2018

THIRD QUARTER AND 9 MONTHS BUSINESS AND FINANCIAL UPDATE

curetis

Forward looking statement (disclaimer)

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THIRD QUARTER 2018 OPERATIONAL AND BUSINESS HIGHLIGHTS

U.S. LAUNCH OF UNYVERO SYSTEM AND LRT APPLICATION CARTRIDGE WITH INITIAL TRACTION

- On 3 April 2018, the Unyvero Platform and the Unyvero LRT Lower Respiratory Tract Infection Application Cartridge received *De Novo* clearance from the U.S.-FDA.
- Following the FDA clearance, Curetis launched the Unyvero System and the Unyvero LRT Application Cartridge for lower respiratory tract infections at the ASM Microbe 2018 Congress in Atlanta, GA, USA on 7 June 2018.
- To drive the commercial roll-out of the Unyvero System and Unyvero LRT as a first application cartridge in the U.S., the Company in the first half of 2018 has completed the operational set-up of its subsidiary Curetis USA Inc. in San Diego, CA, USA and its field-based commercial team across the U.S.
- Since the launch, the U.S. commercial team has qualified about 140 accounts in the top 1,000 hospitals initially targeted with about 80 being deeply vetted. Several accounts have entered into clinical and commercial evaluation agreements and with a dozen Unyvero Analyzers placed beyond FDA trial sites have since then started the on-site evaluation of the Unyvero System and LRT Application Cartridge. These and many further of these vetted accounts are expected to be converted to commercial accounts over the next several quarters with about a dozen accounts constituting near-term opportunities currently at the contract negotiation stage. These initial accounts on average are expected to have Unyvero LRT cartridge volumes of 700 to 800 annually once they become commercial customers with some accounts having significantly higher total potential annual testing volumes.

COMMERCIAL DEVELOPMENT

- In all EMEA direct markets combined revenues from cartridges and instruments grew by more than 207 % comparing the first nine months 2018 with the first nine months of 2017. Total revenue was up by 43% compared to the first nine months of 2017.
- In August 2018, Curetis expanded its geographic presence into the Northern African and Latin American markets signing exclusive distribution partnerships with Future Horizon Scientific for Egypt, with Quimica Valaner S.A. for Mexico and with Biko S.A. for Uruguay. Each of the three new distribution partners intends to commercialize all five Unyvero application cartridges that are currently CE-IVD-marked, namely HPN, ITI, BCU, IAI and UTI. These partners in total have committed to purchasing a minimum of 45 instrument systems at Curetis' typical distributor transfer prices over the respective three-year contractual terms. In addition, they have committed to minimum purchases of several thousand Unyvero application cartridges over the terms of the agreements.
- With these additional distribution partnerships in place, Curetis to-date has 17 distribution partners signed-up that cover 29 countries. The Company is planning to further expand its distribution network and commercial reach through additional partnerships with suitably positioned distributors. Curetis believes it has a strong pipeline of further potential distribution partners covering additional markets that may lead to further near-term distribution agreements.

GLOBAL INSTALLED BASE

- Upon completion of a pharmaceutical partner's phase III clinical trial, Curetis in Q1-2018 had exercised an option to buy back multiple Unyvero Systems deployed in this clinical trial and due to financing availability has concurrently taken a cautious working capital management approach with much stronger focus on higher priority accounts and conversion efficiency throughout Q3-2018, which has

led to a re-deployment of Unyvero Analyzers resulting in a temporary decrease in the installed base of Unyvero Analyzers to 166 Analyzers as of the end of the first nine months 2018, down by a net of 9 Analyzers compared to 175 Analyzers at year-end 2017. The Company expects to offset this decrease through additional future U.S. placements and by entering into additional distribution partnerships and has also identified a significant number of EMEA direct market opportunities for new Unyvero placements.

CHINA MARKET ACCESS

- Following the successful completion of analytical testing in the first 9 months of 2018, in October, Curetis and BCB expanded their strategic collaboration for the Unyvero A50 System and Application Cartridges in Greater China, including an exclusive Unyvero A50 distribution agreement to eight years. This minimum commitment would indicate potential revenues to Curetis of over EUR 30 million annually in years six through eight of commercialization in China in addition to potential cumulative revenues of more than EUR 60 million for years one through five of commercialization in China as agreed upon previously. Assuming a final submission in 2019 and a CFDA approval in late 2019 or early 2020, Curetis anticipates generating initial revenues from commercial sales in China starting in 2020.

