2017

THIRD QUARTER AND 9 MONTHS 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 Q3 / 9-M report 2017 give a true and fair view of Curetis N.V.'s assets, liabilities, and financial position as at September 30, 2017, and the results of its consolidated operations for the 9-M 2017 financials; and (ii) the Report includes a fair review of the position as of September 30, 2017, and the development and performance during the third quarter and nine months of the financial year 2017 of Curetis N.V.

Forward looking statement (disclaimer)

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THIRD QUARTER 2017 OPERATIONAL AND BUSINESS HIGHLIGHTS YTD

U.S. FDA CLEARANCE DECISION ON UNYVERO LRT APPLICATION PENDING & U.S. LAUNCH PREPARATIONS UNDER WAY

- Recently completed all work packages, wet-lab testing and risk & benefit analysis previously agreed upon with the U.S. FDA. In early November, the Company also provided all responses to the FDA's questions from the Additional Information request letter. Subject to completion of the interactive review and subsequent final review, Curetis expects an FDA clearance decision in due course.
- Curetis continues to work closely with the U.S. FDA in the interactive review of its *510(k)* submission (Unyvero Platform and the Unyvero LRT Lower Respiratory Tract Infection Cartridge).
- On January 5, 2017, Curetis submitted a *510(k)* application to the FDA for its Unyvero Platform and the Unyvero LRT Application. Since March, Curetis has been in interactive review with the FDA to discuss details on pathogens, antibiotic resistance markers, sample types, etc. During this process, Curetis made the strategic decision in May to move forward with the review of tracheal aspirate samples first and to add bronchial lavage (BAL) as a second sample type at a later stage. This phased approach could give the Company a timing advantage, being the first to market with a diagnostic solution of this kind.
- 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.
- Recruiting activities for additional commercial positions at Curetis USA Inc. have continued, with select key hires in operations, including a clinical application specialist and field service engineering support. A further expansion of the team is in progress with the hiring of the sales force in the field expected in due course.
- As Curetis recognizes the importance of antibiotic stewardship programs, and the goal of limiting inappropriate use of antibiotics, Curetis USA Inc. hosted a KOL roundtable discussion with PharmD Infectious Disease specialists in the U.S. in San Diego during IDWeek.

SECOND U.S. FDA CLINICAL TRIAL FOR UNYVERO IJI APPLICATION

- Following Institutional Review Board (IRB) approvals, Curetis has initiated sample collection for its second multi-center FDA study for its Unyvero IJI Invasive Joint Infections Cartridge. The IJI Cartridge presents a newly developed U.S. version of the CE-IVD marked Unyvero ITI Cartridge. The Unyvero ITI Implant and Tissue Infection Application is commercially available in Europe and other parts of the world.
- Among the sites that have already entered the trial for sample collection of microbiology-positive synovial fluid patient samples are sites that previously participated in the Unyvero LRT trial (e.g. Beaumont Hospital, Royal Oak, MI), as well as new sites (e.g. Froedtert Hospital and the Medical College of Wisconsin, Milwaukee, WI), med fusion, (Lewisville, TX) and a leading reference lab in the Southwestern United States. The Company is expecting further expansion of the network to include additional sites in the coming months.
- The overall trial design is similar to the Unyvero LRT study. Based on FDA guidance, the IJI clinical trial is expected to enroll more than 1,500 prospective test samples, complemented with

archived microbiology-positive specimens to reach significant numbers for each of the analytes in the IJI panel, as well as a comprehensive analytical testing data package.

- Development of the Unyvero IJI Application Cartridge has also advanced well. The Company expects availability of the cartridges and the initiation of the prospective arm of the FDA trial to begin in 2018.

BUSINESS DEVELOPMENT

- Following the announcement of a strategic Memorandum of Understanding and initial R&D collaboration between MGI (a BGI Affiliate) in China and Curetis / Ares Genetics in September, MGI has already commenced the feasibility study for Next-Generation Sequencing in-vitro diagnostic assays for microbial infections. Together with MGI, Curetis participated at a major conference in China. Curetis and MGI are continuing negotiations about potential future expansion of their strategic collaboration under the Memorandum of Understanding towards elements of an R&D and OEM collaboration focused on the Unyero Lysator technology and instruments.
- Ares Genetics GmbH, a wholly owned subsidiary of Curetis, has progressed additional partnering discussions relating to its genetic antibiotic and susceptibility database GEAR to term sheet stage(s). Additional GEAR related partnering activities are anticipated in the coming quarters. 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.
- Curetis' partner Biotest expected to enroll the first patient into the PEPPER clinical trial. This is the fourth pharma partnership Curetis is supporting and Curetis continues to explore further pharma clinical trials that might benefit from the use of Unyvero.
- The Unyvero System and its application cartridges for pneumonia (HPN), implant and tissue infections (ITI) and bloodstream infections (BCU), have recently been cleared by the regulatory authorities for commercial use in Israel.
- Working towards a future Chinese market clearance, analytical testing of Unyvero HPN Cartridges by Curetis' partner BCB in China is progressing as expected. Analytical testing is a key requirement and precondition to Curetis' partner initiating the prospective Chinese FDA clinical trials in 2018.
- The regulatory review of Unyvero in Singapore is in progress and it is anticipated that a clearance decision will be made in the coming months.

