# 2017

# FIRST QUARTER BUSINESS AND FINANCIAL UPDATE

curetis

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# FIRST QUARTER 2017 OPERATIONAL AND BUSINESS HIGHLIGHTS YTD

## UNYVERO LRT U.S. FDA SUBMISSION

- Curetis has 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 on 5 January 2017. The FDA trial submission is for Unyvero as an aid in the diagnosis of lower respiratory tract infections in the U.S. 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 spring, Curetis received a letter from the FDA with questions for details on pathogens, antibiotic resistance markers, sample types, etc. To clarify remaining open issues, a so-called `submissions Issues` meeting was held on 21 April 2017. Following this meeting, Curetis has submitted draft minutes to the FDA. Curetis continues to respond to the Agency's requests during interactive review, and expects to provide complete responses on remaining open items in the coming months. Curetis expects a clearance decision from the FDA in the second half of 2017.
- The Company also continues to prepare for its second FDA trial with the goal of clearing the second Unyvero Cartridge in the U.S. The second Unyvero Cartridge is expected to be a version of the Unyvero Implant and Tissue Infection (ITI) Cartridge, which is tailored to U.S. customer and market needs with a key focus on (prosthetic) joint infections (PJI).

## CORPORATE GROWTH

- Curetis has established a new wholly-owned subsidiary - Ares Genetics GmbH - in Vienna, Austria. Ares Genetics builds on the GEAR GEnetic Antibiotic Resistance and Susceptibility Database and associated assets acquired from Siemens in 2016. The Company will use GEAR to investigate the genetic foundations of antibiotic resistance and to develop and subsequently commercialize novel approaches to improve the rapid detection of antibiotic resistance in patients with microbial infections as well as tools to accelerate antibiotic research. Ares Genetics is headed by Dr. Andreas Posch, who joined Curetis in March from Siemens as Director GEAR & Bio-IT and as one of the Managing Directors of Ares Genetics. Dr. Posch headed the bioinformatics activities at Siemens Healthcare and was responsible for GEAR prior to the asset transfer to Curetis. Via its subsidiary Ares Genetics, Curetis will use GEAR as a biomarker engine to rapidly identify potential novel biomarkers, biomarker combinations, and algorithms predicting antibiotic resistance, as well as potential novel targets for antimicrobial drugs. In the future, GEAR may also pave the way towards fully genetic antibiograms and provide a reference for NGS-based clinical diagnostics.
- To advance R&D and product and platform related growth, Curetis has drawn down a first tranche of EUR 10 million of the non-dilutive debt financing facility provided through the European Investment Bank (EIB) in April 2017.

## PRODUCT DEVELOPMENT

- Curetis has successfully completed the CE performance evaluation study and subsequently launched its Unyvero IAI Intra-Abdominal Infections (IAI) Cartridge during ECCMID 2017 in April. The CE-IVD marked IAI application aims to support clinicians in 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.

- Together with a clinical lab partner in the U.S., Curetis has completed a clinical feasibility study for its U.S. version of a PJI panel (based on the European ITI cartridge). Having run over 80 synovial fluid patient samples with available clinical microbiology data, the overall weighted average sensitivity after discrepant result resolution was 93.5% at an overall weighted average specificity of 99.8%. The panel identified several anaerobic pathogens otherwise missed by standard of care microbiology. Next step will be finalization of specs for a U.S. panel of pathogens and resistance markers to be included, and completion of development of such a U.S. PJI cartridge ready for starting clinical trials in the U.S. later this year.
- All other R&D programs and product development projects remain on track and in line with guidance provided during the financial year 2016 conference call in April.