BUSINESS DEVELOPMENT

- In January 2018, Curetis and MGI (a BGI Group Company, Shenzhen, China) had signed R&D collaboration and supply agreements focused on the Unyvero Lysator technology and instruments. Under the agreement, MGI can utilize Curetis' Lysator technology to develop and commercialize a universal automated solution for next generation sequencing (NGS)-based molecular microbiology that can process any sample type routinely obtained from patients for microbiological analysis. With the feasibility phase recently completed with all pre-defined performance criteria met, the collaboration has now entered the development phase for a first integrated product. Study data resulting from the collaboration were presented at the ICG-13 Conference in Shenzhen, China, on 24-28 October 2018. Further potential areas of collaboration, including the development and near-term commercialization of an NGS-based molecular microbiology application, are currently being discussed.
- Going forward, Curetis aims to enter into further value-adding R&D and commercial partnerships with well-known industry players around the Unyvero Platform and the ARES Technology Platform.

PRODUCT DEVELOPMENT

- To expand the label claim of its recently U.S.-FDA cleared Unyvero LRT Application Cartridge for lower respiratory tract infections, Curetis plans to file for the clearance of bronchoalveolar lavage (BAL) as an additional sample type. In a pre-submission meeting with the U.S.-FDA at the end of September 2018, the Agency has confirmed the suitability of the 510(k) clearance pathway for Curetis' Unyvero LRT Application Cartridge specifically optimized for detection of microbial pathogens in bronchoalveolar lavage ("BAL") samples. The U.S. FDA further confirmed that data required for the submission could be largely based on clinical samples previously collected during the original Curetis U.S. FDA trial for the Unyvero LRT Application Cartridge. Overall, the Company believes that U.S. FDA feedback has substantially de-risked the planned submission of the Unyvero LRT Application Cartridge for BAL and that the requirements agreed upon with the U.S. FDA should allow Curetis to accelerate generating the required data for an early submission, with an expected clearance decision in 2019.

  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 for this additional sample type would increase the total

addressable market for Unyvero LRT Application Cartridge in the U.S. accordingly.

Curetis also expects to include data on an assay for one additional pathogen, *Pneumocystis jirovecii*, as part of the 510(k) submission. This fungus is particularly relevant in lower respiratory tract infections in patients with compromised immune status, such as transplantation or AIDS patients.

- 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.
- Curetis expects to provide a more detailed update on its R&D pipeline and priorities following the most recent financing around the JP Morgan conference in early 2019.

ARES GENETICS

- In July 2018, Ares Genetics launched the ARES & CO (Antibiotic REsistance Solutions by COoperative R&D) pharma partnering program. The program is supported and largely funded by the Vienna Business Agency and aims to establish an alliance for antibiotic stewardship with pharmaceutical companies and contract research organizations. The goal of the program is to counteract antibiotic resistance and to foster antibiotic stewardship by applying advanced data-driven solutions to antimicrobial drug development and life cycle management of existing antimicrobial drugs.
- Ares Genetics initiated the development of its ARES*upa* Universal Pathogenome Assay. The assay for the diagnosis of microbial infections and antimicrobial drug response is based on the Company's proprietary ARES Technology Platform and genetic antimicrobial resistance database ARES*db*. While planning to launch the test as a laboratory-developed test at first, Ares Genetics ultimately aims to seek regulatory approval as an in vitro diagnostic test for broad and scalable commercialization. Ares Genetics is further exploring fast-track options to launch ARES*upa* as a laboratory-developed test in the U.S., once development of a first-generation ARES*upa* has been completed.
- Going forward, ARES aims to expand existing collaborations and enter into further value-adding R&D and commercial partnerships with well-known players in the life science, pharmaceutical and diagnostic industries around ARES*db* and the ARES Technology Platform.
- With initial seed funding of Ares Genetics provided by Curetis and non-dilutive funding through grants, Ares Genetics is currently identifying strategic partners and exploring options for accessing venture capital funding to accelerate the further development, particularly for the ARES*upa* Universal Pathogenome Assay and its future commercial deployment.

