2018

FIRST QUARTER BUSINESS AND FINANCIAL UPDATE

curetis

Forward looking statement (disclaimer)

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FIRST QUARTER 2018 OPERATIONAL AND BUSINESS HIGHLIGHTS YTD

UNYVERO SYSTEM AND LRT CARTRIDGE CLEARED BY U.S. FDA

- On April 3, 2018, the Unyvero Platform and the Unyvero Lower Respiratory Tract Infection (LRT) Cartridge received *De Novo* clearance from the U.S. FDA with 29 out of 36 assays cleared, including 19 of 20 pathogen assays and 10 antibiotic resistance marker assays.
- Unyvero LRT covers more than 90% of infection cases of hospitalized patients with pneumonia and provides clinicians with a comprehensive overview on genetic antibiotic resistance markers detected. As the first-in-class molecular test for lower respiratory tract infections with no direct molecular diagnostics competition, it addresses a high unmet medical need that causes over $10bn in annual costs for the U.S. healthcare system.
- In a multi-center U.S. evaluation study, Unyvero LRT showed excellent weighted average sensitivity and specificity of 91.4% and 99.5% across the panel of microorganisms, respectively.
- Commercial launch of the Unyvero LRT in the U.S. has been initiated and systems are being broadly rolled out starting from Q2 2018.

COMMERCIAL DEVELOPMENT

- In all EMEA direct selling markets and under the new leadership of the Director of Commercial Operations EMEA, Riwat Lim, the focus on the commercial conversion of high priority accounts has resulted in revenues from cartridges and instruments growing by 518% compared to Q1 2017. Revenue growth from cartridges in the EMEA direct selling markets was 79% year-on-year.
- To expand its commercial reach, Curetis is further evaluating multiple distribution partnering opportunities, which would allow it to enter into new geographies and could also potentially contribute positively to system and cartridge sales over time.

SINGAPOREAN APPROVAL FOR UNYVERO HPN AND BCU APPLICATIONS

- The Unyvero Hospitalized Pneumonia (HPN) and Blood Culture (BCU) Applications were approved by the Singapore Health Sciences Authority (HSA) and fully registered as a Class C IVD medical devices with the Singapore Medical Device Register. After having initially placed Unyvero Systems under the GN-27 exemption at early adopter sites, the approval allows Curetis' Singaporean distribution partner Acumen Research Laboratories Ltd. to initiate a more comprehensive roll-out in Singapore as a bridgehead to the further markets in the ASEAN region. Acumen and Curetis intend to also submit the Unyvero Implant and Tissue Infection (ITI) Application and Unyvero Intra-Abdominal Infection (IAI) Application for HSA approval and registration.

CHINESE FDA TRIALS

- Working towards a Chinese market clearance by the Chinese Food and Drug Administration (CFDA), analytical testing of the Unyvero HPN Cartridge by Curetis' partner Beijing Clear Biotech (BCB) in China was initiated in Q4 2017 and was nearing completion in Q1 2018 under the auspices of the Beijing Institute of Medical Device Testing. Analytical testing is a key requirement and precondition for Curetis' partner BCB to initiate the prospective CFDA clinical trial in 2018 with an expected regulatory submission in 2019.

GLOBAL INSTALLED BASE

- Following the completion of a pharmaceutical partners' phase III clinical trial, Curetis in Q1 2018 has exercised a very attractive option to buy back multiple Unyvero Systems deployed in this clinical trial at a discounted price. Additionally, Curetis has increased its focus on higher priority accounts and conversion efficiency, which has led to a re-deployment of Unyvero Systems resulting in a temporary decrease of the installed base of Unyvero Analyzers to 167 Analyzers by the end of the first quarter 2018, down by a net of 8 Analyzers compared to 175 Analyzers by year-end 2017.
- With the launch of Unyvero in the U.S. and the ongoing and anticipated commercial uptake in non-U.S. territories, the Company reiterates its target of a global installed base of 250 to 300 Unyvero Analyzers by year-end 2018. Of these, Curetis aims at placing 40 to 50 Analyzers in the U.S. by year-end and 60 to 80 Analyzers within the first twelve months of full commercial launch in the U.S. Given the expected sales cycle of 6 to 9 months in the U.S., Curetis does not anticipate any material impact on revenue before end of 2018 from the U.S. placements.

BUSINESS DEVELOPMENT

- In January 2018, Curetis and MGI (a BGI Group Company, Shenzhen, China) signed R&D collaboration and supply agreements focused on the Unyvero Lysator technology and instruments. 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 at entering into further value-adding R&D and commercial partnerships with well-known industry players around ARES*db* and the ARES Technology Platform as well as the Unyvero Platform.

