



## **Curetis Reports Full-Year 2016 Financial Results and Updates 2017 Guidance**

- *Company strengthens commercial footprint in EMEA; expands installed base by 47%***
- *Acquisition of GEAR database and Gyronimo platform increase scale and scope of Unyvero offering***
- *Preparation for Unyvero market launch in the U.S.***

**Amsterdam, the Netherlands, and Holzgerlingen, Germany, April 12, 2017** -- 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, 2016, and provided further details on its outlook for 2017.

### **2016 Operational Highlights**

- Reported positive topline data from U.S. FDA trial of Unyvero System and LRT Cartridge. Submitted 510(k) application for U.S. FDA clearance of Unyvero on January 5, 2017.
- Successfully completed two key acquisitions: GEAR database of proprietary antibiotic resistance markers and IP from Siemens, qPCR platform Gyronimo from Carpegen / Systec.
- Increased installed base of Unyvero Analyzers to 142 by year-end of 2016 and 151 by January 2017, a 47% growth rate from 103 at the end of year 2015.
- Launched CE-IVD marked Unyvero BCU Cartridge for severe bloodstream-associated infections.
- Completed development of Unyvero Intra-Abdominal Infection (IAI) Cartridge.
- Launched second generation CE-IVD marked Unyvero ITI Cartridge with a significantly broadened panel.
- Secured up to EUR 25 million debt financing from the EIB (European Investment Bank).
- Appointed Christopher M. Bernard as President & CEO of newly-formed U.S. subsidiary and Willem Haagmans Head of Sales EMEA.
- Completed build-out of EMEA direct sales teams and commercial subsidiaries in the UK, France, the Netherlands and Switzerland.
- Elected Prabhavathi Fernandes, Ph.D., to supervisory board.
- Established Medical Advisory Board (MAB) with leading experts from multiple fields.
- Expanded distribution partnership network to a total of 13, now covering a total of 26 countries.

### **2016 Financial Highlights**

- Revenues: EUR 1.3 million (EUR 2.1 million in 2015).
- Expenses: EUR 16.7 million total cost of sales, distribution costs, administrative expenses and research & development expenses (EUR 14.3 million in 2015).
- Operating loss: EUR 15.2 million (EUR 12.1 million in 2015).
- Net loss: EUR 15.2 million (net profit of EUR 13.8 million in 2015).

- Cash & cash equivalents: EUR 22.8 million plus a VAT receivable of EUR 1.2 million as of Dec. 31, 2016 (EUR 46.1 million plus a VAT receivable of EUR 0.5 million as of December 31, 2015); excluding the EIB debt financing facility of up to EUR 25 million, of which none has been disbursed as of April 12, 2017 but expected disbursement of EUR 10 million tranche later in April 2017.
- Net cash burn from operating activities: EUR 15.7 million (EUR 8.5 million in 2015)
- Net cash burn from investing activities: EUR 7.4 million (EUR 1.1 million in 2015) primarily driven by the two asset acquisition deals.

Commenting on Curetis' 2016 results, Oliver Schacht, CEO of the Company stated: "We started 2016 as a publicly listed company and have continued to execute on our growth strategy at full speed. We are proud that we have achieved all relevant milestones we laid out, and that we also added considerable assets to our company which will generate results in the coming years in terms of new products and business opportunities. With a strong cash position and access to an additional up to EUR 25 million under the non-dilutive debt financing agreement with the European Investment Bank, we are in a very good position to ensure continuous corporate growth as well as the significant expansion of our Unyvero Platform, our pipeline and our commercial reach – both to new market segments and to additional infectious disease indication areas."