ORGANIZATIONAL EVOLUTION IN EMEA DIRECT SALES MARKETS

- Following the shift of global sales responsibility to Chris Bernard (announced in August 2017) there have been several additional changes to the team composition and organization in our EMEA direct selling markets. Riwat Lim has joined Curetis from QIAGEN as Managing Director of Curetis UK Ltd. and Head of Marketing and Scientific Affairs. To maximize synergies across all customer-facing teams and leverage Riwat's deep expertise and strong leadership capabilities, he has recently been appointed as Director of Commercial Operations EMEA.
- In his new, role Riwat leads and oversees all EMEA commercial operations including Sales, Customer Support and Services, Scientific Affairs and Marketing. Riwat will continue shaping and evolving the EMEA commercial team.

COMMERCIAL TRACTION IN EMEA & INSTALLED BASE

- Curetis' global installed base of Unyvero Analyzers has been expanded to 165 at the end of the third quarter of 2017 (a 36.4% increase over the 121 as of 30 September 2016). During Q3, a total of 9 new Analyzers were installed and 5 were brought back following completion of the demo and evaluation phase.
- System placements and cartridge sales over the summer months have been slow, which has led to some prolonged customer discussions and contracting in Germany, France and the UK. Therefore, several new system placements have been postponed into Q4. In the fourth quarter to-date, several new systems have been installed in Europe.
- In the U.S., paperwork has been put in place for multiple Unyvero Analyzers to be installed in Q4 2017 under an Investigational Use Only (IUO) labeling. With an FDA clearance decision now expected towards the end of the year, the impact on installed base overall from the U.S. will be rather limited in FY 2017, but is expected to accelerate significantly upon commercial launch following potential FDA clearance.
- Curetis USA Inc. is expected to place a first significant stocking order with Curetis GmbH in late Q4-2017 for inventory purposes ahead of an anticipated U.S. launch and commercial roll-out. Given this timing, it is now expected that the installed base target of 200 Unyvero Analyzers will be reached in Q1-2018 rather than by 31 December 2017.
- Currently, Curetis has identified over a dozen customers across key EMEA direct selling markets where demos and evaluations have been completed successfully, and commercial conversion discussions are ongoing. We expect many of these customers to start buying Unyvero Cartridges in the next several months.

PRODUCT DEVELOPMENT

- Development of the Unyvero UTI Urinary Tract Infection Cartridge has been completed and is pending verification and validation. Curetis aims to launch this as a CE IVD marked product at a major European conference in Q2 2018.
- Curetis has finalized the specifications of the Unyvero Invasive Joint Infections (IJI) Application, in collaboration with KOLs and clinical experts. The company has continued related application development efforts in preparation for the second U.S. clinical trial (see above).
- All other R&D programs and product development projects also continue to progress on track and in line with Curetis' guidance, e.g. the completion of development of a Unyvero Sepsis Host Response Cartridge (SHR) which will be provided under an IUO (Investigational Use Only) label for further clinical validation and testing.
- Curetis has integrated the former Gyronimo platform into the Unyvero suite of products as the future Unyvero A30 RQ Analyzer which will add rapid and, where needed, quantitative testing capabilities. The development program is on track for completion by the end of 2018.

THIRD QUARTER / 9-MONTH 2017 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 830.9 k (vs. EUR 1,077.4 k in the nine months ended 2016). For detailed background information on factors influencing the commercial traction and revenue generation in Q3-2017 please see the discussion points above. 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 14.8 million (vs. EUR 12.0 million in the nine months ended 2016). The increase is in line with the operational and organizational growth, and driven by higher distribution costs especially at our U.S. subsidiary 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 946k in 9-M-2017 (EUR 363k in the first nine months of 2016).
- **Gross loss:** EUR 663.5 k (vs. EUR 109.4 k in the nine months ended 2016). Key driver of the higher COGS were depreciation on Unyvero Systems by way of marketability discounts with EUR 521k in the first 9 months of 2017 (EUR 268k in 9M 2016) as well as increased warranty costs.
- **Net loss for the period**: EUR 14.6 million (vs. EUR 10.7 million in the nine months ended 2016).
- **Cash and cash equivalents**: EUR 21.6 million as of September 30, 2017 (vs. EUR 22.8 million as of December 31, 2016). The net cash decrease in the nine months ended 2017 was EUR 1.2 million. The net cash outflow from operating and investing activities was EUR 10.9 million (vs. EUR 10.5 million in 9M-2016) with EUR 10.0 million cash inflow during Q2-2017 from the EIB debt financing tranche draw-down.

THIRD QUARTER 2017 CONSOLIDATED FINANCIAL STATEMENTS

CURETIS N.V.