FINANCING

- To further strengthen Curetis' efforts to secure non-dilutive funding, in June 2018, the Company contracted The Freemind Group LLC, Boston, MA, USA, as an advisor to identify grant opportunities in the U.S. and support the drafting and submission process. Several grant applications for potentially significant non-dilutive funding have been submitted since then.
- In October 2018 Curetis secured up to EUR 20 million in growth capital through the issuance of convertible notes with share subscription warrants to YA II PN, LTD., an investment fund managed by Yorkville Advisors Global LP, an U.S. based management firm. To date, Curetis has drawn down EUR 3.5 million of the first tranche.
- In November, Curetis raised €8.9 million through private placements to institutional investors in Europe and the U.S. In this transaction, 4,450,000 out of 7,085,546 offered new ordinary shares were placed at an offer price of €2.00 per share, resulting in additional available funds of €7.3 million. The Company intends to use the proceeds from the sale of the Offer Shares for (i) funding the commercialization of its Unyvero Platform and LRT Application Cartridge in the U.S., (ii) its European commercialization activities, (iii) working capital requirements, (iv) research and development

programs and (v) for general corporate purposes but will re-assess the priorities and allocation of proceeds to fund these in the light of the lower than expected proceeds from this offering and will inform its shareholders on such priorities as well as any potentially required changes to its guidance once this assessment has been completed.

- Curetis will continue to assess all tactical and strategic options and operational requirements to secure appropriate funding and cash for its continued operations for at least the next 12 months and to ensure it has the financial resources to continue as a going concern.

THIRD QUARTER / 9-MONTH 2018 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 1,191 k (growing by about 43 % compared to EUR 831 k in the nine months ended 30 September 2017). EMEA direct sales have grown by 207 % year over year.
- **Expenses:** EUR 18,774 k total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 14,771 k in the first nine months of 2017). The increase is in line with the operational and organizational growth, and driven by higher distribution costs, higher research & development expenses as well as G&A costs.
- **Operating loss:** EUR -17,237k (vs. EUR -13,865k in the first nine months of 2017).
- **Net loss of the period**: EUR -17,719k (vs. EUR -14,574 k in the first nine months of 2017).
- **Cash and cash equivalents**: EUR 5,541k as of 30 September 2018 (vs. EUR 16,311 k as of 31 December 2017).
- **Cash burn and financing:** Net cash burn in the first nine months ended 30 September 2018 was EUR -11,066 k. In April 2018, Curetis had raised EUR 4.1 million in a private equity placement and issued 854,166 new shares and signed an additional USD 10 million equity facility offered by Global Corporate Finance (GCF) New York, NY, USA. In October, Curetis secured up to EUR 20 million in growth capital through the issuance of convertible notes with share subscription warrants to YA II PN, LTD., an investment fund managed by Yorkville Advisors Global LP, an U.S. based management firm. To date, Curetis has drawn down EUR 3.5 million of the first tranche and hence for the time being will not be able to draw on the GCF equity line. In November 2018, Curetis raised €8.9 million through private placements of 4,450,000 new ordinary shares to institutional investors in Europe and the U.S. resulting in additional available funds of €7.3 million. Cash outflow from operations and investments totaled EUR 17,846 k in 9M-2018.

THIRD QUARTER 2018 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 Note 3.3 of our Consolidated interim financial statements as of 30 June 2018 as the statements made in this note in the half-year 2018 financial report are also applicable to the consolidated financial statements as of 30 September 2018. Hence these Q3-2018 financials should be read in conjunction with the disclosure in the half-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 30 September 2018 and 30 September 2017

in kEuro	Nine months ended 30 September 2018	Nine months ended 30 September 2017
Revenue	1,191	831
Cost of sales	-2,126	-1,494
Gross loss	-935	-663
Distribution costs	-6,228	-5,530
Administrative expenses	-3,136	-2,735
Research & development expenses	-7,284	-5,012
Other income	346	75
Impairment losses / gains IFRS 9	0	0
Operating loss	-17,237	-13,865
Finance income	325	22
Finance costs	-800	-711
Finance results - net	-475	-689
Loss before income tax	-17,712	-14,554
Income tax expenses	-7	-20
Loss for the period	-17,719	-14,574
Other comprehensive income for the period, net of tax*	-135	123
Total comprehensive loss for the period**	-17,854	-14,451

Loss per share attributable to the ordinary equity holders of the company	Nine months ended 30 September 2018	Nine months ended 30 September 2017
Basic	-1.11	-0.93
Diluted	-1.11	-0.93

* 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 30 September 2018 and 31 December 2017

in kEuro	30 September 2018	31 December 2017
Current assets	14,779	24,009
Cash and cash equivalents	5,541	16,311
Trade receivables	159	200
Inventories	6,972	6,946
Other current assets	2,107	552
Non-current assets	**11,151**	11,506
Intangible assets	7,444	7,524
Property, plant and equipment	3,285	3,566
Other non-current assets	167	182
Other non-current financial assets	157	156
Deferred tax assets	98	78
Total assets	25,930	35,515

CURETIS N.V.

