Curetis Announces Financial Results for the First Six Months of 2018

- Successful U.S. launch of Unyvero System and LRT Application Cartridge, with strong pipeline of sales opportunities

- Unyvero UTI Application Cartridge launched as CE-IVD product, BCU and HPN Application Cartridges approved in Singapore

- Commercial reach expanded to Latin America and Northern Africa

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, August 14, 2018, 01:30 am EDT -- Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today reported its financial results for the first six months ended June 30, 2018, and provided a business update for 2018 year-to-date and its outlook for the future.

Operational and Business Highlights 2018 Year-to-Date

Successful U.S. Launch of Unyvero System and LRT Cartridge

- Following the U.S.-FDA clearance in April 2018, Curetis **launched the Unyvero System and the Unyvero LRT Application Cartridge** for lower respiratory tract infections in the U.S. market at the ASM Microbe 2018 Congress in Atlanta, GA, USA on June 7, 2018.
- Since the launch, the U.S. commercial team has initially **qualified more than 125 accounts** as potential first buyers of Unyvero out of a total of about 1,000 hospitals considered by Curetis to be initial targets for Unyvero LRT. Of those qualified accounts, more than 50 have been thoroughly vetted and many are expected to be converted to commercial accounts over the next several quarters with approximately **ten accounts constituting near-term opportunities** currently at the contract negotiation stage. These initial ten accounts on average are expected to have **LRT cartridge volumes of 700 to 800 annually** once they become commercial customers. The estimated LRT cartridge volume potentials for the more than 50 accounts in advanced stages of qualification range from around 250 to over 1,600 p.a.

Commercial Development

- In all EMEA direct markets, combined **revenues from cartridges and instruments grew by more than 257%** comparing the first half 2018 with the first half of 2017. **Total revenue was up by 36%** compared to the first half 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 **16 distribution partners covering 29 countries** and believes to have a strong pipeline of further potential distribution partners covering additional markets that may lead to further near-term distribution agreements.

Installed Base

- Upon completion of a pharmaceutical partner's phase III clinical trial, Curetis in Q1-2018 exercised an option to buy back multiple Unyvero Systems deployed in this clinical trial and has concurrently taken a stronger focus on higher priority accounts and conversion efficiency throughout H1-2018, which has led to a re-deployment of Unyvero Analyzers resulting in a temporary decrease in the installed base of Unyvero Analyzers to **162 Analyzers as of the end of the first half-year 2018**, down by a net of 13 Analyzers compared to 175 Analyzers at year-end 2017. The Company expects to offset this decrease through future U.S. sales and the entry into additional distribution partnerships and has also identified a significant number of EMEA direct market opportunities for new Unyvero placements. Overall, the Company's more selective placement of Unyvero Systems has resulted in improved working capital management in H1-2018.

Product Launches and Regulatory Approvals

- In April 2018, Curetis **launched the CE-IVD marked Unyvero Urinary Tract Infection (UTI) Application Cartridge** at ECCMID 2018. The UTI panel covers 103 diagnostic targets, including 88 pathogens and 15 resistance markers. Unyvero UTI primarily targets urinary tract infections in patients with complicated and severe UTIs.
- In April 2018, the **Unyvero HPN and BCU Application Cartridges were approved by the Singapore Health Sciences Authority (HSA)** and fully registered as Class C IVD medical devices with the Singapore Medical Device Register. The approval allows Curetis' Singaporean distribution partner Acumen Research Laboratories Ltd. to initiate a more comprehensive roll-out in Singapore.

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**. 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 commonly obtained from patients for microbiological analysis. With the feasibility phase completed and with all pre-defined performance criteria met, the collaboration has entered the development phase for a first integrated product. Results from the collaboration are expected to be presented at the ICG-13 Conference in Shenzhen, China, on October 24-28, 2018.
- Going forward, Curetis aims to expand existing collaborations and enter into further **value-adding R&D and commercial partnerships** around the Unyvero Platform with well-known diagnostic industry players.

