



2016

FIRST HALF-YEAR
BUSINESS AND
FINANCIAL
UPDATE



FIRST HALF-YEAR 2016 OPERATIONAL AND BUSINESS HIGHLIGHTS

UNYVERO U.S. FDA TRIAL

- The **U.S. FDA** trial for the **Unyvero LRT Application** in lower respiratory tract infections is almost completed. Prospective and retrospective **sample enrolment** has been successfully concluded **on schedule** in the first half of 2016. In less than a year, a total number of more than 2,250 samples including approximately 1,700 prospective and over 550 retrospective patient samples, have been enrolled at nine clinical trial sites across the U.S. Among others, trial sites included the Mayo Clinic, Northwestern University, Johns Hopkins Hospital, UCLA and Columbia University Medical Center.
- Curetis targets completion of the contrived specimen study, molecular composite comparator testing for all samples and ancillary preclinical work packages in the second half of 2016, with top line data expected to be available after un-blinding, not before fall 2016.
- The submission of Curetis' (de novo) **510(k) data package** to the **U.S. FDA** is anticipated by year-end 2016 with the goal of achieving FDA clearance for Unyvero and starting commercialization in the first half of 2017.
- Curetis has begun preparing to **enter U.S. FDA trials** for its next U.S. product. To that end, the Company has already submitted a so-called pre-submission package to the U.S. FDA, which outlines the intended use claims and a proposed study design for a U.S. version of its **Unyvero ITI Cartridge**. Depending on the FDA's feedback later this year, Curetis will determine appropriate next steps and timelines for a U.S. FDA trial for its second product. Further details will be announced later this year.

UNYVERO CHINESE REGULATORY TRIALS

- The Company and its partner BCB are progressing the regulatory trials for **product clearance in China** with important data and preclinical parts of the trial expected to be run in H2-2016 under the auspices of the Beijing Institute of Medical Device Testing of the Beijing Center for Medical Device Quality Supervision and Testing of the Chinese State Food and Drug Administration (CFDA). BCB has expressed its goal to obtain CFDA clearance in 2017 and to begin commercialization in mainland China thereafter. **Commercial efforts in Hong Kong and Taiwan**, which are not subject to first obtaining CFDA approval, have already begun with a first commercial installation at a major hospital in Hong Kong, which was successfully completed in July.

UNYVERO SINGAPOREAN REGULATORY APPROVAL

- Curetis' partner **Acumen** has recently **submitted a filing** to the regulatory authorities in **Singapore** with the goal of achieving regulatory clearance for the **Unyvero HPN (Hospitalized Pneumonia) Application** which is equivalent to the current EU P55 Pneumonia cartridge. Acumen has also already started preparing respective filing documents for the **Unyvero BCU Blood Culture Application** and plans to apply for the **ITI Application** once the second-generation has been CE-IVD marked in Europe. Regulatory approval for the Unyvero Platform and Products is expected not before 2017.

UNYVERO JAPANESE PATENT

- The **Japanese Patent Office** has decided to grant a **key patent for the Unyvero Platform** combining PCR amplification and array-based detection in the Unyvero Cartridges. The patent will become effective with the issuance of an official note by the Japanese patent office.

COMMERCIAL EXPANSION

- **United States**

Direct Sales: The Company has appointed **Christopher M. Bernard** to the newly-created role of **President and Chief Executive Officer** of the newly-formed North American subsidiary **Curetis USA, Inc.** in July 2016. Christopher Bernard is a seasoned executive with significant expertise in sales, marketing and commercialization of in-vitro diagnostic platforms. Prior to Curetis, he has worked in several executive management roles at Epic Sciences, Metabolon, Inc., Abaxis, Inc. and Cytoc Corporation (Hologic, Inc.). At Curetis, he will be responsible for the development of the new subsidiary and will lead the marketing and sales initiatives of Curetis in the U.S. Curetis USA, Inc. is based in San Diego, CA, and was founded to drive the future development and sales of the Company's Unyvero Platform in North America. Curetis is planning direct commercialization of all Unyvero Products in the U.S. hospital market.

