



2019

FIRST QUARTER
BUSINESS AND
FINANCIAL
UPDATE



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 Q1 / 3-M report 2019 give a true and fair view of Curetis N.V.'s assets, liabilities, and financial position as of 31 March 2019, and the results of its consolidated operations for the financial Q1 / 3-M report 2019; and (ii) the Report includes a fair review of the position as of 31 March 2019, and the development and performance during the first quarter and the three months of the financial year 2019 of Curetis N.V.

Forward looking statement (disclaimer)

This quarterly report does not, and is not intended to, constitute or form part of, and should not be construed as, an offer to sell, or a solicitation of an offer to purchase, subscribe for or otherwise acquire, any securities of the Company, nor shall it or any part of it form the basis of or be relied upon in connection with or act as any inducement to enter into any contract or commitment or investment decision whatsoever. This quarterly report is not an offer of securities for sale in the United States. The securities of the Company have not been registered under the U.S. Securities Act of 1933, as amended (the "securities act") or with any securities regulatory authority of any state or other jurisdiction of the United States and may not be offered or sold in the United States unless registered under the Securities Act or pursuant to an exemption from such registration.

This quarterly report is made available on the expressed understanding that it does not contain all information that may be required to evaluate and will not be used by the recipients in connection with the purchase of or investment in any securities of the Company. This quarterly report is accordingly not intended to form the basis of any investment decision and does not constitute or contain (express or implied) any recommendation by the Company or any of its directors, officers, employees, agents, affiliates or advisers.

Certain information in this quarterly report is based on management estimates. By their nature, estimates may not be correct or complete. Accordingly, no representation or warranty (express or implied) is given that such estimates are correct or complete.

This quarterly report 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 QUARTER 2019 OPERATIONAL AND BUSINESS UPDATES

U.S. COMMERCIALIZATION OF UNYVERO SYSTEM AND LRT APPLICATION CARTRIDGE

- As of 31st March 2019 Curetis USA Inc. had an installed base of 15 Unyvero Analyzers across the USA and in different types of hospitals and labs. Clinical and commercial evaluations are ongoing at multiple of these accounts.
- Curetis USA Inc. has built a solid funnel of target accounts and opportunities that spans more than 60 thoroughly vetted accounts and more than 10 near term opportunities for additional evaluations and some near-term commercial account conversion opportunities. A few additional evaluation contracts have already been signed for Q2-2019.
- Following the re-organization Curetis USA Inc. in January 2019, which has reduced the size of the team in the USA to currently 11 full time staff with the majority being based in the field, the expectation for 2019 is to increase the installed base of Unyvero Analyzers to about 30 to 40 by year-end 2019 with a continuously growing proportion of installations at commercial accounts in the second half of 2019.

EMEA COMMERCIALIZATION OF UNYVERO PRODUCT LINE – MENARINI PARTNERSHIP

- On 26th March 2019 Curetis and A. Menarini Diagnostics (Menarini) announced an exclusive strategic pan-European commercial distribution partnership. Initially this partnership covers 11 countries including key markets such as Germany, France, UK, Italy, as well as Spain and Portugal, Switzerland, BeNeLux and Sweden.
- The Menarini collaboration was launched at ECCMID 2019 in Amsterdam from 13-16 April 2019. A total of nine clinical data sets and studies with Unyvero applications across many different indication areas such as pneumonia, joint infections, blood stream infections, and intra abdominal infections were presented at this key European conference for clinical microbiology .
- Menarini and Curetis in the initial agreement are also foreseeing a further expansion of the collaboration in the future to potentially include additional EMEA markets that might become available for distribution from time to time.
- Curetis, following the successful re-organization of Curetis GmbH initiated in December 2018 and largely completed at the end of Q1-2019, will maintain a strong and highly experienced commercial partner support team and customer service. This team will support Menarini as well as all other international distribution partners in EMEA, Asia, and Latin America.