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 a second sample type**. To this end, Curetis will have a **pre-submission meeting with the U.S.-FDA** at the end of September 2018 to discuss submission requirements and details for a Unyvero LRT Application Cartridge optimized for BAL samples and including a further diagnostic target as compared to the LRT Application Cartridge currently marketed in the U.S.
- To rapidly expand its Unyvero Application Cartridge portfolio in the U.S., Curetis has **started an FDA trial for its next U.S. Product, the Unyvero IJI Application Cartridge for severe invasive joint infections**, a variant of its Unyvero ITI Cartridge specifically designed and developed for the U.S. market. The collection of retrospective samples to augment the prospective arm of the trial is ongoing and Curetis aims to finalize the U.S. clinical trial for Unyvero IJI in 2019.
- Working towards a **China market clearance** by the Chinese Food and Drug Administration (CFDA), analytical testing of the **Unyvero HPN Application Cartridge** by Curetis' partner in China, Beijing Clear Biotech (BCB), was initiated in Q4-2017 under the auspices of the Beijing Institute of Medical Device Testing and finalized in Q2-2018 with Unyvero HPN meeting all performance requirements for the entire panel. Analytical testing is a key requirement and precondition for BCB to initiate the prospective CFDA clinical trial later in 2018. Based on recently published new guidance by the Chinese State Council, Curetis together with BCB is currently exploring how the substantial clinical data available from the CE-IVD and U.S.-FDA studies could help accelerate the CFDA approval process.
- All other **R&D programs and product development projects remain on track** and in line with previous 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 a first A30 *RQ* Application Cartridge in late 2019.

Ares Genetics

- 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).
- Further, Ares Genetics has been selected as a **winner of the "GoSiliconValley" competition** of the Austrian Economic Chambers (WKO). The award includes an incubator stay in Silicon Valley, CA, USA, which is aimed at facilitating U.S. market entry and access to U.S. venture and growth capital. In addition, Ares Genetics won the **PerMediCon Award 2018** as runner-up.
- 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.
- All **R&D Programs** related to the further development, expansion and **antibiotic resistance marker** mining of **ARES*db*** and the further development of the **ARES Technology Platform** utilizing Artificial Intelligence approaches are on track.

- Going forward, ARES aims to expand existing and enter into further **value-adding R&D and commercial partnerships** with well-known industry players around ARESdb and the ARES Technology Platform.

Scientific Advisory Board

- In April 2018, Curetis established a **dedicated U.S. Scientific Advisory Board (SAB),** expanding its scientific network and clinical expertise to support U.S. adoption of the recently FDA-cleared Unyvero System and LRT Cartridge. Five renowned U.S. infectious disease experts have been appointed to the SAB. The newly formed U.S. Scientific Advisory Board complements the Curetis Medical Advisory Board, which has been renamed the EU Scientific Advisory Board.

Annual General Meeting (AGM) and Supervisory Board

- **All items on the agenda of the AGM held in Amsterdam on June 21, 2018, were approved by shareholders.** Oliver Schacht, Ph.D. and Dr. Achim Plum have been re-appointed as Managing Directors. Furthermore, Dr. Rudy Dekeyser and Dr. Werner Schaefer have been re-elected to the Supervisory Board. Further, the shareholders approved three authorized capital to increase the Company's share capital (two authorizations of up to 10% and one of up to 50%) providing the management with strategic flexibility in further commercially growing the Company.

- Dr. Holger Reithinger, General Partner at venture capital company Forbion Capital Partners, resigned from Curetis' Supervisory Board effective April 30, 2018. After Dr. Reithinger's resignation, the Supervisory Board now consists of six members.

Financial Highlights H1-2018, Financing

- **Revenues:** EUR 807k (growing by about 36% compared to EUR 595k in the first half-year 2017). EMEA direct sales have grown 257% year over year.

- **Expenses:** EUR 12,443k total cost of sales, distribution costs, administrative expenses and research & development expenses (vs. EUR 9,907k in the first half-year 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 -11,365k (vs. EUR -9,262k in the first half-year 2017).

- **Net loss of the period:** EUR -11,561k (vs. EUR -9,662k in the half-year 2017).

