

# **CURETIS N.V. FULL-YEAR 2018 FINANCIAL RESULTS CONFERENCE CALL**

**Conference Call Presentation April 11, 2019** 





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## FY2018 FINANCIAL RESULTS CONFERENCE CALL

#### TELEPHONE CONFERENCE DIAL-IN AND WEBCAST DETAILS

### **Telephone Conference & Webcast**

#### Dial-in Numbers

■ Belgium: +32 24019516

■ Germany: +49 69201744220

■ The Netherlands: +31 207168020

■ UK: +44 2030092470

■ US: +1 8774230830

Participant PIN Code: 46052411#

Webcast Access Link: <a href="https://webcasts.eqs.com/curetis20190411/no-audio">https://webcasts.eqs.com/curetis20190411/no-audio</a>



# **ON THE CALL WITH YOU TODAY**



Oliver Schacht, Ph.D.
Chief Executive Officer



**Heiko Schorr**Director Finance



Dr. Achim PlumChief Business Officer



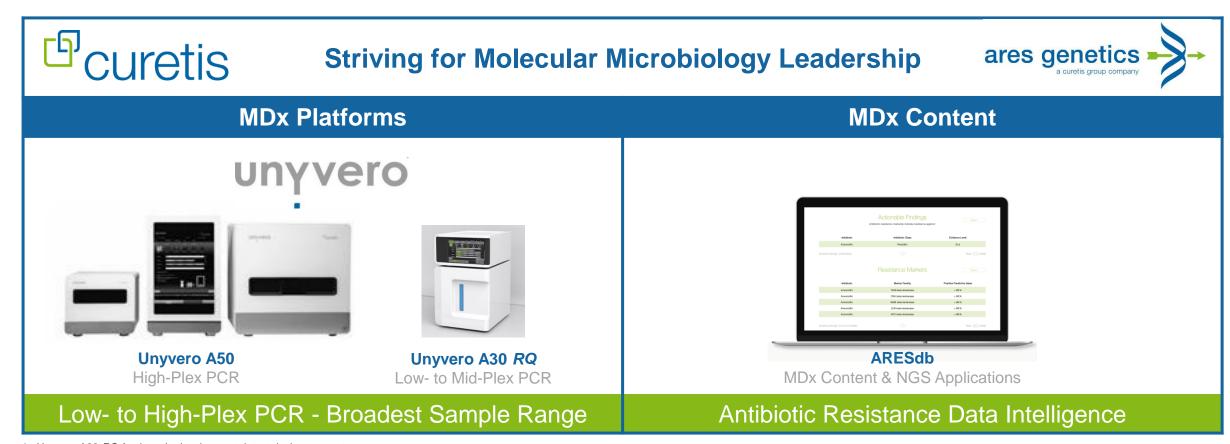
# **AGENDA**

- > KEY MILESTONES FULL-YEAR 2018 & 2019 YTD
- > FINANCIAL RESULTS FULL-YEAR 2018
- > OUTLOOK
- > Q&A SESSION



## **CURETIS' VISION**

#### MOLECULAR MICROBIOLOGY LEADERSHIP THROUGH PROPRIETARY PLATFORMS AND CONTENT



Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ



### **CURETIS AT A GLANCE**

#### A COMMERCIAL STAGE MOLECULAR DIAGNOSTICS COMPANY



Molecular Diagnostics Company with Focus on Severe Infections

Publicly Listed on Euronext Amsterdam and Brussels

Proprietary Unyvero Platform & Content

Commercial with CE-IVD and U.S.-FDA-cleared Unyvero Products

**Growing Global Presence** 

Attractive R&D Pipeline

Multiple Strategic Partnering Opportunities



# **KEY EVENTS 2018 & 2019 TO-DATE (I)**

#### **EXPANDED COMMERCIAL REACH TROUGH APPROVALS AND PARTNERSHIPS**

Received **U.S. FDA clearance** for Curetis' Unyvero System and Unyvero LRT Application on April 3, 2018, **and launched Unyvero LRT** in the U.S. at ASM Microbe in June 2018 – made first Unyvero placements for evaluations in fall 2018

Moved to **distribution-only model in Europe** and signed exclusive strategic pan-European distribution agreement with **A. Menarini Diagnostics** for the Unyvero A50 Platform and Application Cartridges initially covering eleven countries

