2017

FIRST HALF-YEAR BUSINESS AND FINANCIAL UPDATE

curetis

Statement of the Board

In accordance with Article 5:25c paragraph 2 sub c of the Financial Supervision Act the Board of the Company confirms that, to the best of their knowledge, (i) the financial statements in this first half-year report 2017 give a true and fair view of Curetis N.V.'s assets, liabilities, and financial position as at June 30, 2017, and the results of its consolidated operations for the financial first half-year 2017; and (ii) the Report includes a fair review of the position as of June 30, 2017, and the development and performance during the first half of the financial year 2017 of Curetis N.V.

Forward looking statement (disclaimer)

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This document may include 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 but not limited to the terms "believes", "estimates", "anticipates", "expects", "intends", "may", "will", or "should", and include statements the Company 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. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

FIRST HALF-YEAR 2017 OPERATIONAL AND BUSINESS HIGHLIGHTS YTD

NEARING THE U.S. FDA CLEARANCE DECISION ON UNYVERO LRT

- 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 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 March, Curetis received a letter from the FDA with requests for details on pathogens, antibiotic resistance markers, sample types, etc.
- To clarify remaining open issues, a meeting was held on 21 April 2017. Based on the outcome of this meeting and further discussions with the reviewers, FDA is moving forward with review of the Unyvero Platform and LRT Application Cartridge for use initially with tracheal aspirate samples. Originally, Curetis had filed for both bronchial lavage (BAL) and tracheal aspirate sample types in its De Novo submission. By making the strategic decision to move forward in this phased approach, Curetis aims to pursue the most expeditious regulatory pathway. Curetis believes that initial clearance of the Unyvero System and LRT Cartridge with one of the most relevant sample types could give the Company a time advantage, being the only provider of a first-in-class diagnostic solution of this kind.
- Curetis expects to continue the 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 in the later parts of the second half of 2017.
- 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 with 80 synovial fluid samples, the Company continues to prepare for its next FDA trial with the goal of enrolment completion by end of 2018. This IJI (invasive joint infections) Application, a derivative of the European CE-marked Unyvero Implant and Tissue Infection (ITI) Application, is tailored to U.S. clinical and market needs.

CORPORATE DEVELOPMENT WITH ADDED FINANCING

- Ares Genetics GmbH was established as a wholly-owned subsidiary in April 2017 in Vienna, Austria and builds on the GEAR (GEnetic Antibiotic Resistance and Susceptibility Database) and related 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. In the future, GEAR may also pave the way towards fully genetic antibiograms and provide a reference for NGS-based clinical diagnostics.
- To leverage the full potential of the GEAR database and bioinformatics platform for life sciences, public health, diagnostic, and pharmaceutical uses over the last several months Ares Genetics has been engaged in numerous partnering discussions with top-tier industry players as well as public health institutions. Furthermore, there are several ongoing negotiations with

various potential partners in the diagnostic and pharmaceutical industries, the public health space, as well as academic institutions.

- Ares Genetics GmbH was recognized in the innovation contest 'Landmarks in the Land of Ideas' for its project "GEAR - Predicting Antibiotic Resistances with Genetic Data". This prestigious award has been granted for the past twelve years through "Germany – Land of Ideas" program and Deutsche Bank.
- To further advance its R&D programs as well as product and platform development, 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.
- Recruiting activities for selected key positions into the U.S. commercial team have commenced and further build-up of the team is expected in H2-2017 with the hiring of the sales force in the field expected closer to the FDA clearance decision.
- To strengthen the EMEA marketing efforts, the Company has recently hired Riwat Lim, MSc, as its Director Marketing & Scientific Affairs EMEA and Managing Director Curetis UK Ltd. to drive further development in the EMEA direct selling markets and to strengthen the support of distribution partners worldwide. Mr. Lim looks back on 15 years of sales and marketing experience in the pharmaceutical and diagnostic industry and has worked 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 a leading position at 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. (see below).
- Curetis recently announced a partnership with Biotest for the use of Unyvero in the clinical trial PEPPER (Personalized Medicine with Pentaglobin® after surgical source control in patients with peritonitis). 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, Cempra and an undisclosed major pharma company, PEPPER is the fourth third-party clinical trial with Unyvero.

PRODUCT DEVELOPMENT ON TRACK

- 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 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.
- Curetis has finalized the specifications of the Invasive Joint Infections (IJI) Application, in collaboration with KOLs and clinical experts. The company has continued 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 CONTINUES TO GROW

- Curetis' global installed base of Unyvero Analyzers has been expanded to 161 at the end of the first half-year 2017 (a 42.5% increase over the 113 as of 30 June 2016).
- In addition to recent placements at key customer sites in Europe, Curetis GmbH has 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 of the Unyvero Platform and Unyvero LRT Cartridge.
- Several EMEA customers have recently finalized studies and evaluations, providing an opportunity for additional publications demonstrating the value of Unyvero, thereby supporting sales efforts going forward.
- Based on the installed base surpassing 160 Unyvero Analyzers in the first half of 2017 with several recent shipments to key EMEA sites in the UK, France and other markets, and the bulk orders from the U.S., the Company maintains its target for global installed base of 200+ Unyvero Analyzers by year-end 2017, subject to the final FDA clearance decision timeline.