GLOBAL INSTALLED BASE

- Following a temporary decrease in global installed base in 2018 due to the various factors such as repurchased units following completion of a pharma project and efficiencies in working capital deployment, Q1-2019 has seen a return to growing numbers in installed Unyvero Analyzers with a total of 172 installed at the end of Q1-2019 compared to 167 at year-end 2018.

MARKET ACCESS ASIA

- Following the successful completion of analytical testing in 2018 and expanded strategic collaboration between Curetis and BCB for the Unyvero A50 System and Application Cartridges in Greater China, BCB has submitted the Unyvero System and HPN Application Cartridge to the Chinese NMPA

(formerly CFDA) in Q1-2019. The NMPA in its initial response has proposed an expert panel discussion for the HPN pneumonia product to be convened in summer of 2019.

- Assuming a final submission in 2019 and a CFDA approval in 2020, Curetis anticipates generating initial revenues from commercial sales in China starting in 2020.
- Curetis' partner Acumen Research Laboratories obtained regulatory approvals for the Unyvero System and HPN as well as BCU cartridges in Malaysia and Thailand in Q1-2019.

BUSINESS DEVELOPMENT

- Following the strategy change announced in December 2018, Q1-2019 saw a broad range of business development discussions, technical feasibility work, negotiations, and due diligence around the Unyvero A30 RQ platform. These ongoing discussions span all key geographies in Europe, the USA and Asia as well as various clinical indication areas such as infectious diseases and oncology.

PRODUCT DEVELOPMENT

- The Unyvero A30 RQ platform which is now targeted for strategic partnering and licensing later in 2019 has seen excellent R&D progress in Q1-2019. First fully functional instrument system prototypes have been available since Q4-2018 and first multiplex real-time PCR assays have been successfully transferred onto the A30 RQ cartridges and successfully benchmarked against their performance on standard PCR instruments. The goal is to have the A30 RQ platform ready for partnering and verification and validation testing with assays by first licensing partners in H2-2019.
- With the current Unyvero LRT Application Cartridge for lower respiratory tract (LRT) infections being cleared for the use with tracheal aspirates as a sample type, Curetis plans to file for the clearance of an LRT application cartridge optimized for use with bronchoalveolar lavage (BAL) as additional sample type. BAL is another common sample type for the diagnosis of lower respiratory tract infections. It is estimated that half of the samples obtained for the diagnosis of lower respiratory tract infections are BALs, and Curetis believes that a clearance of an Unyvero LRT Application Cartridge for this additional sample type would increase the total addressable market for Unyvero in the U.S. accordingly.
- In Q1-2019 Curetis successfully completed the analytical testing and significantly progressed the clinical validation testing of the LRT BAL Application Cartridge. Clinical data is expected in Q2-2019 and the FDA submission for a 510(k) expected around mid year 2019.
- In addition, Curetis has continued the collection of retrospective samples for its U.S. trials for the Unyvero IJI Invasive Joint Infection product to augment the future prospective arm of the clinical trial. An initiation of the prospective arm of the trial will depend on Curetis partnering for the further development as well as the commercialization of this unique Application Cartridge.

ARES GENETICS

- Ares Genetics signed an exclusive global BioIT licensing and collaboration agreement with QIAGEN in February 2019. This constitutes the third strategic collaboration agreement following the deals with Sandoz and an undisclosed global IVD corporation in Q4-2018.
- Ares Genetics announced the expected mid-year 2019 launch of its next generation sequencing (NGS) lab service offering. To that end Ares has begun building its lab infrastructure and operations team in Vienna, Austria.
- In Q1-2019 Ares also announced the co-funding of a EUR 1.3 million project to advance AI powered NGS called Triple-A (Assay Development and Artificial Intelligence to Diagnose Antibiotic Resistant Infections) by the Vienna Business Agency.

- In collaboration with the Curetis team, Ares Genetics released a beta testing version of the AMR Atlas, a knowledge base on antimicrobial resistance markers specifically designed to support users of the Curetis Unyvero Platform. The initial focus of the Unyvero AMR Atlas is on antibiotic resistance markers detected by the Unyvero HPN Application Cartridge in pneumonia patients.