#### **Anticipated Milestones**

- Based on current forecasts and expansion plans, Curetis expects the Unyvero Installed Base to grow to 200 to 240 Analyzers by the end of 2017. Significant growth in cartridge sales expected in 2017 as well.
- Expected FDA clearance and U.S. launch of Unyvero and its LRT Cartridge in H2-2017. Further details are expected following Q2-2017 "Submissions Issues" meeting with the FDA. Depending on the timing of the FDA clearance, Curetis aims to start its second FDA trial later in 2017. The Company targets an installed base of 25 to 40 Unyvero Analyzers in the U.S. within 6 to 9 months of launch.
- In conjunction with the expected U.S. FDA clearance, the Company intends to expand its U.S. team by 20+ new hires in sales, application specialists, field service, and operations later this year.
- EMEA launch of the Intra-Abdominal Infection Cartridge (IAI) is targeted for ECCMID in April 2017.
- Plans to add further differentiated Unyvero Cartridges to the pipeline with next cartridges for urinary tract infections (UTI) and sepsis host response (SHR) already in development.
- Curetis expects to drive development of Gyronimo Analyzer module toward completion by end of 2018, with commercial launch not expected before early 2019.
- The Company intends to accelerate its product pipeline from 1-2 new tests p.a. to 3-4 new tests p.a. over the coming years, giving customers broader menu faster.
- Continued development of Unyvero as an integrated any-plex platform, while focusing on leveraging unique GEAR antibiotic resistance content and complementing internal IVD development pipeline through strategic partnering.
- Curetis expects to complete the establishment of a Vienna-based operation dedicated to leveraging the GEAR asset with core team of bioinformatics and project management experts headed by Dr. Andreas Posch (Director GEAR Bio-IT) in Q2-2017.
- Continued submission of applications for non-dilutive grant funding internationally and opening of GEAR for innovative partnering opportunities with IVD, NGS and pharma companies with potential upside from deal-making activities in the coming 12 to 24 months.
- Completion of the Chinese CFDA trial to be carried out by BCB is not expected before end of 2018 with no significant commercial impact before 2019. This is subject

to evolving CFDA regulatory framework and the need for a significant pre-clinical data package.

- Curetis will continue to drive the gradual evolution of its Supervisory Board composition to include additional independent non-executive directors with significant industry expertise in the coming years. Dr. Nils Clausnitzer will stand for election at the upcoming AGM on June 23, 2017.
- In April 2017, Dr. Melissa Miller from the University of North Carolina has joined the MAB to further strengthen Curetis' KOL network.

## **Full-year 2016 Financial Results**

For the twelve months ended December 31, 2016, revenues were EUR 1.3 million, as compared to revenues of EUR 2.1 million in 2015. The underlying product revenues (excluding 2015 non-recurring revenues of EUR 0.9 million in system sales to Asian partners for clinical trials and regulatory clearances and EUR 0.3 million of pharma revenue) grew by ca. 44%, from EUR 0.9 million in 2015 to EUR 1.3 million in 2016.

Gross loss for the year totaled EUR 290 thousand, compared with a gross loss of EUR 74 thousand in 2015 as under IFRS accounting the cost of goods for the Unyvero cartridges still include significant elements of as-yet unutilized capacity to allow for future expansion in manufacturing output. The full-year 2016 gross margin was -22.2%, compared with -3.5% for 2015.

Operating loss in 2016 totaled EUR 15.2 million, compared with EUR 12.1 million in 2015. The increased operating loss was mainly related to acceleration of the Company's commercial and global expansion.

Net loss for the year was EUR 15.2 million compared with a net profit of EUR 13.8 million in 2015. This difference is due to the finance income of EUR 27.8 million net, resulting mainly from the fair value measurement of the preferred and common shares of Curetis AG, triggered by the corporate reorganization of the Company in preparation for its IPO in November 2015.

On 31 December 2016, Curetis Group's cash, cash equivalents and financial assets amounted to EUR 22.8 million (excluding EIB loan facility of up to EUR 25 million) compared with EUR 46.1 million on 31 December 2015. The Company expects to draw down the first tranche of EIB debt financing in 2017 and believes to be well-funded for the coming 12 to 18 months. However, with expected increases in operating cash outflows for commercial team expansion in the U.S. as well as incremental low single digit million in R&D expenditure due to Gyronimo, the Company is also assessing all possible tactical and strategic financing options on the debt, equity and non-dilutive grant funding as well as partnering cash-inflows for the coming year. Curetis has requested disbursement of EUR 10 million in debt from the EIB in early April 2017 and expects the tranche to be paid in the coming weeks.