Significantly expanded strategic collaboration with **Beijing Clear Biotech** for greater China and **filed for Unyvero System and HPN Application approval in China** 

Expanded geographical presence in Northern Africa and Latin America with three new distribution partnerships in **Egypt**, **Mexico and Uruguay** and entered into a new distribution agreement for **Ireland** 

Received several approvals for Unyvero Application Cartridges in countries of the ASEAN region, including Singapore Thailand and Malaysia

Launched novel CE-IVD-marked Unyvero UTI Application Cartridge for critical urinary tract infections

Progressed **Unyvero A30** *RQ* **platform** to fully functional prototype stage and engaged in **multiple strategic partnering and licensing negotiations** for this platform in all key global geographies and multiple indication areas



# **KEY EVENTS 2018 & 2019 TO-DATE (II)**

#### SECURED FUNDING TOTALLING EUR 19.5 MILLION – REVISED STRATEGY

Raised EUR 4.1 million in PIPE transaction

Signed financing facility of up to EUR 20 million of convertible notes with Yorkville, accessed first EUR 3.5 million tranche in Q4-2018

Closed follow-on offering with EUR 8.9 million gross proceeds in November 2018

Drew down EUR 3 million tranche of EIB debt financing facility after meeting U.S. FDA approval milestone

**Revised strategy** to sharpen focus on near-term strategic value drivers as a consequence of overall lower than expected proceeds from financing

Reduced headcount by approximately 25% and targeting reduction of cash burn by up to 50% in 2019



# **KEY EVENTS 2018 & 2019 TO-DATE (III)**

#### CURETIS GROUP MEMBER ARES GENETICS EXECUTED MULTIPLE PARTNERING DEALS

Entered into bioinformatics partnership with QIAGEN to create a bioinformatics community platform for antimicrobial resistance research

Launched ARES & CO pharma partnering program and teamed up with Sandoz to develop digital anti-infectives platform

Initiated feasibility study with an undisclosed global IVD player

Advanced development of ARESupa Universal Pathogenome Assay

Secured public co-funding of R&D projects with project volumes totaling approximately EUR 3 million



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#### 2018 ANNUAL REPORT PUBLISHED TODAY INCLUDING AUDITED 2018 FINANCIAL STATEMENTS



Access our Annual Report 2018 through the following link on our corporate website:

https://curetis.com/investors/#financial-reports



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

For the years ended 31 December

In kEuro	2018	2017
Revenue Cost of sales	1,419 -2,233	1,187 -1,649
Gross loss	-814	-462
Distribution costs Administrative expenses Research & development expenses Other income	-8,155 -4,095 -10,568 721	-7,302 -3,755 -7,362 314
Operating loss	-22,911	-18,567
Finance income Finance costs	406 -1,204	21 -1,004
Finance result – net	-798	-983
Loss before income tax	-23,709	-19,550
Income tax expenses	-36	52
Loss for the period	-23,745	-19,498
Other comprehensive income for the period, net tax	-283	171
Total comprehensive loss for the period	-24,028	-19,327
Loss per share attributable to the ordinary equity holders of the company		
Basic	-1.41	-1.26
Diluted	-1.41	-1.26

Please refer to 2018 Annual Report of Curetis N.V. for the notes to the financial statements. Such notes form an integral part of these financial statements. Link to 2018 Annual Report:

https://curetis.com/investors/#financial-reports



### **CONSOLIDATED STATEMENT OF FINANCIAL POSITION - ASSETS**

In kEuro	31 December 2018	31 December 2017
Current assets	18,095	24,009
Cash and cash equivalents	10,279	16,311
Trade receivables	323	200
Inventories	6,734	6,946
Other current assets	759	552
Non-current assets	11,012	11,506
Intangible assets	7,425	7,524
Property, plant and equipment	3,196	3,566
Other non-current assets	162	182
Other non-current financial assets	158	156
Deferred tax assets	71	78
Total assets	29,107	35,515

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### **CONSOLIDATED STATEMENT OF FINANCIAL POSITION – LIABILITIES & EQUITY**