PRODUCT DEVELOPMENT

- In April 2018, Curetis launched the CE-IVD marked Unyvero Urinary Tract Infection (UTI) Cartridge at ECCMID 2018. The UTI panel covers 103 diagnostic targets, including 88 pathogens (Gram-positive & Gram-negative, important fungi such as *Candida auris*) and 15 resistance markers (incl. emerging markers such as *mcr-1*). The novel Unyvero UTI Cartridge primarily targets urinary tract infections in patients with complicated and severe UTIs. This includes pregnant women, pediatric patients, and hospitalized patients with anatomical, structural and functional alterations, renal impairments and impaired immune status, as well as catheter-associated urinary tract infections (CAUTI), patients failing to respond to therapy, and urosepsis patients. The CE-IVD marking was based on a prospective multi-center evaluation study with a total of 443 patient samples analyzed that demonstrated an overall weighted average sensitivity of 95.6% at an overall weighted average specificity of 99.3% across the panel of microorganisms covered.
- To extend the label claim of its recently U.S. FDA-cleared Unyvero LRT Cartridge for lower respiratory tract infections, Curetis plans to file for the additional clearance of bronchoalveolar lavage (BAL) as a second sample type. To this end, Curetis will work closely with the FDA reviewers to identify the most appropriate path to develop or augment the bronchoalveolar lavage (BAL) data package, which it intends to submit as part of a proposed future label claim expansion as soon as practicable.
- In addition, Curetis has started its second FDA trial for its next U.S. product, the Unyvero Invasive Joint Infections (IJI) Cartridge for severe invasive joint infections, a variant of its Unyvero Implant and Tissue Infection (ITI) Cartridge specifically designed and developed for the U.S. market. Curetis has submitted a presubmission package to the FDA, which outlines the intended use claims and a proposed study design. A collection of retrospective samples to augment the prospective arm of the trial has been initiated and Curetis aims at finalizing the U.S. clinical trial for Unyvero IJI in 2019.
- All other R&D programs and product development projects remain on track and in line with

guidance. In particular, Curetis has advanced the development of its new analyzer module, Unyvero A30 *RQ*, and expects CE-IVD marking of the instrument as well as first A30 *RQ* Application Cartridges in 2019.

CLINICAL STUDIES

- At ECCMID 2018 in Madrid, Spain, on April 21-24, Curetis' Unyvero products were featured in a number of contributions by independent research groups reflecting the increasing clinical adoption of Curetis' innovative solutions for molecular microbiology. Three posters presented results from studies of the utility of the Unyvero HPN and LRT Applications in the rapid detection of pathogens in lower respiratory tract infections in hospitalized patients (Posters #P0567, #P0567 and #P0567). Three additional posters presented studies of the Unyvero ITI Application Cartridge for the detection of pathogens and their antibiotic resistances in periprosthetic joint infections, shoulder surgery infections and diabetic foot infections (Posters #P0712, #P0714 and #P0716).

SCIENTIFIC ADVISORY BOARD

- In April 2018, Curetis established a dedicated U.S. Scientific Advisory Board (SAB) and thereby expanded its scientific network and clinical expertise to support U.S. adoption of the recently U.S. FDA-cleared Unyvero System and LRT Cartridge. Five renowned U.S. infectious disease experts have been appointed to the SAB: Debra Goff, Pharm.D. (The Ohio State University Wexner Medical Center, OH, USA), Donna Mildvan, M.D. (Icahn School of Medicine at Mount Sinai, NY, USA), Melissa Miller, Ph.D. (University of North Carolina at Chapel Hill School of Medicine, NC, USA), Frederick Nolte, Ph.D. (Medical University of South Carolina, SC, USA), and Robin Patel, M.D. (Mayo Clinic, MN, USA). The newly formed U.S. Scientific Advisory Board complements the Curetis Medical Advisory Board, now renamed the EU Scientific Advisory Board.

FINANCING

- In April 2018, Curetis raised EUR 4.1 million in an equity offering of 854,166 new shares to qualified investors in Europe and the United States. In addition, Curetis secured access to an additional USD 10 million equity facility offered by Global Corporate Finance (New York City, NY, USA) allowing the Company solely at its request to raise additional equity over a period of up to 36 months subject to certain pre-agreed floor pricing.

- Curetis' subsidiary Ares Genetics received a funding commitment for its project "The Digital Microbe" with a total project volume of EUR 1.6 million by the Austrian Research Promotion Agency (FFG). This project is a substantial extension of the ARES Technology Platform and aims at developing deep machine learning tools and advanced bioinformatics algorithms for modeling, diagnostics and prediction of antibiotic resistances.

SUPERVISORY BOARD

- Dr. Holger Reithinger, General Partner at Forbion Capital Partners, has resigned from Curetis' Supervisory Board effective April 30, 2018. Dr. Reithinger has served on the Supervisory Board of Curetis N.V. since the IPO in November 2015. Previously, he had already served on the Supervisory Board of the predecessor company, Curetis AG, to which he had been elected in 2011 to represent Forbion, one of the first venture capital companies that invested in Curetis. Following the recent private placement, Forbion currently holds about 8.5% of Curetis' share capital. After Dr. Reithinger's resignation, the Supervisory Board consists of six members.

