



2016

FIRST QUARTER  
BUSINESS AND  
FINANCIAL  
UPDATE





# FIRST QUARTER 2016 OPERATIONAL AND BUSINESS HIGHLIGHTS

## UNYVERO US FDA TRIAL

- The **US FDA** trial for the **Unyvero LRT Application** in lower respiratory tract infections is nearing completion, with expected enrolment targets to be reached by mid-year. At the end of March 2016, more than 1,600 patient samples had been enrolled, with over 2,000 prospective and retrospective patient samples enrolled to-date;
- Curetis anticipates completing 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 upon unblinding, not before fall 2016;
- The submission of 510(k) data package to the US FDA is expected before year-end 2016.
- The Company also continues to prepare for the **second Unyvero Application Cartridge to enter US FDA trials** in the second half of 2016. Further details will be announced later this year.

## COMMERCIAL EXPANSION

- 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**, significantly strengthening its direct commercial footprint and positioning the Company to accelerate new Unyvero installations in these key markets.
- Curetis has established a **wholly owned sales subsidiary** in the UK (Curetis UK Ltd, London, UK) at the beginning of May 2016 and anticipates to incorporate further subsidiaries in France (Curetis France SARL) and the Netherlands (Curetis Benelux BV) in the first half of 2016.

## PRODUCT DEVELOPMENT

- Curetis has successfully completed the CE performance evaluation study and subsequently **launched its Unyvero BCU Blood Culture Application Cartridge** during ECCMID 2016 in Amsterdam in April. 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 Company has advanced the development of a **second-generation Unyvero ITI Application Cartridge** (expected European launch in mid-2016) and **IAI Intra-Abdominal Infection Cartridge** (expected development completion by year-end 2016). In addition, the partnered **Sepsis Host Response program** (anticipated completion in late 2017) is progressing according to plan.

- Curetis has established a Medical Advisory Board with experts from the US (Robin Patel, MD, Mayo Clinic), Belgium (Jean-Louis Vincent, MD, Erasme University Hospital), Switzerland (Reno Frei, MD, University Hospital Basel), and Germany (Mathias Pletz, MD, Jena University Hospital). The advisors bring strong expertise in intensive care, clinical microbiology, sepsis and prosthetic joint infections.

Recently, Curetis added Dr. Laurent Poirel (University of Fribourg, Switzerland), an expert in antibiotic resistance markers, to its MAB. Dr. Poirel has a long-standing scientific career at the French National Institute of Health and Medical Research (INSERM) in Paris / France with a focus on the genetics, biochemistry and epidemiology of antibiotic resistance determinants. In addition, he and his team have jointly developed a variety of rapid diagnostic tests for the detection of extended-spectrum  $\beta$ -lactamases and carbapenemases.

## INSTALLED BASE

- Curetis has **expanded the installed base of Unyvero Analyzers** to 107 at the end of the first quarter 2016 (vs. 58 at the end of the first quarter 2015).
- The Company reiterates its guidance of an expected global installed base of 150 to 200 Unyvero Analyzers by year-end 2016.

## SUPERVISORY BOARD

- Curetis announced the **nomination of Dr. Prabhavathi Fernandes**, CEO of Cempra Pharmaceuticals Inc., Chapel Hill, NC, USA, as a candidate for Curetis N.V.'s **Supervisory Board**. The election is to be held during the upcoming Annual General Meeting on June 16, 2016. Further important resolutions in the agenda are the resignation of Dr. Frank Mühlenbeck, and the re-election of Dr. Holger Reithinger and Dr. Rudy Dekeyser for another one-year term.

## FIRST QUARTER 2016 FINANCIAL HIGHLIGHTS

- **Revenues:** EUR 132.8 k (vs. EUR 228.4 k in the first quarter 2015). 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 3.3 million (vs. EUR 2.7 million in the first quarter 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, only partly compensated by lower cost of sales.
- **Gross loss:** EUR 30.1 k (vs. EUR 54.2 k in the first quarter 2015). This is mainly due to IFRS accounting requiring idle capacity of manufacturing line and facility to be allocated to cartridge output.
- **Net loss of the period:** EUR 3.2 million (vs. EUR 2.6 million in the first quarter 2015).
- **Cash and cash equivalents:** EUR 43.2 million (vs. EUR 46.1 million as of 31 Dec 2015). Net cash burn in the first quarter 2016 was EUR 2.9 million.

# FIRST QUARTER 2016 CONSOLIDATED FINANCIAL STATEMENTS

## CURETIS N.V.

### CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the period ended 31 March, 2016

in Euro	three months ended 31 March 2016	three months ended 31 March 2015
Revenue	132,810	228,422
Cost of sales	162,941	282,635
<b>Gross loss</b>	<b>-30,131</b>	<b>-54,213</b>
Distribution costs	890,547	619,702
Administrative expenses	715,312	416,903
Research & development expenses	1,543,990	1,395,815
Other income	55,409	25,306
<b>Operating loss</b>	<b>-3,124,571</b>	<b>-2,461,327</b>
Finance income	38,621	7,460
Finance costs	82,687	4,939
Finance income / costs fair value measurement	0	129,343
<b>Finance costs - net</b>	<b>-44,066</b>	<b>-126,822</b>
<b>Profit / loss before income tax</b>	<b>-3,168,637</b>	<b>-2,588,149</b>
Income tax expenses	-	-
<b>Profit / loss for the year</b>	<b>-3,168,637</b>	<b>-2,588,149</b>
Other comprehensive income for the year, net tax	-	-
<b>Total comprehensive income for the year</b>	<b>-3,168,637</b>	<b>-2,588,149</b>

	three months ended 31 March 2016	three months ended 31 March 2015
<b>Earnings / loss per share</b>		
Basic	-0.20	-1.97
Diluted	-0.20	-1.97