## CLINICAL STUDIES

- Several presentations at ECCMID 2017 demonstrate the advantages of rapid diagnostic testing with the Unyvero Implant and Tissue Infection Cartridge (ITI) in Prosthetic Joint Infections as well as clinical and health economic benefits. Rapid testing of sonication fluid from explanted joint prostheses demonstrated a shortened length of hospital stay and savings of EUR 2,040 on average per patient. In addition, two studies from Charité showed for the first generation Unyvero ITI that performance was similar to culture for sonication fluids and synovial fluids with the advantages of shorter processing time and of handling a fully automated Unyvero System. One of the aforementioned studies calculated the advantage of time-to-result as 5 hours versus 6.8 days.
- Researchers at the Institute of Medical Microbiology, University Hospital Essen (Essen, Germany) published data on Unyvero P55 concluding that the "Unyvero Application is a useful diagnostic tool for the early and rapid detection of pathogens in respiratory specimens". They reported a significantly higher detection rate when using Unyvero as compared to culture methods and a considerably reduced time-to-result, from a median of 48h to a median of 7.5 hours. The team has tested the Unyvero P55 Pneumonia Cartridge in daily clinical routine with 439 respiratory specimens from 342 patients. Results from the European Study were presented during this year's 5th Joint Conference of the DGHM & VAAM / VAAM Annual Meeting 2017 and published.
- Data on the Unyvero System and the LRT Application Cartridge will be presented at the American Thoracic Society International Conference, in Washington D.C. on May 19-24, 2017. The data will be presented by Dr. Robin Patel at a workshop session WS7: Molecular Diagnostics for Acute Pneumonia: Practical Impact and Future Horizons, titled "Novel Pneumonia Diagnostics: View from the Clinical Microbiology Laboratory" (May 24, 2017; 12:25-12:45PM). Dr. Patel is Professor of Medicine and Professor of Microbiology, Director of the Clinical Bacteriology Laboratory and the Infectious Diseases Research Laboratory and Chair of the Division of Clinical Microbiology, Mayo Clinic, U.S.

  In addition, Curetis will host its inaugural Circle of Diagnostic Excellence (CODE) forum on May 23, 2017, at International Square Building, 1875 I Street, Fifth Floor "The Capitol Room" Washington, DC 20006, U.S. World renowned experts in the field of pulmonology will gather to discuss advanced approaches to diagnosis of lower respiratory tract infections and exchange knowledge about new ways to potentially improve the management of these patients.
- Significant clinical data updates on the Unyvero System and LRT Application Cartridge as an aid in the diagnosis of pneumonia / lower respiratory tract infections will be presented at ASM Microbe 2017, being held June 1-5 in New Orleans, LA, U.S. Detailed data from Curetis' U.S. FDA clinical study of the Unyvero System and the LRT cartridge for the diagnosis of lower respiratory tract infections will be presented by Dr. Matthew Sims, Director, Infectious Diseases Research at Beaumont Research Institute and one of the U.S. FDA study's principal investigators. Dr. Sims will present the study during an oral presentation titled *Multicenter Evaluation of the Curetis*

*Lower Respiratory Tract Infection Cartridge on the Unyvero-Platform* in session 481, "Pneumonia: Novel Epidemiology, Novel Approaches" (June 5, 2017, 12:15-12:30 PM, Room 208).

- In addition, Dr. Sims will present clinical data from the portion of the study conducted at Beaumont Hospital, Royal Oak, MI. His presentation *Potential Impact of Rapid Diagnostics in Management of Suspected Pneumonia*, will be given in the session "Antimicrobial and Diagnostic Stewardship" (June 2, 2017, 12:45-2:45 PM, Exhibit Hall D, Exhibit and Poster Hall).

## MEDICAL ADVISORY BOARD

- Curetis' Medical Advisory Board has been expanded. 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. While her research interests span from the epidemiology of drug resistant organisms to accurate cost-effective molecular detection of viral infections, her special interest applies to health economic evaluation with regard to the implementation of new molecular technologies.
- The Medical Advisory Board now comprises 6 renowned experts from the U.S. (Robin Patel, MD, Mayo Clinic; Melissa Miller, Ph.D., University of North Carolina), Belgium (Jean-Louis Vincent, MD, Erasme University Hospital), Switzerland (Reno Frei, MD, University Hospital Basel; Laurent Poirel, University of Fribourg), and Germany (Mathias Pletz, MD, Jena University Hospital). The advisors bring strong expertise in intensive care, clinical microbiology, antibiotic resistances, pathology, sepsis and prosthetic joint infections. The Medical Advisory Board meets several times per year and chairs roundtables with further key opinion leaders to advise Curetis on important trends and issues as well as novel product concepts.

## INSTALLED BASE

- Curetis' global installed base of Unyvero Analyzers amounted to 151 at the end of the first quarter 2017 (vs. 107 at the end of the first quarter 2016 and compared to 142 at year-end 2016).
- During the first quarter of 2017, over a dozen of new Unyvero Analyzers were shipped and a handful of Analyzers were brought back in following successful completion of customer evaluations. Placements were made in particular at key sites in France and the UK, regions that have picked up momentum since the establishment of dedicated local sales teams in 2016. Several accounts have been progressed from successful product evaluation to contract negotiation stage.
- Customers have finalized several studies providing a base for additional publications demonstrating the value of Unyvero and thereby supporting sales efforts going forward.
- Based on the installed base approaching 160 Unyvero Analyzers during the course of Q2 with several recent shipments to key sites in the UK, the Company reiterates its guidance of an expected global installed base of 200 to 240 Unyvero Analyzers by year-end 2017.