#### As of 31 December

In kEuro		31 December 2018	31 December 2017
<b>Current liabilities</b>		6,064	2,926
	Trade and other payables	957	928
	Provisions current	65	124
	Tax liabilities	22	24
	Other current liabilities	1,235	1,226
	Other current financial liabilities	3,785	624
Non-current liabilities		13,993	10,385
	Provisions non-current	44	43
	Other non-current financial liabilities	13,949	10,342
Total liabilities		20,057	13,311
Equity		9,050	22,204
	Share capital	209	155
	Capital reserve	162,967	152,793
	Other reserves	9,176	8,527
	Currency translation differences	-143	143
	Retained earnings	-163,159	-139,414
Total equity and liabilities		29,107	35,515

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## **CONSOLIDATED STATEMENT OF CASH FLOWS (I)**

For the years ended 31 December

In kEuro	2018	2017
Loss after income tax for the period	-23,745	-19,498
Adjustment for:		
- Net finance income / costs	798	983
- Depreciation, amortization and impairments	1,256	1,327
- Gain on disposal of fixed assets	0	2
- Changes in provisions	-60	75
- Changes in equity settled stock options	649	1,167
- Net exchange differences	-375	371
- Changes in deferred tax assets and liabilities	7	-78
Changes in working capital relating to:		
- Inventories	212	-1,076
- Trade receivables and other receivables	-312	1,008
- Trade payables and other payables	659	911
Effects of exchange rate differences not realized from consolidation	89	-199
Income taxes received (+) / paid (-)	36	-52
Interests paid (-)	-1,173	-622
Net cash flow used in operating activities	-21,959	-15,681

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## **CONSOLIDATED STATEMENT OF CASH FLOWS (II)**

For the years ended 31 December

In kEuro	2018	2017
Payments for intangible assets	-118	-111
Payments for property, plant and equipment	-669	-320
Interests received	0	10
Net cash flow used in investing activities	-787	-421
Proceeds from other non-current financial liabilities	3,000	10,000
Proceeds from current financial liabilities	3,109	0
Payments for finance lease liabilities	0	-48
Proceeds from issue of ordinary shares	13,200	0
Payments for financing costs for issue of ordinary shares	-2,972	0
Net cash flow provided by financing activities	16,337	9,952
Net decrease / increase in cash and cash equivalents	-6,409	-6,150
Net cash and cash equivalents at the beginning of the year	16,311	22,832
Net decrease in cash and cash equivalents	-6,409	-6,150
Effects of exchange rate changes on cash and cash equivalents	377	-371
Net Cash and cash equivalents at the end of the period	10,279	16,311

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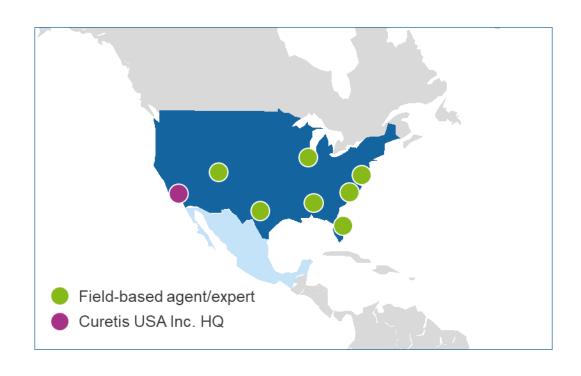
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## **OUTLOOK: U.S. COMMERCIALIZATION**

#### STRONG FUNNEL OF COMMERCIAL OPPORTUNITIES FOR UNYVERO LRT



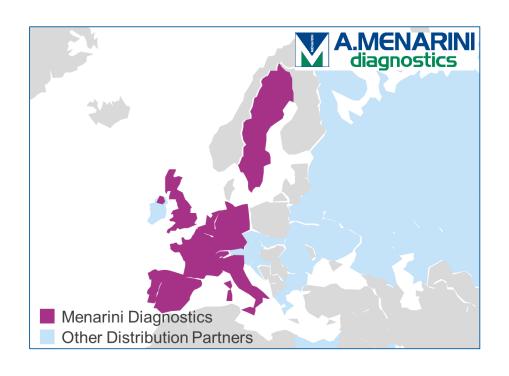
- > Built solid funnel of sales opportunities since launch in mid-2018
- Increased focus on high-volume, early-adopter accounts as a consequence of down-sizing the U.S. commercial operation in early Q1-2019 as part of the overall re-org process of Curetis Group
- > As of end Q1 there were 15 Unyvero A50 Analyzers installed with numerous commercial evaluations ongoing – installed new system at major IDN in Western USA this week
- Multiple near-term opportunities for additional evaluations with some new contracts already signed for Q2