FINANCING

- Following the November 2018 financing Curetis continues to explore all strategic and tactical financing options. In Q1-2019 primary focus was on finding an agreement with EIB for the next EUR 5.0 million debt financing tranche.
- In Q1-2019 and 2019 year to date Yorkville has converted a total of EUR 1.5 million in notes into equity. A total of 1,290,726 new shares have been issued in 2019 year to date and Curetis expects to also access a further EUR 1.5 million (gross) tranche of the Yorkville convertible notes facility in 2019.

FIRST QUARTER 2019 KEY FINANCIALS

- **Revenues:** EUR 708 thousand (growing by approximately 45 % compared to EUR 490 thousand in the three months ended 31 March 2018).
- **Expenses:** EUR 5,180 thousand total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 6,081 thousand in the first three months of 2018). The decrease is mainly based on the successful implementation of the recent re-organization and reduction in organizational size, complexity and staffing levels as well as R&D pipeline and commercial channel partnering and revised commercial strategy.
- **Operating loss:** The operating loss in Q1-2019 has been reduced by approximately 19% to EUR -4,413 thousand (vs. EUR -5,412 thousand in the first three months of 2018).
- **Total comprehensive loss of the period:** EUR -4,746 thousand (vs. EUR -5,701 thousand in the first three months of 2018).
- **Cash and cash equivalents:** EUR 6,158 thousand as of 31 March 2019 (vs. EUR 10,279 thousand as of 31 December 2018). Net cash burn in the first three months ended 31 March 2019 was EUR -4,326 thousand.

FIRST QUARTER 2019 CONSOLIDATED FINANCIAL STATEMENTS

These financial statements have been prepared on a going concern basis. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if Curetis were unable to continue as a going concern. We refer to Notes 1.5 and 3.24 of our Consolidated annual financial statements as of 31 December 2018 as the statements made in these notes in the full-year 2018 financial report are also applicable to the consolidated financial statements as of 31 March 2019. Hence these Q1-2019 financials should be read in conjunction with the disclosure in the full-year 2018 notes. Despite having signed the Yorkville convertible facility and completed the recent equity raise a material uncertainty as to the ability to continue as going concern still exists.

CURETIS N.V.

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

For the periods ended 31 March 2019 and 31 March 2018

in kEuro	Three months ended 31 March 2019	Three months ended 31 March 2018
Revenue	708	490
Cost of sales	-609	-821
Gross profit / gross loss	99	-331
Distribution costs	-1,688	-1,955
Administrative expenses	-860	-1,070
Research & development expenses	-2,023	-2,235
Other income	59	179
Operating loss	-4,413	-5,412
Finance income	211	5
Finance costs	-377	-350
Finance results - net	-166	-345
Loss before income tax	-4,579	-5,757
Income tax expenses	-11	-29
Loss for the period	-4,590	-5,786
Other comprehensive income for the period, net of tax*	-156	85
Total comprehensive loss for the period**	-4,746	-5,701
Loss per share attributable to the ordinary equity holders of the company	Three months ended 31 March 2019	Three months ended 31 March 2018
Basic	-0.22	-0.37
Diluted	-0.22	-0.37

* Relates to exchange differences on translation of foreign operations, which may be recycled through profit and/or loss in the future

** Total comprehensive loss is solely attributable to owners of the company

CURETIS N.V.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) - ASSETS

As of 31 March 2019 and 31 December 2018

in kEuro	31 March 2019	31 December 2018
Current assets	13,488	18,095
Cash and cash equivalents	6,158	10,279
Trade receivables	195	323
Contractual assets	109	-
Inventories	6,420	6,734
Other current assets	606	759
Non-current assets	12,343	11,012
Intangible assets	7,397	7,425
Property, plant and equipment	3,107	3,196
Right of use assets	1,391	-
Other non-current assets	229	162
Other non-current financial assets	159	158
Deferred tax assets	60	71
Total assets	25,831	29,107

CURETIS N.V.