## SUPERVISORY BOARD

- Dr. Nils Clausnitzer has been nominated as a candidate for Curetis N.V.´s Supervisory Board. The election for a three-year term is to be held during the upcoming Annual General Meeting on June 23, 2017. 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 will run for re-election for another one-year term.

# FIRST QUARTER 2017 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 347.2 k (growing 2.6 times vs. EUR 132.8 k in the first quarter 2016). 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:** EUR 4.7 million (vs. EUR 3.3 million in the first quarter 2016). The increase is in line with the operational and organizational growth, and driven by higher distribution costs as well as G&A costs.
- **Gross loss:** EUR 175.7 k (vs. EUR 30.1 k in the first quarter 2016).
- **Net loss of the period**: EUR 4.4 million (vs. EUR 3.2 million in the first quarter 2016).
- **Cash and cash equivalents**: EUR 19.3 million (vs. EUR 22.8 million as of 31 December 2016). Net cash burn in the first quarter 2017 was EUR 3.5 million. Also, in April 2017 the company has drawn down EUR 10.0 million from the EIB debt financing facility.

# FIRST QUARTER 2017 CONSOLIDATED FINANCIAL STATEMENTS

## CURETIS N.V.

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME (UNAUDITED)

For the period ended 31 March

| in Euro | Three months ended 31 March 2017 | Three months Ended 31 March 2016 |
|---|---|---|
| Revenue | 347,166 | 132,810 |
| Cost of sales | 522,893 | 162,941 |
| Gross loss / gross margin | -175,727 | -30,131 |
| Distribution costs | 1,828,203 | 890,547 |
| Administrative expenses | 854,476 | 715,312 |
| Research & development expenses | 1,470,290 | 1,543,990 |
| Other income | 25,618 | 55,409 |
| Operating loss | -4,303,078 | -3,124,571 |
| Finance income | 11,133 | 38,621 |
| Finance costs | 54,804 | 82,687 |
| Finance costs - net | -43,671 | -44,066 |
| Profit / loss before income tax | -4,346,749 | -3,168,637 |
| Income tax expenses | 5,432 | - |
| Profit / loss for the period | -4,352,181 | -3,168,637 |
| Other comprehensive income for the year, net of tax | -25,979 | - |
| Total comprehensive income for the period | -4,378,160 | -3,168,637 |

| Earnings / loss per share | Three months ended 31 March 2017 | Three months Ended 31 March 2016 |
|---|---|---|
| Basic | -0.28 | -0.20 |
| Diluted | -0.28 | -0.20 |

# CURETIS N.V.

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) - ASSETS

As at 31 March 2017 and 31 March 2016

| in Euro | 31 March 2017 | 31 December 2016 |
|---|---|---|
| Current assets | 26,202,524 | 30,272,260 |
| Cash and cash equivalents | 19,309,529 | 22,832,117 |
| Trade receivables | 202,952 | 101,398 |
| Inventories | 6,042,965 | 5,870,167 |
| Other current assets | 647,078 | 1,468,578 |
| Non-current assets | 12,203,286 | 12,514,826 |
| Intangible assets | 7,513,247 | 7,520,048 |
| Property, plant and equipment | 4,170,680 | 4,466,462 |
| Other non-current assets | 203,579 | 211,870 |
| Other non-current financial assets | 315,780 | 316,446 |
| Deferred tax assets | - | - |
| Total assets | 38,405,810 | 42,787,086 |