**CURETIS N.V.****CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

As of 31 March, 2016

## Assets

in Euro	31 March 2016	31 December 2015
<b>Current assets</b>	<b>47,649,250</b>	<b>50,573,547</b>
Cash and cash equivalents	43,190,446	46,060,397
Trade receivables	186,929	1,072,131
Inventories	3,767,367	2,786,887
Other current assets	504,508	654,132
<b>Non-current assets</b>	<b>6,483,830</b>	<b>6,823,465</b>
Intangible assets	610,608	645,120
Property, plant and equipment	5,294,954	5,605,496
Other non-current assets	229,002	223,846
Other non-current financial assets	349,266	349,003
Deferred tax assets	-	-
<b>Total assets</b>	<b>54,133,080</b>	<b>57,397,012</b>

**CURETIS N.V.****STATEMENT OF FINANCIAL POSITION**

As of 31 March, 2016

## Equity and Liabilities

in Euro	31 March 2016	31 December 2015
<b>Current liabilities</b>	<b>2,386,929</b>	<b>2,446,095</b>
Trade and other payables	734,381	863,342
Liability PSOP	367,308	367,308
Provisions current	13,300	29,300
Other current liabilities	683,147	676,502
Other current financial liabilities	588,793	509,643
<b>Non-current liabilities</b>	<b>119,798</b>	<b>155,926</b>
Provisions non-current	38,035	38,035
Provision PSOP	-	-
Other non-current financial liabilities	81,763	117,891
Financial liability for preferred and common shares	-	-
Deferred tax liability	-	-
<b>Total liabilities</b>	<b>2,506,727</b>	<b>2,602,021</b>
<b>Equity</b>	<b>51,626,353</b>	<b>54,794,991</b>
Share capital	155,384	155,384
Capital reserve	152,793,347	152,793,347
Other reserves	6,592,373	6,592,372
Retained earnings	-107,914,751	-104,746,112
<b>Total Equity and liabilities</b>	<b>54,133,080</b>	<b>57,397,012</b>

## CURETIS N.V.

### STATEMENT OF CASH FLOWS

For the period ended 31 March, 2016

in Euro	three months ended 31 March 2016	three months ended 31 March 2015
Profit before income tax	-3,168,637	-2,588,149
Adjustment for:		
- Net finance income / costs	44,066	126,822
- Depreciation, amortization and impairments	447,570	410,901
- Gain on disposal of fixed assets	207	1,889
- Changes in provisions	-16,000	573,408
- Changes in valuation of PSOP-liability	0	0
- Net exchange differences	87,325	-6,160
Changes in working capital relating to:		
- Inventories	-980,480	-16,616
- Trade receivables and other receivables	1,029,407	21,377
- Trade payables and other payables	-44,849	-313,865
Income taxes received (+) / paid (-)	0	0
Interests paid (-)	-82,687	-4,945
<b>Net cash flow provided by operating activities</b>	<b>-2,684,078</b>	<b>-1,795,338</b>
Payments for intangible assets	-3,524	-1,280
Payments for property, plant and equipment	-99,200	-234,565
Proceeds from sale of property, plant and equipment	0	0
Interests received	38,621	7,460
<b>Net cash flow used in investing activities</b>	<b>-64,103</b>	<b>-228,385</b>
Payments for finance lease liabilities	-34,445	-32,842
Cash received from capital increase	0	6,789,027
Proceeds from issue of ordinary shares	0	0
Payments for financing costs for IPO of old shares	0	0
Transaction costs for issue of ordinary shares	0	0
<b>Net cash flow provided by financing activities</b>	<b>-34,445</b>	<b>6,756,185</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>-2,782,626</b>	<b>4,732,462</b>
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	-2,782,626	4,732,462
Effects of exchange rate changes on cash and cash equivalents	-87,325	6,160
<b>Net Cash and cash equivalents at the end of the year</b>	<b>43,190,446</b>	<b>7,732,505</b>

## CURETIS N.V.

### CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY

As of 31 March, 2016

	in Euro	Share capital	Capital reserve	Other reserve	Retained earnings	TOTAL equity
<b>Balance at 1 January 2015</b>		<b>50,000</b>	<b>0</b>	<b>0</b>	<b>-118,585,704</b>	<b>-118,535,704</b>
Loss of Q1-2015					-2,588,149	-2,588,149
Other comprehensive income					0	0
<b>Balance as of 31 March 2015</b>		<b>50,000</b>	<b>0</b>	<b>0</b>	<b>-121,173,853</b>	<b>-121,123,853</b>

	in Euro	Share capital	Capital reserve	Other reserve	Retained earnings	TOTAL equity
<b>Balance at 1 January 2016</b>		<b>155,384</b>	<b>152,793,347</b>	<b>6,592,372</b>	<b>-104,746,112</b>	<b>54,794,991</b>
Loss of Q1-2016					-3,168,638	-3,168,638
Other comprehensive income					0	0
<b>Balance as of 31 March 2016</b>		<b>155,384</b>	<b>152,793,347</b>	<b>6,592,372</b>	<b>-107,914,750</b>	<b>51,626,353</b>

**CURETIS N.V.**

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