- **Cash and cash equivalents:** EUR 11,646k as of June 30, 2018 (vs. EUR 16,311k as of December 31, 2017).

- **Net cash burn** in the first half-year 2018 was EUR -4,912k. In April 2018, Curetis raised EUR 4.1 million in a private equity placement and issued 854,166 new shares and secured access to an additional USD 10 million equity facility offered by Global Corporate Finance (GCF) in New York allowing the Company solely at its request to raise additional capital over a period of up to 36 months subject to certain pre-agreed floor pricing. Cash outflow from operations and investments totaled EUR 11,692k in H1-2018.

- Curetis in H1-2018 has continued to **assess all tactical and strategic financing options** in the debt and equity capital markets globally and aims to raise additional growth capital as either equity or debt in 2018 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.

Outlook

Going forward, Curetis expects to:

- Convert **U.S. and EMEA pipeline of commercial opportunities** for Unyvero into near-term deal closures and revenue contribution.
- Expand its **global Unyvero distribution network** and commercial reach through further partnerships with suitably positioned distributors.
- Continue to work with BCB to finalize the **CFDA study** and regulatory submission for Unyvero HPN to gain market access in China.
- Execute on and expand the **partnership with MGI / BGI** to develop and commercialize solutions for NGS-based Molecular Microbiology.
- Execute on all **R&D programs** including a Unyvero LRT Cartridge label claim extension for BAL, IJI clinical studies in the U.S., Unyvero A30 *RQ* development expected for CE-IVD launch in late 2019, and further development of ARES*db* and the ARES Technology Platform.
- Enter 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.
- Continue to **assess all tactical and strategic financing options** in the debt and equity capital markets globally to raise additional growth capital as either equity or debt in 2018 in order to fund continued operations for at least the next 12 months.

"We achieved a key corporate milestone in the first half of 2018 with the FDA clearance and commercial launch of the Unyvero System and Unyvero LRT Application Cartridge in the U.S.," said Oliver Schacht, Chief Executive Officer of Curetis. "As the largest molecular diagnostics market in the world, the U.S. is crucial not only for Curetis, but for all diagnostics companies, and our U.S. launch has been a major value inflection point for Curetis. To broaden our U.S. product offering, we are currently conducting an FDA trial for our second U.S. product, Unyvero IJI for invasive joint infections, and are seeking U.S. FDA input on the most efficient regulatory approach to extend the label claim for the Unyvero LRT Application Cartridge to BAL samples. In addition, we have significantly broadened our global commercial reach by closing exclusive distribution partnerships for Mexico, Uruguay and Egypt, and have significantly advanced in our efforts to gain market access in China."

Conference Call and Webcast

Curetis will host a public conference call and webcast on August 14, 2018, at 12:30 pm CEST / 06:30 am EDT to present the H1-2018 financial results, highlight the most important events and provide an outlook for the second half of 2018 and beyond.

The conference call will be supplemented by a presentation, which can be accessed during the call at:
http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html

For participating in the earnings conference call, please access the presentation at
https://webcasts.eqs.com/curetis20180814

To access the call, please dial the following numbers using the passcode 93120684#:

NL:	+31 107137273
BE:	+32 11500307
DE:	+49 6922 222 9043
UK:	+44 2030 092 452
US:	+1 855 4027766
China:	+86 4006815483
Hong Kong:	+852 30773565

Further country-specific dial-in numbers can be found at:
http://events.arkadin.com/ev/docs/International Access Numbers _UKFELBRI1_SU7.pdf

The full H1-2018 Report will be available as of 14 August 2018, at:
http://www.curetis.com/en/investors/financial-reports-and-conferences/financial-reports.html

The live webcast and a replay will be available at:
https://webcasts.eqs.com/curetis20180814

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About Curetis

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis' wholly owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARES*db*, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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CURETIS N.V.