## **Earnings Conference Call and Webcast**

Curetis will host a public earnings conference call and webcast today, April 12, 2017, at 03:00pm CET / 09:00am EST to discuss the financial results of 2016, highlight the most important events and provide an outlook for 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>

For participating in the earnings call conference please access the presentation at <http://www.audio-webcast.com> using the passcode curetis0417.

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\\_%20UKFELBRI1SU7.pdf](http://events.arkadin.com/ev/docs/International%20Access%20Numbers_%20UKFELBRI1SU7.pdf)

The full annual financial report 2016 will be available as of today, April 12, 2017, at <http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html>

The live webcast and a replay will be available at <http://curetis120417-live.audio-webcast.com>

#### **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.**

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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](http://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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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.

According to §§ 190 ff. German Reorganization Act (UmwG) and by way of enrolment in the commercial register at district court Stuttgart on March 15, 2016 Curetis plc (AG) changed its legal form into Curetis Ltd. (GmbH).

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## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

| in Euro   | 2016               | 2015               |
|---|--------------------|--------------------|
| Revenue [4]   | 1,306,398          | 2,086,726          |
| Cost of sales [5]                                   | 1,596,267          | 2,160,778          |
| <b>Gross loss / gross margin</b>                    | <b>-289,869</b>    | <b>-74,052</b>     |
| Distribution costs [7]                              | 5,090,697          | 2,786,967          |
| Administrative expenses [8]                         | 3,023,585          | 2,598,424          |
| Research & development expenses [9]                 | 7,026,938          | 6,712,341          |
| Other income [11]                                   | 197,838            | 121,139            |
| <b>Operating loss</b>                               | <b>-15,233,251</b> | <b>-12,050,645</b> |
| Finance income                                      | 101,056            | 29,566             |
| Finance costs                                       | 29,765             | 1,929,762          |
| Finance income / costs fair value measurement       | 0                  | -27,790,433        |
| <b>Finance costs - net [12]</b>                     | <b>71,291</b>      | <b>25,890,237</b>  |
| <b>Profit / loss before income tax</b>              | <b>-15,161,960</b> | <b>13,839,592</b>  |
| Income tax expenses [13]                            | 10,336             | -                  |
| <b>Profit / loss for the period</b>                 | <b>-15,172,296</b> | <b>13,839,592</b>  |
| Other comprehensive income for the year, net of tax | -27,736            | -                  |
| <b>Total comprehensive income for the period</b>    | <b>-15,200,032</b> | <b>13,839,592</b>  |
| <b>Earnings / loss per share [14]</b>               | <b>2016</b>        | <b>2015</b>        |
| Basic   | -0.98              | 1.18               |
| Diluted   | -0.98              | 1.18               |

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

### Assets

| in Euro                                 | 31 December 2016  | 31 December 2015  |
|---|-------------------|-------------------|
| <b>Current assets</b>                   | <b>30,272,260</b> | <b>50,573,547</b> |
| Cash and cash equivalents [15]          | 22,832,117        | 46,060,397        |
| Trade receivables [16]                  | 101,398           | 1,072,131         |
| Inventories [18]                        | 5,870,167         | 2,786,887         |
| Other current assets [19]               | 1,468,578         | 654,132           |
| <b>Non-current assets</b>               | <b>12,514,826</b> | <b>6,823,465</b>  |
| Intangible assets [20]                  | 7,520,048         | 645,120           |
| Property, plant and equipment [21]      | 4,466,462         | 5,605,496         |
| Other non-current assets [22]           | 211,870           | 223,846           |
| Other non-current financial assets [23] | 316,446           | 349,003           |
| Deferred tax assets [31]                | -                 | -                 |
| <b>Total assets</b>                     | <b>42,787,086</b> | <b>57,397,012</b> |