- Dr. Werner Schaefer and Dr. Rudy Dekeyser will run for re-election for another two-year and one-year term, respectively, at the annual general meeting 2018 in Amsterdam on June 21, 2018.

FIRST QUARTER 2018 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 490 k (growing by more than 40% compared to EUR 347 k in the first quarter 2017). 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 6,081 k (vs. EUR 4,675 k in the first quarter 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 general and administrative expenses.
- **Gross loss:** EUR -331 k (vs. EUR -176 k in the first quarter 2017).
- **Net loss of the period**: EUR -5,786 k (vs. EUR -4,351 k in the first quarter 2017).
- **Cash and cash equivalents**: EUR 11,367 k as of March 31, 2018 (vs. EUR 16,311 k as of December 31, 2017). Net decrease in cash and cash equivalents in the first quarter 2018 was EUR -4,825 k.

FIRST QUARTER 2018 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 2018	Three months ended 31 March 2017
Revenue	490	347
Cost of sales	-821	-523
Gross loss	-331	-176
Distribution costs	-1,955	-1,828
Administrative expenses	-1,070	-854
Research & development expenses	-2,235	-1,470
Other income	179	26
Operating loss	-5,412	-4,302
Finance income	5	11
Finance costs	-350	-55
Finance results - net	-345	-44
Loss before income tax	-5,757	-4,346
Income tax expenses	-29	-5
Loss for the period	-5,786	-4,351
Other comprehensive income for the year, net of tax*	85	13
Total comprehensive loss for the period**	-5,701	-4,338

Loss per share attributable to the ordinary equity holders of the company	Three months ended 31 March 2018	Three months ended 31 March 2017
Basic	-0.37	-0.28
Diluted	-0.37	-0.28

*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 at 31 March 2018 and 31 March 2017

in Euro	31 March 2018	31 December 2017
Current assets	18,685	24,009
Cash and cash equivalents	11,367	16,311
Trade receivables	449	200
Inventories	6,263	6,946
Other current assets	606	552
Non-current assets	11,306	11,506
Intangible assets	7,512	7,524
Property, plant and equipment	3,404	3,566
Other non-current assets	177	182
Other non-current financial assets	155	156
Deferred tax assets	58	78
Total assets	29,991	35,515

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

As at 31 March 2018 and 31 March 2017

in Euro	31 March 2018	31 December 2017
Current liabilities	2,762	2,926
Trade and other payables	314	928
Provisions current	95	124
Tax liabilities	29	24
Other current liabilities	1,451	1,226
Other current financial liabilities	873	624
Non-current liabilities	10,514	10,385
Provisions non-current	43	43
Other non-current financial liabilities	10,471	10,342
Total liabilities	13,276	13,311
Equity	16,715	22,204
Share capital	155	155
Capital reserve	152,793	152,793
Other reserves	8,740	8,527
Currency translation differences	228	143
Retained earnings	-145,201	-139,414
Total Equity and liabilities	29,991	35,515

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

For the period ended 31 March 2018 and 31 March 2017

in Euro	Three months ended 31 March 2018	Three months ended 31 March 2017
Profit after income tax	-5,786	-4,351
Adjustment for:		
- Net finance income / costs	345	44
- Depreciation, amortization and impairments	315	375
- Changes in provisions	-29	35
- Changes in equity settled stock options	213	412
- Net exchange differences	116	46
- Changes in deferred tax assets and liabilities	20	0
Changes in working capital relating to:		
- Inventories	683	-173
- Trade receivables and other receivables	-297	729
- Trade payables and other payables	-35	-454
Effects of exchange rate differences not realized from consolidation	-31	-33
Income taxes received (+) / paid (-)	29	0
Interest paid (-)	-228	-1
Net cash flow provided by operating activities	-4,685	-3,371
Payments for intangible assets	-27	-30
Payments for property, plant and equipment	-113	-43
Interest received	0	4
Net cash flow used in investing activities	-140	-69
Proceeds from other non-current financial liabilities	0	0
Payments for finance lease liabilities	0	-36
Net cash flow provided by financing activities	-	-36
Net decrease in cash and cash equivalents	-4,825	-3,476
Net cash and cash equivalents at the beginning of the year	16,311	22,832
Net decrease in cash and cash equivalents	-4,825	-3,476
Effects of exchange rate changes on cash and cash equivalents	-119	-46
Net Cash and cash equivalents at the end of the period	11,367	19,310

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CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 31 March 2018 and 31 March 2017

In Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at 1 January 2017	155	152,793	7,360	-28	-119,918	40,362
Loss of Q1-2017					-4,352	-4,352
Other comprehensive income				13		13
Total comprehensive income	0	0	0	13	-4,352	-4,339
Transactions with owners in their capacity as owners						
Equity stock option program 2016			412			412
Balance as of 31 March 2017	155	152,793	7,772	-15	-124,270	36,435

in Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at 1 January 2018	155	152,793	8,527	143	139,414	22,204
Loss of Q1-2018					-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

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