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

For the periods ended 30 September

in Euro	Nine months ended 30 September 2017	Nine months ended 30 September 2016
Revenue	830,933	1,077,412
Cost of sales	1,494,405	1,186,774
Gross loss / gross margin	-663,472	-109,362
Distribution costs	5,530,001	3,445,681
Administrative expenses	2,734,894	2,112,341
Research & development expenses	5,011,995	5,239,429
Other income	74,797	146,537
Operating loss	-13,865,565	-10,760,276
Finance income	21,749	68,729
Finance costs	710,970	48,973
Finance costs - net	-689,221	19,756
Profit / loss before income tax	-14,554,786	-10,740,520
Income tax expenses	19,555	
Profit / loss for the period	-14,574,341	-10,740,520
Other comprehensive income for the year, net of tax	122,539	9,417
Total comprehensive income for the period	-14,451,802	-10,731,103

Earnings / loss per share	Nine months ended 30 September 2017	Nine months ended 30 September 2016
Basic	-0.93	-0.69
Diluted	-0.93	-0.69

CURETIS N.V.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) - ASSETS

As of 30 September 2017 and 31 December 2016

in Euro		30 September 2017	31 December 2016
Current assets		28,480,715	30,272,260
	Cash and cash equivalents	21,561,076	22,832,117
	Trade receivables	119,696	101,398
	Inventories	6,341,600	5,870,167
	Other current assets	458,343	1,468,578
Non-current assets		11,598,844	12,514,826
	Intangible assets	7,521,627	7,520,048
	Property, plant and equipment	3,733,497	4,466,462
	Other non-current assets	187,357	211,870
	Other non-current financial assets	156,363	316,446
	Deferred tax assets	-	-
Total assets		40,079,559	42,787,086

CURETIS N.V.

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

As of 30 September 2017 and 31 December 2016

in Euro	30 September 2017	31 December 2016
Current liabilities	2,965,622	2,384,156
Trade and other payables	667,282	721,113
Liability PSOP	-	-
Provisions current	108,000	51,000
Tax liabilities	18,545	10,128
Other current liabilities	1,401,406	1,120,299
Other current financial liabilities	770,389	481,616
Non-current liabilities	10,254,517	40,522
Provisions non-current	40,522	40,522
Other non-current financial liabilities	10,213,995	-
Deferred tax liability	-	-
Total liabilities	13,220,139	2,424,678
Equity	26,859,420	40,362,408
Share capital	155,384	155,384
Capital reserve	152,793,347	152,793,347
Other reserves	8,308,637	7,359,821
Currency translation differences	94,801	-27,736
Retained earnings	-134,492,749	-119,918,408
Total equity and liabilities	40,079,559	42,787,086

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

For the periods ended 30 September

in Euro	Nine months ended 30 September 2017	Nine months ended 30 September 2016
Profit before income tax	-14,574,341	-10,740,520
Adjustment for:		
- Net finance income / costs	689,221	-19,756
- Depreciation, amortization and impairments	1,003,875	1,353,620
- Gain on disposal of fixed assets	2,351	1,550
- Changes in provisions	57,000	-3,000
- Changes in equity settled stock options	948,816	362,782
- Changes in the PSOP-liability	0	0
- Net exchange differences	303,047	35,374
Changes in working capital relating to:		
- Inventories	-471,433	-2,700,708
- Trade receivables and other receivables	1,176,533	431,424
- Trade payables and other payables	806,282	3,081,207
Effects of exchange rate differences not realized from consolidation	-180,510	-25,956
Income taxes received (+) / paid (-)	-19,555	0
Interest paid (-)	-393,594	-7,596
Net cash flow provided by operating activities	-10,652,308	-8,231,579
Payments for intangible assets	-69,287	-2,016,199
Payments for property, plant and equipment	-205,552	-320,191
Proceeds from sale of property, plant and equipment	0	0
Interest received	7,419	62,726
Net cash flow used in investing activities	-267,420	-2,273,664
Proceeds from borrowings	10,000,000	0
Payments for finance lease liabilities	-48,266	-104,560
Net cash flow provided by financing activities	9,951,734	-104,560
Net increase (decrease) in cash and cash equivalents	-967,994	-10,609,803
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	-967,994	-10,609,803
Effects of exchange rate changes on cash and cash equivalents	-303,047	-35,374
Net Cash and cash equivalents at the end of the period	21,561,076	35,415,220

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CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 30 September 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 9M-2016					-10,740,520	-10,740,520
IFRS 2 Valuation of equity settled stock options			362,782			362,782
Other comprehensive income				9,417		9,417
Balance as of 30 September 2016	155,384	152,793,347	6,955,154	9,417	-115,486,632	44,426,670

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 9M-2017					-14,574,341	-14,574,341
Equity settled ESOP			948,816			948,816
Other comprehensive income				122,537		122,537
Balance as of 30 September 2017	155,384	152,793,347	8,308,637	94,801	-134,492,749	26,859,420

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