# CURETIS N.V.

## STATEMENT OF FINANCIAL POSITION (UNAUDITED) - EQUITY AND LIABILITIES

As at 31 March, 2017 and 31 March 2016

| in Euro | 31 March 2017 | 31 December 2016 |
|---|---|---|
| Current liabilities | 1,930,100 | 2,384,156 |
| Trade and other payables | 515,415 | 721,113 |
| Liability PSOP | - | - |
| Provisions current | 86,000 | 51,000 |
| Tax liabilities | 15,577 | 10,128 |
| Other current liabilities | 922,541 | 1,120,299 |
| Other current financial liabilities | 390,567 | 481,616 |
| Non-current liabilities | 40,522 | 40,522 |
| Provisions non-current | 40,522 | 40,522 |
| Other non-current financial liabilities | - | - |
| Deferred tax liability | - | - |
| Total liabilities | 1,970,622 | 2,424,678 |
| Equity | 36,435,188 | 40,362,408 |
| Share capital | 155,384 | 155,384 |
| Capital reserve | 152,793,347 | 152,793,347 |
| Other reserves | 7,772,073 | 7,359,821 |
| Currency translation differences | -15,026 | -27,736 |
| Retained earnings | -124,270,590 | -119,918,408 |
| Total Equity and liabilities | 38,405,810 | 42,787,086 |

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

For the period ended 31 March, 2017

| in Euro | Three months ended 31 March 2017 | Three months ended 31 March 2016 |
|---|---|---|
| Profit before income tax | -4,352,181 | -3,168,637 |
| Adjustment for: | | |
| - Net finance income / costs | 43,671 | 44,066 |
| - Depreciation, amortization and impairments | 375,209 | 447,570 |
| - Gain on disposal of fixed assets | 0 | 207 |
| - Changes in provisions | 35,000 | -16,000 |
| - Changes in equity settled stock options | 412,252 | 0 |
| - Changes in the PSOP-liability | 0 | 0 |
| - Net exchange differences | 45,980 | 87,325 |
| | | |
| Changes in working capital relating to: | | |
| - Inventories | -172,798 | -980,480 |
| - Trade receivables and other receivables | 728,903 | 1,029,407 |
| - Trade payables and other payables | -452,929 | -44,849 |
| | | |
| Effects of exchange rate differences not realized from consolidation | -33,270 | 0 |
| Income taxes received (+) / paid (-) | 0 | 0 |
| Interest paid (-) | -1,265 | -82,687 |
| Net cash flow provided by operating activities | -3,371,428 | -2,684,078 |
| Payments for intangible assets | -30,093 | -3,524 |
| Payments for property, plant and equipment | -42,534 | -99,200 |
| Proceeds from sale of property, plant and equipment | 0 | 0 |
| Interest received | 3,574 | 38,621 |
| Net cash flow used in investing activities | -69,053 | -64,103 |
| Payments for finance lease liabilities | -36,127 | -34,445 |
| Cash received from capital increase | 0 | 0 |
| Proceeds from issue of ordinary shares | 0 | 0 |
| Payments for financing costs for IPO of old shares | 0 | 0 |
| Transaction costs for issue of ordinary shares | 0 | 0 |
| Net cash flow provided by financing activities | -36,127 | -34,445 |
| | | |
| Net increase (decrease) in cash and cash equivalents | -3,476,608 | -2,782,626 |
| 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 | -3,476,608 | -2,782,626 |
| Effects of exchange rate changes on cash and cash equivalents | -45,980 | -87,325 |
| Net Cash and cash equivalents at the end of the period | 19,309,529 | 43,190,446 |

# CURETIS N.V.

## CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 31 March 2017 and 31 March 2016

| In Euro | Share capital | Capital reserve | Other reserve | Currency transl. diff. | Retained earnings | TOTAL equity |
|---|---|---|---|---|---|---|
| Balance at 1 January 2016 | 155,384 | 152,793,347 | 6,592,372 | 0 | -104,746,112 | 54,794,991 |
| Loss of Q1-2016 | | | | | -3,168,637 | -3,168,637 |
| Other comprehensive income | | | | | | 0 |
| Balance as of 31 March 2016 | 155,384 | 152,793,347 | 6,592,372 | 0 | -107,914,749 | 51,626,354 |

| in Euro | Share capital | Capital reserve | Other reserve | Currency transl. diff. | Retained earnings | TOTAL equity |
|---|---|---|---|---|---|---|
| Balance at 1 January 2017 | 155,384 | 152,793,347 | 7,359,821 | -27,736 | -119,918,408 | 40,362,408 |
| Loss of Q1-2017 | | | | | -4,352,182 | -4,352,182 |
| Equity settled ESOP | | | 412,252 | | | 412,252 |
| Other comprehensive income | | | | 12,710 | | 12,710 |
| Balance as of 31 March 2017 | 155,384 | 152,793,347 | 7,772,073 | -15,026 | -124,270,590 | 36,435,188 |

# CURETIS N.V.

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