KEY PATENTS GRANTED RECENTLY

- Curetis has recently been granted its first European key patent for its *"Universally Applicable Lysis Buffer And Processing Methods For The Lysis Of Bodily Samples"*. The patent is also granted in the U.S. and Japan. In Australia and Singapore the patent has already been granted in 2015. Therefore, this core patent is effective in all of these key markets.
- In addition, Curetis holds another core patent for its *"Reaction Vessel for PCR Device and Method for Performing PCR"* in China, Singapore, Japan and in the U.S. This patent is pending in Europe.
- Curetis also received recent information about key patent grants for *its "Apparatus and Method for a Lysis of a Sample"* in Australia in 2016 and most recently in Japan in 2017. In China the patent is now intended to be granted while in Europe and the U.S. it is still pending.

STRONG CLINICAL DATA PRESENTED IN U.S. AND EUROPE

- Several presentations at ECCMID 2017 have demonstrated 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 older 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 were presented at the American Thoracic Society International Conference, in Washington D.C. on May 19-24, 2017. The data was 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". 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 hosted its inaugural Circle of Diagnostic Excellence (CODE) forum on May 23, 2017, in Washington DC. Several U.S. KOLs and world-renowned experts in the field of pulmonology gathered to discuss advanced approaches to diagnosis of lower respiratory tract infections and exchanged 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 were presented at ASM Microbe 2017, held from June 1-5 in New Orleans, LA. 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 was 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 presented 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" on June 5, 2017.
- In addition, Dr. Sims presented independent data from a study conducted at Beaumont Hospital, Royal Oak, MI, which found that only 15% of the patients with suspected pneumonia were treated adequately, whereas 63% were over-treated and 22% undertreated with antibiotics, based on their culture results. A significant majority of these patients could have had a modified final clinical outcome by having Unyvero data available. On average, patients' length of stay in the hospital was 28.2 days at an average cost of USD 2,538 per day. Unyvero delivers results within 4 to 5 hours compared to 2.7 days with routine culture techniques. With faster diagnostic data at hand, potentially harmful antibiotic side effects could have been avoided and overall costs could have been decreased, while managing antibiotic use and reducing the potential for development of antibiotic resistance. Dr. Sims' data on *Potential Impact of Rapid Diagnostics in Management of Suspected Pneumonia*, was given in the session "Antimicrobial and Diagnostic Stewardship" on June 2, 2017.

MANAGEMENT BOARD EVOLVING

- Effective 31st August 2017, Andreas Boos, CTO and co-founder of Curetis, has decided today to step down from the Management Board of Curetis N.V., 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.
- At the same time, Chris Bernard, President and CEO of Curetis USA Inc., has been appointed as Executive VP of Global Sales and he will assume direct management responsibility for the EMEA sales organization and will report directly to Curetis N.V. CEO Oliver Schacht and will advise the Supervisory Board on all sales-related matters.
- In this context, Dr. Achim Plum assumes the role of CBO (Chief Business Officer) for Curetis N.V. In this function, he will continue to lead EMEA marketing, customer service & support, scientific affairs, and global business development. This allows him to dedicate more time to market

development and expansion of Unyvero and – as one of the managing directors of Ares Genetics GmbH in Vienna – to accelerating the partnering and development activities of GEAR-related programs.

SUPERVISORY BOARD ELECTIONS AT 2017 AGM

- Dr. Nils Clausnitzer has been appointed as a member of Curetis N.V.'s Supervisory Board for a three-year term during this year's Annual General Meeting. 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 re-elected for another one-year term. In addition, the proposed extension of authorization of the Management Board to limit or exclude pre-emptive rights on newly issued shares or rights to subscribe for shares as well as an extension of authorization of the Management Board to repurchase shares were also approved by the shareholders.

MEDICAL ADVISORY BOARD

- 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 special interest applies to health economic evaluation with regard to the implementation of new molecular technologies.

FIRST HALF-YEAR 2017 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 594.8 k (vs. EUR 654.7 k in the first half-year 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:** 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 due 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 (EUR 0 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 of the period**: 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). 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 compensated for by the EUR 10.0 million cash inflow from financing activities from 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 each tranche drawdown, 5 years interest only, no warrants attached).

FIRST HALF-YEAR 2017 CONSOLIDATED FINANCIAL STATEMENTS

CURETIS N.V.

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

For the periods ended 30 June

in Euro	Six months ended 30 June 2017	Six months ended 30 June 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	-9,648,335	-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 30 June 2017	Six months ended 30 June 2016
Basic	-0.61	-0.43
Diluted	-0.61	-0.43

CURETIS N.V.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) - ASSETS

As of 30 June 2017 and 31 December 2016

in Euro		30 June 2017	31 December 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

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CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) – EQUITY AND LIABILITIES

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

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CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

For the periods ended 30 June

in Euro	Six months ended 30 June 2017	Six months ended 30 June 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

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CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 30 June 2017

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 H1-2016					-6,705,382	-6,705,382
Other comprehensive income				6,044		6,044
Balance as of 30 June 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 1 January 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 30 June 2017	155,384	152,793,347	8,181,376	89,277	-129,581,005	31,638,379

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