STATEMENT OF FINANCIAL POSITION (UNAUDITED) - EQUITY AND LIABILITIES

As of 31 March 2019 and 31 December 2018

in kEuro	31 March 2019	31 December 2018
Current liabilities	5,454	6,064
Trade and other payables	829	957
Provisions current	78	65
Tax liabilities	18	22
Other current liabilities	1,023	1,235
Other current financial liabilities	3,081	3,785
Current lease liabilities	425	-
Non-current liabilities	15,142	13,993
Provisions non-current	44	44
Other non-current financial liabilities	14,128	13,949
Non-current lease liabilities	970	-
Total liabilities	20,596	20,057
Equity	5,235	9,050
Share capital	215	209
Capital reserve	163,721	162,967
Other reserves	9,350	9,176
Currency translation differences	-302	-143
Retained earnings	-167,749	-163,159
Total Equity and liabilities	25,831	29,107

CURETIS N.V.

STATEMENT OF CASH FLOWS (UNAUDITED)

For the periods ended 31 March 2019 and 31 March 2018

in Euro	Three months ended 31 March 2019	Three months ended 31 March 2018
Profit after income tax	-4,590	-5,786
Adjustment for:		
- Net finance income / costs	166	345
- Depreciation, amortization and impairments	396	315
- Gain on disposal of fixed assets	3	0
- Changes in provisions	13	-29
- Changes in equity settled stock options	174	213
- Net exchange differences	-205	116
- Changes in deferred tax assets and liabilities	11	20
Changes in working capital relating to:		
- Inventories	314	683
- Trade receivables and other receivables	104	-297
- Trade payables and other payables	-120	-35
Effects of exchange rate differences not realized from consolidation	46	-31
Income taxes received (+) / paid (-)	11	29
Interest paid (-)	-370	-228
Net cash flow provided by operating activities	-4,047	-4,685
Payments for intangible assets	-20	-27
Payments for property, plant and equipment	-156	-113
Payments for leased rights of use (IFRS 16)	-104	0
Interest received	1	0
Net cash flow used in investing activities	-279	-140
Proceeds from borrowings	0	0
Payments for finance lease liabilities	0	0
Proceeds from issue of ordinary shares	760	0
Repayment of convertible loan	-760	0
Payments for financing costs of issue of ordinary shares	0	0
Net cash flow provided by financing activities	0	0
Net increase (decrease) in cash and cash equivalents	-4,326	-4,825
Net cash and cash equivalents at the beginning of the year	10,279	16,311
Net increase (decrease) in cash and cash equivalents	-4,326	-4,825
Effects of exchange rate changes on cash and cash equivalents	205	-119
Net Cash and cash equivalents at the end of the period	6,158	11,367

CURETIS N.V.

CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 31 March 2019 and 31 March 2018

in kEuro	Share capital	Capital reserve	Other reserve	Currency translation difference	Retained earnings	TOTAL equity
Balance at 1 January 2018	155	152,793	8,527	143	-139,414	22,204
Loss of the period					-5,787	-5,787
Other comprehensive income				85		85
Total comprehensive income	0	0	0	85	-5,787	-5,702
Transactions with owners in their capacity as owners						
Equity stock option program 2016			213			213
Balance as of 31 March 2018	155	152,793	8,740	228	-145,201	16,715

in kEuro	Share capital	Capital reserve	Other reserve	Currency translation difference	Retained earnings	TOTAL equity
Balance at 1 January 2019	209	162,967	9,176	-143	-163,159	9,050
Loss of the period					-4,590	-4,590
Other comprehensive income				-159		-159
Total comprehensive income	0	0	0	-159	-4,590	-4,749
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	6	754				760
Transaction costs for the issue of ordinary shares		0				0
Equity stock option program 2016			174			174
Balance as of 31 March 2019	215	163,721	9,350	-302	-167,749	5,235

CURETIS N.V.

FIRST QUARTER 2019
BUSINESS AND FINANCIAL
UPDATE

IMPRINT © 2019 CURETIS N.V.



Max-Eyth-Straße 42 | 71088 Holzgerlingen | Germany
Tel.: +49 (0)7031 49195 10 | Email: contact@curetis.com
www.unyvero.com | www.curetis.com