- **Europe**

Direct Sales: The Company has hired **Willem Haagmans** as **Head of Sales EMEA**. He brings a strong track record and extensive leadership experience with both large and small-to-medium sized molecular diagnostics companies. Prior to joining Curetis, he worked as General Manager Benelux at Beckman Coulter. Previously, Haagmans held international management positions at Roche, Nimblegen, and Vela Diagnostics. In addition, the Company has hired **key commercial staff** in the **UK, France and Benelux**, that is currently being on-boarded. These new hires will significantly strengthen Curetis' direct commercial footprint and position the Company to accelerate new Unyvero installations in these key markets. The total commercial team size in Europe is now at around 20, effectively doubling in size since the end of 2015.

Curetis has established **wholly owned sales subsidiaries** in the **UK** in May and the **Netherlands** for the Benelux area in June. Furthermore, the Company is in process of setting up a subsidiary in France and is planning to establish a subsidiary in Switzerland in Q3-2016.

Indirect Sales: The Company signed an exclusive, three-year **distribution agreement with Axon Lab AG** for Curetis' Unyvero products in Central and Eastern European countries, including **Austria, the Czech Republic, Slovakia, Slovenia and Croatia**. This partnership is part of the commercial effort in Western Europe leading to an expansion of the distribution network by four additional countries and transferring commercialization responsibilities for the former direct selling territory Austria to Axonlab which allows to leverage Curetis' existing installed base in Austria, with Axonlab acquiring multiple commercially installed Unyvero Systems for cash up-front. Axonlab will deploy a core team of several dedicated molecular diagnostics commercial representatives covering these markets. This deployment structure will ensure optimal resource allocation for Curetis in the region. Axonlab has dedicated microbiology and molecular diagnostics franchises and direct offices in each of the countries covered under the agreement, and it is well positioned to accelerate the commercial launch of Unyvero in the CEE markets.

PRODUCT DEVELOPMENT

- Curetis successfully completed the CE performance evaluation study and subsequently **launched its Unyvero BCU Blood Culture Application Cartridge** during ECCMID 2016 in Amsterdam. The CE-marked BCU Application is designed for diagnosing infections spreading through the blood stream in positively flagged blood cultures. The comprehensive panel covers 87 of the most relevant pathogens, including Gram negative and Gram positive bacteria, and 16 related resistance markers.
- The interim analysis **on approximately 100 prospective patient samples** using the Unyvero BCU Application Cartridge demonstrated a **concordance of 98% with conventional microbiology**. Additional pathogens that escaped detection by conventional microbiology were found in several cases. On average, **Unyvero results were available 24 hours earlier** and in some cases **up to two days earlier** than results obtained by routine diagnostic methods. The data also confirm compatibility with most commonly used blood culture systems, namely BacT/ALERT® (BioMérieux) and BD BACTEC™ (Becton Dickinson).
- The Company is in the final stage of completing the development of its **second-generation Unyvero ITI Application Cartridge** (expected European launch in Q3-2016) and is progressing the development of its **IAI Intra-Abdominal Infection Cartridge** (expected development completion by year-end of 2016). In addition, the partnered **Sepsis Host Response program** (anticipated completion not before the end of 2017) is progressing according to plan.
- Additionally, Curetis has established a **Medical Advisory Board** with experts from the U.S. (Robin Patel, MD, Mayo Clinic), Belgium (Jean-Louis Vincent, MD, Erasme University Hospital), Switzerland (Reno Frei, MD, University Hospital Basel as well as Laurent Poirel, MD, University of Fribourg), and Germany (Mathias Pletz, MD, Jena University Hospital). The advisors bring strong expertise in intensive care, clinical microbiology, sepsis, prosthetic joint infections and antibiotic resistance.
- Together with its **Medical Advisory Board**, the Company is in the process of defining and prioritizing multiple additional new **infectious disease indication areas** of high unmet medical need for further Unyvero Application Cartridge developments and will update its product pipeline shortly.