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

For the periods ended 30 June 2018 and 30 June 2017

in kEuro	Six months ended 30 June 2018	Six months ended 30 June 2017
Revenue	807	595
Cost of sales	-1,435	-1,052
Gross loss	-628	-457
Distribution costs	-4,214	-3,846
Administrative expenses	-2,111	-1,848
Research & development expenses	-4,683	-3,161
Other income	271	50
Operating loss	-11,365	-9,262
Finance income	274	20
Finance costs	-496	-406
Finance results - net	-222	-386
Loss before income tax	-11,587	-9,648
Income tax expenses	26	-14
Loss for the period	-11,561	-9,662
Other comprehensive income for the period, net of tax*	-171	117
Total comprehensive loss for the period**	-11,732	-9,545

Loss per share attributable to the ordinary equity holders of the company	Six months ended 30 June 2018	Six months ended 30 June 2017
Basic	-0.73	-0.61
Diluted	-0.73	-0.61

* 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 June 2018 and 31 December 2017

in kEuro	30 June 2018	31 December 2017
Current assets	20,348	24,009
Cash and cash equivalents	11,646	16,311
Trade receivables	250	200
Inventories	6,891	6,946
Other current assets	1,561	552
Non-current assets	11,156	11,506
Intangible assets	7,511	7,524
Property, plant and equipment	3,193	3,566
Other non-current assets	172	182
Other non-current financial assets	157	156
Deferred tax assets	123	78
Total assets	31,504	35,515

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STATEMENT OF FINANCIAL POSITION (UNAUDITED) - EQUITY AND LIABILITIES

As of 30 June 2018 and 31 December 2017

in kEuro	30 June 2018	31 December 2017
Current liabilities	3,180	2,926
Trade and other payables	447	928
Provisions current	54	124
Tax liabilities	26	24
Other current liabilities	1,442	1,226
Other current financial liabilities	1,211	624
Non-current liabilities	13,647	10,385
Provisions non-current	43	43
Other non-current financial liabilities	13,604	10,342
Total liabilities	16,827	13,311
Equity	14,677	22,204
Share capital	164	155
Capital reserve	156,565	152,793
Other reserves	8,954	8,527
Currency translation differences	-30	143
Retained earnings	-150,976	-139,414
Total Equity and liabilities	31,504	35,515

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

For the periods ended 30 June 2018 and 30 June 2017

in kEuro	Six months ended 30 June 2018	Six months ended 30 June 2017
Profit after income tax	-11,561	-9,663
Adjustment for:		
- Net finance income / costs	222	386
- Depreciation, amortization and impairments	618	694
- Changes in provisions	-70	35
- Changes in equity settled stock options	427	822
- Net exchange differences	-249	217
- Changes in deferred tax assets and liabilities	-45	0
Changes in working capital relating to:		
- Inventories	55	-336
- Trade receivables and other receivables	-1,050	1,071
- Trade payables and other payables	612	94
Effects of exchange rate differences not realized from consolidation	76	-100
Income taxes received (+) / paid (-)	-26	-14
Interest paid (-)	-471	-175
Net cash flow provided by operating activities	-11,462	-6,969
Payments for intangible assets	-67	-51
Payments for property, plant and equipment	-163	-152
Interest received	0	6
Net cash flow used in investing activities	-230	-197
Proceeds from other non-current financial liabilities	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	-4,912	2,786
Net cash and cash equivalents at the beginning of the year	16,311	22,832
Net increase (decrease) in cash and cash equivalents	-4,912	2,786
Effects of exchange rate changes on cash and cash equivalents	247	-217
Net Cash and cash equivalents at the end of the period	11,646	25,401

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CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY (UNAUDITED)

As of 30 June 2018 and 30 June 2017

In kEuro	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 H1-2017					-9,663	-9,663
Other comprehensive income				117		117
Total comprehensive income	**0**	**0**	**0**	**117**	**-9,663**	**-9,546**
Transactions with owners in their capacity as owners						
Equity stock option program 2016			822			822
Balance as of 30 June 2017	155	152,793	8,182	89	-129,581	31,638

in kEuro	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 H1-2018					-11,562	-11,562
Other comprehensive income				-173		-173
Total comprehensive income	**0**	**0**	**0**	**-173**	**-11,562**	**-11,735**
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			427			427
Balance as of 30 June 2018	164	156,565	8,954	-30	-150,976	14,677