Expect installed base of 30-40 Unyvero A50 Analyzers by year-end 2019 with continuously growing number of Analyzers generating revenue; consider adding synergistic sales & distribution partner channel alongside direct sales and marketing strategy



## **OUTLOOK: EMEA COMMERCIALIZATION**

### Focus on Hand-over of Direct Selling Markets to Menarini



#### A. Menarini Diagnostics Partnership

- > Covers the entire Unyvero A50 product line
- > Initial countries: BE, CH, DE, ES, FR, IT, LU, NL, PT, SE, UK
- > Exclusive 5-year partnership for the above Territories
- Option to extend and also expand partnership to further EMEA countries
- Launch of partnership at ECCMID 2019 (Amsterdam, April 13-16, 2019)

Expect to see possible temporary consolidation of the installed base of Unyvero A50 Analyzers in former direct selling markets but also expect that will be offset by a much stronger commercial organization now behind Unyvero in these 11 countries over the course of 2019



## **OUTLOOK: U.S. PRODUCT PIPELINE**

# EXPANSION OF U.S. PRODUCT PORTFOLIO: LRT-BAL ON TRACK IJI CLINICAL TRIAL SUBJECT TO AVAILABILITY OF SUFFICIENT FUNDING VIA PARTNERING DEAL





# Unyvero LRT Application for bronchoalveolar lavage (BAL) samples:

- > Running final clinical testing in-house in Q2-2019
- > Expect 510(k) filing for mid-2019, with an expected clearance decision in H2-2019

# **Unyvero IJI Application Cartridge for invasive joint infections:**

Finalizing the development and running the clinical trials subject to identifying a suitable partner providing co-funding for late-stage clinical development and collaborating on the future commercialization

Further U.S. FDA trials for Unyvero A50 applications are expected to follow in 2020 and beyond, continuing the expansion of the portfolio of differentiated testing applications in the U.S., subject to the availability of additional capital or partnerships



### **OUTLOOK: MARKET ACCESS CHINA**

# PARTNER BEIJING CLEAR BIOTECH (BCB) DRIVING MARKET ACCESS - FIRST SUBMUISSION TO NMPA IN FEBRUARY 2019



- > BCB covers China, Taiwan, and Hong Kong (via Technomed)
- > BCB will conduct and fully fund all clinical trials for NMPA approval
- > BCB committed to minimum purchase of Unyvero Systems (360) and Application Cartridges (1.5 Mio) over 8 year period from NMPA approval
- Successfully completed analytical testing and submitted for approval of Unyvero instrument and Unyvero HPN Cartridge based on US-FDA and EU CE-IVD clinical study data in February 2019

Expect BCB to complete further steps potentially required by the Chinese NMPA (formerly CFDA) to support the submission for approval of the Unyvero System and HPN in China with an expected clearance decision in 2020



## **OUTLOOK: UNYVERO A30 RQ DEVELOPMENT**

#### **FOCUS ON PARTNERING READINESS BY MID-2019**



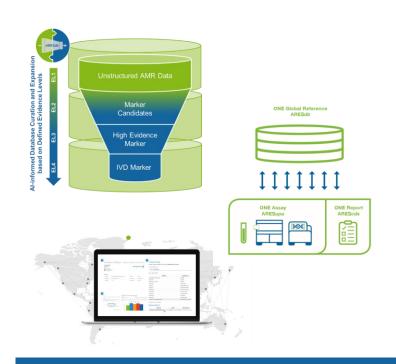
- > First series of fully integrated and functional prototype systems available
- Manufacturing aspects fully specified and in development or implementation phase
- > Development to full V&V readiness by Curetis
- > Further development timelines and potential future product launches will depend on Curetis entering into agreements with suitable diagnostics industry partners for the final stages of platform and product development
- > Feasibility testing phases are ongoing with potential partners

Expect to complete the development of a small series of manufacturing prototypes ready for verification and validation studies with application cartridges of future partners by H2-2019.



