.

Expenses in the first six months of 2016 amounted to EUR 7.5 million (vs. EUR 6.4 million in the first half-year 2015). The increase is in line with the operational and organizational growth and driven by higher R&D expenses, increased marketing, sales and distribution costs as well as G&A costs.

Gross loss for the first six months of 2016 totaled EUR 9 thousand, compared with a gross profit of EUR 77 thousand for the same period in 2015. The relatively low gross margin is mainly due to IFRS accounting requiring idle capacity of manufacturing line and facility to be allocated to cartridge output.

Net loss for the first six months of 2016 was EUR 6.7 million compared with a net loss of EUR 12.4 million in the same period in 2015.

As of June 30, 2016, the Company had a strong cash position of EUR 39.7 million cash on hand and a net cash burn of EUR 6.4 million for all operating, investment and financing activities combined. The company expects a cash position of 31 to 32 million at the end of 2016.

Earnings Conference Call and Webcast

Curetis will host a public earnings conference call and webcast today, August 19, 2016, at 03:00pm CET / 09:00am EST to discuss the financial results of the first six months 2016, highlight the most important events and provide an outlook for the second half 2016 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 curetis0816). The live webcast and a replay will be available at <http://curetis120416-live.audio-webcast.com>

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

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 2016 will be available as of today, August 19, 2016, at <http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html>

Disclaimer

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on the Curetis Unyvero technology is currently available for sale in the United States of America or Canada. The analytical and clinical performance characteristics of any Curetis Unyvero product which may be sold at some future point in time in the U.S. have not yet been established.

###

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. The company is based in Holzgerlingen near Stuttgart, Germany. Curetis has signed collaboration agreements with Heraeus Medical and Cempra Inc. as well as several international distribution agreements covering many countries across Europe, the Middle East and Asia.

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.

The information contained in this press release has been carefully prepared. However, Curetis bears and assumes no liability of whatever kind for the correctness and completeness of the information provided herein. Curetis does not assume an obligation of whatever kind to update or correct information contained in this press release whether as a result of new information, future events or for other reasons.

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.

Contact details

Curetis
Max-Eyth-Str. 42
71088 Holzgerlingen, Germany
Tel. +49 7031 49195-10
pr@curetis.com or ir@curetis.com
www.curetis.com - www.unyvero.com

International Media & Investor Inquiries

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68

U.S. Media & Investor Inquiries

The Ruth Group
Lee Roth
lroth@theruthgroup.com
Tel. +1 646 536 7012

CURETIS N.V.
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER
COMPREHENSIVE INCOME (UNAUDITED)

For the period ended June 30, 2016

in Euro	six months ended June 30, 2016	six months ended June 30, 2015
Revenue	654,682	742,035
Cost of sales	663,657	665,151
Gross loss / gross margin	-8,975	76,884
Distribution costs	2,095,227	1,396,725
Administrative expenses	1,406,161	1,365,739
Research & development expenses	3,301,211	2,943,167
Other income	85,976	41,235
Operating loss	-6,725,598	-5,587,512
Finance income	61,343	5,493
Finance costs	41,127	8,866
Finance income / costs fair value measurement	0	6,782,819
Finance costs - net	20,216	-6,786,192
Profit / loss before income tax	-6,705,382	-12,373,704
Income tax expenses	-	-
Profit / loss for the half- year	-6,705,382	-12,373,704
Other comprehensive income for the half-year, net tax	6,044	-
Total comprehensive income for the half-year	-6,699,338	-12,373,704

Comparative figures for six months ended June 30, 2015, are those of Curetis GmbH (former AG).

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

As of June 30, 2016

in Euro	June 30, 2016	December 31, 2015
Current assets	45,115,373	50,573,547
Cash and cash equivalents	39,708,145	46,060,397
Trade receivables	589,879	1,072,131
Inventories	4,395,280	2,786,887
Other current assets	422,069	654,132
Non-current assets	6,033,064	6,823,465
Intangible assets	573,324	645,120
Property, plant and equipment	4,928,949	5,605,496
Other non-current assets	236,788	223,846
Other non-current financial assets	294,003	349,003
Deferred tax assets	-	-
Total assets	51,148,437	57,397,012

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

As of June 30, 2016

in Euro	June 30, 2016	December 31, 2015
Current liabilities	3,014,748	2,446,095
Trade and other payables	974,908	863,342
Liability PSOP	367,308	367,308
Provisions current	2,300	29,300
Other current liabilities	959,471	676,502
Other current financial liabilities	710,761	509,643
Non-current liabilities	38,035	155,926
Provisions non-current	38,035	38,035
Other non-current financial liabilities	-	117,891
Total liabilities	3,052,783	2,602,021
Equity	48,095,654	54,794,991
Share capital	155,384	155,384
Capital reserve	152,793,347	152,793,347
Other reserves	6,592,373	6,592,372
Currency translation differences	6,044	-
Retained earnings	-111,451,494	-104,746,112
Total equity and liabilities	51,148,437	57,397,012

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

For the period ended June 30, 2016

in Euro	six months ended June 30, 2016	six months ended June 30, 2015
Profit before income tax	-6,705,382	-12,373,704
Adjustment for:		
- Net finance income / costs	-20,216	6,786,192
- Depreciation, amortization and impairments	897,324	834,625
- Gain on disposal of fixed assets	1,550	1,889
- Changes in provisions	-26,998	1,444,870
- Net exchange differences	39,316	-4,635
Changes in working capital relating to:		
- Inventories	-1,608,393	-45,528
- Trade receivables and other receivables	756,373	-351,259
- Trade payables and other payables	547,066	181,731
Effects of exchange rate differences not realized from consolidation	6,044	0
Income taxes received (+) / paid (-)	0	0
Interests paid (-)	-41,127	-3,373
Net cash flow provided by operating activities	-6,154,443	-3,529,192
Payments for intangible assets	-3,524	-2,230
Payments for property, plant and equipment	-147,008	-251,606
Interests received	61,343	1,889
Net cash flow used in investing activities	-89,189	-251,947
Payments for finance lease liabilities	-69,304	-66,078
Cash received from capital increase	0	6,789,027
Net cash flow provided by financing activities	-69,304	6,722,949
Net increase (decrease) in cash and cash equivalents	-6,312,936	2,941,810
Net cash and cash equivalents at the beginning of the year	46,060,397	2,993,883
Net increase (decrease) in cash and cash equivalents	-6,312,936	2,941,810
Effects of exchange rate changes on cash and cash equivalents	-39,316	4,635
Net cash and cash equivalents at the end of the half-year	39,708,145	5,940,328

Comparative figures for six months ended June 30, 2015, are those of Curetis GmbH (former AG)