STATEMENT OF FINANCIAL POSITION (UNAUDITED) - EQUITY AND LIABILITIES

As of 30 September 2018 and 31 December 2017

in kEuro	30 September 2018	31 December 2017
Current liabilities	3,427	2,926
Trade and other payables	1,117	928
Provisions current	74	124
Tax liabilities	26	24
Other current liabilities	1,502	1,226
Other current financial liabilities	708	624
Non-current liabilities	13,816	10,385
Provisions non-current	43	43
Other non-current financial liabilities	13,773	10,342
Total liabilities	17,243	13,311
Equity	8,687	22,204
Share capital	164	155
Capital reserve	156,565	152,793
Other reserves	9,089	8,527
Currency translation differences	3	143
Retained earnings	-157,134	-139,414
Total Equity and liabilities	25,930	35,515

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

For the periods ended 30 September 2018 and 30 September 2017

in Euro	Nine months ended 30 September 2018	Nine months ended 30 September 2017
Profit after income tax	-17,719	-14,574
Adjustment for:		
- Net finance income / costs	475	689
- Depreciation, amortization and impairments	966	1,004
-Gain on disposal of fixed assets	0	2
- Changes in provisions	-50	57
- Changes in equity settled stock options	562	949
- Net exchange differences	-296	303
- Changes in deferred tax assets and liabilities	-20	0
Changes in working capital relating to:		
- Inventories	-26	-471
- Trade receivables and other receivables	-1,500	1,177
- Trade payables and other payables	975	806
Effects of exchange rate differences not realized from consolidation	156	-181
Income taxes received (+) / paid (-)	7	-20
Interest paid (-)	-772	394
Net cash flow provided by operating activities	-17,242	-10,653
Payments for intangible assets	-95	-69
Payments for property, plant and equipment	-509	-206
Interest received	0	8
Net cash flow used in investing activities	-604	-267
Proceeds from borrowings	3,000	10,000
Payments for finance lease liabilities	0	-48
Proceeds from issue of ordinary shares	4,100	0
Payments for financing costs of issue of ordinary shares	-320	0
Net cash flow provided by financing activities	6,780	9,952
Net increase (decrease) in cash and cash equivalents	-11,066	-968
Net cash and cash equivalents at the beginning of the year	16,311	22,832
Net increase (decrease) in cash and cash equivalents	-11,066	-968
Effects of exchange rate changes on cash and cash equivalents	296	-303
Net Cash and cash equivalents at the end of the period	5,541	21,561

CURETIS N.V.

CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 30 September 2018 and 30 September 2017

in kEuro	Share capital	Capital reserve	Other reserve	Currency translation difference	Retained earnings	TOTAL equity
Balance at 1 January 2017	**155**	**152,793**	**7,359**	**-28**	**-119,918**	**40,361**
Loss of 9M-2017					-14,574	-14,574
Other comprehensive income				123		123
Total comprehensive income	**0**	**0**	**0**	**123**	**-14,574**	**-14,451**
Transactions with owners in their capacity as owners						
Equity stock option program 2016			949			949
Balance as of 30 September 2017	**155**	**152,793**	**8,308**	**95**	**-134,492**	**26,859**

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 9M-2018					-17,719	-17,719
Other comprehensive income				-135		-135
Total comprehensive income	**0**	**0**	**0**	**-135**	**-17,719**	**-17,854**
Capital						
Transactions with owners in their capacity as owners						
Issue of ordinary shares	9	4,091				4,100
Transaction costs for the issue of ordinary shares		-319				-319
Equity stock option program 2016			562			562
Balance as of 30 September 2018	**164**	**156,565**	**9,089**	**8**	**-157,133**	**8,693**

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