### **OUTLOOK: ARES GENETICS R&D**

#### STRINGENT EXECUTION OF BUSINESS PLAN AND PARTNERING STRATEGY



- > Execution on revenue-generating R&D service projects with pharma and IVD partners
- Further enhancement of ARESdb and AI-powered ARES technology platform
- > Set-up of ARESlab for NGS services in Vienna ongoing with labspace available and experienced NGS Lab Director hired
- Development of ARESupa Universal Pathogenome Assay service offerings for public health, pharma partners and eventually future diagnostic use
- All strategic R&D projects co-funded by grants minimizing cashout for Curetis Group

Expect the further development of NGS service offerings for pharma and public health with an anticipated launch by mid-2019 followed by the development of a first laboratory-developed test for human diagnostic use.



### **OUTLOOK: BUSINESS DEVELOPMENT & PARTNERING**

#### RAMPING-UP PARTNERING ACTIVITIES TO LEVERAGE HIGH-VALUE ASSETS



- Numerous ongoing partnering discussions on key assets such as the Unyvero A30 RQ Platform:
   Global / Regional Infections Disease / Oncology Exclusive / Non-exclusive
- > ARESdb, and the ARES Technology Platform: expect to see further validating partnerships beyond initial Sandoz, QIAGEN, and undisclosed IVD feasibility deals
- Continue expansion of global distribution network world-wide for Unyvero A50 Platform

Expect to enter into further significant licensing / partnering and distribution agreements over the course of 2019 with expected significant contribution to cash-inflow as part of non-dilutive financing strategy and revenue generation in 2019 and beyond



## **OUTLOOK: INSTALLED BASE & REVENUE**

# EXPECT SIGNIFICANT REVENUE GROWTH FROM COMMERCIAL OPERATIONS AND LICENSING DESPITE SIGNIFICANTLY SMALLER ORGANIZATIONAL SIZE

#### **Global Installed Base**

- > Temporary decrease of Unyvero A50 installed base in 2018 from 175 to 167 by year-end
  - > Buy-back of Analyzers deployed in a clinical phase III trial
  - > Increasing focus on high-priority accounts and conversion efficacy
- > Expect some further temporary consolidation as part of the hand-over to Menarini in EMEA that is likely to be off-set over the course of 2019 by new installations

Expect to grow the global installed base of Unyvero A50 Analyzers to increase from 167 at year-end 2018 to more than 200 by year-end 2019

#### Revenue

- > Revenue from
  - > Commercial operations with Unyvero A50
  - > Licensing, and partnering of key assets such as Unyvero A30 RQ and ARESdb
- > Revenue recognition under IFRS 15 for partnering or licensing deals and contracts will depend on the exact nature and details of contracts

Expect to more than double revenue from EUR 1.4 million in 2018 to over EUR 3 million in 2019



## **OUTLOOK: FINANCING**

# SECURE APPROPRIATE FUNDING AND CASH FOR CONTINUED OPERATIONS FOR THE COMING 12+ MONTHS



- > EUR 10.3 million cash available at year-end 2018
- > Expect further financing in 2019 with clear path to access the next EUR 5.0 million debt financing tranche from EIB (waiver of milestone conditions and agreed upon equity linked incentive fee structure to EIB upon maturity of tranche)
- > Potential access to further EUR 1.5 million tranche under the Yorkville convertible notes facility in the near-term
- Continue to assess all available strategic and tactical financing options going forward to secure appropriate funding and cash for continued operations for the coming at least 12 months including but not limited to
  - > non-dilutive financing options such as government grants or licensing and partnering deals with significant up-front cash components
  - > raising equity capital funding directly into Ares Genetics
- > Evolve shareholder base and continue to reduce the venture capital overhang and further improve liquidity of the stock



### **SUMMARY**

#### **EXECUTION OF REVISED STRATEGY**

Successfully implemented revised strategy and adjusted cost base to reflect funding constraints on current capital markets

Continued execution on U.S. commercial strategy with leaner, targeted commercial direct sales & marketing team

Switched to centralized 'distribution-only' in EMEA with Menarini as strong pan-European distribution partner

Advancement of novel low- to mid-plex solution **Unyvero A30** RQ to verification and validation studies by mid-2019

Continued execution of **Ares Genetics** business plan and partnering strategy

Further advancing numerous licensing and partnering opportunities for key assets

Agreed terms for accessing **EUR 5.0 million debt financing tranche** from EIB with equity participation, continuing to assess all available **strategic and tactical financing options** going forward

Target: doubling of revenues in 2019, reaching global installed base of > 200 Analyzers by end of 2019



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# **QUESTIONS? – WE WILL ANSWER!**



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