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

### Liability & Equity

| in Euro                                      | 31 December 2016  | 31 December 2015  |
|--|-------------------|-------------------|
| <b>Current liabilities</b>                   | <b>2,384,156</b>  | <b>2,446,095</b>  |
| Trade and other payables [24]                | 721,113           | 863,342           |
| Liability PSOP [25]                          | -                 | 367,308           |
| Provisions current [26]                      | 51,000            | 29,300            |
| Tax liabilities                              | 10,128            | -                 |
| Other current liabilities [27]               | 1,120,299         | 676,502           |
| Other current financial liabilities [28]     | 481,616           | 509,643           |
| <b>Non-current liabilities</b>               | <b>40,522</b>     | <b>155,926</b>    |
| Provisions non-current [26]                  | 40,522            | 38,035            |
| Other non-current financial liabilities [29] | -                 | 117,891           |
| Deferred tax liability [31]                  | -                 | -                 |
| <b>Total liabilities</b>                     | <b>2,424,678</b>  | <b>2,602,021</b>  |
| <b>Equity [32]</b>                           | <b>40,362,408</b> | <b>54,794,991</b> |
| Share capital                                | 155,384           | 155,384           |
| Capital reserve                              | 152,793,347       | 152,793,347       |
| Other reserves                               | 7,359,821         | 6,592,372         |
| Currency translation differences             | -27,736           | -                 |
| Retained earnings                            | -119,918,408      | -104,746,112      |
| <b>Total Equity and liabilities</b>          | <b>42,787,086</b> | <b>57,397,012</b> |

## CONSOLIDATED STATEMENT OF CASH FLOWS

| in Euro  | 2016               | 2015              |
|--|--------------------|-------------------|
| Profit before income tax   | -15,172,296        | 13,839,592        |
| Adjustment for:  |                    |                   |
| - Net finance income / costs [12]                                    | -71,291            | -25,890,237       |
| - Depreciation, amortization and impairments [20, 21]                | 1,744,049          | 1,708,401         |
| - Gain on disposal of fixed assets                                   | 1,550              | 15,586            |
| - Changes in provisions [25, 26]                                     | 23,124             | -784,082          |
| - Changes in equity settled stock options                            | 767,448            | 0                 |
| - Changes in the PSOP-liability [25]                                 | -367,308           | 3,045,839         |
| - Net exchange differences   | -29,811            | -10,404           |
| Changes in working capital relating to:                              |                    |                   |
| - Inventories [18]   | -3,083,280         | 366,250           |
| - Trade receivables and other receivables [16, 19, 22, 23]           | 200,820            | -1,530,884        |
| - Trade payables and other payables [24, 25, 28, 29]                 | 270,338            | 773,011           |
| Effects of exchange rate differences not realized from consolidation | 2,075              | 0                 |
| Income taxes received (+) / paid (-)                                 | 0                  | 0                 |
| Interest paid (-)  | -9,612             | -30,423           |
| <b>Net cash flow provided by operating activities</b>                | <b>-15,724,194</b> | <b>-8,497,351</b> |
| Payments for intangible assets                                       | -7,024,734         | -487,439          |
| Payments for property, plant and equipment                           | -455,695           | -608,583          |
| Proceeds from sale of property, plant and equipment                  | 0                  | 0                 |
| Interest received  | 51,092             | 29,566            |
| <b>Net cash flow used in investing activities</b>                    | <b>-7,429,337</b>  | <b>-1,066,456</b> |
| Payments for finance lease liabilities                               | -104,560           | -133,749          |
| Cash received from capital increase                                  | 0                  | 13,578,054        |
| Proceeds from issue of ordinary shares                               | 0                  | 44,310,330        |
| Payments for financing costs for IPO of old shares                   | 0                  | -1,899,339        |
| Transaction costs for issue of ordinary shares                       | 0                  | -3,235,379        |
| <b>Net cash flow provided by financing activities</b>                | <b>-104,560</b>    | <b>52,619,917</b> |
| <b>Net increase (decrease) in cash and cash equivalents</b>          | <b>-23,258,091</b> | <b>43,056,110</b> |
| 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                 | -23,258,091        | 43,056,110        |
| Effects of exchange rate changes on cash and cash equivalents        | 29,811             | 10,404            |
| <b>Net Cash and cash equivalents at the end of the period</b>        | <b>22,832,117</b>  | <b>46,060,397</b> |