INSTALLED BASE

- Curetis has continued to expand the **installed base** of Unyvero Analyzers to 113 as of June 30, 2016 (vs. 70 instruments as of June 30, 2015). With the commercial teams in all **European direct selling markets** now in place and getting up to speed, the Company believes that there are several dozen well-qualified Unyvero placement opportunities for H2-2016. Therefore, the Company reiterates its guidance of an expected **global installed base of 150 to 200 Unyvero Analyzers** by year-end 2016.

AGM & SUPERVISORY BOARD

- During the Annual General Shareholder Meeting (AGM) held on June 16, 2016, **Dr. Prabhavathi Fernandes**, CEO of Cempra Pharmaceuticals Inc., Chapel Hill, NC, USA, has been **elected as a member of the Curetis N.V. Supervisory Board**. Dr. Prabhavathi Fernandes has profound knowledge in infectious diseases and antibiotics as well as experience in successfully founding, building up and leading several biotech companies and taking one public on Nasdaq raising more than half a billion U.S. dollars.

- Moreover, **Dr. Holger Reithinger** and **Dr. Rudy Dekeyser** were **re-elected** for another one-year term, respectively. In addition, the proposed **resignation of Dr. Frank Mühlenbeck**, the creation of a new **Stock Option Program** for the Company and associated changes to the **Supervisory Board remuneration policy** as well as changes to the **Management Board's Remuneration Policy** and **Stock Option grants** were also **approved** by the shareholders.

FIRST HALF-YEAR 2016 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 655 thousand (vs. EUR 742 thousand in the first half-year of 2015). While revenues in the first half of 2015 included EUR 297k Unyvero Systems sales to a pharma partner, revenues in the same period in 2016 did not include any such system sales to pharma. 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 7.5 million (vs. EUR 6.4 million in the first half-year of 2015). The increase is in line with the operational and organizational growth, and driven by higher R&D expenses, distribution costs as well as G&A costs.
- **Gross loss:** EUR 9 thousand (vs. a gross profit of EUR 77 thousand in the first half-year of 2015). The relatively low gross margin is mainly due to IFRS accounting requiring idle capacity of manufacturing line and facility to be allocated to cartridge output.
- **Net loss:** EUR 6.7 million (vs. EUR 12.4 million in the first half-year of 2015).
- **Cash and cash equivalents:** A strong cash position of EUR 39.7 million as of June 30, 2016 (vs. EUR 46.1 million as of December 31, 2015) and a **net cash burn** of EUR 6.4 million for all operating, investment and financing activities combined. The company expects a cash position of 31 to 32 million at the end of 2016.

FIRST HALF-YEAR 2016 CONSOLIDATED FINANCIAL STATEMENTS

CURETIS N.V.

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

For the period ended June 30, 2016

in Euro	six months ended June 30, 2016	six months ended June 30, 2015
Revenue	654,682	742,035
Cost of sales	663,657	665,151
Gross loss / gross margin	-8,975	76,884
Distribution costs	2,095,227	1,396,725
Administrative expenses	1,406,161	1,365,739
Research & development expenses	3,301,211	2,943,167
Other income	85,976	41,235
Operating loss	-6,725,598	-5,587,512
Finance income	61,343	5,493
Finance costs	41,127	8,866
Finance income / costs fair value measurement	0	6,782,819
Finance costs - net	20,216	-6,786,192
Profit / loss before income tax	-6,705,382	-12,373,704
Income tax expenses	-	-
Profit / loss for the half-year	-6,705,382	-12,373,704
Other comprehensive income for the half-year, net tax	6,044	-
Total comprehensive income for the half-year	-6,699,338	-12,373,704

Comparative figures for six months ended June 30, 2015, are those of Curetis GmbH (former AG).

CURETIS N.V.**CONSOLIDATED STATEMENT OF FINANCIAL POSITION –ASSETS
(UNAUDITED)**

As of June 30, 2016

in Euro	June 30, 2016	December 31, 2015
Current assets	45,115,373	50,573,547
Cash and cash equivalents	39,708,145	46,060,397
Trade receivables	589,879	1,072,131
Inventories	4,395,280	2,786,887
Other current assets	422,069	654,132
Non-current assets	6,033,064	6,823,465
Intangible assets	573,324	645,120
Property, plant and equipment	4,928,949	5,605,496
Other non-current assets	236,788	223,846
Other non-current financial assets	294,003	349,003
Deferred tax assets	-	-
Total assets	51,148,437	57,397,012

CURETIS N.V.**CONSOLIDATED STATEMENT OF FINANCIAL POSITION –
LIABILITY & EQUITY (UNAUDITED)**

As of June 30, 2016

in Euro	June 30, 2016	December 31, 2015
Current liabilities	3,014,748	2,446,095
Trade and other payables	974,908	863,342
Liability PSOP	367,308	367,308
Provisions current	2,300	29,300
Other current liabilities	959,471	676,502
Other current financial liabilities	710,761	509,643
Non-current liabilities	38,035	155,926
Provisions non-current	38,035	38,035
Other non-current financial liabilities	-	117,891
Total liabilities	3,052,783	2,602,021
Equity	48,095,654	54,794,991
Share capital	155,384	155,384
Capital reserve	152,793,347	152,793,347
Other reserves	6,592,373	6,592,372
Currency translation differences	6,044	-
Retained earnings	-111,451,494	-104,746,112
Total equity and liabilities	51,148,437	57,397,012

CURETIS N.V.

CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

For the period ended June 30, 2016

in Euro	six months ended June 30, 2016	six months ended June 30, 2015
Profit before income tax	-6,705,382	-12,373,704
Adjustment for:		
- Net finance income / costs	-20,216	6,786,192
- Depreciation, amortization and impairments	897,324	834,625
- Gain on disposal of fixed assets	1,550	1,889
- Changes in provisions	-26,998	1,444,870
- Net exchange differences	39,316	-4,635
Changes in working capital relating to:		
- Inventories	-1,608,393	-45,528
- Trade receivables and other receivables	756,373	-351,259
- Trade payables and other payables	547,066	181,731
Effects of exchange rate differences not realized from consolidation	6,044	0
Income taxes received (+) / paid (-)	0	0
Interests paid (-)	-41,127	-3,373
Net cash flow provided by operating activities	-6,154,443	-3,529,192
Payments for intangible assets	-3,524	-2,230
Payments for property, plant and equipment	-147,008	-251,606
Interests received	61,343	1,889
Net cash flow used in investing activities	-89,189	-251,947
Payments for finance lease liabilities	-69,304	-66,078
Cash received from capital increase	0	6,789,027
Net cash flow provided by financing activities	-69,304	6,722,949
Net increase (decrease) in cash and cash equivalents	-6,312,936	2,941,810
Net cash and cash equivalents at the beginning of the year	46,060,397	2,993,883
Net increase (decrease) in cash and cash equivalents	-6,312,936	2,941,810
Effects of exchange rate changes on cash and cash equivalents	-39,316	4,635
Net Cash and cash equivalents at the end of the half-year	39,708,145	5,940,328

Comparative figures for six months ended June 30, 2015, are those of Curetis GmbH (former AG)

CURETIS N.V.
CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY
(UNAUDITED)

As of June 30, 2016

in Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at January 01, 2015	50,000	0	0	0	-118,585,704	-118,535,704
Loss of H1-2015					-12,373,704	-12,373,704
Other comprehensive income for H1-2015					0	0
Balance as of June 30, 2015	50,000	0	0	0	-130,959,408	-130,909,408

in Euro	Share capital	Capital reserve	Other reserve	Currency transl. diff.	Retained earnings	TOTAL equity
Balance at January 01, 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 for H1-2016				6,044		6,044
Balance as of June 30, 2016	155,384	152,793,347	6,592,372	6,044	-111,451,494	48,095,653

Comparative figures for period from January 01, 2015, to June 30, 2015, are those of Curetis GmbH (former AG)

CURETIS N.V.

FIRST HALF-YEAR 2016
BUSINESS AND FINANCIAL
UPDATE

IMPRINT ©2016 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